WASHINGTON STATE DEPARTMENT OF ECOLOGY

Comments on the Amendments to the Model Toxics Control Act Cleanup Regulation Chapter 173-340 WAC and the Draft Environmental Impact Statement

Toxics Cleanup Program
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WASHINGTON STATE DEPARTMENT OF ECOLOGY

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Toxics Cleanup Program

October 1990

Proposed Amendments to
the Model Toxics Control Act Cleanup Regulation
Chapter 173-340 WAC (WSR 90-15-066: August 1, 1990)
and the
Draft Environmental Impact Statement (July 1990)

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Richland, September 10, 1990

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Spokane, September 11, 1990

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September 17, 1990

RECEIVED
SEP 17 1990
ECOLOGY

Mr. Dave Bradley
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Re: Proposed Rules, Chapter 173-340 WAC, Model Toxics Control Act Cleanup Regulation (WSR 90-15-066).

Dear Mr. Bradley:

Enclosed you will find the comments of ASARCO Incorporated on the above-referenced proposed regulations. Asarco's comments are contained in the following documents:

1. Comments on proposed amendments to Model Toxics Control Act Cleanup Regulation, WAC 173-340.

2. Memorandum from Tom Schadt to Marcia Newlands dated September 14, 1990.

3. Memorandum to Marcia Newlands from Joyce Tsuji, ETI, dated September 5, 1990.

4. Memorandum to Mike Thorp from Joyce Tsuji, ETI, dated September 12, 1990.

We urge the Department of Ecology to carefully consider our comments. The proposed Model Toxics Control Act Cleanup Regulations require revision or they will most likely delay, rather than expedite, cleanups in this state. Asarco and its consultants are willing to work with Ecology toward the goal of establishing workable and reasonable cleanup regulations. If you wish to discuss this matter with me, or if we can provide further input into this process, please give me a call.

Very truly yours,

Thomas L. Aldrich

Thomas L. Aldrich

TLA:vf

<u>COMMENTS ON PROPOSED AMENDMENTS TO MODEL TOXICS CONTROL ACT CLEANUP REGULATION</u>

<u>WAC Chapter 173-340</u>

WAC 173-340-200 Definitions.

"All practicable methods of treatment." The last sentence of this definition should be deleted. To include "all known available and reasonable methods of treatment" and "best available control technologies" within the definition of "all practicable methods of treatment" will be unworkable. AKART and BACT are specific to water discharge and air programs. In most cases, they are not particularly applicable to hazardous substance site cleanups and should only be included where they would otherwise constitute an ARAR given the circumstances at a particular site. The best course would simply be to delete this sentence from the definition. Alternatively, the exact types of situations in which AKART or BACT will be legally applicable should be delineated, and specific reference to statutory and Washington Administrative Code citations should be made.

"Applicable State and Federal Laws." The reference to "relevant and appropriate requirements" should be deleted. Calling a relevant and appropriate law "applicable" will lead to the unwarranted inference that it is a requirement which must apply to a given circumstance. "Applicable" laws should therefore, be limited to those which are legally applicable as is the case in the federal law.

"Carcinogen." This definition perpetuates the problem associated with distinction between benign and malignant tumors in animal studies. Carcinogenicity is generally considered to be related to malignant, as opposed to benign, tumors and should be so limited in the definition. In addition, the cancer potency factor is not always set at the upper 95th percentile confidence limit of the dose-response curve.

"Conditional Cleanup Level." The restriction to the use of conditional cleanup levels only when restricted site use conditions apply is inappropriate. There may well be other circumstances where it is appropriate to use conditional cleanup levels, and still be fully protective of human health and the environment independent of the question of whether such restrictions were applied. Also, use of institutional controls could be sufficient. This definition would additionally increase the problem associated with on and off site contamination and the use of conditional cleanup levels offsite.

"Hazardous Waste Site." This definition is incorrect. The term "hazardous waste" is restricted to those wastes which have been determined to be hazardous pursuant to Federal EPA regulation. The term is not synonymous with "hazardous substance." Therefore, throughout this rule, the term used should be "hazardous substance site." This definition should be changed accordingly.

"Null Hypothesis." The definition of null hypothesis is a sort of "guilty until proven innocent" approach. As such, it has no place in regulatory language. Furthermore, the definition is scientifically incorrect and inconsistent with U.S. EPA Risk Assessment Guidance.

"Owner or Operator." The portion of this definition dealing with abandoned facilities should be changed to reflect that the standard of liability set forth in RCW 70.105D.040(1)(b) limits the liability of former owners to those who "owned or operated the facility at the time of disposal or release of the hazardous substances."

"Permanent Solution." This definition would mean that a cleanup involving the transport of materials to an offsite permitted landfill or incinerator would not constitute a permanent solution. While there is some rationality with respect to offsite landfills, this seems particularly onerous with respect to incinerators which destroy the hazardous constituents just because of the production of ash or because some future action may be required at that incinerator facility. Even with respect to offsite landfills, it could readily be argued that such disposal presents far fewer permanent risks than many recycling or reuse techniques which have a higher priority.

"Practical Quantification Limit." The word "achieve" should be replaced by the word "measured" to accurately represent the intent of this definition.

"Site Use Restrictions." We presume that site use restrictions are intended to be the same thing as "restricted site use conditions" as used in the definitions of "conditional cleanup level." This should be made clear. If so, it is not necessarily the access to the site that is important. It may be more the elimination or minimization of exposure at the site that constitutes a site use restriction. For example, if contaminated soil is left onsite but is capped with concrete, one may not intend to restrict the access to the site but only to restrict the removal of the concrete.

"Subchronic Reference Dose." This definition seems to provide too much flexibility in that a dose with an uncertainty of an order of magnitude or more could mean an uncertainty of 25 orders of magnitude or more. If we are dealing with that type of uncertainty it should have no place in these regulations. The definition should, instead, attempt to state the conservativeness of the estimate in a different way.

"Wetlands." This definition should be replaced. The definition proposed by Ecology is identical to the definition initially published by the U.S. Fish & Wildlife Service in 1979. This definition has not been used for regulatory purposes, but typically has been employed in the process of assembling inventories of wetland areas. For regulatory purposes, the following definition which is used by the Environmental Protection Agency and the Corps of Engineers for regulatory purposes be used:

> "Those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support and that under normal circumstances do support a prevalence of vegetation typically adapted for life in saturated soil conditions."

WAC 173-340-360.

WAC 173-340-360(4). This subsection deals with various presumptions which are intended to be interpretation of certain requirements regarding applicable state and federal laws. However, the provisions in subsection (4) would, therefore, not apply to the general requirement of this section in subsection (2) that all cleanup actions comply with cleanup standards. Therefore the provisions contained in (4) may not modify the requirements of compliance with cleanup standards. This would mean that the provisions regarding requirements for groundwater treatment to achieve standards may only apply to the ARAR portions of the standards and not to the risk derived cleanup levels. I don't believe this was the department's intent. This subsection should be rewritten to make it clear that it applies to the general requirements under both subsection(2)(a)(i) and (2)(a)(ii).

WAC 173-340-360 (4)(b)(i). The AKART requirement set forth in the State's Clean Water Act is generally designed for wastewater streams or other discharges of water under the direct control of the permit holder. As such, it is designed for prevention activities, not remedial activities. It will not always fit situations found at hazardous substance release sites which involve either the movement of stormwater, uncontrolled surface water, or groundwater. Therefore, Ecology is attempting to impose, in all situations, a statutory and regulatory scheme that may not apply to all sites. Furthermore, to the extent that AKART may go beyond what is required to eliminate any significant threats to human health or the environment, or go beyond the cleanup standards, AKART's application to remedial activities would become treatment for treatment's sake and not be authorized by MTCA.

WAC 173-340-360(4)(b)(ii). This section requires the use of AKART when dealing with protection and restoration of the quality of groundwater affected by a release from a site. The above comments regarding AKART therefore apply. This section is unclear whether this AKART requirement is mitigated by the provisions of its subsections (A) through (D). Assuming this was the intent, then the AKART is modified by a practicality standard unless the public interest demands more. This wording should be clarified to ensure that these are limitations to the opening paragraph of (ii) and that this whole section applies to both 360(2)(a)(i) and (ii).

Subsection (A) seemingly requires the use of groundwater treatment to achieve standards where such treatment is either practicable or in the public interest. This ignores other possibilities for meeting the standards. Thus while we agree that where groundwater treatment is not practicable, other alternatives are necessary, the reverse is not necessarily true. In addition, subsection (B)(II) presents problems as well. There are many circumstances wherein implementing containment to the maximum extent practicable would provide no significant increased benefit to the groundwater resource. For example, while a plume may be expanding, it may be doing so in a way which, due to dispersion, attenuation, biodegradation, etc., poses no significant threat to human health or the environment even though some violation of groundwater cleanup standards does occur near the source of the plume. If treatment of the portions of the plume which violates the standards is not practicable, it would probably in such circumstances, be a waste of money to do containment "to the maximum extent practicable."

WAC 173-340-360(4)(b)(iii). This subsection applies the "best available control technologies" requirement as set forth in the State's Clean Air Act to cleanup actions at a hazardous substance release site. As with the comment immediately above, the BACT statutory and regulatory scheme in most cases will not be applicable to a cleanup action. BACT was designed to be applied to gas streams under the control of an operator. It generally consists of such items as passage of the gas stream through a baghouse, a precipitator, a scrubber, or some such device. On the other hand, in most cases, air emissions from hazardous substance release sites will be fugitive emissions from soils or volatilizing organics. Again, the most likely form of cleanup will be some form of source control through removal, treatment, or containment. The use of an air emission control device will often not be practicable. This subsection should be rewritten to reflect that the BACT requirement will only be used in those situations for which it would qualify as an ARAR.

WAC 173-340-360(6). This subsection deals with "permanent solutions" and establishes a hierarchy of cleanup alternatives. This section should be revised.

First, there is no indication whether the selection criteria are weighted or whether they are all given equal consideration during the decision-making process. Second, we assume that a higher preference technology that fails the selection criteria such as overall protectiveness of human health and the environment, is automatically rejected and a lesser technology can be chosen even though the higher technology is "practicable." This should be so stated. Finally, subsection WAC 173-340-360(6)(e)(v) should be deleted. This subsection provides that a cleanup action relying only on isolation or containment of hazardous substances shall not be used if a cleanup action alternative that utilizes the higher preference cleanup technology or method for all or a portion of the site is technically practicable. This means that the other balancing criteria would be irrelevant, and that even if an isolation alternative is the best alternative for protection of human health and the environment, it would be rejected. This is inappropriate, especially given the fact that there are many circumstances where selection of another, higher priority alternative could substantially increase the risks to human health or the environment.

Ecology should make the criteria of overall protection of human health and the environment the primary criteria in selecting a cleanup method. In no event should a higher preference treatment method be required simply because it is technically practicable without taking into account the overall protection of human health and the environment.

WAC 173-340-360(8). Subsection (a)(ix) of this subsection relates to natural degradation processes at the site. Similarly, natural degradation processes affecting contaminants migrating from the site are relevant to the question of the restoration time frame. This subsection should be amended to include natural degradation at both locations.

Subsection (8)(d) provides a good example of where there needs to be flexibility in determining the cleanup standard levels. If a PLP is to reduce concentrations of contaminants to those that are technically feasible, which by definition is irrespective of cost, it should not be required to deem the actions simply an interim action unless the remaining risks are substantial or at least significant. If technology is not capable of reaching the conditional cleanup level, which given the parameters required by Method B may occur in several instances, either the PLP should not be required to conduct the cleanup until such levels are achievable, or it should be considered a final remedial action. Leaving the technically feasible alternative as only an interim action would likely result in the refusal of many PRPs to conduct the action in the first place if they are doing all that is technically feasible, but still gain no potential for release from liability. Furthermore, what they do in the way of technically feasible response actions could end up being counterproductive with respect to any new technologies that may be developed far into the future to do more.

Subsection (8)(e) is also subject to abuse. It indicates that one cannot extend the restoration time frame as a substitute for active cleanup actions which are technically practicable. The question of extending from what is not answered. For example, if the restoration time frame of one year could avoid the need for an expensive but technically practicable solution, would it make sense in all cases to implement the technically practicable solution at substantial cost. The same question could be asked with respect to one month or ten years.

WAC 173-340-440. Institutional Controls.

Ecology should revise this section to give itself some flexibility on the imposition of institutional controls. As currently drafted, this section would require the institution of such controls in the circumstances set forth in WAC 173-340-440(1). This would be satisfactory if the regulation applied only to the standard hazardous substance release site, such as an industrial facility. Ecology should keep in mind, however, that it is likely that these regulations will apply to large-scale residential cleanups and other situations involving off-site contamination. In such cases, Ecology may want to consider some form of institutional controls other than deed restrictions. Imposing deed restrictions on hundreds of homeowners with the attendant Ecology oversight may not be satisfactory to either Ecology or the homeowners. As this section is currently written, Ecology would have no flexibility under such circumstances.

WAC 173-340-450. Releases from Underground Storage Tanks.

WAC 173-340-450(2)(b). The requirement that the UST owner must remove as much of the hazardous substance from the UST as is necessary to prevent further release to the environment within 24 hours of the UST release is an absolute requirement that in many cases may not be possible. This requirement should be rewritten to allow some flexibility so that, while the target is to make the removal within 24 hours, the owner is not automatically in violation of the regulation if this is simply not possible.

WAc 173-340-450(8)(b). The requirement that a UST owner or operator "comply with any conditions imposed by the Department" when doing an independent cleanup action is not justified. There are simply no restrictions on what conditions may be imposed and, while the Department would certainly have the opportunity to make additional requirements if a party conducting an independent cleanup action did not meet all the requirements of the regulations, it should not be able to impose unjustified conditions or conditions which restrict the progress of the independent cleanup action. Since a party performing such an action does so at its own risk, the Department does not need this provision.

WAC 173-340-700. General Procedures.

Technical practicability must be considered in selecting a cleanup level. The establishment of cleanup levels in this section fails to adequately address technical impracticability, even though many standards developed from either Methods A or B or conditional cleanup levels may still be below limits of practicability by available methods. This section must be revised to provide a means for modifying cleanup levels based on impracticability. There have been several suggestions for how to accomplish this, with most involving some increase in the risk level range if necessary to allow for selection of a technically practicable response action. One possibility for carcinogens would be to allow for a deviation from use of the upper 95% confidence level, such as use of the most probable value, when the cancer potency factor for the contaminant in question has a great deal of uncertainty. Similarly, with non-carcinogens, a lower safety factor for the NAOEL could be used when necessary to allow a technically practicable response.

WAC 173-340-700(2). The last sentence of this subsection should be eliminated. There is nothing in the MTCA which states any goal of establishing cleanup levels "as close as possible to natural background levels." There is no automatic relationship between protection of human health and the environment and "natural background levels."

WAC 173-340-700(4). This section, along with the referenced sections which, in reality, establish the exposure assumptions, does not provide sufficient flexibility to give realistic estimates of maximum exposures. Procedures should be identified to allow a PLP to provide justifiable site-specific reasonable maximum exposure estimates for purposes of determining Method B cleanup standards.

WAC 173-340-700(5). This whole section has lost much of its meaning throughout this process. Initially, Method A compliance levels were intended to be very conservative levels which could be applied to routine cleanups. Method B was developed to provide a more flexible approach which could take the specifics of a particular case into account and thereby avoid some of the conservative assumptions in Method A where appropriate.

Conditional cleanup levels were intended to provide some relief from the strict levels set forth in A and B where institutional controls were developed or other appropriate factors pertained. However, after many changes in the tables reflecting the Method A compliance levels in order to make such levels justifiable or within some realm of rationality, Method B will now often result in more stringent cleanup levels than Method A. Likewise, with many of the assumptions that have changed regarding the conditional cleanup levels, they become almost indistinguishable from levels calculated using Method B. It certainly makes no sense to have a routine site be allowed to clean up to a certain level, but another site which is not as "routine" be required to clean up to a more stringent level even though it has much greater level of review and study.

WAC 173-340-700(5)(d)(i). The reference to subsection (8) at the end of this subsection should be deleted. We agree that where compliance cleanup levels established by Methods A or B are below area background concentrations, conditional cleanup levels should be established at concentrations that are equal to area background concentrations. The reference to subsection (8) completely nullifies the preceding portion of the subsection. That is because subsection (8) goes back to establishing cleanup levels equal to concentrations established under applicable state and federal laws, etc. Therefore, the reference to subsection (8) should be deleted.

WAC 173-340-700(5)(d)(ii). Likewise, reference to subsection (8) in this subsection should be deleted. Again, the intent of this subsection is to provide a process for setting a conditional cleanup level protective of human health and the environment, and while the general idea is good, the entire process is nullified by the reference to subsection (8) which sets cleanup levels that then cannot be modified. Furthermore, it is nonsensical, and contrary to the objectives of MTCA, to require a cleanup which would increase the overall threat to human health or the environment, whether or not concentrations specified in subsection (8) would be violated.

WAC 173-340-700(5)(d)(iii). Again, the reference to subsection (8) should be deleted, as it nullifies the remainder of the subsection. One can only be expected to do what is technically feasible.

WAC 173-340-700(5)(d)(iv). In this case, subsection (b) should be deleted. There is no reason to condition use of an alternate cleanup level on not using a containment or isolation technology. Both are well recognized as often being both technically feasible and fully capable of protecting human health and the environment. This provision would unduly limit the application of this subsection. In addition, subsection (8) requires modification as set below if this subsection is to remain meaningful.

WAC 173-340-700(5)(d)(v). Subsection (B) should be eliminated for reasons set forth immediately above. Containment, isolation, and institutional controls are recognized methods for remediating hazardous substance releases such that human health and the environment are protected. Use of a conditional cleanup level should not be conditioned upon elimination of these alternatives. In addition, subsection (C) should be eliminated or changed. Conditioning the choice of a conditional cleanup level on the use of money saved by approval of the conditional level to fund actions "not otherwise required under applicable state and federal laws" is certainly not authorized by the MTCA and is probably illegal.

Furthermore, if the goal of this section is to encourage use of limited financial resources which provide the greatest net environmental benefit, the use of the funds only for actions that are not otherwise required by law is not always appropriate. A facility might, if required to meet a compliance cleanup level, simply not have sufficient monies to even comply with other environmental requirements. Instead, the company might be forced out of business. Certainly, the net environmental benefit is what should be obtained by this provision.

WAC 173-340-700(5)(e). The word "natural" should be eliminated. Ecology should recognize that natural background concentrations have been elevated because of local, regional and global activity. It is unreasonable and impractical to require PLPs to cleanup to natural background concentrations. Background concentrations as defined in WAC 173-340-200 as "Area background" should be utilized instead.

WAC 173-340-700(5)(f). This provision presents some significant difficulties in that the PQL established by U.S. EPA is often much more than ten times the method detection limits depending on the waste matrix. Thus, if one had a site where the PQL was greater than ten times the method detection limit, one could never conclude that the cleanup standards had been attained pursuant to this paragraph.

WAC 173-340-700(6)(a)(iii). This subsection should be deleted. As set forth above, Ecology does not have the authority to reserve the right to determine on an ad hoc basis "any other concentrations which the department determines are necessary to protect human health and the environment." The setting of such concentrations would be subject to further rulemaking and review. This subsection is not authorized by the MTCA and should be deleted. In addition, this provision may be unconstitutionally vague.

WAC 173-340-700(7)(a)(iii)(B). Ecology should establish an excess cancer risk range of 1 x 10^{-4} to 1 x 10^{-6} or, alternatively, establish similar flexibility through a change in the use of upper bounds confidence limits or other assumptions in the methodology. This is the range that EPA has established and it gives the agency some flexibility in determining cleanup levels. Establishment of a strict 1 x 10^{-6} risk may make some cleanups virtually impossible. Ecology should provide some greater flexibility in this determination.

WAC 173-340-700(7)(a)(iv). As set forth above in comments to Section 173-340-700(6)(a)(iii), the Department of Ecology does not have authority to reserve this unlimited discretion.

WAC 173-340-700(8). This subsection should emphasize that establishment of conditional cleanup levels should avoid levels for which attainment would require a treatment technology or methods or combination thereof that would cause a greater overall threat to human health and the environment.

WAC 173-340-700(8)(a)(iii)(B). This subsection should, at the least, be modified so as to adopt a 10^{-4}, as opposed to a 10^{-5}, upper limit on carcinogenetic risk.

WAC 173-340-700(8)(a)(iv). This subsection should be eliminated for the reasons set forth in comments to WAC 173-340-700(6)(a)(iii).

WAC 173-340-700(8)(b). This provision basically ensures that most sites with a mixture of contaminants will have the same conditional cleanup level as they will compliance cleanup level under Method B. This results from the fact that, again, the total excess cancer risk of 10^{-5} is used, which is the same total used for Method B. Since concentrations of many carcinogens at or below the detection limits would add up to a 10^{-5} risk, the two methods may become equivalent almost by definition.

WAC 173-340-705. General Principles.

WAC 173-340-705(6). It is appropriate that Ecology consider new scientific information as it becomes available. It is unclear how this subsection relates to the remainder of the substantive portion of the regulation actually setting cleanup standards. Does this mean that, notwithstanding the mandatory provisions of the regulation establishing cleanup levels, Ecology reserves the right to establish some other cleanup level based on "new scientific information"? If that is the case, and we think it should be, Ecology should make this point specific, either in a general portion of the regulation, or as subsections to the actual cleanup standards.

WAC 173-340-705(10). This provision indicates that as a matter of policy the Department defines various exposure parameters to be used when estimating cleanup levels under this chapter. This is far too limiting in that the standard exposure assumptions may be totally inappropriate for various site-specific conditions. For example, surface water cleanup standards require certain assumptions regarding fish consumption rates. These assumptions could be extremely far off base for given streams where there are not edible fish populations.

WAC 173-340-705(11)(e). The general assumption that measurements below the practical quantification limit should be assigned a value equal to the method detection limit does not seem consistent with the Department's approach with respect to assigning values below the method detection limit. The use of one-half of the practical quantification limit should also be used.

WAC 173-340-710. Applicable State and Federal Laws.

In this section, Ecology attempts to define "all applicable state and federal laws" to include those which are only relevant and appropriate, as opposed to legally applicable. Not only should these remain separate and distinct for reasons outlined above, but the MTCA may not allow requirements which are merely relevant and appropriate as defined in these proposed regulations.

WAC 173-340-720. Groundwater cleanup standards.

The reasonable maximum exposure for groundwater is generally based on drinking water being the highest beneficial use. Therefore, a cleanup level below a maximum contaminant level should not be required. Cleaning up groundwater to more stringent levels is clearly excessive and a waste of resources. It simply does not make sense to cleanup groundwater, especially at a compliance point where it is not being used, to levels presenting less risk than that allowed for public water supplies. For the same reason, a 10^{-6} risk level at the compliance point (which, through natural processes of biodegradation, dispersion and attenuation, would be much lower at the point of use) is inappropriate since any of the chlorinated public water supplies would present substantially more risk due to the presence of chloroform. We should not be expending limited resources to make groundwater at a compliance point substantially lower risk than our public drinking water supplies.

Requiring cleanups to comply with MCLG's and secondary maximum contaminant levels may also result in an unwarranted commitment of resources and should not be required unless, perhaps, if the MCLG's or secondary standards qualify as relevant and appropriate. In fact, it is doubtful that 2° standards are legally appropriate under MTCA since, in general, compliance with 2° standards is not necessary to protect human health or the environment.

Therefore, cleanup levels which meet or exceed health based MCLs will be protective of the highest beneficial use of groundwater and the regulation must state that cleanup in excess of such levels is not required. Use of secondary MCLs as cleanup standards requires case-by-case consideration and should not be an automatic standard.

WAC 173-340-720(1)(a)(ii). A new subsection (D) should be added. This subsection should make it clear that the use of groundwater as a source of drinking water will not be considered with regard to groundwater present in a man-made aquifer. For example, there are situations in which filling activity is at such a depth that groundwater has permeated portions of the fill. By its very nature as fill, usually industrial, it is not suitable as a source of drinking water. Therefore, there should be another category which automatically excludes that groundwater from consideration of drinking water purposes. Drinking water should be limited to natural aquifers.

WAC 173-340-720(1)(a)(ii)(B). Groundwater is often considered unfit for drinking with much lower levels of total dissolved solids than 10,000 mg/l. Hence, the definition of drinking water should not be dependent on this value and the last sentence of this subsection should be deleted.

WAC 173-340-720(2)(a)(iii). This subsection should be eliminated as beyond Ecology's authority. See discussion above pertaining to WAC 173-340-700(6)(a)(iii).

WAC 173-340-720(2)(a)(i). Table 1 raises several problems. First, several of the levels are still below the MCL. See above comments. Others have been included at levels equivalent to the MCL. This raises the question why some are set at the MCL and others substantially below it. Additionally, some values in the table have been set at the secondary MCL, which is also inappropriate. See comments above. Certain of the values in Table 1 would appear to be below the minimum detection level (see vinyl chloride and potentially PAH's). Also, the rationale for using total chromium is unclear since only hexavalent chromium is expected to present any risks at these levels.

While the purpose for establishing tables setting forth Method A compliance cleanup levels is presumably to provide consistent and clear levels at which routine cleanups can occur, these tables also present problems regarding the potential use by entities such as lenders, regulators and potential purchasers. If the tables are to remain, there should be a clear explanation of their intended use and the fact that they do not, of themselves, constitute ARARs or establish cleanup levels for a site. Instead, it should be explained they are designated cleanup levels that will be approved but may not be necessary at any given site.

WAC 173-340-720(3)(a)(i). See comments above. MCLG's and secondary drinking water standards should not be requirements of this section.

WAC 173-340-720(3)(a)(iii). This subsection should be modified as beyond Ecology's authority. See discussion pertaining to WAC 173-340-700(6)(a)(iii). In addition, WAC 173-340-720(3)(a)(iii)(E) should be revised to read:

> "(E) Concentrations which protect nearby surface waters. In general, these will be based on meeting chronic water quality criteria in the receiving water near the point(s) the groundwater enters the surface water. (See discussion regarding WAC 173-340-720(6)(d) below.)

WAC 173-340-720(4)(a)(ii)(B). The use of 10^{-5} for the total incremental cancer risk for a conditional cleanup level will, in most cases, result in conditional compliance cleanup levels identical to Method B cleanup levels. Thus, the whole purpose of the conditional cleanup level will be thwarted.

WAC 173-340-720(6)(c). The limitation of the point of compliance to the property boundary could create a substantial problem in many cases. For example, if hazardous substances are left on the cleanup site, but beyond the property boundary, in a contained position, the point of compliance would have to be within or underneath the contained substances. This could prove to be totally unworkable. There are certainly instances where the neighboring property owners will not sell the property so as to move the property boundary to alleviate this problem.

WAC 173-340-720(3)(a)(iii). This subsection should also be eliminated as beyond Ecology's authority. See discussion pertaining to WAC 173-340-700(6)(a)(iii).

WAC 173-340-720(6)(d). This provision <u>apparently</u> requires compliance with surface water standards within the groundwater as close as practicable to the interface between the groundwater and the surface water. It also indicates that a dilution zone to demonstrate compliance with surface water cleanup levels will not be allowed. This is simply inappropriate and does not reflect cleanup levels based on impacts to surface water as it should. If the cleanup level is based on aquatic surface water criteria, then compliance should be measured in the surface water, not in the groundwater. To the extent the cleanup levels are measured in the surface water, there will, by definition, be some dilution pertaining since groundwater will likely be substantially diluted as it enters the surface water.

To require meeting surface water criteria within the groundwater would result in needlessly expensive cleanup actions with no overall benefit to human health or the aquatic environment. These changes are also necessary to meet several of the other objectives for cleanup standards, including the preservation of the integrity of existing programs in a scientifically and legally defensible system. Comments regarding these other objectives are as follows:

1. The mixing zone regulation being developed by the state is acknowledging that even stormwater will not have to meet acute criteria at the end of pipe and will be eligible for a dilution zone.

2. Fresh water flows into salt water bodies both by surface flow and by ground water seep. Fresh water is acutely toxic to marine organisms due to the lack of salt, yet somehow marine organisms survive these events. The toxicity is naturally reduced (salt is added) by dilution.

3. WAC 173-201-035(2) Notes that "In brackish waters of estuaries, where the fresh and marine water quality criteria differ within the same classification, **the criteria shall be interpolated on the basis of salinity;"** Salinity changes happen only with dilution, so interpolation of standards imply some dilution whether or not a formal dilution zone has been assigned in a permit.

4. The determination of whether a dilution zone may be permitted is usually done in a permit on a case-by-case basis considering such things as the volume of flow and the volume of a receiving water, or the flow in the receiving water. The problem is that dilution zones are only allowed for authorized discharges under the NPDES system and ground water flow doesn't fit that neat category.

5. In the case of ground water flows into surface waters, the flow that would be associated with a contaminated site will (in most cases) be small relative to the total ground water flow to the surface water body. The flow in the surface water past the site may be quite large by comparison. The volume of the receiving water may be considerable. If the surface water is tidally influenced, the ground water may be diluted by tidal action in the water table before it even emerges. The hardness may change. Dissolved metals may bind to organic particles or precipitate out due to chemical changes as the ground water nears the point at which it will emerge. Once ground water emerges to a salt water body, it will very briefly be fresh

water and then be diluted with the salt water. Hence, the fresh water standard would apply, at the hardness of the water when it emerged, and then the standard would change to a salt water standard, requiring interpolation over a salinity gradient. Such interpolation between standards, already required by WAC 173-201-035(2), carries with it a de facto consideration of dilution. A comparable dilution consideration is appropriate for a discharge to fresh water.

In light of these facts, the following changes to WAC 173-340-720(6)(d) are suggested:

> "(d) At sites where affected ground water ~~discharges to nearby~~ enters a surface water, the cleanup level may often be based on protection of the surface water. The point of compliance in such a situation shall be in the receiving water near the point where the ground water enters the surface waters. ~~If a~~ conditional point of compliance ~~is approved at such a site it shall be located within the ground water and at an upland location that is as close as practical to the interface between the ground water and surface water~~ that monitors groundwater shall not incorporate a surface water standard unless it can be modified to reflect 1) the rate of ground water flow, 2) the area over which the flow emerges, 3) the currents in the adjacent receiving water, 4) the volume of water flowing past the area over which the ground water flow emerges, 5) physical-chemical transformations that may occur to the constituents of concern that result from the cross-media movement from ground water to surface water (including, if applicable, the change from fresh water to salt water). ~~At those sites, use of a dilution zone under WAC 173-201-035 to demonstrate compliance with surface water cleanup levels shall not be allowed.~~ Because these numerous factors are very difficult to assess, the preferred approach to demonstrate compliance with surface water standards is to require receiving water monitoring near the shore for the parameters of concern."

WAC 173-340-720(8)(a). This subsection requires analysis of unfiltered groundwater samples to demonstrate compliance, but allows (as a less preferred choice) filtered samples where it provides a more representative measure of ground water quality. Unfiltered samples do not properly characterize what is bio-available in groundwater and are not, in most cases, representative of contaminants that are mobile in the groundwater system. Filtered samples should be the preferred method for analysis.

WAC 173-340-730. Surface water cleanup standards.

This entire section should be deleted. Cleanups of surface waters are accomplished by source controls. If the sources are point sources, they are dealt with under the NPDES system and do not belong here. If the source of concern is a contaminated groundwater flow, that is handled under the cleanup of the affected groundwater and soils. With surface waters, dispersion and replacement is far more rapid than with ground water or soils.

WAC 173-340-730(2)(a)(ii). This subsection should be revised to indicate that federal water quality criteria are not automatically applicable, but should be required only as relevant and appropriate on a site-by-site basis depending on the nature of the organisms found at the site and the type of organisms upon which the water quality criteria were based.

WAC 173-340-730(2)(b). As set forth above, this subsection should be eliminated as beyond the authority of the Department of Ecology.

WAC 173-340-730(3). Comparison between Method B compliance cleanup levels and Method A compliance cleanup levels clearly demonstrates that Method B levels simply contain more requirements than those for Method A. Thus, Method B levels are more stringent than those for Method A, a result which isn't necessarily in keeping with the theory of the distinctions between Method A and Method B cleanup levels.

WAC 173-340-730(3)(d). As set forth above, this subsection should be eliminated as it is beyond Ecology's authority.

WAC 173-340-730(4)(d). As set forth above, this subsection should be eliminated as it is beyond Ecology's authority.

WAC 173-340-730(6). This subsection should be changed to read:

> "(b) Where hazardous substances are released to the surface water by a ground water ~~discharge~~ flow to the surface water ~~no dilution zone shall be allowed to demonstrate~~ compliance with surface water cleanup levels shall be demonstrated by receiving water monitoring. See WAC 173-340-720(6)(d) for additional discussion concerning ~~requirements in~~ this situation."

WAC 173-340-730(7)(d). As set forth above, measurements above the method detection limit but below the practical quantification limit should be assigned a value equal to one-half the practical quantification limit.

WAC 173-340-740. Soil cleanup standards.

WAC 173-340-740(2)(a). Table 2 has the same concerns as Table 1 with respect to the use of these tables and the necessary limitations on such use. In addition, there are several problems with this table. Several of the levels indicated are simply unrealistic with respect to many typical concentrations found in soils. For example, Ecology lists the arsenic cleanup level in soil as 20.0 mg/kg. Information from the Puget Sound region indicates that natural background is in the neighborhood of 40 mg/kg. The level of 20 mg/kg would be virtually impossible to attain. Likewise, the Environmental Protection Agency has determined that a lead cleanup level of 500 to 1,000 mg/kg is appropriate. The Ecology level of 250 mg/kg is without basis.

The PAH concentrations listed are also significantly below many common background levels and the chromium level listed doesn't specify whether it is intended to be total or hexavalent. Again, hexavalent chrome is the form of concern.

WAC 173-340-740(2)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(3)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(3)(c)(iv). This subsection should be eliminated as it is overly vague. It reserves the authority to Ecology to determine a more stringent cleanup level based on Ecology's determination that such levels are "necessary to protect the groundwater at a particular site." As there are no limits on what Ecology might determine is necessary, the regulation is unduly vague and, therefore, invalid.

WAC 173-340-740(3)(c)(v). This subsection should also be eliminated or rewritten, as it is unduly vague.

WAC 173-340-740(4)(b)(i)(A). This subsection requires that conditional soil cleanup levels shall be at least as stringent as concentrations equal to or less than one hundred times the ground water compliance cleanup level established in accordance with WAC 173-340-720. Since WAC 173-340-720 provides that in some cases groundwater could be required to meet surface water chronic criteria, without any dilution, this means that a conditional soil cleanup level could be equal to or less than one hundred times the surface water chronic criteria. The use of a factor of 100 is arbitrary here. The use of a factor of 100 for metals and high molecular weight organic compounds is far too conservative as has been repeatedly demonstrated in many cleanup actions, governmental tests, etc. Just as a more realistic factor should have been used for developing the numbers in Table 2 which were based on such a factor, the presumption of the factor of 100 should not apply to those metals and high molecular weight organic compounds. The application of surface water criteria to groundwater without consideration of dilution, is flawed and has been commented on elsewhere (see comments for WAC 173-340-720 (3) (a) (iii) (E). Accordingly, it would be an incredible leap of faith to set a soil cleanup standard based on an arbitrary factor applied to a groundwater cleanup level that was itself inappropriately set by a standard from an entirely different medium (surface water), which in all likelihood, may not have had any measurable impacts because of the much more rapid and intense processes of dispersion and dilution that occurs in surface waters.

WAC 173-340-740(4)(b)(iv). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(6)(d) and (e). These subsections will render the cleanup of soils in large non-industrial sites virtually impossible. First, there is no basis for establishing that all sites must automatically be cleaned to a depth of one foot. Moreover, there is no basis for establishing a presumption that the point of compliance will be 15 feet deep throughout the site. The point of compliance should be established on a site-by-site basis and should take into account all of the factors associated with that site, including site use, nature of hazardous substance, toxicity of that substance, mobility of that substance, applicability and effectiveness of institutional restrictions and other relevant factors. The one foot/15 feet requirements of these sections are arbitrary, have no basis, and are unworkable.

WAC 173-340-740(7)(g). Again, detectable levels below the practical quantification limit should generally be assigned a value equal to one-half the practical quantification limit.

WAC 173-340-745. Soil cleanup standards for industrial sites.

WAC 173-340-745(1)(b). Change the first sentence to read,

"To demonstrate industrial site use the site <u>or appropriate portions thereof</u> shall: ...."

A cleanup site may include both industrial and non-industrial land. The land that is industrial should not be required to meet the more stringent non-industrial criteria just because some of the cleanup site is not on industrial land.

WAC 173-340-745(1)(c). This subsection should be eliminated. First, there is no justification for setting soil cleanup levels on industrial property at the same levels as those used for residential use. Second, the phrase "as close as practicable" has no standards by which Ecology employees may be guided. Thus, it is unduly vague and should not be present in a regulation. This provision would disregard the reasonable maximum exposure rationale for these regulations.

WAC 173-340-745(2)(a). See comments re WAc 173-340-740(2)(a).

WAC 173-340-745(2)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-745(3)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAc 173-340-745(5). Unlike the case with groundwater, the proposed regulations regarding point of compliance for soil contamination do not take into account containment issues. For example, for soil cleanup levels based on the protection of groundwater, the point of compliance is required to be established throughout the site. However, for soil contamination which is remediated through containment, even though the soil throughout the site may exceed the standards, the groundwater would be protected and its point of compliance could be outside of the area that contains soil. For soil cleanup levels based on human exposure via soil ingestion, again the point of compliance is said to be established throughout the site at various depths. In containment situations this point of compliance would never be met even though no human ingestion could occur. This section needs rewording.

WAC 173-340-745(5)(d) and (e). These two subsections should be revised or eliminated in accordance with the comments to WAC 173-340-740(6)(d) and (e) above.

WAC 173-340-750. Cleanup standards to protect air quality.

The most important flaw in Section 750 is that it ignores Ecology's proposed rules for toxic air pollutants. Ecology's air program has released draft air toxics rules for new sources, and is working on draft rules for existing sources. These rules will include "acceptable source impact levels" (ASILs) for a large universe of toxic air pollutants. The new source rules expressly apply to sites undergoing cleanup under the MTCA. <u>See</u> proposed WAC 173-460-030(1)(b)(iii). The air toxics rules are more comprehensive and detailed than Section 750. For instance, they deal with such critical issues as dispersion modeling protocols and fugitive emissions.

Given this coverage, the worst thing Ecology could do would be to adopt a second set of rules covering the same subjects. This would violate the cleanup standard objective of preserving the integrity of existing programs. WAC 173-340-750 should contain nothing other than a statement that cleanup actions under this chapter must comply with the toxic air pollutant standards contained in WAC ch. 173-460.

If Ecology concludes that air emissions from cleanup sites must be subject to double regulation, Section 750 contains several significant problems. First, Section 750 contains protocols for deriving "Method A" and "Method B" cleanup levels. To maintain as much consistency with the existing program as possible, the regulation should specific that Method A will be used wherever WAC ch. 173-460 (the new source air toxics rules) specifies ASILs for the hazardous substances emitted at a sites.

Where other laws do not specify ambient concentration limits for the air pollutants emitted at a cleanup site, Section 750 directs Ecology to employ two formulas to derive cleanup levels. The formula for non-carcinogens directs the agency to employ a reference dose "as specified in WAC 173-340-705(7)." The latter section directs Ecology to employ an "inhalation reference dose," defined in WAC 173-340-200 as a daily inhalation exposure "that is likely to be without appreciable risk of adverse effects <u>during a lifetime.</u>" Section 750(7), however, demands compliance with this lifetime exposure limit <u>over a 24-hour averaging interval</u>. The use of a lifetime no-effects exposure level to set a 24-hour concentration limit has no basis in logic or science. Nor is there any scientific basis to use a child's weight and breathing rate to derive an ambient concentration limit that will produce no adverse health effects after a lifetime of exposure.

Some sites may emit hazardous substances that pose a short term health risk. Acute exposure limits may be needed for these sites. But such limits must be based on acute health effects projections or data. One source of such limits may be OSHA permissible exposure limits for short term exposures to various hazardous chemicals. It is irresponsible to base 24-hour ambient concentration limits on a lifetime exposure reference dose.

Another problem with Section 750 is that the conditions for approval of a conditional cleanup level (CCL) gravely restrict Ecology's authority to approve a meaningful CCL. For instance, a party whose site is already cleaner than background should not have to employ "best available control technology" to obtain a CCL. <u>See</u> comments on WAC 173-340-360(4)(b)(iii).

The continued use of the 10^{-5} and 10^{-6} risk levels for the air cleanup levels is even more problematic than the use of those levels for the other media. In most, if not all, of the urban areas of the state, for example, existing background risks exceed these levels. Expenditures to reduce air emission risks to these levels when the background is far greater than these levels would be wasteful at best, as would the necessary monitoring to establish the precise background level and sources of contamination surrounding an existing site.

Finally, Section 750, like other sections of the proposed cleanup standards, contains an impermissibly broad delegation of authority to Ecology program managers to set cleanup standards. The United States and Washington constitutions require that any grant of authority to a regulatory agency must be accompanied by standards to guide and confine the agency's discretion. Section 750 repeatedly invites Ecology to impose "Any other concentrations which the department determines are necessary to protect human health and the environment." See WAC 173-340-750(1)(a)(v), (2)(b), (3)(c) and (4)(c). This broad statement of intent does not provide sufficient guidance to meet constitutional due process standards.

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MEMORANDUM

to: Marcia Newlands — September 14, 1990

from: Tom Schadt

re: Comments on the July 18 Draft MTCA Clean-up Regs

WAC 173-340-720 Groundwater Cleanup Standards
(6)(d) Point of Compliance

The proposed language does not take into account what the receiving water or nearby surface water standards are based on. These standards are typically based on aquatic toxicology studies. The standards are established based on an intention to protect aquatic life. The proposed language suggests that standards based on aquatic organism protection should be imposed at a location within the ground water. This is too stringent given that the organisms the standards are based on do not live in the ground water. We suggest the following language be used in place of the existing version:

At sites where affected ground water discharges to nearby surface water, the cleanup level may be tied to protecting the surface water body. In these cases, one consideration for establishing ground water cleanup levels is to use the available criteria/standards for the surface water. If this approach is selected, the point of compliance should be the point where aquatic life in the nearby surface water first experience the ground water. This is particularly important for surface waters that are marine, and the chemical complex of the ground water may change as it mixes with a saline receiving water. If the compliance point is located upgradient in the ground water, it may not accurately reflect what the aquatic organisms in the receiving water will experience.

WAC 173-340-720 Groundwater Cleanup Standards
(8)(g) Compliance Monitoring

Depending on the specific site, the method in which values below the detection limit are handled may have a significant effect on determining compliance. At sites with numerous monitoring wells and a site-averaging approach to determining compliance, more lenient language should be used for values below detection limit. In certain situations it may be appropriate to use less than one half the detection limit and the regulation should reflect this.

WAC 173-340-730 Surface Water Cleanup Standards
(6)(b) Point of Compliance

The exclusion of dilution zones from the surface water compliance is contrary to state practices on permitted point source discharges. Even though groundwater is non-point source, it should be provided the opportunity for dilution before compliance criteria are enforced. An interesting analogy to consider is stormwater. Stormwater discharge is a non-point source discharge, yet soon to come under the jurisdiction of NPDES permits. If you apply the same logic the state is taking on ground water to stormwater, it would mean that stormwater needs to meet the receiving water criteria before any dilution or mixing occur. For stormwater discharging to marine receiving waters, it would mean that the stormwater would have to meet marine chronic criteria established by EPA. Based on a general characterization of urban run-off, the stormwater would require extensive treatment before it could be discharged, and even with BAT it may not be possible to clean it to the levels required by marine chronic criteria.

Also, requiring ground water compliance without allowing for mixing or dilution raises the same concerns expressed before for marine receiving waters. The chemical complex of the ground water may change as it mixes with a saline receiving water. If the compliance point does not reflect mixing with the saline receiving water, it may not accurately reflect what the aquatic organisms in the receiving water will experience.

WAC 173-340-740 Soil Cleanup Standards
(6)(d) Point of Compliance

The use of 15 feet as a compliance point is arbitrary and assumes extensive excavation. Although Section (6)(e) allows for a variance based on individual sites, it still sets an arbitrary standard that will be used as a point of comparison. The regulation should delete Section (6)(d), and revise (6)(e) to reflect that each site should have an independent point of compliance determined based on site characteristics and potential future uses. Also, the regulation should reflect the potential for soil capping and deed restrictions that limit future excavation of the cap. This type of cleanup would eliminate and/or reduce the depth for the point of compliance and should be reflected in the regulations.

WAC 173-340-745 Soil Cleanup Standards for Industrial Sites
(5)(d) Point of Compliance

See response to WAC 173-340-740(6)(d) above.

to: Marcia Newlands
from: Tom Schadt
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WAC 173-340-830 Analytical Procedures
(2)(c)(d)(e) General Requirements

The requirements listed in this section tend to be generic and catch-all phrases. There is nothing specific that is technically inappropriate. Some of the dictatorial statements regarding the detection limits are of concern. Lower detection limits are generally more costly and in some cases not achievable. There is a general concern that the department consider each site/case carefully to determine if lower detection limits are necessary and achievable.

Environmental Toxicology International, Inc.

MEMORANDUM

To: Mike Thorp, Heller, Ehrman, White, and McAuliffe

From: Joyce Tsuji JT

Date: 12 September 1990

Re: Additional Review of WDOE Model Toxics Control Act

In follow up to our discussion earlier this week, we have reviewed the additional issues that you indicated for The Model Toxics Control Act Cleanup Regulation and Proposed Amendments, Chapter 173-340 WAC (July 27, 1990 revision) of the Washington Department of Ecology (WDOE). This memo is in addition to our previous comments on this document (5 September 1990). As before our review is primarily from a health risk and toxicology perspective.

We have outlined our specific comments below by topic. Issues on which we have no comment or have previously commented are not mentioned. We refer to the sections reviewed as the "Proposed Amendments".

DEFINITIONS (WAC 173-340-200)

1. Bioconcentration Factor

WDOE should recognize that these factors are for the most part out of date and often based on laboratory data which have little relevance for the field because of differences in conditions, environmental factors, and organisms at a specific site. In addition, the chemical form that is accumulated in tissues may not be toxicologically the same as the form in the environment. A good example is inorganic arsenic which fish convert to the relatively non-toxic organic form (USEPA, 1988, Battelle, 1989).

2. Carcinogen

The cancer potency factor is usually, but not always, the upper 95th percentile of the confidence limit of the slope of the dose-response curve (USEPA, 1989b). Sometimes the actual slope is used for example when there is high confidence in the data because they are from a large study involving a human population.

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It should also be stated that as for the reference dose, carcinogen potency factors are associated with an order of magnitude or more uncertainty.

3. Developmental Reference Dose

These criteria are not available and are still under considerable review and development by the EPA. Because the development of scientifically defensible criteria are a task that should involve nation-wide review by known experts and health agencies, the development of such criteria for each site should not be a requirement given the present lack of EPA guidance.

4. Inhalation Reference Dose

We find it curious that a reference dose for inhalation exposures is defined but not one for oral exposures. U.S. EPA defines chronic reference doses for both inhalation and oral pathways.

5. No Observed Adverse Effect Level or NOAEL

As stated by the Proposed Amendments, this definition could be misinterpreted to mean the highest level at which *any* exposed test organism does not show an adverse effect. Thus, the NOAEL derived for one species could result in toxic effects in other test organisms, because species differ radically (as much as 1000 times) in sensitivity to chemicals.

It would be clearer to state that the NOAEL is "the exposure level at which there are no statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered to be adverse, nor precursors to specific adverse effects" (USEPA, 1989b, p. 7-2). Further, when a dose-response experiment shows more than one NOAEL, the regulatory focus is on the highest one (USEPA, 1989b).

6. Null Hypothesis (WAC 173-340-200)

As we stated in our previous comments, the definition of "null hypothesis" in the Proposed Amendments is scientifically incorrect. The U.S. EPA risk assessment guidance document (USEPA, 1989b, p. 4-8) correctly defines and explains statistical hypothesis testing for hazardous waste sites: "A statistical test of a hypothesis is a rule used for deciding whether or not a statement (i.e., the null hypothesis) should be rejected in favor of a specified alternative statement (i.e., the alternative hypothesis). In the context of background contamination at hazardous waste sites, the null hypothesis can be expressed as 'there is no difference between contaminant concentrations in background areas and onsite,' and the alternative hypothesis can be expressed as 'concentrations are higher onsite.' This expression of the alternative hypothesis implies a one-tailed test of significance."

What the Proposed Amendments present as a definition for the null hypothesis is thus the definition for the alternative hypothesis. In the context of the Proposed Amendments, the null hypothesis should be "the site is not contaminated at concentrations that exceed cleanup levels."

7. <u>PAHs (carcinogenic)</u>

"Dibenzo(z,h)anthracene" should be "dibenzo(a,h)anthracene".

8. <u>Polychlorinated biphenyls</u>

This group of compounds is defined as those aromatic compounds containing two benzene nuclei with two or more substituted chlorine atoms. Such a definition is too encompassing and will result in noncarcinogenic compounds such as dichlorobiphenyl being evaluated as the carcinogenic products containing predominantly six or more chlorines. The PCB potency slope is based on animal studies of the commercial product containing 60% chlorine, whereas products containing less than 54% chlorine have not been found to be carcinogenic. Carcinogenicity and bioaccumulation and persistence decrease with decreasing chlorine content. A better way to describe the group of concern would be to base the definition on percentage of chlorine (e.g., 48% chlorine or greater, to be conservative).

9. <u>Reference Dose</u>

A more accurate definition of reference dose (RfD) as defined by the U.S. EPA risk assessment guidance document (USEPA, 1989b) is that it is the upper bound of the tolerance range within which there is essentially no chance of adverse effects associated with this dose, even to sensitive populations.

10. <u>Subchronic Reference Dose</u>

It should be recognized that the limited number of subchronic reference doses currently available are considered interim values since they have not received verification by an intra-Agency workgroup (USEPA, 1989b). As such, subchronic reference doses are not listed in the IRIS database. In addition, subchronic criteria may be overly conservative because data on subchronic toxicity tests are often not as complete as for chronic tests, which have been EPA's focus.

Subchronic reference doses are intended to be protective for shorter than lifetime exposure periods on the order of two to seven years. They are not intend for evaluation of acute or short-term exposures occurring within a few day or weeks. In fact, if experimental toxicity data are available for shorter exposure durations than desired, additional uncertainty factors are applied to make the reference dose more conservative (USEPA, 1989b). In addition, when a suitable subchronic test is not available, the subchronic criteria is adopted from the chronic criteria (USEPA, 1989b). We have noticed in reviewing the interim subchronic criteria that this has been the case for many chemicals that have such criteria. As stated by the U.S. EPA guidance document, however, chronic RfDs "pertain to lifetime or other long-term exposures and may be overly protective if used to evaluate the potential for adverse health effects resulting from substantially less-than-lifetime exposures" (USEPA, 1989b, p. 7-8).

The U.S. EPA also does not have sufficient guidance for calculation of subchronic exposures at this time. Because of all these uncertainties and inaccuracies, cleanup decisions should not be based on use of these interim values.

11. <u>Type I and Type II Error</u>

Because the Proposed Amendments have incorrectly defined the null hypothesis the Type I and Type II error definitions are similarly incorrect. WDOE should refer to U.S. EPA (1989b, p. 4-8 and 4-9) for correct definitions. In addition, according to the Proposed Amendments, a Type II error results when one accepts a true null hypothesis. This is not an error. Correctly stated, a Type II error is the acceptance of a false null hypothesis.

GENERAL PROCEDURES (WAC 173-340-700)

Conditional Cleanup Levels (8)

Some allowance should be made for the possibility that concentrations established under applicable state and federal laws are out-dated. For example, many of the water quality criteria are as much as 10 years old and have not been updated. As a result, the arsenic ambient water quality criteria for protection of human health via fish ingestion is based on the old arsenic cancer potency factor, which is now an order of magnitude lower (less conservative).

"Concentrations which eliminate or minimize the potential for food chain contamination" are not absolutely necessary for the protection of health and the environment. The protection of health and the environment depends on the extent of food chain contamination, the magnitude of exposure, and the relative toxicity of the chemical.

GENERAL PRINCIPLES (WAC 173-340-705)

1. Reference Doses (7)

See comments under "Definitions" for developmental reference dose and subchronic reference dose.

The conversion given for computing the inhalation reference dose from an acceptable air concentration is inappropriate given the equation presented for assessing cleanup levels for noncarcinogenic effects via inhalation. The exposure parameters used in the equation are those of a small child, yet the computed reference dose would be that appropriate for assesss lifetime or adult exposure. As a result, the cleanup level would be underestimated (too conservative). The correct procedure would be to either use 10 m^3/day and 16 kg for computing the inhalation reference dose or to use 20 m^3/day and 70 kg in the ambient air cleanup equation.

2. Bioconcentration Factors (9)

See comments under "Definitions" above.

GROUNDWATER CLEANUP STANDARDS (WAC 173-340-720)

1. Table 1: Method Compliance Cleanup Levels - Ground Water

The rationale behind many of these numbers is unclear. In particular the cleanup level presented for cadmium is 5 ppb, whereas the MCL is 10 ppb. Based on the current RfD for cadmium, and U.S. EPA drinking water exposure assumptions (2 L/day and 70 kg body weight), the MCL would also be health protective. The cleanup levels for several volatile chemicals (ethylbenzene, toluene, and xylenes) are one to three orders of magnitude lower than necessary to protect human health via drinking water according to the current RfDs and U.S. EPA drinking water assumptions for these chemicals. We also conservatively assumed that inhalation exposure to volatiles would increase exposure by five times. A comparison of values is shown below:

	Method A ppb	Risk-Based ppb
Cadmium	5	17.5
Ethylbenzene	20	700
Toluene	40	2100
Xylenes	20	14,000

2. Inhalation Correction Factors (7)

It would seem more appropriate to assess the amount of exposure via inhalation of volatiles using the inhalation reference dose and not the oral reference dose as shown in the cleanup equation.

3. Compliance Monitoring (8.g.)

The U.S. EPA recognizes that assuming non-detectable samples are 1/2 the detection limit can result in problems and artificially high estimates of exposure concentrations. For example, because of potential sample-specific problems such as matrix interferences, detection limits for some samples may be unusually high and can greatly exceed the positive results reported for the same chemical in other samples in the data set. Consequently, U.S. EPA (1989b p. 5-10) recommends that one "exclude the samples from the quantitative risk assessment if they cause the calculated exposure concentration...to exceed the maximum detected concentration for a particular sample set." U.S. EPA also indicates that zero could be assigned to non-detected values in the case where site-specific information indicates that a chemical is not likely to be present in a sample.

This comment also applies to similar text in following sections.

SURFACE WATER CLEANUP STANDARDS (WAC 173-340-730)

Conditional Cleanup Levels; Dietary Fraction of Fish Ingested (4.c.i. and ii)

If the site is to have restricted use, it is hard to imagine that a person would eat 20% of their fish diet fraction (30 grams/day) at the site. Recreational fishing at a restricted site should be very limited to non-existent.

SOIL CLEANUP STANDARDS (WAC 173-340-740)

1. Table 2: Method A Compliance Cleanup Levels - Soil

The value presented for lead, 250 ppm is unnecessarily conservative given the actual data by the Centers for Disease Control (CDC, 1985) on lead exposure in children and the guidance of both the CDC and the U.S. EPA (1989a) that lead levels of 500 to 1000 ppm do not result in measurable increases in children's blood lead levels. The U.S. EPA has set an interim cleanup level at Superfund sites of 500 to 1000 ppm (USEPA, 1989a).

3. Conditional Cleanup Levels (4.b.ii. and iii)

Chronic effects should be evaluated for lifetime exposure and not instantaneously for a small child. Consequently, a soil ingestion rate of 100 mg/day and body weight of 16 kg are incorrect. Adult soil ingestion rates and body weights should be used (see also previous comments on soil ingestion rates, 5 September). Also if access to the site is to be restricted, it is highly unlikely that children would be exposed to the site and also unlikely that one would be exposed for a lifetime.

4. Compliance Monitoring (7.e.)

The authors of the Proposed Amendments have shot themselves in the foot by specifying that a one-tailed test of the null hypothesis should be used. In doing so they have increase the power to reject and made it more likely that the null hypothesis (that the site exceeds the cleanup levels) will be rejected. If the null hypothesis were correctly defined (see definitions above) and one had *a prior* reason to believe that the site were contaminated, then a one-tailed test would be appropriate. [This appears to be the result of wanting to have one's cake and eat it too!]

5. <u>Target Soil Concentration Versus Removal Level</u>

The Proposed Amendments do not make a distinction between exposure concentrations and removal levels. The cleanup levels calculated by the equations provided are actually average exposure concentrations that would result in the target risk level given the exposure assumptions. The implication is that this concentration, which is achieved by back-calculation from the risk equations, should be used as a removal level at a site. In other words, all concentrations at the site must be below this level. If the goal of cleanup is to achieve a specified target risk level, the removal limit should be that which would result in a mean exposure concentration (target exposure level) that is associated with the target risk level. If the target exposure level is used as a removal level, then the actual mean exposure concentration at the site after cleanup will be considerably lower (i.e., by an order of magnitude or more) than the target goal.

Another way to look at this situation is to consider a site for which the risk assessment determines that exposure to site concentrations would not result in risks exceeding the target level. If cleanup levels were calculated as specified by the Proposed Amendments, this site would still have to be cleaned up because many of the levels on site will exceed the target exposure concentration. Because no one is exposed for a lifetime continuously to the maximum concentration at a site, there is no justified reason to use the exposure concentration as calculated by the risk assessment equations as the removal level.

The more scientifically justified approach is to set the cleanup level as a level above which concentrations are to be removed and replaced with background soil concentrations to result in an overall site mean that meets target risk levels. This upper limit could also be examined to ensure that no acute effects would result from short-term exposure to concentrations at the cleanup level.

CLEANUP STANDARDS TO PROTECT AIR QUALITY (WAC 173-340-750)

1. Conditional Cleanup Levels (4.b.i.)

See comment #1 above concerning conversion factors to use for reference doses under "General Principles".

2. Compliance Monitoring (7)

According to the Proposed Amendments, compliance with ambient air cleanup levels for noncarcinogens is to be based on 24-hour time weighted averages. This in effect compares acute exposure concentrations to cleanup levels developed using chronic (lifetime) reference doses. As noted by the U.S. EPA (1989b), however, chronic reference doses may be overly protective if used to evaluate the potential for adverse effects resulting from substantially less than lifetime exposures. Because of the way that chronic inhalation reference doses are derived, annual averages should be used instead to determine compliance.

I hope this review is helpful. Please feel free to contact me if I can provide any further information.

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RECEIVED
SEP - 6 1990
HELLER, EHRMAN

MEMORANDUM

Environmental Toxicology International, Inc.

To: Marcia Newlands: Heller, Ehrman, White, and McAuliffe

From: Joyce Tsuji

Date: 5 September 1990

Re: Review of WDOE Model Toxics Control Act

As requested, we have reviewed The Model Toxics Control Act Cleanup Regulation and Proposed Amendments, Chapter 173-340 WAC (July 27, 1990 revision) of the Washington Department of Ecology (WDOE). Specifically, our review from a health risk and toxicology perspective focuses on cleanup level calculations (e.g., exposure parameters), target risk levels, and the definition of null hypothesis. These topics are within the proposed amendments and new sections as highlighted in the text of the Act.

I hope this review fulfills your needs. Since I will be out of town and difficult to reach September 4-7, I will try to contact you in case you have any questions. Otherwise, I will be back in the office the week of September 10.

REVIEW

Our general findings are that some of these guidelines involve methods that are out-dated and not scientifically justified. Because guidelines for assessing health risks are constantly being up-dated as more information is available, it is imperative that WDOE should start out with the most current methods and information. In addition, although this latest revision does contain some language that implies that the process can be sensitive to new scientific information, we suggest that more emphasis be placed on making the process flexible enough to allow for changes in scientific data and risk assessment procedures as well as for site-specific data. Inflexible cleanup levels and simplistic risk equations that must be protective of any and all types of sites will necessarily be overly conservative for most sites. At the same time, if the guidelines lack clear allowance for new or site-specific information, the cleanup levels could be over or under-protective of health and the environment.

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We have outlined our specific comments below by topic. We refer to the sections reviewed as the "Proposed Amendments".

1. Null Hypothesis (WAC 173-340-200 - DEFINITIONS)

The definition of "null hypothesis" in the Proposed Amendments has turned the statistical definition and correct usage of this term on end. The Proposed Amendments have defined the null hypothesis as "the site is contaminated at concentrations which exceed the cleanup levels". By definition, a "null" hypothesis is one in which no effect has occurred. Such a hypothesis is tested to determine whether it should be rejected or accepted. The definition used by Proposed Amendments seems statistically and scientifically naive. It should be recognized that the null hypothesis is independent of whether or how thoroughly tests are conducted to determine whether this hypothesis is true or false. To achieve Deprtment of Ecology's assumed goal with this definition, the regulations could always say the the burden of proof is on the responsible party to demonstrate that the null hypothesis (e.g., that the site has not been contaminated) should be accepted. Similar language is presented under WAC 173-340-705-5.

In addition, the null hypothesis as defined by the Proposed Amendments implies that even sites with no evidence of contamination are considered contaminated. (It sounds somewhat like the assumption that the site is presumed guilty until proven innocent.) The intent and implications of the proposed definition cannot be disputed on a scientific basis, but there may be policy or legal considerations that Heller Ehrman may wish to pursue.

2. Protection (WAC 173-340-700-2 - GENERAL PROCEDURES)

This section states that the goal of cleanup actions is to assure protection of human health and the environment. Yet, little attention is given in the methods A, B, or C to protection of the environment. Most text only states that cleanup concentrations are expected to result in no significant adverse effect to wildlife. Protection of the environment can be far more relevant than of human health for some sites. For example, using soil cleanup standards based on protection of humans via soil ingestion is likely to be totally irrelevant for a contaminated wetland. Cleanup levels based on protection of the ecosystem in this case is of greater importance.

This section further states that "the goal is to establish cleanup levels as close as possible to natural background levels". Background levels do not assure protection of human health and the environment. More importantly, this goal may be counter productive in that achieving background levels at a site that are far below those necessary to protect human health and the environment can take away funds needed to cleanup other sites.

3. Reasonable Maximum Exposure (WAC 173-340-700-4)

The Proposed Amendments state that cleanup levels are to be based on Reasonable Maximum Exposure (RME); however, the definition of this exposure needs further clarification. As stated by the latest U.S. EPA guidance document on risk assessment procedures for Superfund site cleanups (USEPA, 1989b), the RME scenario is a reasonable estimate of the maximum exposure that is likely to occur at the site. Under this approach, some intake variables may not be at their individual maximum values, but in combination with other exposure and toxicity variables will result in estimates of the RME. For example, U.S. EPA uses average soil ingestion rates and upper 95% percentile estimates of toxicity criteria. The U.S. EPA recognizes by these comments that the use of maximum exposure rates for all parameters in a risk assessment will not result in exposure that is "reasonable". The suggestion is made by the U.S. EPA that the determination of reasonable is to be based on both quantitative information and professional judgment. This section would be more scientifically reasonable if it clarified that not all exposure parameters are expected to be upper 95% estimates or maximums.

4. Target Risk Level (WAC 173-340-700-7,8,9)

The target risk level for carcinogenic chemicals specified by WDOE is 10^{-6} for residential exposure under Method B and 10^{-5} for industrial exposure or conditional exposure (e.g., see WAC 173-340-720 to 173-340-760). These risk levels are 10 to 100 times more conservative than the target risk level set by the U.S. EPA for exposures to small populations, such as those exposed to contaminated waste sites. A review of decisions of the U.S. EPA indicates that 10^{-4} is the risk level below which action has never been taken to reduce risk for these smaller populations (Travis *et al.*, 1987).

When multiple chemicals are involved at a site, the Proposed Amendments designate a target risk level that is similar to the risk level for individual chemicals. Setting the overall cleanup level close to or at the same level as for individual chemicals (e.g., 10^{-5}) means that risks associated with individual chemicals must be, for example, two orders of magnitude lower (e.g., 10^{-7}) in order that total risks do not exceed a target level of 10^{-5}. Consequently, this goal will be rarely met because analytical detection limits will not be able to meet the low concentrations required and these concentrations will also probably be below background levels. The U.S. EPA recognizes this problem in their National Contingency Plan (NCP) guidance that the target risk level when multiple carcinogens are involved shall be 10^{-4}.

5. Multiple Hazardous Substances (WAC 173-340-700-9,10)

In evaluating the additive effects of multiple noncarcinogenic chemicals at a site, the level at which toxic effects occur should be considered along with whether chemicals have similar "toxic responses". For example, many chemicals will have various similar toxic effects in the body at high enough exposure levels. The relevant effects for determining cleanup levels, however, are only those that occur for each chemical at their lowest doses. Thus, these sections should clarify that in evaluating additive effects, the toxic responses to consider are only those on which the reference doses (RfDs) are based and not on those which occur at higher doses.

6. Exposure Parameters (WAC 173-340-705-10)

The Proposed Amendments allow for modification of only three parameters: "where there is clear and convincing scientific data which demonstrates (sic) that one or more of the following parameters should be modified for an individual hazardous substance or site: (i) gastrointestinal absorption rate; (ii) inhalation correction factor; or (iii) bioconcentration factor. Nevertheless, scientific evidence does exist for modification of other exposure parameters which are currently invariant by the proposed amendments "as a matter of policy". Examples of these other exposure parameters are soil ingestion rates and inhalation absorption rates, which are discussed in some detail below.

Some explicit mention should also be made that chemical form can have a large effect on exposure parameters, such as absorption and bioconcentration, and on toxicity of a chemical. For example, it has been established that arsenic accumulated in seafood is generally only 1% in the toxic inorganic form; the rest is the relatively nontoxic methylated form (USEPA, 1988; Battelle, 1989). As a result, exposure may be overestimated by 100 times if chemical form is not taken into account in this case. Consequently, scientific or site-specific information on the chemical form present should be considered.

7. Lifetime (WAC 173-340-720, 730, 740, 750)

The lifetime used in all equations should be should be 75 not 70 years. The current U.S. EPA guidance (USEPA, 1989a,b,c) is to use 75 years based on national data. Using 70 years overestimates carcinogenic risk.

8. Evaluation of Noncarcinogenic Risk (WAC 173-340-740-3,4; WAC 173-340-750-3)

The equations of the Proposed Amendments assess noncarcinogenic risks and cleanup levels by evaluating the dose for a young child only. Thus, the body weight and soil ingestion rates shown in the cleanup level equations are the average daily dose for the age group which has the highest dose per body weight.

This method for assessing noncarcinogenic risk is now recognized as no longer scientifically valid. Chronic RfDs are developed for evaluation of lifetime exposure and hence are not appropriate for evaluation of less than lifetime exposure such as only during a few childhood years. Thus, current EPA risk assessment guidelines are to evaluate the average lifetime exposure and compare this dose to the RfD. For example, daily doses for children and adult age groups are weighted by the amount of time spent in each age group, totalled, and the total is divided by the total period of exposure, i.e., lifetime. This procedure calculates the average lifetime exposure (i.e., childhood and adulthood).

9. Soil Ingestion Rates (WAC 173-340-740)

The assumption for soil ingestion rates in the soil cleanup calculations is based on U.S. EPA recommended levels. For the Reasonable Maximum Exposure (RME) scenario, U.S. EPA Region X uses 200 mg/day for children ages 0-6, and 100 mg/day for 6 years of age and older (USEPA, 1989a). These ingestion rates are equivalent to those presented in the Risk Assessment Guidance for Superfund (RAGS; USEPA, 1989b), which are derived from two tracer element studies conducted on children's fecal material (Clausing *et al.*, 1987; Binder *et al.*, 1986). These studies are described in more detail in the Exposure Factors Handbook (USEPA, 1989c). The Exposure Factors Handbook specifies that recommended soil ingestion rates are considered to be an average rate for each age group. Nevertheless, as noted in recent studies (Calabrese *et al.*, 1989; Davis, *et al.*, 1990), neither of the two earlier studies accounted for the contribution of diet to the tracer element content of the fecal material studied. Thus, based on more recent information, the rates recommended by U.S. EPA may not be scientifically accurate. According to the up-to-date studies, more appropriate soil ingestion rates are on the order of 10 to 80 mg/day (Calabrese *et al.*, 1989; Davis, *et al.*, 1990); U.S. EPA is currently debating the merit of these studies.

10. Frequency of Exposure for Workers (WAC 173-340-745)

In calculating soil cleanup levels for workers, it is unclear why a different frequency of contact (1 or 100%) is used for assessing noncarcinogenic risks than for carcinogenic risks (0.3 or 30%). Although the chronic RfDs are not valid for short-term exposures, U.S. EPA (1989a,b) allows evaluation of less than 100% frequency of contact by workers for assessing noncarcinogenic risks, and uses the same exposure frequency as for carcinogenic risk calculations (0.36 or 36%). At worst-case, for long term exposure (over much of a lifetime), workers would only be expected to be present at a site for five out of seven days of the week. Some weeks they may work more days of the week, but also vacations and sick days would decrease the number of days worked over the years. The WDOE should also consider that the northern climate in Washington would decrease the amount of soil and dust ingested for much of the year.

11. Inhalation Absorption Rate (WAC 173-340-750)

An inhalation absorption parameter should be added to the equation for calculating cleanup levels protective of noncarcinogenic and carcinogenic effects of chemicals. For some chemicals such as arsenic, the toxicity criteria (e.g., cancer potency) is based on an absorbed dose. The U.S. EPA risk assessment procedures state that toxicity criteria based on an absorbed dose should be compared to an absorbed and not an administered dose (USEPA, 1989b). Therefore, for arsenic, an absorption parameter of 30% should be used as specified by the U.S. EPA (1984; 1989b). Using the equation as presented in the Proposed Amendments would be scientifically incorrect.

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October 1, 1990

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ECOLOGY

Mr. David Bradley:
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, WA 98504-8711

Re: State Register 90-15-066, Public Consent

Dear Dave:

I wish to make one brief comment on the proposed cleanup standards. I will not repeat the many comments I have submitted as part of the Cleanup Standards Work Group, but I do appreciate the opportunity to have participated in that process. Instead, I wish to draw your attention to an issue which caught my eye on page 7-13 of the Draft Environmental Impact. It states there that each truckload of soil removed from a site in Seattle to Arlington, Oregon, poses an increased risk of transportation-related deaths of 1.1×10^{5} [sic - I assume this was meant to be 10^{-5}]. In comparison, the greatest lifetime incremental risk of cancer allowed at a cleanup site, even under conditional cleanup levels, is 10×10^{-5}.

In other words, each truckload of dirt removed from a site poses a greater risk to the public than is allowed from the site for a lifetime of exposure. It thus seems clear that to the extent the cleanup standards require soil removal to lower cancer risks from 1.0×10^{-5} to 1.0×10^{-6} in order to attain compliance cleanup levels, they pose a net risk to the public. This is the concept Dr. Landau has espoused on the Scientific Advisory Board.

In short, Ecology should reconsider its absolute floor of a 1.0×10^{-5} risk level, and re-examine whether conditional cleanup

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Bellevue/October 1, 1990

levels are appropriately available where attaining compliance cleanup levels would result in a net risk to the public.

Sincerely yours,

DAVIS WRIGHT TREMAINE

Jeff Belfiglio

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JB:sbc

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LYNDA L. BROTHERS

September 17, 1990

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VIA TELEFAX, HARD COPY TO FOLLOW

David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

RE: State Register 90-15-066, Public Comment

Dear David:

The Department of Ecology ("DOE") is to be congratulated for the effort and innovation incorporated into the Proposed Amendments to Ch. 173-340 WAC ("Amendments"). However, the Amendments are not consistent with the statutory authority granted to DOE, and fail to adequately consider economic and cost impacts. The Amendments are based upon a risk based analysis which fails to consider certain major costs in the determination of cleanup standards and the Economic Impact Statement is based on an irrelevant cost analysis model. The Amendments raise serious policy and legal questions as to the authority of the DOE to require institutional controls, and the EIS and the Economic Impact Analysis both fail to evaluate the impacts of such institutional controls. The Economic Impact Statement sets forth cost mitigation measures which are neither established by rule or policy as required in compliance with the Regulatory Fairness Act.

1. Institutional Controls in the Amendments are beyond the authority granted to DOE, and not evaluated in either the Environmental Impact Statement ("EIS") or the Economic Impact Statement ("Statement").

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Seattle

Proposed WAC 173-340-440 requires,

> Institutional controls that restrict the use of the site and natural resources affected by releases of hazardous substances from the site shall be required to assure continued protection of human health and the environment or integrity of an interim action or clean up action . . . .

The "institutional controls" are to take the form of "a restrictive covenant executed by the property owner and recorded with the register [sic] of deeds for the county in which the site is located." Id.

Nowhere in the Model Toxics Control Act ("MTCA") is DOE granted authority to require restrictive covenants or to require the recordation thereof with the county. Absent such delegation of authority by statute proposed WAC 173-340-440 exceeds DOE's authority and should be deleted from the proposed regulation. See e.g., Kaiser Aluminum v. Pollution Control Hearings Board, 33 Wn. App. 352 (1982). We recognize that under certain circumstances DOE may seek to place limitations of the use of property, however such limitation can be accomplished through the use of existing administrative procedures.

The EIS fails to evaluate any of the impact of the institutional controls contained in the proposed WAC 173-340-440. The failure to analyze the impacts of institutional controls is significant and the omission distorts the conclusions reached in the EIS. Experience indicates that such restrictions limit the uses and transferability of property. To require institutional controls where a clean up[1] has been conducted is tantamount to an unconstitutional taking of property. The environmental impacts of institutional restrictions on property

[1] Although WAC 173-340-173(5) provides for the removal of restrictive covenants under certain circumstances, that subsection does not alter this analysis, since it has not been shown when or how many, if any, sites will qualify for removal of the covenants.

have been ignored in the EIS; such impacts may include expansion of industrial facilities into previously unused, residential or otherwise"clean" properties and lost opportunities for clean up actions at contaminated.

The Economic Impact Statement fails to address the costs associated with imposition of institutional controls. These cost may represent a disproportionate burden for small businesses.

In conclusion, proposed WAC 173-340-440 should be deleted. It exceeds the authority granted to DOE, its impacts were not evaluated in the EIS, and its economic impacts on small business has not been evaluated.

2. Costs have not been adequately considered in the clean up standards under the Amendments, the Economic Impact Statement or the EIS.

First, as you and I have discussed on numerous occasions, Section 3(2)(d) of the MTCA requires inclusion of the requirements of CERCLA Section 121, which expressly require the consideration of cost in the choice of clean up standard.[2] In addition, consideration of cost is clearly contemplated by Section 3(1)(b) which requires consideration of practicability in the choice of remedial actions. The courts have consistently interpreted practicability to include cost considerations. It is interesting to note that DOE's existing regulations also make it clear that cost considerations are paramount throughout the remedial process. Payment of DOE's remedial action costs is discussed in WAC 173-340-550 which limits recovery of costs to those "reasonably attributable to the site." Also, DOE requires consideration of cost in the feasibility studies required under WAC 173-340-350. Third, DOE has premised its analysis in the Economic Impact Statement on the availability of mitigation measures for costs associated with implementation of the Amendments, reiterating the economic and cost impacts on small business.

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[2]The legal support for this position has been supplied to DOE in the past, both in verbal and written comments and therefor is not included here.

The Economic Impact Statement ("Statement") is based on a model which does not accurately reflect the provisions of the proposed Amendments. The Statement employs the Environmental Protection Agency's Cost of Remedial Action ("CORA") Model, yet nowhere in the Statement is that usage justified. The CORA model contains assumptions unique to the federal program. The Statement recognizes, but fails to rectify, this problem. See, Statement at 2. Further, the EIS makes clear that the federal and state clean up programs are different. See, for example, the following:

> Ultimately, Ecology would have legal authority to take independent action at the site and impost the MTCA clean up levels.

EIS at 3-36.

> This requirement does not preclude the adoption of state standards that are stricter than federal standards.

Id.

> . . . the proposed MTCA rules are designed to be more uniform than the Superfund rules, with less flexibility available in determining site-specific clean up levels.

EIS at 3-37.

The cumulative effect of the above statements in the EIS indicate that the MTCA rules are very different from the Federal clean up program. Yet the Economic Statement is based upon the CORA model which is based on the federal Superfund program.

The Discussion of alternatives in the EIS apparently fails to fully consider the impact of different options for evaluating cost. At page 3-31, the EIS sets forth certain options for the evaluation of cost, yet the impact of those options are evaluated.

Thank you for the opportunity to comment upon the proposed Amendments, Environmental Impact Statement and the Economic

Impact Statement. For the reasons stated above, we believe the DOE should consider alterations to the Amendments. Please don't hesitate to call if you have any questions.

Very truly yours,

DAVIS WRIGHT TREMAINE

Lynda L. Brothers/pd

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Duane Berentson
Secretary of Transportation

September 6, 1990

Mr. Dave Bradley
Department of Ecology
Mailstop PV-11
Olympia, WA 98504-8711

Dear Sir:

Attached are the Washington State Department of Transportation's comments relative to the Department of Ecology's proposed rule, Chapter 173-340 WAC, as published in WSR 90-15-066. We request that these comments and this transmittal letter be included in the official administrative rule record.

We have noted that some of our written comments to your earlier draft were incorporated into the present version, while the bulk of our comments were not. In some instances, similar comments were incorporated in one section and ignored in another. We believe that this shows an inconsistently in your handling of the comments.

We request that you furnish us with copies of comments you received relative to the March 9, 1990 Draft.

Sincerely,

E. R. Burch

E. R. "SKIP" BURCH, P.E.
State Design Engineer

ERB:pac/F587
JLM (HYD)

Attachment

COMMENTARY
CLEANUP STANDARDS AMENDMENTS
TO
MODEL TOXICS CONTROL ACT CLEANUP REGULATION
Washington State Register, Issue 90-15
Washington State Department of Transportation
September 4 , 1990

The following comments, which we request to be made a part of the administrative rule record, are referenced to section and page numbers:

700 (2) Protection, page 169, last sentence. Lists goal as establishing cleanup goals as close as possible to natural background levels. The cleanup goal should be a defined standard based on the overall threat to human health and the environment, but cannot be more stringent than either the natural background level of the material, or the sensitivity of the tests used for detection of the material.

700 (3) (c), page 169. This requirement appears to contradict (3) (a) on page 169. If Ecology eliminates from consideration the hazardous substances that contribute a small percentage to the overall threat to human health and the environment, it would make no sense for Ecology to turn around and require biological tests on substances that they already have considered insignificant.

700 (4) (a) page 169. Estimated future resource uses and potential future site use conditions cannot be used to establish a standard, unless Ecology gives a method to estimate the future resource use and the potential future site use in the administrative rule.

705 (6), page 171 - If Ecology wishes to set standards based on new scientific information, the administrative rules should be changed to reflect this new scientific information. Ecology must share the content of new scientific information in a clear and concise manner with those it intends to regulate, and make this determination available for all to see and judge.

705 (7) (d), page 171. If Ecology intends to dispute the reference doses established by EPA, Ecology must outline in the administrative rules the exact standard it will use for the determination of "clear and convincing scientific data" that will be used to determine that use of the EPA data is inappropriate.

705 (8) (d), page 172. If Ecology desires to use a carcinogenic potency factor other than that established under (a) of this subsection, Ecology must define the

"scientific rationale" for this decision and include it in this administrative rule.

705 (9) (a),(b) page 172. If Ecology desires to use a bioconcentration factor other than that established by EPA, Ecology must define in this administrative rule what constitutes "clear and convincing scientific data" which demonstrates that this is appropriate.

705 (11) (e), page 172. Not logical to deal with values lower than the detection level. To assign a value of one-half the method of detection limit is arbitrary. Use the accepted practice of indicating that the substance was present in a concentration less than the detection limit.

705 (12) (d), page 172. If Ecology desires the use of improved analytical techniques with lower practical quantification limits, they should amend the administrative rules to reflect these techniques.

710 (1), page 172. It would appear that it is Ecology's responsibility to list applicable state and federal laws in the administrative rule.

720 (8) (g), page 175. Cleanup levels less than the method of detection limits for approved analytical methods do not make any sense from a technical standpoint.

730 (2) (b), page 175. Ecology should list other concentrations that are necessary to protect human health and the environment, with the caveat that under no circumstance should cleanup levels be lower than either the natural background level, or the limits of detection for approved analytical methods. This comment also applies to 730 (3) (d) page 175, and 730 (6) (d) page 176.

740 (1) (a), page 176. Ecology cannot establish a future use that is not specifically defined in the administrative rule.

740 (2) (c), page 176. Again, Ecology should list the criteria used in determining all concentrations that are necessary to protect human health or the environment.

740 (7) (g), page 178. Again, Ecology should not be concerned with measurements below the method detection limit for an approved technical analysis.

745 (2) (c), page 178, and 745 (4) (c) page 179. Concentrations necessary to protect human health and the environment not listed in 740 (3) (c) should be listed here if Ecology wishes them to be a standard.

750 (2) (b), page 179, 750 (3) (c), page 179, and 750 (5) (c) page 180. Other concentrations that Ecology believes are necessary to protect human health and the environment should be listed in the administrative rule.

830 (2) (e), page 180. If Ecology is to require modification of the standard analytical methods required in this section, then Ecology should give the criteria for the modification and the content of the modification in the administrative rule.

Golder Associates Inc.
CONSULTING ENGINEERS

September 14, 1990

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ECOLOGY

Our ref: 773-1910

Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia, WA 98504-8711

ATTENTION: Mr. Dave Bradley

RE: COMMENTS ON PROPOSED AMENDMENTS TO THE MODEL TOXICS CONTROL ACT CLEANUP REGULATIONS (CHAPTER 173-340 WAC)

Dear Dave:

Please find enclosed our comments on the proposed cleanup standards for the Model Toxics Control Act Cleanup Regulations.

Sincerely,

GOLDER ASSOCIATES INC.

for Anthony S. Burgess
Principal

J. Scott for
Douglas G. Dunster
Senior Environmental Scientist

Enclosure

ASB/DGD/ah

COMMENTS ON PROPOSED AMENDMENTS TO MODEL TOXIC CONTROL ACT CLEANUP REGULATION (CHAPTER 173-340 WAC)

1. Sec. -200 "Applicable state and federal laws" - The definition includes relevant and appropriate requirements as "applicable". We do not believe that relevant and appropriate requirements should be redefined by the regulations as being applicable. Applicable laws should be only those that meet the definition provided for "Legally applicable requirements". As indicated in EPA's guidance on applicable or relevant and appropriate requirements (ARARs) in <u>Cercla Compliance with other Laws Manual</u> (OSWER Directive 9234.1-01), there is much more discretion in determining whether laws that are not legally applicable may be relevant and appropriate to the conditions of a specific site. We believe it is important to maintain this distinction and flexibility in the cleanup standards.

2. Sec. -200 "Type II error" - The last sentence in the definition of Type II error is incorrect. The proper definition should be: "... This is acceptance of the null hypothesis when it is false."

3. Sec. -360 General Comment - We recommend this section include language similar to that provided in the National Contingency Plan (NCP) in 40 CFR 300.430 (a)(iii), which states EPA expectations in selecting realistic and appropriate remedial alternatives. Such language would greatly simplify the selection of a remedy as compared to the language provided in section 360 of the proposed regulations.

4. Sec. -360 (2)(b)(ii) - This section requires that cleanup actions that meet -360 (2)(a) be technically practicable. Section 360 (2)(a)(ii) requires that cleanup actions comply with all applicable state and federal laws. There is no provision for waiver of compliance with applicable laws were it is not practicable. This will result in unenforceable and unimplementable requirements for cleanup. We recommend that the waiver provisions for compliance with ARARs provided for in CERCLA Section 121 (d)(4) be included in the state regulations. We acknowledge that there may be some limitations imposed on the Department by the language in RCW 70.105D.030 (2)(d). This should be a high priority to be addressed with statutory amendments to the Model Toxics Control Act.

   The proposed regulations go beyond the limitations imposed by the statutory language due to the definition of "applicable state and federal laws" as noted above, and elsewhere throughout the regulations. For example, Section 720 (2)(a)(ii) defines maximum contaminant levels (MCLs) and maximum contaminant level goals (MCLGs) under 40 CFR 141, and secondary MCLs under 40 CFR 143 as applicable laws for groundwater cleanup. Under the Safe Drinking Water Act, MCLs are only applicable at the tap, and MCLGs and secondary MCLs are not enforceable. Section 300.430 (e)(2) of the NCP states that MCLs and MCLGs shall be attained for ground and surface waters that are current or potential sources of drinking water, where they are <u>relevant and appropriate to the circumstances of the release</u>. Thus, the proposed standards result in more stringent requirements than are imposed by the statutory language.

This combined with the lack of waiver provisions provided by CERCLA will likely result in major burdens to PLPs, and will result in non-attainable expectations for cleanup.

5. Sec. 360 (4)(b)(ii) - We question whether all known, available and reasonable methods of treatment (AKART), specified as policy in RCW 90.48.080.010, should be defined in this section as an applicable state law for restoration of groundwater. This law applies to prevention, however, we question whether it is applicable to restoration. This as well as other language in Section 360 seems to promote treatment for treatment sake. For example 360 (4)(b)(ii)(A) states that groundwater treatment shall be required when it is "practicable <u>or</u> in the public interest". This should be practicable <u>and</u> in the public interest. Failure to meet both criteria should be sufficient to justify selection of other alternatives. Treatment should not be required just because it is practicable, but rather it should be utilized where it is determined to be the most suitable alternative (or portion of an alternative) based on evaluating all the criteria conducted during the feasibility study.

6. Sec. 700 (2) - The last sentence of this paragraph states, "The goal is to establish cleanup levels as close as possible to natural background levels." This sentence should be deleted. There is no apparent statutory authority in RCW 70.105D for the Department to establish standards based on this goal. The preceding statement in this paragraph adequately states the goal for cleanup (i.e. assure protection of present and future human health and the environment). In addition, this goal does not appear to be reflected in the proposed regulations and is not necessary or appropriate for such regulations. Stating this as a goal for cleanup only serves to create unrealistic and unattainable expectations.

7. Sec. 700 (3)(c) - What sort of biological testing is envisioned. Bioassays used for dangerous waste designation under WAC 173-303 may not be particularly meaningful for establishing cleanup levels. Systemic toxicity and carcinogenicity testing, the forms of testing most appropriate to the overall objectives of MTCA, are long-term, expensive and highly controversial.

8. Sec. 700 (4)(a) and (b) - Recommend that "reasonable anticipated" be inserted before "potential future site use" in these paragraphs.

9. Sec. 700 (5)(d) - General Comment. This entire section needs to be rewritten. It currently contains so many caveats and limitations on the use and levels that must be attained for conditional cleanups that one wonders whether they could ever be employed. In addition, the conditional cleanup levels specified in 700 (8) and throughout Sections 720 through 750 do not provide for significantly different cleanup levels than is provided by Method B. For example it appears that conditional cleanup levels for groundwater are identical to Method B levels for carcinogens, and the only modification for toxic compounds is the assumption of adult exposure (i.e. body weight and drinking water intake rate) versus that of a child.

10. Sec. 700 (5)(d)(i), (ii), (iii), and (iv) - The last part of these paragraphs, "but in no cases greater than concentrations specified in subsection (8) of this section" should be deleted.

- A PLP should not be required to cleanup below area background as required by (i).

- It does not make sense to require compliance with the conditional cleanup level specified in subsection (8) if it results in creating a significantly greater overall threat to human health and the environment as required by paragraph (ii).

- If conditional cleanup levels are not technically feasible, how will these levels be attained as required by (iii)?

- If conditional cleanup levels are not technically practicable, how will these levels be attained as required by (iv)?

11. Sec. 700 (5)(d)(v)(B) - This paragraph needs to be revised. Realistically, containment and isolation will be a <u>principal</u> component of many cleanup actions. Containment and isolation are highly effective means of reducing or eliminating potential health or environmental threats posed by contaminated sites. We acknowledge the desire to emphasize permanent solutions to the maximum extent practicable. However, the regulations can accommodate this goal without specifying unrealistic requirements and expectations. EPA states in the NCP (40 CFR 300.430 (a)(1)(iii) that they expect to use engineering controls, such as containment, for waste that poses a relatively low long-term threat or where treatment is impracticable.

12. Sec. 700 (7)(b) - The last sentence of this paragraph states that the total excess cancer risk of 1 in 100,000 shall also apply to sites where there is exposure to a single hazardous substance by one exposure pathway. If this applies to both multiple and individual exposures what is the purpose of the 1 in 1,000,000 excess cancer risk used in the formulae in sections 720 through 750.

13. Sec. 700 (8) - It appears that in some cases conditional cleanup levels will not be significantly different than Method B levels. As indicated in comments 9 and 12 above, groundwater cleanup levels for carcinogens appear to be identical for Method B and conditional cleanups. We recommend that the excess cancer risk for conditional cleanups be 1 in 10,000. EPA through several of their regulations (i.e. the Safe Drinking Water Act, CERCLA, and RCRA) has determined that this level is "protective" of human health.

14. Sec. 705 (10) - This section states that exposure parameters cannot be modified with the exception of the exposure parameters specified in (b). This is too limiting. For example, the surface water cleanup standard requires use of a fish consumption rate of 30 grams/day and a fish diet fraction of 0.5. These exposure assumptions may be totally inappropriate for site specific conditions. There are probably only very isolated conditions where these assumptions would be valid as "reasonable maximum exposure". We understand the desire to establish consistent levels of cleanup, while reducing areas of potential dispute. However, there should be more flexibility to allow

realistic reasonable maximum exposure parameters to be developed for determining site specific cleanup levels.

15. Sec. 705 (11)(d) - We do not understand the rationale and there is no statistical basis specified for requiring 10 or more samples for determining natural background and 20 or more for area background. While some statistical tests such as the Chi-Squared Test for distribution require as much as 20 samples, in many situations assumption of a normal distribution is acceptable and will be conservative. When using the tolerance interval approach as specified in the regulations, increasing the sample size from 10 to 20 will only modify the test statistic or tolerance factor (K) from 2.911 to 2.396 respectively, while doubling the cost of determining area background. In addition, this number of samples may be impracticable to attain for certain media at some sites. For example how would these requirements be applied to determining background for groundwater? Would it require 10 or 20 background wells? Fewer wells sampled several times would not be true independent samples and would violate basic statistical assumptions. We suggest that the regulations not include specific sample numbers for determining background. This should be determined by qualified scientists.

16. Sec. 705 (11)(e) - We suggest using 0.5 of the sample quantitation limit (SQL) when measurements are above the method detection limit but below the practical quantitation limit.

17. Sec. 710 (1) - See comment 1.

18. Sec. 720 - 750 Method B formulae for carcinogens - EPA currently recommends a 75 year lifetime for the assessment of carcinogenic risks.

19. Tables 1-3 - General Comment - The basis for the cleanup levels provided in these tables has not been provided. It is impossible to determine the appropriateness of these standards without knowing the rationale behind their derivation. For example why do the Method A cleanup levels for PCP equal the industrial standards? The standard is apparently not based on protection of human health due to soil ingestion.

20. Table 1 - Gross Beta Particle Activity. A mrem/yr dose can not be calculated for gross beta radiation; a specific beta emitting radionuclide must be known. We suggest that the cleanup level of gross beta particle activity be set based on the MCL in 40 CFR 141 of 50 pCi/L [as long as H-3 and Sr-90 do not in combination exceed 20,000 pCi/L (H-3) + 8 pCi/L (Sr-90) $\leq$ 1].

21. Sec. 720 (1)(a) - The conditions under which drinking water is presumed to not be a current of likely potential future use of drinking water should include; Where ground water is not and will not be used based on location and availability of other sources of supply (e.g. it is extremely unlikely that ground water in the urban area of Seattle will ever be developed for drinking water supply). Ground water should not have to be remediated to drinking water standards if it is situated in a location where it is extremely unlikely that it will ever be used.

22. Sec. 720 (2)(a)(ii) - MCLGs and secondary MCLs should only be considered as potentially relevant and appropriate cleanup standards and not as applicable requirements. See also Comments 1 and 4.

23. Sec. 720 (4)(ii)(B) - This will result in a conditional compliance cleanup level identical to Method B. See also comments 9, 12, and 13.

24. Sec. 720 (6)(d) - Assigning the point of compliance for ground water discharges to surface water as locations in ground water without allowance of dilution zones in the surface water is not appropriate. In many circumstances the flux of contaminants discharging from ground water to surface water will be insignificant, will not violate ambient water quality criteria, will not pose a threat to human health or the environment, and may not be measurable in the surface water. We can not see any justification for not allowing a dilution zone for ground water discharges to surface water. There are numerous site specific physical-chemical processes that occur and will affect the actual impacts of contaminated ground water discharges to surface water. Defining the ground water as the point of compliance will result in needless expensive cleanup actions with no overall benefit to the people of the state or the aquatic environment. We recommend that compliance be determined in the receiving water near areas of groundwater discharge.

25. Sec. 720 (8)(a) - Use of unfiltered ground water samples is not appropriate in most cases for determining compliance with the ground water standards. One of the principle data quality objectives for an environmental investigation is to ensure that samples are representative. In many situations unfiltered samples from monitoring wells (particularly in low yield monitoring intervals) will not provide samples that are representative of contaminants that are mobile in the ground water flow system. A representative sample of ground water should contain only those constituents that are mobile in the ground water flow system under natural gradients or what would enter a water supply well. Groundwater flow systems contain dissolved constituents and suspended colloids, but do not contain settleable solids.

    There are fundamental differences between the construction and operation of a water supply well and a monitoring well. When initially drilled, a drinking water well produces water that may contain particulates in substantial amounts. Suspended solid particles in a water sample is called turbidity. Such wells are developed or stabilized by running sufficient water through the system to ensure that the sediments are exhausted. As a result, the turbidity of water supply wells usually stabilizes at extremely low levels. Many contaminants are extremely sensitive to turbidity as a result of high absorption to soil particles in the aquifer matrix due to high soil-water partition coefficients. EPA recognizes the importance of turbidity in the analysis of ground water and generally requires a turbidity of less than 5 N.T.U. when the analytical method is sensitive to turbidity.

    Ideally the same well development procedure should be followed for monitoring wells to ensure that samples are representative of those that would be obtained from a supply well. However, this is not normally feasible with a monitoring well. Extremely large quantities of water, potentially requiring collection and treatment, would be produced to develop a monitoring well to the degree a supply well is developed.

Many monitoring wells are installed in low yield fine-grained formations where such development is not possible. In addition, monitoring wells are normally only used periodically for sampling and are not in continual use like a supply well. This allows the buildup of sediments and precipitates that would require redevelopment each time the well is sampled to ensure a representative ground water sample is obtained.

We recommend that unfiltered ground water samples only be required if it is feasible to obtain samples having a turbidity less than 5 N.T.U. or it can be demonstrated the parameters being analyzed are not sensitive to turbidity. Filtered samples should be allowed (without having to make a demonstration) for certain parameters sensitive to turbidity (i.e. metals) when turbidity exceeds 5 N.T.U. Other methods such as settling, centrifugation, and decanting may be required for certain parameters (i.e. semi-volatile organic compounds) for which filtering may not be appropriate.

26. Sec. 730 - The formula for Method B surface water cleanup levels for systemic toxins has a typographical error. C,D,C should be UCF1.

27. Sec. 730 (7)(e) - Sampling of fish to supplement water column sampling is rarely prudent. Fish can be highly mobile and long-lived; therefore, controlled field experimentation to determine compliance with surface water cleanup standards would be quite difficult and likely inconclusive.

28. Sec. 740 (7)(a) - Reducing larger soil particles to 2 mm would likely result in a lower overall concentration in the reduced size fraction not an increased concentration.

29. Sec. 745 (1)(c) - This paragraph should be deleted. This paragraph states, "Soil cleanup levels established under this section shall be as close as practicable to compliance cleanup levels established in accordance with WAC 173-340-740." This language essentially negates the industrial standards by requiring cleanup levels as close as practicable to nonindustrial compliance levels. Any site, regardless of whether cleanup levels are based on industrial site use or residential use, can only be cleaned to levels that are practicable.

30. Sec. 830 - This section should acknowledge and authorize the appropriate use of field and rapid screening analytical methods during remedial activities. This appears to be precluded by this section as currently written. Field or rapid-screening techniques are widely recognized and utilized during remedial activities. Obviously field analysis should be conducted in accordance with proper quality assurance procedures including verification by analyzing a percentage of the samples at an accredited laboratory.

Waste Management of North America, Inc.
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Suite 424 • 303/770-3324

September 24, 1990

David Bradley
Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia, WA 98504-8711

Dear Mr. Bradley:

On behalf of Waste Management of North America Companies operating in the State of Washington, I thank you for the opportunity to review and comment upon this second public review draft of proposed cleanup standards developed by the Washington State Department of Ecology (DOE). This version has been extensively rewritten, and it represents a significant improvement over its predecessor in many respects. Despite the progress embodied in this new draft, however, there are still several areas in which we recommend improvement. Our comments and suggestions follow.

GENERAL COMMENTS

The following comments are offered as a follow-up to our April 13, 1990, letter to DOE in response to the March 1990 public draft of this proposed rule.

The focus of this proposal is clearly on "how clean is clean." Unfortunately, improved protection of public health and the environment in Washington State demands a different starting point. The construction of the proposed rule seems to indicate a failure to ask some more fundamental questions. First, what are the sources and constituents that pose significant current or potential human health risk, or that threaten our environment? Second, which of these sources or pollutants are under the regulatory authority of DOE? It seems that without having asked and answered these questions the proposed DOE rule may be addressing the wrong question.

The standard equations and assumptions proposed for use in deriving acceptable "hazardous substance" concentrations in various media have been modified since the March 9, 1990 public review draft, and the Department is to be commended for abandoning some of the extreme and unrealistic exposure assumptions contained in the earlier draft. Nonetheless, many extreme default and surrogate exposure assumptions remain. Again, we strongly recommend that site-specific assumptions be permitted in the risk computations.

As we stated in our response to the March public draft, we believe that it is inappropriate to place the equations and assumptions which implement the cleanup standards directly into a regulation. It is far better to place such information in a more readily updated guidance manual that would be incorporated by reference than it would be to codify it. In a field evolving as rapidly as risk assessment, this would avoid the inevitable pitfalls of attempting to update and modify regulations.

The proposal still fails to recognize or discuss uncertainty. The DOE cleanup levels and cleanup level methodology establish "bright line" criteria to discriminate between "acceptable" and "unacceptable" health risk. Unfortunately, the extremely conservative and unbalanced exposure and toxicity assumptions used in the risk assessment will exaggerate already conservative potential health risk estimates and consequently greatly limit the risk management options that the DOE may allow for a site.

While we are sensitive to the Department's need for consistent and protective remedies, we believe that the essentially mechanical risk assessment process proposed in these regulations, the low compliance cleanup levels, and the methods for determining compliance with conditional or compliance cleanup levels will inevitably hinder and frustrate progress. Since the proposed rule is closely modeled after the Federal Superfund program, we fear it may face a similar end -- acrimony and paralysis. Since most sites can only achieve "interim" remedies, a huge and burgeoning number of facilities will be added to the roles of sites under the DOE's purview resulting in the diversion of scarce health protection resources and the dilution of Departmental effectiveness.

Under DOE's proposed regulations, State and local governments and lending institutions could become custodians of tens of thousands of miles of soils contaminated with lead, carcinogenic polyaromatic hydrocarbons (PAH) and other toxic substances due to motor vehicle tailpipe emissions being deposited on roadsides. The contamination levels in these soils could easily exceed the proposed clean soil levels, and thus would require remediation under the proposal. Furthermore, the cumulative State governmental burden for remediating "hazardous substances" from DOE permitted discharges, emissions from motorized vehicles and unpermitted sources will become staggering. Conversely, the reduction in public health risk from such "facility" cleanups would be minute.

As described in our comments on the March 1990 public review draft, the DOE is mistaken in its use of the Method Detection Limit (MDL) instead of the Practical Quantitation Limit (PQL) as the basis of demonstrating compliance with cleanup levels in instances where measured concentrations are less than the PQL but greater than the MDL. U.S. EPA has addressed this issue in its rulemaking under several of its environmental statutes, and has consistently chosen PQLs as the proper benchmark for compliance. In a recent announcement, the U.S. EPA explained its rationale for this position:

> PQLs provide a reasonable degree of certainty that true values, rather than false negatives (or false positives) are presented. (If the true sample concentration is equal to the MDL, the analytical results will not be quantitative, i.e., will be reported as "less than the MDL" on about 50 percent of all analyses.)
>
> The PQL takes into account a number of factors that are generally difficult to control and that contribute to the uncertainty associated with the MDL, such as high background levels, significant matrix interference, and operator and instrument variability. PQLs therefore provide a greater degree of certainty as the actual the the (sic) constituent concentrations. [53 Federal Register 31, 38 (1988)]

In our comments on the March draft, we explained why filtered sampling data is more appropriate for groundwater and surface waters. It should also be borne in mind that public water supplies require filtration under federal turbidity requirements. It seems reasonable to conclude that if Maximum Contaminant Levels (MCLs) for public water supplies are based upon a water supply attaining a certain standard for turbidity, then samples from other water bodies should likewise be permitted to be filtered prior to evaluating their compliance with DOE cleanup levels. Groundwater samples from wells in unconsolidated soils are always susceptible to high turbidity. The high turbidity can lead to false positive exceedances (a Type II error) for metals.

In our comments on the March draft, we commented upon the use of a bioconcentration factor (BCF). The bioconcentration factor (BCF) should be at least a site- and species-specific value when one is proposing cleanup levels on the basis of human health protection. That is, the BCF should be derived from either empirical field measurements, or from a properly conducted laboratory study. The BCF used should come from measured contaminant concentrations in the edible portion of the fish, and of an indigenous species that is actually consumed by people of the State of Washington.

Finally, in response to the March 1990 public review draft we commented upon the proposed DOE authority to "...require biological testing to assess the potential interactive effects associated with chemical mixtures." The described authority is overly broad and it should be narrowed. The proposal should specifically mention the types of testing authorities it requires. These authorities should enable the Department to satisfy legitimate information needs, and generate data that are conducive to remediation of "facilities." It should not be a mechanism to fulfill the world's toxicological research needs. For instance, authority to conduct in vitro assays, or in vivo fish tank bioassays for surface water discharge effluent should provide the Department with sufficient information for effective environmental decision making, without trying to duplicate the authority of U.S. EPA under the Toxic Substances Control Act. Also, the inordinate cost of such tests, and the limited ability to interpret data generated from them bodes ill for indiscriminant testing authorities.

SPECIFIC COMMENTS

WAC 173-340-200, Definition of "Carcinogen"

Under "carcinogen", the definition of the carcinogenic potency factor (CPF) is only partly correct. The CPF is an upper 95th percentile confidence limit on the slope of the dose-response curve only for those substances for which the CPF was derived from animal data. However, for a number of substances the CPF is derived from human epidemiological studies, usually from occupational cohort studies. At last count, U.S. EPA had derived 14 CPFs for inhalation or ingestion of carcinogenic substances from human epidemiological studies. In these instances, the CPF is the maximum likelihood estimate of carcinogenic potency, not a 95th percentile upper-bound estimate.

WAC 173-240-200, Definition of "Exposure Pathway"

The definition of "exposure pathway" could be made more useful by adopting the four elements of the definition presented in EPA's Risk Assessment Guidance for Superfund [Vol. I, Human Health Evaluation Manual (Part A), Interim Final, December 1989, page 6-8]: (1) a source and mechanism of chemical release; (2) an environmental transport medium; (3) a point of potential human contact with the contaminated medium; and (4) a human exposure route. Absent one of these elements, the exposure pathway is incomplete.

WAC 173-340-200, Definition of "Facility"

The definition of "facility" as currently proposed is a verbatim quote of the definition in the Model Toxics Control Act (Initiative 97) or "Act". While this ensures consistency between the Act and the implementing regulations, it does not provide any guidance as to the actual scope of the regulation. For example, no guidance is given for determining what constitutes a "consumer product in consumer use". Regulatory interpretation is essential to ensure consistency in application.

A consumer's use of a degreaser solvent such as trichloroethylene (TCE) in his septic tank could potentially be as damaging as industrial use. If one liter of TCE enters the groundwater upwards of 77 million gallons of groundwater could be contaminated to the proposed cleanup level of 5 ug/L. Those individuals who drink such contaminated water would be indifferent to the purpose for which the chemical was being used, or whether a consumer or an industrial facility had allowed it to enter the groundwater.

The broad definition given for "facility," especially when coupled with the extremely stringent cleanup standards, means that some public water supply distribution systems would require remediation. It is well-known that public water supplies often contain a myriad number of inorganic and organic "hazardous substances" defined in the Act. These substances may originate from the water source, drinking water treatment additives, or from the piping and storage tanks used in the distribution system. For instance, lead and asbestos-cement piping (with or without PAH coatings) have been used for decades to convey water to residences and industry. These two "hazardous substances" (lead and asbestos) are commonly found in the public water supplies. Such public water supplies presumably would be forced to meet the same cleanup levels as other "facilities", particularly since there is no issue about potential exposure. Otherwise, consumers of public water supplies would receive a lower degree of protection for their health than a hypothetical consumer of contaminated groundwater in a plume.

Additionally, regulatory interpretation of the potential for liability for any hazardous substance which "come[s] to be located" at a facility is needed. Without guidance, the definition could impose liability on landowners who have contaminated groundwater flowing beneath their property. While the landowner might be able to avail himself of the innocent landowner defense, to do so, under the Act he must show that he took the utmost care with respect to the hazardous substances, the foreseeable acts or omissions of other parties, and the foreseeable consequences thereof.

WAC 173-340-200, Definition of "Federal Cleanup Law"

The proposed definition of "Federal cleanup law" should be expanded to include the corrective action authorities promulgated pursuant to the Resource Conservation and Recovery Act of 1976 and the Hazardous and Solid Waste Amendments of 1984.

WAC 173-340-200, Definition of "Natural Background"

The proposed definition of "natural background" should be modified by deleting the word "natural". Also, a better distinction should be made between the presence of naturally-occurring and anthropogenically-related hazardous substances in environmental media. For the latter category, the difference between site-related and nonsite-related contamination would be best illustrated on a smaller scale (e.g., local smelter emissions) rather than by the global example provided (nuclear weapons testing fallout).

WAC 173-340-200, Definition of "Release"

The definition for "release" in DOE's draft regulations is identical to that in Initiative 97. Some regulatory interpretation is needed. Liability should only be triggered in the event of a release or potential release of a regulatorily set threshold quantity of a hazardous substance, i.e., an action level in excess of health standards. Otherwise, the potential exists to hold parties liable who have not posed any threat to the public or the environment. Before liability is imposed it should be shown that the release violates (or that a threatened release is likely to violate) an applicable state or federal standard.

WAC 173-340-200, Definition of "Type II Error"

The definition of "type II error" is incorrect. Also, the phrasing of the definitions for "type I error" and "type II error" should be changed. Our suggested definitions are:

> "Type I error" means the error made when one rejects a true null hypothesis and inappropriately concludes that no statistically significant exceedance of cleanup levels has occurred at the site, although an exceedance has occurred. That is, a false negative has occurred.
>
> "Type II error" means the error made when one fails to reject a false null hypothesis and inappropriately concludes that a statistically significant exceedance of cleanup levels has occurred at the site, although an exceedance has not occurred. That is, a false positive has occurred.

WAC 173-340-200, Definition of "Volatile Organic Compound"

It would be helpful if the definition of "volatile organic compound" were more precise. For instance, the definition could be framed in terms of an intrinsic physical property of a chemical, such as vapor pressure, or it could be framed in terms of a reference to a common analytical list of volatile organic compounds, such as one derived from the Priority Pollutant List used by most federal and state environmental protection agencies.

WAC 173-340-360, Selection of Cleanup Actions

WAC 173-340-360(7) of the draft regulations indicates that cost factors are to be taken into account in determining whether a cleanup action meets the requirement of technical practicability of subsection (2) (b) (ii). While cost factors are indeed a crucial element of this determination, cost factors are also an integral part of other determinations and should be expressly included in other provisions of the regulations. For example, use of the term "practicable" with regard to employment of permanent solutions requires consideration of cost factors when evaluating a permanent remedy. As long as the solution is protective of human health and the environment and complies with applicable state and federal laws, cost should be a primary factor in determining the remedy. While the obligation to employ permanent solutions "to the maximum extent practicable", is a clear directive, it should not be construed so as to constrain DOE's flexibility to select cost-effective remedies.

Waste Management agrees that the preferred remedy should not rely heavily on long-term operation and maintenance, but the order of preference for selecting a protective remedy provided for in draft WAC 173-340-360 (6)(b)(i) through (b)(vi) is improper. "Permanence" should be evaluated relative to the degree of risk presented by the hazardous substances found at a site. Permanence may well be achieved without reliance on destruction or detoxification if the substances are not particularly toxic or mobile in the first instance. Containment, particularly secure containment, of stabilized or otherwise relatively immobile substances, may be effectively permanent. The regulations should recognize that reuse or recycling or destruction or detoxification may not be realistic for some sites, especially landfills with large volumes of low concentrated materials. The regulations should recognize that the decontamination of a site will not be practicable in many situations. Where sites have large volumes of materials containing low concentrations of hazardous substances, or where the waste is highly variable in composition, treatment is likely to be impracticable.

Additionally, when considering criteria for selecting a cleanup action under subsection (8)(a), it would be prudent to include a factor relating to the likelihood of exposure in developing restoration time frames. The DOE is to be commended on the scope of the factors compiled in this section. In particular, the natural degradation processes factor identified in subsection (8)(ix) is an important addition. The DOE should further consider including attenuation and dispersion in this subsection as other natural processes that affect the concentration of hazardous substances in media at a site.

The conditional provision under subsection (12) wherein the Department may use a record of decision under the Federal cleanup law to meet the requirements of this section should be changed to an absolute proviso. Cleanups performed pursuant to CERCLA and RCRA already incorporate the spirit of the requirements of DOE's proposal (e.g., including stipulations for public comment on the cleanup action, and attainment of all Federal and state ARARs). Needless duplication and redundancy should be avoided by changing the conditional "may" to "shall".

WAC 173-340-440, Institutional Controls

The DOE is to be commended for including the provision for institutional controls as part of an overall site remedy that protects human health and the environment.

WAC 173-340-700, General Procedures

The goal expressed in draft WAC 173-340-700(2) "to establish cleanup levels as close as possible to natural background levels" is inappropriate. This goal could result in a serious misallocation of resources, unnecessarily diverting scarce funds to cleaning up waste sites that pose little or no risk. As noted by the U.S. Environmental Protection Agency in the recently revised National Contingency Plan, "cleaning up to background levels may not be necessary to achieve protection of human health." 55 Fed. Reg. at 8717 (March 8, 1990). The incremental cost of cleaning up a site from a level of residual contamination that is fully protective of human health and the environment to one that achieves "background levels" is not in the public interest since it could jeopardize the ability to address more significant public health threats. Monies should be expended on sites that pose a health risk rather than encouraging expenditures of funds at sites that pose no health risk but at which "background" levels have not been attained.

Additionally, incorporation of the word "possible" rather than "practicable" implies that legitimate countervailing factors, including but not limited to costs, will not be taken into account when setting the remediation goal. The cleanup goal would be inappropriately set without regard to cost, potential ancillary adverse affects of achieving background levels or any other factors save the technical feasibility of achieving the goal.

Waste Management strongly urges that the proposed remediation goal be deleted. Instead, cleanup should, as noted in the first sentence of WAC 173-340-700(2), "attain a degree of cleanup of hazardous substances and control of further releases of hazardous substances that assures protection of present and future human health and the environment."

DOE's proposed cleanup standards [see, e.g., WAC 173-340-700 (4) and WAC 173-340-720(1)(a)] are based on a "reasonable maximum exposure" scenario and a variety of other assumptions which guarantee that the risks estimated for a site are far greater than any actual risk posed. Such use of hypothetical risk in lieu of actual risk will undermine the goal to cleanup high risk sites. Such an overly conservative methodology may well result in an over estimation of risk and could result in erroneous public perceptions as to the hazards presented by a site.

The DOE is to be commended for including the provision for allowing alternate exposure scenarios as part of a cleanup action. Recent research sponsored by the U.S. EPA has shown that the "reasonable maximum exposure" (RME) scenario fails to accurately predict human exposures. In simulations run with the Agency's lead biokinetic model it was found that use of the RME (which is the product of a sequence of upper-bound estimates on exposure parameters) grossly over predicts the distribution of blood-lead concentrations found in the U.S. population. By using average exposure parameter values in the model, the model was able to provide a nearly identical match of the blood-lead distribution reported from national survey data.

The requirement under proposed WAC 173-340-700 (5)(d)(iv)(B) that "neither containment or isolation of hazardous substances nor institutional controls" may be a principal component of the cleanup action is inappropriate and may not be technically feasible or economically practical. It should be recognized that for hazardous substances found at many sites, such as dense non-aqueous phase liquids (DNAPLs), inorganic metals, asbestos, and radionuclides, containment, isolation, and institutional controls may be the only feasible or practical remedies for years to come. Additionally, permanence may be achieved without reliance on destruction or detoxification of hazardous substances if the substances are not particularly toxic or mobile in the first instance, if site characteristics effectively isolate the substances, or if stabilization technologies may be used to render the substance immobile.

As noted above, sites with large volumes of materials containing low concentrations of hazardous substances, or where waste is highly variable in composition, may not be amenable to treatment. At sites containing primarily municipal waste, containment or isolation may be fully appropriate for 99 percent of the waste, with more aggressive measures for a limited portion of the site where hazardous wastes are of concern.

It should be borne in mind constantly that the sophistication of analytical chemistry instrumentation, to measure minute concentrations of substances in various media, long ago surpassed our ability to interpret their biological significance. The legitimacy of using the currently proposed but outdated model of carcinogenesis, which uses an "acceptable" hazard index of unity for noncancer effects and an "acceptable" upper-bound excess individual cancer risk of 1 in 100,000 or 1 in 1,000,000, for decision making.

The DOE is referred to the recent paper by Drs. Samuel Cohen and Leon Ellwein. ["Cell Proliferation in Carcinogenesis," Science, 249: 1007-1011 (1990)] Drs. Cohen and Ellwein posit that the tumors observed in laboratory animals are primarily due to the excessive doses administered to them under the guise of the "maximally tolerated dose." The policy and resource implications of this race to regulate animal "carcinogens" on the basis of what may be testing artifacts are clear. Also, the DOE is referred to the key paper by Drs. Richard Doll and Richard Peto on estimates of the sources contributing to cancer in the United States. ["The causes of cancer: quantitative estimates of avoidable risks of cancer in the United States today," J. National Cancer Inst. 66: 1193-1308 (1981)] The study is nearly a decade old, but the estimates it contains on the likely causes of cancer have held up to intense scrutiny. Their conclusions are worth rereading.

WAC 173-340-700, General Principles

The wording proposed in WAC 173-340-700 (7)(e) and (8)(b) should be changed to reflect that a Reference Dose (RfD) or CPF may be established using the cited reference or methods. The conditional wording is necessary because there will always be cases in which the toxicological data are absent or suspect.

For example, sometimes only a qualitative judgement as to a substance's carcinogenicity, and not a quantitative evaluation of its potency, is the best scientific position possible. Such is the case with lead. U.S. EPA has classified lead as a B2 (probable human) carcinogen based upon the results of animal bioassays. However, the strange dose-response data (only animals administered the highest dose responded) has led EPA to refrain from developing a cancer potency factor. Also, EPA has not promulgated an RfD for lead because of concerns, based on epidemiological studies, about whether or not its noncancer health effects have a threshold upon which to base an RfD.

WAC 173-340-720, Ground Water Cleanup Standards

DOE's proposed classification of drinking water aquifers in WAC 173-340-720 (1)(a)(ii)(A) fails to adequately account for the yield of water-bearing formations. Aquifers must provide an average sustainable yield of several gallons per minute to be of any beneficial use. Waste Management recommends that the regulations be revised to provide that if the sustained yield is less than 200 gallons per day, the groundwater will not be considered a potential future source of drinking water.

The "Table 1, Method A Compliance Cleanup Levels -- Ground Water," are inconsistent with acceptable levels promulgated under other state and federal statutes. For instance, the Maximum Contaminant Level (MCL) for arsenic in public water supplies, established under the Federal Safe Drinking Water Act, is 50 ug/L. Where then is the DOE's rationale for requiring ground water cleanup to 5 ug/L of arsenic? We are particularly concerned about the proposed order of magnitude reduction from the federal MCL given the new scientific information regarding detoxification of even moderately high levels of arsenic (200-250 ug/d), and the possibility of it being an essential human dietary nutrient [U.S. EPA Science Advisory Board, September 28, 1989, EPA-SAB-EHC-89-038; and U.S. EPA, "Special Report on Ingested Inorganic Arsenic," EPA/625/3-87-013, July 1988]. The enormity of these incongruities with federal MCLs and science have been inexplicably ignored. The DOE should review these documents and amend its proposal to conform with the toxicological evidence.

The MCL for vinyl chloride is set at the PQL of 2 ug/L, while the DOE ground water cleanup level for it is 0.2 ug/L. This latter value is likely due, in part, to use of an MDL and partly to assuming both inhalation and ingestion exposures to this volatile organic compound could occur from ground water that may serve as a potential drinking water source. Similarly, proposed values for chromium, ethylbenzene, lead, PAHs (carcinogenic), PCBs, pentachlorophenol, toluene, and xylenes are 5- to 40-fold lower than existing or proposed drinking water MCLs. The DOE may be unaware that the standard 2 liter per day water ingestion assumption is nearly double the actual adult average value.[U.S. EPA, "Exposure factors handbook," EPA/600/8-89/043, March 1989] Thus, the conservatism built into the MCL derivation process already incorporates an additional margin of safety for potential inhalation exposure of drinking water volatile organic compounds.

The proposed use of a screening level analytical test, total petroleum hydrocarbons (TPH), seems inappropriate as gasoline contains hazardous constituents with much lower Method A cleanup values than those proposed for TPH. This proposal may lead to disparate levels of protection for different types of facilities. For instance, a facility with gasoline in upgradient (background) monitoring wells may have its own contaminants obscured by the catchall term "total petroleum hydrocarbons. This is not environmentally sound. Chemical-specific analyses, such as BTEX, should be required at all facilities.

What is the logic behind restricting contaminant levels in water that may serve as a potential drinking water supply, but that ignores the risk to actual consumers of water? It would seem logical that if the DOE were to promulgate an acceptable concentration of any "hazardous substance" in groundwater it should apply those same standards to all public water supplies.

WAC 173-340-740, Soil Cleanup Standards

Utilization of risk-based analysis for soil is a more effective means of assuring protection of human health than setting a fixed numerical value. At a minimum, DOE is advised to defer setting Method A compliance levels until comparable values have been set by U.S. EPA.

We again thank you for the opportunity to comment on these regulations. If we may further assist you in this task, please do not hesitate to call.

Very truly yours,

Leonard J. Butler

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Region Environmental Vice President

cc: Doug Coenen, Patty DeJong, Dave Dolan, Peter Kelly, Rich O'Hara, Lynn Walker

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Distinguished Contribution to Risk Analysis

Risk Management, Assessment, and Acceptability[1,2]

Chauncey Starr[3]

Health and safety are moral sentiments generally given very high priority in most societies and by individuals. Like other moral sentiments—such as peace, freedom, and happiness—health and safety are not absolutes that can be defined in a quantitative sense, or specified in detail. They are, in fact, intangibly measured by the absence of undesirable elements which tend to reduce these objectives. Good health is considered a state of physical and emotional well being which is achieved by the absence of detectable disease, physical malfunctions, or early death. Safety is considered a circumstance of living in which physical injury or imminent threat of such injury is absent.

It is characteristic of such moral sentiments that each one is considered a social imperative justifying unlimited application of available resources. Obviously, no society has enough resources to fully meet such open ended commitments. As a practical matter, therefore, national resources are allocated either by the operations of a free market, if one exists, or by governmental actions which mandate and regulate such allocations. In this presentation, I would like to discuss the interlocking roles of risk management, assessment, and public acceptability in the formulation of social policy and government actions which lead to the allocation of our national resources for the improvement of public health and safety.

Analysis of the potential for harm from operational systems for delivering goods and services, and the quantitative assessment of risk probabilities and consequences, provides a very powerful tool for revealing the principle characteristics which can impair health and safety. I am an enthusiast for this process of quantitative analysis. It highlights the important risk-creating areas and thus encourages remedial changes. It encourages foresight rather than hindsight. It also provides a knowledge base for all subsequent actions taken by government or individuals to cope with these risks. And finally, the quantitative assessment provides a crude measure of the relative scale of the consequences of a specific risk in the total spectrum of all the other risks that we must live with. In combination with the corresponding spectrum of the benefits provided by various social activities, comparative risk assessment helps to provide a basis for the rational distribution of society's resources to improve public health and safety.

Nevertheless, the professional fascination with the methodology for the quantification of risk assessment, and public reactions to specific numerical findings, has tended to obscure the practical, functional end-objective which instigates assessment studies in the first place—namely, to assist society in setting criteria and allocating available funds for the management of risk.

Let me illustrate my point with a simple analogy. Almost every big city has a zoo, and in any popular zoo there is usually a tiger. It would be intriguing to make a public risk assessment of the consequences of the tiger escaping from the zoo. Perhaps we might crudely estimate that there is a probability of one in a thousand per day (or once in 3 years) of the tiger escaping and killing a nearby resident; or if we do a more sophisticated analysis, we may estimate the probability is one in a hundred thousand per day (once in 300 years) of such an occurrence. Regardless of probability, such an event can certainly occur. What are the options to protect the public? There are basically three—political, technical, and managerial. A political solution is to order the elimination of all

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[2] An address given October 1, 1984 at annual meeting of Society for Risk Analysis on the occasion of receiving distinguished contribution award.

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tigers from zoos. A technical solution is to declaw and defang the tiger. A managerial solution is to cage the tiger securely and provide alert zookeepers to keep the access gates closed. How has the public chosen among these three?

The public acceptability of zoos is obviously not influenced by risk assessments. Even though we know that wild animals occasionally escape from zoos, the public certainly considers them safe and acceptable enough to visit them with their children frequently. What is obviously acceptable to the public is the assurance by the zoo keeper that the tiger is securely caged. The point I wish to make is that it is not the risk assessment of the hazard from escaping tigers which is key to societal acceptance of zoos, but rather confidence that the management approach to coping with the risk is reasonably reliable.

My point is very simple. *Public acceptance of any risk is more dependent on public confidence in risk management than on the quantitative estimates of risk consequences, probabilities, and magnitudes.* This, of course, shifts the important assessment from a frequency/consequence analysis to a determination of what is meant by "reasonably reliable" risk management. I am suggesting that the practical public answer to the question, "How safe is safe enough?", depends more heavily on the operations established for the management of risk than it does on the quantitative description derived from risk assessments. If this is indeed so, then we should recognize this in our public discussions of the societal acceptability of risks.

Much has been professionally written on the subject of risk assessment and its contribution to the decision process for choosing among alternatives for providing a specific service. For example, the electricity generation options of coal, nuclear power, and hydroelectricity have been compared as to benefits and risks, and have been persuasively defended by their proponents. In retrospect, the past decade has shown that the comparative risk perspective provided by such quantitative analysis has not been an important component of the past decisions to build any of these plants. Historically, initial choices have been made on the basis of performance economics and political feasibility, even in the nuclear power program. *Pragmatic issues which permit a plant to be built and operated economically have guided the final choices.* In every case, it has always been assumed by the decision makers that operation of any generating plant can be managed to meet reasonable objectives of public safety (i.e., that the "tiger" can be kept in its cage).

For example, let us consider the recent concern with bioengineering and recombinant DNA, and specifically, the proposed field experimentation using bacteria that have been genetically altered. As you may recall, these experiments were recently challenged by a few individuals fearful that bacteria genetically engineered for specific purposes might create unknown and substantial risks on a widespread scale. The court injunction halting these experiments was presumably based on the issue of whether the National Environmental Protection Act requirement for the filing of an Environmental Impact Statement had been properly followed. The opponents of such experimental activity ask for proof that atrocious effects will not occur, and focus on hypothetical worst-case consequences. As a decision problem in a new scientific domain, the issue appears unsolvable. The uncertainties about the hypothetical risks can be made to appear very large, and the consequences can be imagined to be global.

However, in my opinion, the ability of the experimenters to manage or control the risk is the key issue. In the particular case of the DNA field experiment, the experiments were successfully carried out in greenhouses; the same experiment had been conducted in the field with bacteria produced by other than gene splicing; and a contingency plan to deal with the spread of the bacteria was part of the original proposal. However, these points were not emphasized in the public description of the issue. I would like to to emphasize that those engaged in the experimental work were fully aware of the need to insure that the "tiger was caged." They recognized intuitively the need for risk management. The pragmatic issue here is not whether some unforeseeable and inadvertent manipulation can hypothetically destroy humanity, but rather whether the field experiments can be confined to specified areas. To ask the proposers of such work to file a ritualistic Environmental Impact Statement will miss this point. Such statements have become loaded with the "what if" and "assume that" issues and denigrate the pertinent questions of risk management.

Public fears can always be aroused by the concept of man's tampering with nature, creating global catastrophies. Such fears can easily be used to stop new scientific developments. The issue for new science is whether a national decision is made early, with little information, to deny or severely limit experimentation, or whether an approach is taken to cautiously manage the risk and expand the range of activity as more information is developed. *Science cannot prove safety, only the degree of existing harm.* Thus, new technologies cannot be proven safe before use. We must recognize that anticipatory arousal of public anxiety can inhibit the creation of new technology.

A comparable situation exists, of course, in the nuclear power field. The emphasis on Probabilistic Risk Analysis (PRA), which has become a recent part of the safety review of the Nuclear Regulatory Commission, has focused professional concern on the frequency of core melt—the most catastrophic failure that can occur with the internals of a nuclear power station. The arguments as to whether such core melt can occur with a projected probability of one in a thousand per year, or in a million per year, represent a misplaced emphasis on these quantitative outcomes. The virtue of these risk assessments is the disclosure of the system's casual relationships and feedback mechanisms, which might lead to technical improvements in the performance and reliability of the nuclear stations. When the probability of extreme events becomes as small as these analyses indicate, the practical operating issue is the ability to manage and stop the long sequence of events which could lead to extreme end results.

The historical nuclear regulatory approach is to assume as inflexible the end impacts of radiation release, and the thrust of regulatory prescriptions has been to reduce their probability rather than to reduce the consequences. This acceptance of end-of-spectrum consequences has perpetuated arguments about evacuation planning, distances, sirens, etc., which I believe are unnecessary and destructive of public confidence. I know this is both an ideological and emotional subject, but let me illustrate my point with a typical example. We know that a rain shower precipitates both dust and soluble gases from the air. In like manner, radioactive particles and gases (except the noble gases) can be precipitated by a manmade rain. The radioactive fall out during rain from the early atmospheric atomic bomb tests illustrated this effect. Thus, if a nuclear power plant was encircled with a man-made spray system, and with a standby pumped water supply, the public could be given reasonable assurance that "the tiger was caged." This has not been seriously considered because the nuclear industry doesn't believe the NRC can be diverted from its obsession with the "what if it didn't work" viewpoint—no matter how feasible the management of the risk might appear. It depends on human intervention—like a fire department.

To repeat, my point is that public acceptability of nuclear power would be more likely to be achieved if it was assured of "reasonably reliable" risk management. This would mean that both the nuclear utilities and the NRC would need to place primary emphasis on the role of human intervention in the management of potential risks. It would also mean that the present NRC programs to establish safety goals based on quantitative risk assessments would become intellectual exercises useful for guideline engineering design, but not become the essence of regulatory policy.

We have a familiar technical system which clearly illustrates the difference between risk assessment and risk management. That is our prevalent form of transportation—the automobile. Every automobile is potentially a lethal device both to its operator and to the public at large. I leave it to you to imagine what an environmental impact statement of the automobile transportation system would reveal if it included the extreme scenarios of either driving with no hands on the steering wheel or with freedom of choice by each driver to go in any direction, at any time, in any manner he chose fit. Then I suggest you compare those end-of-spectrum consequences with the actual risk situation which, while large in the aggregate (50,000 deaths per year), is individually small enough that almost every one of us drives routinely on every errand. The answer, of course, is that a risk assessment which estimates the spectrum of frequency and consequences of auto accidents does not determine our social behavior in the use of the automobile. Obviously, we have learned how to manage the potential risks of the automobile by using both technical system design (roads and autos) and human intervention (good driving). While there is much that can be done to marginally improve the management of automobile risk, it is interesting that the public enthusiasm for such marginal improvements is not very strong. I am referring here to seat belt use, air bag proposals, and the attempts to reduce drunk driving.

In all these cases there is a common thread. And that common thread is that real risk management involves capable human intervention, as well as the inherent characteristics of the technical system. Of course, it is easier to write a prescription for a technical design than it is to write a prescription for human behavior. We now use double insulated electrical appliances rather than teaching people to keep them out of the bathtub. It is also easier to regulate technology than to regulate people. We expect machines to be obedient and predictable—and we realize that people are likely to be neither. For this reason, most regulatory agencies concerned with public health and safety find it most convenient to place the emphasis for acceptable performance on the shoulders of the technical system. There are systems where this is sufficient and preferable (e.g., the control of routine effluents). Unfortunately, we have found by experience that the machines occasionally fail and often in unpredictable ways. Happily, we have also found by experience that people can perform reliably, intelligently, and responsibly in novel situations—if the system is designed with positive interventions in mind.

Most every real operating system eventually involves man–machine collaboration, regardless of the regulatory approach. We attempt to design its technical characteristics to minimize potential risks, but we also depend upon human participation through operation and intervention to manage the situation. For example, our national policy is to develop drugs which are beneficial and yet minimize the risk to potential users. At the same time, because all drugs can be misused, we suggest or require medical supervision in their use. The public apparently finds this very acceptable. In like manner, the public accepts a myriad of daily risk exposures on the basis that these risks are reasonably managed by people.

Consider a few familiar additional examples of the dependence of risk management on human intervention. I call your attention to hour home fire insurance. Based presumably on actuarial experience, there are several principal factors which determine your insurance premium. The materials used in the construction of your house, certainly are important—these are the technical aspects. However, the location of the nearest fire department and hydrant are also very important—these are the human intervention aspects. In urban areas where these are available, the insurance premiums are about half of those in rural areas where they are absent. The feasibility of human intervention makes the difference.

As another example, consider medical services in a community. The technical aspects encompass the quality of physician training and skills, and the quality of hospital facilities, particularly diagnostic and surgical equipment. Even with good doctors and good facilities, the data on recovery from natures's accidents, such as heart attacks and strokes, indicates that the availability of a quick response by an ambulance service with skilled paramedics can make a very large difference on the probability of recovery. We even try to teach lay persons the rudiments of CPR (cardiopulmonary resuscitation) in recognition of the value of a quick human response. Again, the importance of human intervention is recognized. When one compares the social consequences of natural disasters in underdeveloped countries with those in the U.S., enormous differences are apparent due to the rapidity and the scale of the response in the U.S. As we have little control over hurricanes or earthquakes, we have been forced to take a responsive approach based on human intervention to the management of these risks.

When the technical system performance is heavily dependent on human behavior, and so not easily managed by prescription, what does the regulator do? This is the case for autos, airplanes, ships, power stations, farm tractors, drugs, foods, manned military equipment—you name it. People can cause accidents, and people can intercede to prevent them. So the regulator ordains the discipline of good habits. We license medical doctors, auto drivers, airplane pilots, nuclear plant operators, and hope for the best. Surprisingly, we have not as yet undertaken to license regulators—but give us time.

Political and government agencies have little faith in human experience, judgment, or skills, and generally assume that these cannot be depended upon to provide effective accident intervention. However, regulators intuitively know that despite its uncertainty such intervention is essential for risk management, so they have undertaken to anticipate and prescribe the forms of human intervention where possible. We thus train operators on flight simulators and nuclear reactor simulators, both of which attempt to reproduce anticipated system failures and accidents. They certainty maintain the alertness of operators to off-design behavior of their systems, and perhaps contribute to their confidence when a real emergency arises. But the history of truly serious accidents indicate that they rarely duplicate each other, and limiting each accident will likely need individually tailored human intervention. One must conclude, therefore, that practical risk management must plan on human initiative to meet the special circumstances at the time of an accident. In fact, regulatory doctrine that discourages such initiative, and tries to prescribe ritualized response for accidents, may increase the danger of serious public consequences.

Returning to the importance of risk management, I should emphasize that it must be credible to lead to public acceptance of a technology. These are clearly conditions when it is not sufficient. You may recall our aborted civil defense program, with underground shelters and emergency supplies. It was unsuccessful in convincing the public that atomic bombs should be considered as merely an extension of our conventional military arsenal. Obviously, it appeared to the public that the civil defense program would only marginally reduce societal damage. While FEMA (the Federal Emergency Management Agency) continues to urge the civil defense concept, it is difficult to find much support for it. It is evident, then, that for risk management programs to create public confidence, they must have a reasonable plausibility that they will "keep the tiger caged."

In the early discussions of public acceptability of risk, I drew the distinction between voluntary and involuntary exposures. This distinction was based upon the degree of individual control on the management of the risk. My most elementary example is the use of the kitchen knife for slicing bread. If you hold both the knife and the loaf of bread, the distance between the knife blade and your hand may be quite small. If someone else holds the knife, you are likely to move your hand further away from the blade. The point of this simple illustration is that under those circumstances where the management of the risk is not under the control of the individual exposed to it, it takes a much higher degree of confidence to make the risk acceptable. *It is that confidence which is at the root of public acceptability of a risk not directly under individual control.*

You will quickly recognize that most of our major public debates on the acceptability of risk fall into this domain of involuntary exposure. We have involuntary public exposure in the domain of water pollution, air pollution, industrial effluents, food additives, drugs, and the like. In almost every one of these involuntary exposures, society has determined that the benefits of the activity involved are sufficiently large that the activity, whether it be food and water supply, the generation of electricity, or the production of an industrial product, should not be foreclosed. *The public perception of benefits always precedes its concern with or the awareness of risks.* In almost all existing cases, the perceived benefits are so large that the option of abandoning an activity is not seriously considered, and society's efforts are focused on reducing risks. In those few cases where it is uncertain that the benefits justify the risks, the issues have become idealogically politicized. (Handgun control in the U.S. is an example).

The political issue, when the benefits are clear, is how much of society's resources should be allocated to reduce a specific involuntary exposure to an acceptable level. The complexity of this problem is familiar to many of us. The benefits of most activities are not uniformly distributed, and the unbeneficial in the form of involuntary risk exposures may be concentrated on a few. If, indeed, both the benefits and risks are focused uniformly on the same group, the question is usually resolved rapidly. A free choice of the group on the acceptable balance should certainly be feasible and forthcoming. Such simple cases must be very rare indeed, because I do not know of many —outside of commercial and business decisions.

We are left then with the question of whether our national approach to regulatory methods and policies are generally capable of achieving the dual objectives of public acceptability and the equitable balance of benefit and risk which maximizes the total public welfare. It is generally assumed by the public that regulatory decisions optimize the public welfare. In fact, this is rarely the case, although public justification of a regulatory decision is often presented in this fashion. However, in almost every case, the regulatory decision is based on the pragmatic feasibility of risk management evaluated either implicitly or overtly. And this feasibility depends on the effectiveness of the triumvirate—technology, management, and politics.

This leads us to a major component of risk management—the political aspects. In the broadest sense, this includes our societal values and public perceptions, and our institutions for implementing regulatory policies. In a democracy such as ours, with a very wide variety of special interests all trying to influence politicians concerned with re-electron, public perceptions have a major influence on legislative decisions related to public health and safety.

In principle, legislators should be focusing on those major issues whose resolution can have the largest aggregate social benefit. In fact, however, most individuals view all health and safety risks as potentially capable of affecting them, and thus want them all addressed. Thus, little distinction is made politically between health risks that might affect a relative few or many. Special interest groups aggravate this situation by concentrating their political pressure on selected risks, as for example, radiation, or food additives, or waste storage. As might be expected, politicians also hesitate to irritate any large group by seeking reduction in risks that require a change in accepted public habits—as for example, smoking, gun ownership, or drunk driving. *Popular support of political decisions determines the legislative action, but not necessarily a societal optimum.*

Such political factors determine our national priorities in risk management, usually without regard to risk magnitude, frequency, or quantitative importance. Political attitudes also determine the structure, policies, and methods of the regulatory agencies created by legislation. Legislative acts often prescribe in detail the administrative mechanisms and criteria to be used by the regulatory agencies, usually in simplistic and idealistic terms. The combination of legislative constraints and mandated idealism has created for our judicial system a major role in interpreting congressional intent, and thus the judiciary also has become an influential determiner of regulatory policy.

An element of our national political attitude on regulation is a basic distrust of the motivations and reliability of the private sector—both corporate and individual—to respond to emergencies. This distrust results in a heightened public belief on the necessity for regulation that will prescribe behavior or on technical fixes. It is usually unacceptable politically for a regulatory agency to openly place reliance for risk management on the personnel at an accident site. Such factors discourage regulatory acceptance of human intervention as a positive element in risk management.

For these reasons, we must consider the political aspects as perhaps the most important in determining the feasibility of risk management. One can only hope that the passage of time will permit the results of quantitative risk assessment, analysis of management options, and the comparison of benefits and risks, to eventually improve the perceptions of both the public, the politicians, and the courts.

Let me now repeat my main points: (1) public acceptance of a risk depends on public confidence in its effective management, and (2) effective risk management requires an optimal combination of risk assessment, technical feasibility, human intervention, and political support. I suggest that our primary analytical emphasis in improving public health and safety should be on our ability to manage risks, rather than on the assessment of end-consequences arising from hypothetical situations. I am suggesting that an Environmental Impact Statement should concentrate on how an anticipated risk will be managed, contained, or limited—rather than on a frequency/consequence presentation of rare hypothetical scenarios. Further, that such a management analysis should include the role of plausible human interventions. I believe that such an approach would create the public confidence needed for public acceptance of new technologies with all their accompanying uncertainties.

I will finish my talk with a theme song tailored to my message (and with apologies to professional song writers):

"Hold that tiger, hold that tiger
We want him around;
Hold that tiger, hold that tiger
Keep him caged and bound."

Epilogue

A few weeks after presenting this illustration, the following appeared as a news item in The New York Times, Friday, Oct. 19, 1984.

Escaped Tiger Slain In Village in Britain

LONDON, Oct. 18 (AP)—A 2-year-old tiger escaped from a zoo near Canterbury today, sped across a half-mile of open fields to a small village and was shot dead by zoo keepers in a backyard, the police said.

The tiger was one of five that ran from Howletts Zoo, 62 miles southeast of London, after an intruder unbolted a large enclosure for Indian tigers, according to a statement by zoo officials.

"The zoo staff managed to get four of these animals back into their enclosure, three by tranquillization and one by guidance," the statement said.

The fifth tiger headed for the nearby village of Littlebourne, where a patrol officer, Nigel Chandler, saw it ambling along one of the side streets. The officer knocked on doors warning villagers to stay inside, and then called the zoo.

Zoo keepers arrived and found the tiger sniffing around in a backyard. The police said that the keepers had shot the tiger without trying to capture it.

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Seattle WA 98101

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Reply to
Attn of: WD-139

David Bradley
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504

Dear Mr. Bradley:

The U.S. EPA Region 10 Underground Storage Tank program and the EPA Office of Regional Counsel have reviewed Ecology's proposed amendments to the Model Toxics Control Act Cleanup Regulation, Chapter 173-340 WAC. We have reviewed this proposed legislation with State program approval in mind. Based on the requirements of 40 Code of Federal Regulations Part 281, the State Program Approval Final Rules, we submit the following comments:

After a thorough review of the proposed amendments, we can find only one area that does not meet the "no less stringent" requirement for state program approval:

Section 280.65 requires owners and operators to conduct investigations of the release, the release site, and the surrounding area ... "if any of the following conditions exist: . . . (3) There is evidence that contaminated soils may be in contact with ground water." No similar language is found in 173-340-450(5)(a). Was this an oversight, or will Ecology **not** require investigations for soil and ground-water cleanup under these conditions? If so, this is one area where EPA believes the requirements are less stringent than the Federal rule.

While we believe these proposed amendments are, for the most part, very well written, we would also **propose** that several sections be changed or augmented slightly to more closely resemble the federal language:

Section 173-340-450(1)(b) states: "Unless the department requires otherwise, UST owners and UST operators shall comply...." What might the department otherwise require BUT these initial response actions? We suggest that the phrase "Unless the department requires otherwise" be removed from Section 173-340-450(1)(b) and inserted in the sections of the state rule that match this language in the federal rule.

Section 280.62(4) of the Federal Rule requires "**Remedy** hazards posed by contaminated soils...." Section 173-340-450(3)(a)ii states: "**Reduce** the threat to human health and the environment posed by contaminated soils...." We do not believe 'reduce' conveys the same meaning as 'remedy.'

Section 280.63(a)(2) requires, in part, data from available sources concerning "climatological conditions." Section 173-340-450(4)(b)iii makes no mention of 'climatological conditions.'

Section 280.67(d) states "The implementing agency must give public notice... if implementation of an approved corrective action plan does not achieve the established cleanup levels in the plan and termination of that plan is under consideration by the implementing agency." There does not appear to be any similar language to this in Section 173-340-600.

If you have any questions regarding these comments, please feel free to contact me at (206) 442-1643 or Denise Baker at (206) 442-2115.

Sincerely,

Joan Cabreza

Joan Cabreza, Manager
Regional UST/LUST Program

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ECOLOGY

Doris Cellarius
2439 Crestline Dr.
Olympia, WA 98502

MODEL TOXICS CONTROL ACT: PROPOSED CLEAN-UP STANDARDS

The overall framework of these proposed clean-up standards suggest that they will fully protect public health and the environment, but they may not, for the following reasons:

1. Cleanup levels based on 'risk assessments" cannot be guaranteed to be as protective as they seem. The formulas derive from a combination of assumptions that could lead the determination to be off by several orders of magnitude. One in a million should be the absolute maximum level of risk accepted. (It is not clear to me why, on page 28, WAC 173-340-700 (7) (b) For a compliance cleanup level, the total excess cancer risk is listed as one in 100,000.)

2. The risk assessments are based on the effects on average adults, so sensitive populations will not be protected, and there currently exist quite a few categories of these.

3. Some carcinogens, such as dioxins or pthallates, have teratogenic or immumosuppressive effects that derive from different properties of the molecule. One risk assessment for these would not be protective. The multiple hazardous substance approach does not address this.

4. The use of conditional cleanup levels has such general application that it will provide a "loophole" that will be difficult to control:
a. The department only "may" require the PLP to provide financial assurances for maintenance -- and even if required, they would not help an exposed individual once exposed.
b. Site restrictions are subject to too much uncertainty. Accidents or natural disasters, such as the storm that opened up the Butler Tunnel, can always happen.

4. Cost considerations are should not determine cleanup levels. It was the intent of Initiative 97 that cost considerations should only be used to decide between two cleanup actions that equally meet cleanup standards. Further, it was the intent of Initiative 97 that the polluter should pay, and different polluters will be paying for cleanups in different areas. They will not be diverting financial resources one from another.

5. Standards for protection of the ecosystems at risk are not spelled out, although protection of the environment is mandated.kk

September 17, 1990
C. J. Chou
117 MacArthur Street
Richland, Washington 99352

Mr. David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Dear Mr. Bradley:

I have read the final version of the draft document, "The Model Toxics Control Act Cleanup Regulation and Proposed Amendments", dated July 18, 1990. My comments concerning the statistics part are listed below:

General Comments:

1. The hypothesis is an assumption about a property or characteristic of a population under study. Before a statistical test is performed it is necessary to clearly specify the null hypothesis (Ho) and the alternative hypothesis (Ha). The goal of statistical inference is to decide which of two complementary hypothesis is likely to be true.

   The null hypothesis as stated is that the site is contaminated at concentrations which exceed cleanup levels (see definition on page 6). That is, the null hypothesis is that the cleanup unit is "dirty" and the alternative hypothesis is that the cleanup unit is "clean". These hypotheses are appropriate for a comparison with a risk-based standards (i.e., one-sample case). However, when the cleanup standards are "background-based" standards (i.e., two-sample case), the hypotheses should be the reverse of those given (in page 6). The corrected hypotheses are stated below:

   Ho: The site is clean or the site has achieved cleanup standards.

   Ha: The site is dirty or the site has not achieved cleanup standards.

   The hypotheses given on page 6 are not appropriate for background-based cleanup standards because they would require the demonstration of the distribution of site measurement data be below that of the background before accepting Ha that the site is clean (note "accept" means fail to reject).

2. A Type I error is defined as the error of rejecting a true null hypothesis and a Type II error is the error of accepting a false null hypothesis (note "accept" means fail to reject). Thus, the definitions of Type I error and Type II error are directly related to the null hypothesis being tested. In case of the risked-based standards, the null hypothesis is that the site is dirty. Hence the Type I error is the error of stating the site is clean when it is contaminated. However, in a two-sample case (i.e., the cleanup standards are background-based standards), the null hypothesis is that the site is clean. Hence the Type I error is the error of stating the site is contaminated when it is clean (see comment 1).

Specific Comments:

3. Page 8, definition of "Type II error"
The last sentence should be revised to "This is the acceptance of a false null hypothesis." (see comment 2).

4. Page 31, WAC 173-340-705 (11) (c)
The upper tolerance limit with a coverage of 95% and a tolerance coefficient of 95% appears to be the default method of defining background concentrations (see WAC 173-340-705 (11) (c) Methods for defining background concentrations). There are situations where an upper 95% confidence interval on the mean concentrations (or that on median concentrations) would be the appropriate background concentrations. For example, after a site has been remediated and a statistical test is to be performed to check whether the cleanup standards have been attained, a test on the means or medians would be appropriate if remediation action is effective.

5. Page 31, WAC 173-340-705 (11) (d)
It is not clear what are the justifications of suggesting a sample size of "10 or more" and "20 or more" for determination of natural background concentrations and area background concentrations, respectively (See WAC 173-340-705 (11) (d)). When the measurements from the background area are not normally or log-normally distributed, an upper one-sided nonparametric tolerance limit with 95% coverage and a tolerance coefficient of 95% requires 59 background samples (Conover, 1980, Practical Nonparametric Statistics, Second Edition, John Wiley and Sons, Inc., New York, New York, pages 117-121 and Table A5, page 447). Hence, the recommended background sample size(s) may not be adequate.

6. Page 31, WAC 173-340-705 (11) (e)
There are other non-parametric statistical tests to detect different types of contamination. The Wilcoxon Rank Sum test (Conover, 1980) may be used to test uniform contamination above background. The Quantile test may be used to test spotty contamination (i.e., whether a small portion of the cleanup unit has concentrations larger than background) (Johnson, R. A., S. Verrill, and D. H. Moore II, 1987, "Two-Sample Rank Tests for Detecting Changes That Occur in a Small Proportion of the Treated Population," Biometrics 43:641-655). These tests can be conducted (without assigning an arbitrary value for less than detection limit datum) even when a large proportion of the data is below the detection limit.

These issues need to be considered in finalizing the document such that the background-based standards can be addressed properly. I hope these comments prove to be useful to you.

Sincerely yours,

Charissa J. Chou

C. J. Chou

2552 Harris Avenue
Richland, Washington
September 15, 1990

David Bradley
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504

Elena Guilfoil
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504

Dear Ms Guilfoil and Mr. Bradley:

Enclosed are comments on the proposed amendments to the Model Toxics Control Act Cleanup Regulation, Chapter 173-340 WAC and the respective Draft Environmental Impact Statement.

Sincerely,

F. Robert Cook

Enclosure as noted:

ENCLOSURE TO LETTER OF SEPTEMBER 15, 1990

SUBJECT: COMMENTS ON MODEL TOXICS CONTROL ACT PHASE II RULEMAKING AND DRAFT ENVIRONMENTAL IMPACT STATEMENT--

FORMAT--To identify the section, subsection or paragraph in the proposed rules--including existing Phase I rules already promulgated--for which a specific comment applies, the comment will be preceded with the appropriate section, subsection, etc. number, for example, 120 (2) (b). The common chapter designator in the Washington Administrative Code (WAC), WAC 173-340 for the Model Toxics Control Act Cleanup Regulation, will be omitted for purposes of brevity. The draft to which the comments apply is the July 18, 1990 draft of this chapter.

Comments on the Draft Environmental Impact Statement are listed under that respective heading. Applicable sections or text are identified with each comment.

DRAFT ENVIRONMENTAL IMPACT STATEMENT--

1. Per Appendix H the ground water modeling of the MEPAS code used by the Department of Ecology (DOE) does not appear to provide for distribution in discrete pathways, for example, fracture zones and buried ancestral stream beds of high conductivity, now covered by deposited soils. Such features in the geology at Hanford provide the most rapid transit times for the groundwater in the unconfined aquifer from contaminated zones to the river and are appropriate to consider in evaluating effects of spreading contamination and its concentration. This mode of ground water distribution is of most importance at Hanford in transport of water from waste disposal areas to the river and areas of the hospitable environment.

2. Per Appendix H it is indicated that the MEPAS code allows evaluation of the dose via <u>any</u> possible pathway, and DOE indicates it is satisfactory for evaluating the relative impact of various alternatives of cleanup standards. However, DOE indicates that the intent of the impact statement is also to determine the effects on natural resources. Considering the fact that terrestrial and aquatic plants and animals are considered natural resources, any methodology selected to evaluate impacts should be able to consider these parts of the natural resource. <u>Therefore the conclusion that human health effects are sufficient to determine the relative impacts of various cleanup standards is invalid.</u> In many cases flora and fauna may be grossly affected, for example, in salt water ecosystems, and human health would not be effected. In desert ecosystems, the same might be true. Drinking water in both cases may not be a pathway of importance in determining effects on humans.

Regarding the stated capabilities of MEPAS in Table H-1, Modifications to the MEPAS code should be made to allow evaluation of the relative effects on terrestrial and aquatic plants and animals as well as human populations. For example, modeling should provide for the evaluation of atmospheric deposition on terrestrial animals as well as terrestrial plants. Likewise groundwater drinking and ingestion/inhalation interactions should consider effects on terrestrial animals, including birds. Bioaccumulation in the terrestrial predator animal chain should be considered and should take into account the ingestion of aquatic animals. (The effect of DDT on predator birds is a classical example of why such a mechanism should be considered.)

3. Risk based effects on populations of flora and fauna species should be established by DOE and used in establishing cleanup actions for each site considered. For example, an appropriate statement of risk might be as follows:

> "Cleanup of hazardous substances shall with 95% confidence be such as to assure no greater than either a 5% increase or decrease in the 10-year average population measured in appropriate units -- individuals per unit area or volume-- for any given species native to the site being considered over a period of 10 generations of the species or 10 years whichever is greater."

Using such a design base for cleanup, the impact statement should consider indicator or limiting species impact. Without it the Statement is incomplete. The fact that good models are not available to assess individual species effects from specific contaminants is not a valid reason for ignoring this issue. Estimates of effects on species from experts in the evaluation of ecological contaminants should be used in the impact assessments.

And even though effects on species of various hazardous substances may not be readily apparent, it is important to establish design bases for specifying what is acceptable and what is not acceptable. As the technical capability develops for assessing species by species risks, the pertinent acceptance standards will be available for determining the acceptability of future cleanup actions.

4. In reviewing the subject Draft Environmental Impact Statement, it is difficult from the definition of "hazardous substance" to ascertain that radio nuclide toxicity is included within the scope of this term.

The Statement should make it clear that the rule and the Impact Statement cover the consideration of cleanup of toxic radio nuclides. To this end specific site scenarios (Appendix H) and remedial technologies (Appendix I) should be modified to incorporate items that address radio nuclides. For example, a site at Henford should be considered together with the remedial technology applicable.

5. The term "threat to the public health or the environment" is used in the DOE's Final Cleanup Policy, dated July 10, 1984, (Appendix E of the Impact Statement). The term "threats to human health and environment" is used in the Model Toxics Control Act under declaration of policy. The definition of these terms may be consistent or may not.

The definitions should be incorporated into the definitions of Chapter 173-340 WAC and utilized appropriately in the Impact Statement. In this regard it is recommended that risk-based quantitative definitions be incorporated into the Chapter to quantify unacceptable "threats". As noted above, risk-based definitions that apply to the various components of the environment, including species, are necessary to clarify the action required by the Chapter.

6. The Technical Summary discusses the definition of "applicable or relevant and appropriate requirements." This section does not directly address the relevant laws in other states. The impact statement should include a review of laws in other states and provide evidence that the standards being proposed are at least as stringent as the "applicable" laws in other states. In this regard the term "applicable" appears to reflect its synonymous meaning "relevant" for purposes of Washington State rules under Chapter 173-340 WAC.

It is obvious that the actual laws in other states do not "legally apply" to the State of Washington. DOE's adopted wording "legally applicable" in the definitions and usage section of 173-340 WAC is unfounded. Relevancy is the key determining factor in deciding the use of cleanup standards specified by laws (and hence state rules) in other states.

Had it been intended by MTCA that the definition proposed by DOE be consistent with that in the National Contingency Plan, such definition would have been incorporated into MTCA.

Thus, the proposed definition of "applicable state and federal laws" incorrectly and/or ambiguously delimits consideration of any other state's law or requirement through the use of "and" instead of the word "or". As indicated above there are no "legally applicable" laws for residents of Washington in other states's statutes. The following words are suggested to correct this ambiguity:

"Applicable state and federal laws" as used in context of the specification of cleanup standards means all relevant current laws and corresponding implementation rules and requirements, any of which reasonably could apply to sites in Washington, promulgated by any federal or state authority or state citizenry."

The additional definitions of "legally applicable requirement" and "relevant and appropriate requirements" in the Draft rules should also be modified to reflect this comment insofar as these definitions may apply to cleanup standards. In this regard, elimination of theses terms from the rule would seem appropriate since they appear to be nearly the same in their meaning as the term "applicable state and federal laws" discussed above.

It is poor rule making to use various similar terms to connote the same meaning. In addition, if slightly different meanings for terms used in the rule are necessary for some reason, the terms selected should be defined so that the intended distinction is obvious. Such has not been accomplished in the proposed rule and this results in confusion and ambiguity.

COMMENTS ON PROPOSED RULE--

1. 200 DEFINITIONS--

a. See comments in the section concerning the Environmental Impact Statement for comments on the following terms:

"Applicable state and federal laws"
"Legally applicable requirement"
"Threats to human health and environment" (proposed addition)
"Hazardous substance."
"Relevant and appropriate requirements"

b. The terms "acute toxicity" and "chronic toxicity" make use of the undefined term "injury" to specify the scope of the two terms. Since acute and chronic toxicity may not be generally interpreted to include allergic health effects from low-level contaminants in a small segment of the society, allergic reactions should be specifically considered in the definitions since the common definition of injury includes items detrimental to comfort as well as health. (The issue is raised in light of the fact that some health authorities and practitioners do not consider allergic reactions the result of acute or chronic toxicity, since such reactions tend to be confined to a limited number of individuals of a given species with no effect in other individuals.)

Also the term "short term" is used to define the maximum time of exposure to a hazardous substance associated with "acute toxicity". Instead of using "short term" the period of 72 hours should be specified. This is generally a conservative specification of short term in toxicity studies and is consistent with OSHA usage in requirements for worker safety.

Correspondingly the term "chronic toxicity" should specify a total exposure time in excess of 72 hours.

c. The term "containment" is defined in a manner inconsistent with the common understanding of the word, in that the proposed definition allows for slow release--hindered release--by structures. Thus, clay, which is slowly permeable to water and contaminants might be considered a suitable material for a container. To make the term consistent with usage in other environmental rules, for example, rules for high-level radioactive waste disposal in 10 CFR 60, the definition should be modified to specifically refer to structures that achieve the confinement of hazardous substances within a defined boundary and prevent the release to the environment.

d. The term "carcinogen" is defined in a very restrictive and non-conservative manner and is inconsistent with goals and conclusions of the Federal Cancer Policy, initiated by OSHA in 1977. The definition used in this policy is as follows:

> "A substance or condition which increases the incidence of generally irreversible benign or malignant tumors, reduces the latency period, or produces unusual tumors in animals or man."

This definition should be used in place of the current definition since it conservatively identifies a carcinogen.

e. The term "carcinogenic potency factor" or "CPF" should be separated from the definition of "carcinogen". In addition the definition for "CPF" does not make sense. The 95th percentile confidence limit of the slope of the dose-response curve is incorrect terminology. In addition "the dose-response curve" is ambiguous. An accurate definition should be included.

A definition of how the CPF is used may be more informative. A sample dose-response curve pertinent to the development of a benign or malignant tumor or reduction in latency period for same should be given as an example with the instruction as to how to determine the appropriate dose in terms of mg hazardous substance exposure per kg of body weight per day of exposure. This dose could vary depending on the number of individual animals tested, if a standard statistical design base is specified, for example, less than a 5% response at the 95% confidence level.

f. The terms "ground water" and "surface water" appear to exclude water in the vadose zone or unsaturated soil of the earth, generally found above saturated zones. It is recommended that the term "ground water" be expanded to explicitly include the water in the vadose zones of soils and stratum.

g. The term "highest beneficial use" ambiguously includes as part of its definition an example which highlights the use of drinking water as an indicator of highest beneficial since it "will generally provide protection for a great variety of other existing and future beneficial uses of ground water." The example, as it is written indicates that drinking water quality may not be the limiting determining factor for all current and future beneficial uses, only a "great variety." The example of drinking water should be deleted. It is not necessary to modify the first clause in the definition. It only acts to create an ambiguity.

h. The term "risk" as part of the definition includes the idea of a probability that a hazardous substance causes an adverse effect. However, an important and useful parameter, confidence, is necessary to further illuminate any particular statement of risk by addressing its validity and thereby give practical meaning to such statements.

Hence, the definition of "risk" should be modified to refer to a confidence statement. An appropriate standard specification for confidence for risk assessments would be 95 percent.

The following is a brief discussion of factors to be considered in quantitatively specifying risk that should be considered in redrafting the definition.

> What constitutes proper quantification? First one must have an estimate of a probability of a postulated event (risk), generally with respect to passage of time. Second one must have an estimate of the confidence of that probability or risk. This latter estimate is a quantitative statement as to the validity of the analyses used to make the risk estimate. Without the confidence statement a risk estimate is not meaningful. And finally, the estimates must be made within the rigors of a quality assurance system applicable to design activities, including research and development.
>
> In risk analyses a confidence statement should be estimated to take account of both the known and uncontrolled effects anticipated in a scenario, as well as the unknown or vaguely known effects. Such estimates, when combined, would serve as a confidence statement for the stated risk.
>
> However, risk analyses commonly utilize mathematical models of the scenario in question, with random selection of independent variables defined for the respective models, to accomplish "thought experiments" producing statistical data. Such data do not allow for determining a confidence statement since re-doing the analyses for any given scenario will produce the same estimate of risk. The

results of such "thought experiments" do not reveal uncertainties in the models themselves. And the validity of the models to represent the scenario in question remains unaddressed.

Typically it takes independent peer reviews to estimate and/or confirm, quantitatively, the uncertainty associated with models used in risk assessments. Conceptually, the "thought experiments" making up the risk analyses should include runs which incorporate bias or uncertainty factors applicable to a model's dependent performance parameters determined by such reviews.

i. The definition for "Subchronic reference dose" includes the parenthetical phrase "(with an uncertainty of an order of magnitude or more)". This confuses the meaning since if would seem some reference doses might not have such large uncertainties. Other ambiguities related to the words "appreciable risk" and "a portion of a lifetime" also confuse and/or leave the definition ambiguous. It is recommended that the definition include the following wording:

"Subchronic reference dose means an estimate of a daily exposure level for the human population, including sensitive subgroups, that is likely to be without a risk greater than 1/1,000,000 at a confidence of 95% of adverse effects during an exposure of 72 hours or greater."

j. The terms "beneficial use", "in the public interest" and "appreciable risk" should be defined since they are key terms in deciding upon actions required by the rule. Appreciable risk should be defined as 1/1,000,000 at 95 % confidence or greater. Beneficial use should include uses that depend upon the ecological integrity of a site as a natural preserve. In the public interest should be consistent with the definition of "beneficial use" and consistent with the intent of MTCA to achieve cleanup to specified standards.

k. The term "reasonable maximum exposure" is defined in a non scientific manner, making use of the word "reasonable". This qualitative expression should be quantified consistent with establishing risk relative to quantitative risk standards. It is unacceptable to allow key aspects of the risk analysis to remain qualitatively stated. Thus, a probability defining reasonable, for example, 99% probability with 95% confidence that maximum exposure will not exceed the expected amount over a 100 year period considering conditions 500 years in the future, should be incorporated into the definition. It is noted that a time frame is warranted to specify for analysts a tractable problem and to standardize the exposure time to be considered for old people.

It should be noted that old people as their livers degrade and become less functional are increasingly vulnerable to health effects and cancer caused by toxins. Therefore, long exposure times are reasonable to consider. In addition it is necessary to correct dose/response data to account for the age and liver/kidney function of individuals. The long time frame for consideration of exposure will assure this phenomena shall be considered in determining a hazard index for individuals.

2. 360 (4)--This section should be modified to recognize other relevant state laws, consistent with comment 6 under Draft Environmental Impact Statement.

3. 360 (7)--This subsection concerning practicability should consider costs associated with loss of future beneficial uses. Intangible benefits, for example nature preserves, should be assigned a worth to allow such evaluation. Such "lost beneficial usage" costs should subtract from costs associated with cleanup actions in evaluation required by item (c).

4. 600--Rules for obtaining public input are extensive specified in this section, however, rules applying to DOE for rational, fair resolution of public input are left out. Such rules for operation of DOE should be included in 173-340 WAC. They should include requirements to propose resolution to comments within a specified time and to publish the resolutions. In addition, resolution of comments should provide for appeal and in the case of citizen advisory groups, should require concurrence.

Where comment resolution of public input is not resolved to the satisfaction of the commentator, an appeal mechanism should be specified to provide for further review and adjudication of comments.

5. 700 (5) (d) (iv) (A)--The comment in item 3 above regarding lost beneficial usage costs should be considered in this paragraph.

6. 700 (4) (a)--The text concerning "reasonable maximum exposure should be revised to reflect the discussion under item 1. k. above.

7. 705 (3)--The frequency specified for review and update of the rule is excessive. Many changes to applicable state and federal laws may occur within a five year period. An annual review should be specified with at least annual updates of the rule accomplished as necessary to be consistent with the RCW 70.105D.030 (2) (d). It is unreasonable to allow a 5 year delay in accomplishing protection of human health and the environment. Procedures for publishing the updated standards should be specified in 173-340-705.

8. 720 (1) (a) (ii)--The criteria for determination of potential future use of ground water are inadequate. Consideration of technological advancement in the capability to remove organic or specific inorganic constituents should be included in the analysis.

Drinking water for farm or domestic animals is a use that should be considered routinely and thus should be specified rather than left to the determination of DOE on a case basis. For example, the accumulation of hazardous substances in milk of cows and goats should be considered.

The second sentence of paragraph (a) is unnecessary. It inappropiately suggests consideration of drinking water as the highest beneficial use in most cases. Such a suggestion adds nothing to the rule.

9. 800--A provision should be included in the facility access rules to allow and facilitate discussion with facility owners and there employees. In addition the rules should prohibit facility owners or their agents or other employees from advising any person not to communicate with State employees or their agents regarding health and environmental hazards. Rules should be included against withholding information by any person pertinent to a State investigation.

David Bradley
Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia, WA 98504-8711

August 21, 1990

Subject: Proposed Amendments to Chapter 173-340 WAC

Attached, are my comments on the subject amendments.

Sincerely,

Stefan Dobratz

Stéfan Dobratz
1716 33rd NE
Olympia, WA 98506

COMMENTS ON CHAPTER 173-340 WAC PROPOSED AMENDMENTS DATED JULY 27, 1990

1. The definition of "exposure" should be change to maintain consistancy with other regulations and common usage. I recommend using a definition consistant with WAC 296-62-05405(15). For example: Exposure or exposed means that an employee, person, or organism is/was subjected to a hazardous substance through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes potential exposure.

2. The definition of "volatile organic compound" is, in my opinion, not acceptable. "Easily evaporates at room temperature" must be clarified and specified.

3. The use of the terms "Method A and Method B" is not clear. They appear to be used mearly to differentiate between the cleanup standards applicable to particular sites and to have no real meaning. In any case, some clarification of their use would be helpful.

4. A non-mandatory appendix should be added to the regulation to explain the "linearized multistage extrapolation model" method of estimating dose-response curves.

5. A non-mandatory appendix should be added to the regulation to explain the risk assessment methodology used to derive the cleanup level equations.

6. WAC 173-340-705(7)(b) uses an inhalation rate of $20m^3$/day and a body weight of 70 kg. The referenced section ,WAC 173-340-750(b)(i), uses a breathing rate of 10 m^3/day and body weight of 16 kg. Is this correct?

7. WAC 173-340-720(4)(a)(ii)(A)&(B) references sections WAC 173-340-720(3)(b)(i)&(ii). These referenced sections do not exist. They could be WAC 173-340-720(3)(a)(ii)(A)&(B).

8. WAC 173-340-730(3)(c)(i)&(ii) reference WAC 173-340-705(6) for the fish bioconcentration factor, this should be 705(9).

09/18/90 14:20

United States
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Region 10
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Seattle WA 98101

Alaska
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EPA

September 18, 1990

Reply to:
Attn of: HW-117

Terry Husseman
Assistant Director for Waste Management
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504

Dear Mr. ~~Husseman~~: Terry

We appreciate the opportunity to comment on the proposed amendments to the Model Toxics Control Act (MTCA) regulations. We are pleased that the hard work of the Ecology staff and the workgroup members have produced a draft regulation that will help further environmental quality in the state of Washington.

As you know, EPA recently promulgated the revised National Contingency Plan (NCP). In many ways, the clean-up standards under these proposed MTCA regulations are more stringent than the clean-up levels EPA could select under the NCP alone. In addition, there would be much less flexibility in how the clean-up levels would be selected. However, the most protective clean-ups would probably be similar under both regulations.

For your information, Region 10's Underground Storage Tank Program will be providing comments separately to Ecology.

We have the following comments for your consideration.

1. <u>Too many significant figures have been attached to the compliance and conditional clean-up levels.</u> In many circumstances specifying the use of a hazard quotient of 1.0 for decision-making is too precise when considering the numerous factors contributing to uncertainty in its derivation. For example, reference doses often incorporate large uncertainty factors (e.g. 100 to 10,000). In these cases, small variation around a hazard quotient of 1.0 are probably not significant.

Many of the same uncertainties also apply to cancer risk estimates. As a result, these estimates are actually no more precise than an order of magnitude, eg. 10-3 vs 10-04. It would be difficult to argue scientifically that risks of 8 x 10-6 and 3 x 10-5 are significantly different.

We believe it would be more scientifically supportable to express the proposed clean-up standards in terms of 1 (rather than 1.0) for the hazard index, and in terms of an order of magnitude for cancer risk. For some chemicals, an even more flexible hazard index is justified.

2. Changes are needed in the soil compliance monitoring and points of compliance sections to ensure that environmentally sound and practicable clean-ups are selected.

A soil conditional point of compliance for the protection of groundwater should be permitted. Soil points of compliance for the protection of groundwater and for protection of direct contact hazards are specified. However, conditional points of compliance for soils are only allowed for direct contact hazards. Therefore, the soil cleanup level based on the protection of groundwater must be met throughout the site, even if wastes must be left on the site. This appears to be inconsistent with the provision for a conditional point of compliance in the groundwater when wastes are left on-site as is likely to be necessary for such sites as municipal landfills.

Assessing compliance with the soil clean-up standards for immobilization remedies should be changed. For many sites, especially those contaminated with heavy metals, immobilization will be either the primary or secondary component of the remedy. However, WAC 173-340-740(7)(a) requires that compliance with soil cleanup levels be based on the total analysis of the soil fraction less than 2 mm in size. If the Department decides that an immobilized material could be reduced to 2 mm or less during future site use, no immobilized material could achieve the soil cleanup standards. On the other hand, if it is decided that the immobilized material would not be reduced to 2 mm or less, then no compliance monitoring requirement would apply. This may not be adequately environmentally protective.

The soil compliance level for the protection of groundwater are total soil concentrations 100 times the groundwater compliance level, unless it can be demonstrated that a higher concentration is protective of the groundwater at the site. This is probably based on some assumptions regarding the leaching of material from soil and the dilution of that leachate. It may be appropriate to change both this standard and the compliance monitoring section for soil so that both the standard and the required monitoring be in terms of a leaching test rather than in terms of total concentrations. At a minimum, this approach should be considered for certain categories of hazardous substances such as heavy metals.

3. The proposed conditional point of compliance for groundwater which discharges to surface water (WAC 173-340-720) is unclear.

The issue of the point of compliance for groundwater discharging to surface water may require additional clarification. The effect of such influences as tides or lateral infiltration from adjacent waterways results in a de facto dilution zone as the premodient component of the sampled water is provided by the surface water feature. If the intent of the standard is to obtain mixed water samples, the language is suitable. However, if the intent is to obtain uninfluenced groundwater samples, the compliance point may be substantially removed from the groundwater/surface water interface.

4. Additional flexibility in the exposure parameters is needed to allow use of new scientific information. Short of revising the regulation, only three exposure parameters may be modified: gastrointestinal absorption rate; inhalation correction factor; and the bioconcentration factor. This is very inflexible. There are many situations which justify the use of other exposure parameters. These include chemical specific factors such as dermal absorption rates, unique land use patterns, and new scientific knowledge.

5. EPA's reference doses are not correctly used in the proposed rule. For example:

a. The cleanup levels based on noncarcinogenic endpoints need to specify exposure duration and averaging time. They currently do not.

b. (Apparently) both childhood and longer term adult exposure are being compared to chronic Rfds, based on the choice of body weights, 16 and 70 kg respectively. It is most appropriate to compare chronic Rfds to an average lifetime exposure (dose) based on an average lifetime bodyweight. Acute or subchronic Rfds would be more appropriate to compare to short term exposure (e.g. childhood) using a correspondingly lower average body weight.

c. There is no distinction between application of Rfds with developmental endpoints and other Rfds. Developmental Rfds should be compared to single doses (e.g. one day) and not adjusted for the duration of exposure, whereas subchronic and chronic Rfds are compared to doses averaged over varying exposure periods.

d. Reference concentrations (ug/cubic meters) in air (WAC 173-340-705(7)(b) should apply to chronic (lifetime) exposures. It is not appropriate to convert them to dosage (mg/kg-day) using a 70 kg body weight and a 20 cubic meters inhalation rate due to the methodology used in their development. At this point it is not clear how to modify these to adjust for variations in exposure duration and inhalation rate.

6. The terms "institutional controls", "site use restrictions", and "under restricted site use conditions" are inconsistently defined. According to the proposed regulation, institutional controls will require a deed restriction. These deed restrictions would run with the land and include many desirable items. According to the definition of site use restrictions, fences and similar barriers would be required, but there is no mention of the deed restrictions required under Institutional Controls (WAC 173-340-440) There may be an additional problem if Ecology or EPA is undertaking the action and the property owner is unwilling to put a deed restriction on the property. Would this mean that if the property owner was unwilling to accept a deed restriction, Ecology and EPA could not apply the conditional clean-up levels or the conditional point of compliance?

7. As currently written, WAC 173-340-700(5)(d)(v) could not be used by either the State of Washington or any federal agency, including EPA. This section allows conditional compliance levels to be used if attainment to the compliance clean-up levels would limit the ability of a person to respond to other environmental threats. One requirement is that the financial savings be used to fund actions that are not otherwise required under applicable state and federal laws. As the clean-ups performed by Ecology and EPA are required under state and federal laws, it appears that conditional compliance levels could not be justified using this option for any Fund-funded or government-funded action. We recommend that this section be changed to allow Ecology and EPA to use this exception when it is necessary.

Please contact Judi Schwarz if you have any questions regarding these comments. She can be reached at (206) 442-2684.

Sincerely yours,

Chuck

Charles E. Findley, Director
Hazardous Waste Division

cc: Dave Bradley

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September 17, 1990
Project 1.00

Mr. David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Re: Comments on Proposed Amendments to Chapter 173-340 WAC

Dear Mr. Bradley:

Sweet-Edwards/EMCON, Inc. is pleased to submit for your review the attached comments on the above-referenced amendments. Should you have any questions on the comments, please feel free to call Anita Lovely at 485-5000.

Thank you for the opportunity to comment.

Sincerely,

Sweet-Edwards/EMCON, Inc.

Lee Fortier

Lee Fortier
President

LF/ch
Enclosure

295/BRADL-CL.917/ch:1(wp)

COMMENTS ON PROPOSED AMENDMENTS TO CHAPTER 173-340 WAC

Sweet-Edwards/EMCON, Inc. has organized our comments on the proposed amendments into two categories : 1) General Comments and 2) Specific Comments.

General Comments

1. We recognize that Ecology has added text and revised text (e.g., added definitions) to make the regulation more readable and hopefully more consistent. However, the regulation is still difficult to read and understand. This is especially the case in determining the selection of cleanup actions and in determining which cleanup levels apply. We understand that additional text revisions would be extremely burdensome to Ecology. Therefore, we recommend that flow charts be developed to more clearly outline the decision pathways in order to reduce the amount of confusion by both PLPs and agency staffers.

2. Ecology has proposed Method A cleanup levels for both ground water and soil cleanups, but has not presented the rationale for the development of the proposed cleanup levels. We request that the rationale for development of the levels be presented or available for review. Only then, can the technical basis for the levels be evaluated.

3. Ecology has proposed a section on cleanup standards to protect air quality. We feel that this section is inappropriately placed in these amendments and should be deleted. Air is not a media that can have cleanup levels like soil and ground water. Air pollution is controlled at the source and environmental compliance is appropriately monitored through compliance standards, not cleanup standards.

Specific Comments

1. WAC 173-340-700 GENERAL PROCEDURES (11) (b) Points of Compliance states that "the point of compliance under this chapter shall be established throughout the site." Under certain circumstances a conditional point of compliance may be established under WAC 173-340-720 through WAC 173-340-750. However, in the case of multiple sites that may share a common pathway (e.g., ground water, surface water), it has also been implied that these sites would undergo "interim cleanups" and not "final cleanups." We understood that the goal of MTCA was to expedite cleanups and particularly final cleanups. If the point of compliance is not reasonable, it will impact the number of cleanups that will be initiated by PLPs. In addition, it will greatly impact property transfer transactions in this state.

2. WAC 173-340-740 SOIL CLEANUP STANDARDS (2) (A) states that for "individual hazardous substances or mixtures, concentrations that are equal to or less than one hundred times the ground water compliance cleanup level established in accordance with WAC 173-340-720 unless it can be demonstrated that a higher concentration is protective of ground water at the site." There appears to be no rationale of how this 100 X number will be representative of protection. It is also not clear what Ecology will consider an adequate demonstration of ground water protection as it relates to soil cleanups. Based on Method B equations, the soil cleanup levels for soils would be much higher based on protection of human health (see Tables 1 and 2). The goal is for protection of human health and the environment. The proposed Method A levels for soil greatly exceed that goal and would place an undue burden on cleanups.

3. WAC 173-340-745 SOIL CLEANUP FOR INDUSTRIAL SITES (3) (A). Like the proposed Method A cleanup levels, the Method B cleanup equations can be used only if you do not exceed the 100 X rule or demonstrate ground water protection. We recommend that cleanup levels be established based on health-based levels. Under the RCRA Corrective Action program, EPA has proposed health-based action levels for both ground water and soil cleanups. We recommend that these levels be reviewed and evaluated for integration into our proposed cleanup levels.

Table 1

Calculated Cleanup Levels for Selected Noncarcinogenic Chemicals

Chemical	RfDs	MTCA Method B Cleanup Levels			MTCA Method A Cleanup Levels	
		Residential Soil Compliance Cleanup Level	Residential Soil Conditional Cleanup Level	Industrial Soil Compliance Cleanup Level	Residential Soil Cleanup Level	Industrial Soil Cleanup Level
	(mg/kg/day)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)
arsenic	1.00E-03	80	320	1400	20	200.0
benzene	—				0.5	0.5
cadmium	5.00E-04	40	160	700	2	10.0
chromium	—				100	500.0
DDT	5.00E-04	40	160	700	1	5.0
1,2 dichloroethane	—					
ethylbenzene	NA				20	20.0
ethylene dibromide	9.00E-02	7200	28800	126000	0.001	0.001
lead	ND				250	1000.0
lindane	—				1	20.0
methylene chloride	6.00E-02	4800	19200	84000	0.5	0.5
mercury. (inorganic)	3.00E-04	24	96	420	1	1.0
PAHs (carcinogenic)	—				1	20.0
PCB mixtures	—				1	10.0
pentachlorophenol	3.00E-02	2400	9600	42000	10	10.0
tetrachloroethylene	1.00E-02	800	3200	14000	0.5	0.5
toluene	3.00E-01	24000	96000	420000	40	40.0
TPH (gasoline)	—				100	100.0
TPH (diesel)	—				200	200.0
TPH (other)	—				200	200.0
1,1,1 trichloroethane	9.00E-02	7200	28800	126000	20	20.0
trichloroethylene	—				0.5	0.5
xylenes	2.00E+00	160000	640000	2800000	20	20.0

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Table 2

Calculated Cleanup Levels for Selected Carcinogenic Chemicals

Chemical	Carcinogenic Potency Factor	MTCA Method B Cleanup Levels			MTCA Method A Cleanup Levels	
		Residential Soil Compliance Cleanup Level	Residential Soil Conditional Cleanup Level	Industrial Soil Compliance Cleanup Level	Residential Soil Cleanup Level	Industrial Soil Cleanup Level
	(mg/kg/day)-	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)	(mg/kg)
arsenic	1.75E+00				20	200.0
benzene	2.90E-02	3.218	128.738	563.218	0.5	0.5
cadmium	ND				2	10.0
chromium	—				100	500.0
DDT	3.40E-01	0.275	10.980	48.039	1	5.0
1,2 dichloroethane	9.10E-02	1.026	41.026	179.487		
ethylbenzene	—				20	20.0
ethylene dibromide	8.50E+01	0.001	0.044	0.192	0.001	0.001
lead	ND				250	1000.0
lindane	—				1	20.0
methylene chloride	7.50E-03	12.444	497.778	2177.778	0.5	0.5
mercury (inorganic)	—				1	1.0
PAHs (carcinogenic)	ND				1	20.0
PCB mixtures	7.70E+00	0.012	0.485	21.21	1	10.0
pentachlorophenol	—				10	10.0
tetrachloroethylene	5.10E-02	1.830	73.203	320.261	0.5	0.5
toluene	—				40	40.0
TPH (gasoline)	—				100	100.0
TPH (diesel)	—				200	200.0
TPH (other)	—				200	200.0
1,1,1 trichloroethane	—				20	20.0
trichloroethylene	1.10E-02	8.485	339.394	1484.848	0.5	0.5
xylenes	—				20	20.0

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295/TABLES.916/ch:2(wp)
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4. WAC 173-340-745 (Table 3). This table has identified Method A Industrial Soil Cleanup Levels. Levels for benzene, toluene, and xylene are presented in the table.

We feel the proposed soil cleanup levels are excessive and should be based on leachability or on risk, providing that the level is technically feasible and is statistically valid. In addition, we feel that contaminants with similar properties and actions should be evaluated by the compound that poses the highest human health and environmental risk (e.g, benzene as an indicator compound for xylene). Therefore, in instances where there is a cleanup level for the indicator compound (i.e., benzene), the other compounds (i.e., toluene, xylene) should be deleted from Table 3.

These cleanup regulations will impact cleanups at all sites where there have been releases of petroleum products, including refineries, petroleum marketing terminals, and gasoline stations. The standards as proposed would significantly affect the time and the cost for remediating smaller sites, especially the typical underground storage tank removal.

It has been our experience that present technologies such as vapor extraction and aeration are well suited in treating gasoline-contaminated soils and water to the present cleanup standards for benzene, toluene, ethylbenzene (BTE) and total petroleum hydrocarbons (TPH). We have found that at the end of soil treatment, where BTE levels meet present standards, xylenes are often still present in concentrations of up to an order of magnitude higher. This in part is due to its lower vapor pressure, or volatility, and low solubility in water.

Xylenes are regarded as the least toxic of the common aromatic hydrocarbons associated with gasoline. While it is entirely possible to achieve the proposed xylene soil level of 20 mg/kg, in effect, the driving force of soil remediation at UST facilities will no longer be benzene, a known carcinogen, but xylenes, a much less toxic compound. In fact, at a typical gas station remediation it won't matter what cleanup levels are attached to the BTE compounds if xylenes are regulated (at 20 mg/kg) as the other BTE compounds will have long been removed in the quest of achieving the xylene target level.

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September 17, 1990

Mr. David Bradley
Toxics Cleanup Program
Washington Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Re: **Proposed Amendments to the Model Toxics <u>Control Act Cleanup Regulation, Chapter 173-340 WAC</u>**

Dear Mr. Bradley:

I am submitting the following comments on the proposed amendments to the Model Toxics Control Act Cleanup Regulation, Chapter 173-340 WAC on behalf of Chemical Waste Management of the Northwest, Inc. (CWMNW). CWMNW operates a hazardous waste treatment, storage and disposal facility in Arlington, Oregon that is fully authorized under federal and Oregon law. CWMNW receives some hazardous waste from the State of Washington for treatment, storage or disposal at its facility.

In these comments, the part of the proposed rule at issue is first quoted in full and then followed by a discussion of the proposed rule and suggested changes to the proposed rule. In the suggested changes, language recommended to be added is underlined and language recommended to be deleted is bracketed with strike throughs.

1.

<u>PROPOSED RULE WAC 173-340-200</u>

"'Permanent solution' means a cleanup action in which the cleanup standards of WAC 173-340-700 through 173-340-760 are achieved without further action being required at the site being cleaned up or any other site involved with the cleanup action, such as an off-site landfill."

<u>DISCUSSION</u>

The definition of "permanent solution" is an important concept in the proposed rules because of the strong preference in the rules for using permanent cleanup solutions. The definition, however, appears ambiguous.

The DOE Draft Environmental Impact Statement indicates that the definition is designed to establish a preference for recovery and reuse of hazardous materials and processes that permanently destroy or detoxify hazardous substance substances. DOE Draft EIS, p. 3-24. The definition can be read also as classifying only on-site cleanup actions as permanent and to exclude categorically any off-site process from being classified as permanent because off-site processes will always require further action. This reading, which we do not believe is intended would be illogical because effective treatment is not dependent on location.

Under the Resource Conservation and Recovery Act, EPA has issued rules which specify treatment standards for most hazardous waste. For many hazardous wastes incineration is the treatment standard. For incineration the DOE Draft Environmental Impact Statement acknowledges that there is no permanent incineration capability existing in Washington and that there is no assured successful completion of such a project. DOE Draft EIS, p. 12-6. Mobile incinerators to treat on-site all hazardous waste in Washington that must be incinerated are not yet a reality. Incineration is equally effective whether conducted off-site or on-site. Clearly, it would make no sense to include on-site incinerators in the definition of "permanent solutions" but not off-site facilities. Exclusion of an off-site process like incineration in the proposed rules thus is inappropriate.

The definition of "permanent solution" is also ambiguous because it can be read to say that every other hazardous waste management process located off-site is not permanent. For example, hazardous waste that is incinerated produces an ash that must still be properly managed. Unless the incineration occurs on-site (which in most cases it will not), the ash must likewise be properly managed. Typically, that waste will be disposed in a federally and state authorized landfill. In this case, under one reading, both the incineration of the hazardous waste and the disposal of the ash in a landfill would not be classified as permanent because it would be occurring off-site. Yet, incineration of the waste and land disposal of the ash would likely be the only option available now and in the near future for certain waste.

Hazardous waste landfills such as CWMNW's in Arlington are the preferred and often the only option available for the residues remaining after treatment of a hazardous waste. Such landfills are the only permanent solution for such treatment residues. CWMNW's Arlington facility in particular is a permanent solution to cleanup of many treatment residuals that have already been treated by the best demonstrated available technology. In addition when disposal occurs in secure arid environment like that existing at CWMNW's Arlington facility there is little that can be done to make the disposal "more permanent".

In summary, the definition of permanent solution should be revised to clarify that the reference to "off-site landfill" means that after a disposal in such a landfill of treatment residuals, no further action is feasible and the clean-up is thus "permanent". Flexibility should exist in the definition so that off-site cleanup actions that are permanent are not excluded and can be used in cleanup actions. In many cases these type of actions are the only option available. In addition, commercial off-site facilities in many instances possess superior knowledge and technical capability in treating hazardous wastes because this is their business. The use of this capability should not be thwarted. The proposed rule should be amended as follows:

SUGGESTED CHANGE TO PROPOSED RULE WAC 173-340-200

"'Permanent solution' means a cleanup action in which the cleanup standards of WAC 173-340-700 through 173-340-760 are achieved without further action being required at the site being cleaned up. ~~{or any other site involved with the cleanup action, such as an off-site landfill.}~~"

2.

PROPOSED RULE WAC 173-340-360(2)(b)

"When evaluating alternative cleanup actions that meet requirements of subsection (2)(a) of this section, the cleanup action selected shall:

(i) Use permanent solutions to the maximum extent practicable;

(ii) Be technically practicable at the site;

(iii) Provide for a reasonable restoration time frame; and

(iv) Consider public concerns."

DISCUSSION

Section (ii) of this proposed rule, which by requires that a cleanup action must "be technically practicable at the site" implies a requirement that only technologies that can be used at the site may be employed. As discussed previously, off-site technologies such as incineration will and must be used for cleanup actions.

By deleting the phrase "at the site" from section (ii), the implication of only on-site actions will be deleted and technically practicability will be required for all cleanup actions both on-site and off-site. The proposed rule should be amended as follows:

SUGGESTED CHANGE TO PROPOSED RULE 173-340-360(2)(b)

"When evaluating alternative cleanup actions that meet requirements of subsection (2)(a) of this section, the cleanup action selected shall:

(i) Use permanent solutions to the maximum extent practicable;

(ii) Be technically practicable [~~at the site~~];

(iii) Provide for a reasonable restoration time frame; and

(iv) Consider public concerns."

3.

PROPOSED RULE WAC 173-340-360(6)(a)

"A permanent solution is one in which the cleanup standards under WAC 173-340-700 through 173-340-760 are achieved without further action being required at the original site or any other site involved with the cleanup action, such as an off-site landfill."

DISCUSSION

See the discussion above for proposed rule WAC 173-340-200.

SUGGESTED CHANGE TO PROPOSED RULE WAC 173-340-360(6)(a)

"A permanent solution means a cleanup action in which the cleanup standards under WAC 173-340-700 through 173-340-760 are achieved without further action being required at the site being cleaned up [~~or without any other site involved with the cleanup action, such as an off-site landfill~~]."

4.

PROPOSED RULE WAC 173-340-360(6)(b)

"In demonstrating compliance with subsection (2)(b)(i) of this section, the technology and method or combination of technologies and methods for site cleanup shall be selected in the following order of decreasing preference:

(i) Reuse or recycling;
(ii) Destruction or detoxification;
(iii) Separation or volume reduction with approved treatment or management of the hazardous substance;
(iv) Immobilization of hazardous substances;
(v) On-site or off-site disposal, isolation, or containment with attendant engineering controls; and
(vi) Institutional controls and monitoring.

DISCUSSION

As discussed previously in the discussion for proposed rule WAC 173-340-200 on pages 1-3, the residue from certain treatment processes of necessity currently does and will continue to be land disposed. It is only the untreated waste for which there should be a preference against land disposal.

Congress recognized that fact in enacting the Comprehensive Environmental Response, Compensation and Liability Act of 1980 by providing: "The off-site transport and disposal of hazardous substances or contaminated materials without such treatment should be the least favored alternative remedial action where practicable treatment technologies are available." CERCLA § 121(b)(1), 42 USC § 9621(b)(1).[1] [Emphasis added.] EPA has also recognized that fact in the commentary to its final rules for the National Oil and Hazardous Substance Pollution Contingency Plan: "EPA notes that CERCLA does not express a preference for or bias against off-site remedies involving treatment and that the NCP is similarly neutral." 55 Fed. Reg. at 8,725 (3/8/90).

The proposed rule should be amended as follows to reflect the realities of current and future cleanup technologies:

SUGGESTED CHANGE TO PROPOSED RULE WAC 173-340-360(6)(B)

"In demonstrating compliance with subsection (2)(b)(i) of this section, the technology and method or combination of technologies and methods for site cleanup shall be selected in the following order of decreasing preference:

---

[1]The Model Toxics Control Act specifically requires that the Department of Ecology adopt cleanup standards at least as stringent as those provided by this statutory provision in CERCLA. RCW 70.105D.030(2)(d).

(i) Reuse or recycling;
(ii) Destruction or detoxification;
(iii) Separation or volume reduction with approved treatment or management of the hazardous substance;
(iv) Immobilization of hazardous substances;
(v) On-site disposal or off-site disposal without treatment, isolation, or containment with attendant engineering controls; and
(vi) Institutional controls and monitoring."

5.
PROPOSED RULE WAC 173-340-360(7)

"Practicability. In determining whether a cleanup action meets the requirement of subsection (2)(b)(ii) of this section, the following factors shall be considered:

(a) Technical feasibility;
(b) Ability to be implemented including consideration of the factors in WAC 173-340-350(6)(e)(vi);
(c) Cost in accordance with the following;
(i) A cleanup action shall not be considered technically practicable if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action;
(ii) For cleanup action alternatives which meet the requirements of subsection (2)(a) of this section and which have an equivalent order of preference under subsection (6)(b) of this section, preference shall be given to the cleanup action which costs the least; and
(iii) Costs considered shall include present and future direct and indirect capital, operation and maintenance costs, and other foreseeable costs."

DISCUSSION

CWMNW supports the principle that in general and for most waste categories, treatment or recycling or reuse technologies should be preferred over the land disposal of untreated wastes. CWMNW also believes, however, that the Department of Ecology should recognize that some contaminated materials, most particularly soil and debris, are not presently amenable to treatment technologies designed for the raw waste, and that a generator of contaminated soil and debris should not have to make the same showing as generators of other wastes (for example, spent solvents) before land disposal occurs.

Carving out a separate category for soil and debris would be consistent with CERCLA, and the recently issued National Contingency Plan, as well as the federal land disposal ban. Similar to the Department's duty under the Model Toxics Control Act, EPA is obligated under CERCLA to select remedial actions that use "permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable." CERCLA § 121 (b), 42 USC § 9621(b). At the same time, Congress, in the Hazardous and Solid Waste Amendments of 1984, postponed the land disposal restrictions for spent solvents and dioxins and California List wastes, where the waste is "contaminated soil or debris resulting from a response action required under [CERCLA] or a corrective action taken under [RCRA]." RCRA § 3004(d)(3) and (e)(3), 42 USC §§ 6924(d)(3), (e)(3). EPA then promulgated an additional two-year nationwide capacity variance for this waste category in its "First-Third" rulemaking. 40 CFR §§ 268.30(c), 268.32(d)(2) (see 53 Fed Reg 31,216).

In addition, in both the First- and Second-Third final rules, EPA granted a two-year variance from any incineration-based treatment standard where the wastes are contaminated soil and debris. 40 CFR § 268.33(c) (see 53 Fed Reg at 31,217); 40 CFR § 268.34(d) (see 54 Fed Reg at 26,648). In the Third-Third final rules, EPA expanded the variance to include any First-, Second-, and Third-Third contaminated soil and debris where the treatment standard is based on incineration, mercury retorting, or vitrification. 40 CFR §268.35(e) (see 55 Fed Reg at 22,689). EPA has granted these variances because of the increased demand placed on treatment capacity by the Superfund program. 54 Fed Reg at 22,649-50.

In the recently-issued final rules on the National Contingency Plan, EPA also recognized that soil and debris pose a treatability dilemma. 55 Fed. Reg. 8,760-62. EPA states:

> "EPA's experience under CERCLA has been that treatment of large quantities of soil and debris containing relatively low levels of contamination using LDR 'best demonstrated available technology' (BDAT) is often inappropriate. 54 FR 45167, 45168 (October 10, 1989). EPA noted that:
>
> 'Experience with the CERCLA program has shown that many sites will have large quantities -- in some cases, many thousands of cubic meters -- of soils that are contaminated with relatively low concentrations of hazardous wastes. These soils often should be treated, but treatment with the types of technologies that would

meet the standard of BDAT may yield little if any environmental benefit over other treatment based remedial options.'

"54 FR 45168 (October 10, 1989). Examples of these and other situations reflecting EPA's experience concerning the inappropriateness of incinerating contaminated soil and debris are included in the record for this rule. In addition, as discussed below, EPA has experienced problems in achieving the current non-combustion LDRs for contaminated soil and debris. Based on EPA's experience to date and the virtually unanimous comments supporting this conclusion, EPA has determined that, until specific standards for soils and debris are developed, current BDAT standards are generally inappropriate or unachievable for soil and debris from CERCLA response actions and RCRA corrective actions and closures. Instead, EPA presumes that, because contaminated soil and debris is significantly different from the wastes evaluated in establishing the BDAT standards, it cannot be treated in accordance with those standards and thus qualifies for a treatability variance from those standards under 40 CFR 268.44.

***

"Similarly, treatability variances are warranted where the applicable numerical treatment standard for the waste cannot be achieved. 40 CFR 268.44(a). For this reason, EPA has found that current BDAT standards based on noncombustion technology also warrant a treatability variance for soil and debris. The complex matrices often present in soil and debris may reduce the effectiveness of stabilization and other noncombustion technologies in treating these wastes. For example, the presence of oil and grease or sulfites in the mixture may substantially interfere with the stabilization process. More generally, stabilization is a complex treatment process and its application to unique soil and debris mixtures is not yet well understood. EPA's development of alternative treatment levels in the Superfund Guidance #6A noted above was based on available data for soil and debris mixtures and thus is more tailored with respect to achievability than the existing BDAT standards for these waste mixtures. The difference between these levels and the existing BDAT standards for these wastes demonstrates the feasibility of achieving the current BDAT standards for soil and debris. These alternative numbers thus support EPA's presumption that the BDAT standards are generally inappropriate or not achievable for soil and debris." 55 Fed Reg at 8,760-61.

This excerpt shows that EPA recognizes soil and debris as a waste category deserving special treatment. Not only is soil and debris typically contaminated with low levels of hazardous constituents, but the material is not amenable to most treatment technologies.

Based on EPA's extensive examination on the treatability of soil and debris, CWMNW believes the Department of Ecology should promulgate a special provision for this material in the final rules. A generator of soil and debris should not have to make the same showing of "practicability" as generators of other wastes. The proposed rule should not be adopted in its present form because it would severely limit a generator's choices of remedial actions for soil or debris contaminated materials and adversely affect the cost of those remedial actions.

The proposed rule should be revised as follows to recognize the current problems with treatment of soil and debris and the treatment variance for soil and debris granted by EPA under 40 CFR Part 268:

SUGGESTED CHANGE TO PROPOSED RULE WAC 173-340-360(7)

"Practicability. In determining whether a cleanup action meets the requirement of subsection (2)(b)(ii) of this section, the following factors shall be considered:

(a) Technical feasibility;

(b) Ability to be implemented including consideration of the factors in WAC 173-340-350(6)(e)(vi);

(c) Cost in accordance with the following;

(i) A cleanup action shall not be considered technically practicable if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action;

(ii) For cleanup action alternatives which meet the requirements of subsection (2)(a) of this section and which have an equivalent order of preference under subsection (6)(b) of this section, preference shall be given to the cleanup action which costs the least; and

(iii) Costs considered shall include present and future direct and indirect capital, operation and maintenance costs, and other foreseeable costs[.];

(d) Treatment of contaminated soil and debris is impracticable for any soil or debris for which the EPA Administrator has issued a variance from treatment under 40 CFR Part 268."

Very truly yours,

for Donald A. Haagensen

Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

90-PPB-187

SEP 7 1990

Mr. David Bradley
State of Washington
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Dear Mr. Bradley:

REVIEW OF PROPOSED MODEL TOXICS CONTROL ACT CLEANUP STANDARD REGULATIONS

Attached for your consideration are comments from the U.S. Department of Energy, Richland Operations Office on the proposed Model Toxics Control Act cleanup regulation published in the Washington State Register, Issue 90-15, dated August 1, 1990. Should you have any questions regarding these comments, please contact Sandy Trine, DOE-RL, at (509) 376-6943.

Sincerely,

R. D. Izatt, Director
Environmental Restoration Division

ERD:SLT

Enclosure:
Comments on Proposed Model Toxics
Control Act Cleanup Standards

cc w/encl:
P. T. Day, EPA
R. E. Lerch, WHC
T. Nord, Ecology

Comments on Proposed Model Toxics Control Act Cleanup Regulation

Reference: Washington State Register, Issue 90-15, pages 156-180, "Chapter 173-340 Washington Administrative Code (WAC), Model Toxics Control Act Cleanup Regulation," dated August 1, 1990.

1. **WAC 173-340-120(2)(a), Scope of release reporting:** The statement indicating that "most current releases of hazardous substances must be reported to the department" is questionable. Reporting requirements would not extend to most spills of gasoline (a hazardous substance) at service stations during vehicle refilling. These spills may be the most common type of hazardous substance releases in terms of number of occurrences. Consider rephrasing the beginning of the sentence in question to indicate that "most spills with potential adverse environmental impact" must be reported, rather than stating that "most spills" must be reported.

2. **WAC 173-340-200, Definition of "volatile organic compound:"** The definition of "volatile organic compound" needs clarification. What exactly is meant by "easily evaporates at room temperature?" Consider establishing some definitive characteristic (e.g., vapor pressure) for identifying a volatile organic compound. As an alternative, consider providing a list of specific compounds.

3. **WAC 173-340-360-(4)(b)(ii), Application of all known available and reasonable methods of treatment (AKART) to ground water remedial actions:** This section requires that AKART be used to protect and restore the quality of ground water affected by a release from a site. The Water Pollution Control Act (RCW 90.48) specifically applies to prevention activities, not remedial activities. If a discharge to ground results because of a cleanup action, then AKART is appropriate, but AKART should not be considered applicable during the initial evaluation of cleanup alternatives. Using AKART in this way could result in requiring "treatment for treatments sake." This is especially true since Section (360)(4)(b)(ii)(A) goes on to say that ground water treatment is required for remedial actions where such treatment is practicable or in the public interest.

   We recommend that the wording be changed in this section to clarify that RCW 90.48 is applicable to discharges to the ground for the prevention of pollution and not for the restoration of contaminated waters.

4. **WAC 173-340-360(4)(b)(ii)(B)(I), Prevention of additional releases to ground water:** This section requires that source control measures be implemented to prevent additional releases to the ground water. Is this intended to apply to any releases, including discharges of clean water, or only to releases which would result in additional discharge of hazardous substances? In the former instance, it may be appropriate to allow discharge of uncontaminated solutions contingent upon a

demonstration that such discharge will not result in significant mobilization of the hazardous substances present in the soil column or in undue spread of contamination already in the ground water.

5. **WAC 173-340-360(6), Hierarchy of Cleanup Alternatives:** This section establishes a hierarchy of cleanup alternatives based on a bias towards permanent solutions. It allows a selection of a lower preference technology or combination of technologies only where it can be justified based on a "balancing" of several criteria.

   a. Are the criteria weighted or are they all given equal consideration during the "balancing?" For example, is practicability given more or less credence than a criteria such as long term effectiveness?

   b. Are any of the criteria "fatal flaws?" For example, if a cleanup method had low overall protectiveness of human health and the environment, would that be automatic justification for a lower preference technology or would you still have to go through the balancing process?

   c. This section refers to balancing of all the criteria, yet isolation and containment and institutional controls and monitoring can not be used if a higher preference technology is technically practicable. This means that even if one of the above actions provided better overall protection to human health and the environment, it could not be selected. This appears to require "treatment for treatments sake" without consideration of the goal of these regulations which is to protect human health and the environment.

   Consider the following recommendations:

   1. Make the criteria "overall protection of human health and the environment," the driving force in selecting a cleanup method. This is consistent with the regulations goal.

   2. Delete Sections (6)(d)(v) and (vi) so that a treatment method is not required simply because it is technically practical.

6. **WAC 173-340-360(8)(c), Deferral of cleanup pending control of offsite sources:** This section indicates that cleanup may be deferred in cases where offsite sources would cause recontamination to levels which exceed cleanup standards. In such cases, the remedial action is considered an interim action. Some clarification is needed regarding the Washington State Department of Ecology (Ecology) intent and authority to require control of offsite sources which are contributing to the area background. Does Ecology intend to require such facilities to halt discharges, even if such discharges are in compliance with all regulatory requirements? If not, does this mean that site cleanup may

remain in "interim action" status for an extremely long period of time?

7. **WAC 173-340-450, Releases from underground storage tanks:** This section of the regulation apparently attempts to impose requirements established in Subpart F of 40 Code of Federal Regulations (CFR) 280. If this is the intent, the proposed WAC 173-340-450 section appears to be deficient with regards to incorporation of the "Corrective Action Plan" requirements in 40 CFR 280.66. The 40 CFR 280.66 requirements include provisions for submittal of such plans, details of plan approval considerations, and submission of plans pursuant to voluntary corrective actions (similar to the "independent cleanup actions" discussed in WAC 173-340-450(8)). If the intent is to implement the requirements of 40 CFR 280 Subpart F via WAC 173-340-450, some revision is appropriate to incorporate corrective action plan submittal.

8. **WAC 173-340-700(2), Background cleanup goal:** The philosophy stated in the last sentence of this section, i.e., that the goal is to establish cleanup levels as close as possible to natural background levels, is not evidenced in the development of the actual standards. To be consistent with the actual standards, consider revising the last sentence to indicate that the goal is to establish cleanup levels which are protective of human health and the environment.

9. **WAC 173-340-700, Modification of cleanup levels based upon technical impracticability:** The discussion in WAC 173-340-360(2)(b)(ii) indicates that technical practicability must be considered in selecting a cleanup level. The establishment of cleanup levels in WAC 173-340-700 fails to address technical impracticability, even though it is very possible that some standards based upon Method A, Method B, or conditional cleanup level requirements may be below limits of feasibility by available technologies. Consider revising WAC 173-340-700 to provide regulatory requirements for modifying cleanup levels based upon technical impracticability.

10. **WAC 173-340-700, Modification of cleanup levels based upon overall threat to human health and the environment:** The discussion in WAC 173-340-360(2)(i) indicates all cleanup actions must be protective of human health and the environment, including complying with cleanup standards. Although it is possible that complying with a conditional cleanup level may require selection of a cleanup method that causes a greater threat to human health (this may be the only method that can achieve the required cleanup level), this is not a consideration in establishing the conditional levels. A good example might be worker exposure or offsite treatment of wastes which are a result of the cleanup remedy. Consider revising WAC 173-340-700(8) to state that "conditional cleanup levels shall be established in accordance with the following procedures except where it will cause the establishment of a cleanup level that would require a treatment method which would cause greater overall threat to human health and the environment."

11. **WAC 173-340-700-(5)(d)(v), Financial benefits resulting from approval of conditional cleanup levels:** The regulations allow a conditional cleanup level if attainment of compliance cleanup levels will limit a person's ability to respond to other environmental threats. This is only allowed if financial benefits resulting from the approval of a conditional cleanup level are used to fund actions that are not otherwise required by law. If Ecology's goal is to encourage the wise use of limited resources, it does not make sense to limit the use of those resources only to actions that are not otherwise required by law. Financial benefits resulting from the use of a conditional cleanup level should be able to be used for actions which result in the greatest net environmental benefit, regardless if the activity is or is not required by law. Consider deleting the wording in (5)(d)(v)(C) which states "that are not otherwise required under applicable state and federal laws."

12. **WAC 173-340-700(8), Clarification of site use restrictions in establishing conditional cleanup levels:** The intended use of conditional cleanup levels is unclear. The definition in WAC 173-340-200 indicates that site use restrictions are a part of conditional cleanup levels. The discussion in WAC 173-340-700(8) seems to rely solely upon specified criteria resulting in concentration-based limits, with no exposure pathway which would allow for site use restrictions. Additionally, no statement is made regarding where the cleanup standard applies. The minimum criteria seem to imply that the conditional cleanup levels would have to be met at the most contaminated area. This approach does not provide any real latitude for site use restrictions if the conditional cleanup levels must meet the criteria throughout a site. This is because the cleanup criteria established in WAC 173-340-700(8)(a)(i), (ii), (iii), and (iv) are the same as those established in WAC 173-340-700(7), with the fairly minor exception that the total excess cancer risk may be 1 in 100,000 rather than 1 in 1,000,000. Thus, as currently written, WAC 173-340-700(8) implies that site use restrictions would only be potentially allowed for contaminated areas where carcinogens are left in concentrations which exceed the 1 in 1,000,000 risk level. There appears to be no allowance for site use restrictions for non-carcinogen constituents.

Consider revising WAC 173-340-700(8) to clearly indicate where the conditional cleanup levels apply and how site use restrictions factor into the development of the levels.

13. **WAC 173-340-705(12)(b)(i), Use of practical quantitation limits (PQL) for determining cleanup effectiveness:** This section states that the PQL may be used for determining that the cleanup level is met only when the PQL is no more than 10 times the method detection limit. In many cases, the PQL for a standard method will be much greater than 10 times the ~~PQL~~, depending upon the waste matrix. For example, Method 8120 of
MDL

the U.S. Environmental Protection Agency (EPA) Test Methods for Evaluating Solid Waste (one of the analytical procedures specified in WAC 173-340-830) indicates that the PQL for ground water contamination is a factor of 10 times the method detection limit (MDL), but the PQL for low-level soil contamination is a factor of 670 times the MDL. In many cases, the calculation of health-based limits for carcinogens could result in a cleanup standard which is well below the MDL,let alone the PQL. The EPA has recognized this problem in the hazardous waste delisting program, and taken that stance that it is inappropriate to penalize a waste generator because the technology is not available to prove that a constituent is not present at a given level. The WAC 173-340 regulations should consider the practicality of this approach. The proposed rules, which could require cleanup levels which cannot be verified by any available analytical technology, may preclude completion of cleanup in many instances.

14. **WAC 173-340-720, WAC 173-340-730, WAC 173-340-740, WAC 173-340-745, Basis for Table 1 limits:** Consider adding a column to Table 1 in these sections to identify the basis for the cleanup level (e.g., natural background concentration, 1 in 1,000,000 excess cancer risk level, acute or chronic toxicity concentration, etc.).

15. **WAC 173-340-720, Ground Water Cleanup Levels:** The definition of drinking water should not be dependent on the criteria of 10,000 milligrams per liter (mg/l) of total dissolved solids. Ground waters are often considered naturally, or with treatment, unfit for drinking water with much less than this amount of total dissolved solids. Since the reasonable maximum exposure for ground water is based on drinking water being the highest beneficial use, a cleanup level should not be required to ever be set below a maximum contaminant level (MCLs), as would be the case with several of the MCLs. Cleaning up ground water to more stringent levels than a health-based drinking water standard will only result in less cleanups due to the unwise use of limited resources. In addition, always requiring cleanup to a secondary maximum contaminant level may also result in the unwise use of resources, particularly for those ground waters that are not current sources of drinking water.

    Consider the following recommendations:

    1. Clearly state that cleanup levels which meet or exceed health-based maximum contaminant levels will be considered protective of the highest beneficial use of ground water.

    2. Add wording that allows cleanup levels for secondary maximum contaminant levels to be established on a case-by-case basis giving consideration to the current use of ground water, the availability of point of use or point of source treatment, and the effects of the elevated secondary contaminants on the useability of the drinking water supply.

3. Incorporate some standard of economic reasonableness into definition of "technically practicable".

16. **WAC 173-340-720 (8), Compliance Monitoring:** This section requires that compliance with ground water cleanup levels will be determined by analyses of unfiltered ground water samples unless it can be demonstrated that a filtered sample provides a more representative measure of ground water quality. The unfiltered ground water sample may not provide a proper characterization of the ground water quality and does not indicate what is bio-available. The U.S. Department of Energy-Richland Operations Office (DOE-RL) recommends the filtered analyses should be considered equally, not subordinately.

17. **WAC 173-340-720, Ground water cleanup levels for environmental protection:** Compliance cleanup levels for Method A and Method B contain the statement that the department may establish cleanup levels that protect human health and the environment. If it is the department's intent that drinking water is, in most cases, the highest beneficial ground water use, concentrations protective of the environment should be established on a case-by-case basis and so stated.

18. **WAC 173-340-720, Ground water discharges to surface water:** For ground waters which directly influence a surface water body, and have no specific beneficial use other than as base flow to the surface water, the cleanup standards should allow establishment of a cleanup level-based on impacts to surface water. If the cleanup level is based on aquatic criteria, then compliance should be measured in the surface water, not ground water. This would more accurately reflect protection of the beneficial use, which in this case is not ground water as a drinking water source, but rather aquatic resources. Consider revising WAC 173-340-720 (3)(a)(iii)(E) to clarify that concentrations will be measured in the surface water.

19. **WAC 173-340-730, Surface Water Cleanup Standards:** Please define the "C, D, C," term in the equation.

20. **WAC 173-340-745, Soil Cleanup Standards for Industrial Sites:** This section requires that industrial site use be demonstrated before industrial soil cleanup levels can be applied. The definition of a site in WAC 173-340-200 includes both onsite and offsite contamination. If an entire site must demonstrate industrial site use, then this could eliminate the use of industrial soil cleanup levels for an industrial site which has contaminated an offsite area which does not meet the industrial site definition. Industrial soil cleanup levels should be able to be used for that portion of a site which meets the definition, as long as cleaning up to those levels will not impact the cleanup on those portions of the site which are not industrial. The DOE-RL

recommends adding language to WAC 173-340-745 (1)(b) which says "To demonstrate industrial site use the site, or portions thereof, shall: ...".

21. **WAC 173-340-745, Soil Cleanup Standards for Industrial Sites:** WAC 173-340-745 (1)(c) states that soil cleanup levels established under this section shall be as close as practicable to compliance cleanup levels established in accordance with WAC 173-340-740. This requires cleanup levels for industrial sites be established as close as practical to those levels required for residential sites, regardless of the demonstrated reasonable maximum exposure. The DOE-RL feels that cleanup levels for industrial sites should be based on the reasonable maximum exposure and not set for residential exposure simply because it is technically practical. Consider deleting this portion of WAC 173-340-745 (1)(c).

22. **WAC 173-340-750, Applicability of air quality cleanup levels:** There appears to be some confusion with regards to when the air quality cleanup standards apply. At one time, discussions with Ecology seemed to imply that the standards would be applicable during the period of cleanup activities (i.e., the airborne constituent concentrations resulting from cleanup activities could not exceed the limits calculated by the formulas in WAC 173-340-750). Is this still the intent, or do the air quality cleanup levels represent maximum ambient air concentrations allowed in the vicinity of a contaminated area? Consider revising this section to clearly identify when air quality cleanup standards apply.

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September 17, 1990

Mr. David Bradley
Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia, WA 98504-8711

Dear Mr. Bradley,

This is a comment letter on the Cleanup Standards Amendments to the Model Toxics Control Act Cleanup Regulation (Chapter 173-340 WAC). The Washington Public Ports Association believes that these regulations have important ramifications for the economic development and international trade mandate of the state's port districts, and we welcome this comment opportunity.

General Comments

As we have stated many times publicly before, the ports believe strongly that it is good public policy to encourage timely, environmentally sound hazardous waste cleanups. This theme is embodied in the current MTCA process rule. However, cleanup standards which are too complicated, burdensome, slow or costly will discourage this goal. This principle should be incorporated into each section of these amendments in order to encourage timely, voluntary and permanent cleanups.

One of the comments that has been made by many individual ports as they have reviewed this rule is that it is far too complex and difficult to understand. Several experienced port environmental planners and analysts have great difficulty understanding this rule as it is written. There are too many internal citation references, and too many complicated concepts with subtle shades of meaning (such as practicable v. technically practicable).

The rule would be immeasurably improved by the addition of a clear section of administrative principles, which puts forth in simple language the general administrative cleanup policies of the Department. This section could clear up some of the current confusion about concepts such as the role of cost, the permanence of cleanups, acceptable risks, etc.

Another general comment is that the current rule places too much reliance on interim cleanups. Timely and final cleanups are important in order for port

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districts to fulfill their responsibilities through such actions as industrial property transactions. Timely industrial property transactions advance the general land use goal of using existing industrial sites to the maximum extent, in preference to developing new industrial sites in rural areas.

A final general comment is that the ports remain concerned about the how this rule will be applied in aquatic cleanups. The proposed rule has reserved the section of the rule dealing with sediment standards and aquatic cleanups. While this section has been properly left to another forum to discuss, it is still somewhat unclear exactly how well this rule will work in practice in aquatic environments where there are complex contribution and ownership patterns.

These general comments are intended to convey to the department some general points which the ports hope to see improved in the rule. We also wish to emphasize our continued support of the efforts of the Public/Private Cleanup Coalition, to which we belong.

<u>Specific Comments</u>

The Washington Public Ports Association will not make extensive technical comments on this rule. Many technical comments have already been received by the department from qualified consulting firms, and this Association generally supports their recommendations.

One important specific point is that Section 360 needs to have a provision for a waiver of compliance with applicable state and federal laws, where compliance is not practicable. In many shallow aquifer nearshore areas, for example, compliance with groundwater standards will be extremely burdensome to PLPs, and the often remote potential for harm to human health results in expensive "treatment for treatment's sake".

Section 360 also appears to have too strong a bias towards permanent solutions, at the expense of more practical solutions which still meet the statutory requirements of protecting human health and the environment. The primary consideration in selection of a final cleanup solution should be "overall protection of human health and the environment", which includes the health of humans and the environment at off-site disposal locations. The extreme difficulty of finding off-site disposal locations and the often prohibitively high cost of on-site permanent solutions require this consideration.

In addition, Section 700 contains too many limitations on the use of compliance cleanup levels. The ports commend the Department for including this concept into the cleanup standards, but in order to be effective these levels need to be applied to more than the occasional PLP.

On a positive note, this draft of the rule contains many improvements over previous drafts, such as the use of Practical Quantification Limits.

I hope these comments are useful as changes are made to the proposed amendments. I also again lend strong support to the pending comments from the Public/Private Cleanup Coalition.

Yours truly,

WASHINGTON PUBLIC PORTS ASSOCIATION

Eric D. Johnson

Eric D. Johnson
Environmental Specialist

Seattle
Solid Waste Utility
Division of Seattle Engineering Department

Gary Zarker, Director of Engineering
Diana Gale, Director, Solid Waste Utility

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September 17, 1990

David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

RE: Comments on the Model Toxics Control Act Cleanup Standards.

Dear Mr. Bradley:

The City of Seattle Solid Waste Utility has the following comments on the proposed amendments to the Model Toxics Control Act Cleanup Regulation:

Section 173-340-440 - Institutional Controls. From information given at the public meeting held September 5, 1990 in Seattle, we understood that institutional controls would apply only to the site itself, not to areas outside the site boundaries. We feel this needs to be clarified, especially concerning the use of restrictive covenants. In addition, we believe that institutional controls should be allowed outside the site boundaries. Not to do so leaves Ecology with little flexibility in certain situations where off-site institutional controls may be a very necessary, though temporary, part of a cleanup action.

Section 173-340-700, (7) and (8). We find the distinction between compliance and conditional cleanups to be virtually nonexistent. As we understand the proposed regulation, a compliance cleanup must restrict individual contaminants to concentrations posing a risk not greater than $1x10^{-6}$, with the sum of risks from individual contaminants not greater than $1x10^{-5}$. For a conditional cleanup, the only difference is that an individual contaminant may pose a risk not greater than $1x10^{-5}$, but the sum of risks must still not exceed $1x10^{-5}$. This leaves very little difference between the two types of cleanup, and very little flexibility for Ecology in setting conditional cleanup levels.

Section 173-340-720 - Point of Compliance. WAC 173-160-205 states that wells shall not be located within one thousand feet of solid waste landfills. Thus, for a solid waste landfill, the point of compliance for the groundwater pathway should be a thousand feet from the boundary of the site.

Thank you for the opportunity to comment.

Yours very truly,

Bruce D. Jones
Director of Landfill Closures

BDJ:HM

cc: Harris Martin
Lin Robinson
Gail Arnold
Saundra Parlow
Cathy Orsi
Marcia Nelson

To: D. Dravley

From: K. Keeley 753-2985; 442-2141

Arsenic Questions

1. Ecology DW regs would designate ASARCO slag as DW for arsenic (assuming 100 ppm arsenic in slag). Ecology MTCA states that slag = soil, and provides soil cleanup levels of 20 ppm, 100 ppm, or 230 ppm Arsenic. How will this discrepancy be addressed for slag which contains ~~more than 230~~ 100-230 ppm Arsenic (permits? DW?) — it's DW but OK via MTCA ?! Will slag w/ >230 As also be a DW?

2. Ecology / EPA are ~~ignoring~~ not actively addressing slag at residential homes in the ASARCO Superfund off site area. How can Ecology ignore slag at residential homes [particularly if large quantities are in rockeries or small quantities in driveways (that may break down easily)] but require containment of slag at industrial sites in the Tideflats area? A double standard?

3. Ecology Site Managers agree that slag is present at numerous sites (e.g., residential homes, Port facilities, log sort yards, graving docks, retaining walls). If we presume that slag is contained at each site (1 ft compliance), who will monitor / track these numerous sites to ensure

institutional controls are maintained?

that, (for example, that a building foundation is not constructed "illegally" within the containment area?).

If one party owns more than one site with slag, will that party be allowed to consolidate all slag from all sites at one property? Will DW require ~~some~~ a permits for transport of DW material?

Per D. Bradley,

1. Ecology will allow parties to identify ~~different~~ CPF and absorption factors for arsenic that are different than those identified in MTCA (assume that CPF and absorption factor for arsenic in slag is different than factors for arsenic in soil). If this is so, and Ecology recognizes the large number of sites that have slag, then why doesn't Ecology come up with a realistic and consistent approach to slag that can be applied? Why must all parties hire consultants to address the same issue?

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LINDA R. LARSON
PARTNER

September 17, 1990

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ECOLOGY

Elena Guilfoil
Toxics Cleanup Program
Washington State Department of Ecology
Mail Stop PV - 11
Olympia, Washington 98504-8711

Re: Comments on Draft Environmental Impact Statement for Cleanup Standards

Dear Ms. Guilfoil:

These comments on the Draft Environmental Impact Statement ("DEIS") for the proposed state cleanup standards under the Model Toxics Control Act ("MTCA") are submitted on behalf of ASARCO Incorporated ("Asarco").

The company believes that the DEIS is inadequate in that it does not carry out the requirements of the State Environmental Policy Act ("SEPA"), chapter 43.21C RCW, in several crucial areas. Its most significant general deficiency is its failure to confine itself to analyzing the environmental impacts of the proposed regulations. Instead, the bulk of the document, especially Chapters 1 -4 and 14, is devoted to justifying the policy decisions made by the Department of Ecology ("Ecology") in drafting the preferred alternative.

The most glaring indication of this failure is the use of a "Regulatory Evaluation of the Alternatives" at pages xiii - xiiii (sic) and in Chapter 14. Although WAC 197-11-440(8) allows the lead agency to include a discussion of other impacts relevant to the agency's decision, the SEPA regulations make it clear that such a discussion should not be the major focus of an EIS. WAC 197-11-448(1) states:

> SEPA contemplates that the general welfare, social, economic, and other requirements and essential considerations of state policy will be taken into account in weighing and balancing alternatives and in making final decisions. However, the environmental impact statement is not required to evaluate and document all of the possible effects and considerations of a decision or to contain the balancing judgments that must ultimately be made by the decisionmakers. Rather, an environmental impact statement analyzes <u>environmental</u> impacts and must be used by agency decisionmakers, along with other relevant considerations or documents, in making final decisions on a proposal. The EIS provides a basis upon which the responsible agency and officials can make the balancing judgment mandated by SEPA, because it provides information on the environmental costs and impacts.

(emphasis in original). This DEIS does not adequately separate Ecology's policy agenda from the environmental consequences of the proposed action, and by doing so presents confusing and biased information about the environmental impacts of the alternatives. Ecology's program goals should be clearly separated from the environmental analysis, so that an objective evaluation of environmental impacts is presented.

The DEIS also fails to comply with the requirements of SEPA in several specific respects. First, the DEIS impermissibly eliminates the No Action Alternative from detailed analysis. Second, it does not analyze all reasonable alternatives available to Ecology. Third, the alternatives that are presented are not adequately analyzed. In addition, the document does not identify the significant adverse impacts of the alternatives that cannot be mitigated.

<u>The No Action Alternative</u>

The DEIS concludes that the "no action" alternative is "illegal" and in any event identical to the ARARs alternative. Consequently, the DEIS does not analyze the "no action" alternative. As a result, the DEIS does not comply with WAC 197-11-440(5)(b)(ii), which provides that the "[t]he 'no action' alternative shall be evaluated and compared to other alternatives".

The DEIS assumes that Ecology is required to promulgate new rules under the MTCA. However, the MTCA merely states in RCW 70.105D.030(1)(f) that Ecology "may" take actions necessary to carry out the act "including the power to adopt rules under chapter 34.05 RCW." Promulgation of new rules is discretionary under the MTCA[1], and Ecology could choose to use the general statutory authority of the MTCA as a supplement to its existing authority under other state laws. Those state laws do not require a consideration of ARARs that results in the automatic use of the lowest conceivable standard at a site. The DEIS should have outlined and analyzed a separate "no action" alternative based on a scenario of the enforcement of existing laws and the MTCA.

Alternatives Presented

WAC 173-11-440 requires an EIS to analyze reasonable alternatives. Reasonable alternatives "shall include actions that could feasibly attain or approximate a proposal's objectives, but at a lower environmental cost or decreased level of environmental degradation". Chapter 3 of the DEIS discusses "significant issues" and "options" that are in fact reasonable, feasible alternatives to the preferred alternative. For example, the DEIS states at page 3-2 that "[t]he acceptable level of protection is the essential policy question for site cleanups . . .". It then goes on to assume that the acceptable level of risk is 1 x 10-5. Yet it also identifies at page 4-16 other jurisdictions which have adopted other acceptable risk levels for cleanup standards. Obviously, then, those other levels are reasonable and feasible. The environmental impacts for each risk level would be significantly different and are essential for a decisionmaker in adopting cleanup standards. Yet the DEIS does not present or analyze these levels as alternatives for consideration.

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[1] The DEIS, by making the assumption that promulgating rules is mandatory, totally ignores the requirement in WAC 197-11-440(5)(c)(vii) to discuss the benefits and disadvantages of delayed implementation of the proposal.

Alternatives Analysis

The DEIS assumes at page 6-3 that the measure of the impacts of the alternatives "is how much higher the levels of residual contamination are than the natural concentration levels of the hazardous substances". This assumption is a fundamental flaw in the analysis of environmental impacts. RCW 43.21C.030(c) calls for the preparation of a detailed statement of the "environmental impact of the proposed action" (emphasis added). The proposed action here is to adopt regulations for standards to clean up sites that are already contaminated. It is an action to decide whether to contaminate pristine areas. Consequently, the DEIS should analyze the measure the impacts of the alternative standards by comparing levels of residual contamination with levels already existing on contaminated sites. Such a comparison would result in significantly different information than that contained in the DEIS and would allow decisionmakers and the public to see a more realistic comparison of the alternatives.

The DEIS also appears to endorse a procedure whereby further environmental analysis takes place after a decision on cleanup standards are made. The DEIS states at page 6-6:

> Because the standards and the preferred alternative are presently in draft form, a qualitative assessment was considered appropriate. Once the regulations are finalized, following public comment and internal review, additional quantitative assessments of impacts will be included in the final EIS.

This procedure, if followed, would directly contravene the major purpose of SEPA, which is to provide decisionmakers with information about the environmental consequences of their actions before a decision is made. See, e.g., Juanita Bay Valley Community Association v. City of Kirkland, 9 Wn.2d 59, 73, 510 P.2d 1140, 1149 (1973). If the information to prepare a more quantitative analysis of the alternatives is available, it must be done now so that it is available to decisionmakers and the public before the regulations are "finalized".

In addition, the DEIS does a poor job of describing mitigation measures, and contains virtually no discussion of the unavoidable adverse impacts of each alternative. The "Technical Summary" states at page xii only that the action "will generally result in some unavoidable adverse impacts", and Chapter 13 does not even have a section on unavoidable adverse impacts. This is not compliance with WAC 197-11-440(6)(c)(v).

Conclusion

As a final matter, Asarco takes strong exception to the implication on page 13-1 that the former operation of its smelter in Tacoma resulted in "area-wide elevation of arsenic concentrations in the Puget Sound area". There is no factual basis for such a statement. Studies conducted by Ecology and the U.S. Environmental Protection Agency in the Ruston/North Tacoma area have shown that elevated levels of arsenic due to smelter emissions are confined to a very discrete geographical area. The DEIS itself notes in earlier sections that natural background concentrations of soil in the Puget Sound area are relatively high. The paragraph on arsenic on page 13-1 should be deleted.

Thank you for this opportunity to comment on the DEIS.

Very truly yours,

HELLER, EHRMAN, WHITE & McAULIFFE

Linda R. Larson

Linda R. Larson
Attorneys for ASARCO, Incorporated

cc: W. Hart
T. Aldrich
C. Dungey
M. Thorp

ali00cd6

Sept. 13, 1990

RECEIVED
SEP 18 1990
ECOLOGY

David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV11
Olympia, WA. 98504-8711

Re: Proposed Amendments to the Model Toxic Control Act Cleanup Regulation - ARAR (Applicable, relevant, & appropriate req.)

Is it legally applicable to not include Magnolia's recreational beach as #1 cleanup priority? The "Pollution Control Commission, permitted West Point's outfall (for a secondary treatment plant for Seattle's water), and Western Processing for hazardous waste treatment by a "sanitation engineer" recently deceased. The "Department of Ecology" approved these and Four Mile Rock Dredge Disposal Site, the Shortfill, ChemPro, and PANOCO at Pier 91- thus by "Superfund cleanups" inflicted hazardous waste on unsuspecting recreationalists, and residents. The unacceptable risk, and "background" have been determined. NOAA Mussel Trends, Metro's Annual Marine Status Reports, Ambient Monitoring etc. have been ignored in hazard ranking, Metro's hazardous waste influent, and effluent, and best available technology - land application after detoxification. Permits and "conditions" bend the law to be practicable. Wetlands, and I, one in a million, are priceless. Permissiveness is not cost effective.

Mean tide flow is north, but West Point's mean effluent flow is South until it hits the Duwamish plume, and then it edys along Magnolia beaches. Renton's effluent takes its turn along Magnolia beaches. The cumulative impact will not cease with secondary treatment, and the current WP outfall. Superfund cleanups had better not continue to threaten me, and mine. I appreciate your trying to site an upland hazardous waste site now. Metro claims the water quality at Four Mile Rock is very good, but NOAA Mussels don't agree, nor do I. DO YOU?

The fecal, and PAH crisis have increased predicted illness rates, and failure to warn has been deceptive to property values, and public health. Weak enforcement created the Model Toxic Control Act. Please share these enclosures with DOH. They should require biological testing for all suspected PAH cleanups. If you allow the West Point expansion, the outfall should catch the ship canal plume to the central basin. Recommend curbing the SOURCE as the most practicable first step to cleanup. Treatment plants should be at the other ends of pipes nearest a cost effective need for nutrient rich, pathogen free effluent (for forests, agriculture, golf courses, and cemetary TOP soil.) RSVP - thankyou.

Bonnie Orme

Bonnie Orme, 1949 Perkins Ln. W. Seattle, Wa. 98199

[illegible] - Magnolia Community Club

The UNIVERSITY of WESTERN ONTARIO
Department of Plant Sciences

July 5, 1990

Ms. Bonnie Orme
1949 Perkins Lane West
Seattle, W.A. 98199
U.S.A.

Dear Ms. Orme:

I have studied the following documents as a part of forming the opinions expressed below:

1. NOAA technical Memorandum NOSOMA49 Mussel Watch Project, August 1989.

2. NOAA technical Memorandum NOSOMA38 Chemical Contaminants in Tissues, December 1987.

3. NOAA technical Memorandum NOSOMA44 Chemical Contaminants in Sediments, November 1988.

4. Sheets Marked Table 61, Comparisons of Concentrations of Contaminants in Puget Sound Sediments (page 187).

5. "Guidance on Characterization of Toxic Substances" Report to the Great Lakes Water Quality Board, March 1987.

6. Report of the Dredging Subcommittee to the Great Lakes Water Quality Board, October 1986.

7. "Infections with E. coli 0157:H7 in Washington State" S. Ostroff, J. Kobayash and J. Lewis, JAMA 262, 355, 1989.

continued...

Biological-Geological Sciences Building • 1151 Richmond Street N. • London, Ontario, Canada • N6A 5B7
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The Great lakes Water Quality Board, (International Joint Commission) established Dredging Guidelines prohibiting deep water dumping of contaminated sediments. These guidelines are respected by both United States and Canada. Normally, contaminated dredgings are landfilled at appropriate sites. It was shocking to observe that Elliot Bay sediments exceeded International Joint Commission (IJC) dredging guidelines for PCB's, cadmium, copper, mercury, nickel and zinc. Studies of fourmile rock, Elliot Bay showed that lead, mercury, copper and PCB's greatly exceeded IJC guidelines by very, very wide margins. Deep water dumping of contaminated sediments greatly promotes general pollution of the coastal and Puget Sound waters.

Landfilling of dredged sediments seems to be the only long term solution to Puget Sound environmental problems. It is noteworthy that Elliot Bay along with other sites in Puget Sound seems to be very greatly more polluted than the areas of concern identified by IJC in the Great Lakes basins. It is tragic that a catastrophic destruction of Puget Sound has been allowed. The present environmentally destructive dredging-dumping practices must be stopped and stopped now.

Elliot Bay mussels contain notably elevated levels of polyaromatic hydrocarbons. As well elevated levels of PCB's, mercury, lead and other toxic metals are observed. Fish liver tissues from Elliot Bay reflected mussel problems with elevated PCB's, chromium, lead and nickel. Certainly Elliot Bay mussels are unfit for human consumption and on the average, fish do not seem to be safe for humans to consume.

I understand that fecal bacteria are found to be accumulating in Elliot Bay mussels. That observation underscores the environmental hazard of those mussels to humans. Only mussels with <u>no</u> fecal bacteria are fit for humans to consume, fecal bacteria can kill people. Recently Washington State observed an outbreak of bloody diarrhea (potentially fatal) caused by a strain of fecal bacterium resistant to all antibiotic therapy. Seattle may be facing a <u>fecal</u> crisis if the city continues to discharge living fecal bacteria into Puget Sound. Care must be taken to ensure mussels are not consumed and beaches are closed in a prudent manner.

Sincerely,

Joseph E. Cummins
Associate Professor

JEC/vw

(Genetics)

Report to the Great Lakes Water Quality Board (IJC) March 1987

PSDDA SL

TABLE 3. Basin specific background levels of pollutants in sediments of the Great Lakes (mg/kg). Additional work is necessary to quantify background levels of pollutants in the basins where no data currently exists.

	LAKE SUPERIOR					LAKE HURON		LAKE MICHIGAN					LAKE ERIE		LAKE ONTARIO			Recommended Dredging Guideline[4]
	DSB	TBB	IRSB	MaB	KB	NoB	SaB	FB	MwB	WaB	SoB	GHB	WeB	CeB	NiB	MiB	RoB	
Total P	800	700	N/A	1200	1000	1000	700	N/A	N/A	N/A	N/A	N/A	700	1100	1000	700	1600	1000
Total N	3070	3000	N/A	3070	2670	3600	4270	N/A	N/A	N/A	N/A	N/A	1500	1500	2700	2300	2300	2000
Ammonia	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100
Hg	0.08	0.08	N/A	0.08	0.07	0.04	0.08	N/A	N/A	N/A	0.03	N/A	0.1	0.1	0.08	0.03	0.09	0.3
Pb	18	23.2	N/A	24.6	20.4	16.2	14.4	N/A	N/A	N/A	27.5	N/A	28	28	32	32	30	50
Zn	117	108	N/A	105	118	88	60	N/A	N/A	N/A	120	N/A	70	110	121	101	108	105
Fe	59400	53700	N/A	56000	58800	51600	32200	N/A	N/A	N/A	22278	N/A	N/A	N/A	52500	46200	46200	45500
Cr	50.7	51.8	N/A	49.8	57.1	28.5	30.0	N/A	N/A	N/A	37.1	N/A	N/A	N/A	N/A	N/A	N/A	120
Cu	69	57	N/A	61	69	51	31	N/A	N/A	N/A	21	N/A	30	40	56	46	46	45
Cd	0.9	0.5	N/A	0.8	0.5	1.0	0.4	N/A	N/A	N/A	0.6	N/A	2.0	2.0	1.5	0.9	1.0	1.5
Ni	63.5	59.7	N/A	57.7	64.4	61.1	29.9	N/A	N/A	N/A	32.8	N/A	N/A	N/A	N/A	N/A		90
Mn	0	1000	N/A	1200	900	1100	400	N/A	N/A	N/A	446	N/A	600	600	2300	2300	1700	1625
As	N/A	N/A	N/A	N/A	5	6	3	N/A	N/A	N/A	1.1	N/A	N/A	N/A	N/A	N/A	N/A	8
Cyanide	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.1
Volatile Solids { LOI 600°C	26300	22900	N/A	27300	24000	27800	35200	N/A	N/A	N/A	N/A	N/A	10000	20000	18400	19100	18400	60000
COD	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	50000
PCB	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.05
Oil & Grease	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1500
Other Organic Contaminants	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Below detection using best available technology. (GLWQA, 1978)

CEB - Central basin
DSB - Duluth sub basin
FB - Fox basin
GHB - Grand Haven basin
IRSB - Isle Royale sub basin
KeB - Keweenaw basin
MaB - Marathon basin
MwB - Milwaukee basin
MiB - Mississauga basin
NiB - Niagara basin
NoB - Nottawasaga basin
RoB - Rochester basin
SaB - Saginaw basin
SoB - Southern basin
TBB - Thunder Bay basin
WaB - Waukegan basin
WeB - Western basin

1 - Kemp and Thomas, 1976
2 - Kemp et al. 1978
3 - Robbins, J (pers. comm.)
4 - Thomas and Mudroch, 1979
N/A = not available

Is West Point effluent safe for Magnolia & Ballard beaches?

Infections With *Escherichia coli* O157:H7 in Washington State

The First Year of Statewide Disease Surveillance

Stephen M. Ostroff, MD; John M. Kobayashi, MD, MPH; Jay H. Lewis

In 1987, Washington became the first state to require that infection with *Escherichia coli* serotype O157:H7 be reported. In the first year of surveillance, 93 cases were reported, yielding an annual incidence of 2.1 cases per 100 000 population. The median age of case patients was 14 years (range, 11 months to 78 years), with the highest attack rate among children younger than 5 years (6.1 cases per 100 000 population per year). Bloody diarrhea was present in 95% of reported cases, 12% of patients developed either hemolytic-uremic syndrome or thrombotic thrombocytopenic purpura, and one patient died. Suspected secondary cases were seen in 5% of households. Fifty-six (60%) cases occurred during June through September, as did 73% of the cases of hemolytic-uremic syndrome or thrombotic thrombocytopenic purpura. Cases reported during the summer months were more likely than cases reported at other times of the year to be in children younger than 10 years. Medications, including antimicrobial medications, did not influence the duration of symptoms, nor did they appear to alter the risk of developing hemolytic-uremic syndrome or thrombotic thrombocytopenic purpura. This newly established surveillance system in Washington demonstrates that *E coli* O157:H7 is an important and common cause of bloody diarrhea in the United States.

(*JAMA*. 1989;262:355-359)

THE *Escherichia coli* serotype O157:H7 was first recognized as a human pathogen during a 1982 investigation of two outbreaks of diarrhea in Oregon and Michigan.[1] Hemorrhagic colitis, a syndrome marked by bloody diarrhea and abdominal cramps with little or no fever, and hemolytic-uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP), conditions marked by microangiopathic hemolytic anemia, thrombocytopenia, and renal failure, have been linked to infection with *E coli* O157:H7.[2-4] Since the original report, investigations of other outbreaks have helped define both the clinical spectrum of illness and modes of transmission of the organism.[5-12] As a result, mild and asymptomatic cases have been recognized, and both person-to-person and foodborne routes of transmission have been identified.

Several studies have also addressed sporadic cases of infection with *E coli* O157:H7 in the United States and Canada.[13-18] While highlighting the occurrence of sporadic illness, these series had only small numbers of cases, were done at a time when screening for the organism was limited, or were confined to small geographic areas. Since surveillance was established in parts of Canada and the United Kingdom,[19,20] the number of detected cases has increased rapidly in both countries; similar data are not available in the United States.

In 1987, infection with *E coli* O157:H7 was made a reportable condition in Washington State. This is the first state in the United States to require that infection with *E coli* O157:H7 be reported. It was anticipated that the reporting requirement would stimulate practitioners and laboratories to screen for the organism. It would also provide an opportunity to better describe the epidemiology of *E coli* O157:H7 in the Pacific Northwest, monitor trends in infection occurrence, improve outbreak detection, and learn more about the response of the organism to therapy.

METHODS

The Communicable Disease Epidemiology Section, Washington State Department of Social and Health Services, receives case reports of patients with reportable illnesses. In 1987, infection with *E coli* O157:H7 became a reportable illness. Information concerning the new reporting requirement was distributed to the medical community through the state's epidemiologic newsletter. Case reports were received from local health departments, clinicians, and microbiology laboratories. Suspected *E coli* O157:H7 isolates from reported cases were referred to the Washington State Public Health Laboratory for serological confirmation using the tube agglutination method for the somatic (O) and flagellar (H) antigens.[21]

A *primary case patient* was defined as a resident of Washington who had an infection with *E coli* O157:H7 confirmed at the Washington State Public Health Laboratory and who was not known to be in contact with other reported case patients. Cases that occurred in the same household were considered *coprimary* if onsets were less than 48 hours apart and *primary* and *secondary* if the interval between onsets was longer. Case patients who had either HUS or TTP had a creatinine level greater than 177 μmol/L; hematocrit less than 0.30, with evidence of red blood cell fragmentation on a peripheral smear; and a platelet count less than 150×10^9/L. Case patients who had TTP also had a fever and a new neurological deficit. Clinicians who cared for case patients who had a confirmed infection with *E coli* O157:H7 were asked to provide clinical data, and an attempt was made during the 30 days after the onset of illness to interview all primary case patients about symptoms, recent exposures, and treatment.

Contingency table analysis employed the Mantel-Haenszel χ^2 test of significance or the two-tailed Fisher's Exact Test when appropriate. The Student's *t* test was used for continuous variables.

From the Epidemiology Program Office, Division of Field Services, Centers for Disease Control, Atlanta, Ga (Dr Ostroff), and the Washington State Public Health Laboratory, Seattle, Wash (Dr Kobayashi and Mr Lewis).

Reprint requests to Centers for Disease Control, 1600 Clifton Rd NE, Bldg 1/5428, Mailstop C09, Atlanta, GA 30333 (Dr Ostroff).

Study finds high toxic levels in Elliott Bay

By Todd Davidson

A recently released national study concluded mussels near Magnolia's Fourmile Rock have some of the highest toxic contents in the nation.

The study comes on the heels of reports last week that employees at Northwest EnviroServices, Inc. allegedly dumped toxic chemicals into Metro's sewer lines.

As part of the National Oceanic and Atmospheric Administration's national status and trends program, Battelle Northwest Marine Laboratory collected and analyzed mussels and sediments from about 25 sites on the East Coast and 50 sites on the West Coast over the past three years.

The samples were analyzed for 17 metals, among them PAHs (polyaromatic hydrocarbons), PCBs (polychlorinated biphenyl) and chlorinated pesticides. The study determined the 20 most contaminated sites in the nation in each category.

Fourmile Rock had the highest PAH count in mussel tissues in the nation. The area was in the top 20 in PCBs (12th), lead (15th), copper (15th), silver (16th), tin (19th), DDT (20th), and mercury (20th) in mussel tissues.

Neighbors split

Jerry Bentler, an ex-employee of Northwest EnviroServices, said at this month's Metro Council meeting he witnessed the illegal dumping of thousands of gallons of toxic materials when he worked as a lab technician and water processor.

"I don't think it was anything small," he said. "Five thousand gallons of hexa-chrome solution going down the sewer is carcinogenic . . . I think it was a very serious violation, and it was covered up."

Northwest EnviroServices, under investigation for suspected violations of federal environmental laws, was made aware of the dumping, Bentler said he told company attorneys water containing sodium dichromate, which contains a cancer-causing agent, was supposed to be processed when it came in from Hanford Reservation. But Larry Johnson, the company's former general manager, had the water dumped into the sewer system, according to Bentler.

Northwest EnviroServices said last week that the former employees quoted in a two-year-old search warrant affida[vit] that was only recen[tly] released are either lying [or] misrepresenting what t[he] company did.

According to Bentl[er,] the warrant was sealed [at] the request of the co[m]pany's counsel, Resto[n,] Thorgrimson, Ellis a[nd] Holman. The same fi[rm] also serves as gene[ral] counsel to Metro.

[redacted]

United States
Environmental Protection
Agency

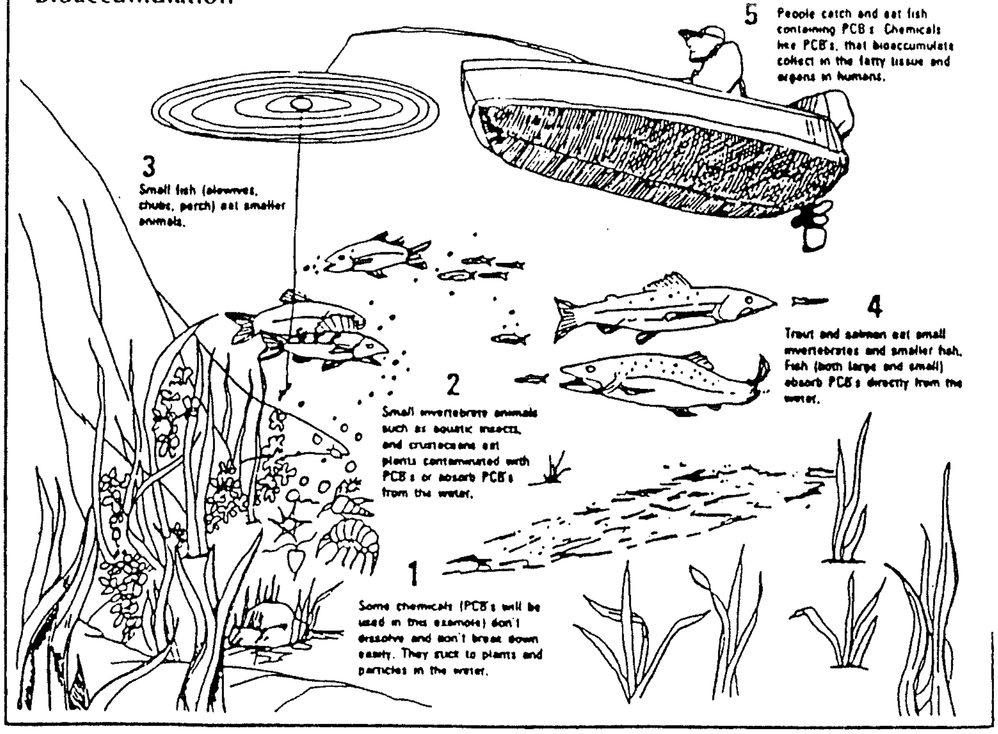
Region 5
Office of Public Affairs
230 South Dearborn Street
Chicago, Illinois 60604

EPA

Toxic Chemicals What They Are, How They Affect You

This fact sheet explains what toxic chemicals are, what they're used for, and how they can be harmful. Although here we examine just a sampling of the approximately 60,000 chemicals that are now in the marketplace, this fact sheet will shed light on some of the more common toxic chemicals EPA encounters.

Bioaccumulation

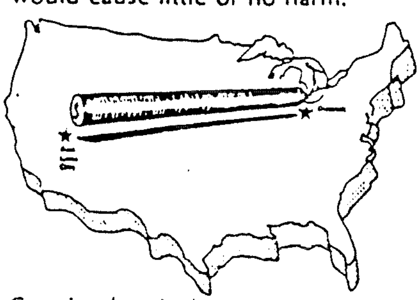


What Does Toxic Mean?

A chemical is toxic if it damages living tissue, impairs the central nervous system, or causes birth defects, illness, or death when eaten, drunk, inhaled, or absorbed through the skin.

How Much Exposure To A Chemical Causes Harm?

It depends on the chemical. The amount needed to trigger a toxic reaction varies with the nature of the substance, the route of exposure, and the length of exposure. Acute toxicity refers to an exposure of short duration. Chronic toxicity refers to repeated or prolonged exposures — often in tiny doses — to substances that in any single exposure would cause little or no harm.



Certain chemicals are so toxic that they are measured in parts per million (ppm) or even smaller parts per billion (ppb). One ppb would be one pound of a chemical in a billion pounds of soil. Or it can be silver dollars stretching from Detroit to Salt Lake City.

But Why Are Such Small Doses Of Some Toxic Chemicals Hazardous?

Besides being poisonous at low levels, PCB's, lead, and various other chemicals are also extremely persistent. That is, they don't break down easily and therefore remain in the environment for years. Prolonged exposure to small doses of such chemicals are thought to cause a variety of health problems, including cancer.

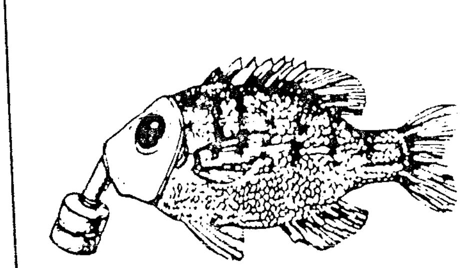
Bioaccumulation

Bioaccumulation is another reason why prolonged exposure to low-level doses can be dangerous. Chemicals such as PCB's and mercury build up in the tissues of humans and animals through the process of bioaccumulation. It works like this: A chemical spilled into a river or lake is ingested and stored by small organisms like plankton; small fish eat the plankton; and larger fish eat the smaller fish. As the process works its way up the food chain times more concentrated in the tissues of the large fish than in the plankton. That's why some fish from parts of the Great Lakes are unsafe to eat.

What Is EPA Doing About Toxic Wastes?

Three major laws help EPA control toxic substances. The **Toxic Substances Control Act** (TSCA) regulates the production of a substance that poses an unreasonable risk to human health or the environment. The **Comprehensive Environmental Response, Compensation, and Liability Act** (CERCLA), commonly called Superfund, enables EPA to address immediate dangers, long-range hazards, and spills at old or abandoned waste sites. The **Resource Conservation and Recovery Act (RCRA) allows** the State and EPA to track hazardous wastes from generation through final disposal. Other laws that also help regulate toxics include the **Clean Water Act, Clean Air Act, Federal Insecticide, Fungicide and Rodenticide Act,** and **Hazardous Materials Transportation Act**.

Most toxic substances can be handled safely. Depending on the substance, however, certain methods of manufacturing, use, and disposal are preferable over others. High-temperature incineration, for example, is highly effective in destroying PCB's and other toxic chemicals, but not toxic metals such as lead and mercury. Secure, lined landfills are an acceptable disposal option for toxic substances. Here are some of the toxic chemicals EPA often finds when studying or cleaning up a Superfund site. (Cleanup water should not go to West Point!)



Asbestos

Asbestos — a building and insulating material widely used for years because of its strength and heat-resisting qualities, has been found to cause asbestosis — a severe lung ailment, certain types of lung cancer, and other respiratory problems. If not completely sealed in a product, asbestos can break into tiny fibers that float almost indefinitely in air. These fibers are smaller and more buoyant than ordinary dust particles and therefore are easily inhaled or swallowed. In 1972, asbestos was banned for use in clothing. In subsequent years it was banned in fire-proofing materials, in electric hair dryers, and in many other products. By 1982, of the 22,723 schools in EPA Region 5 that were inspected for asbestos problems, 4,634 required corrective measures.

Acrylonitrile

Acrylonitrile — a chemical used in the production of synthetic fibers, plastics, and acrylics. In 1980, 1.8 billion pounds were produced in the United States, making it the 42nd highest volume chemical produced in the Nation. Acute symptoms of acrylonitrile exposure are similar to cyanide poisoning: headaches, dizziness, tremors, and jaundice. Long-term exposure to acrylonitrile can cause damage to the liver, the kidneys, and the central nervous system. It's a suspected carcinogen in humans.

Arsenic

Arsenic — a grayish white element found naturally in the environment. Arsenic has been used in the production of boric acid, pharmaceutical products, and pesticides. It is a byproduct of copper, zinc, and lead smelting. Doses taken over long periods can cause birth defects and genetic damage in test animals; there is evidence that it can cause skin and lung cancer in humans.

Benzene

Benzene — used more and more in recent years in the synthesis of chemical compounds and drugs and in the rubber industry. It is also added to gasoline as an octane booster. Eight million tons are produced annually. Benzene is released into the air primarily through the distribution and use of petroleum products. Evidence shows that long-term exposure in the workplace can cause leukemia and that high dosages are fatal. EPA estimates that three-fourths of all Americans have probably been exposed to benzene in varying degrees. Much of the exposure occurs when pumping gas at gasoline stations.

Cyanide

Cyanide — a poison that asphyxiates the cells in the body. Warning signs of cyanide poisoning include dizziness, numbness, rapid pulse, and nausea. A large dose can cause immediate unconsciousness. It is primarily used in the extraction of ore, in electroplating, and in metal treatment. It is also used in fumigation and in the ... pharmaceuticals

Dioxin

Dioxin — a generic term for a group of 75 related compounds known as polychlorinated dibenzo-p-dioxins. The most toxic compound of this group is 2,3,7,8-tetrachloro-dibenzo-p-dioxin (2,3,7,8-TCDD). Nobody produces dioxin on purpose. It is an unwanted but almost unavoidable byproduct that comes from manufacturing several commercial substances, chiefly the pesticide 2,4,5-TC Dioxin was also a contaminant in Agent Orange, the defoliant used during the V Nam War. Tests on laboratory animals indicate that 2,3,7,8-TCDD is one of the most toxic substances made by man. It is also a suspected carcinogen in humans, although scientists are still mystified by this chemical's effect on the human body EPA has now begun a national study to determine the extent of dioxin in the environment.

Formaldehyde

Formaldehyde — a colorless, pungent g used in plastics, plywood, foam insulatic products, textiles, embalming fluids, roc deodorants, and as a preservative in cosmetics. Prolonged exposure can caus eye irritation, respiratory problems, and fatigue. EPA is currently evaluating formaldehyde and may soon issue regulations to reduce exposure to this chemical.

Leachate

Leachate — a common term when talking about landfills. Leachate is not a specific chemical itself; it's a liquid that has percolated through wastes and contains components of those wastes. For instance, water may mix with leaking wastes inside a landfill, become contaminated, and then seep into the water table, polluting drinking water wells.

PCB's

Polychlorinated Biphenyls (PCB's) — are a family of organic compounds used since 1926 in electric transformers as insulators and coolants, in lubricants, carbonless copy paper, adhesives, and caulking compounds. They are also produced in certain combustion processes. PCB's are extremely persistent in the environment because they do not break down into new and less harmful chemicals. PCB's are stored in the fatty tissues of humans and animals through the bioaccumulation process. EPA banned the use of PCB's in 1976. In general, PCB's are not as toxic ir acute short-term doses as some other chemicals, although acute and chronic exposure can cause liver damage. PCB's have also caused cancer in laboratory animals. When tested, most people show traces of PCB's in their blood and fatty tissues.

Heavy Metals

(carcinogenic when inhaled!
(from leather?)

Cd **Cadmium**—used in electroplating, in the manufacture of batteries, and as a pigment. Chronic exposure to cadmium damages the liver and kidneys. It also has been associated with hypertension. Heavy smoking appears to increase the risk of cummulative toxic effects of cadmium exposure. Studies on animals have shown that cadmium can produce tumors and birth defects.

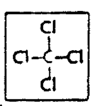
Cr **Chromium**—used in electroplating, in photography, and as a paint pigment. Acute ingestion of one form of chromium causes hemorrhages of the gastrointestinal tract. Airborne chromium has caused lung and other respiratory cancers in workers who were frequently exposed to it on the job.

Pb **Lead** — a byproduct of metal smelting, it is used in the manufacture of batteries and pigments. It also is added to gasoline to improve octane ratings, although in August 1984 EPA proposed to dramatically reduce the level of lead in gasoline. Exposure to low levels of lead over long periods can cause brain, bone, and neurological damage, and learning disabilities in children. Studies have shown a direct correlation between levels of lead in gasoline and levels of lead in children's blood.

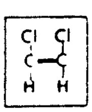
Hg **Mercury**—a silvery, liquid heav) metal found primarily in Spain, Yugoslavia, Mexico, Canada, an Algeria. Mercury is highly toxic and can be absorbed through the skin. It is used thermometers, batteries, flourescent ligl bulbs, pharmaceuticals, and many other products. Mercury bioaccumulates in th tissues of fish, making many larger ones unsafe to eat. Prolonged exposure can cause kidney, brain, and neurological damage.

Chlorinated Organic Compounds

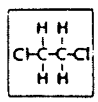
EPA Region 5 has initiated a 10-year testing progran to examine every community's underground water supply for these and similiar chemicals, including T



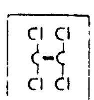
Carbon Tetrachloride is a colorless liquid used in refrigerants, metal degreasers, agricultural fumigants, and as a dry-cleaning agent. Exposure to it can cause damage to the central nervous system, liver, and kidneys. Alcohol intensifies the likelihood of these effects. Studies of workers exposed to carbon tetrachloride have concluded that it is a carcinogen.



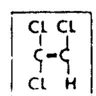
Dichloroethylene is a clear, colorless, volatile liquid used in cement latexes, film coating lacquers, paper coatings, and certain fibers. It causes health effects similiar to carbon tetrachloride.



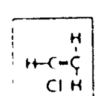
Dichloroethane (EDC) is used in the production of vinyl chloride and as a chemical feedstock. It's also used as a lead scavenger, a leaded-gas additive, an extraction agent for caffeine, and a dry cleaning agent. In high doses, dichloroethane can cause damage to the liver, kidneys and lungs.



Tetrachloroethylene (PCE) is used in dry cleaning, metal degreasing, textile dyeing, and various pesticides. It's a central nervous system depressant that can cause liver and kidney damage in animals.



Trichloroethylene (TCE) is used an industrial degreaser; a solver for oils, paints, and varnishes; a dry-cleaning agent; and an anesthetic. T is most often found in ground water because of spills at industrial facilities a other locations where TCE is used as a cleaning agent. The chemical is a centr nervous-system depressant. People exposed to high levels of TCE become sleepy, experience headaches, and may develop liver or kidney damage. Anim exposed to high doses of TCE have developed cancer. Also, drinking alcoh beverages tends to make the symptom TCE more severe.



Vinyl Chloride is a gaseous ra material used in plastics, floo tiles, food packaging, and as a propellant in aerosol containers. Stud have shown that vinyl chloride causes cancer. Lung cancer and cancer of the lymphatic and nervous systems have a been reported.

EFFECTS OF COAL-DERIVED TARS ON SELECTED AQUATIC AND MAMMALIAN ORGANISMS

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INTRODUCTION

The chemical analysis of synthetic fuels and effluents from coal processing plants has prompted appropriate concern for the environmental hazards that these industries may incur. Coal-derived fuels are generally much more toxic than petroleum products (1,2), and many aquatic organisms are particularly sensitive to these materials (3-5). Also, the relatively high polycyclic aromatic hydrocarbon (PAH) content of these coal-conversion products poses possible carcinogenic dangers. Indeed, studies have shown a significant increase in the number of specific-organ cancers, especially lung cancer, in workers associated with synthetic fuel production (6). From an ecosystem standpoint, bottom-feeding fish living near coal-processing facilities have shown an unusually high occurrence of lip, intestinal, and hepatic tumors (7-9), which is believed to be related to direct exposure to the pollutants found in the water and sediment below the effluent outfalls. Laboratory experiments, aquatic and mammalian, have shown that epidermal and hepatic neoplasms can be induced by PAH exposure (10-13). The objectives of the present study are (1) to study the reproductive and cellular effects of a coal-derived material (SRC-II HD) in a mammalian screen, (2) to determine the embryo-toxicity of the SRC-II HD in vertebrate fish, (3) to determine the uptake and elimination of the SRC-II HD in brown bullhead catfish, and (4) to compare the toxicity and ultrastructural changes of two fractions of an extract from a polluted river sediment to selected aquatic organisms.

MATERIALS AND METHODS

Chemicals

A solvent refined coal heavy distillate (SRC-II HD, boiling point range 260-450°C) produced at the Fort Lewis, WA, pilot plant was provided by Battelle Pacific Northwest

Laboratory (since this material was of pilot plant origin, it may not be representative of future commercial scale products). A polluted sediment from the Black River of Ohio was supplied by the Columbia National Fisheries Research Laboratory, Columbia, MO. The sediment was extracted, characterized, and fractionated into a PAH plus sulfur heterocycle (PAH/PASH) fraction (A-2) and a nitrogen-containing polycyclic aromatic compound (N-PAC) fraction (A-3) using modified procedures from Later et al. (14). Extensive characterization was done by West et al. (15).

Organisms

Female CD-1 mice (60-80 days old) and timed-pregnant animals of the same age were obtained from Charles River Breeding Laboratories. Rainbow trout (*Salmo gairdneri*) were obtained from Spring Lake Fish Hatchery, Payson, Utah. Cutthroat embryos (*Salmo clarki*) were obtained from Bicknell Fish Hatchery, Bicknell, Utah. Brown bullheads (*Ictalurus nebulosis*) were obtained from Peterson's Trout Farm, Peterson, Minnesota. *Daphnia magna* came from a culture at Brigham Young University.

Toxicity and Reproductive Effects on Mice

Female CD-1 mice were dosed with solutions of SRC-II HD in corn oil. The maximum tolerable dose (MTD) was defined as the lowest concentration which caused some degree of toxicity. The final determination of the MTD was based on gross mortality, general visceral damage, and liver/body weight ratios. Animals were randomly assigned to individual cages on day 1 of dosing. There were 4 treatment groups (250, 500, 1000, and 2000 mg/kg) and one control with 10 mice per group, for a total of 50 mice. Stock solutions in corn oil were based on the average weight per mouse on the day prior to the initial dose. Treatments were administered orally by gavage in 0.25 mL quantities. The mice were dosed for eight consecutive days, then allowed a six-day recovery period before being sacrificed and necropsied. Individual body weights were recorded on days 1, 4, and 8 of dosing, and 4 and 6 days after the final dose. Liver and intestinal weights were recorded for those animals surviving the entire 14-day experimental period. Using the MTD value (750 mg/kg), timed-pregnant mice were treated orally by gavage for 8 consecutive days beginning on day 7 of gestation (day 1 was considered the first day that a sperm plug was observed). The stock concentration was based on the average day 6 dam

weight. There were 20 animals in the treatment group and 20 in the control (corn oil only). Dam weights were recorded on days 7 and 18 of gestation, and day 3 postpartum. Those animals failing to deliver were weighed on day 23 of gestation. Pup weights and litter sizes were recorded on day 1 (12 to 24 hours after delivery) and on day 3 (48 hours after day 1) postpartum. All mice were sacrificed by cervical dislocation and the uteri were removed and immersed in a 10% sodium sulfide solution to determine the number of implantations per dam. For electron microscopy, six mice, independent of the above studies, were treated with the SRC-II HD. Two animals were treated in each of three groups (control, 1000, and 2000 mg/kg) according to the same protocol used in the MTD portion. The mice were sacrificed by cervical dislocation and samples of liver tissue were processed for electron microscopy using procedures described by Gardner et al. (16), except that the tissue was fixed in 3% gluteraldehyde in 0.2M phosphate buffer (pH 7.2-7.4). In addition, four liver samples were taken from dams surviving the reproductive portion (1 control and 3 treated mice) and processed in the same fashion.

Toxicity and Cellular Effects on Aquatic Organisms

Cutthroat embryos (17 hours old) were subjected to the SRC-II HD at concentrations of 0, 6.25, 12.5, 25, 50, and 100 ppb using a circular flow-through mini-diluter. By day 12, all embryos had hatched. Sac-fry from each tank were then culled until 15 remained in each of 24 tanks (4 replications of each of the 6 treatments). The lengths of the trout were measured weekly using a photographic method. At various points throughout the test, fish from various concentrations were sacrificed in formaldehyde, weighed, and photographed to record morphological anomalies. At the end of the study, toxicity, length, and weight data were tallied, summarized, and analyzed. The flow-through study took 45 days (12 pre-hatch and 33 post-hatch).

For the brown bullhead catfish SRC-II HD bioconcentration studies, a set of 22 one-gallon glass jars were cleaned and filled with 3.8 L of fresh spring water. Two jars were assigned to each sampling period; the sampling periods were 1, 5, 24, and every 24 hours thereafter up to 216 hours. Appropriate quantities of the ^{3}H-HD acetone solution were added to each jar to give concentrations which were about 10% of the LC50 (the LC50 for brown bullheads was roughly 1.56 ppm with a 95% confidence interval of 1.12-2.08 ppm). Technical acetone was added to give a concentration of 0.5%. At time 0, each jar was sampled to determine the total radioactivity, which was found to be 0.112 ppm ± 5%. Two fish (average weight each = 3g) were then placed into each of the jars and the accumulation phase begun. At 96 hours, the remaining fish were transferred to clean jars with fresh water (containing 0.5% acetone) for the elimination phase. At each sampling period, the fish were rinsed with water and immediately frozen. For analysis, each fish head, tail, and fin was removed and the viscera and gills separated from the edible tissue. The viscera, gills, and edible tissue were then weighed, combusted, and analyzed for ^{3}H-HD by liquid scintillation methods.

The static toxicity of the A-2 and A-3 fractions from the extract of the Black River sediment was evaluated using daphnids and brown bullhead catfish. Ten daphnids, no more than 36 hours old, were placed into replicated (3X) 200 mL of spring water in various concentrations of A-2 and A-3. Controls were run with each sample. Forty-eight hours after the commencement of the test, the number of living daphnids was determined. The results were analyzed using probit analysis employing an SAS program. Brown bullheads (2 per 2.0 L of spring water) were also evaluated for sensitivity to A-2 and A-3 fractions in the static systems for 96 hours. These data also were subjected to probit analysis.

The pathological effects of the crude SRC-II HD extract and the A-2 and A-3 fractions from the Black River sediment extract were evaluated at the cellular and ultrastructural level. Basically, the liver and gill-bars were selected for light and electron microscopy following 12-18 hour in vivo exposures of brown bullheads and rainbow trout. These two tissue-types were processed as soon as possible using standard electron microscope techniques described in the mammalian section.

RESULTS AND DISCUSSION

Mouse Toxicity

Individual weights recorded over the treatment and recovery periods failed to indicate toxicity in any form of a dose-response. In fact, the day 4 weights of the 500 and 1000 mg/kg groups showed significant weight gains over controls; however, this trend was not consistent in subsequent weighings (data not shown). Two mice died in the 2000 mg/kg group, presumably due to treatment, and one mouse

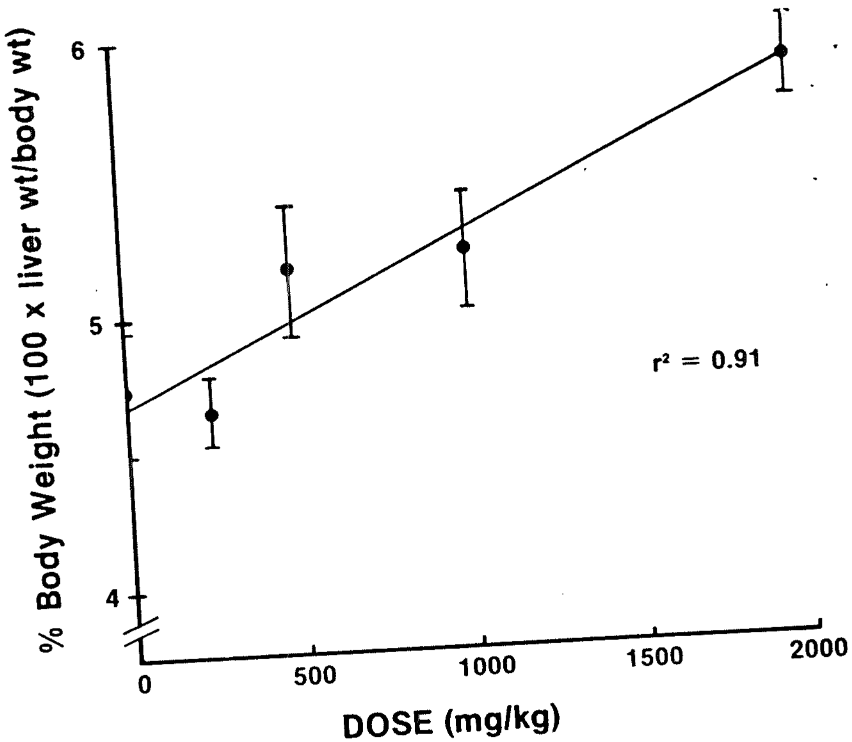

FIGURE 1. Plot of mouse liver weight to body weight ratio against increasing doses of the SRC-II HD.

was inadvertently killed by esophageal puncture in the 1000 mg/kg group. Necropsis of the three dead animals revealed severe intestinal damage and darkened portions of the liver. The data summarized in Table 1 show the general increase in liver and intestinal weights as a response to increasing dose. Comparison of the relative percentage body weight of the livers shows a significant increase in size from the 500 to 2000 mg/kg groups (Figure 1). Intestinal weights followed a trend similar to liver weights, except that the increased intestinal weight of the 500 and 1000 mg/kg groups was not significant compared with the control weight gains. The electron micrographs (EM) in Figure 2 show a striking difference between treatment and control livers. Liver cells of the heavy distillate-treated non-pregnant mice (Figure 2, B & C) contained noticeably larger quantities of agranular

FIGURE 2. (A) Control mouse liver; (B) and (C) non-pregnant mouse liver treated with 2,000 mg/kg SRC-II HD. B, bile canaliculi; CM, cytoplasmic membrane; M, mitochondria; N, nucleus; RV, ribosome-surrounded vacuole; RER, rough endoplasmic reticulum; SER, smooth endoplasmic reticulum. (X17,250).

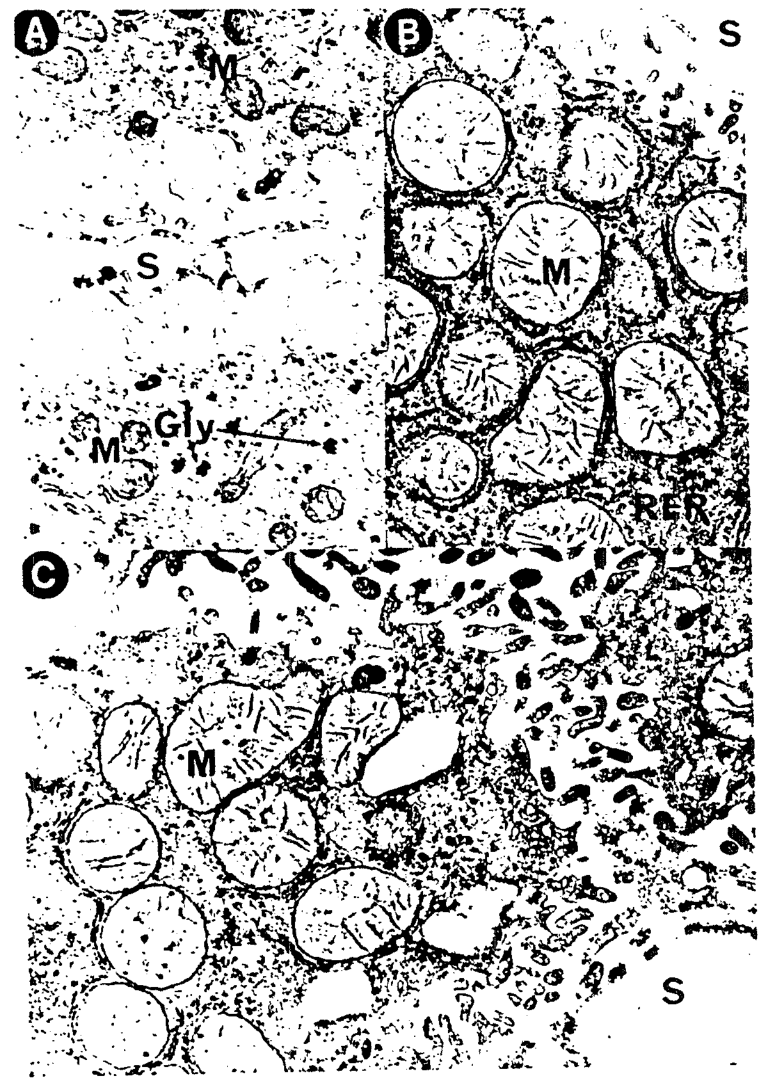

FIGURE 3. (A) Control pregnant mouse liver; (B) and (C) pregnant mouse liver treated with 750 mg/kg SRC-II HD. Gly, glycogen; M, mitochondria, RER, rough endoplasmic reticulum; S, sinusoid. (X17,250).

TABLE 1

RELATIVE LIVER AND INTESTINE WEIGHTS OF NON-PREGNANT MICE

Compound	Dose (mg/kg)	Body Wt[a] (g)	Liver Wt[b] (g)	Intestine Wt[b] (g)	Relative % Organ Wt[c] (Liver)	(Intestine)
Control		26.93 ± .36	1.27 ± .05	2.88 ± .10	4.72	10.7
SRC-II	250	27.46 ± .41	1.27 ± .03	3.02 ± .10	4.62	11.0
	500	28.04 ± .68	1.45 ± .07[d]	3.37 ± .12[d]	5.17[d]	12.0
	1000	26.70 ± .48	1.39 ± .03	3.15 ± .19	5.21[d]	11.8
	2000	28.23 ± .69	1.66 ± .04[e]	3.83 ± .19[e]	5.88[e]	13.6[e]

[a] Final weight on day 14 ± SE.

[b] Organ weight on day 14 ± SE.

[c] (Organ weight/Body weight) x 100.

[d] $p < 0.05$.

[e] $p < 0.005$.

TABLE 2

PREGNANCY AND RESORPTION INDICES OF CONTROL AND TREATED MICE

Compound	Total Pregnant[a]	Number Litters	Pregnancy Index[b]	Total Implants	Total Pups Delivered	Resorption Index[c]
Corn Oil (control)	18	17	0.944	201	175	0.129
SRC-II (750 mg/kg)	15	6[d]	0.400[d]	166	41[d]	0.753[d]

[a] Total pregnant verified by sodium sulfide treatment.

[b] Number Litters/Total Pregnant.

[c] (Total Implants - Total Pups Delivered)/Total Implants.

[d] $p < 0.005$.

EFFECTS OF COAL-DERIVED TARS

endoplasmic reticulum (ER), greatly enlarged mitochondria, and the cytoplasm appeared less continuous when compared with controls. Also, treated liver cells frequently had irregularly shaped ribosome-surrounded vacuoles. Nuclear and cytoplasmic membranes appeared normal for treatment and control groups; some disruption was observed in the mitochondrial membranes at the highest concentrations. Comparison of the EM in Figure 3 shows an even more dramatic increase in mitochondrial size of the pregnant 750 mg/kg treated liver cells over the controls. A is the control; B and C are the typical pregnant treated group response. These results suggest that the SRC-II HD is an alimentary irritant which induces hypertrophy of liver tissue. Liver/body weight increases have been reported as a characteristic response to a number of xenobiotic compounds (17-20), but mitochondria are also known to undergo alteration in shape in response to physiological conditions and during various energy phases (21-23).

Mouse Reproductive Study

The data from the reproductive study (Table 2) shows a significant decrease in the number of viable litters delivered by the SRC-II treated dams. The number of implantations were statistically the same for treatment and control groups, but the number of pups delivered was reduced in the treatment groups. Also, the average litter weight of the treatment group was reduced. Pups in both groups gained weight equally during the first three days.

Vaginal bleeding was detected in 50% of the treated mice as early as the second day of dosing and periodically throughout gestation. Of those found bleeding, only three delivered, and only one litter was in the normal size range of the controls Parturition of the litters from the treated mice group was ‿elayed 12 to 24 hours compared with the controls. This study indicates that the SRC-II HD reduces fecundity and pup weight, and increases the number of dams with complete litter resorptions.

Cutthroat Trout Embryos - Larval Bioassay

Using concentrations of 0, 6.3, 12.5, 25.0, 50.0, and 100 ppb, the fish successfully hatched; but distinct abnormalities were present. The fins of the larvae became eroded, and vascularization of the yolk sac was lacking. At the end of 30 days post-hatch, following continuous exposure to the SRC-II HD, the fish were weighed and measured. A dose

AFT's don't agree but I do - do you?

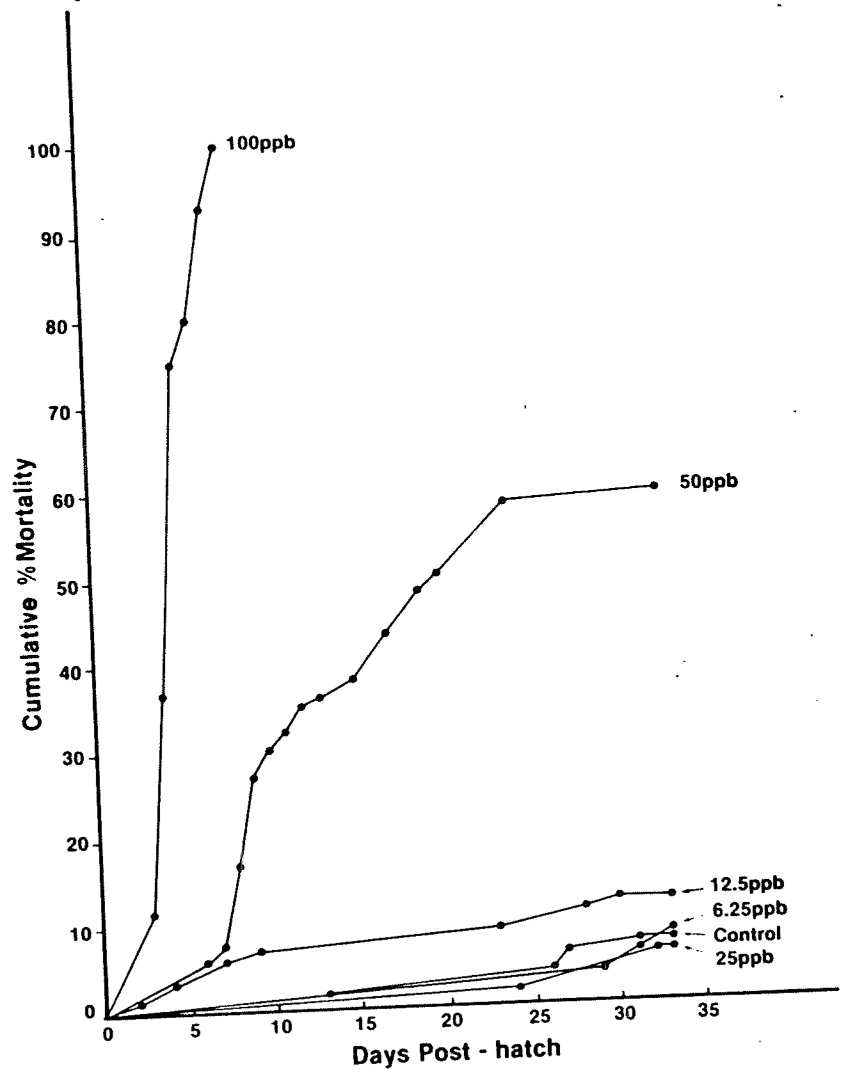

FIGURE 4. Plot of cumulative % mortality of cutthroat juveniles against days post-hatch during exposure to the SRC-II HD.

response was generally noted. The fish which were exposed to higher concentrations were lighter, smaller, and had extensive erosion of the fins. All fish at the 100 ppb concentration had died (Figure 4).

Aquatic Organism Toxicity

Figure 5 (A and B) shows some EM of trout livers exposed to approximately 10 ppm of the A-3 and A-2 fractions (weighed as tars), respectively, of the extracted river sediment. Figure 5B clearly shows an intense accumulation of A-2 material throughout the cell, but no apparent accumulation from the A-3 treatment (Figure 5A). Figures 5 (C, D, gill) and 6 (A, B, liver) are brown bullhead gill and liver EM showing the effects of a 16 hour treatment with 1.0 ppm SRC-II HD. In the treated gill tissue (Figure 5C) the cristae are swollen with some enlargement of the mitochondria concurrent with general disruption of the endoplasmic reticulum (ER) compared with the control gill EM (Figure 5D). Liver tissue in treated bullhead experiments (1.0 ppm) shows extensive swelling of the mitochondria with disruption of the cristae. Also note the considerable disruption of the ER and a general dispersion of glycogen (Figure 6B). Compare this figure with the untreated liver tissue in Figure 6A. In general, the SRC-II HD elicits the same mitochondrial response in both mice and brown bullhead catfish, i.e. swollen mitochondria and cristae disruption. Liver and gill tissue (not shown) also had peculiar characteristics under examination by light microscopy. Gill filaments developed hyperplasia and became clubbed. The liver tissues developed pycnotic nuclei, disruption of normal hepatic structure, vascular proliferation, and the appearance of lipid accumulation. Many authors have shown similar hepatic and gill pathology (24-28).

The daphnia LC50's were determined for the A-2 (PAH/PASH) and the A-3 (PANH) fractions for the SRC-II HD and the extracted river sediment. They were: HD A-2, 0.211 ppm; HD A-3, 0.356; river sediment A-2, 0.0167; and river sediment A-3, 0.353. The river sediment A-2 fraction appears to be more toxic than the SRC-II HD to Daphnia magna, while the toxicity of the A-3 fraction was about the same for both extracts.

The LC50's for brown bullheads using the fractions for the HD and the river sediment were: HD crude 1.56 ppm; A-2 HD, 0.75; A-3 HD, 0.75; river sediment A-2, 72.5 ppm, and river sediment A-3, 53.0 ppm. The LC50 for the HD crude

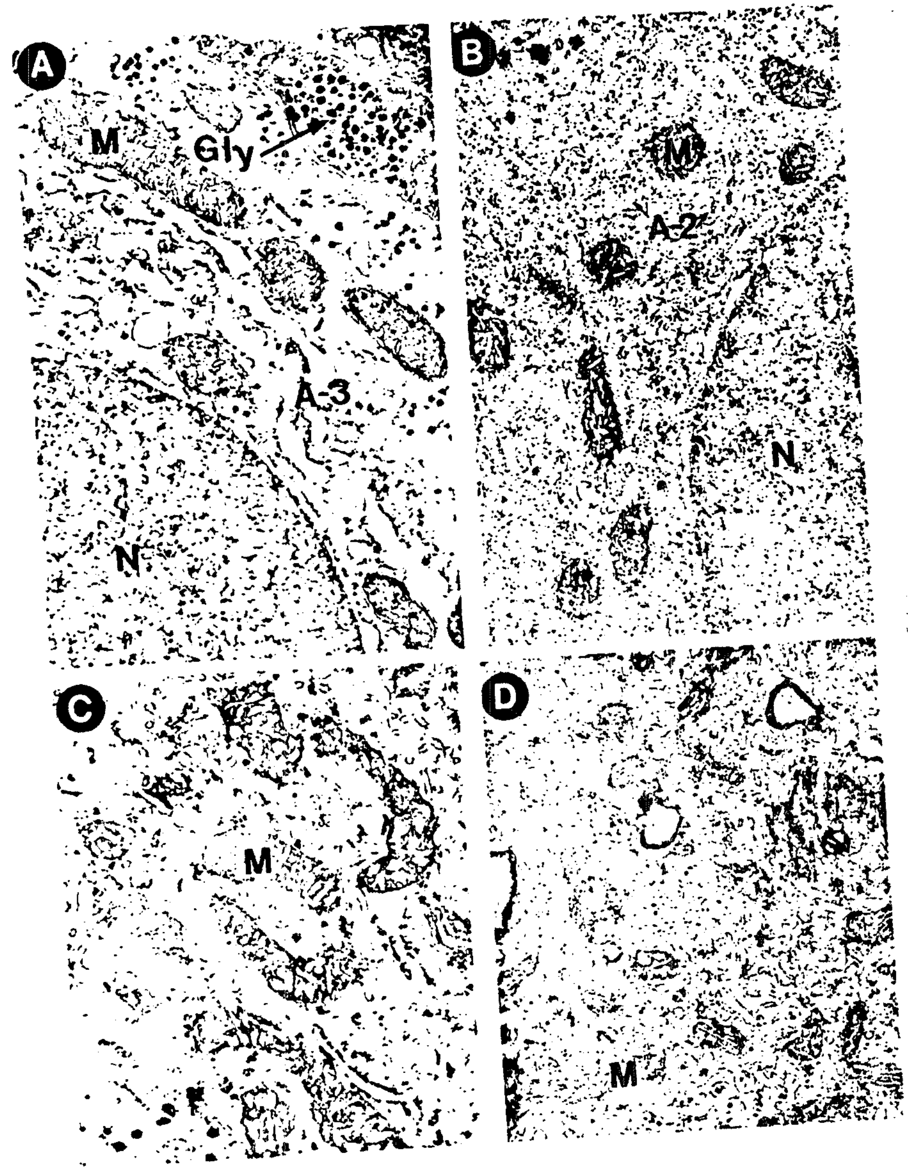

FIGURE 5. (A) Trout liver exposed to 10 ppm river sediment A-3 fraction for 16 hrs; (B) trout liver exposed to 10 ppm river sediment A-2 fraction for 16 hrs; (C) bullhead gill exposed to 1.0 ppm SRC-II HD for 18 hrs; (D) bullhead gill control exposed 18 hrs. N, nucleus; M, mitochondria; Gly, glycogen. (X22,800).

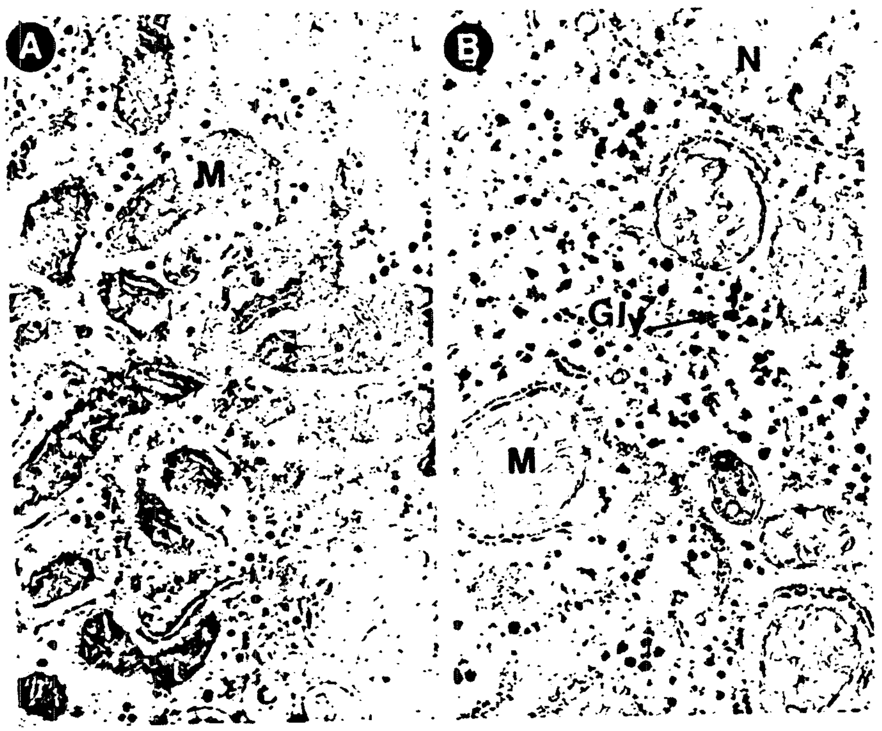

FIGURE 6. (A) Bullhead liver control exposed 18 hrs; (B) bullhead liver exposed to 1.0 ppm SRC-II HD 18 hrs. N, nucleus; M, mitochondria; Gly, glycogen. (X22,800).

corresponds closely with data reported for Ictalalurus punctatus (5). The river sediment appears to be less toxic than the HD to brown bullheads.

Figure 7 (hour 216 not shown) shows the accumulation-elimination curves for the brown bullhead viscera and gills, the edible tissue, and the total tissue. Viscera accumulation levels increased rapidly to 78 ppm at 48 hours and then dropped off rapidly to 32 ppm at 96 hours. The elimination curve dropped to 15 ppm at 114 hours, rose to 20 ppm at 168 hours, then leveled off at 14 ppm at 192 and 216 hours. The $t_{\frac{1}{2}}$ in the viscera was about 48 hours. During the accumulation phase, the edible tissue rose to 5.8 ppm at 24 hours and then generally dropped to 0.8 ppm at 96 hours. The elimination curve oscillated over time with an average of

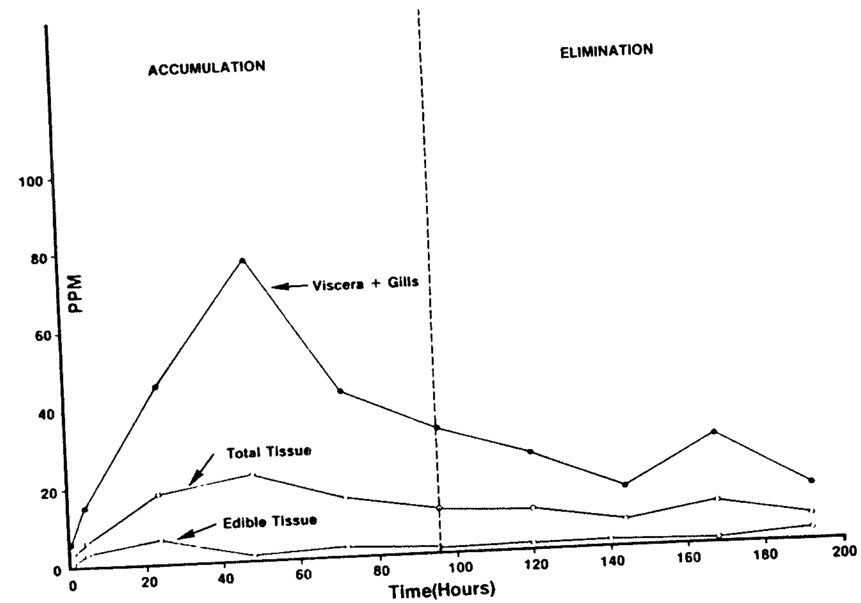

FIGURE 7. Accumulation and elimination of ^{3}H-HD by brown bullhead catfish.

1.19 ppm ± 0.6. An elimination half-life was not calculated for the edible tissue since the residues did not clearly drop through time. Also shown in Figure 7 is a plot of the total residues (viscera and gills, and edible tissue). These data show a peak level of 22 ppm at 48 hours and dropping to 11 ppm at 96 hours. A peak bioconcentration factor level for the total tissue was 280.

CONCLUSIONS

The mammalian work shows that coal-derived tars are irritants to the alimentary tract and cause liver-mitochondrial hypertrophy. Gravid females show more severe hepatocellular responses than non-gravid females. Fertility and litter weights are decreased. Aquatic results show that growth of cutthroat trout embryos growth will be stunted with definite abnormalities at low concentrations. The SRC-II HD produces similar liver pathology in *Ictalurus nebulosus* and in the mouse. Also, the bullhead gill shows pathological response to the SRC-II HD. The A-2 fraction of the river sediment accumulates throughout the trout liver, while the A-3 fraction is not apparent in the tissue. It may be that the lipophilicity of the A-2 fraction contributes to its accumulation in the liver.

ACKNOWLEDGMENTS

This work was supported through a cooperative agreement with the Columbia National Fisheries Research Laboratory, Columbia, MO, and the Biomedical Sciences Program from the University of Illinois. We thank Dr. R. Gray of Battelle Pacific Northwest Laboratories for providing the SRC-II HD, and Larry Ludke, Paul Merhle, and Paul Bauman from the Columbia National Fisheries Research Laboratory for providing the sediment and for helpful discussions.

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HARTCROWSER

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J-1747-49

September 17, 1990

Mr. David Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Re: Comments on Proposed Amendments to the Model Toxics Control Act Cleanup Regulation; Chapter 174-340 WAC

Dear Mr. Bradley:

Hart Crowser, Inc., has reviewed the proposed amendments to the Model Toxics Control Act (MTCA) Cleanup Regulation, particularly those sections which define the requirements for establishing cleanup standards. We have also applied the proposed standards to several hazardous waste sites in Washington in an effort to evaluate the workability of the proposed amendments. The following represents the opinions of Hart Crowser.

Overall, we feel the proposed amendments are a positive step towards the identification and selection of appropriate remedial actions at hazardous waste sites. The proposed regulations appear to be consistent with similar programs underway at the federal level, and this consistency will provide for a minimum of confusion at sites where both state and federal involvement occurs. The generally clear application of risk assessment methodology in the proposed cleanup standards also provides an easily understandable technical foundation upon which to base future cleanup actions.

We have, however, identified a number of weaknesses and inconsistencies in the proposed regulations. Our specific comments are provided below.

1. Although most of the exposure assumptions used to derive the cleanup standards are consistent with current scientific information, the data upon which the exposure assumptions are based is evolving rapidly. It is therefore likely that in a period of a few years, at least some of the exposure assumptions defined by the proposed regulation (e.g., soil ingestion and dermal absorption rates) may soon be outdated, and likely modified for the federal Superfund program. In this situation, significant inconsistencies between various programs is possible, and the technical foundation upon which the MTCA cleanup standards are based will erode.

   Though the proposed regulations make some provision for changes in technical data such as toxicologic information, these provisions are not, in our opinion, sufficient to allow the necessary program flexibility. We recommend that the proposed amendments include a requirement that Ecology, in cooperation with the Department of Health, EPA, the scientific community, and the community at large, **annually** provide an update (with public review) of exposure assumptions and available toxicologic data which will form the basis for the cleanup standards.

2. You are undoubtedly aware that cleanup standards computed using Method B equations are often considerably different from the tabulated Method A values, particularly for soil media. Several comments pertain to this condition. First, Ecology should explain the rationale for selecting the Method A values, so that this rationale may be applied on a site specific basis (see comment #3 below regarding lead cleanup standards). Second, it is not clear from the proposed regulation whether Method A and Method B values can be "mixed and matched" for various chemicals present within a given media. Clearly, Ecology's judgement has entered into the selection of Method A values, but is this judgement also applicable to Method B? We believe that it is Ecology's intent that this judgement **is** applicable, but it is currently not sufficiently evident in the regulation. We recommend that a clear statement clarifying the use of and relationship between Method A and Method B values be inserted in the cleanup standards portions of the regulations (e.g., in 173-340-740.3).

3. Lead is likely among the primary contaminants present at hazardous waste sites in Washington state, and most of the potential exposure associated with this metal appears from our experience to be related to soil accumulations. However, as you are certainly aware, a relative paucity of toxicologic data currently exists to develop risk-based cleanup standards for lead. Verified chronic reference doses or cancer potency slopes for lead are not currently available from EPA, and development of such values is apparently not planned for the near future.

   Numeric standards for lead in air and water media are available from EPA, and can thus form the basis for the cleanup regulation, but similar data do not exist for soil media. All that is apparently available is the Centers for Disease Control report (cited in the Cleanup Standards Draft EIS) which correlated increased childhood blood lead levels in residential areas with a threshold soil concentration range of approximately 500 to 1,000 mg/kg. Has Ecology used these data to "back-calculate" a reference dose? We believe that it is critical that Ecology provide the **technical** rationale which formed the basis for selection of the 250 mg/kg and 1,000 mg/kg Method A soil lead standards for residential and industrial areas, respectively. Without such a technical rationale, there appears to be no verified basis to develop risk-based (Method B) levels for soils.

4. After lead, polycyclic aromatic hydrocarbons (PAHs) are probably among the most widespread contaminant group, again largely present in site soils. The proposed cleanup regulation addresses carcinogenic risks posed by PAHs by summing all seven PAHs currently identified by EPA as potential (B2) carcinogens. However, while this approach is consistent with previous EPA procedures for assessing PAH risks, the current approach, as defined by upcoming drinking water advisories and regulations, is to utilize toxicity equivalence factors (TEFs). The TEF methodology is much more consistent with current scientific consensus regarding the carcinogenicity of PAH mixtures, as compared with the proposed MTCA regulation, and has been adopted by other states (e.g., Oregon).

   We recommend that Ecology include in the cleanup standard regulation an approved methodology for developing PAH cleanup standards based on the

TEF approach. The methodology may even consider analysis of all PAHs known to be potential carcinogens but not currently on EPA's priority pollutant list (e.g., anthanthrene). Routine analytical techniques are becoming available to analyze for a large number of PAH compounds.

5. Although the proposed standards make an important distinction between residential and industrial land uses for the soil cleanup standards, many land uses do not fall into these two categories. We believe that distinctly different types of exposure assumptions apply to other land use types (e.g. limited duration exposure in open space land uses) which result in different lifetime risks. Recognizing the complexity of addressing a variety of land uses, we recommend the addition of a section which specifically addresses open space and commercial land use types.

6. Assuming that the overall intent of groundwater standards under WAC 173-340-720 of MTCA and WAC 173-200 (Water Quality Standards for Groundwaters of the State of Washington) is similar, we recommend Ecology address the differences between these two proposed sets of standards. Although different standards may apply to different sites, we envision numerous difficulties arising from the application of two different sets of groundwater quality standards to groundwaters of the State of Washington. Furthermore, federal drinking water standards for maximum contaminant levels under 40 CFR also differ for several constituents. We feel that a consensus should be reached within the agency on a groundwater concentration adequately protective of human health and the environment on a compound-by-compound basis. If no consensus can be reached due to different objectives, we recommend clarification of site specific application.

7. In the proposed regulation, Ecology has made a distinction between the majority of groundwaters of the state and those which produce less than 0.5 gpm or have high salinity (greater than 10,000 mg/L). A distinction should also be made for groundwaters that are seasonal, isolated, or of poor natural quality. This should be consistent with the proposed groundwater quality standards (e.g. TDS levels of 500 ppm) and is especially important for groundwater in selected industrial areas.

8. It is extremely difficult in many shallow Puget Sound aquifers comprised of silt and sand to construct a well that is sediment free. Our concern in such aquifers is that concentrations of metals, for example, are often erroneously elevated due to the detection of sediment associated metals. We recommend that Ecology include in the regulations an allowance for filtering metal samples under such conditions. In addition, in sediment-laden groundwater samples, compounds such as PAHs are often not detectable at concentrations which MTCA has indicated to be detection limits. Thus, we recommend the inclusion of specific language to address this commonly occurring situation.

Thank you for this opportunity to comment on the proposed MTCA regulations.

Sincerely,

HART CROWSER, INC.

CLAYTON R. PATMONT
Manager, Environmental Services Division

M. MARIAN WINEMAN
Senior Project Engineer/Toxicologist

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KRISTINE GEBBIE
Secretary

90-370

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August 15, 1990

TO: David Bradley, DOE Toxics Cleanup Program

FROM: Don Peterson, DOH Division of Radiation Protection

SUBJECT: Comments on Phase II amendments to Chapter 173-340 WAC

We have reviewed the phase II amendments of WAC 173-340 and have the following comments:

-710(3): The ARAR "relevant and appropriate requirements" should be broader, i.e. it should include such things as federal guidance and health advisories. These are not law, but are often the best you have to go with in setting requirements.

-Table 1: These numbers come from drinking water standards. The following changes should be made: (1) the gross alpha particle activity should exclude uranium; (2) gross beta activity should include photon (gamma) activity. This makes it equivalent to the Board of Health radionuclide primary standards for radionuclides contained in WAC 248-54.

-720 through 750: Under the subsections on Method A the wording for ARARs are laws "including the following requirements". Is this an exhaustive list? It should not be and the wording should make that clear. It is recommended that the wording be: "including, but not limited to, the following requirements".

-Method A subsections for soil and air cleanup standards don't list specific ARARs. For air the various NESHAPs promulgated under the Clean Air Act should be listed. The radionuclide NESHAP is contained in WAC 173-480.

Thank you for this opportunity to comment on these proposed regulations.

DP/sag
cc: Bob Mooney
F1.-17

Natural Resources Defense Council

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STATEMENT OF

DAN W. REICHER, ESQ.

AND

JAMES D. WERNER

ON BEHALF OF

THE NATURAL RESOURCES DEFENSE COUNCIL

BEFORE

THE HOUSE ARMED SERVICES COMMITTEE
SUBCOMMITTEE ON PROCUREMENT AND MILITARY NUCLEAR SYSTEMS

REGARDING

THE PROCESS USED BY THE DEPARTMENT OF ENERGY
TO SET PRIORITIES FOR RESOLVING ENVIRONMENTAL
PROBLEMS AT ITS NUCLEAR WEAPONS FACILITIES.

FEBRUARY 24, 1989

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NRDC is a national environmental organization with over 100,000 members and contributors and a staff of over 120 lawyers, scientists, resource specialists and support personnel at offices in New York, Washington, and San Francisco. NRDC pursues a broad range of environmental, energy, and defense issues. The organization has long been concerned about safety and environmental problems at Department of Energy (DOE) nuclear facilities. Over the past twelve years, the NRDC Nuclear Project has won a series of lawsuits to enforce federal environmental laws at DOE facilities including Hanford, Washington; Oak Ridge, Tennessee; and the Savannah River Plant, South Carolina.

We are pleased to have this opportunity to present our views to the Subcommittee on the process used by the Department of Energy (DOE) to set priorities for resolving environmental problems at its nuclear weapons facilities.

SUMMARY

We are reporting today our preliminary analysis of the process used by the Department of Energy (DOE) to set priorities for resolving environmental problems at its nuclear weapons facilities. DOE uses a model called the Multimedia Environmental Pollutant Assessment System (MEPAS) in setting cleanup and budget priorities. The results of MEPAS are the basis for the DOE's prioritization report, released in December, 1988, which ranks the severity of the health and environmental threats at the

Finally, to address the larger concerns about DOE's management of its environmental problems, the Committee should report out favorably H.R. 765, recently introduced by Representative Dingell (D-MI). The bill would establish a special temporary Commission to review and make recommendations about contamination and cleanup of DOE facilities. If created the Commission could, among other things, review MEPAS as recommended above.

A. Background on MEPAS and POS

The Multimedia Environmental Pollutant Assessment System (MEPAS) model was developed to rank environmental problems at DOE facilities in terms of their severity. MEPAS was developed as a part of the Environmental Survey program, which was one of a number of environmental initiatives announced in September 1985, by then Secretary of Energy Herrington.[1] MEPAS was the basis for DOE's September, 1988 Environmental Survey Preliminary Summary

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[1] A second component of the Survey program was field audits of nearly 40 DOE facilities across the country, which resulted in a series of "Preliminary Reports" reviewing environmental problems at each facility. The field surveys cost approximately $6 million and involved four teams with 7 technical specialists each. The third component of the Survey program was sampling and analysis of soil, wastes and water at several DOE facilities visited by the Survey. This component involved dozens of technical specialists from the DOE laboratories and cost approximately $45 million.

objectives. DOE used the results from POS in developing its FY90 budget request[5].

Although POS is structurally very different from MEPAS[6], it relies almost exclusively on the MEPAS model for its input on the relative environmental threat posed by existing problems. In fact, the weighting factor assigned in the POS system to "health and safety" was 94 percent. The other two factors considered in POS -- regulatory responsiveness, and public, State and community concern -- were assigned weighting factors of only five percent and one percent, respectively.[7]

B. Problems with MEPAS

Outlined below are some of the technical and policy problems we have identified with the MEPAS model.

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[5] "Priority System for Department of Energy Defense Complex Environmental Restoration Program, A Report Prepared for the House Armed Service Committee," U.S. Department of Energy (August 1988), at page 17.

[6] POS differs significantly from the MEPAS model in that it considers other factors in addition to environmental and public health risks. POS also takes into account the need to comply with regulatory and legal requirements, program costs, and public, State and community concerns.

[7] Merkhofer, L. and K. Jenni, A Program Optimization System for Aiding Defense Programs Environmental Restoration Decisions. Applications to FY90 Budgeting: Final Report, Prepared for the DOE Defense Programs Office, Hazardous Waste and Remedial Actions Division, Washington, DC. (August 8, 1988) at page 34.

determining overall population risks. Using this information a decisionmaker can identify immediate responses to protect individuals at greatest risk as well as long-term needs to reduce risks to overall populations.

MEPAS, however, is incapable of calculating MEI risks. Because MEPAS calculates risk only in 70-year increments it cannot identify more specific risks. A report prepared for EPA criticized the absence of the MEI component: "the absence of exposure and risk estimates to the most exposed individual ... could cause [the model] to underestimate the hazard of a site where risk to the MEI is large but risk to the total population is small."[9] This is a serious defect in a model intended to aid in decisionmaking.

3. MEPAS Uses an Inappropriate Combination of Carcinogenic and Non-Carcinogenic Effects

Another technical problem with the MEPAS model involves its mixing of carcinogenic and non-carcinogenic effects. The scientific literature in toxicology generally concludes that there is a threshold below which non-carcinogens do not have a toxic effect, but that no such threshold for carcinogens appears to exist. For example, iodine in low doses, such as is present in table salt, is considered to be an essential nutrient, but at

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[9] Industrial Economics Corporation (IEC), Analysis of Alternatives to the Superfund Hazard Ranking System Prepared for the EPA Office of Policy Analysis/Office of Policy Planning and Evaluation, Washington, D.C. (November 1988), at D-10.

million]; this is strictly a policy judgement."[11] This hidden policy judgement, contrasts sharply with DOE's own description of MEPAS as, "an objective, scientifically-based computer ranking system." [12]

4. MEPAS Fails to Consider Multiple Contaminants

Another serious problem with the MEPAS model is its failure to account for the additive effects of multiple contaminants at a site. The standard risk assessment methodology[13] is to add the effects of all of the non-carcinogenic contaminants at a site. For example, the potential effects of iodine are added to effects of cadmium and ammonia. Instead of adopting this standard practice, MEPAS multiplies the Risk Factor (see Section B.3. above) by the exposed population (and an exponential weighting factor) to arrive at a preliminary hazard index (PI) for each contaminant. Then MEPAS takes the highest single contaminant PI as the basis for the Hazard Potential Index (HPI), which is the final score used for ranking. Hence, in a situation where there are three contaminants at a site -- two with PI scores of 0.5 and one with a PI of 0.6 -- MEPAS would not add them to get a score of 1.6 but instead would

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[11] IEC at D-10.

[12] DOE Preliminary Summary Report, September 1988, at 1-5

[13] See e.g., Environmental Protection Agency, Office of Emergency and Remedial Response, Public Health Evaluation Manual, (October 1986).

Because the data requirements of the MEPAS model far exceed the level of data generally available, a large number of assumptions have to be made for its operation. In making these assumptions, DOE has relied primarily on generalized, inaccurate and/or subjective sources of information. In fact, 104 out of 138 sites ranked in DOE's Preliminary Summary Report relied on a "moderate" or "significant amount of assumptions" for "critical data." Only 34 of the sites used "monitored or measured" data.[15] For example, the amount of waste buried in landfills for which no records were kept was often established by assuming recent disposal rates. However, in many instances, historical rates of disposal were far higher than present rates. Furthermore, many of the numbers used in the model relied on no data whatsoever and were developed based only on the speculation of the Survey team members in sessions eerily called "Prioritization Decision Meetings". Additionally, in many situations generalized numbers known as "default" values, were incorporated into the model to be used whenever a site specific number was not available. <u>The essential point is that the final prioritization ranking on which the September Preliminary Summary Report was based suggests an aura of objectivity that is simply not warranted by the process used to develop the scores</u>.

In the Preliminary Summary Report, DOE suggested that its Sampling and Analysis program would help to fill these data

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15 DOE Preliminary Summary Report, at 2-17, 2-20, and 2-26.

6. MEPAS is Too Complex

MEPAS is an extremely complex model. It was developed on a large, sophisticated main-frame (Digital Equipment Corporation VAX) computer. It requires hundreds of potential inputs for each environmental problem. If an error occurs during input, it is extremely difficult to track down. Some calculations in MEPAS require so much computer time during implementation that they are left overnight to process.

In contrast, the HRS model used in the Superfund Program is much easier to apply than MEPAS. It can be used quite simply by filling out a series of forms with a hand-held calculator.[20] Of course, being complicated and sophisticated is not necessarily undesirable, but in the case of a model intended to be operated on a minimal amount of input, and applied to a large number of sites, it is simply inappropriate.

7. Priorities Set By MEPAS May Conflict with Legal Obligations

A fundamental question which DOE has not squarely addressed is how the priorities set by MEPAS will be reconciled with what may be very different priorities set by state and federal regulatory agencies and courts under RCRA and CERCLA. RCRA section 3004(u) gives EPA and certain states authority to

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20 U.S. EPA, Uncontrolled Hazardous Waste Site Ranking System A Users Manual, (1984) at HW-10.

1988. DOE's failure to acknowledge clearly the essential link between the two models is especially troubling in light of the serious flaws we have identified with MEPAS.

9. MEPAS Has Never Been Subject to Formal Public Comment

DOE might have avoided many of the problems with MEPAS had it solicited public comment on the model as well as its results. Unfortunately, the same closed-door mentality that has characterized DOE's operations for years prevailed in the case of MEPAS. There was not a single opportunity for interested agencies, private organizations or citizens to comment on this multi-million dollar ranking model and its critical results.

In contrast, EPA published the entire Hazard Ranking System in the Federal Register and solicited public comment.[22] EPA also routinely publishes for comment its proposed National Priority List sites, which are the product of HRS.

The Department of Defense also released for public comment its own priority-setting model called the Defense Priority Model (DPM).[23] EPA, as well as other agencies and individuals filed comments on DPM to which DOD is now responding.[24]

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22 47 Fed. Reg. 10972 (July 16, 1982).

23 52 Fed. Reg. 44202 (November 18, 1987). It should be noted that unlike MEPAS the DOD's Defense Priority Model is used in conjunction with EPA's HRS model.

24 See e.g., Letter from J. Winston Porter, EPA, to William H. Parker III, DOD, August 11, 1988.

asking nothing more of DOE than what DOD and EPA already undergo in their priority-setting systems.

Finally, to address the larger concerns about DOE's management of its environmental problems, the Committee should report out favorably H.R. 765, which was recently introduced by Mr. Dingell (D-MI) with 25 cosponsors. The bill would establish a special temporary Commission to review and make recommendations about contamination and cleanup of DOE facilities. The Commission could, among other things, review MEPAS as recommended above. In fact, one of the Commission's responsibilities under H.R. 765 is to "recommend a process for setting National priorities for environmental remediation activities".[25]

CONCLUSION

There are serious flaws with DOE's process for establishing environmental cleanup priorities at its nuclear weapons facilities. These problems demand careful analysis in an open, public process if meaningful improvements are to be made. We stand ready to assist DOE and Congress with this important task so that cleanup can move forward on a sound footing.

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[25] H.R. 765, Section 3(b)2.

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September 17, 1990

Mr. David Bradley
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Dear Mr. Bradley:

On behalf of our Company, I would like to submit the following comments regarding the proposed MTCA clean up standards. I would also like to take this opportunity to congratulate you on persisting in this difficult process. We believe that there has been substantial improvements made in the regulations since they were first proposed and trust additional changes will be made.

GUIDANCE

We encourage the Department of Ecology to consider developing an appropriate guidance manual or preamble to the regulations which could clarify how the process of establishing a clean up level and selecting a remedy should work. We would be willing to assist in the development of such a document as well as organizing a staff of experienced professionals to assist the Department in this effort. The regulations are complex and we believe that additional clarification on their use is needed.

RISK LEVELS

We believe the range of risk levels proposed (10^{-5} to 10^{-6}) are far too restrictive and will result in disincentives to achieving permanent remedies. The range used by EPA is more appropriate, has precedence in Washington, and will facilitate the remediation of many sites. We believe the proposed 10^{-5} to 10^{-6} levels may result in non-attainable remedies unless off-site disposal is used (i.e. technology is not available to attain the proposed level).

DISCHARGE OF GROUNDWATER TO SURFACE WATER

(WAC 173-340-720(6))

We believe a mixing zone for groundwater with surface water should be allowed. The proposed standard applies chronic water quality criteria at the point the groundwater discharges to the surface water. This results in the absurd situation that an NPDES point source discharge could have higher levels of contaminants than the groundwater discharging to the same surface water body.

Once again we appreciate the opportunity to submit those comments and would be pleased to offer our assistance in developing a guidance document or clarifying preamble.

Best regards,

John R. Ryan

John R. Ryan
Vice President

JRR/pm

PORT of TACOMA U.S.A.

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September 17, 1990

Mr. David Bradley
Toxics Cleanup Program
Department of Ecology
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Olympia, Washington 98504-8711

Dear Mr. Bradley:

The Port of Tacoma has reviewed the proposed amendments to Chapter 173-340 WAC and provides general and specific comments below. The Port of Tacoma is committed to fulfilling our responsibilities relative to the cleanup of Commencement Bay. Our intent is that our comments be useful in helping Ecology develop a workable regulation for the cleanup program. These comments should be considered together with oral testimony provided at the September 6th Seattle public hearing.

We understand that considerable effort and committee input went into the drafting of these regulations. We also understand the consensus is that voluntary cleanups are crucial to the success of this program.

Frankly, the proposed regulation will not only discourage voluntary cleanups, but it is likely many willing parties will be unable to ever conclude a cleanup. Standards are overly conservative, criteria for technical decisions are confusing and arbitrary, choice of reasonable cleanup options is overly restricted, and too frequently the responsible party is required to pursue studies and attempt answers to questions that no one has ever satisfactorily answered. Proceeding through the proposed "how clean is clean" decision process can in itself be extremely costly and time consuming. Hidden costs are the cost of proving and attaining negligible risk levels and the cost of responding to the inevitable challenge that data is inadequate.

Much of the problem is that conservative assumption is piled on top of conservative assumption. For example, risks are arbitrarily considered additive in defining cleanup levels. Thus, requirements compound quickly to a unattainable degree of complexity and stringency--particularly in Commencement Bay where multiple chemical and multiple media contamination is the norm. The regulation needs to provide a basis for stepping back and taking a realistic view of site contamination in context of the surrounding area and the realistic level of exposure and risk. Improvement must be emphasized over perfection.

Specific comments follow.

Time limits and obligations of participating agencies should be generally described to ensure timely and specific agency evaluation and to ensure proper coordination. Many investigations and cleanup actions are seasonally sensitive; minor delays can compound to yearly delays.

Points of Compliance: As written, the regulation penalizes smaller sites, sites where low to moderate exceedances exist, and sites where offsite contamination contributes to or causes contamination. Regulations are too rigid with regard to number of

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samples and percentage of samples for indicating compliance. The general requirement (173-340-700 (11)(b) that the point of compliance be demonstrated "throughout the site" conflicts with more media specific guidance and conflicts with logical monitoring requirements should remediation include containment, isolation, or barriers. The confusion is in part semantic. The regulation speaks to "point of compliance" in the context of "throughout the site".

How will point of compliance be determined in cases of cross media contamination? Concurrent application of specific media point of compliance requirements will be very restrictive.

What happens if a contamination source from neighboring property meets federal program standards (for example, RCRA) but doesn't meet MTCA standards? This situation is fairly routine in Commencement Bay.

Groundwater: Dilution zones should be permitted where groundwater discharges to surface waters. A dilution zone concept acknowledges the change in media, the disparate concentrations between and within the two media, and increased natural recovery processes. The regulation implies the extremely conservative and incorrect assumption that groundwater concentrations are indicative of recieving water concentrations or sediment concentrations. Point of compliance will be very difficult to prove in situations where separate aquifers at various depths are interactive, particularly if background levels or sources vary by aquifer as happens in Commencement Bay.

Surface Water: Point of compliance must take into account surrounding contributions and not penalize the targeted site for contributions from neighbors or upstream properties. Chronic marine standards are frequently too restrictive relative to typical urban stormwater runoff. \

ARAR's: The proposed broadening of the definition of applicable standards to include relevant and appropriate criteria will have serious repercussions in mixed federal/state sites, and could lead to very subjective application of state or department policies which have not been subject to public review.

Conditional Cleanup Levels: While the concept is critical to a workable program and to ensuring cleanup progress, the qualifying criteria are so restrictive that the likelihood that they can be used is limited. Also, as written, regardless of method used (Method A, Method B, and methods for computing conditional cleanup levels) compliance with ARAR's is required. It is thus intuitively unclear how alternate cleanup levels can be justified.

Background Levels: The proposed method of proving a background level will be very difficult in large industrial areas with multiple sources and many separate properties.

Sensitive Areas: This definition and the associated ability of Ecology to establish discretionary cleanup levels takes away all certainty to the process.

Sediment Standards: Without seeing sediment standards, it is difficult to evaluate how this regulation will apply to is multi-media contamination in estuary environments.

Confusing Citations: The text makes frequent references to other sections within the regulation and to other RCW's, making it very difficult to follow the regulation.

Cleanup Methods: The concurrent emphasis on permanence and waste management priorities will severely limit choice of affordable cleanup options. The analysis required to demonstrate practical feasibility (in contrast to technical feasibility) in light of restrictive cleanup standards will further complicate choice of methods. And while we appreciate consideration of costs, the means of demonstrating "disproportionate cost to benefit" is very unclear. Compliance (and the supporting analysis) will be at the expense of timely expedited cleanups.

Cleanup Numerical Standards: Ecology should take special care in documenting how various numbers were derived. This analysis will be critical in justifying alternate levels.

Risk Exposure: Risk assumptions and exposure scenarios are extremely conservative.

Review of Standards: Standards should be reviewed annually, not once every five years to accomadate increased knowledge in this field. Data documenting alternate standards or cleanup methods should be publicized as it is recieved.

We obviously have numerous concerns with this regulation. Given the complexity of the regulation and because we did not receive a copy until the August 13th public meeting, our comments at this time are limited to criticism. We normally prefer to take the next step and recommend alternate language. In any case, although negative, we hope our comments are useful. The Port of Tacoma sincerely wants to see a process in place that will facilitate cleanups. Please feel free to call me at (206) 383-5841 if you wish specific citations.

Sincerely,

Leslie Sacha

Leslie Sacha
Director, Environmental Affairs

c: John Terpstra

LANDAU
ASSOCIATES.
INC.
Geoenvironmental Engineering and Technologies

September 14, 1990

Mr. Terry Husseman
Hazardous Waste Program
Washington Department of Ecology
Olympia, WA

Dear Terry:

Members of the Science Advisory Board would like to take this opportunity to submit our comments on the July 18, 1990 draft MTCA cleanup regulations. These comments represent the consensus opinion of Board members on several issues influencing the draft cleanup regulations. We hope that Ecology will find these comments useful and constructive.

I wish to expressly acknowledge the efforts of all Board members in developing these comments, and especially Dave Eaton's coordination of our efforts. His many valuable contributions over the past year as Chair of the Science Advisory Board are appreciated. As the new Chair, I look forward to working closely with your staff as they move toward the completion of the final cleanup regulations.

Very truly yours,

LANDAU ASSOCIATES, INC.

By:

Hank

Henry G. Landau, Ph.D., P.E.
Science Advisory Board Chair

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'Cleanup Standards' Position Paper

Science Advisory Board (SAB) for the Model Toxics Control Act

submitted to the Washington State Department of Ecology September 14, 1990

The SAB has reviewed the draft Model Toxics Control Act Cleanup Regulation and Proposed Amendments, Chapter 173-340 WAC, dated July 18, 1990, which was presented for public comment on August 1, 1990. The Board compliments Ecology for its accomplishments in addressing the widely varying social and political perspectives on the acceptability of involuntary risks, and the scientific and technical uncertainties which pervade the issue of "how clean is clean", while under extreme time pressure. Throughout this process, the SAB has attempted to provide coherent feedback to Ecology staff, and is appreciative of the many instances where Ecology staff have directly responded to our comments and criticisms in the many revisions of the draft cleanup standards that have been developed. However, there remain several areas of scientific interest for which the SAB believes that the draft cleanup regulations do not allow for the best and fullest use of scientific information.

During the past year, the SAB has not formally provided a consensus opinion on the draft cleanup regulations. During recent discussions, SAB members agreed to develop a consensus position on major issues that influence the substance of this proposed regulation and amendments. The SAB also agreed that minor comments regarding details of the draft would not be discussed in a consensus opinion, but rather individual Board members were encouraged to provide such comments in writing to Ecology. The Board identified eight conceptual issues for which the extent and quality of use of scientific information in the draft cleanup regulations was questionable or unclear. Each issue was discussed extensively among the Board, and a concensus position was developed for each after circulation and review of drafts. The comments in this position paper supersede any comments contained in earlier review drafts. The major issues and the SAB's consensus position on each are delineated below, in no particular order of priority.

1. Is the basic framework of the Draft Regulation workable, and does it allow for the best and fullest use of available scientific information in the establishment of cleanup standards?

<u>Consensus Opinion:</u> The Board commends Ecology for the enormous effort that went into developing these regulations, and agrees that the basic framework for implementation of the cleanup standards is workable. However, there are several areas where the Board believes that revision and clarification is needed. Although the Board recognizes that policy considerations based on non-scientific issues influence ultimate decisions, certain portions of the document do not yet appear to allow for the best and fullest use of scientific information.

2. Is the use of "natural background" as a cleanup goal consistent with current scientific thinking on "background risk," and is it necessary to adequately protect human health and the environment (as required by law)?

Consensus Opinion: The Board agrees that the use of natural background as a cleanup goal is not scientifically justified. The Board is concerned that inclusion of background as a goal could result in serious delays in the negotiations and implementation of site cleanups, with little or no improvement in protection of human health or the environment. The Board shares the idealistic and philosophical desires of Ecology, other environmental and health regulatory agencies, environmental and citizen's action groups, and most businesses and industries to live in a world free of pollution. However, the enormous advances in analytical chemistry over the past two decades now make the identification of extremely minute and biologically insignificant concentrations of synthetic organic chemicals commonplace. The "vanishing zero" for chemical identification in environmental samples is now a reality. In addition, in certain locations naturally occuring concentrations of heavy metals or other inorganic species are above drinking water or other applicable standards *in the absence of anthropogenic input*. The pursuit of "background" (e.g., zero exposure, in many circumstances) as a cleanup goal for the protection of human health and the environment is not supported by most current scientific perspectives on very low dose chemical risks. The Board believes that it is important to distinguish between requirements that are necessary to adequately protect human health and the environment and those that serve other purposes. To not do so could seriously impair the effectiveness of the Model Toxics Control Act, and could paradoxically result in increased human health risks and environmental degradation as a result of inaction and delays in cleanup that inevitably occur when negotiating parties have widely divergent perspectives on what is reasonable and necessary to protect human health and the environment.

3. Do the cleanup levels as currently presented in the tables in the Draft Regulations allow for the best and fullest use of scientific information?

Consensus Opinion: The Board found it impossible to determine whether the numeric cleanup levels presented in the draft cleanup regulations are scientifically supportable because the assumptions and derivations used to calculate the values are not provided in the document. When reviewing Tables 1 and 2, it becomes apparent that many of the levels are not based on the formulas presented on pages 35, 41 and 42; the values were apparently derived by some other unspecified procedure. Although there may be reasonable justification for alternative means of arriving at the cleanup level for a given chemical, it is impossible to identify the basis for many of the levels. For each tabulated value, the rationale for selection of the cleanup level should be clearly delineated.

4. Does the use of a 'default' acceptable additional lifetime risk level of "1 in a million" (10^{-6}), and a limitation in the range of alternative "acceptable risk" to a range of 1 order of magnitude higher (10^{-5}) allow for the best and fullest use of available scientific information, and is it necessary for the protection of human health and the environment?

Consensus Opinion: The Board understands that the selection of any specific risk level [e.g., one in a million (10^{-6}) risk level] as the *acceptable* additional lifetime risk is a decision based on both policy and science. Although scientific theory (*e.g.*, the non-threshold concept of chemical carcinogenesis) plays an important role in characterizing potential risks, the *acceptability* of such theoretical risks is largely determined by social, political, and philosophical perspectives that are perhaps influenced more by the absence of scientific information than by the use of sound scientific data. Based on numerous scientific considerations, examples of which can be found in Appendix A, the SAB is in unanimous agreement that strict adherence to a 10^{-6} lifetime risk level for potential chemical carcinogens as a compliance cleanup standard may go beyond what is necessary to reasonably protect human health, and may not be scientifically justified in specific situations.

The proposed cleanup regulations provide for use of an alternative 10^{-5} risk level in certain situations, such as the industrial soil cleanup levels. The Board believes that inclusion of the 10^{-5} risk range provides some desirable flexibility. However, the Board also believes that the strict adherence to even the 10^{-5} risk range, as is currently required in the proposed regulations, may not allow for full consideration of available technical and scientific information in some circumstances, and encourages Ecology to broaden the risk range by an additional order of magnitude, as is commonly the case with federal regulations using similar approaches to defining acceptable risk levels for chemical carcinogens. Broadening the risk range provides additional flexibility to deal with sites on a case-by-case basis, allowing decisions to be made where site-specific circumstances clearly indicate that actual risk is substantially lower than that predicted by the standard quantitative risk assessment approach, yet still allows for strict enforcement of cleanup where site-specific circumstances warrant protection of human health at a 10^{-5} or 10^{-6} risk level. The increase in flexibility gained by expanding the risk range should enable cleanup standards to be applied to all sites without the need for modification as the knowledge base in toxicology and epidemiology advances.

Under no circumstances should a cleanup action be required that results in a net *increase* in total risk to human health or the environment. Although it is imperative that hazardous waste sites be dealt with in a manner that is adequately protective of human health and the environment, it must also be recognized that decisions made to ameliorate one risk inevitably result in introduction of other risks. Once contamination has occurred, one must consider the trade-offs that result when remedial actions are implemented. Seldom do such actions **eliminate** risks, rather they result in actions that **substitute** risks. Thus, in remedy selection, reduction of total risk should become the goal, and time and effort should not be spent pursuing actions that result in no net gain in human health and/or environmental protection.

5. ***Do the Draft Regulations clearly and consistently address the difference between cleanup standards and cleanup levels?***

Consensus Opinion: The Board believes that the precise meaning and intent of the terms "cleanup level" and "cleanup standard" is important, and is concerned that the draft regulations do not clearly differentiate between cleanup standards and cleanup levels. Unless the two are clearly defined, it is not possible to establish if usage has been consistent.

The regulations define "cleanup *level*" as the concentration of a hazardous substance that is protective of human health and the environment under certain site use conditions. The definition of "cleanup *standards*" refers to the standards promulgated under RCW 70.105D.030(2)(d). This chapter of RCW 70.105D (Model Toxics Control Act) does not promulgate specific standards, rather it requires Ecology to publish and periodically update minimum cleanup standards at least as stringent as the standards under Section 121 of the federal cleanup law, 42 U.S.C. Sec 9621 (CERCLA) and at least as stringent as all applicable state and federal laws. Section 121 of CERCLA, titled Cleanup Standards, includes provisions for selection of the remedial actions and degree of cleanup. It does not, however, define specific cleanup levels except by reference to other applicable laws.

It is the opinion of the Board, consistent with the stated intent of the MTCA (see WAC 173-340-100), that the appropriate criterion to trigger site cleanup and to address the sufficiency of cleanup is *risk to human health and the environment*. The level of risk is a function not only of the concentration (level) of a constituent and its toxicity, but also the magnitude and duration of exposure, the biological availability of the chemical at the site, and other site and chemical specific characteristics that may influence either toxicity or exposure to current and future receptors. Referring to the definition of cleanup level, it is the Board's opinion that it is misleading to define the *concentration* of a given constituent as protective of human health and the environment without acknowledging that this definition is based on an assumed set of conditions that may or may not be applicable to a given site. Doing so conveys the inaccurate perception that exceedance of a cleanup *level necessarily* requires some removal or treatment action to address the concentration of the constituent.

The uncertainty relating to cleanup levels and cleanup standards also results in confusion relative to the interaction between cleanup levels (or standards) and selection of the appropriate cleanup action. WAC 173-340-700-4a states: "Cleanup levels shall be based on estimates of current and future resource uses and reasonable maximum exposures expected to occur under both current and potential future site use conditions." The July 18, 1990 draft apparently deviates from or significantly modifies this approach in the definition of conditional cleanup levels (WAC 173-340-700-5d). Factors such as technical feasibility, technical practicability, and incremental cost are included in the set of criteria used to select the cleanup level. While these factors are certainly important considerations in the selection of the appropriate cleanup action (WAC 173-340-360), the consistency and clarity of the regulations is adversely impacted when they are addressed in the definition of cleanup levels.

6. Should the regulations specifically recognize site uses other than residential and industrial for soil and drinking water for ground water?

<u>Consensus Opinion:</u> The Board agrees that, where appropriate, compliance cleanup levels for soil and air should be based on residential use, and for ground water should be based on drinking water use. The Board also supports the specific recognition of alternate *compliance* cleanup levels, such as industrial soil cleanup levels, for other site uses. Other site uses should be considered and may include, but are not limited to, recreational and agricultural uses.

The Board agrees that alternate compliance cleanup levels developed based on site use should be clearly differentiated from conditional cleanup levels that consider the number of contaminants present. It is not evident that there is a scientific basis for this approach.

8. Does use of the default value of "100 times the groundwater level" to derive soil cleanup levels allow for the best and fullest use of scientific information?

Consensus Opinion: The Board believes that there is little scientific foundation or justification for the use of the "100 times groundwater cleanup level" in arriving at compliance cleanup levels for soil. Because there are many site-specific and compound-specific factors that affect the relationship between soil contamination levels and the likelihood for future groundwater contamination, the Board recommends that compound-specific, or at least chemical class-specific factors be included in the derivation of soil cleanup levels that are based on potential for groundwater contamination. The Board appreciates the difficulties in balancing regulatory simplicity and clarity against scientific justification to set soil cleanup levels, and is interested in working with Ecology to attain these objectives.

The Science Advisory Board respectfully submits these comments in the spirit of providing constructive criticisms, with the hope that implementation of the Model Toxics Control Act can be accomplished in a manner that is both consistent with the law and that allows for the most reasonable and complete use of science.

David Eaton, Ph.D.

Henry Landau, Ph.D.

Thomas Sibley, Ph.D.

KNona Liddell, Ph.D.

Donald Wood, Ph.D.

David Eaton, Ph.D.

Henry Landau, Ph.D.

KNona Liddell, Ph.D.

Thomas Sibley, Ph.D.

Donald Wood, Ph.D.

factors such as technical feasibility, technical practicability, and incremental cost. The definition of conditional cleanup levels in WAC 173-340-720 should be modified to reflect this distinction. The goal of setting industrial soil cleanup levels as close as practicable to the compliance levels established in accordance with WAC 173-340-740 (as stated in WAC 173-340-745-1c) is appropriate for *conditional* cleanup levels but is not appropriate for industrial cleanup levels and other alternate *compliance* cleanup levels.

The Board agrees that different risk ranges would be appropriate in developing cleanup levels for different site uses. The regulations should allow for consideration of cleanup levels that yield theoretical risks in excess 10^{-5} for chemical carcinogens (and commensurate adjustments to factors of safety for noncarcinogen reference doses) at certain sites where it can be demonstrated to adequately protect human health and the environment.

7. ***Are the methods for environmental sampling and analysis described by the draft regulation adequate?***

Consensus Opinion: The Board was in unanimous agreement that use of appropriate statistical methods is important when evaluating background concentrations and compliance cleanup levels. The approach developed by Ecology in the draft regulation appears to be justified. However, the Board does have several specific concerns regarding the procedures detailed in the regulation.

The first of these are the methods for handling environmental samples with concentrations at or below the detection limit. It appears quite likely that the accepted procedures for such samples will change significantly over the next few years, and it would be desirable to maintain flexibility in the wording of the regulation. This could be done by listing several different methods for handling censored data.

With regard to sampling procedures, the Board believes that it is important to distinguish between cases in which the same location is to be sampled repeatedly over a period of time (e.g., a monitoring well) and cases in which a set of samples is to be taken at the same time from selected representative locations. The justification for applying the same statistical tests in both situations is not evident. For example, the confidence interval approach, which assumes random sampling of a normally distributed population, does not appear to be applicable to multiple samples taken from the same monitoring well.

The requirements of WAC 173-340-720 (7)(e)(ii) and (iii) and (7)(f), in contrast to those of (7)(e)(i), may under certain circumstances provide a disincentive to adequate sampling. The confidence interval approach should tend to lead to extensive sampling, since taking a greater number of samples will reduce the error in the sample statistics. However, it would also be expected that for measurements near the MDL (or PQL), and near the compliance cleanup level, the analysis will be more difficult and the error unavoidably larger. In such a circumstance, it will not be uncommon for a single sample to have a concentration two times the cleanup level or for 10% of samples to exceed the cleanup level by a small amount. Specific numerical factors such as these should be based on experience from prior successful cleanups or should be set on a case-by-case basis, taking into account both the characteristics of the site and those of the contaminant.

Finally, the Board is concerned that the effect of the regulation will be to apply the same procedures described for individual constituents to all sites irrespective of

Appendix A - Scientific Considerations in Estimating Acceptable Risk Levels for Potential Carcinogens

Although there is a strong regulatory history of utilization of a "one in a million lifetime risk" as the socially acceptable, ("de minimus") additional lifetime risk for environmental carcinogens, recent scientific advances in understanding the molecular basis of chemical carcinogenesis, as well as more in-depth examination of common lifetime risks associated with naturally occurring chemicals, provides a new and useful perspective on the true public health significance associated with a 10^{-6} risk level. The following discussion provides some perspective on what a 10^{-6} risk level actually means, and why the Board believes that flexibility and discretion in the use of this risk level is important.

According to the approaches defined in the proposed regulations, adhering strictly to the 10^{-6} risk level for groundwater contaminated with trichloroethylene or methylene chloride would require cleanup of contaminated groundwater to a concentration of 5 ppb. Thus, for example, individuals or communities consuming groundwater contaminated with 50 ppb of either of these chemicals (10 times greater than the standard) may well be forced to be placed on chlorinated public water supplies, often at substantial expense. Using the same assumptions and procedures to estimate the theoretical cancer risk for halo-organics (such as chloroform in public water supplies) as is used in estimating cleanup standards, it will become immediately apparent that the groundwater contaminated with 50 ppb of methylene chloride or TCE (**10 times greater** than the proposed cleanup standards) is actually no less "risky", and in fact is very likely substantially "safer", than the chlorinated public water supply which becomes the alternative water supply. In fact, when one examines closely the scientific data implicating methylene chloride and TCE as carcinogens, the case is considerably weaker than that for chloroform. There is no argument that the philosophical *ideal* would be that the groundwater be in its original pristine condition. However, once contamination has already occurred, one must consider the trade-offs that occur when remedy decisions are made. Seldom do such decisions **eliminate** risks; rather they result in actions which **substitute** risks.

The use of 10^{-6} as an acceptable risk level for chemical carcinogens has a long regulatory history, and is often justified because of this. However, it should be recognized that, from a public health perspective, such an acceptable risk level is extremely conservative. This is especially true when it is recognized that the calculations used to arrive at the 10^{-6} theoretical risk level represent the upper bound on risk and not the expected risk level. Depending upon the nature of assumptions, this may result in overestimation of true risks by several orders of magnitude. Recent advances in our understanding of "background risks" from naturally occurring chemicals in our diet and general environment lend further support to the notion that 10^{-6} risk is extremely conservative. For example, at current rates, approximately 25% of the population will die from cancer in the U.S., equivalent to a "background" risk of about 0.25. A 10^{-6} additional risk then raises this from 0.25 to 0.250001. While there is little question that some of the 0.25 "background" risk is a result of chemical contamination of our environment, experts in the field of cancer etiology generally concur that the total contribution of excess risk from pollution from synthetic chemicals is quite small relative to naturally occurring carcinogens in our environment. For example, the naturally occurring mycotoxin , aflatoxin B_1 (a byproduct of fungus growth), is ubiquitously present in peanuts, corn and some other common foods. Applying the same rules used to calculate cancer risks for chemicals at hazardous waste sites described in the proposed regulations, the acceptable theoretical cancer risk of 1 x 10^{-6} for aflatoxin would limit the consumption of peanut butter containing the estimated *average* concentration of aflatoxin in peanut butter (2 ppb) to about one peanut butter sandwich every 8 years.[1] It should be noted that the allowable limits of aflatoxin in peanut products (20 ppb) is actually 10 times greater than the estimated average. Although mechanistic studies suggest that humans may be equally or more sensitive to aflatoxin as rats, and human epidemiologic studies in areas of the world where dietary contamination of aflatoxin is high confirm that it is indeed a human carcinogen, studies on the incidence of liver cancer in the US indicate that these current levels of aflatoxin in the U.S. diet do not apparently present any significant health risk to the public. This is but one example of the numerous recent advances in our understanding of natural carcinogens that call into question the scientific justification of using the current approaches to quantitative risk estimation and the 10^{-6} risk level to define acceptable levels of exposure.

A second relevant example comes from the application of the same procedures to the estimation of cancer risks from natural background radiation. Using human data, the estimated **lifetime** dose of radiation associated with a theoretical additional lifetime risk of 10^{-6} is 1.25 mrem (Beir V report), which if distributed over a lifetime of 70 years would result in an "acceptable" annual dose of 0.018 mrem per person per year. The estimated **annual** background radiation dose for an average person is about 360 mrem per year, or 20,000 times higher than the "acceptable" lifetime risk of 10^{-6}. The vast majority of background radiation exposure is from natural sources (radon, cosmic radiation, natural isotopes of potassium and other elements in the body, etc).

The above examples provide a brief perspective on the public health significance of a 10^{-6} additional lifetime risk. Although it is both necessary and desirable that hazardous waste sites be dealt with in a manner that is adequately protective of human health and the environment, it must also be recognized that we do not live in a risk-free world, and that decisions made to ameliorate one risk inevitably result in introduction of other risks. It is imperative that decisions made in the guise of protecting public health recognize the magnitude of true public health protection that is obtained by the implemented actions. This requires that the actions to reduce a specific risk at a hazardous waste site (e.g. lowering the concentration of a potential carcinogen in drinking water) be placed in some perspective of total lifetime risk from other substances, as well as a careful evaluation of the risks of alternatives that are forced when remedial actions are taken.

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1 The EPA has calculated a potency factor for aflatoxin B_1 of 2900 $(mg/kg/day)^{-1}$ based on rat carcinogen bioassays. One ounce of peanut butter (32 grams) containing the U.S. average of 2 ng/gm (2ppb) of aflatoxin would result in a daily dose of 64 ng/day. For an average adult weight of 60 - 70 kg, this would result in an exposure of about 1 ng/kg/day, or 1 x 10^{-6} mg/kg/day. When this is multiplied by the potency factor ($1 \times 10^{-6} * 2.9 \times 10^{3}$), the theoretical cancer risk from consuming one ounce of average peanut butter per day is equal to about 3×10^{-3}. Thus, to arrive at a 1 x 10^{-6} risk, the "daily lifetime dose" would need to be reduced by 3,000 times, which is equivalent to reducing consumption from one ounce per day to one ounce every 8.2 years.

detection limit (MDL). This is repeated in the compliance monitoring section for each matrix (ground water, surface water, etc.) as well as in WAC 173-340-705(11) for background concentrations. The statement will be confusing to interpret when PQLs and MDLs are not in the same units of measurement. Instructions should be added regarding adjustment of the MDL to the proper units, and for dilution due to extraction or digestion of each matrix.

Finally, once these instructions are developed, it will be evident that the MDL for each matrix is 5 to 10 times lower than the PQL. As stated in the Draft EIS on Cleanup Standards (page 4-7), PQLs are designed to reduce the random error which is ordinarily high in measurements close to detection limits. If standards are set at the MDLs rather than the PQLs, they will not be accurately measurable in any situation. This could prevent final cleanup status from ever being attained.

Due to the number of areas still subject to misinterpretation or question, we request that final adoption of the proposed amendments to the MTCA cleanup regulation be delayed until questions have been adequately investigated and additional responses have been provided. Analyzing case studies for cleanups under various methods is one way to allow further consideration of the impact the regulations will have on real-world situations.

We realize the importance of providing cleanup standards in a timely manner, but want to be sure adequate attention has been paid to development and consistent interpretation of the proposed amendments. We would rather see time set aside for this consideration now, and avoid a scenario that would have us wait for the proposed amendments to be implemented before the effects of realistic application of the standards are known.

Thank you for the opportunity to comment on the proposed MTCA cleanup regulations. If you have any questions regarding these comments, please contact me at (206) 223-0500.

Sincerely,

Dennis F. Stefani

Dennis F. Stefani
Vice-President, Regulatory Affairs

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VIA TELECOPY

September 17, 1990

Mr. David Bradley
Washington Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia, Washington 98504-8711

Dear Mr. Bradley,

Re: Proposed Amendments to the Model Toxics Control Act (MTCA) Cleanup Regulation (WAC 173-340)

Chemical Processors, Inc. (Chempro) has reviewed the July 18, 1990 proposed amendments to the MTCA Cleanup Regulation, and offers the following comments for your consideration.

Some improvements have been made with each new draft of the proposed amendments, and we appreciate the work Ecology and it's advisors have put into the task. However, many of the comments we have submitted to you on previous occasions are still relevant. See our letter to you dated April 13, 1990 for a summary of our previous comments.

In general, we are still concerned that the cleanup standards will discourage voluntary and final cleanups, that the method of determining cleanup levels is not clear enough or consistent between alternative methods, and that the standards may be inappropriately used for purposes for which they were not intended.

We also still have numerous questions about the technical basis for analytical procedures and cleanup standards. For example, proposed amendments under WAC 173-340-705(12)(c)(ii) allow use or development of specialized analytical techniques to improve the method detection limit or practical quantitation limit for hazardous substances. This amendment provides an opportunity for widely varying procedures to be considered on a case-by-case basis, with no standard for comparison between specialized analytical techniques or for consistency with SW-846 procedures.

Also, proposed amendments under WAC 173-340-740(7)(g) state that if compounds are detected below a practical quantitation limit (PQL), they should be assigned a value equal to a method

HEAL
Hanford Education
Action League

SUBJECT: COMMENTS ON MODEL TOXICS CONTROL ACT PHASE II RULEMAKING

FORMAT--To identify the section, subsection or paragraph in the proposed rules--including existing Phase I rules already promulgated--for which a specific comment applies, the comment will be preceded with the appropriate section, subsection, etc. number, for example, 120 (2) (b). The common chapter designator in the Washington Administrative Code (WAC), WAC 173-340 for the Model Toxics Control Act Cleanup Regulation, will be omitted for purposes of brevity. The draft to which the comments apply is the July 18, 1990 draft of this chapter.

Comments on the Draft Environmental Impact Statement are listed under that respective heading. Applicable sections or text are identified with each comment.

DRAFT ENVIRONMENTAL IMPACT STATEMENT --

1. Per Appendix H the ground water modeling of the MEPAS code used by the Department of Ecology (DOE) does not appear to provide for distribution in discrete pathways, for example, fracture zones and buried ancestral stream beds of high conductivity, now covered by deposited soils. Such features in the geology at Hanford provide the most rapid transit times for the groundwater in the unconfined aquifer from contaminated zones to the river and are appropriate to consider in evaluating effects of spreading contamination and its concentration.
This mode of ground water distribution is of most importance at Hanford in transport of water from waste disposal areas to the river and areas of the hospitable environment.

2. Per Appendix H it is indicated that the MEPAS code allows evaluation of the dose via <u>any</u> possible pathway, and DOE indicates it is satisfactory for evaluating the relative impact of various alternatives of cleanup standards. However, DOE indicates that the intent of the impact statement is also to determine the effects on natural resources. Considering the fact that terrestrial and aquatic plants and animals are considered natural resources, any methodology selected to evaluate impacts should be able to consider these parts of the natural resource.
<u>Therefore the conclusion that human health effects are sufficient to determine the relative impacts of various cleanup standards is invalid.</u> In many cases flora and fauna may be grossly affected, for example, in salt water ecosystems, and human health would not be effected. In desert ecosystems, the same might be true. Drinking water in both cases may not be a pathway of importance in determining effects on humans.

Regarding the stated capabilities of MEPAS in Table H-1, Modifications to the MEPAS code should be made to allow

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September 14, 1990

David Bradley
Department of Ecology
Toxics Cleanup Program
Mail Stop PV-11
Olympia WA 98504-8711

Dear Mr. Bradley:

Enclosed please find HEAL's written comments on the draft toxics rule.

If you have any questions, please do not hesitate to call us.

Sincerely,

Lynne Stembridge

Lynne Stembridge
Executive Director

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evaluation of the relative effects on terrestrial and aquatic plants and animals as well as human populations. For example, modeling should provide for the evaluation of atmospheric deposition on terrestrial animals as well as terrestrial plants. Likewise groundwater drinking and ingestion/inhalation interactions should consider effects on terrestrial animals, including birds. Bioaccumulation in the terrestrial predator animal chain should be considered and should take into account the ingestion of aquatic animals. (The effect of DDT on predator birds is a classical example of why such a mechanism should be considered.)

3. Risk based effects on populations of flora and fauna species should be established by DOE and used in establishing cleanup actions for each site considered. For example, an appropriate statement of risk might be as follows:

> "Cleanup of hazardous substances shall with 95% confidence be such as to assure no greater than either a 5% increase or decrease in the 10-year average population measured in appropriate units -- individuals per unit area or volume-- for any given species native to the site being considered over a period of 10 generations of the species or 10 years whichever is greater."

Using such a design base for cleanup, the impact statement should consider indicator or limiting species impact. Without it the Statement is incomplete. The fact that good models are not available to assess individual species effects from specific contaminants is not a valid reason for ignoring this issue. Estimates of effects on species from experts in the evaluation of ecological contaminants should be used in the impact assessments.

And even though effects on species of various hazardous substances may not be readily apparent, it is important to establish design bases for specifying what is acceptable and what is not acceptable. As the technical capability develops for assessing species by species risks, the pertinent acceptance standards will be available for determining the acceptability of future cleanup actions.

4. In reviewing the subject Draft Environmental Impact Statement, it is difficult from the definition of "hazardous substance" to ascertain that radio nuclide toxicity is included within the scope of this term.

The Statement should make it clear that the rule and the Impact Statement cover the consideration of cleanup of toxic radio nuclides. To this end specific site scenarios (Appendix H) and remedial technologies (Appendix I) should be modified to incorporate items that address radio nuclides. For example, a site at Hanford should be considered together with the remedial technology applicable.

5. The term "threat to the public health or the environment" is used in the DOE's Final Cleanup Policy, dated July 10, 1984, (Appendix E of the Impact Statement). The term "threats to human health and environment" is used in the Model Toxics Control Act under declaration of policy. The definition of these terms may be consistent or may not.

The definitions should be incorporated into the definitions of Chapter 173-340 WAC and utilized appropriately in the Impact Statement. In this regard it is recommended that risk-based quantitative definitions be incorporated into the Chapter to quantify unacceptable "threats". As noted above, risk-based definitions that apply to the various components of the environment, including species, are necessary to clarify the action required by the Chapter.

6. The Technical Summary discusses the definition of "applicable or relevant and appropriate requirements." This section does not directly address the relevant laws in other states. The impact statement should include a review of laws in other states and provide evidence that the standards being proposed are at least as stringent as the "applicable" laws in other states. In this regard the term "applicable" appears to reflect its synonymous meaning "relevant" for purposes of Washington State rules under Chapter 173-340 WAC.

It is obvious that the actual laws in other states do not "legally apply" to the State of Washington. DOE's adopted wording "legally applicable" in the definitions and usage section of 173-340 WAC is unfounded. Relevancy is the key determining factor in deciding the use of cleanup standards specified by laws (and hence state rules) in other states.

Had it been intended by MTCA that the definition proposed by DOE be consistent with that in the National Contingency Plan, such definition would have been incorporated into MTCA.

Thus, the proposed definition of "applicable state and federal laws" incorrectly and/or ambiguously delimits consideration of any other state's law or requirement through the use of "and" instead of the word "or". As indicated above there are <u>no</u> "legally applicable" laws for residents of Washington in other states's statutes. The following words are suggested to correct this ambiguity:

"Applicable state and federal laws" as used in context of the specification of cleanup standards means all relevant current laws and corresponding implementation rules and requirements, any of which reasonably could apply to sites in Washington, promulgated by any federal or state authority or state citizenry."

The additional definitions of "legally applicable requirement" definition allows for slow release--hindered release--by structures. Thus, clay, which is slowly permeable to water and contaminants might be considered a suitable material for a container. To make the term consistent with usage in other environmental rules, for example, rules for high-level radioactive waste disposal in 10 CFR 60, the definition should be modified to specifically refer to structures that achieve the confinement of hazardous substances within a defined boundary and prevent the release to the environment.

d. The term "carcinogen" is defined in a very restrictive and non-conservative manner and is inconsistent with goals and conclusions of the Federal Cancer Policy, initiated by OSHA in 1977. The definition used in this policy is as follows:

> "A substance or condition which increases the incidence of generally irreversible benign or malignant tumors, reduces the latency period, or produces unusual tumors in animals or man."

This definition should be used in place of the current definition since it conservatively identifies a carcinogen.

e. The term "carcinogenic potency factor" or "CPF" should be separated from the definition of "carcinogen". In addition the definition for "CPF" does not make sense. The 95th percentile confidence limit of the slope of the dose-response curve is incorrect terminology. In addition "the dose-response curve" is ambiguous. An accurate definition should be included.

A definition of how the CPF is used may be more informative. A sample dose-response curve pertinent to the development of a benign or malignant tumor or reduction in latency period for same should be given as an example with the instruction as to how to determine the appropriate dose in terms of mg hazardous substance exposure per kg of body weight per day of exposure. This dose could vary depending on the number of individual animals tested, if a standard statistical design base is specified, for example, less than a 5% response at the 95% confidence level.

f. The terms "ground water" and "surface water" appear to exclude water in the vadose zone or unsaturated soil of the earth, generally found above saturated zones. It is recommended that the term "ground water" be expanded to explicitly include the water in the vadose zones of soils and stratum.

g. The term "highest beneficial use" ambiguously includes as part of its definition an example which highlights the use of drinking water as an indicator of highest beneficial since it "will generally provide protection for a great variety of other existing and future beneficial uses of ground water." The example, as it is written indicates that drinking water quality may not be the limiting determining factor for <u>all</u> current and future beneficial uses, only a "great variety."

and "relevant and appropriate requirements" in the Draft rules should also be modified to reflect this comment insofar as these definitions may apply to cleanup standards. In this regard, elimination of theses terms from the rule would seem appropriate since they appear to be nearly the same in their meaning as the term "applicable state and federal laws" discussed above.

It is poor rule making to use various similar terms to connote the same meaning. In addition, if slightly different meanings for terms used in the rule are necessary for some reason, the terms selected should be defined so that the intended distinction is obvious. Such has not been accomplished in the proposed rule and this results in confusion and ambiguity.

COMMENTS ON PROPOSED RULE--

1. 200 DEFINITIONS--

a. See comments in the section concerning the Environmental Impact Statement for comments on the following terms:

"Applicable state and federal laws"
"Legally applicable requirement"
"Threats to human health and environment" (proposed addition)
"Hazardous substance."
"Relevant and appropriate requirements"

b. The terms "acute toxicity" and "chronic toxicity" make use of the undefined term "injury" to specify the scope of the two terms. Since acute and chronic toxicity may not be generally interpreted to include allergic health effects from low-level contaminants in a small segment of the society, allergic reactions should be specifically considered in the definitions since the common definition of injury includes items detrimental to comfort as well as health. (The issue is raised in light of the fact that some health authorities and practitioners do not consider allergic reactions the result of acute or chronic toxicity, since such reactions tend to be confined to a limited number of individuals of a given species with no effect in other individuals.)

Also the term "short term" is used to define the maximum time of exposure to a hazardous substance associated with "acute toxicity". Instead of using "short term" the period of 72 hours should be specified. This is generally a conservative specification of short term in toxicity studies and is consistent with OSHA usage in requirements for worker safety.

Correspondingly the term "chronic toxicity" should specify a total exposure time in excess of 72 hours.

c. The term "containment" is defined in a manner inconsistent with the common understanding of the word, in that the proposed determined by such reviews.

i. The definition for "Subchronic reference dose" includes the parenthetical phrase "(with an uncertainty of an order of magnitude or more)". This confuses the meaning since if would seem some reference doses might not have such large uncertainties. Other ambiguities related to the words "appreciable risk" and "a portion of a lifetime" also confuse and/or leave the definition ambiguous. It is recommended that the definition include the following wording:

> "Subchronic reference dose means an estimate of a daily exposure level for the human population, including sensitive subgroups, that is likely to be without a risk greater than 1/1,000,000 at a confidence of 95% of adverse effects during an exposure of 72 hours or greater."

j. The terms "beneficial use", "in the public interest" and "appreciable risk" should be defined since they are key terms in deciding upon actions required by the rule. Appreciable risk should be defined as 1/1,000,000 at 95 % confidence or greater. Beneficial use should include uses that depend upon the ecological integrity of a site as a natural preserve. In the public interest should be consistent with the definition of "beneficial use" and consistent with the intent of MTCA to achieve cleanup to specified standards.

k. The term "reasonable maximum exposure" is defined in a non scientific manner, making use of the word "reasonable". This qualitative expression should be quantified consistent with establishing risk relative to quantitative risk standards. It is unacceptable to allow key aspects of the risk analysis to remain qualitatively stated. Thus, a probability defining reasonable, for example, 99% probability with 95% confidence that maximum exposure will not exceed the expected amount over a 100 year period considering conditions 500 years in the future, should be incorporated into the definition. It is noted that a time frame is warranted to specify for analysts a tractable problem and to standardize the exposure time to be considered for old people.

It should be noted that old people as their livers degrade and become less functional are increasingly vulnerable to health effects and cancer caused by toxins. Therefore, long exposure times are reasonable to consider. In addition it is necessary to correct dose/response data to account for the age and liver/kidney function of individuals. The long time frame for consideration of exposure will assure this phenomena shall be considered in determining a hazard index for individuals.

2. 360 (4)--This section should be modified to recognize other relevant state laws, consistent with comment 6 under Draft Environmental Impact Statement.

The example of drinking water should be deleted. It is not necessary to modify the first clause in the definition. It only acts to create an ambiguity.

h. The term "risk" as part of the definition includes the idea of a probability that a hazardous substance causes an adverse effect. However, an important and useful parameter, confidence, is necessary to further illuminate any particular statement of risk by addressing its validity and thereby give practical meaning to such statements.

Hence, the definition of "risk" should be modified to refer to a confidence statement. An appropriate standard specification for confidence for risk assessments would be 95 percent.

The following is a brief discussion of factors to be considered in quantitatively specifying risk that should be considered in redrafting the definition.

> What constitutes proper quantification? First one must have an estimate of a probability of a postulated event (risk), generally with respect to passage of time. Second one must have an estimate of the confidence of that probability or risk. This latter estimate is a quantitative statement as to the validity of the analyses used to make the risk estimate. Without the confidence statement a risk estimate is not meaningful. And finally, the estimates must be made within the rigors of a quality assurance system applicable to design activities, including research and development.
>
> In risk analyses a confidence statement should be estimated to take account of both the known and uncontrolled effects anticipated in a scenario, as well as the unknown or vaguely known effects. Such estimates, when combined, would serve as a confidence statement for the stated risk.
>
> However, risk analyses commonly utilize mathematical models of the scenario in question, with random selection of independent variables defined for the respective models, to accomplish "thought experiments" producing statistical data. Such data do not allow for determining a confidence statement since re-doing the analyses for any given scenario will produce the same estimate of risk. The results of such "thought experiments" do not reveal uncertainties in the models themselves. And the validity of the models to represent the scenario in question remains unaddressed.
>
> Typically it takes independent peer reviews to estimate and/or confirm, quantitatively, the uncertainty associated with models used in risk assessments. Conceptually, the "thought experiments" making up the risk analyses should include runs which incorporate bias or uncertainty factors applicable to a model's dependent performance parameters

3. 360 (7)--This subsection concerning practicability should consider costs associated with loss of future beneficial uses. Intangible benefits, for example nature preserves, should be assigned a worth to allow such evaluation. Such "lost beneficial usage" costs should subtract from costs associated with cleanup actions in evaluation required by item (c).

4. 600--Rules for obtaining public input are extensive specified in this section, however, rules applying to DOE for rational, fair resolution of public input are left out. Such rules for operation of DOE should be included in 173-340 WAC. They should include requirements to propose resolution to comments within a specified time and to publish the resolutions. In addition, resolution of comments should provide for appeal and in the case of citizen advisory groups, should require concurrence.

Where comment resolution of public input is not resolved to the satisfaction of the commentator, an appeal mechanism should be specified to provide for further review and adjudication of comments.

5. 700 (5) (d) (iv) (A)--The comment in item 3 above regarding lost beneficial usage costs should be considered in this paragraph.

6. 700 (4) (a)--The text concerning "reasonable maximum exposure should be revised to reflect the discussion under item 1. k. above.

7. 705 (3)--The frequency specified for review and update of the rule is excessive. Many changes to applicable state and federal laws may occur within a five year period. An annual review should be specified with at least annual updates of the rule accomplished as necessary to be consistent with the RCW 70.105D.030 (2) (d). It is unreasonable to allow a 5 year delay in accomplishing protection of human health and the environment. Procedures for publishing the updated standards should be specified in 173-340-705.

8. 720 (1) (a) (ii)--The criteria for determination of potential future use of ground water are inadequate. Consideration of technological advancement in the capability to remove organic or specific inorganic constituents should be included in the analysis.

Drinking water for farm or domestic animals is a use that should be considered routinely and thus should be specified rather than left to the determination of DOE on a case basis. For example, the accumulation of hazardous substances in milk of cows and goats should be considered.

The second sentence of paragraph (a) is unnecessary. It inappropiately suggests consideration of drinking water as the highest beneficial use in most cases. Such a suggestion adds nothing to the rule.

9. 800--A provision should be included in the facility access rules to allow and facilitate discussion with facility owners and there employees. In addition the rules should prohibit facility owners or their agents or other employees from advising any person not to communicate with State employees or their agents regarding health and environmental hazards. Rules should be included against withholding information by any person pertinent to a State investigation.

Puyallup Tribe of Indians

September 25, 1990

RECEIVED
SEP 28 1990
ECOLOGY

Mr. Dave Bradley
Toxics Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Re: Comments of the Puyallup Tribe of Indians on the DOE's Draft EIS Cleanup Standards

Dear Mr. Bradley:

Enclosed are the comments of the Puyallup Tribe of Indians on the Department of Ecology's draft EIS Cleanup Standards. Thank you for the opportunity to comment on the proposed cleanup standards. The Puyallup Tribe wishes to acknowledge DOE's efforts to develop working relationships with our Tribe on a government-to-government basis.

Ecology's proposed regulations are a matter of great concern to our Tribe. The recently approved Land Settlement Act envisions a permanent homeland for the Puyallup Tribe.

Indian Reservations are unique and, for all practical purposes, they are not being made anymore. The Puyallup Reservation provides the homeland for the Puyallup Tribe. Damage to, or destruction of, the Reservation environment is a critical threat to the Tribe. Tribal members do not have the same flexibility in packing up and moving away from their homeland as do many other United States citizens. Tribal members have cultural, spiritual ties to the land, air and water that forms their homeland.

The Puyallup Tribe is concerned that the proposed cleanup standards may not be adequate to protect Tribal resources. This matter is especially important to the Puyallup Tribe because many of the hazardous waste cleanups are located in the Commencement Bay Tideflats and nearshore environment. Many of these sites are within the 1873 boundary of the Puyallup Reservation. These sites will need to conform to Ecology's regulations.

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Based on my preliminary review of Ecology's cleanup standards, I have noted the following concerns:

* TREATY RIGHTS: There is neither recognition nor protection of Tribal treaty resources;

* PROTECTION: The cleanup levels may not be adequate to protect Tribal interests. Ecology's application of the risk-based method at the General Metals facility resulted in recommended PCB soil clean up levels in excess of 21 parts per million;

* STANDARDS: Ecology has proposed the establishment of clean up levels at the "practical quantitation limit". This level of control may be substantially more relaxed than accepted detection limits. Proposed WAC section 173-340-705(12)(b);

* TRIBAL DIET: The risk assessment clean up based methodology utilizes fish comsumption rates that may not accurately reflect the diet of Tribal members. Proposed WAC 173-340-730(3); and

* ECONOMICS: Cost considerations are established throughout Ecology's proposed regulations and may result in clean ups less protective of human health and the environment than would otherwise be allowed.

In light of the above, the Puyallup Tribe has serious concerns about whether Ecology's proposed cleanup standards will adequately provide for effective remediation in Commencement Bay. The Puyallup Tribe respectively requests that Ecology take our comments into consideration when finalizing their cleanup standards. If you have any questions, please don't hesitate to contact me at (206) 597-6200, ext 387.

Thank you for your consideration.

Bill Sullivan

Bill Sullivan, Director
Environmental Program Puyallup Tribe

BS/klk

cc: Tribal Council
    Richard DuBey

HELLER, EHRMAN, WHITE & McAULIFFE
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DANIEL D. SYRDAL
PARTNER

September 18, 1990

David Bradley
Department of Ecology
Toxic Cleanup Program
Mail Stop PV-11
Olympia, Washington 98504-8711

Dear Mr. Bradley:

Enclosed please find the hard copy of our comments on the proposed cleanup standard regulations and the DEIS. As you know, we faxed you copies yesterday.

Also enclosed please find additional enclosures which were too lengthy to fax, but which are particularly relevant to your consideration of the proposed cleanup standard regulations. I would particularly direct your attention to pages 3 and 13-26, which take positions with which we certainly agree.

Thank you for your consideration of these matters.

Very truly yours,

HELLER, EHRMAN, WHITE & McAULIFFE

Dan Syrdal

Daniel D. Syrdal

Enclosures

HELLER, EHRMAN, WHITE & McAULIFFE
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September 15, 1990

David Bradley
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Mail Stop PV-11
Olympia, Washington 98504-8711

Re: Comments on Proposed Cleanup Standards Dated July 18, 1990

Dear Mr. Bradley:

Pursuant to the Department's request for comments on its proposed cleanup standards implementing the Model Toxics Control Act, the following comments are provided. General comments are first provided, followed by more detailed comments on specific sections. Also attached are comments on the draft environmental impact statement regarding the proposed regulations.

As a member of the Department's cleanup standards work group, we believe that the most recent draft of the regulations is a substantial improvement over earlier drafts in most respects. However, there are still very significant problems associated with the proposed draft which could severely limit the viability of the posed regulations with respect to what the department is attempting to accomplish. The department's objectives, with which we agree, which you have often noted during the process, are stated as follows:

- Protection of human health and the environment.
- Scientifically and legally defensible.
- Preserve the integrity of existing programs

- Promote efficient cleanup of contaminated sites.
- Provide a consistent level of protection.
- Provide the flexibility to address individual site characteristics.

Unfortunately, we believe that several aspects of the proposed cleanup standards do not meet these objectives and will, in fact, actually serve to thwart the attainment of these objectives.

Another goal shared by all concerned is cleanup standards which are workable and facilitate rapid response as necessary to protect human health and the environment. This will likely not occur if the standards are so burdensome as to require responses which are neither cost effective nor constitute a reasoned response in light of the true risks presented at or from a facility. For this reason, we believe the regulations should contain a great deal of flexibility to adjust to the actual environmental risks presented at each facility and to provide a more cost effective response that appropriately deals with those risks.

Because of the provisions of the MTCA requiring cleanup actions to comply with the cleanup standards adopted by regulations, this flexibility must, of necessity, be found within the cleanup standards themselves. It is, therefore, extremely difficult to develop a regulatory program that provides the necessary flexibility at only the implementation stage. Any such attempt will be subject to continual challenge of the department's discretion in making remedial actions selection decisions regarding such things as how long before a cleanup standard must be met, what types of techniques may be used to meet the cleanup standard, where the cleanup standard must be met, etc. While flexibility in the remedial action selection phase is an important adjunct to flexibility in the standards themselves, it cannot remove many of the inequities and inconsistencies associated with developing nearly uniform cleanup standards to apply in all of the dramatically different situations to which these regulations will apply.

For this reason, our most serious concern regarding these proposed cleanup standards is the lack of flexibility within the cleanup standards themselves. There are many noteworthy examples of this failing, most of which will be more thoroughly discussed in the specific comments below. Some of the more important failures in this regard include the regulations' failure to provide an alternative cleanup level where greater risk to human health or the environment would occur by meeting the risk based or ARAR standard than by setting a lower standard for the cleanup.

Perhaps the second most important failure in this regard is the lack of sufficient consideration of technical practicability in setting conditional cleanup standards. In essence, these regulations are designed to set the cleanup levels at the most stringent level which would be derived from any one of a combination of approaches including technical feasibility, application of other standards (ARAR) or risk assessment techniques using extremely low risk levels. In doing so, the standards do not give adequate consideration to technical practicability, including costs, associated with meeting these standards. All of the extremely conservative assumptions that go into the risk assessment approach are given equal weight in the development of standards irrespective of the potential cost associated with meeting such standards. This approach certainly flies in the face of many of the above objectives. For example, consideration of the potentially massive cost associated with meeting a particular risk based standard would be excluded despite the fact that the particular standard in question might have many orders of uncertainty regarding its risk and there may be little if any actual exposure to the risk in question. This type of approach is (1) not necessary to protect human health and the environment; (2) not scientifically legally defensible; (3) does not promote efficient cleanup of contaminated sites; and (4) does not provide the flexibility to address individual site characteristics. As such, it violates four of the six objectives stated by the department for cleanup standards.

Another example of the failure in necessary flexibility for cleanup standards to be applied at particular sites is the approach taken by the regulations in deciding which ARARs should apply. Under the federal system, while legally applicable requirements may apply in all cases, the application of relevant and appropriate standards to a particular case is judged on a case by case basis. Unfortunately, the department in these regulations has chosen a substantially different path. Perhaps the primary example of this is the decision to apply MCLG's and secondary drinking water standards as cleanup standards for groundwater. Secondary MCLs are not health related standards and thus, by definition, not necessary to protect human health. Whether or not the compliance with secondary standards is necessary to protect the environment, the only other possible goal allowed by the MTCA, is certainly a question to be determined on a case by case basis. Despite this fact, the regulations provide that the secondary drinking water standards must be met as a cleanup level in virtually all cases. Thus, without regard to the potentially tremendous cost of cleaning groundwater to the secondary drinking water standards in certain cases, such standards would be deemed applicable even though they might not meet the various factors for determining whether something is relevant and appropriate in a given circumstance.

Another basic failing of these regulations is the lack of flexibility with respect to the level of risk at which the standards are to be set. The basic assumption is, of course, that the cleanup levels should be set so that the incremental risk is no greater than 1 in a million excess cancer risk. Under certain limited circumstances this level could be reduced to 1 in a 100,000. Furthermore, the regulations provide a series of assumptions to be used for calculating these risk numbers. These assumptions vary between residential and industrial sites but do not allow any variations for the actual circumstances at any given site to be considered.

There are a great number of factors which suggest that the very stringent risk approach utilized in these regulations is inappropriate. First, it must be remembered that the state act is to apply to those sites which are not "bad enough" to be designated as Federal Superfund sites. Under federal law, all cleanups must be cost effective, and costs and other practicability issues are utilized to determine what level of risk is appropriate to use as a cleanup goal for a federal site. In general, the federal regulations in the national contingency plan provide that the risk level should lie somewhere between 10^{-4} and 10^{-6}. By requiring a 10^{-6}, with some possibility of going to 10^{-5}, risk level, the state is applying a standard which is up to 100 times more stringent than the federal government even though the sites to which it applied presumably do not present the same magnitude of risk to public health. Even the State of California has determined, in adopting regulations to implement __________.

As has been clearly stated by the department's own science advisory board, by routinely applying the 10^{-6} risk level as a cleanup standard, the department is also, irrespective of the cost of meeting such standards or the technical feasibility of doing so, requiring the risk at a contaminated site to be reduced to levels which are far lower than many of the every day risks to which society voluntarily and involuntarily exposes itself everyday. Perhaps most illustrative of this problem is how these requirements relate to health related groundwater standards. Under the proposed regulations, in the groundwater affected by a contaminated site will, in general, have to be cleaned to a level of 10^{-6} incremental cancer risk. This requirement would generally not be modified on the basis of whether someone is currently using the groundwater or is likely to ever use the groundwater. Instead it is calculated on the basis of the assumption that the total population has access to using the groundwater throughout a 70 year lifetime at a consumption rate of two liters per day.

In contrast to the extremely low probability of exposures at the required assumption level, drinking water standards which apply to public drinking water supplies where such exposures are likely allow contaminant levels which would produce risk estimates using the same methodology far in excess of 10^{-6} for many different chemicals. In fact, any chlorinated public water supply, such as those of Seattle and Tacoma, would be calculated to have a risk level approximately 100 times higher than the cleanup standard applied at some isolated contaminated site where the contaminated groundwater is not being used. Thus, under the proposed regulations, a site would have to be cleaned up to carcinogenic risk levels much lower than those associated with drinking water from major public water supplies. While this may be appropriate in certain circumstances at certain sites, it is not appropriate to require such cleanup standards at sites where the population is not being exposed and where it would be extremely expensive to provide that level of cleanup.

Another reason why there needs to be more flexibility in the risk number utilized by these cleanup standards relates to the uncertainty of the risk numbers themselves. First, the basis risk methodology utilized by the Environmental Protection Agency and these regulations is currently the subject of a great deal of controversy. For example, most of the cancer potency factors have been developed through the use of animal studies where the animals are exposed to what's called the maximum tolerable dose. Many recent studies has suggested that this approach is inherently flawed because exposure to the maximum tolerable dose, a dose which is far larger than any exposures associated with most contaminated sites, greatly enhances the risk of carcinogenicity due to the dosage killing healthy cells and thereby inducing carcinogenicity that otherwise wouldn't occur. In addition, the basic assumption utilized in the methodology in these proposed regulations, that there is not threshold dose for carcinogenicity, is also subject to a great deal of scientific controversy at this time.

Assuming that the methodology utilized in the risk assessment approach adopted by these regulations is correct, even the supporters of the methodology recognize there is great deal of inherent uncertainty in the resultant risk level calculation. For most contaminants, the calculation of the cancer potency factor depends upon a very conservative extrapolation from very high dose levels in animal experiments. As pointed out by the Science Advisory Board, these extrapolations themselves involve a very high degree of uncertainty in most cases. This uncertainty may range several orders of magnitude. The cancer potency factor derived from these extrapolations, and thus the resultant cleanup standard, could thus be several orders of magnitude higher than the actual risk if the experiments could be conducted at the exposure levels associated with a contaminated site.

In addition to the orders of magnitude uncertainties with regard to the cancer potency factor, there are also additional conservative assumptions applied in the department's methodology regarding the exposure variables. While there is an allowed differentiation between industrial sites and residential sites in terms of certain exposure assumptions, for the most part the exposure assumptions are not allowed to reflect reality at a given contaminated site. Instead, the assumptions are required to be conservative so as to ensure that they do not understate the risk.

While the application of conservative assumptions to this methodology may well be appropriate in order to assure that one is not understating risk, the uncertainties should be taken into account in deciding the role of technical practicability in modifying the risk levels with which a particular cleanup must comply. For example, if a particular risk calculation involves four orders of magnitude uncertainty and since the methodology assumes that the uncertainty lies in the direction of lower risk, it is inappropriate to use a 10^{-6} risk level if the use thereof would not be economically or technically practicable. This is one of the reasons that the Environmental Protection Agency has chosen to use a risk range of 10^{-4} to 10^{-6} in evaluating cleanup remedies. If, for example, it would take an additional $100,000,000 to cleanup to the 10^{-6} level as compared to the 10^{-4} level, it would certainly be relevant to know that the uncertainty of the risk level calculated in a given circumstance was four orders of magnitude such that the 10^{-6} level calculation was most probably only meaning somewhere between 10^{-6} and 10^{-10} actual risk increment.

As a further indication that the 10^{-6} standard contained in the proposed regulations should, when necessary to avoid technically impracticable solutions, be modified to a higher risk level, one need only review some of the comparative risks data supplied to the department by the Science Advisory Board. For example, a U.S. citizen currently has a 1 in 4 chance, or 0.25, of dying from cancer from any and all causes. If a site were cleaned to the 10^{-6} risk level, and assuming that person in fact was exposed in accordance with the risk assumptions associated with that calculation such as drinking two liters of water per day from a monitoring well at the compliance point over a 70 year lifetime, that person's risk would increase to .250001. Taking the uncertainty of the methodology into account and again assuming the validity of many potentially unrealistic, but conservative, exposure assumptions, that person's risk may really only have increased to something like .2500000001 or less. Despite these facts, the department under these regulations would not be free to consider a lesser cleanup standard even if no one was, or was likely to be, so exposed.

It is also pertinent to note that if a site were cleaned to a 10^{-6} risk level it would mean someone exposed to all of the conservative exposure assumptions at that site would have approximately the same risk of dying from that exposure as that person currently has in the United States of dying of measles, and a much lower risk than the person would have of dying from a small pox vaccination, lightning, electrocution, drowning, etc. Perhaps more importantly, the risks associated with many contaminants at the 10^{-6} risk level is far lower than the risks associated with many other voluntary and involuntary exposures that person accepts or incurs nearly everyday. For example, the risks are much lower than a person experiences in eating three ounces of bacon, drinking two liters of chlorinated water per day, or eating one ounce of peanut butter per day. While this still does not justify necessarily exposing people to additional risks, it certainly should be relevant in determining what level of risks, and what level of conservative assumptions in calculating such risks, should be applied when one is considering the expenditure of scarce resources.

With respect to the noncarcinogens, the arguments for providing greater flexibility on a site by site basis are even stronger. Many of the noncarcinogenic effects have a far lower risk of serious consequences to human health. For example, many of the health effects occur only over a specific segment of the community, occur only on long term, as opposed to sporadic, exposures, are reversible, etc. As such, the role of technical practicability in selecting cleanup levels based on such noncarcinogenic responses should be even greater.

Another concern we have regarding the proposed cleanup regulations relates to the values presented in the tables implementing Method A and how those numbers relate to numbers calculated pursuant to Method B. In initial drafts of the Table A, the Department attempted to use the formula from Method B to calculate the values. Many of these values turned out to be substantially below minimum detection limits and health-related standards. As a result, several of these numbers have been adjusted in the Table A values to be more realistic and workable. The formula used in Method B has not, however, been similarly adjusted. Therefore, if one is not involved in a routine cleanup, cleanup standards under Method B could be developed which have the same problems with unrealistic levels that the Department has attempted to correct in the later versions of the tables. Thus, application of Method B at non-routine sites could result in the requirement to meet unrealistic standards the Department has already rejected in the tables. This also points out another ironic situation. That is, the tables were supposed to be conservative numbers that one could ensure would always be safe, with the calculations of Method B designed to allow more flexibility. For many contaminants, this situation is now reversed, in that Method B would produce more conservative cleanup levels than Table A.

As final general comment, these regulations are unnecessarily broad in requiring the application of AKART and BACT to cleanup actions. AKART and BACT were designed to apply to new and ongoing discharges, not to remedial action. Unless the AKART and BACT requirements are, in fact, ARARs, they should not be required. Application of AKART and BACT where it is not legally required or relevant and appropriate could cause very significant increases in cost without any necessary benefits to human health or the environment. For example, application of AKART to a groundwater treatment system may, in fact, require cleanup to levels far lower than any other recognized risk level would dictate. While these measures might be extremely expensive, they would, therefore, provide no significant benefit to human health or the environment. In such case, expenditures just to comply with AKART or BACT would not be justified. Instead, the increase cost could serve to frustrate the ability for rapid cleanup of the facility.

We hope you will carefully consider these general comments and the more specific comments attached. We look forward to continuing work with the Department in an attempt to produce a workable regulation that meets the Department's stated objectives.

Very truly yours,

HELLER, EHRMAN, WHITE & McAULIFFE

Daniel D. Syrdal

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COMMENTS ON PROPOSED AMENDMENTS TO MODEL TOXICS CONTROL ACT CLEANUP REGULATION

WAC Chapter 173-340

WAC 173-340-200 Definitions.

"All practicable methods of treatment." The last sentence of this definition should be deleted. To include "all known available and reasonable methods of treatment" and "best available control technologies" within the definition of "all practicable methods of treatment" will be unworkable. AKART and BACT are specific to water discharge and air programs. In most cases, they are not particularly applicable to hazardous substance site cleanups and should only be included where they would otherwise constitute an ARAR given the circumstances at a particular site. The best course would simply be to delete this sentence from the definition. Alternatively, the exact types of situations in which AKART or BACT will be legally applicable should be delineated, and specific reference to statutory and Washington Administrative Code citations should be made.

"Applicable State and Federal Laws." The reference to "relevant and appropriate requirements" should be deleted. Calling a relevant and appropriate law "applicable" will lead to the unwarranted inference that it is a requirement which must apply to a given circumstance. "Applicable" laws should therefore, be limited to those which are legally applicable as is the case in the federal law.

"Carcinogen." This definition perpetuates the problem associated with distinction between benign and malignant tumors in animal studies. Carcinogenicity is generally considered to be related to malignant, as opposed to benign, tumor and should be so limited in the definition. In addition, the cancer potency factor is not always set at the upper 95th percentile confidence limit of the dose-response curve.

"Conditional Cleanup Level." The restriction to the use of conditional cleanup levels only when restricted site use conditions apply is inappropriate. There may well be other circumstances where it is appropriate to use conditional cleanup levels, and still be fully protective of human health and the environment independent of the question of whether such restrictions were applied. Also, use of institutional controls could be sufficient. This definition would additionally increase the problem associated with on and off site contamination and the use of conditional cleanup levels offsite.

"Hazardous Waste Site." This definition is incorrect. The term "hazardous waste" is restricted to those wastes which have been determined to be hazardous pursuant to Federal EPA regulation. The term is not synonymous with "hazardous substance." Therefore, throughout this rule, the term used should be "hazardous substance site." This definition should be changed accordingly.

"Null Hypothesis." The definition of null hypothesis is a sort of "guilty until proven innocent" approach. As such, it has no place in regulatory language. Furthermore, the definition is scientifically incorrect and inconsistent with U.S. EPA Risk Assessment Guidance.

"Owner or Operator." The portion of this definition dealing with abandoned facilities should be changed to reflect that the standard of liability set forth in RCW 70.105D.040(1)(b) limits the liability of former owners to those who "owned or operated the facility at the time of disposal or release of the hazardous substances."

"Permanent Solution." This definition would mean that a cleanup involving the transport of materials to an offsite permitted landfill or incinerator would not constitute a permanent solution. While there is some rationality with respect to offsite landfills, this seems particularly onerous with respect to incinerators which destroy the hazardous constituents just because of the production of ash or because some future action may be required at that incinerator facility. Even with respect to offsite landfills, it could readily be argued that such disposal presents far fewer permanent risks than many recycling or reuse techniques which have a higher priority.

"Practical Quantification Limit." The word "achieve" should be replaced by the word "measured" to accurately represent the intent of this definition.

"Site Use Restrictions." We presume that site use restrictions are intended to be the same thing as "restricted site use conditions" as used in the definitions of "conditional cleanup level." This should be made clear. If so, it is not necessarily the access to the site that is important. It may be more the elimination or minimization of exposure at the site that constitutes a site use restriction. For example, if contaminated soil is left onsite but is capped with concrete, one may not intend to restrict the access to the site but only to restrict the removal of the concrete.

"Subchronic Reference Dose." This definition seems to provide too much flexibility in that a dose with an uncertainty of an order of magnitude or more could mean an uncertainty of 25 orders of magnitude or more. If we are dealing with that type of uncertainty it should have no place in these regulations. The definition should, instead, attempt to state the conservativeness of the estimate in a different way.

"Wetlands." This definition should be replaced. The definition proposed by Ecology is identical to the definition initially published by the U.S. Fish & Wildlife Service in 1979. This definition has not been used for regulatory purposes, but typically has been employed in the process of assembling inventories of wetland areas. For regulatory purposes, the following definition which is used by the Environmental Protection Agency and the Corps of Engineers for regulatory purposes be used:

> "Those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support and that under normal circumstances do support a prevalence of vegetation typically adapted for life in saturated soil conditions."

WAC 173-340-360.

WAC 173-340-360(4). This subsection deals with various presumptions which are intended to be interpretation of certain requirements regarding applicable state and federal laws. However, the provisions in subsection (4) would, therefore, not apply to the general requirement of this section in subsection (2) that all cleanup actions comply with cleanup standards. Therefore the provisions contained in (4) may not modify the requirements of compliance with cleanup standards. This would mean that the provisions regarding requirements for groundwater treatment to achieve standards may only apply to the ARAR portions of the standards and not to the risk derived cleanup levels. I don't believe this was the department's intent. This subsection should be rewritten to make it clear that it applies to the general requirements under both subsection(2)(a)(i) and (2)(a)(ii).

WAC 173-340-360 (4)(b)(i). The AKART requirement set forth in the State's Clean Water Act is generally designed for wastewater streams or other discharges of water under the direct control of the permit holder. As such, it is designed for prevention activities, not remedial activities. It will not always fit situations found at hazardous substance release sites which involve either the movement of stormwater, uncontrolled surface water, or groundwater. Therefore, Ecology is attempting to impose, in all situations, a statutory and regulatory scheme that may not apply to all sites. Furthermore, to the extent that AKART may go beyond what is required to eliminate any significant threats to human health or the environment, or go beyond the cleanup standards, AKART's application to remedial activities

WAC 173-340-360(6). This subsection deals with "permanent solutions" and establishes a hierarchy of cleanup alternatives. This section should be revised.

First, there is no indication whether the selection criteria are weighted or whether they are all given equal consideration during the decision-making process. Second, we assume that a higher preference technology that fails the selection criteria such as overall protectiveness of human health and the environment, is automatically rejected and a lesser technology can be chosen even though the higher technology is "practicable." This should be so stated. Finally, subsection WAC 173-340-360(6)(e)(v) should be deleted. This subsection provides that a cleanup action relying only on isolation or containment of hazardous substances shall not be used if a cleanup action alternative that utilizes the higher preference cleanup technology or method for all or a portion of the site is technically practicable. This means that the other balancing criteria would be irrelevant, and that even if an isolation alternative is the best alternative for protection of human health and the environment, it would be rejected. This is inappropriate, especially given the fact that there are many circumstances where selection of another, higher priority alternative could substantially increase the risks to human health or the environment.

Ecology should make the criteria of overall protection of human health and the environment the primary criteria in selecting a cleanup method. In no event should a higher preference treatment method be required simply because it is technically practicable without taking into account the overall protection of human health and the environment.

WAC 173-340-360(8). Subsection (a)(ix) of this subsection relates to natural degradation processes at the site. Similarly, natural degradation processes affecting contaminants migrating from the site are relevant to the question of the restoration time frame. This subsection should be amended to include natural degradation at both locations.

Subsection (8)(d) provides a good example of where there needs to be flexibility in determining the cleanup standard levels. If a PLP is to reduce concentrations of contaminants to those that are technically feasible, which by definition is irrespective of cost, it should not be required to deem the actions simply an interim action unless the remaining risks are substantial or at least significant. If technology is not capable of reaching the conditional cleanup level, which given the parameters required by Method B may occur in several instances, either the PLP should not be required to conduct the cleanup until such levels are achievable, or it should be considered a final remedial action. Leaving the technically would become treatment for treatment's sake and not be authorized by MTCA.

WAC 173-340-360(4)(b)(ii). This section requires the use of AKART when dealing with protection and restoration of the quality of groundwater affected by a release from a site. The above comments regarding AKART therefore apply. This section is unclear whether this AKART requirement is mitigated by the provisions of its subsections (A) through (D). Assuming this was the intent, then the AKART is modified by a practicality standard unless the public interest demands more. This wording should be clarified to ensure that these are limitations to the opening paragraph of (ii) and that this whole section applies to both 360(2)(a)(i) and (ii).

Subsection (A) seemingly requires the use of groundwater treatment to achieve standards where such treatment is either practicable or in the public interest. This ignores other possibilities for meeting the standards. Thus while we agree that where groundwater treatment is not practicable, other alternatives are necessary, the reverse is not necessarily true. In addition, subsection (B)(II) presents problems as well. There are many circumstances wherein implementing containment to the maximum extent practicable would provide no significant increased benefit to the groundwater resource. For example, while a plume may be expanding, it may be doing so in a way which, due to dispersion, attenuation, biodegradation, etc., poses no significant threat to human health or the environment even though some violation of groundwater cleanup standards does occur near the source of the plume. If treatment of the portions of the plume which violates the standards is not practicable, it would probably in such circumstances, be a waste of money to do containment "to the maximum extent practicable."

WAC 173-340-360(4)(b)(iii). This subsection applies the "best available control technologies" requirement as set forth in the State's Clean Air Act to cleanup actions at a hazardous substance release site. As with the comment immediately above, the BACT statutory and regulatory scheme in most cases will not be applicable to a cleanup action. BACT was designed to be applied to gas streams under the control of an operator. It generally consists of such items as passage of the gas stream through a baghouse, a precipitator, a scrubber, or some such device. On the other hand, in most cases, air emissions from hazardous substance release sites will be fugitive emissions from soils or volatilizing organics. Again, the most likely form of cleanup will be some form of source control through removal, treatment, or containment. The use of an air emission control device will often not be practicable. This subsection should be rewritten to reflect that the BACT requirement will only be used in those situations for which it would qualify as an ARAR.

are simply no restrictions on what conditions may be imposed and, while the Department would certainly have the opportunity to make additional requirements if a party conducting an independent cleanup action did not meet all the requirements of the regulations, it should not be able to impose unjustified conditions or conditions which restrict the progress of the independent cleanup action. Since a party performing such an action does so at its own risk, the Department does not need this provision.

WAC 173-340-700. General Procedures.

Technical practicability must be considered in selecting a cleanup level. The establishment of cleanup levels in this section fails to adequately address technical impracticability, even though many standards developed from either Methods A or B or conditional cleanup levels may still be below limits of practicability by available methods. This section must be revised to provide a means for modifying cleanup levels based on impracticability. There have been several suggestions for how to accomplish this, with most involving some increase in the risk level range if necessary to allow for selection of a technically practicable response action. One possibility for carcinogens would be to allow for a deviation from use of the upper 95% confidence level, such as use of the most probable value, when the cancer potency factor for the contaminant in question has a great deal of uncertainty. Similarly, with non-carcinogens, a lower safety factor for the NAOEL could be used when necessary to allow a technically practicable response.

WAC 173-340-700(2). The last sentence of this subsection should be eliminated. There is nothing in the MTCA which states any goal of establishing cleanup levels "as close as possible to natural background levels." There is no automatic relationship between protection of human health and the environment and "natural background levels."

WAC 173-340-700(4). This section, along with the referenced sections which, in reality, establish the exposure assumptions, does not provide sufficient flexibility to give realistic estimates of maximum exposures. Procedures should be identified to allow a PLP to provide justifiable site-specific reasonable maximum exposure estimates for purposes of determining Method B cleanup standards.

WAC 173-340-700(5). This whole section has lost much of its meaning throughout this process. Initially, Method A compliance levels were intended to be very conservative levels which could be applied to routine cleanups. Method B was developed to provide a more flexible approach which could take the specifics of a particular case into account and thereby avoid some of the conservative assumptions in Method A where appropriate.

feasible alternative as only an interim action would likely result in the refusal of many PRPs to conduct the action in the first place if they are doing all that is technically feasible, but still gain no potential for release from liability. Furthermore, what they do in the way of technically feasible response actions could end up being counterproductive with respect to any new technologies that may be developed far into the future to do more.

Subsection (8)(e) is also subject to abuse. It indicates that one cannot extend the restoration time frame as a substitute for active cleanup actions which are technically practicable. The question of extending from what is not answered. For example, if the restoration time frame of one year could avoid the need for an expensive but technically practicable solution, would it make sense in all cases to implement the technically practicable solution at substantial cost. The same question could be asked with respect to one month or ten years.

WAC 173-340-440. Institutional Controls.

Ecology should revise this section to give itself some flexibility on the imposition of institutional controls. As currently drafted, this section would require the institution of such controls in the circumstances set forth in WAC 173-340-440(1). This would be satisfactory if the regulation applied only to the standard hazardous substance release site, such as an industrial facility. Ecology should keep in mind, however, that it is likely that these regulations will apply to large-scale residential cleanups and other situations involving off-site contamination. In such cases, Ecology may want to consider some form of institutional controls other than deed restrictions. Imposing deed restrictions on hundreds of homeowners with the attendant Ecology oversight may not be satisfactory to either Ecology or the homeowners. As this section is currently written, Ecology would have no flexibility under such circumstances.

WAC 173-340-450. Releases from Underground Storage Tanks.

WAC 173-340-450(2)(b). The requirement that the UST owner must remove as much of the hazardous substance from the UST as is necessary to prevent further release to the environment within 24 hours of the UST release is an absolute requirement that in many cases may not be possible. This requirement should be rewritten to allow some flexibility so that, while the target is to make the removal within 24 hours, the owner is not automatically in violation of the regulation if this is simply not possible.

WAc 173-340-450(8)(b). The requirement that a UST owner or operator "comply with any conditions imposed by the Department" when doing an independent cleanup action is not justified. There requires modification as set below if this subsection is to remain meaningful.

WAC 173-340-700(5)(d)(v). Subsection (B) should be eliminated for reasons set forth immediately above. Containment, isolation, and institutional controls are recognized methods for remediating hazardous substance releases such that human health and the environment are protected. Use of a conditional cleanup level should not be conditioned upon elimination of these alternatives. In addition, subsection (C) should be eliminated or changed. Conditioning the choice of a conditional cleanup level on the use of money saved by approval of the conditional level to fund actions "not otherwise required under applicable state and federal laws" is certainly not authorized by the MTCA and is probably illegal.

Furthermore, if the goal of this section is to encourage use of limited financial resources which provide the greatest net environmental benefit, the use of the funds only for actions that are not otherwise required by law is not always appropriate. A facility might, if required to meet a compliance cleanup level, simply not have sufficient monies to even comply with other environmental requirements. Instead, the company might be forced out of business. Certainly, the net environmental benefit is what should be obtained by this provision.

WAC 173-340-700(5)(e). This subsection should indicate that "cleanup levels shall not exceed concentrations established under subsections (5), (7), (8), (9), or ~~and~~ (10) of this section . . . ."

WAC 173-340-700(5)(f). This provision presents some significant difficulties in that the PQL established by U.S. EPA is often much more than ten times the method detection limits depending on the waste matrix. Thus, if one had a site where the PQL was greater than ten times the method detection limit, one could never conclude that the cleanup standards had been attained pursuant to this paragraph.

WAC 173-340-700(6)(a)(iii). This subsection should be deleted. As set forth above, Ecology does not have the authority to reserve the right to determine on an ad hoc basis "any other concentrations which the department determines are necessary to protect human health and the environment." The setting of such concentrations would be subject to further rulemaking and review. This subsection is not authorized by the MTCA and should be deleted. In addition, this provision may be unconstitutionally vague.

WAC 173-340-700(7)(a)(iii)(B). Ecology should establish an excess cancer risk range of 1×10^{-4} to 1×10^{-6} or, alternatively, establish similar flexibility through a change in

Conditional cleanup levels were intended to provide some relief from the strict levels set forth in A and B where institutional controls were developed or other appropriate factors pertained. However, after many changes in the tables reflecting the Method A compliance levels in order to make such levels justifiable or within some realm of rationality, Method B will now often result in more stringent cleanup levels than Method A. Likewise, with many of the assumptions that have changed regarding the conditional cleanup levels, they become almost indistinguishable from levels calculated using Method B. It certainly makes no sense to have a routine site be allowed to clean up to a certain level, but another site which is not as "routine" be required to clean up to a more stringent level even though it has much greater level of review and study.

WAC 173-340-700(5)(d)(i). The reference to subsection (8) at the end of this subsection should be deleted. We agree that where compliance cleanup levels established by Methods A or B are below area background concentrations, conditional cleanup levels should be established at concentrations that are equal to area background concentrations. The reference to subsection (8) completely nullifies the preceding portion of the subsection. That is because subsection (8) goes back to establishing cleanup levels equal to concentrations established under applicable state and federal laws, etc. Therefore, the reference to subsection (8) should be deleted.

WAC 173-340-700(5)(d)(ii). Likewise, reference to subsection (8) in this subsection should be deleted. Again, the intent of this subsection is to provide a process for setting a conditional cleanup level protective of human health and the environment, and while the general idea is good, the entire process is nullified by the reference to subsection (8) which sets cleanup levels that then cannot be modified. Furthermore, it is nonsensical, and contrary to the objectives of MTCA, to require a cleanup which would increase the overall threat to human health or the environment, whether or not concentrations specified in subsection (8) would be violated.

WAC 173-340-700(5)(d)(iii). Again, the reference to subsection (8) should be deleted, as it nullifies the remainder of the subsection. One can only be expected to do what is technically feasible.

WAC 173-340-700(5)(d)(iv). In this case, subsection (b) should be deleted. There is no reason to condition use of an alternate cleanup level on not using a containment or isolation technology. Both are well recognized as often being both technically feasible and fully capable of protecting human health and the environment. This provision would unduly limit the application of this subsection. In addition, subsection (8) the use of upper bounds confidence limits or other assumptions in the methodology. This is the range that EPA has established and it gives the agency some flexibility in determining cleanup levels. Establishment of a strict 1 x 10^{-6} risk may make some cleanups virtually impossible. Ecology should provide some greater flexibility in this determination.

WAC 173-340-700(7)(a)(iv). As set forth above in comments to Section 173-340-700(6)(a)(iii), the Department of Ecology does not have authority to reserve this unlimited discretion.

WAC 173-340-700(8). This subsection should emphasize that establishment of conditional cleanup levels should avoid levels for which attainment would require a treatment technology or methods or combination thereof that would cause a greater overall threat to human health and the environment.

WAC 173-340-700(8)(a)(iii)(B). This subsection should, at the least, be modified so as to adopt a 10^{-4}, as opposed to a 10^{-5}, upper limit on carcinogenetic risk.

WAC 173-340-700(8)(a)(iv). This subsection should be eliminated for the reasons set forth in comments to WAC 173-340-700(6)(a)(iii).

WAC 173-340-700(8)(b). This provision basically ensures that most sites with a mixture of contaminants will have the same conditional cleanup level as they will compliance cleanup level under Method B. This results from the fact that, again, the total excess cancer risk of 10^{-5} is used, which is the same total used for Method B. Since concentrations of many carcinogens at or below the detection limits would add up to a 10^{-5} risk, the two methods may become equivalent almost by definition.

WAC 173-340-705. General Principles.

WAC 173-340-705(6). It is appropriate that Ecology consider new scientific information as it becomes available. It is unclear how this subsection relates to the remainder of the substantive portion of the regulation actually setting cleanup standards. Does this mean that, notwithstanding the mandatory provisions of the regulation establishing cleanup levels, Ecology reserves the right to establish some other cleanup level based on "new scientific information"? If that is the case, and we think it should be, Ecology should make this point specific, either in a general portion of the regulation, or as subsections to the actual cleanup standards.

WAC 173-340-705(10). This provision indicates that <u>as a matter of policy</u> the Department defines various exposure parameters to be used when estimating cleanup levels under this chapter. This is far too limiting in that the standard exposure assumptions may be totally inappropriate for various site-specific conditions. For example, surface water cleanup standards require certain assumptions regarding fish consumption rates. These assumptions could be extremely far off base for given streams where there are not edible fish populations.

WAC 173-340-705(11)(e). The general assumption that measurements below the practical quantification limit should be assigned a value equal to the method detection limit does not seem consistent with the Department's approach with respect to assigning values below the method detection limit. The use of one-half of the practical quantification limit should also be used.

WAC 173-340-710. Applicable State and Federal Laws.

In this section, Ecology attempts to define "all applicable state and federal laws" to include those which are only relevant and appropriate, as opposed to legally applicable. Not only should these remain separate and distinct for reasons outlined above, but the NTCA may not allow requirements which are merely relevant and appropriate as defined in these proposed regulations.

WAC 173-340-720. Groundwater cleanup standards.

The reasonable maximum exposure for groundwater is generally based on drinking water being the highest beneficial use. Therefore, a cleanup level below a maximum contaminant level should not be required. Cleaning up groundwater to more stringent levels is clearly excessive and a waste of resources. It simply does not make sense to cleanup groundwater, especially at a compliance point where it is not being used, to levels presenting less risk than that allowed for public water supplies. For the same reason, a 10^{-6} risk level at the compliance point (which, through natural processes of biodegradation, dispersion and attenuation, would be much lower at the point of use) is inappropriate since any of the chlorinated public water supplies would present substantially more risk due to the presence of chloroform. We should not be expending limited resources to make groundwater at a compliance point substantially lower risk than our public drinking water supplies.

Requiring cleanups to comply with MCLG's and secondary maximum contaminant levels may also result in an unwarranted commitment of resources and should not be required unless, perhaps, if the MCLG's or secondary standards qualify as relevant and appropriate. In fact, it is doubtful that 2° standards are legally appropriate under MTCA since, in general, compliance with 2° standards is not necessary to protect human health or the environment.

Therefore, cleanup levels which meet or exceed health based MCLs will be protective of the highest beneficial use of groundwater and the regulation must state that cleanup in excess of such levels is not required. Use of secondary MCLs as cleanup standards requires case-by-case consideration and should not be an automatic standard.

WAC 173-340-720(1)(a)(ii). A new subsection (D) should be added. This subsection should make it clear that the use of groundwater as a source of drinking water will not be considered with regard to groundwater present in a man-made aquifer. For example, there are situations in which filling activity is at such a depth that groundwater has permeated portions of the fill. By its very nature as fill, usually industrial, it is not suitable as a source of drinking water. Therefore, there should be another category which automatically excludes that groundwater from consideration of drinking water purposes. Drinking water should be limited to natural aquifers.

WAC 173-340-720(1)(a)(ii)(B). Groundwater is often considered unfit for drinking with much lower levels of total dissolved solids than 10,000 mg/l. Hence, the definition of drinking water should not be dependent on this value and the last sentence of this subsection should be deleted.

WAC 173-340-720(2)(a)(iii). This subsection should be eliminated as beyond Ecology's authority. See discussion above pertaining to WAC 173-340-700(6)(a)(iii).

WAC 173-340-720(2)(a)(i). Table 1 raises several problems. First, several of the levels are still below the MCL. See above comments. Others have been included at levels equivalent to the MCL. This raises the question why some are set at the MCL and others substantially below it. Additionally, some values in the table have been set at the secondary MCL, which is also inappropriate. See comments above. Certain of the values in Table 1 would appear to be below the minimum detection level (see vinyl chloride and potentially PAH's). Also, the rationale for using total chromium is unclear since only hexavalent chromium is expected to present any risks at these levels.

While the purpose for establishing tables setting forth Method A compliance cleanup levels is presumably to provide consistent and clear levels at which routine cleanups can occur, these tables also present problems regarding the potential use by entities such as lenders, regulators and potential purchasers. If the tables are to remain, there should be a clear explanation of their intended use and the fact that they do not, of themselves, constitute ARARs or establish cleanup levels for a site. Instead, it should be explained they are designated cleanup levels that will be approved but may not be necessary at any given site.

WAC 173-340-720(3)(a)(i). See comments above. MCLG's and secondary drinking water standards should not be requirements of this section.

WAC 173-340-720(3)(a)(iii). This subsection should be modified as beyond Ecology's authority. See discussion pertaining to WAC 173-340-700(6)(a)(iii). In addition, WAC 173-340-720(3)(a)(iii)(E) should be revised to read:

> "(E) Concentrations which protect nearby surface waters. In general, these will be based on meeting chronic water quality criteria in the receiving water near the point(s) the groundwater enters the surface water. (See discussion regarding WAC 173-340-720(6)(d) below.)

WAC 173-340-720(4)(a)(ii)(B). The use of 10^{-5} for the total incremental cancer risk for a conditional cleanup level will, in most cases, result in conditional compliance cleanup levels identical to Method B cleanup levels. Thus, the whole purpose of the conditional cleanup level will be thwarted.

WAC 173-340-720(6)(c). The limitation of the point of compliance to the property boundary could create a substantial problem in many cases. For example, if hazardous substances are left on the cleanup site, but beyond the property boundary, in a contained position, the point of compliance would have to be within or underneath the contained substances. This could prove to be totally unworkable. There are certainly instances where the neighboring property owners will not sell the property so as to move the property boundary to alleviate this problem.

WAC 173-340-720(3)(a)(iii). This subsection should also be eliminated as beyond Ecology's authority. See discussion pertaining to WAC 173-340-700(6)(a)(iii).

WAC 173-340-720(6)(d). This provision <u>apparently</u> requires compliance with surface water standards within the groundwater as close as practicable to the interface between the groundwater and the surface water. It also indicates that a dilution zone to demonstrate compliance with surface water cleanup levels will not be allowed. This is simply inappropriate and does not reflect cleanup levels based on impacts to surface water as it should. If the cleanup level is based on aquatic surface water criteria, then compliance should be measured in the surface water, not in the groundwater. To the extent the cleanup levels are measured in the surface water, there will, by definition, be some dilution pertaining since groundwater will likely be substantially diluted as it enters the surface water.

To require meeting surface water criteria within the groundwater would result in needlessly expensive cleanup actions with no overall benefit to human health or the aquatic environment. These changes are also necessary to meet several of the other objectives for cleanup standards, including the preservation of the integrity of existing programs in a scientifically and legally defensible system. Comments regarding these other objectives are as follows:

1. The mixing zone regulation being developed by the state is acknowledging that even stormwater will not have to meet acute criteria at the end of pipe and will be eligible for a dilution zone.

2. Fresh water flows into salt water bodies both by surface flow and by ground water seep. Fresh water is acutely toxic to marine organisms due to the lack of salt, yet somehow marine organisms survive these events. The toxicity is naturally reduced (salt is added) by dilution.

3. WAC 173-201-035(2) Notes that "In brackish waters of estuaries, where the fresh and marine water quality criteria differ within the same classification, **the criteria shall be interpolated on the basis of salinity;"** Salinity changes happen only with dilution, so interpolation of standards imply some dilution whether or not a formal dilution zone has been assigned in a permit.

4. The determination of whether a dilution zone may be permitted is usually done in a permit on a case-by-case basis considering such things as the volume of flow and the volume of a receiving water, or the flow in the receiving water. The problem is that dilution zones are only allowed for authorized discharges under the NPDES system and ground water flow doesn't fit that neat category.

5. In the case of ground water flows into surface waters, the flow that would be associated with a contaminated site will (in most cases) be small relative to the total ground water flow to the surface water body. The flow in the surface water past the site may be quite large by comparison. The volume of the receiving water may be considerable. If the surface water is tidally influenced, the ground water may be diluted by tidal action in the water table before it even emerges. The hardness may change. Dissolved metals may bind to organic particles or precipitate out due to chemical changes as the ground water nears the point at which it will emerge. Once ground water emerges to a salt water body, it will very briefly be fresh water and then be diluted with the salt water. Hence, the fresh water standard would apply, at the hardness of the water when it emerged, and then the standard would change to a salt water standard, requiring interpolation over a salinity gradient. Such interpolation between standards,

already required by WAC 173-201-035(2), carries with it a de facto consideration of dilution. A comparable dilution consideration is appropriate for a discharge to fresh water.

In light of these facts, the following changes to WAC 173-340-720(6)(d) are suggested:

> "(d) At sites where affected ground water ~~discharges to nearby~~ enters a surface water, the cleanup level may often be based on protection of the surface water. The point of compliance in such a situation shall be in the receiving water near the point where the ground water enters the surface waters. ~~If a~~ conditional point of compliance ~~is approved at such a site it shall be located within the ground water and at an upland location that is as close as practical to the interface between the ground water and surface water~~ that monitors groundwater shall not incorporate a surface water standard unless it can be modified to reflect 1) the rate of ground water flow, 2) the area over which the flow emerges, 3) the currents in the adjacent receiving water, 4) the volume of water flowing past the area over which the ground water flow emerges, 5) physical-chemical transformations that may occur to the constituents of concern that result from the cross-media movement from ground water to surface water (including, if applicable, the change from fresh water to salt water). ~~At those sites, use of a dilution zone under WAC 173-201-035 to demonstrate compliance with surface water cleanup levels shall not be allowed.~~ Because these numerous factors are very difficult to assess, the preferred approach to demonstrate compliance with surface water standards is to require receiving water monitoring near the shore for the parameters of concern."

WAC 173-340-720(8)(a). This subsection requires analysis of unfiltered groundwater samples to demonstrate compliance, but allows (as a less preferred choice) filtered samples where it provides a more representative measure of ground water quality. Unfiltered samples do not properly characterize what is bio-available in groundwater and are not, in most cases, representative of contaminants that are mobile in the groundwater system. Filtered samples should be the preferred method for analysis.

WAC 173-340-730. Surface water cleanup standards.

This entire section should be deleted. Cleanups of surface waters are accomplished by source controls. If the sources are point sources, they are dealt with under the NPDES system and do not belong here. If the source of concern is a contaminated groundwater flow, that is handled under the cleanup of the affected groundwater and soils. With surface waters, dispersion and replacement is far more rapid than with ground water or soils.

WAC 173-340-730(2)(a)(ii). This subsection should be revised to indicate that federal water quality criteria are not automatically applicable, but should be required only as relevant and appropriate on a site-by-site basis depending on the nature of the organisms found at the site and the type of organisms upon which the water quality criteria were based.

WAC 173-340-730(2)(b). As set forth above, this subsection should be eliminated as beyond the authority of the Department of Ecology.

WAC 173-340-730(3). Comparison between Method B compliance cleanup levels and Method A compliance cleanup levels clearly demonstrates that Method B levels simply contain more requirements than those for Method A. Thus, Method B levels are more stringent than those for Method A, a result which isn't necessarily in keeping with the theory of the distinctions between Method A and Method B cleanup levels.

WAC 173-340-730(3)(d). As set forth above, this subsection should be eliminated as it is beyond Ecology's authority.

WAC 173-340-730(4)(d). As set forth above, this subsection should be eliminated as it is beyond Ecology's authority.

WAC 173-340-730(6). This subsection should be changed to read:

> "(b) Where hazardous substances are released to the surface water by a ground water ~~discharge~~ <u>flow</u> to the surface water ~~no dilution zone shall be allowed to demonstrate~~ compliance with surface water cleanup levels <u>shall be demonstrated by receiving water monitoring</u>. See WAC 173-340-720(6)(d) for additional <u>discussion concerning</u> ~~requirements in~~ this situation."

WAC 173-340-730(7)(d). As set forth above, measurements above the method detection limit but below the practical quantification limit should be assigned a value equal to one-half the practical quantification limit.

WAC 173-340-740. Soil cleanup standards.

WAC 173-340-740(2)(a). Table 2 has the same concerns as Table 1 with respect to the use of these tables and the necessary limitations on such use. In addition, there are several problems with this table. Several of the levels indicated are simply unrealistic with respect to many typical concentrations found in soils. For example, Ecology lists the arsenic cleanup level in soil as 20.0 mg/kg. Information from the Puget Sound region indicates that natural background is in the neighborhood of 40 mg/kg. The level of 20 mg/kg would be virtually impossible to attain. Likewise, the Environmental Protection Agency has determined that a lead cleanup level of 500 to 1,000 mg/kg is appropriate. The Ecology level of 250 mg/kg is without basis.

The PAH concentrations listed are also significantly below many common background levels and the chromium level listed doesn't specify whether it is intended to be total or hexavalent. Again, hexavalent chrome is the form of concern.

WAC 173-340-740(2)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(3)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(3)(c)(iv). This subsection should be eliminated as it is overly vague. It reserves the authority to Ecology to determine a more stringent cleanup level based on Ecology's determination that such levels are "necessary to protect the groundwater at a particular site." As there are no limits on what Ecology might determine is necessary, the regulation is unduly vague and, therefore, invalid.

WAC 173-340-740(3)(c)(v). This subsection should also be eliminated or rewritten, as it is unduly vague.

WAC 173-340-740(4)(b)(i)(A). This subsection requires that conditional soil cleanup levels shall be at least as stringent as concentrations equal to or less than one hundred times the ground water compliance cleanup level established in accordance with WAC 173-340-720. Since WAC 173-340-720 provides that in some cases groundwater could be required to meet surface water chronic criteria, without any dilution, this means that a conditional soil cleanup level could be equal to or less than one hundred times the surface water chronic criteria. The use of a factor of 100 is arbitrary here. The use of a factor of 100 for metals and high molecular weight organic compounds is far too conservative as has been repeatedly demonstrated in many cleanup actions, governmental tests, etc. Just as a more realistic factor should have been used for developing the numbers in Table 2 which were based on such a factor, the presumption of the factor of 100 should not apply to those metals and high molecular weight organic compounds. The application of surface water criteria to groundwater without consideration of dilution, is flawed and has been commented on elsewhere (see comments for WAC 173-340-720 (3) (a) (iii) (E). Accordingly, it would be an incredible leap of faith to set a soil cleanup standard based on an arbitrary factor applied to a groundwater cleanup level that was itself inappropriately set by a standard from an entirely different medium (surface water), which in all likelihood, may not have had any measurable impacts because of the much more rapid and intense processes of dispersion and dilution that occurs in surface waters.

WAC 173-340-740(4)(b)(iv). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-740(6)(d) and (e). These subsections will render the cleanup of soils in large non-industrial sites virtually impossible. First, there is no basis for establishing that all sites must automatically be cleaned to a depth of one foot. Moreover, there is no basis for establishing a presumption that the point of compliance will be 15 feet deep throughout the site. The point of compliance should be established on a site-by-site basis and should take into account all of the factors associated with that site, including site use, nature of hazardous substance, toxicity of that substance, mobility of that substance, applicability and effectiveness of institutional restrictions and other relevant factors. The one foot/15 feet requirements of these sections are arbitrary, have no basis, and are unworkable.

WAC 173-340-740(7)(g). Again, detectable levels below the practical quantification limit should generally be assigned a value equal to one-half the practical quantification limit.

WAC 173-340-745. Soil cleanup standards for industrial sites.

WAC 173-340-745(1)(b). Change the first sentence to read,

"To demonstrate industrial site use the site <u>or appropriate portions thereof</u> shall: ...."

A cleanup site may include both industrial and non-industrial land. The land that is industrial should not be required to meet the more stringent non-industrial criteria just because some of the cleanup site is not on industrial land.

WAC 173-340-745(1)(c). This subsection should be eliminated. First, there is no justification for setting soil cleanup levels on industrial property at the same levels as those used for residential use. Second, the phrase "as close as practicable" has no standards by which Ecology employees may be guided. Thus, it is unduly vague and should not be present in a regulation. This provision would disregard the reasonable maximum exposure rationale for these regulations.

WAC 173-340-745(2)(a). See comments re WAc 173-340-740(2)(a).

WAC 173-340-745(2)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAC 173-340-745(3)(c). As set forth above, this subsection should be eliminated as beyond Ecology's authority.

WAc 173-340-745(5). Unlike the case with groundwater, the proposed regulations regarding point of compliance for soil contamination do not take into account containment issues. For example, for soil cleanup levels based on the protection of groundwater, the point of compliance is required to be established throughout the site. However, for soil contamination which is remediated through containment, even though the soil throughout the site may exceed the standards, the groundwater would be protected and its point of compliance could be outside of the area that contains soil. For soil cleanup levels based on human exposure via soil ingestion, again the point of compliance is said to be established throughout the site at various depths. In containment situations this point of compliance would never be met even though no human ingestion could occur. This section needs rewording.

WAC 173-340-745(5)(d) and (e). These two subsections should be revised or eliminated in accordance with the comments to WAC 173-340-740(6)(d) and (e) above.

WAC 173-340-750. Cleanup standards to protect air quality.

The most important flaw in Section 750 is that it ignores Ecology's proposed rules for toxic air pollutants. Ecology's air program has released draft air toxics rules for new sources, and is working on draft rules for existing sources. These rules will include "acceptable source impact levels" (ASILs) for a large universe of toxic air pollutants. The new source rules expressly apply to sites undergoing cleanup under the MTCA. See proposed WAC 173-460-030(1)(b)(iii). The air toxics rules are more comprehensive and detailed than Section 750. For instance, they deal with such critical issues as dispersion modeling protocols and fugitive emissions.

Given this coverage, the worst thing Ecology could do would be to adopt a second set of rules covering the same subjects. This would violate the cleanup standard objective of preserving the integrity of existing programs. WAC 173-340-750 should contain nothing other than a statement that cleanup actions under this chapter must comply with the toxic air pollutant standards contained in WAC ch. 173-460.

If Ecology concludes that air emissions from cleanup sites must be subject to double regulation, Section 750 contains several significant problems. First, Section 750 contains protocols for deriving "Method A" and "Method B" cleanup levels. To maintain as much consistency with the existing program as possible, the regulation should specific that Method A will be used wherever WAC ch. 173-460 (the new source air toxics rules) specifies ASILs for the hazardous substances emitted at a sites.

Where other laws do not specify ambient concentration limits for the air pollutants emitted at a cleanup site, Section 750 directs Ecology to employ two formulas to derive cleanup levels. The formula for non-carcinogens directs the agency to employ a reference dose "as specified in WAC 173-340-705(7)." The latter section directs Ecology to employ an "inhalation reference dose," defined in WAC 173-340-200 as a daily inhalation exposure "that is likely to be without appreciable risk of adverse effects <u>during a lifetime.</u>" Section 750(7), however, demands compliance with this lifetime exposure limit <u>over a 24-hour averaging interval</u>. The use of a lifetime no-effects exposure level to set a 24-hour concentration limit has no basis in logic or science. Nor is there any scientific basis to use a child's weight and breathing rate to derive an ambient concentration limit that will produce no adverse health effects after a lifetime of exposure.

Some sites may emit hazardous substances that pose a short term health risk. Acute exposure limits may be needed for these sites. But such limits must be based on acute health effects projections or data. One source of such limits may be OSHA permissible exposure limits for short term exposures to various hazardous chemicals. It is irresponsible to base 24-hour ambient concentration limits on a lifetime exposure reference dose.

Another problem with Section 750 is that the conditions for approval of a conditional cleanup level (CCL) gravely restrict Ecology's authority to approve a meaningful CCL. For instance, a party whose site is already cleaner than background should not have to employ "best available control technology" to obtain a CCL. <u>See</u> comments on WAC 173-340-360(4)(b)(iii).

The continued use of the 10^{-5} and 10^{-6} risk levels for the air cleanup levels is even more problematic than the use of those levels for the other media. In most, if not all, of the urban areas of the state, for example, existing background risks exceed these levels. Expenditures to reduce air emission risks to these levels when the background is far greater than these levels would be wasteful at best, as would the necessary monitoring to establish the precise background level and sources of contamination surrounding an existing site.

Finally, Section 750, like other sections of the proposed cleanup standards, contains an impermissibly broad delegation of authority to Ecology program managers to set cleanup standards. The United States and Washington constitutions require that any grant of authority to a regulatory agency must be accompanied by standards to guide and confine the agency's discretion. Section 750 repeatedly invites Ecology to impose "Any other concentrations which the department determines are necessary to protect human health and the environment." See WAC 173-340-750(1)(a)(v), (2)(b), (3)(c) and (4)(c). This broad statement of intent does not provide sufficient guidance to meet constitutional due process standards.

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COMMENTS ON DRAFT ENVIRONMENTAL IMPACT
STATEMENT FOR CLEANUP STANDARDS

We believe that the DEIS is inadequate in that it does not carry out the requirements of the State Environmental Policy Act ("SEPA"), chapter 43.21C RCW, in several crucial areas. Its most significant general deficiency is its failure to confine itself to analyzing the environmental impacts of the proposed regulations. Instead, the bulk of the document, especially Chapters 1 -4 and 14, is devoted to justifying the policy decisions made by the Department of Ecology ("Ecology") in drafting the preferred alternative.

The most glaring indication of this failure is the use of a "Regulatory Evaluation of the Alternatives" at pages xiii - xiiii (sic) and in Chapter 14. Although WAC 197-11-440(8) allows the lead agency to include a discussion of other impacts relevant to the agency's decision, the SEPA regulations make it clear that such a discussion should not be the major focus of an EIS. WAC 197-11-448(1) states:

> SEPA contemplates that the general welfare, social, economic, and other requirements and essential considerations of state policy will be taken into account in weighing and balancing alternatives and in making final decisions. However, the environmental impact statement is not required to evaluate and document all of the possible effects and considerations of a decision or to contain the balancing judgments that must ultimately be made by the decisionmakers. Rather, an environmental impact statement analyzes <u>environmental</u> impacts and must be used by agency decisionmakers, along with other relevant considerations or documents, in making final decisions on a proposal. The EIS provides a basis upon which the responsible agency and officials can make the balancing judgment mandated by SEPA, because it provides information on the environmental costs and impacts.

(emphasis in original). This DEIS does not adequately separate Ecology's policy agenda from the environmental consequences of the proposed action, and by doing so presents confusing and biased information about the environmental impacts of the alternatives. Ecology's program goals should be clearly separated from the environmental analysis, so that an objective evaluation of environmental impacts is presented.

The DEIS also fails to comply with the requirements of SEPA in several specific respects. It does not analyze all reasonable alternatives available to Ecology. Secondly, the alternatives that are presented are not adequately analyzed. In addition, the document does not identify the significant adverse impacts of the alternatives that cannot be mitigated.

Alternatives Presented

WAC 173-11-440 requires an EIS to analyze reasonable alternatives. Reasonable alternatives "shall include actions that could feasibly attain or approximate a proposal's objectives, but at a lower environmental cost or decreased level of environmental degradation". Chapter 3 of the DEIS discusses "significant issues" and "options" that are in fact reasonable, feasible alternatives to the preferred alternative. For example, the DEIS states at page 3-2 that "[t]he acceptable level of protection is the essential policy question for site cleanups . . .". It then goes on to assume that the acceptable level of risk is 1 x 10-5. Yet it also identifies at page 4-16 other jurisdictions which have adopted other acceptable risk levels for cleanup standards. In fact, the federal government has adopted a range of 10^{-4} to 10^{-6} for federal Superfund sites. Obviously, then, there are other levels are reasonable and feasible. The environmental impacts for each risk level would be significantly different and an analysis of these differences is essential for a decisionmaker in adopting cleanup standards. Yet the DEIS does not present or analyze these levels as alternatives for consideration.

Alternatives Analysis

The DEIS assumes at page 6-3 that the measure of the impacts of the alternatives "is how much higher the levels of residual contamination are than the natural concentration levels of the hazardous substances". This assumption is a fundamental flaw in the analysis of environmental impacts. RCW 43.21C.030(c) calls for the preparation of a detailed statement of the "environmental impact <u>of the proposed action</u>" (emphasis added). The proposed action here is to adopt regulations for standards to clean up sites <u>that are already contaminated.</u> It is not an action to decide whether to contaminate pristine areas. Consequently, the DEIS should analyze and measure the impacts of the alternative standards by comparing levels of residual contamination with levels already existing on contaminated sites, as well as potential impacts of the remedial actions necessary to comply with the standards. Such a comparison would result in significantly different information than that contained in the DEIS and would allow decisionmakers and the public to see a more realistic comparison of the alternatives.

The DEIS also appears to endorse a procedure whereby further environmental analysis takes place <u>after</u> a decision on cleanup standards are made. The DEIS states at page 6-6:

> Because the standards and the preferred alternative are presently in draft form, a qualitative assessment was considered appropriate. Once the regulations are finalized, following public comment and internal review, additional quantitative assessments of impacts will be included in the final EIS.

This procedure, if followed, would directly contravene the major purpose of SEPA, which is to provide decisionmakers with information about the environmental consequences of their actions <u>before</u> a decision is made. <u>See, e.g.</u>, <u>Juanita Bay Valley Community Association v. City of Kirkland</u>, 9 Wn.2d 59, 73, 510 P.2d 1140, 1149 (1973). If the information to prepare a more quantitative analysis of the alternatives is available, it must be done now so that it is available to decisionmakers and the public before the regulations are "finalized".

In addition, the DEIS does a poor job of describing mitigation measures, and contains virtually no discussion of the unavoidable adverse impacts of each alternative. The "Technical Summary" states at page xii only that the action "will generally result in some unavoidable adverse impacts", and Chapter 13 does not even have a section on unavoidable adverse impacts. This is not compliance with WAC 197-11-440(6)(c)(v).

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REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT

APRIL 1, 1990 - MARCH 31, 1991

PART I. OVERVIEW

TABLE OF CONTENTS

This is the *Regulatory Program of the United States Government* issued pursuant to Executive Order 12498, and the first of the Administration of President George Bush. Part I, entitled "Overview," describes the functions of the 1990 Regulatory Program, and how it relates to the overall structure of regulatory oversight President Bush has adopted. Part II, entitled "The Regulatory Program by Agency," contains the regulatory programs for 1990–1991 of 24 agencies.

Regulation is a key governmental tool for moderating public health and safety risks and for protecting the effective operation of free markets. At the beginning of a new decade, the United States Government continues to utilize regulations to meet a number of significant challenges: cleaning up our environment, protecting the health and safety of our consumers and workers, and maximizing the value of our human capital. New regulations will be needed. Old ones will have to be overhauled or taken off the books.

Presidential regulatory oversight is a process necessary to ensure that agencies of the United States Government meet those challenges in a manner consistent with Administration policies and statutory direction. This document reflects the President's commitment to that process. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has been charged with continuing its role as steward of Presidential regulatory oversight.

The regulatory review process is intended to help resolve the continuing dilemma America faces: regulation is necessary, but its cost can increasingly put the United States at a competitive disadvantage in a global economy. Costs have to be paid if the Government is to mandate reduction in some of the risks that living in a highly complex, modern society poses to Americans. And regulatory interventions may be necessary to protect the free markets that are the underpinning of America's free enterprise system. However, the costs of regulation add to the prices that consumers pay for goods and services and that industries charge for exports. President Bush seeks a regulatory structure that appropriately balances the benefits and costs of Federal regulations for the country's long-term well-being, and ensures that the regulatory activity of the Government produces net benefits for its citizens.

Two Executive orders establish principles of sound regulatory management for agencies to follow in developing regulations. The orders combine with the Paperwork Reduction Act of 1980 to ensure that the paperwork and regulatory burdens the Government imposes are necessary, tolerable, and cost-effective.

Both Executive orders are the outgrowth of successive Presidents' efforts since the 1960s to establish procedures for Executive regulatory oversight. Executive Order 12291 (see appendix I for the complete text) sets out fundamental regulatory principles: it directs agencies to justify the need for regulations, weigh their costs and benefits, and choose the most cost-effective regulatory options. It also directs OIRA to review the agencies' rationales and assumptions and to ensure that agency regulations are consistent with Presidential policies and statutory intent. Executive Order 12498 established the *Regulatory Program of the United States Government* as a vehicle for agency regulatory planning and coordination (see appendix II for the complete text).

Taken together, the two Executive Orders form a coherent framework for creating a regulatory structure that is humane, effective, and economically sensible. Congress and the President, through the enactment and approval of agency enabling legislation, have charged agencies with the ultimate responsibility for acting within their specific policy areas. Presidential regulatory oversight promotes a careful weighing of such actions, and also seeks to harmonize conflicts between competing agency mandates. It thus fulfills the President's Constitutional obligation to manage the executive branch. The establishment of a formal oversight process during the past decade provides a method for rationalizing the Federal Government's maze of regulatory requirements, increasing benefits and lowering costs. In the 1990s, this process will guide the continuing evolution of regulations that are both effective and prudent.

The Regulatory Program of the United States and Executive Order 12498

Executive Order 12498 requires the annual publication of the *Regulatory Program of the United States Government*. This document outlines the regulatory priorities and important upcoming actions of all the regulatory agencies. Most important is what the document represents—a process for planning and coordinating agency actions in advance of rulemaking.

The 1990–1991 Regulatory Program sets forth each agency's objectives for the 1990 program year, spanning April 1, 1990, to March 31, 1991. It outlines the issues agencies see as requiring immediate attention, as well as the steps each agency is taking to ensure the cost-effectiveness of the regulatory approach it proposes. The Regulatory Program thus allows Congress and the American people to understand the policy directions of the regulatory agencies. The actions listed in the Regulatory Program represent the major initiatives of the regulatory agencies, and may be substantially revised over time, through Administration decisions to guide and coordinate these agency actions.

Future Policies and Proposed Conferences

This overview discusses areas for further action on regulatory issues, including possible next steps in reforming economic regulation, efforts to develop a system of regulatory budgeting, key issues in developing scientific risk assessments as a part of the development of sound regulatory policy, and the use of information as a regulatory tool. The review also provides a discussion of OMB's final regulatory impact analysis (RIA) guidelines, and OIRA's response to the comments received on the draft guidelines published for comment in the 1988 Regulatory Program. Earlier Regulatory Programs identified some major inconsistencies and shortcomings in Federal agency analysis of major regulatory actions.[1] Because of these inconsistencies and shortcomings, and the potentially large net benefits that would result from improved analysis, OMB recognized the need for specific guidelines for preparing RIAs. The revised final RIA guidelines are published in this Regulatory Program in Appendix V.

OIRA plans to seek advice on these regulatory issues from the affected public and from academic and other experts on regulations and regulatory policies

[1] Regulatory Program (1986–1987), pp. xix–xxvi; Regulatory Program 1987–1988, pp. xv–xxii; and Regulatory Program 1988–1989, pp. 31–37.

and practices. OMB is considering a series of workshops and conferences, open to the public, on the following:

- The impact of the regulatory reform initiatives of the 1980s;
- Guidance and coordination for ranking risks (risk assessment, management, and communication);
- The potential for development of the regulatory budget concept; and
- The use of information strategies and public disclosure requirements to complement and possibly replace more direct regulatory intervention.

Introductory discussions of these topics are presented below in the sections entitled "Reforming Economic Regulation," "Regulatory Review and the Case for a Regulatory Budget," "Current Regulatory Issues in Risk Assessment," and "Information as a Regulatory Strategy." OIRA seeks comments on all these topics. Please send comments to the Office of Information and Regulatory Affairs, Washington, DC 20503.

The Council on Competitiveness

Maintaining American economic competitiveness into the next century depends on the initiative and innovativeness of the private sector. The Federal Government can foster competitiveness by encouraging a vigorous and competitive market environment both in this country and in the world economy. One of the more important steps the Federal Government can take in promoting a competitive market environment is to avoid unnecessary regulation.

Government regulation has an important role in advancing societal goals—such as public health and safety—where the market fails to protect such goals. But regulation can also impose substantial costs on American business, State and local governments, and consumers that burden our competitiveness abroad and our welfare at home. It is thus important to assess, on a continuing basis, the need for both new and existing regulations, balance the immediate objectives of such regulation with the broader objectives of promoting the Nation's welfare, and promote a reliance on markets wherever such opportunities exist.

To assist regulatory oversight, President Bush announced in *Building a Better America*, on February 9, 1989, that Vice President Quayle would chair the Council on Competitiveness:

> The Council will review regulatory issues, and such other issues as may be referred by the President, bearing on competitiveness. In reviewing regulatory matters, the Council will be continuing the work of the former President's Task Force on Regulatory Relief—chaired in the Reagan Administration by then Vice President Bush.

The Council will work closely with OIRA to augment the regulatory review process, ensure that the benefits of regulation outweigh their costs, and coordinate development of legislative and administrative initiatives to reduce unnecessary regulatory burdens.

Reforming Economic Regulation

The United States has traditionally relied on a "cost-of-service" approach to setting prices or rates for public utilities or other industries that are considered to be "natural monopolies." Cost-of-service regulation involves cumbersome and highly judgmental determinations of (1) the value of a firm's rate base, that is, its assets dedicated to providing a good or service; (2) the fair rate of profit (return) on those assets; and (3) all other costs associated with providing the good or service. In addition, the process of determining the "price" involves substantial costs to both the regulatory commission and the regulated industry because of complex and time-consuming ratemaking procedures.

Most students of public utility regulation believe that regulated industries are not as efficient or as innovative as they could be.[3] When regulated rates are tied directly to an individual firm's costs, those firms have a reduced incentive to achieve long-term cost reductions. Under this regulatory system, all cost savings are eventually "passed through" to consumers; the firm benefits only during the period of "regulatory lag," (that is, until rates are adjusted to reflect the firm's reduced costs). Firms subject to cost-of-service

[3] See Alfred E. Kahn, *The Economics of Regulation: Principles and Institutions*, New York: John Wiley & Sons, 1970, Chapter 2, pp. 47-94.

regulation may thus have an incentive to overinvest in capital, to inflate their rate bases, and to develop technologies that are more capital-intensive than optimal. The fact that allowable industry profits are a function of such past investments tends to discourage conversion to newer, more cost-effective technologies. In addition, cost-of-service regulation can distort the choice of research and development (R&D) projects and the level of R&D efforts by underrewarding R&D investments in some cases and overrewarding such investments in other cases.

Finally, cost-of-service regulation has often been associated with government-imposed restrictions on entry into the industry. This further reduces a regulated firm's need to seek innovations so as to remain competitive.[3]

DEREGULATION AS AN APPROACH TO REGULATORY REFORM

The last decade has witnessed regulatory reform in many of the industries once subject to traditional rate-of-return regulation. Some industries, such as trucking and airlines, have been almost completely deregulated because they are subject to pervasive competition. Others, like railroads, have been deregulated only as to services they perform in a competitive context.

In the railroad industry, the Interstate Commerce Commission (ICC) has used its authority under the Staggers Rail Act of 1980 to rely on market forces where railroads face intense competition from trucks. Similarly, in the telephone industry, customer-premises equipment has been completely deregulated, and entry has been allowed in the long-distance market, although the Federal Communications Commission (FCC) continues to regulate American Telephone and Telegraph's (AT&T's) rates. Such reductions in the scope of regulation, where feasible, eliminate enormous regulatory costs and burdens for both industry and the Government, reduce the prices paid for goods and services by consumers, and contribute to the efficient allocation of the Nation's resources.[4]

Regulatory reform has yielded substantial benefits for the consumers and firms served by the natural-monopoly industries. For example, the Council of Economic Advisers reported that airline deregulation has produced gains to airlines and travelers of approximately $15 billion per year.[5] Trucking deregulation has generated estimated savings in excess of $30 billion annually.[6] Finally, about $15 billion in annual benefits have resulted from an increased reliance on market forces in the railroad industry.[7]

ALTERNATIVE APPROACHES: FORMS OF INCENTIVE REGULATION

In those markets that cannot reasonably be expected to produce competitive outcomes, alternative approaches to cost-of-service regulation might improve industry performance over traditional public utility regulation. Various forms of "incentive regulation" are being considered, including the use of a cap on rates or prices. Price-cap regulation operates by setting (or capping) initial rates—or an index for a group of rates—and then allowing adjustment of the cap based on variables or factors that reflect changes in the underlying cost of providing service and are, at the same time, beyond the influence of the regulated firm. The crucial feature of price-cap regulation is that it severs the direct link between rates and individual company costs that characterizes cost-of-service regulation. If price caps are adjusted only for changes in costs that occur independently of a firm's behavior, improvements in efficiency that lower costs will translate into higher profits. Thus, a price-cap approach provides substantial incentives for cost-reducing efficiency improvements.

There are some difficult issues, however, that must be addressed in designing a price-cap approach. These issues include setting the price cap for the base period, designing a mechanism for adjustment in the price cap that reflects changes in the underlying cost of providing service, and avoiding a deterioration in the quality of service. A base price arbitrarily adjusted over an extended period by the consumer price index, for example, may bear little resemblance to the costs of providing service. The cumulative effect of an inappropriate adjustment would either lead the regulated industry to bankruptcy or allow it to realize monopoly profits. If frequent intervention by a regulatory agency is required to correct cumulative errors in adjusting the price cap, price-cap regulation may

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[3] For example, Kahn reports that in those situations where it is feasible, "Competition is far more powerful than regulation in forcing businesses to explore the slope of their cost functions and elasticity of their demands, and to push down costs." Ibid., p. 112.

[4] While such partial deregulation has the potential to increase efficiency and reduce regulatory burden, it may also provide opportunities for the regulated firm to avoid regulation, by shifting accounting costs from nonregulated operations to the regulated rate base.

[5] *Economic Report of the President*, Washington, DC: Executive Office of the President, 1988, p. 206.

[6] Diane S. Owen, *Deregulation in the Trucking Industry*, Washington, DC: Federal Trade Commission, Bureau of Economics, May 1988.

[7] Christopher C. Barnekov and Andrew N. Kleit, "The Efficiency Effects of Railroad Deregulation in the United States," *International Journal of Transport Economics*, Volume 17, No. 1, February 1990.

result in the same disincentives or distortions as cost-of-service regulation.

In some cases, though, there may be industry-specific ways of developing an effective approach for rate-cap adjustment. For example, the price of similar products or services in competitive markets could be used as a basis for adjusting the price cap in those markets where the regulated firm retains market power. Alternatively, a rate-cap approach might be appropriate where some markets are in transition to a workably competitive structure and a price-cap approach is designed to be in place for a limited period before regulation would be removed completely.

RECENT INITIATIVES

The Administration has already taken some important steps that would reduce the scope of regulations or increase the incentives of regulated firms to behave efficiently. These steps include support for the deregulation of natural gas wellhead prices, the transmittal of legislation that would deregulate oil pipelines, actions to improve electrical power regulation, and recent FCC action to establish an alternative incentive-based regulation of long-distance telecommunications services. Each of these initiatives is described below.

Oil Pipeline Regulatory Reform

Oil pipelines have been federally regulated since 1906. However, the industry differs from the trucking or railroad industries in that regulation has been directed at prices only, without any restrictions on entry or exit. Therefore, the pipeline industry has remained quite competitive even with Federal regulation. In fact, Federal regulatory agencies—first the ICC, and now the Federal Energy Regulatory Commission (FERC)—set pipeline rates that, in most cases, have been nonbinding because competitive forces have kept actual rates lower.

In 1984 the D.C. Circuit Court of Appeals, construing the existing legislation, ordered the FERC to develop a methodology for imposing strict rates of return on oil pipelines based on historical costs. Strict rate regulation could have serious consequences for both the industry and the Nation by discouraging new investment in pipelines and perhaps even deterring the development of new oil fields.

Characteristics of the Industry

In 1986, the Department of Justice (DOJ) completed a study of the oil pipeline industry.[8] It concluded that although pipelines appear to have all the characteristics of a natural monopoly, they actually face significant competition in many markets from other pipelines, from local crude oil producers and refineries, and in port areas, from river barges and ocean-going tankers. Recognizing this, the DOJ study examined the markets in which oil pipelines operate, to distinguish between competitive markets and those where pipelines may have substantial market power. The study concluded that all crude pipelines and most product pipelines (accounting for over 70 percent of 1983 barrel-miles) were operating under sufficiently competitive conditions in all of their markets to be safely deregulated.

The Regulatory Reform Initiative

As a result, proposals for regulatory reform were developed to deregulate those pipelines operating under competitive conditions while using price-cap regulation of 11 product pipelines that could potentially exercise market power. On July 28, 1989, the Administration transmitted the Oil Pipeline Regulatory Reform Act to Congress, that would deregulate all competitive pipeline markets.[9] For the small proportion of remaining markets where pipelines retain market power, the bill would set base prices at their current level (unless that level is determined to be the result of market power). In these remaining markets, it would adjust base prices semiannually by a "Competitive Pipeline Price Index," which is calculated as the change in average revenue per barrel-mile (total revenue of all the competitive pipelines divided by total barrel-miles). This index is independent of the actions of an individual pipeline, but it effectively captures events that affect the cost of operation.

For those 11 pipelines that would still be regulated under the bill, system-wide regulation to address market power in discrete geographic areas does not appear to be the best regulatory solution. Traditional cost-of-service regulation (setting a maximum allowed rate of return) provides the pipeline substantial flexibility in setting prices in individual geographic markets. This flexibility makes regulation ineffective in these noncompetitive markets. Cost-allocation problems alone preclude the use of this approach on a market-by-market basis. Price caps, on the other hand, offer a means of deregulating these pipelines in all but those specific areas where they may exercise market power. Price caps also avoid the generic drawbacks of cost-of-service regulation, which distorts investment, innovation, and entry.

[8] U.S. Department of Justice, *Oil Pipeline Deregulation*, Washington, DC: Author, May 1986.

[9] An earlier version was transmitted to Congress by the Administration in August 1988.

The proposed Oil Pipeline Regulatory Reform Act approach promises to be both less intrusive and more effective than traditional cost-of-service regulation. First, most of the industry can be deregulated, and second, regulatory attention can be focused on the small number of noncompetitive markets. Because the majority of the industry is competitive, prices in the regulated markets can be pegged to prices charged in competitive markets. By targeting markets for regulation instead of entire pipelines, this approach not only reduces the scope of regulation, but more effectively regulates the few pockets of market power that remain.

Natural Gas Price Regulation

The Natural Gas Act (1938) imposed Federal rate regulation on interstate pipelines carrying natural gas, on the theory that they were natural monopolies. The Supreme Court's *Phillips* Decision (1954) extended rate regulation to wellhead prices for natural gas sold to the interstate market. Legislative efforts to deregulate wellhead prices for natural gas began immediately after the *Phillips* Decision, but failed for a variety of reasons.

In the 1970s, the regulation of the wellhead price for gas sold in the interstate market created severe shortages in the "consuming" States in the Midwest and along the Eastern Seaboard, in that unregulated gas could be sold at higher prices in the intrastate markets of producing States. This disparity in performance between the regulated interstate and the unregulated intrastate markets served to highlight the problems with wellhead price regulation. The Natural Gas Policy Act of 1978 extended Federal regulation of wellhead prices to the intrastate market in order to "correct" the distortions that had been created by dual regulation. This bill eliminated the regulatory distinction between the interstate and intrastate markets, replacing it with a new kind of two-tiered market: a deregulated market for certain "new" categories of gas, and an "old" gas market price-capped at a lower level.

This distinction between "old" and "new" gas introduced a new distortion into the natural gas market. Investments that would enhance the production of "old" gas were not undertaken, while far more costly investments were made to bring "new" gas into production. These production decisions, coupled with an unexpected fall in the world price of oil, produced the anomalous result of both higher gas prices and an attendant surplus (or "bubble") in natural gas production.

The FERC has taken several steps to introduce more freedom into natural gas markets in the past few years. The chief effect has been to allow consumers greater opportunity to shop around for the lowest-cost suppliers. Two statutory constraints have limited the effect of FERC's administrative reforms: the ceiling price on "old" gas that makes it uneconomical to produce; and the inability of consumers to arrange transportation from the low-cost supplier to the point of consumption.

The Reagan administration made several attempts to deregulate natural gas wellhead prices, including the transmission to Congress of a comprehensive proposal entitled "Natural Gas Consumer Regulatory Reform Amendments of 1983." Despite the efforts of the Administration and extensive debate by both the House and the Senate, however, neither House passed a bill.

Legislation in the Bush Administration

The success of oil deregulation and the experience with regulation in natural gas markets has persuaded most people that deregulation of wellhead prices is in the interest of consumers. In his first budget message to Congress, President Bush expressed the belief that "... at long last the Federal Government should fully decontrol natural gas." As a result, the Administration actively supported legislation as it moved through Congress, and President Bush signed the legislation phasing out wellhead price controls on July 26, 1989.

Electric Power Regulation

The Federal Power Act (FPA) was enacted as part of the Public Utility Act of 1935, in part to provide Federal rate regulation over interstate sales and transmission of electricity by investor-owned electric utilities. Regulation of "intrastate" sales remained with the States. The Public Utility Holding Company Act (PUHCA) was also enacted as part of the Public Utility Act of 1935, to dismantle inefficient holding-company systems and regulate the nonrate aspects of public utility holding companies. Congress, however, exempted certain public companies from PUHCA (e.g., holding companies whose electric utilities operate within a single State or in contiguous States).

Since many electric utilities were not interconnected in 1935, the potential for interstate sales was limited to roughly 10 percent of all sales of electricity. However, since 1935 interconnected transmission systems have become commonplace. Today, interstate sales account for in excess of 25 percent of all power sales. Essentially all wholesale electricity sales, with the exception of sales in Hawaii, Alaska, and part of Texas, are subject to the jurisdiction of the Federal Energy Regulatory Commission (FERC).

In the 1970s, increases in both fuel prices and the cost of new generating capacity brought to an end several decades of declining electricity prices (in real terms). The resulting reduction in growth of demand left the industry with capacity under construction far in excess of its needs. Ratepayers generally bore the brunt of the cost of this excess capacity, although in a number of States shareholders absorbed these costs, because regulators did not allow the costs of some plants into the rate base (either because they were imprudently constructed or because the plant was not needed).

This experience prompted utility managers and regulators to seek solutions to the traditional rate-of-return regulation problem that limits shareholders' return on investment while exposing them to potentially large risks. One approach is to determine, up front, the prudent costs needed to meet future demand growth, thus limiting utility regulatory risk. Another approach is to provide incentive-return mechanisms. Under incentive-return approaches, the utility or power producer realizes as additional profit a portion of any reduction in costs from "projected" cost levels that can be achieved by the power producer. FERC has the flexibility under current statutes to carry out either approach, although the Commission has to date not utilized the first approach (up-front prudence). In its regulation of cogenerators, small power producers, and so-called independent power producers, the Commission has explored the use of incentive mechanisms.

Under the Public Utility Regulatory Policies Act of 1978 (PURPA), incentives were provided for encouraging the development of cogeneration and small power-production facilities, termed "qualifying facilities" (QFs). These incentives include relief from most Federal and State regulation and an obligation on the part of electric utilities to take power from these facilities at a price equal to the utilities' "avoided cost." However, PURPA places restrictions on the size of small power-production facilities and the technologies that qualify for these incentives. In addition, setting avoided cost through an administrative process has proven to be difficult and subject to influence. To overcome this problem, competitive bidding is now being used in some States. Experience to date suggests that some administrative changes are warranted to make the current program more effective in meeting the need for additional capacity in the 1990s.

FERC attempted to address some of these problems with PURPA in several notices of proposed rulemaking (NPRMs) issued in 1988. Two NPRMs dealt with the administrative determination of avoided costs and some other technical aspects of the QF program. A third NPRM addressed the legality of using bidding to set avoided costs under PURPA.

The experience gained from PURPA indicates that the generation of electric power may no longer exhibit the attributes of a natural monopoly. As a result, FERC has issued a fourth NPRM that deals with the regulatory treatment of a new class of power producers, the independent power producers (IPPs). These producers do not qualify for PURPA incentives, but fall outside of the traditional regulatory concern of the FPA because they lack market power. The NPRM proposed to relax rate and nonrate regulation of these producers (so long as they lack market power) under the FPA to allow them to charge the market price. Although these rulemakings are still pending and are unlikely to go forward in their current form, FERC is approving a relaxed regulatory treatment in a wide variety of case-by-case situations.

Apart from these several NPRM initiatives, FERC also recognizes the importance of transmission access. A report of the FERC Transmission Task Force to the Commission in the fall of 1989 concluded that open access to transmission was essential for the full development of competitive generation markets. The task force examined various proposals for encouraging broader access and found that, for the time being, no legislative action was necessary. As a result, the Commission recently conditioned approval of the PP&L-UP&L merger on acceptance by the utility of an open-access transmission policy. This was the first time such conditioning authority has been claimed or used by the Commission.

Finally, PUHCA may be a major barrier to the development of IPPs and a competitive market for procuring electric capacity. Legislation is now before committees in the Senate and the House to reform PUHCA by providing an exemption for wholesale generators that lack market power.

Telecommunications Regulation

The settlement of the Government's antitrust suit against AT&T resulted in AT&T's divestiture of its local operating companies in 1984. As a result, AT&T can no longer control access to local exchange markets to monopolize long-distance service. Since the divestiture, competition in long-distance markets has increased. In 1980, prior to divestiture, AT&T earned about 96 percent of long-distance revenues.[10] By late 1988, AT&T's share of revenues had fallen to about 78 percent, while the shares of two competitors, MCI and Sprint, had grown to about 10 percent and 7 percent, respectively.[11] In addition, AT&T now faces one or more competitors in all but a few geographic areas. Finally, AT&T appears to be responding to competitive pressure from its rivals. It has been modernizing its network and taking other steps to cut costs and provide better service.[12] AT&T also recently filed a request with the Federal Communications Commission (FCC) to cut its rates to reflect reductions in costs, including access charges.[13]

Under current FCC regulations, only AT&T is considered to be dominant among the major long-distance carriers, and therefore subject to regulation. MCI, Sprint, and other providers are presumed to be nondominant carriers; they must report their costs and prices to the FCC, but their rates of return are not constrained.

AT&T claims that rate-of-return regulation imposes heavy administrative costs—for example, it spent about $250 million on regulatory compliance in 1984.[14] However, the primary problem associated with rate-of-return regulation of long-distance service is that it substantially limits carrier incentives to reduce their costs. Cost inflation may take the form of excessive investment in capital, or the even more profitable practice of cross-subsidization—accounting procedures that shift costs from a firm's unregulated businesses to its regulated ones. The effect of this real (or accounting) cost shifting is regulatory evasion that raises the allowed prices for the regulated product or service. In the context of the current market structure of long-distance telecommunications, rate caps may offer a significantly more efficient regulatory alternative.

The FCC's Price-Cap Approach to Incentive Regulation

Effective July 1, 1989, the FCC began implementing price-cap regulation of AT&T long-distance services. Under this new incentive regulatory scheme, AT&T's rates are separated into three baskets of services that are regulated by means of a price cap. The FCC will also monitor carrier operations, profits, and service quality under price caps, and, at the end of three years, it will conduct a comprehensive review of the entire price-cap approach. The FCC believes that this approach will provide the carrier with greater flexibility to reduce costs and at the same time it will significantly streamline the tariff filing process.

The rates in each of the service baskets will be subject to a formula that reflects changes in the cost of doing business plus an annual 3 percent decrease in rates, to reflect AT&T's historic gain in productivity, including a consumer productivity dividend of 0.5 percent.

The first of these service baskets involves residential and small-business services. AT&T will be permitted to change prices for the six separate categories in this basket so long as the aggregate weighted price for all services in the basket does not exceed the price cap. In addition, AT&T may raise prices in any of these categories a maximum of about 5 percent per year above the change in the price-cap index without triggering a rate review. Increases greater than the annual limit must be justified to the FCC's satisfaction by additional cost data. As an added protection to residential users, the FCC is requiring that AT&T calculate an average residential rate for all services in the residential basket and guarantee that this average rate will not increase by more than 1 percent per year.

The second basket covers "800" services, a market where the FCC believes AT&T still retains substantial market power. Rates for individual service categories in this service basket cannot increase by more than 5 percent annually without triggering detailed review by the FCC. The final basket consists of all other AT&T business services, the most competitive portion of the telecommunications market. Rate increases or decreases larger than 5 percent annually in any of these categories would trigger more detailed review by the FCC.

As noted above, AT&T currently faces one or more competitors in most of its markets, and this competition is expected to be sufficient, in the absence of regulation, to discipline AT&T's pricing in these markets. Since the Federal Communications Act of

[10] M. Porter, "Competition in the Long Distance Telecommunications Market: An Industry Structure Analysis," (Appendix A to AT&T Comments to FCC in CC Docket No. 87-313).

[11] A. Myerson, "Ganging Up on the Big Boys," *New York Times*, October 16, 1988, p. F5.

[12] J. Guyon, "AT&T's Third-Quarter Net Rose 17 Percent; $5 Billion Write-Off Possible for Year," *Wall Street Journal*, October 21, 1988, p. A2.

[13] J. Guyon, "AT&T to Cut Long-Distance Rates by 3.8 Percent," *Wall Street Journal*, October 18, 1988, p. A5.

[14] National Telecommunications and Information Administration, *NTIA Regulatory Alternatives Report*, Washington, DC: Author, July 1987, p. 22.

1934 may prevent the FCC from moving to complete deregulation, the FCC believes that a price-cap approach will improve competitive incentives and provide the management flexibility necessary to allow efficient behavior in long-distance telecommunications. AT&T's competitors will assure that service quality will be maintained and that some of the gains of this more flexible regulatory approach will be passed on to the consumer.[15]

Finally, the FCC is continuing to explore the application of incentive approaches to local telephone exchange carrier (LEC) access charges and has asked for public comment on a specific price-cap approach. Since most LECs have a monopoly in their local markets, local exchange is likely to require long-term regulation. The FCC has proposed changes in its current tariff-filing rule which would replace its current rate-of-return regulatory model with a price-cap approach that directly limits local exhange carriers' rates. Under the proposed price-cap approach, local exchange carriers would file tariffs annually. Carriers would also be required to file quarterly service-quality-monitoring reports to avoid any degradation of service to the consumer. LECs would still be required to file rate-of-return reports annually as a check to ensure that prices remained just and reasonable, as required by the Communications Act of 1934. The FCC is currently reviewing comments on the proposal.

Setting up a regulatory incentive approach for the LECs presents a more difficult problem because, under long-term regulation, cumulative errors in the method that is used to adjust the price cap over time may result in a cap that is too high, allowing the firm to charge the monopoly price, or a cap that is too low, forcing the firm into bankruptcy. The possibility of a cap that is too high is much less of a problem in markets that are in transition to competition, since market forces will tend to discipline the firm's pricing even in the absence of a binding cap. For this reason, it is much more important for regulation of local exchange markets to devise an adjustment mechanism that closely tracks the LECs' costs without actually being tied directly to these costs.

While further study should be done, one possible approach would be to base the price-adjustment mechanism for each LEC on an index of the costs of all other LECs. This would divorce the allowed prices for each LEC from its own costs while maintaining a fixed link between costs and prices system-wide.[16] In addition to increasing the efficiency of Federal regulation, implementation of such a system by the FCC could encourage States to shift to a similar price-cap mechanism for local telephone services, increasing the efficiency of State regulation and, possibly, permitting the elimination of State restrictions on new competitive entry into the provision of local exchange services.

NEXT STEPS

There continue to be some important areas where improvements are needed in Federal regulation of prices and entry—especially in the energy area. Progress in these areas presents a greater challenge, because it is more difficult to identify appropriate regulatory solutions. Incentive regulation approaches, properly tailored for application in each industry, could provide regulated firms with greater flexibility to pursue innovative approaches and ultimately reduce costs to the consumer. As a result, an assessment of next steps for regulatory reform in these areas should be undertaken.

Regulatory Review and the Case for a Regulatory Budget

Executive Order 12291 requires the evaluation of individual regulatory actions to assure that new rules yield the greatest net benefit to society.[17] Some argue that a more comprehensive process is needed, as a complement to the Executive Order 12291 process, in order to control the substantial aggregate costs that Federal regulation places on the American economy. One approach that has gained widespread interest in recent years is the development of a regulatory budget process. A regulatory budget would be implemented by setting overall caps on the total cost of Federal regulation and the regulatory costs imposed by individual agencies. Supporters of this approach argue that it would provide a decentralized process allowing each agency (within the allowed level of total regulatory costs) the flexibility to select a regulatory strategy

[15] The United Kingdom adopted a price-cap regulatory approach for British Telecom in 1984, and recent evidence on British Telecom's performance suggests that this approach has succeeded in improving efficiency.

[16] In developing an LEC cost index, one would have to examine how factors such as business volume affect unit costs.

[17] Because this review process tends to concentrate on individual regulations, OMB also develops the Regulatory Program, pursuant to E.O. 12498, as an annual review of the scope of the major regulatory initiatives, to provide a broader perspective on the major forthcoming regulatory actions.

that best meets its basic goals. At the same time, it would require both Congress and the Executive Branch to recognize explicitly the increasing regulatory burden on the private sector and the need to address tradeoffs among different regulatory programs.

REGULATORY PROGRAMS: ANALOGUE TO FEDERALLY FUNDED PROGRAMS

Federal regulatory programs are in many ways similar to directly funded Federal programs. The expenditures that regulations require, for example, have many of the same effects on production, employment, prices, and growth as budget outlays. The Federal Government taxes and borrows to fund programs, diverting those resources from the private sector. Regulations similarly divert these resources when businesses are forced to borrow, increase prices, or reduce dividends, to finance compliance.

Furthermore, the expenditures required by regulations may be an alternative means of achieving policy objectives that otherwise might be accomplished through budget outlays, taxes, or loan guarantees. Regulations, for example, may require firms to treat their wastewater before discharging it. Another alternative would be for the Government to build or improve sewage treatment plants. The basic allocative effects are similar, although one approach might prove more efficient.[18] Thus, regulations and federally funded programs raise many similar economic issues.

Because of these similarities in the effects of direct Federal expenditures and private expenditures caused by Federal regulatory programs, supporters of the regulatory budget approach argue that there are important reasons—analogous to those justifying the fiscal budget process—to establish a process to account for and coordinate Federal regulation. Such a process would provide more information to the public on the cost of regulation, and would establish the same kind of public accountability that applies to the fiscal budget.

FIRST STEPS AND PROPOSALS IN REGULATORY COST BUDGETING

The regulatory budget process could evolve, over time, as did the fiscal budget process, beginning with the use of currently available information.[19] Analysis of regulatory costs began in 1974 when President Ford issued Executive Order 11821, which required agencies to prepare inflation impact statements for their major regulations. Presidents Carter and Reagan both issued additional Executive orders to extend, refine, and tighten this requirement. Agencies are now required to list all significant planned regulatory activities in the Regulatory Program, but they only need to prepare regulatory analysis for certain "major" regulations, generally ones with a projected impact of over $100 million.

This Regulatory Program moves the regulatory oversight process towards a regulatory budget process, but it does not yet deal systematically with the overall effect of regulatory activities, in that there is as yet no method for estimating the annual incremental costs that regulations impose.

President Reagan, in issuing the Economic Bill of Rights on July 3, 1987, proposed requiring cost estimates for legislative proposals, as well as for all new and proposed regulations. These "financial impact statements" were to include evaluations of the costs to the general economy and consumers, and of the impact on the international competitiveness of U.S. industries. These estimates were to be available for public comment and criticism, improving decisionmaking on regulations and legislation.

Requiring a "regulatory cost ceiling" in any legislation that imposes costs on the private sector and State and local governments would be a logical next step. Each new statute would include a cap on the total costs agencies could impose on the non-Federal sector in implementing a program. The ceiling could not be breached without legislative approval of a higher ceiling or offsetting changes in other regulatory programs that would keep total private-sector costs within the limit.

[18] There may be other differences as well. For example, a reliance on regulation may have different implications for income distribution.
The incentives for working, saving, and investing may also be different under Federal regulatory programs than for an income tax program.
Tax liability is more directly tied to earnings, profits, and interest income than are regulations. Regulation may more closely resemble
user fees and excise taxes.

[19] The accounting concepts used for Government outlays and receipts have been continually refined as the fiscal budget evolved from
the Treasury Act of 1789. However, a comprehensive Federal budget system was not established until the Budget and Accounting Act of
1921. The accounting principles and standards for the budget have continued to change as a result of both executive and legislative action.
The information-collection budget has evolved in a similar manner. The Federal Reports Act of 1942 first required agencies to measure
and control the paperwork burdens they impose. Executive Order 12174, entitled "Paperwork," was issued on November 30, 1979. The
Order required agencies to plan and budget paperwork requirements, in much the same way as their fiscal budget requests. The Paperwork
Reduction Act of 1980 directed OMB to establish general policies and procedures for controlling information collections.

Supporters of this system argue that it would provide an incentive for better estimates of the costs of legislative proposals and a basis for an explicit discussion of the costs and tradeoffs of such proposals. High cost ceilings would focus attention on the expected benefits of the program, and alternative approaches; cost ceilings that were too low would prevent agencies from issuing implementing regulations. Such an approach would, needless to say, give agencies an incentive to choose regulatory approaches that would produce the greatest benefits at the lowest costs.

ISSUES AND AREAS FOR FURTHER STUDY

While the fiscal budget process provides a continuous record of actual expenditures, there is no comparable record of the cost of meeting regulatory requirements.[20] Members of Congress and the past two Administrations have considered developing an accounting framework to record direct regulatory expenditures, but more work needs to be done to solve the practical accounting problems inherent in measuring the private expenditures that Federal regulations mandate. These include:

- Developing a record of actual expenditures while minimizing the recordkeeping burden on the private sector;
- Identifying an appropriate "baseline," recognizing that some costs would be incurred even in the absence of Federal regulation; and
- Estimating the costs of forgoing certain products where Federal regulation prohibits production or distribution.

Each of these raises difficult issues in designing an effective regulatory budget process. For example, the costs of banning a product are not directly measurable and can only be estimated using complex statistical models. However, measuring only the direct compliance costs for oversight purposes creates a bias toward banning substances and products instead of controlling them.

As a first step in determining the feasibility of the regulatory budget concept, OMB has begun systematically to collect the costs of all significant published regulatory actions. Analysis of these data should aid in the development of ways to overcome the problems of regulatory budgeting, uncover unforeseen problems in developing cost estimates, and more fully refine a workable regulatory budgeting process.

Current Regulatory Issues in Risk Assessment and Risk Management

Many Federal agency regulatory decisions are intended to reduce risks to human life and health. Government regulations control which agricultural chemicals may be used to reduce insect damage, increase farm yields, and improve the quality of food products. Other rules govern hazards in the Nation's workplaces and emissions from its factories. There are regulations directing the way in which automobiles must be manufactured, commercial aircraft maintained, and trains operated. Hardly any widespread human activity that entails risk is free of some degree of social control, often achieved through government regulation.

Regulatory decisions involving risk require agencies to address questions such as, "How safe is 'safe'?" and "How clean is 'clean'?" When government agencies promulgate regulations intended to reduce a risk or mitigate a hazard, they are engaging in what has become known as *risk management*. These policy choices inevitably involve consideration of both the risks entailed by the underlying activity and the social consequences of regulatory intervention. Thus, the first challenge of risk management is to set priorities to determine which risks are worth reducing and which are not.

For government to carry out its risk-management responsibilities, there must be an extensive investment in the careful assessment and quantification of risks. The term *risk assessment* means the application of credible scientific principles and statistical methods to develop estimates of the likely effects of natural phenomena and human activities.

The need to keep risk assessment and risk management separate has long been the objective of responsible public officials. In 1983, the National Academy of Sciences (NAS) studied the process of managing risk

[20] Researchers, using different methods, assumptions, and time periods, have formed incomplete estimates by adding up the cost of individual regulations. These estimates accordingly show considerable variation for current annual costs ranging from $60 billion to $175 billion a year—5 to 15 percent of current Federal outlays.

in the Federal Government and offered the following recommendations, among others:

> *Recommendation 1:* Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[21]

> *Recommendation 2:* Before an agency decides whether a substance should or should not be regulated as a health hazard, a detailed and comprehensive written risk assessment should be prepared and made publicly available. This written assessment should clearly distinguish between the scientific basis and the policy basis for the agency's conclusions.[22]

The belief that risk assessment and risk management should be kept separate enjoys widespread support among professional risk-assessment practitioners and risk-management officials.[23] Others have emphasized the importance of ensuring that policy biases do not distort the analysis of alternative risk-management choices.[24] The NAS principles have also have been endorsed by a number of Federal agencies, including the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS).[25]

Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.

This section explores some of the continuing difficulties that plague the practice of risk assessment, and describes briefly their policy implications. It can be summarized in three observations:

The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude. Many risk assessments are based on animal bioassays utilizing sensitive rodent species dosed at extremely high levels. Conservative statistical models are used to predict low-dose human health risks, based on the assumption that human biological response mimics that observed in laboratory animals. Worst-case assumptions concerning actual human exposure are commonly used instead of empirical data, further exaggerating predicted risk levels.

Conservative biases embedded in risk assessment impart a substantial "margin of safety". The choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments. Estimates of risk often fail to acknowledge the presence of considerable uncertainty, nor do they present the extent to which conservative assumptions overstate likely risks. Analyses of risk-management alternatives routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action. Decisionmakers and the general public often incorrectly infer a level of scientific precision and accuracy in the risk-assessment process that does not exist.

Conservatism in risk assessment distorts the regulatory priorities of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address more substantial threats to life and health. Distortions are probably most severe in the area of cancer-risk assessment, because many conservative models and assumptions were developed specifically for estimat-

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[21] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC: National Academy Press, 1983 (hereinafter, *NAS Risk Management Study*), p. 151.

[22] Ibid., p. 153.

[23] For representative views of risk-assessment practitioners see, e.g., Lester B. Lave, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, DC: Brookings, 1981; Lester B. Lave, "Methods of Risk Assessment," Chapter 2 in *Quantitative Risk Assessment in Regulation*, Lester B. Lave, ed., Washington, DC: Brookings, 1982, esp. pp. 52–54. For representative views of risk-management officials see, e.g., William D. Ruckelshaus, "Science, Risk, and Public Policy," *Vital Speeches of the Day*, Volume 49, No. 20, August 1, 1983, pp. 612-615.

[24] See, e.g., Howard Kunreuther and Lisa Bendizen, "Benefits Assessment for Regulatory Problems," and Baruch Fischhoff and Louis Anthony Cox, Jr., "Conceptual Framework for Regulatory Benefits Assessment," Chapters 3 and 4, respectively, in *Benefits Assessment: The State of the Art*, Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower, eds., Dordrecht, Netherlands: D. Reidel, 1986, pp. 44–45, 59–61.

[25] See U.S. Office of Science and Technology Policy, "Chemical Carcinogens: A Review of the Science and Its Associated Principles," Principle 29 (50 FR 10378, March 14, 1985, hereinafter, *OSTP Risk Assessment Guidelines*); U.S. Environmental Protection Agency, "Guidelines for Carcinogen Risk Assessment," 51 FR 34001 (September 24, 1986, hereinafter, *EPA Carcinogen Risk Assessment Guidelines*); U.S. Department of Health and Human Services, *Risk Assessment and Risk Management of Toxic Substances*, April 1985, p. 20.

ing upper bounds for these risks. Risk-assessment methods with similar conservative biases are less common elsewhere, particularly in those areas where real-world data are available, or where the mechanism by which injury or illness occurs is better understood.

A renewed commitment to the NAS recommendations is clearly warranted. As quantitative risk assessment plays an increasingly significant role in risk management, the need to separate science from policy becomes ever more important, if either process is to maintain public confidence. As former EPA Administrator William D. Ruckelshaus has noted:

> Risk assessment...must be based on scientific evidence and scientific consensus *only*. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk.[26]

ALTERNATIVE RISK-ASSESSMENT METHODOLOGIES

Risk assessments of chemical substances in general (and of possible carcinogens in particular) involve a mixture of facts, models, and assumptions. There is considerable debate concerning the scientific merits of the models and assumptions commonly used in risk assessments. In some cases, a scientific consensus has developed to support a particular model or assumption. In other instances, however, certain models and assumptions are relied upon because they reflect past practices rather than the leading edge of science. Furthermore, a scientific basis for several of the most critical models and assumptions simply does not exist.

Most scientists agree that these models and assumptions impart a conservative bias: that is, they lead to risk projections that the actual (but unknown) risk is very unlikely to exceed. These "upper-bound" estimates are often useful as a screening device, to exclude from regulatory concern potential hazards that are insignificant even under worst-case conditions. Unfortunately, upper-bound risk estimates are routinely employed for altogether different purposes, such as estimating the likely benefits of regulatory actions. Policymakers are required to act on the basis of biased representations of both the magnitude of the underlying hazard and the extent to which Government action will ameliorate it.

Contemporary risk assessment relies heavily upon animal bioassay and epidemiology. Each approach has theoretical advantages and disadvantages. In practice, both can be misused to bolster preestablished conclusions. The following discussion emphasizes problems in carcinogenic risk assessment, because the prevention and cure of cancer plays such a major role in policy issues involving risks to life and health.

Animal Bioassay

Animal testing enables scientists to estimate risks ex ante, before human health effects materialize, whereas epidemiological studies can only detect such effects ex post. In addition, animal tests can be conducted under tightly controlled laboratory conditions, which provide more reliable estimates of exposure and avoid many of the confounding factors that often plague epidemiological investigations. The relatively short lifetimes of experimental mammals (such as rats and mice) allow scientists to ascertain the possible effects of long-term exposure in just a few years.

Animal testing suffers serious limitations, however, arising from certain critical assumptions. Despite its routine application, there is no accepted scientific basis for the assumption that results can be meaningfully extrapolated from test animals to humans.[27] Some scientists believe that animal data should not be used in assessing human health risks.[28]

Another critical limitation is the reliance on very high doses to generate adverse effects in test animals.[29] A mathematical model must be used to bridge the gap between these high-dose exposures and the low-dose exposures more typically faced by people. Many different mathematical models can be constructed to fit the data at high doses. These models often vary enormously, however, in their predictions of risk at low doses.

Beyond these unavoidable methodological constraints, the results of animal bioassays may be subject to conflicting scientific interpretation or strongly influenced by the choice of research method.

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[26] William D. Ruckelshaus, (*op. cit.*), p. 614.

[27] *OSTP Guidelines*, Guideline 8, p. 10376.

[28] See, e.g., Bruce Ames, Renae Magaw, and Lois Swirsky Gold, "Ranking Possible Carcinogenic Hazards," *Science*, Vol. 236, April 17, 1987; Gio Batta Gori, "The Regulation of Carcinogenic Hazards," *Science*, Vol. 208, April 18, 1980.

[29] *OSTP Guidelines*, Guideline 11, p. 10377.

Tissue preparation and histology present obvious opportunities for error, as experts may disagree as to how slides should be interpreted.[30] This problem generally is not significant at high doses, where malignancies are often obvious. At low doses, however, pathologists often differ in how they distinguish tumors from hyperplasia. Subjectivity cannot be avoided where such interpretations of the data must be made.[31]

Epidemiology

Epidemiology is attractive because it largely avoids these two problems. It focuses on observable human health effects instead of on hypothesized outcomes based on animal experimentation, and it relies upon real-world exposures to generate empirical data. Many of the serious problems associated with animal studies can be avoided, allowing researchers to develop risk estimates that are directly related to human health.

Unfortunately, epidemiological research suffers from its own set of limitations. For example, retrospective studies often have difficulty correlating morbidity and mortality with exposure to specific substances. Exposure data are commonly lacking, incomplete, imprecise, or affected by systematic recall or selection biases. Furthermore, the risks these studies seek to detect are often very small relative to background, thus making statistically significant effects difficult to observe. When health effects are latent, correlating exposures to illness is even harder.

Besides these unavoidable methodological limitations, epidemiological studies often suffer from outright bias. Many studies employ scientifically questionable procedures aimed at demonstrating positive relationships between specific substances and human illness.[32] Some researchers use inappropriate statistical procedures to "mine" existing databases in search of associations. One result of these practices is that epidemiological studies often display contradictory results.[33]

Despite these constraints, properly conducted animal bioassays and epidemiological studies both have useful roles to play in quantitative risk assessment. Indeed, they are complementary. The usual weaknesses of epidemiological investigations—unreliable exposure data, confounding effects—are readily avoided in laboratory experiments on animals. The weaknesses of animal bioassays—high- to low-dose extrapolation, animal-to-man conversion—do not arise in epidemiological studies. Careful risk assessment incorporates both types of analysis to ensure that the emerging picture of human health risk is as complete as possible, and that inferences derived from this picture are themselves internally consistent.

ISSUES IN RISK ASSESSMENTS DERIVED LARGELY FROM ANIMAL BIOASSAYS

Animal bioassays tend to dominate current risk assessments. An important reason for this is that the derivation of dose-response relationships is a critical regulatory motive for performing quantitative risk assessment. Animal studies are ideally suited to serve this purpose by virtue of the controlled conditions under which dose and response can be calibrated. Epidemiological studies often are relegated to providing merely a "reality check" to ensure that the implications of animal bioassays are plausibly consistent with real-world experience. Because of this heavy emphasis on animal testing, the focus here is on several major problems that arise with respect to risk assessments primarily based on the results of animal bioassays.

The Use of Sensitive Test Animals

To enhance the power of animal tests, scientists typically rely on genetically sensitive test animals. It

[30] In the original analysis of the rat bioassay used to derive the dose-response function for dioxin, 9 of 85 controls were said to develop liver tumors. An independent review of this data resulted in 16 of the 85 controls being classified as having such tumors. See U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2, 3, 7, 8-TCDD, Appendix A*, EPA/600/6-88/007Ab, June 1988 (hereinafter, *Dioxin Risk Assessment Appendix A*), pp. 2–3.

[31] Colin N. Park and Ronald D. Snee, "Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis," Chapter 4 in *Risk Management of Existing Chemicals*, Rockville, MD: Government Institutes, 1983, p. 56.

[32] Alvan R. Feinstein, "Scientific Standards in Epidemiological Studies of the Menace of Daily Life," *Science*, Vol. 242, December 2, 1988, pp. 1257–1263.

[33] Linda C. Mayes, Ralph I. Horowitz, and Alvan R. Feinstein, "A Collection of 56 Topics with Contradictory Results in Case-Control Research," *International Journal of Epidemiology*, Vol. 17, No. 3 (1988), pp. 680–685.

is unclear whether these species accurately mimic biological responses in humans.

Some test species are extremely sensitive. For example, approximately one-third of all male B6C3F1 mice, a common test species, spontaneously develop liver tumors.[34] The same phenomenon occurred in an important bioassay concerning dioxin using female Sprague-Dawley (Spartan) rats. Tumors observed in dosed animals were predominantly located in the liver. However, approximately one-fifth of the animals in the control group also developed liver tumors.[35] The relevance of elevated liver tumors in hypersensitive species has been questioned by scientists and is not universally considered probative evidence of carcinogenicity. Nevertheless, cancer risk assessments often proceed on the assumption that these data are sufficient to conclude that a substance is indeed a carcinogen.[36]

The reliance on sensitive test animals also biases risk assessments in a more subtle way. It establishes powerful incentives to search for and develop increasingly sensitive test species. As test animals become more sensitive, repeated testing using identical protocols will tend to result in higher and higher estimates of risk even if all other factors are held constant.

Selective Use of Alternative Studies

In their respective risk-assessment guidelines, both OSTP and EPA recommend that relevant animal studies should be considered irrespective of whether they indicate a positive relationship.[37] In practice, however, studies that demonstrate a statistically significant positive relationship routinely receive more weight than studies that indicate no relationship at all.[38] For example, the plant growth regulator daminozide (Alar) and its metabolite unsymmetrical 1,1-dimethylhydrazine (UDMH) recently received B2 classifications ("probable human carcinogen"). Each of these classifications was based on a single positive animal bioassay.[39] Overcoming such a classification requires, at a minimum, two "essentially identical" studies showing no such relationship.[40] In the case of Alar and UDMH, however, a more stringent test was apparently applied: Three high-quality negative studies showed no significant effects; these studies appear to have received little or no weight in the classification decision.[41]

Selective Interpretation of Results

Risk-assessment guidelines generally give the greatest weight to the most sensitive test animals. Thus, if a substance has been found to cause cancer in one

[34] Ames *et al.*, *(op. cit.)*, p. 276.

[35] *Dioxin Risk Assessment Appendix A*, pp. 2–3.

[36] See Ames *et al.*, *(op. cit.)*, p. 276 (arguing that such data are irrevelant); *OSTP Guidelines* Guideline 9, p. 10377 (concluding that such data "must be approached carefully"); and *EPA Carcinogen Risk Assessment Guidelines*, p. 33995 (making the policy judgment that such data are sufficient evidence of carcinogenesis). Liver tumors dominated in EPA's dioxin risk assessment. See *Dioxin Risk Assessment*, appendix A, pp.2–3.

[37] See *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 33995.

[38] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33999–34000. A single animal test that shows a positive result "to an unusual degree" (p. 33999) is sufficient to warrant at least a B2 classification ("probable human carcinogen"), even if this result occurs in a species known to have a high rate of spontaneous tumors. A strong animal bioassay or epidemiological study showing no evidence of carcinogenic effect cannot overcome this presumption (p. 34000).

[39] See "Second Peer Review of Daminozide (Alar) and UDMH (Unsymmetrical 1,1-dimethylhydrazine)," Memorandum from John A. Quest to Mark Boodee, U.S. Environmental Protection Agency, OPTS, May 15, 1989 (hereinafter, *Alar/UDMH Internal Peer Review No. 2*). This internal OPTS panel reviewed several recent studies on Alar and UDMH.

One study of Alar yielded a statistically significant increase in common lung tumors in mice, but only for one of three dosage levels. Results were not statistically significant at one higher and two lower dosages, and controls also displayed unusually high tumor incidence. 90% of the lung tumors in dosed mice were benign, versus 89% in the controls.

One study of UDMH yielded statistically significant increases in common lung and uncommon liver tumors in mice, but only for the higher of two dosages. 97% of the lung tumors in dosed mice were benign, versus 100% in the controls. 29% of the liver tumors in dosed mice were benign; no tumors were observed in the controls.

Prior studies that purported to show a carcinogenic response had been judged inadequate by EPA's Scientific Advisory Panel, an external peer review group. The Office of Pesticides and Toxic Substances (OPTS) panel noted that a different internal EPA risk-assessment panel (the Carcinogen Assessment Group) considered these studies sufficient to justify B2 classifications when it evaluated them for EPA's Office of Solid Waste and Emergency Response. Despite the scientific controversy, the OPTS panel interpreted these prior studies as "supporting evidence" under EPA's risk-assessment guidelines.

[40] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33995 (establishing the need for replicate identical studies showing no effect), and p. 33999 (establishing the minimum requirement of two well-designed studies showing no increased tumor incidence to warrant a "no evidence" determination).

[41] *Alar/UDMH Internal Peer Review No. 2*, pp. 6, 8, 9. EPA's scheme for carcinogen classification is itself an issue among scientists. See, e.g., U.S. Environmental Protection Agency, Risk Assessment Forum, *Workshop Report on EPA Guidelines for Carcinogen Risk Assessment*, EPA/625/3-89/015, Washington, DC: March 1989, pp. 21–26.

species or gender but shown to exhibit no effects elsewhere, the results pertaining to the sensitive species or gender typically will be used to develop estimates of human-health risks. For example, if male mice develop cancer from a substance but female mice and rats of both genders do not, then the results from the male mouse often will be used to derive estimates of cancer risks to humans.[42]

Once a positive result has been obtained in an animal bioassay, a substance often will be provisionally classified as a probable human carcinogen. The statistical burden of proof then shifts to the no-effect hypothesis. Because it is logically impossible to prove a negative, however, this practice establishes a virtually irrebuttable presumption in favor of the carcinogenesis hypothesis.

Severe Testing Conditions

Current risk-assessment protocols require the use of very high doses. Unfortunately, high doses are often toxic for reasons unrelated to their capacity to cause cancer. A common procedure is to use what is called the maximum tolerated dose (MTD), which is the most that can be administered to a test animal without causing acute toxicity. At such exposure levels, substances often cause severe inflammation and chronic cell killing. For example, formaldehyde causes nasal tumors in rats when administered in high doses. However, MTD administration severely inflames nasal passage tissues. It is therefore unclear whether the cancers induced are caused by formaldehyde per se or by the toxic effects of high doses.

Results such as these have caused some scientists to question the validity of rodent tests performed at the MTD for estimating human health risks that arise from exposure at low doses.[43] By combining very high doses with highly sensitive test subjects, some animal bioassays are predisposed to discover apparent carcinogenic effects.

Relevance of Animal Bioassay Results

An important reason why animals vary in their sensitivity is that they have different physiologies, metabolic processes, reproductive cycles, and a host of other species-specific characteristics that largely result from unique evolutionary paths. Each of these factors needs to be carefully considered in evaluating the significance of animal data with respect to human health. This is recognized in both the OSTP and EPA guidelines, but it is often neglected when the guidelines are applied to specific substances.[44]

The most important assumption in this regard is that animal test results can be meaningfully extrapolated to humans. A recent study of chemicals tested under the auspices of the U.S. National Toxicology Program shows that this assumption can lead to the erroneous classification of many chemicals as probable human carcinogens.[45] Positive associations have been obtained in either rats or mice for half of 214 chemicals tested. However, results were consistent across these two genetically similar species only 70 percent of the time. If it is assumed that rodent bioassays have the same sensitivity and selectivity with respect to human carcinogens as they do between rodent species, and it is further assumed that 10 percent of all chemicals are in fact human carcinogens, then 27 of every 100 randomly selected chemicals would be misclassified as probable human carcinogens. Only three chemicals would be misclassified as noncarcinogens. Thus, "false positives" would be 9 times more common than "false negatives."[46]

Of course, this ratio of false positives to false negatives reflects highly conservative "upper-bound" assumptions concerning sensitivity and selectivity. Given the high degree of similarity between rats and mice and the limited resemblance between rodents and humans, the sensitivity of rodent bioassays with respect to human carcinogenicity is probably much lower than 70 percent. Furthermore, other research indicates that selectivity may be as low as 5 percent.

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[42] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33997 (data from long-term animal studies showing the greatest sensitivity should generally be given the greatest emphasis).

[43] See, e.g., Ames *et al.*, *(op. cit.)*, pp. 276–277.

[44] *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 34003 (responding to comments on the draft guidelines and affirming agreement with OSTP Guideline 25).

[45] Lester B. Lave, Fanny K. Ennever, Herbert S. Rosenkranz, and Gilbert S. Omenn, "Information Value of the Rodent Bioassay," *Nature*, Vol. 336 (December 15, 1988), pp. 631–633.

[46] *False negatives* occur when a test fails to detect effects when they are in fact present. *Sensitivity* refers to the capacity of a test to minimize false negatives. *False positives* occur when a test appears to detect effects that in fact are absent. *Selectivity* refers to a test's ability to minimize false positives. The 9 to 1 ratio of false positives to false negatives calculated by Lave *et al.* assumes that both selectivity and sensitivity equal about 70%.

Adjusting only for this lower selectivity suggests that false positives are almost 30 times more common than false negatives. This raises serious questions concerning the practical utility of the current approach to animal bioassays for the purpose of quantitative risk assessment.[47]

Other factors should also be considered when relying upon animal bioassay results as the primary basis for quantitative risk assessments. For example, certain substances are toxic or even carcinogenic by one pathway but not by others. Nevertheless, animal bioassay protocols often emphasize the most sensitive pathway. As long as human exposure is likely to arise the same way, then this choice may be reasonable. However, the pathway to which the test species is sensitive sometimes reflects an exposure route that is implausible or irrelevant for humans. For example, formaldehyde causes nasal tumors in rats at 12 times the rate observed in the next most sensitive animal species. This extreme sensitivity may be related to the fact that rats breathe only through the nose.

There may be important differences between animals and humans that make specific tumors irrelevant. For example, some chemicals cause cancer in the zymbal gland of the rat; because humans lack such a gland it is unclear whether these results matter in estimating human health risk. Other substances induce cancer through biochemical mechanisms not found in humans.

A greater controversy surrounds the question whether the same weight should be given to benign and malignant tumors. The scientific consensus is that benign and malignant tumors should be aggregated only when it is scientifically defensible to do so.[48] In practice, however, benign and malignant tumors are routinely aggregated unless a strong case can be made *against* the practice.[49] The difference between these default assumptions is significant: One approach counts only carcinomas that *are* present, whereas the other counts tumors that *might become* carcinomas. In an extreme case, a substance that promotes benign tumors but never causes cancer could be classified as a probable human carcinogen simply because benign and malignant tumors are treated equally.

In addition, tumor incidence is commonly pooled across sites to obtain a total estimate of carcinogenic effects.[50] This implicitly assumes that cancer induction is independent across sites and not the result of either metastasis or the same biological mechanism. Given the extreme sensitivity of test species and the regular use of MTD administration, other explanations for tumors occurring at multiple sites appear just as plausible.

The Choice of Dose-Response Model

No single mathematical model is accepted as generally superior for extrapolating from high to low doses.[51] Consequently, Federal agencies often use a variety of different models. Rather than being a scientific footnote to the risk-assessment process, however, the choice of model is actually an important policy issue. The multistage model appears to be the most commonly used method for estimating low-dose risks from chemicals, and there are two major sources of bias embedded in this choice: its inherent conservatism at low doses, and the routine use of the "linearized" form in which the 95 percent upper bound is used instead of the unbiased estimate.

The *multistage model* essentially involves fitting a polynomial to a data set, with the number of "stages" identified by the number of terms in the polynomial. Since animal bioassays rarely have more than three dose levels, it is unusual to see applications of the multistage model with more than two stages. Although the multistage model enjoys some scientific support because it is compatible with multistage theories of carcinogenesis, in practice the model fails to include enough stages, due to the absence of sufficient alternative exposure cohorts.

The multistage model typically yields low-dose risk estimates that are higher than most other models. For example, when five different dose-response models were analyzed in a recent risk assessment of cadmium, estimates of cancer risks at moderate doses varied by a factor of 100. This difference among

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[47] Lave *et al., (op. cit.)*, p. 631. Adjusting also for less sensitivity reduces the ratio of false positives to false negatives. For example, if sensitivity is only 10 percent and all other parameters remain unchanged, then this ratio declines to 9.5 to 1. However, this implies that both types of statistical errors are rampant, which raises questions concerning the practical utility of animal bioassays. This is, in fact, precisely the concern raised by Lave *et al., (op. cit.)*, who conclude that such tests are cost-effective investments in information only under extraordinary conditions.

[48] *OSTP Guidelines*, p. 10376.

[49] *EPA Carcinogen Risk Assessment Guidelines*, p. 33997.

[50] *Id.*

[51] *OSTP Guidelines*, Guideline 26, p. 10378; Ames *et al., (op. cit.)*, p. 276.

estimates widened as doses declined toward the very low levels within the range of regulatory concern. At very low doses, two of the five models predicted excess lifetime cancer risks greater than one in one thousand (10^{-3}), a risk oftentimes regarded by policymakers as unacceptable. However, two other equally plausible models predicted essentially no excess cancer risk at all. Since none of the five models offers a scientifically superior basis for deriving low-dose risks, the choice of model is therefore a pivotal policy decision. The accepted practice under these circumstances is to develop a subjectively-derived "best" estimate while fully informing decisionmakers as to the extent of uncertainty surrounding it.[62] In the cadmium case, as in most others, this practice was not followed: Estimates of the number of statistical cancers that would be prevented by regulation were presented based only on the multistage model.[63]

The *linearized multistage model (LMS)* is a special version of the multistage model in which the 95 percent upper confidence limit of the linear term is used instead of the unbiased estimate. That is, the model identifies the largest value for the linear term that cannot be rejected at the 95 percent confidence level and uses it in place of the unbiased estimate. Assuming that the model has been correctly specified, there is only a 5 percent chance that the true risk exceeds this level.

The LMS has become the preferred statistical approach because estimates derived from it appear to be more "stable" than estimates obtained from the ordinary multistage model. The "stability" issue originally arose because unbiased estimates of low-dose risks are very sensitive to the maximum-likelihood estimate (MLE) of the value of the linear term. When the MLE of the linear term is positive, it dominates estimated risks at low doses. In some instances, however, the MLE of the linear term is zero, and low-dose risk estimates decline precipitously. Using the 95 percent upper confidence limit ensures that the linear term is always positive, thus eliminating the inherent "instability" of low-dose risk estimates derived from the multistage model.[64]

Another often-cited advantage of the LMS procedure is that it provides a "yardstick" for comparing potencies across chemicals.[65] A uniform risk-assessment procedure such as the LMS, it is argued, enables policymakers to better understand the relative significance of a broad array of chemical hazards and set regulatory priorities accordingly.

Finally, the LMS is often defended on the ground that it is prudent to err on the side of caution when dealing with potentially carcinogenic chemicals. Because the LMS generates upper-bound risk estimates, policymakers can be confident that actual risks are likely to be lower.

None of these purported advantages of the LMS approach has a sound statistical basis. It is a fundamental axiom of statistics that unbiased estimates are generally preferred to biased ones. Using the upper confidence limit instead of the unbiased estimate exaggerates underlying specification errors instead of eliminating them. "Instability" is overcome, but at the cost of greater errors in specification.

The inherent instability of the multistage model reflects a generalized misspecification of dose-response—that is, the real human dose-response relationship is often very different from what the multistage model constrains it to be. The model is extremely sensitive to small differences in observed tumor incidence, which can cause dramatic changes in estimated low-dose risks. The LMS procedure eliminates this sensitivity without remedying the underlying specification error. Proper statistical procedure requires correcting model misspecification, not masking its symptoms behind biased parameter estimates.

The LMS procedure inflates low-dose risk estimates by a factor of two or three when the MLE of the linear term is positive. However, it increases low-dose risk estimates by orders of magnitude when the MLE of the linear term is zero.[66] This means that the degree of hidden conservative bias is substantially greater for what are demonstrably lower risks.

By its very nature, the LMS cannot serve as a useful yardstick for comparing the relative risk of a variety of potential carcinogens. If a given statistical procedure generated identical biases across substances tested,

[62] See, e.g., *OSTP Guidelines*, Guidelines 27, 29, and 31, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, pp. 33999, 34003.

[63] Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 FR 4076 (February 6, 1990).

[64] Albert L. Nichols and Richard J. Zeckhauser, "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," Chapter 3 in *Advances in Applied Micro-Economics, Volume 4: Risk, Uncertainty, and the Valuation of Benefits and Costs*, V. Kerry Smith, ed., Greenwich, CT: JAI Press, 1986, pp. 55–82, esp. pp. 62–63. A nontechnical version of this paper is available by the same authors as "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation," *Regulation*, November/December 1986, pp. 13–24.

[65] U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD*, EPA/600/6-88/007Aa, June 1988 (hereinafter, *Dioxin Risk Assessment*), pp. 45–46.

[66] Nichols and Zeckhauser, *op. cit.*, pp. 62–63.

then it would still yield an accurate rank-ordering of theoretical hazards. Similarly, if the procedure added a stochastic bias from a uniformly distributed random variable, the resulting rank-ordering would still be accurate on an expected-value basis. The problem with the LMS is that it generates biases that intensify with the degree to which the multistage model misspecifies the true dose-response relationship. Even if the multistage model provided an accurate rank-ordering of hazards, the LMS could not do so, because it injects biases that are systematic with statistical misspecification.

The LMS procedure (and the multistage model itself) is also fatally flawed as a yardstick for regulatory priority setting because it fails to take account of human exposure in the calculation of unit risks. Regardless of the procedure's capacity to accurately rank-order *hazards*, failing to adjust unit risks by relative human *exposure* virtually guarantees that regulatory priorities will be misordered. Resources tend to be focused on reducing the greatest theoretical *hazards* rather than the most significant human health *risks*.[57]

Finally, the "margin of safety" argument in favor of the LMS unequivocally contradicts the widely recognized need to distinguish science from policy.[58] The LMS introduces into each risk assessment a conservative bias of varying but unknown magnitude. This practice fundamentally alters regulatory decisionmaking. Instead of leaving policy decisions to policymakers, the LMS disguises fundamental policy decisions concerning the appropriate margin of safety behind the veil of science.

In summary, the LMS cannot be justified as a method of scientific risk assessment. The "yardstick" defense implicitly asserts that scientific advancements in risk-assessment methodology should take a back seat to the preservation of an outdated and misguided statistical procedure. The "margin of safety" argument tacitly usurps from policymakers the authority and responsibility for risk-management decisions. Finally, the statistical "instability" overcome by the LMS is an artifact of specification error, not any scientific theory of human carcinogenesis that warrants the intentional use of biased parameter estimates. The habitual reliance upon either the multistage model or its LMS descendant cannot be supported by sound scientific principles.

Alternative models are available, of course, and they have been applied in many quantitative risk assessments. Because proper model specification is the foundation of applied statistical methodology, alternatives to the multistage model should be expected and encouraged. Indeed, innovation is the hallmark of scientific inquiry; policies that institutionalize any particular model specification effectively stifle scientific advancement.

Unfortunately, models other than the multistage model are often discouraged in practice.[59] Agencies may require substantial scientific evidence in support of an alternative model before allowing it to be used. Alternative models thus face a burden of demonstrating scientific plausibility that the multistage model cannot satisfy. Even in the extraordinary case in which this burden can be satisfied, estimates may be required from the linearized multistage model anyway.[60]

The potential human health threat posed by dioxins provides an excellent example of the problem of model selection. Using the same linearized multistage model, EPA, the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) have arrived at upper-bound risk estimates that span an order of magnitude.[61] Depending on the data and assumptions used, the linearized multistage model predicts unit risk factors that vary by as much as 1,200, with the

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[57] Some scientists have attempted to devise alternative indexes of relative human health risk that explicitly account for variations in human exposure. Ames *et al.*, (*op. cit.*), pp. 272–273, describe one such alternative (the Human Exposure/Rodent Potency index, or HERP) and report index values for 36 substances. Because the HERP index is based on a relative rather than absolute scale, the distorting effect of conservative biases embedded in the underlying risk assessments has been significantly reduced. Many substances suspected of being environmental carcinogens rank very low on the HERP index, suggesting that regulatory priorities have been seriously misdirected.

[58] See, *e.g.*, *NAS Risk Management Study*, p. 161; *OSTP Risk Assessment Guidelines*, Principle 29, p. 10378; and *EPA Carcinogen Risk Assessment Guidelines*, p. 34001.

[59] See, *e.g.*, Ames *et al.*, *(op. cit.)*, p. 276 (continued reliance on linear models despite the accumulation of evidence against linearity); and Lester B. Lave, "Health and Safety Risk Analysis: Information for Better Decisions," *Science*, Vol. 236, April 17, 1987, pp. 291–295, esp. p. 292 (agencies often resist modeling improvements and data that yield lower risk estimates).

[60] *EPA Carcinogen Risk Assessment Guidelines*, pp. 33997–33998. "In the absence of adequate information to the contrary, the linearized multistage procedure will be employed. . . . Considerable uncertainty will remain concerning responses at low doses; therefore, in most cases, an upper-limit risk estimate using the linearized multistage procedure should also be presented."

[61] *Dioxin Risk Assessment Appendix A*, p. 13. Unbiased risk estimates vary by a similar factor.

three risk estimates mentioned earlier clustered at the high end of the range.[62] Risk assessments based on different models have led other governments to establish unit risk factors that are a thousand times less stringent than the most commonly used of these three; one study suggests that this particular estimate overstates the most likely risk estimate by a factor of almost 5,000.[63]

Conversion from Animals to Humans

Once risk has been extrapolated to low doses in rodents, scientists must convert them to human dose-equivalents. The two most common approaches involve the use of body-weight or surface-area conversions, and there are scientific reasons for choosing either approach in individual cases. The surface-area approach leads to estimates of risk that are between 7 and 12 times greater than those based on the body-weight method, depending upon the test species. Despite the ambiguity of the underlying science, the more conservative surface-area method is often applied reflexively.[64]

ISSUES ARISING FROM HUMAN EXPOSURE ESTIMATES

In addition to developing estimates of the dose-response function, agencies must estimate the likely level of human exposure. This section examines some of the issues and problems that arise in conducting an exposure assessment.

It is a generally accepted principle of exposure assessment that estimates should be based on the most likely scenario, with appropriate consideration of uncertainty.[65] Nevertheless, agencies often use conservative assumptions for exposure when real-world data are unavailable. When each of these assumptions tends to overstate likely human risks, the multiplicative effect of even a small overstatement at each stage in an exposure assessment will yield a substantial overestimate of actual exposure. For example, the multiplicative effect of overstating risk by a factor of two at five different points in an exposure assessment will overstate actual risk by a factor of thirty-two.

Worst-Case Environmental Conditions

When data are available they often relate to unusually sensitive environments or highly contaminated conditions. When estimating regional or nationwide exposures, agencies often use data from these local "hot spots" in developing more general national estimates of health risks. However, such data are never representative and estimates extrapolated from them are generally unreliable and misleading.

In addition, chemicals often degrade naturally after they have been released to the environment. In some cases, degradation occurs very quickly, whereas in others the process may take many years or even decades. A common practice in exposure assessment modeling is to assume that exposures remain constant over time—that is, chemicals are assumed never to degrade, or degradation by-products are assumed to pose identical risks.

The Maximum-Exposed Individual

In addition to estimating the amount of a substance that may actually be present in the environment, a risk analysis must also consider the conditions under which humans may be exposed. Actual risks vary considerably depending on location, mobility, and a host of other factors. Nevertheless, estimates often are based on the upper-bound lifetime cancer risk to the maximum-exposed individual (MEI), the hypothetical person whose exposure is greater than all others. Sometimes, risks to the entire population are estimated by assuming that everyone is exposed at the MEI level. Because environmental regulations are often justified using MEI-based risk assessments, actual risks may be substantially lower than what decisionmakers and the general public perceive them to be.

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[62] *Dioxin Risk Assessment*, pp. 46–49. 10^{-6} risk-specific doses (RsDs) derived from the linearized multistage model span the range from 0.001 to 1.2 picogram/kg/day. The RsDs of EPA, CDC, and FDA are 0.006, 0.03, and 0.06 pg/kg/day, respectively.

[63] *Dioxin Risk Assessment*, p. 4.

[64] *EPA Carcinogen Assessment Guidelines*, p. 33998. "EPA will continue to use this [surface area] scaling factor unless data on a specific agent suggest that a different scaling factor is justified."

[65] EPA guidance documents have historically called for unbiased estimates of exposure. See, e.g., U.S. Environmental Protection Agency, "Guidelines for Exposure Assessment," 50 FR 34042–34054 (September 24, 1986, hereinafter, *EPA Exposure Assessment Guidelines*); U.S. Environmental Protection Agency, *Superfund Public Health Evaluation Manual*, OSWER Directive 9285.4–1, October 1986; and U.S. Environmental Protection Agency, *Superfund Exposure Assessment Manual* (Revised Draft), OSWER Directive 9285.5–1, December 1986. EPA recently abandoned the calculation of unbiased exposure estimates for Superfund sites on the ground that it was insufficiently conservative. EPA's new protocol requires the estimation of "reasonable maximum exposure" instead of the average and upper-bound estimates. Reasonable maximum exposure constitutes a new term of art that EPA intends to be "well above the average case" but not as extreme as the upper-bound. It provides a new opportunity for embedding conservative assumptions into exposure assessment and exaggerating estimates of actual human-health risk at Superfund sites. See *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), Interim Final*, EPA/540/1-89/002, December 1989, Chapter 6, pp. 5, 47–50.

In developing the MEI risk level, analyses invariably assume that the level of exposure is continuous over a 70-year lifetime. This assumption overstates actual risks, because people are mobile, encounter a constantly changing portfolio of daily risks to life and health, and can take actions that reduce risk.

Assumptions vs. Real-World Exposure Data

The thread that connects these exposure assessment issues is that simple constructs which overstate exposure are typically used in lieu of real-world data, often because such data are unavailable. The risk estimates generated by these models depend on the validity of their assumptions; even small biases in exposure assessment assumptions can result in a substantial overstatement of risk.

For example, regulatory agencies may not have statistically reliable real-world data on pesticide residues in agricultural products. They also may not know the proportion of a given crop that has been treated with a particular pesticide. A common resolution of these uncertainties is to assume that residues are equal to the regulatory "tolerance"—the maximum level allowed to be present in food sold in interstate commerce—and that 100 percent of the relevant crop has been treated. Both assumptions overstate actual exposure, but are encouraged by agency guidance as a way to instill conservatism in risk assessment.[66] When data are available, however, the extent of this conservative bias becomes evident. In a recent special review for the pesticide Captan, for example, EPA reduced its earlier upper-bound lifetime cancer risk estimate by two orders of magnitude when it replaced the original conservative assumptions with real-world data. Even with these improvements, EPA still reported that upper-bound risks were probably overstated. For example, field tests were performed based on applications at the maximum legal rate and as close to harvest as the label permits. Similarly, feeding studies assumed that animal diets were dominated by feedstuffs that happened to contain high residues relative to other feedstuffs, such as almond hulls and raisin waste. As EPA noted, even if these assumptions accurately represented typical animal diets, they would do so only for portions of California where these crops are grown; nationwide extrapolations based on these "hot-spots" would very likely overstate exposure.[67] Since two of the highest product-specific risks were attributed to milk and meat, these remaining conservative biases can be expected to be significant.

IMPLICATIONS OF CONSERVATIVE RISK ASSESSMENT FOR RISK MANAGEMENT AND REGULATORY DECISIONMAKING

The primary purpose of risk assessment is to provide data as a basis for risk management decisions. Providing useful data requires the synthesis of information concerning risks and exposure levels into a coherent package that can be used to develop regulatory options. Decisionmakers then can use these risk estimates in evaluating regulatory alternatives. Unfortunately, the way in which risk information is characterized tends to overstate risks, making them appear much greater than they are likely to be. As a result, decisionmakers may make regulatory choices that are very different from the ones they would make if they were fully informed.

Quantification of Uncertainty

In accordance with the recommendations of the National Academy of Sciences, the *OSTP Guidelines* explicitly call for the quantification of uncertainty, particularly as it arises in the selection of dose-response models and exposure assumptions.[68] Unfortunately, Federal regulatory proposals that utilize risk assessment rarely provide this information, nor do they analyze the implications of uncertainty for decisionmaking. Instead, many risk assessments only identify a lifetime upper-bound level of risk.[69]

The differences between upper-bound and expected-value estimates may be considerable. As we indicated earlier, the upper-bound risk estimate for dioxin may be 5,000 times greater than the most likely estimate. Plausible risk estimates for perchloroethylene (the primary solvent used in dry cleaning) vary by a factor of about 35,000.[70]

In some instances, decisionmakers may not be informed that risk estimates differ because of policy choices hidden in the risk-assessment methodology. In EPA's proposed rule limiting emissions from coke

[66] *EPA Exposure Assessment Guidelines*, p. 34053. "When there is uncertainty in the scientific facts, it is Agency policy to err on the side of public safety."

[67] See, e.g., U.S. Environmental Protection Agency, "Captan: Intent to Cancel Registrations; Conclusion of Special Review," 54 FR 8127–8128 (February 24, 1989).

[68] *OSTP Guidelines*, (Guideline 27), p. 10378.

[69] See, e.g., *EPA Carcinogen Risk Assessment Guidelines*, p. 33998.

[70] Nichols and Zeckhauser, *(op. cit.)*, pp. 64–65.

ovens, for example, cancer risks were estimated based on the LMS model—a model that is designed to yield upper-bound estimates of risk. In previous rules involving similar types of risks, however, EPA used the unbiased maximum likelihood estimate. To the extent that decisionmakers were not informed that the higher estimate of risk was largely due to a different low-dose extrapolation procedure, regulatory decisions based on this risk assessment were likely to reflect misunderstanding rather than science.[71]

Plausible estimates of likely cancer risk can often be found buried in regulatory background documents. However, *Federal Register* rulemaking notices seldom present such estimates alongside upper-bound estimates. This practice overstates baseline human health threats, as well as the amount of risk reduction that may be accomplished by regulation. Policymakers and the public are misled because they typically see only the upper-bound estimates of the threat.

The prevalent Federal agency practice is to calculate the benefits of Federal regulatory initiatives based solely on upper-bound estimates of risk and exposure. In a recent proposal to reduce occupational exposure to cadmium, for example, the Occupational Safety and Health Administration (OSHA) developed risk estimates based on five alternative models for animal data, and two alternative models for human data. Across these seven data/model combinations, estimated excess lifetime cancer risk at the least stringent of the two proposed exposure standards varied from 0 to 153 cases per 10,000 workers occupationally exposed for 45 years. OSHA based its proposed exposure standards on *one* of these data/model combinations—the multistage model applied to animal data. This data/model combination predicted an excess lifetime cancer risk of 106 per 10,000 exposed workers, and was used to estimate aggregate cancer incidence and the risk-reduction benefits attributable to the new standard. Uncertainties in the underlying risk assessment, which span several orders of magnitude, were not carried forward through the exposure assessment and benefit calculation stages. This analytic error effectively obscured the uncertainty surrounding the true incidence of cadmium-induced lung cancer, and resulted in benefit estimates that may exceed actual reductions in occupational illness by several orders of magnitude.[72]

Misordered Priorities, Perverse Outcomes

Logically, one would expect that the routine overstatement of likely risks would lead to inefficient regulatory choices. Decisionmakers, convinced that a certain substance or activity poses a significant threat to public health, might well take actions that they would otherwise resist. Alternatively, they might take actions that address the wrong real-life risks.

To the extent that risk assessments differ in the degree to which they adopt conservative assumptions, it is difficult to determine which activities pose the greatest risks and hard to establish reasonable priorities for regulatory action. Because conservatism in risk assessment is especially severe with respect to carcinogens, it is reasonable to expect that other health and safety risks tend to receive relatively less attention and weight. As a result, society may actually incur greater total risk, because of misordered priorities caused by conservative biases in cancer risk assessment.[73]

A perverse and unfortunate outcome of using upper-bound estimates based on compounded conservative assumptions is that the practice may actually increase risk, even in situations where cancer is the only concern. Regulatory actions taken to address what are in fact insignificant threats may implicitly tolerate or ignore better known, documented risks that are far more serious. For example, before it was banned, ethylene dibromide (EDB) was used as a grain and soil fumigant to combat vermin and molds. Vermin transmit disease, and molds harbor the natural and potent carcinogen aflatoxin B. The estimated human cancer risk from the aflatoxin contained in one peanut butter sandwich is about 75 times greater than a full day's dietary risk from EDB exposure. On this basis alone, it might have been appropriate to accept a small increase in cancer risk from EDB to reduce the much larger cancer risk from aflatoxin. By eliminating the relatively small hazard from EDB, Federal risk managers may have intensi-

[71]Letter from Wendy Gramm (Administrator of the Office of Information and Regulatory Affairs) to Lee Thomas (Administrator of the Environmental Protection Agency), August 12, 1986, p. 3.

[72]Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 *Federal Register* 4076, 4080, 4093.

[73] This is precisely the policy issue raised by Nichols and Zeckhauser, (*op. cit.*), pp. 69–71, who note that EPA's 1985 decision to limit lead in gasoline was threatened by concerns about potential increases in benzene exposure. Any tradeoff between lead and benzene risks would have been biased against lead; as estimates of benzene risks are more conservative simply because it is a carcinogen, whereas lead is not.

fied the relatively potent threat of aflatoxin associated with an increase in the prevalence of mold contamination.[74]

The emphasis on risks faced by the maximum-exposed individual may also cause a perverse result by increasing overall population risks. For example, EPA's proposed regulation of the disposal of sewage sludge would probably create more public health risk than it eliminates. The proposal outlines a regulatory scheme that would shift disposal from generally safe practices to relatively risky alternatives. Thus, setting sludge quality standards to achieve an MEI upper-bound lifetime cancer risk of one in 100,000 (10^{-5}) would prevent 0.2 statistical cancer cases resulting from monofilling and land application. However, it would cause 2.0 additional statistical cancers by forcing a shift away from these disposal approaches toward incineration.[75]

These problems can be addressed by providing decisionmakers with the full range of information on the risks of a substance or an activity. Thus, decisionmakers should be given the likely risks as well as estimates of uncertainty and the outer ranges of the potential risk. Then, if regulatory decisionmakers want to choose a very cautious risk management strategy, they can do so and a margin of safety can be applied explicitly in the final decision. This approach is superior to one in which the expected risk and an unknown margin of safety are hidden behind the veil of a succession of upper-bound estimates adopted at key points in the risk-assessment process.

The public and affected parties also benefit from knowing both the expected risk and the margin of safety rather than being given upper-bound estimates that are probably very different from actual risks. People are likely to have a better intuitive understanding of the significance of averages than they have of unlikely extremes. To the extent that a margin of safety is appropriate—perhaps to protect unusually sensitive subpopulations—the magnitude of this margin can be more readily communicated if made explicit. In addition, providing information in this way should help improve public confidence in quantitative risk assessment as the basis for decisionmaking.

AVOIDING CONSERVATIVE BIASES IN RISK ASSESSMENT

Risk assessment remains a powerful and useful scientific tool for estimating many of the risks that arise in a technologically advanced society. Unfortunately, it is also susceptible to hidden biases that may undermine its scientific integrity and the basis for policymakers' reliance on such information in risk management decisions. For policymakers and the public to continue to rely on risk assessment in the development of regulatory initiatives, a renewed effort must be made to separate science from policy and provide risk information that is both meaningful and reliable.

Expected Value Estimates

Perhaps the most important current need in regulatory decisionmaking is for carefully prepared and scientifically credible estimates of the likely risks involved. Relying on worst-case analysis based on extremely conservative risk assessment and exposure models leads to widespread misunderstanding on the part of both Government officials and individual citizens. Decisionmakers at all levels need unbiased and impartial risk information so they can focus their attention on significant problems and avoid being distracted by minutiae.[76]

Weight-of-Evidence Determinations

Similar procedures are needed for assigning weights to each relevant study in the risk-assessment literature. Current practice gives undue weight to studies that show positive relationships. Resulting risk classifications are thus conservatively biased estimates derived from samples of similarly biased observations.

Full Disclosure

Efficient and responsible decisionmaking requires that policymakers and the public be fully informed about the implications of the regulatory alternatives among which they must choose. Meeting this requirement demands a careful discrimination between science and policy. When risk estimates depend on assumptions and judgments instead of data, the meaning and implications of these nonscientific parameters must be clearly articulated.

Avoiding Perverse Outcomes

Careful attention needs to be paid to the likely results of regulatory alternatives, with an eye toward avoiding choices that have the perverse effect of increasing net risk. All human activity involves risk.

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[74] Ames *et al.*, *(op. cit)*, p. 273.

[75] U.S. Environmental Protection Agency, "Standards for the Disposal of Sewage Sludge; Proposed Rule," 54 FR 5746–5902 (February 6, 1989).

[76] Nichols and Zeckhauser, *op. cit.*, pp. 72–76.

Decisionmakers need to be sure that specific actions taken in the name of risk-reduction in one area do not make matters worse elsewhere. Quantitative risk assessment can help in this regard so long as the methods applied are not inherently biased in a way that undermines comparisons across alternatives, each of which entails some degree of risk.

Our discussion has covered only the highlights of risk-assessment methods, yet we have identified several independent places at which conservative assumptions are commonly used. Individually, each of these assumptions might appear to be prudent responses to scientific uncertainty. In combination, however, they result in a distortion equal to the product of the individual conservative biases. To illustrate, suppose that there are ten independent steps in a risk assessment and prudence dictates assumptions that in each instance result in risk estimates two times the expected value. Such a process would yield a summary risk estimate that is more than 1,000 times higher than the most likely risk estimate. Because there are usually many more than ten steps, and many of them will incorporate conservative biases that exceed an order of magnitude, risk estimates based on such practices will often exceed the most likely value by a factor of one million or more.

When risk assessments contain hidden value judgments, their scientific credibility is inevitably compromised. To the extent that policymakers and the public fail to understand the magnitude of the margin of safety embedded in quantitative risk assessments, policy choices are distorted from the course that would have been selected if decisionmakers had been better informed of the actual risks. Ironically, these policy decisions may actually increase total societal risk. Too much attention is focused on relatively small hazards that have been exaggerated by conservative risk assessments, leaving alone larger risks that have been estimated using unbiased procedures.

Information as an Alternative Regulatory Strategy

Federal regulation was initiated to deal with economic problems caused by monopoly and so-called "excess competition." Subsequent events have shown that, in general, economic regulation—fixing prices, establishing restrictive terms of trade, and erecting barriers to entry—is usually inefficient and detrimental to innovation. In response to these lessons, Federal regulation of this type has been under increasing criticism. As indicated above, however, much more needs to be done to reform economic regulation and restore competition.

Federal regulation has more recently been initiated to deal with what economists call externalities, situations in which participants in voluntary market transactions do not bear the full costs or capture all of the benefits of these exchanges. Common examples of externalities include environmental pollution and traffic congestion, common property resources such as fisheries and public forests, and "public goods" such as basic scientific research. In each of these instances, regulation may be an appropriate mechanism to modify or restore distorted market processes, or to establish markets where heretofore they have not existed, to maximize net social benefits (including environmental, health, and safety benefits). The key ingredient is the determination that existing markets are, in some significant manner, failing to perform efficiently.

The traditional regulatory approach to externalities has been the promulgation of standards. Because this approach often remedies existing externalities by creating new ones, economic incentive instruments are becoming an increasingly popular alternative to standards. The principal attraction of economic incentives is that they rely on market forces rather than attempt to suppress them.

This section explores another alternative regulatory strategy—the production, provision, or mandated disclosure of information. The first subsection briefly summarizes the economics of information as it relates to regulatory decisionmaking. Three points stand out in this discussion. First, because information is costly to acquire and the capacity to process it is limited, there is an optimal level of information for every market transaction. Second, differences in the amount and quality of information between buyers and sellers are normal and do not necessarily indicate market failure. Rather, these differences generally reflect variations in the costs and benefits that are attributable to information. Third, competitive markets provide powerful incentives for buyers and sellers to reveal relevant information. Market processes, not government regulations, provide the dominant motivation for generating, acquiring, and disclosing information. The role of government regulation thus should be to supplement these processes when they prove to be inadequate, not to supplant them when they work well.

The second subsection identifies three rationales for government intervention in the production or mandated disclosure of information. Two of these are economic—the public-good character of some types of information, and the absence of actual or potential competition in markets where information production or disclosure is relatively important. The third rationale for intervention is strictly ethical—a policy judgment that there exists a broad "right to know" which justifies compelling certain market participants to produce or reveal information at their expense but for the benefit of others. This concept overlaps somewhat with the public-good notion. The distinguishing feature of the right-to-know rationale is that it applies only to those cases in which society's collective willingness-to-pay is insufficient to justify regulatory coercion based on economic efficiency alone.

The final section provides illustrative examples of how regulatory strategies utilizing information have been recently used or considered. The purpose of the regulatory approach in each of these cases involves communicating information concerning certain hazards that may bear upon where individuals choose to live and work, and what they eat. The intent here is to stimulate discussion, not to identify particular areas as "targets" for regulation (or regulatory reform).

EFFICIENCY IN THE PRODUCTION AND ACQUISITION OF INFORMATION

If information were free, more of it generally would be better than less. Like other commodities, however, information is costly to produce, acquire, and disseminate, and costs typically increase with quality. These costs differ considerably across market participants, but for no one does valuable information come free of charge. The more one already possesses, the more the cost of getting slightly more or better data tends to increase. In economic terms, the *marginal cost* of producing, acquiring, and disseminating information increases with the quantity (and quality) produced or acquired.

There are also practical limits to the amount of information anyone profitably can use. Consumers of information set priorities, searching for the most important data first and lesser material as time and money permit. Slightly more or better data is valued highly when one possesses very little information; as one's information base increases, however, similar improvements in quantity or quality contribute less. In economic terms, the *marginal benefit* of additional information generally declines the more one already possesses.

For each participant in the marketplace (and by extension, the economy as a whole), the right amount of information is achieved when the benefit from the last unit of information obtained precisely equals the additional cost of obtaining it. Any other combination of information expenditures and acquisitions either wastes resources in the pursuit of too much information or fails to exploit valuable learning opportunities by seeking too little. This means that buyers and sellers will rarely, if ever, have precisely the same amount or quality of information at their disposal before they make decisions.

Such an informational asymmetry by itself does not necessarily mean that either side to a transaction is disadvantaged. It simply reflects differences in the costs and benefits of producing and acquiring information. Similarly, mere ignorance or uncertainty does not necessarily mean that private markets have failed to provide the proper amount of information. Neither ignorance nor uncertainty can be fully vanquished; every market participant, in balancing the benefits of more information against its costs, must accept some measure of both ignorance and uncertainty.

Indeed, market processes often reduce ignorance and uncertainty by stimulating information exchanges. Those who have information or can produce it cheaply offer it to those who value it highly but cannot produce it except at great expense. In some markets it is sellers who control relevant information; in other instances, it is buyers who are better informed. In a competitive market where sellers possess information relevant to buyers, a decision by one seller to withhold it will be countered by other sellers who will be willing to disclose it. Buyers who choose not to reveal information relevant to sellers will be outbid by other buyers who willingly share what they know. Competition will elicit the efficient amount of information, ignorance, and uncertainty as long as there are numerous potential buyers and sellers.

RATIONALES FOR INFORMATION AS A REGULATORY STRATEGY

Private markets fail to display efficient informational attributes under two broad sets of circumstances. First, when information has strong public-good aspects, private markets will produce too little of it and thus inhibit or prevent efficient exchanges from taking place. Second, vital information may be subject to monopoly control and thus be underprovided. A regulatory strategy based on information must be designed with careful consideration of which of these problems is actually present. Errors in identifying the problem may result in regulatory prescriptions that fail to address the disorder and may even exacerbate it.

Information as a Public Good

Too little information will be produced if the benefits of information can be captured without having to pay the full social cost of producing it. Efficient incentives to develop and disseminate information will be stifled, and government action may be warranted to overcome the limitations of private-market forces. Basic research is a common example of information that is not adequately generated by private markets—information that has widespread potential application and cannot be readily subjected to protection by patent or copyright laws.

Monopoly Control over Information

Too little information is produced (or disclosed) when particular market participants control access to information or the capacity to produce it. Certain types of information are more susceptible to monopoly control, such as data related to a specific firm, plant, process, or product. The capacity to control, however, is only a necessary condition for market failure, because all market participants possess information that is unavailable to others. The crucial economic test is whether the social value of this information—as measured by the collective willingness-to-pay of those who would benefit from it— exceeds the cost of production and dissemination, plus any attendant losses that disclosure would impose. This is a complex economic problem for which simple answers are generally unavailable.

Right-to-Know

A third rationale for regulatory intervention lies beyond the usual confines of economics, but in some respects may be more important. This rationale is founded not on the value of information to an individual or society as measured by willingness-to-pay, but on the ethical judgment that people have the right to be informed. Conventional economic analysis is often neglected when rights are involved, on the ground that no price can be placed on a right. Economic analysis is still useful, however, for measuring the relative informational content of alternative regulatory strategies that seek to advance a particular societal value. A cost-effective regulatory strategy based on a right-to-know rationale would utilize the least expensive means of achieving the desired informational state. Economic analysis also helps clarify the social cost of establishing such a right. Indeed, any ethical basis for a right-to-know rationale must logically encompass the right to know how much it costs to have it.

THE REGULATORY CONTEXT OF INFORMATION: ILLUSTRATIVE EXAMPLES

Information arises in a wide variety of regulatory contexts in each of these forms. Regulatory strategies utilizing information represent a valuable alternative to traditional approaches when informational issues appear to be important.

The remainder of this section offers three vignettes in which an informational strategy has been used or considered instead of the traditional standard-setting approach, concerning hazard communication in the workplace, hazard communication in the community, and Federal policy on food labeling. These vignettes are intended only to illustrate the issues involved. They do not establish or advance a particular point of view or seek to imply that discussion should be limited to a narrow set of applications.

OSHA's Hazard Communication Standard

The Occupational Safety and Health Act of 1970 states that safety and health standards "shall prescribe the use of labels or other appropriate forms of warnings as are necessary to ensure that employees are apprised of all hazards to which they are exposed . . . and proper conditions and precautions of safe use of exposure." (29 U.S.C., Section 655(b)(7)). In economic terms, such information requirements are warranted when employers are presumed to possess monopoly control over information concerning workplace hazards. If workers are not sufficiently informed, then their wages would fail to reflect premiums that economists contend would have to be present to compensate them for bearing greater risks.

In carrying out its mandate, OSHA in 1983 promulgated a Hazard Communication Standard (HCS) applicable to the manufacturing sector. The rule was designed to provide employees with information about the potential hazards of chemicals to which they may be exposed at work. The scope of the HCS was expanded in 1987 to encompass virtually all of the private sector.

The HCS requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import. They must develop technical hazard information for material safety data sheets (MSDSs) and labels for hazardous substances. This information must be transmitted downstream to users of these substances. All employers are required to pass on this information to their workers through a comprehensive hazard communication program that includes individual training. In calculating the potential benefits from this information—the prevention of occupational cancers and other illnesses—OSHA stated that ". . . it is not unreasonable to assume that if employers and employees are provided with meaningful risk information they will take appropriate protective action" (48 FR 53324).

However, OSHA recognized that the deceptively simple goal of informing workers about the hazards of workplace chemicals becomes exceedingly complicated when applied to millions of different workplaces, work conditions, and products across the country. The sheer volume of paperwork was tremendous. In 1988 the HCS required employers to spend 54 million hours to comply with the paperwork requirements, making its paperwork requirement the fourth most burdensome in the entire Federal Government, exceeded only by the 1040 tax form and two Department of Defense procurement requirements. The logistics of coordinating the flow of information from manufacturers to end users proved formidable. Complaints arose about the quality of information that was provided. Confusion about the requirements was widespread, especially within the small-business community.

Under the authority of the Paperwork Reduction Act, OMB held two public meetings on the HCS.[77] Several problems were identified. Some of these were start-up problems inherent in any regulatory program of this magnitude. However, others raised questions about the basic design of the standard and its effectiveness in changing the behavior of employers and employees.

The most common problem mentioned was information overload. OSHA intended the HCS to be comprehensive, to inform employees of all potential safety or health risks from chemicals regardless of magnitude. OSHA therefore gave suppliers and employers little flexibility to assess exposures and risks before determining what information to provide. One result was that employers and employees were bombarded with information that had little relevance and, worse, diverted attention from real risks. Some employers even reported risk information concerning paper bags and hand soap.

There were also significant problems in ensuring that the information provided was accurate and comprehensible. Employers complained that the information was too technical to be understood and used by employers and employees, and that much of it was erroneous. These problems undermined the effectiveness of the HCS, and may indicate that revisions are needed in the standard if OSHA is to accomplish its objective of changing behavior in the workplace to reduce risks from hazardous chemicals.

The HCS case demonstrates the importance of fully understanding the rationale for regulatory intervention before promulgating rules of this scope. Instead of identifying those situations in which the private labor market had failed to achieve an efficient allocation of risk, OSHA established a comprehensive set of information requirements. In order to justify such a comprehensive program in economic terms, there would have to be a systematic market failure across virtually all potentially hazardous chemicals.

Even if the problem of workplace chemical risks was as widespread as OSHA believed, the HCS failed to distinguish serious from trivial risks. OSHA thus treated all risk-related information as if it were equally valuable to workers. This led to an information strategy that apparently was much broader than the underlying problem it was supposed to remedy.If the HCS appears to generate too much information of uneven quality, this may be evidence that the optimal amount of information is actually much smaller than initially believed.

EPA's Community Right-to-Know Program

In 1986, Congress passed the Emergency Planning and Community Right-to-Know Act (EPCRA).[78] Despite its name, EPCRA was primarily intended to provide a specific public good: enhanced emergency planning and response to (primarily) chemical-related accidents.

EPCRA established requirements for firms and individuals to report the quantities of potentially hazardous chemicals stored or released into the environment. In addition, Federal, State, and local governments are directed, under EPCRA, to use these reports to develop emergency-response plans that would reduce public health risks in the event of an accidental release. Users of potentially hazardous chemicals are required to report to their local fire departments information regarding the types and quantities of chemicals stored and where they are located. Furthermore, respondents are directed to provide information concerning the potential health effects that might result from exposure. Users also must report releases of these substances to the EPA and to their State governments. By law, both inventory and release reports must be updated annually.

In crafting these regulations, EPA faced the difficulty of balancing the cost of generating and disseminating this information against the social benefits of enhanced emergency response. The most important factor in determining total societal cost appears to be the minimum quantity of chemicals that triggers inventory and release reporting. The lower these

[77] In *Dole v. Steelworkers*, No. 88-1434 (February 21, 1990), the Supreme Court held that the public protection clause of the Paperwork Reduction Act (PRA) did not extend to agency rules mandating disclosure by regulated entities to third parties. Hence, much of the Hazard Communication Standard is no longer subject to OMB approval or disapproval under the PRA.

[78] EPCRA was incorporated as Title III of the Superfund Amendments and Reauthorization Act (SARA) (42 U.S.C. 9601 et seq.); thus, EPCRA is also known as SARA Title III.

thresholds, the more entities must submit reports, and the greater the total social cost. However, the importance of emergency-response planning to the community diminishes as the amounts of chemicals involved declines. Large potential releases suggest greater potential public health threats, whereas small potential releases may indicate relatively minor risks. In addition, local emergency-response planners face limits as to the amount of information they can effectively comprehend and manage. The more stringent the reporting thresholds, the more information they have to process to develop their emergency response plans.

EPCRA established an initial inventory-reporting threshold of 10,000 pounds per year. In the absence of EPA action, this threshold would have declined to zero pounds in 1990. EPA promulgated final inventory-reporting requirements in late 1987, with initial reports due at the end of 1988. These rules maintained the 10,000-pound threshold for over 250 chemicals. However, for any substance classified as an extremely hazardous substance," the threshold was set at 500 pounds. Based on these thresholds, EPA estimated that almost four million firms and individuals would be required to submit inventory reports. EPA estimated that the cost of these requirements would exceed $1 billion during the first year alone.

The gains to emergency-response planning arising from these reporting requirements depend on the likelihood and magnitude of possible releases, and the nature of the chemicals involved. However, in the regulatory impact analysis submitted in support of its implementing regulations, EPA was unable to estimate specific benefits. Thus, the regulations were developed without any idea as to how much information would be appropriate. Subsequent analysis attempting to measure the social utility of alternative thresholds has led EPA to propose a permanent threshold of 10,000 pounds.

Extensive reporting requirements such as these often overlap with other Federal information-collection requirements. This situation challenges regulators to identify and mitigate duplication wherever possible. For example, operators of over 500,000 facilities using underground storage tanks (such as gasoline retailers) have an existing requirement to submit a form to both EPA and their State governments which contains much the same data as required under the EPCRA regulations. In cooperation with EPA, OMB recently solicited comments on ways to reduce this duplicative reporting. Similarly, many of the data required under the EPCRA release reports are already submitted to EPA and the States to obtain operating permits under several other environmental statutes. As a result, regulators must be vigilant in their efforts to ensure that efforts to use information as a regulatory alternative are carefully targeted and that duplication is minimized.

Food Labeling as an Informational Strategy

Food marketing involves a significant investment in providing information to consumers through product labeling and promotion. Generic product names alone may be sufficient to convey the necessary information about some products, such as milk or skim milk. However, additional information on the nutritional value or ingredients is often desired by consumers and provided by producers. Finally, some consumers may require certain information about ingredients, perhaps because of specific food allergies or because they are concerned about the possible health risks of certain chemical constituents.

Government can act to enhance efficiency in food markets in a variety of ways, depending upon the nature of the underlying market imperfection. For example, some information may have public-good aspects that warrant governmental provision or subsidization. In certain cases, growers, food processors, brokers, or retailers may have monopoly control over information that consumers consider vital to informed decisionmaking.

Nutritional Labeling as a Public Good

Food marketers possess a substantial amount of information that is generally unavailable to consumers, such as information concerning fat, sodium, and cholesterol levels. The FDA currently requires food marketers to provide this information in a variety of circumstances, especially when producers seek to make nutritional claims concerning their products. For example, a label which asserts that a product is "low" in sodium, fat, or cholesterol must provide explicit quantitative information on the label to back up this claim. This requirement is intended to reduce the chance that consumers will misinterpret a nutritional claim or fail to understand its context.

As consumers become increasingly health conscious, competition has driven more and more producers to provide nutritional information. Many food products have been altered so as to satisfy these changes in consumer requirements for information. Nevertheless, not all products have nutritional information on their labels, and some observers have asserted that all food products should bear such labels. The FDA is planning to propose such a mandatory requirement. The question facing FDA is whether the public-good benefits of regulation would exceed the costs of imposing it.

Ingredient Labeling as a Public Good

Some food ingredients may pose a serious health risk to certain segments of the population. A recent example is the case of sulfites, a class of preservatives to which some people are known to be allergic. One approach is to simply ban the use of such ingredients, thereby assuring the protection of the most sensitive members of the public. This approach has two serious problems, however. First, it is unclear what the appropriate sensitivity threshold should be, either in terms of the severity of health effects or the numbers of persons affected. Second, ingredient bans prevent those who are not sensitive from realizing the benefits of continued use. In the case of sulfites, FDA determined that a ban was justified only in a limited number of uses. For most applications, however, FDA continues to rely on an informational approach. Mandated disclosure of sulfite use enables sensitive people to easily avoid products that contain them while preserving the benefits of continued use for the majority of consumers.

Health Messages as Public Goods

Until recently, Federal regulators have rigidly enforced prohibitions against the publication or other use of health messages by food marketers. Because such messages historically lacked any credible scientific basis, Federal action against them prevented the dissemination of information that was false and misleading.

More recently, however, Federal and private sector investments in basic health research—another public good—have created a considerable body of scientific literature concerning the health consequences of a variety of foods. For example, certain foods contain high levels of cholesterol or saturated fat, both of which have been associated with increased risk of heart disease. Other foods are now believed to reduce the risk of certain forms of cancer. Because so many Americans are concerned about these risks, food marketers have shown an increased interest in providing information concerning the health benefits of reducing dietary levels of cholesterol and saturated fat. At the same time, there is a strong public policy interest in promoting the dissemination of such information. Based on this research and increased interest, food marketers have launched promotional campaigns and sought label changes intended to inform interested consumers as to the health benefits of their products.

To the extent that consumer interest in such information drives food marketers to provide it, competitive markets yield the qualitatively correct result. The remaining question is whether socially optimal amounts and kinds of health-related information are provided. If not, then there may be public-good benefits to Federal regulations that allow such information, so long as it is truthful and not misleading. In cases where food marketers seek to provide information that corresponds to prevailing scientific consensus, then competitive markets have the capacity to disseminate the same kind of information that Federal risk managers want to communicate through public-service announcements and publications.

Monopoly Power in Food Marketing

It has been asserted that by virtue of their control over production, food marketers possess a form of monopoly control over information such that government intervention is necessary to prevent or eliminate a market failure. However, it is unclear how food marketing enterprises differ from firms in other industries in the extent to which they have incentives to reveal information. As we indicated earlier, competitive markets are typically sufficient to assure that sellers reveal favorable information about their products, as well as unfavorable information about the products of their competitors. As in other markets, only where competition is lacking will sellers retain any market power derived from superior information. Even in these instances, it is unclear how the exercise of such market power would result in food that is less safe. In any event, it is often difficult in these cases to see how the Federal Government can effectively intervene to correct such problems.

Food Safety and "Right-to-Know"

The public-good rationale discussed above covers the vast majority of cases in which government intervention may be warranted. In sum, a market failure exists when the collective willingness-to-pay of society exceeds the costs that individuals acting alone are willing to bear. Typically, these situations are limited to cases in which one individual's consumption does not affect the amount available for others to consume, and it is impractical to exclude individuals who are unwilling to pay ("free riders") from receiving benefits.

With respect to food, neither of these conditions appears to exist. Food that is consumed by one person cannot be made available for anyone else. Similarly, the quality attributes of any foodstuff can be enjoyed only by the person doing the consumption. Information about food, however, may appear to satisfy the usual conditions for a public good. Information does not vanish after it has been put to use by a single person, and the capacity to exclude "free riders" is severely limited. Thus, it is important to distinguish between food per se and information that may lead to more informed consumers.

Some citizens may believe that because food is a necessity no amount of information determined by market processes (or by government requirements to supplement the market in the case of public goods) can be sufficient. Instead, they may feel that the public should be given all relevant information irrespective of whether consumers value it. In this view, information concerning food safety is not a public good at all, but rather a right that should be enforced by government action.

Any such basis for government action lies outside of the field of economics. Nevertheless, economic analysis is well suited for measuring the social costs of establishing and enforcing such a right. These social costs come in several forms.

First, the establishment of a "right-to-know" constitutes an abandonment of existing private markets for information. This change would have significant effects on both food marketers and consumers. Food marketers no longer would have incentives to provide information in response to competition. They would cease investing resources in the production and dissemination of health-related information except to the extent required to comply with governmental mandates. The cost of compliance, of course, would be reflected in higher prices at the supermarket—an unambiguous social cost.

Similarly, consumers would face a uniform body of food-safety information that diverged substantially from what most of them had received in the past when information was traded in the market. Those who place a relatively low value on food-safety information would gain little in additional benefits, but they would pay higher food prices. In contrast, consumers who value food-safety information highly would gain disproportionate benefits. Because of the diversity of consumer demand for food-safety information, any uniform standard would be inefficient. On balance, any such requirement would have greater costs than benefits.

Second, Federal standards would be needed to implement such a "right-to-know," and it is unclear what basis would be used to determine the required level of disclosure. When rights are involved, design standards tend to be preferred over performance standards. In the case of information, the absence of meaningful units makes performance standards even more difficult to develop. The general inefficiency of design standards constitutes another significant social cost.

Third, the removal of food-safety information from a market context deters innovation and thus causes long-term damage to economic institutions. Firms' incentives to invest in new products and technologies would be severely weakened. Each new product or technology would face the additional hurdle of satisfying an informational transfer burden that might or might not provide benefits to consumers. These costs make innovation more expensive, and thus less of it would be expected to occur.

Finally, the equity implications of a "right-to-know" concerning food safety may also be unpleasant. "Right-to-know" would redistribute income from those consumers who do not value such information toward those consumers who do. To the extent that people who value food-safety information highly also tend to be wealthier, then the establishment of a "right-to-know" may cause a redistribution of wealth from the poor to the rich.

In situations where economic principles are intentionally abandoned in favor of rights, the role of economics is to put a price tag on this choice. Rights are neither free nor infinitely valuable. By calculating the social cost, economics informs both Federal policymakers and the general public as to the sacrifice that must be borne to provide such rights. An integral part of any "right-to-know" is the right to know what it will cost to have it.

Regulatory Impact Analysis Guidance: Discussion of Comments

In response to many department and agency requests, OMB published a draft guidance document in the 1988 Regulatory Program to help departments and agencies in the preparation of regulatory impact analyses (RIAs). A guidance document became necessary because of substantial uncertainty concerning the appropriate level of analysis to be performed for a satisfactory RIA. This uncertainty led to inconsistencies within and across departments and agencies that made it difficult for both OMB and outside parties to evaluate and compare RIAs.

Some departments and agencies wanted OMB to publish a detailed set of requirements that, if followed, would guarantee compliance with the RIA requirement of Executive Order 12291. We understand this desire for an analytical "cookbook," but concluded that such an approach would fail to take account of the diversity of regulatory initiatives subject to the

Executive order. OMB decided instead to prepare a guidance document that would establish a three-part performance standard. RIAs must include:

1. A statement of the potential need for a proposed regulatory initiative;
2. An examination of alternative regulatory approaches; and
3. An analysis of benefits and costs expected to result from the regulatory initiative.

This chapter discusses the significant comments we have received concerning issues and procedures discussed in the draft guidance. Written comments were received from the Departments of Agriculture, Commerce, Labor, Transportation, and Veterans Affairs, and from the Environmental Protection Agency.[79] The final guidance reflects changes made as a result of these comments and appears as Appendix V of this document.

STATEMENT OF POTENTIAL NEED FOR THE PROPOSAL

An essential element of a satisfactory RIA is a statement of need for regulatory action. According to the draft RIA guidance, "analysis should demonstrate that (a) market failure exists that is (b) not adequately resolved by measures other than Federal regulation." OMB received comments addressing (a) what constitutes market failure, and (b) what rationales besides market failure justify Federal regulatory action.

The Definition of Market Failure

The draft RIA guidance identified three types of market failure: externalities, natural monopoly, and inadequate information. Externalities arise when individual actions or market transactions impose costs upon (or generate benefits for) third parties. Natural monopoly is defined as the existence of economies of scale so extensive that lowest-cost production of a good or service is obtained when there is a single seller. Finally, inadequate information refers to a particular type of market failure in which competitive forces fail to generate either the efficient production of information or the efficient pattern of information disclosure. Information issues were treated separately in the draft guidelines not because they are different in kind from other types of externalities, but because they pose economic problems that deserve a somewhat different regulatory approach.

One commenter felt that OMB's classification scheme failed to take account of a rich variety of market failures that arise within the commenter's particular regulatory area. Most of the unusual forms of "market failure" listed by this commenter are captured within the externality and inadequate information frameworks outlined in the draft guidance. However, this commenter also identified several phenomena that are not "market failures." It was asserted, for example, that safety regulations may be justified because "safety is relative and probabilistic." In a similar vein, this commenter argued that "it is generally not acceptable to discover that a product is unsafe only after it is in widespread use and has killed many people."

These alleged market *failures* are in fact undesirable market *outcomes*. The "relative" or "probabilistic" character of product safety mirrors similar uncertainties with respect to almost all market transactions. The existence of uncertainty does not imply a market failure. Many products and activities are inherently risky; the mere presence of a safety hazard cannot be prima facie evidence of market failure.

Some commenters identified examples of "market failure" that cannot be properly attributable to markets. Many of these alleged market failures are actually undesirable market *responses* to prior regulatory actions. For example, a commonly accepted (but poorly documented) side effect of stringent hazardous waste disposal regulations is an increased propensity for some individuals and firms to engage in illegal disposal. Departments and agencies facing situations like this should devote considerable attention to understanding the incentive effects of regulations, and strive to design regulations that yield appropriate behavioral incentives. For purposes of analysis and policy justification, these problems should be characterized as a failure of regulation rather than a failure of markets.

Another often-heard justification for regulation is the need for a "level playing field." Despite the wide array of circumstances in which the need for a "level playing field" has been asserted, a generally accepted definition of the phrase has not emerged. Sometimes, the perceived need for leveling appears to result from the competitive or regulatory advantages of others. In other cases, it is assumed to be necessary for unspecified equity reasons. In neither instance, however, does the absence of a "level playing field" indicate any malfunction in market processes. Imbalances that result from government actions (e.g., incentive-distorting subsidies for the extraction and use of certain virgin natural resources) generally should be addressed by the elimination of these perverse incen-

[79] The full text of all written comments is available for inspection and copying in the docket library of the Office of Information and Regulatory Affairs, Office of Management and Budget.

tives, not by additional government actions (e.g., incentive-distorting subsidies for recycling) that attempt to overcome the perverse outcome without confronting the inefficient incentives that caused it.

Alternative Rationales for Federal Regulation

This requirement implements section 2(a) of Executive Order 12291 and section 3(b)(1) of Executive Order 12612 ("Federalism").[80] The Agency's discussion of the need for Federal regulation should be based on the principles of Executive Order 12291. These principles establish unequivocally that the basis for regulatory action is market failure—that is, distortions in market outcomes arising from natural monopoly, externality, or inadequate information. In each of these instances, regulation may be an appropriate mechanism to modify or restore distorted market processes or to establish markets where heretofore they have not existed, to maximize net social benefits (including environmental, health, and safety benefits). Moreover, the policy view enunciated by Executive Order 12612 is that Federal (as opposed to State or local) regulatory action must be premised on the conclusion that the underlying problem to be addressed is Federal in scope, and not merely common to the States. In combination, these Administration policy statements require that RIAs performed in support of proposed Federal regulatory actions document that market failure is the underlying cause of the problem they are intended to remedy, and that the market failures in question are Federal in scope rather than merely common to the States.

Some commenters felt that the draft guidance placed too much emphasis on market failure. These objections represent a challenge to Executive Order 12291, however, not to the draft RIA guidance. The basic philosophy of the Executive order clearly identifies market failure as the principal (if not exclusive) rationale for Federal regulation. The final guidance for conducting RIAs is based on the clear language and purpose of the Executive order; objections to the Executive order must be addressed in another forum.

Some commenters questioned the required documentation of market failure on the ground that it failed to take account of statutory limitations that may conflict with Executive Order 12291. For example, regulations may be promulgated to implement a variety of legislative missions that derive from other public purposes besides remedying market failure. These purposes may include such activities as the redistribution of income, or the provision of benefits to favored groups or sectors of the economy. These commenters feared that a strict application of a "market failure requirement" in the RIA guidance thus would be inconsistent with their fundamental government function.

These comments may reflect misunderstanding concerning the scope of Executive Order 12291. Nothing in the Executive order repeals or otherwise modifies statutory requirements. Section 2 of the order prescribes that regulatory actions adhere to the order's stated principles "to the extent permitted by law." When departments and agencies must implement laws that conflict with the Executive order, the relevant laws always govern. However, the Executive order requires departments and agencies to apply its fundamental principles to the extent that they have discretion in interpreting their statutory mandate.

Even when governing statutes clearly conflict with the principles of section 2 of Executive Order 12291, the order's good-government requirements for full public disclosure and careful analysis still apply.[81] Departments and agencies are expected to (a) state in such cases that their regulatory actions are based on specific statutory requirements, (b) clearly explain why these requirements conflict with Executive Order 12291, (c) indicate whether these requirements address a genuine market failure or serve some other public purpose, and (d) perform analysis required by the Executive order to estimate the social opportunity cost of these conflicts. OMB believes that full opportunity cost accounting of statutory conflicts is necessary to implement Executive Order 12291.

Identification of Specific Statutory Requirements that Conflict with Executive Order 12291

Departments and agencies often have considerable discretion in the interpretation of statutory authorities. Unambiguous conflicts between statutes and the Executive order are relatively rare. Nevertheless, such conflicts do arise and should be carefully documented. It is insufficient, however, to assert broad exceptions to the Executive order in lieu of identifying specific statutory bases for conflict.

[80] Executive Order 12291, Section 2(a): "Administrative actions shall be based on adequate information concerning *the need for* and consequences *of proposed government action*" (emphasis added); Executive Order 12612, Section 3(b)(1): "It is important to recognize the distinction between problems of national scope (which may justify Federal action) and problems that are merely common to the States (which will not justify Federal action because individual States, acting individually or together, can effectively deal with them."

[81] Section 3(d)(4) of Executive Order 12291 reads: "[Each preliminary and final RIA shall contain] . . . a description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of [the] potential benefits and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted."

Clear Explanation of Reasons for Conflict

Having identified specific statutory language that conflicts with the principles of the Executive order, departments and agencies must cogently explain the nature of these conflicts. Legislative histories and other documents may be helpful for developing such explanations. However, it is important that these sources not be used to displace plain statutory language. Departments and agencies bear the burden of showing how specific statutory requirements conflict with the principles of the Executive order.

Analysis Estimating the Opportunity Cost of Statutory Conflicts

Because Executive Order 12291 reflects cardinal principles for the conduct of good government, Federal regulatory actions that depart from these principles deserve unusual care and public scrutiny. An essential element of this effort involves the estimation of the social opportunity cost of such departures. Opportunity cost is the value of the resources society must sacrifice to accomplish conflicting statutory objectives.

Analysis is a necessary prerequisite to an informed electorate. It provides policymakers and citizens a better understanding of the consequences of governmental actions. For government, careful analysis satisfies a "truth in regulation" disclosure burden that ultimately results in more carefully reasoned policy choices.

EXAMINATION OF ALTERNATIVE APPROACHES

The draft guidance encouraged departments and agencies to consider a wide range of regulatory alternatives, and include in their RIAs analysis addressing "a manageable number of them." The draft guidance did not dictate a specific number of alternatives to analyze, noting that "there must be some balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis." Alternative regulatory actions examined should be reasonably expected to remedy the identified market failure; it is not sufficient to identify legitimate market failures that cannot be remedied by the proposed governmental action.

Commenters generally supported the emphasis on breadth in the draft guidance, and the use of a "performance standard" approach which recognizes that all potential regulatory actions do not warrant equally intensive study. However, some commenters felt that the draft guidance imposed an unnecessarily heavy analytical burden that could not be satisfied in practice. OMB recognizes that the appropriate depth and level of analysis should vary with the nature and scope of the proposed regulatory action. However, OMB believes that the analytical burden imposed by the RIA requirement is never excessive given the magnitude of effects which result from "major" Federal regulations.[88]

The draft guidance also directed departments and agencies to examine innovative regulatory approaches. Foremost among these alternative approaches were performance-oriented standards, differential requirements for distinguishable sectors of the regulated community, information measures, and market-based incentive strategies. Commenters were either silent or supportive of this emphasis on creative, targeted, market-oriented solutions.

Finally, the draft guidance encouraged departments and agencies to consider reasonable alternatives that might be precluded by statute. Some commenters asserted that such analysis is unnecessary and contributes little to the regulatory process. OMB believes that the analysis of statutorily precluded alternatives is essential to inform long-run policy debate and thus is generally worth the effort, even if it has no immediate effect on short-run decisions. The final RIA guidance explicitly requires departments and agencies to evaluate statutorily precluded alternatives as necessary, thereby providing estimates of the opportunity cost imposed by statutory constraints.

ANALYSIS OF BENEFITS AND COSTS

Comments concerning the benefit-cost analysis requirement of the draft guidance generally fell into one of the following five categories: (1) the identification of values suitable for regulatory analysis, (2) appropriate methods for valuing nonmarket goods, (3) the derivation of benefit estimates based on quantitative risk assessment, (4) distributional effects, and (5) discounting.

Identification of Values Suitable for Analysis

Several commenters felt that the draft guidance gave inadequate attention to the problems of quantifying and monetizing benefits that accrue in the form of

[88] "Major" rules are defined by section 1(b) of Executive Order 12291 to include any regulatory action likely to result in (1) $100 million in annual effects on the economy; (2) a major increase in costs to consumers, industries, governments, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or international competitiveness. Regulatory actions that do not appear to meet these criteria but establish important policy precedents may also qualify as major rules.

nonmarket goods such as environmental amenities. Commenters suggested a variety of measures for estimating the benefit of nonmarket goods, indicated by such terms as *use value, option price, option value, existence value, preservation value,* and *intrinsic value*. Unfortunately, there are considerable differences of opinion concerning the appropriate definitions for these terms, and even less agreement concerning their proper application. In the interest of consistency, we distinguish between the nature of a benefit and the methods used to estimate it.[83]

Physical and Psychological Use (Use Value)

The benefits from environmental amenities derive from a continuum of sources ranging from intensive physical use to intangible psychological enjoyment. Some individuals may value an environmental resource for the outdoors activities it provides, such as hunting, fishing, camping, or boating. Others may value it for timber that could be harvested to provide lumber for new homes. Still others may attach value to preserving an environmental resource as wilderness, free from intensive recreational and developmental uses. Both physical and psychological uses are fully captured by the term *use value*, even though psychological uses often are characterized by the terms *existence, intrinsic,* and *preservation values*. There is no difference in theoretical "legitimacy" between physical and psychological uses. Problems arise only with respect to measurement.

The principles of positive economics do not provide any means for ranking alternative sources of "utility" apart from willingness-to-pay. Rather, the objective task of economics is to ascertain such rankings based on the revealed or otherwise discernable preferences of individuals. In most cases, preferences are revealed through actual behavior, and market transactions provide the forum in which society, as a collection of independently acting individuals, communicates an aggregate valuation for these preferences. Market transactions provide tangible evidence of individuals' willingness-to-pay, thereby allocating goods and services to the highest-valued use. Markets reveal value, and positive economics treats virtually all market-determined values as ethically equivalent.[84]

The "problem" of valuing physical and psychological uses of environmental amenities does not appear to be significant where property rights are well-defined and readily enforceable by law. Owners and operators of such resources allocate them to their highest- valued uses, charging use or access fees that reflect market-determined values. Markets for common-property environmental amenities often can be created by establishing well-defined and enforceable property rights. The right to fish in a public lake is often constrained by the number of licenses available, which is generally limited by the carrying capacity of the lake. Opportunities to backpack in a Federal wilderness area similarly are limited by the number of permits, which exist to protect permit owners from the encroachment of others. In the absence of well-defined and enforceable property rights, however, market prices will be misleading where markets exist and generate resource allocations that are both economically inefficient and environmentally unsound. Common-property resources characterized by well-defined property rights, however, enable full opportunity-cost accounting to determine the highest-valued use.

Economics does not arbitrarily assign higher values to some uses than others. Nevertheless, some uses are more readily observed and estimated because there are market-based transactions that reveal individuals' willingness-to-pay. If property rights are well-defined and readily enforceable, markets will exist for such varied uses as timber harvesting, fishing, hiking, and birdwatching. In each case, individuals physically visit the environmental amenity to "consume" it. Where such markets exist, they should be relied upon to derive estimates of willingness-to-pay.

However, markets for the preservation of environmental amenities apart from physical use generally do not exist. The willingness-to-pay for preservation may be equal or greater than the willingness-to-pay for physical use, but high transactions costs typically prevent the formation of markets. Nevertheless, the same principle for measurement applies. A variety of analytic methods may be acceptable as long as they yield estimates that reflect market-based principles of valuation and comport with reasonable expectations of what markets would generate if in fact markets existed.

Innovative strategies for overcoming these problems have been developed in recent years. For example,

[83] The following discussion uses environmental amenities as a surrogate for all nonmarket goods.

[84] Many economists would exclude the utility obtained from illegal acts and transactions. As a general rule, however, the burden rests on those who would exclude certain sources of utility as illegitimate. Utility derived from legal markets is per se legitimate and cannot be excluded.

many States offer voluntary check-offs for environmental preservation on their income tax returns. These check-offs may provide a useful real-world measurement of willingness-to-pay for environmental preservation apart from physical use, where they increase taxpayers' financial liability to the State on a dollar-for-dollar basis.[65]

Option Price

This term reflects an individual's willingness-to-pay for the opportunity of future use. For a risk-neutral individual, it is equivalent to the present-value willingness-to-pay for physical or psychological use, multiplied by the probability that use will actually occur.[66] Risk-averse individuals will generally pay more than the expected value for actions that reduce variability in outcomes; for them, option price will exceed willingness-to-pay.

Option Value

This term is defined as the mathematical difference between option price (an ex ante measure of welfare change) and the expected value of consumer surplus (an ex post measure of welfare change). It reflects a risk-averse individual's willingness-to-pay for insurance against the threat of an undesirable event. Option value is zero for risk-neutral individuals because they are only concerned with the expected value of consumer surplus and are indifferent with respect to the amount of uncertainty surrounding the expected value. Because option value is a risk premium, it will not be a large fraction of the expected value of consumer surplus except for individuals who are extraordinarily risk averse. Moreover, option value for an individual will tend to be associated with unique resources. Even if option value is unusually large for an individual, it will not be substantial in the aggregate unless this uniqueness is shared by many such individuals.[67]

Other Valuation Terms

The remaining valuation terms suggested by commenters are either captured elsewhere, or they are unrelated to an individual's actual or potential "use" of an environmental amenity and should be excluded from consideration in regulatory analysis. *Bequest value* may be thought to represent an individual's interest in preserving a resource for the current or future enjoyment of others. To the extent that this constitutes a psychological "use," it is already captured within the use value definition. An alternative meaning for *bequest value*, however, is an individual's desire to bequeath an (environmental) amenity that is not part of the individual's asset portfolio. In this instance, bequest value is illegitimate, because it represents the individual's asserted claim on the disposition of assets owned by others.

Intrinsic value has been discussed in the context of other psychological uses, such as *preservation value* and *existence value*. However, the term is also used to refer to the "value" of animals, plants, and inanimate objects independent of the willingness-to-pay of individuals or societies. In this context, the term appears to be based on a valuation system that is independent of human experience. Because it is grounded in human wants and desires, policy analysis cannot be expected to accommodate this alternative definition of "value."

Valuation of Nonmarket Goods

Use value is theoretically equivalent to an individual's willingness-to-pay for access to and enjoyment of an environmental resource. In practice, physical use values can be estimated based on the observation of actual behavior or through the use of survey instruments. In general, neither approach is fully satisfactory. Survey instruments often suffer from biases because they attempt to measure hypothetical tradeoffs; revealed preference methods sometimes require data that cannot be reasonably obtained.

Survey estimates may be necessary to estimate certain physical and psychological uses, because relevant behavior is unobservable. However, the problems that arise in the estimation of use value through survey methods are considerably more serious. Great care needs to be taken to ensure that survey designs do not introduce systematic biases by departing from market-based valuation principles. For example, slight changes in the way questions are presented can sometimes result in dramatic changes in responses, because of the hypothetical nature of data derived from survey instruments. This hypothetical character means that survey methods offer considerable opportunities for abuse. Analyses relying on survey instruments to estimate benefits should devote considerable efforts to quality control, data verification, and real-world hypothesis testing. Major

[65] Tax return check-offs give a lower bound of willingness-to-pay because of the existence of "free riders," individuals who obtain psychological enjoyment from preservation without actually contributing to it.

[66] Use may be automatic for psychological uses, because it is not contingent on the expenditure of additional scarce resources to convert from speculative to actual consumption. Option prices for psychological use should be identical to willingness-to-pay.

[67] For option value to be large in the aggregate, two conditions must apply: (1) individuals must be risk-averse; (2) use of the environmental amenity must constitute a very large proportion of each individual's asset portfolio.

departures from market-based principles can lead to serious distortions in the allocation of our Nation's scarce resources.

Because of the potential for misuse of survey methods, RIAs generally should avoid relying exclusively on value estimates derived through survey approaches. An exception to this rule may arise in special cases where nationally recognized unique resources (e.g., "national treasures") will suffer *irreversible* damage in the absence of regulatory action. This limitation allows the consideration of value estimates that are based solely on survey results in instances where they are most likely to be significant, while discouraging their widespread and indiscriminant application where they are likely to be small.

Finally, departments and agencies that develop benefit estimates which rely heavily on the results of survey instruments bear an extraordinary burden to show that estimates obtained are reasonably consistent with observable market behavior and common sense. For example, survey-derived estimates of willingness-to-pay for wilderness preservation should comport with observable behavior, such as voluntary income-tax return check-offs. Estimates of individuals' willingness-to-pay for *reversible* environmental harms, such as visibility impairment, may be even more difficult to corroborate based on observable behavior.

The Use of Quantitative Risk Assessments in the Development of Benefit Estimates

The draft RIA guidance focused considerable attention on how quantitative risk assessments should be employed in producing appropriate estimates of the benefits accruing from regulatory actions aimed at health and safety objectives. The draft guidance indicated that analytically sound benefit estimates can only be based on expected-value estimates of human health risks.[88] The use of upper-bound risk assessments and worst-case exposure assumptions leads to upwardly biased benefit measures. These biases transform objective benefit-cost accounting into a subjective procedure that inherently favors regulatory action.[89]

A few commenters objected to OMB's emphasis on expected-value risk assessment on two grounds. First, these commenters argued that expected-value estimates fail to take account of high-risk subpopulations, which deserve special regulatory protection. Second, the uncertainties surrounding quantitative risk assessment are so great that prudent public health policies warrant conservative risk estimates.

Both of these criticisms suffer from a misunderstanding of the purpose of estimating benefits. The National Academy of Sciences clearly articulated the basis for expected-value risk assessment in its seminal 1981 report:

> Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[90]

Regulatory agencies that fail to develop expected-value benefit estimates violate this fundamental principle.

The desire to protect certain high-risk subpopulations does not justify embedding conservative biases within ostensibly scientific risk assessments. Whether high-risk subpopulations deserve special consideration is a policy matter for which government risk managers are responsible. It has no bearing on the correct practice of policy analysis. Departments and agencies are free to quantify the effects of potential regulatory actions on sensitive subpopulations, particularly as quantification enriches policymakers' understanding of the tradeoffs across regulatory alternatives. However, it is not acceptable to focus on sensitive subpopulations *instead of* examining expected-value impacts.

Similarly, uncertainty per se cannot justify biased benefit estimates. Uncertainty is endemic to regulatory analysis. However, conservative biases and "margins of safety" embedded in the analysis of the effects of regulatory actions (e.g., those purporting to reduce environmental and occupational cancer risks) fundamentally distort public policy in unpredictable ways. Benefit estimates derived from upper-bound risk assessments and worst-case exposure assumptions mislead policymakers and the general public about the true dimensions of the underlying problem.

[88] The full distribution of possible benefits is the theoretically preferred measure. Departments and agencies generally produce only a point estimate, however, in part because it is impossible to develop the full distribution. The RIA guidance calls for benefit estimates to point estimate, however, in part because it is impossible to develop the full distribution. The RIA guidance calls for benefit estimates to be based on expected values whenever departments and agencies choose to provide only point estimates, because only the expected value be based on expected values whenever departments and agencies choose to provide only point estimates, because only the expected value is unbiased. OMB has long supported efforts to characterize the full distribution, rather than relying on point estimates.

[89] Issues concerning risk assessment are addressed in more detail earlier in this overview, in *Current Regulatory Issues in Risk Assessment and Risk Management*.

[90] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC: National Academy Press, 1983, p. 153.

Expected-value benefit estimation simply treats both sides of the ledger in the same manner. Departments and agencies do not (and should not) use upper bounds and worst-case assumptions to estimate regulatory costs; instead, they provide "best estimates" that are often subject to considerable uncertainty. Intellectual fairness demands a similar treatment of uncertainty on the benefit side. The severe uncertainties characteristic of quantitative cancer risk assessment are typical of the difficulties of performing rigorous policy analysis in general. Howver, instead of limiting analysis (or inserting a specific bias) government agencies have the duty to devote resources to reducing uncertainty when the value of this information exceeds the cost of providing it. This cannot be accomplished as long as agencies continue to construct biased benefit estimates derived from upper-bound risk assessments and worst-case exposure assumptions.

Distributional Effects

Several commenters suggested that the final RIA guidance should require that analyses present the distributional effects of regulations. Those persons who bear the costs of a regulation and those who enjoy its benefits are often not the same. For example, the costs of changes to production processes intended to improve worker safety are often borne by consumers, in the form of higher product prices. The costs and benefits of regulation can also be distributed unevenly over time, spanning several generations.

A strict regulatory decision framework designed to maximize net benefits does not take such distributional effects into account. Rather, it is based on the Kaldor-Hicks criterion, which states that policy A (e.g., a regulation) is preferred to policy B (e.g., the status quo) if the gainers could compensate the losers and still be better off. The Kaldor-Hicks criterion does not require that gainers actually compensate losers—something for which the Kaldor-Hicks criterion has been criticized. Ironically, requiring such compensation would intensify the implicit preference given to the status quo, by restricting changes to those which are Pareto-superior.

There is no generally accepted way to monetize (and thus incorporate directly into the benefit-cost analysis) potential distributional effects. However, policymakers may wish to take these effects into account. Therefore, in situations where there are potentially important differences between those who stand to gain and those who stand to lose under alternative regulatory options, the RIA should identify these groups and indicate the nature of the differential effects. It is not acceptable to merely assert the existence of intergenerational effects. The RIA must present full benefit and cost streams as well as present-value estimates for each relevant group. This approach leaves to policymakers the responsibility for determining the weights that should be explicitly applied to certain groups or to future generations.

Discounting

The draft RIA guidance incorporated the fundamental economic principle that both benefits and costs should be discounted. This practice takes account of the fact that any fixed resource is worth more today than at any future date. Comments were received addressing the appropriate methodology for discounting nonmonetized costs and benefits, the use of "steady-state" approaches instead of discounting, and the selection of the discount rate.

Discounting Effects That Are Not Monetized

One commenter argued that only effects which can be monetized should be subject to discounting. This commenter argued that regulatory effects which are not traded in markets do not exhibit the same value-of-time preference underlying the discounting of monetized commodities.

This argument has three fatal flaws. First, it is based on a misunderstanding of the theory of intertemporal exchange. Second, it can lead to absurd policy implications under certain circumstances. Third, it is refuted by empirical evidence.

The commenter's argument is apparently based on the mistaken belief that nonmonetized effects must be either (a) "directly" tradable across different time periods or (b) amenable to valuation in monetary terms, and that in many instances neither condition holds. This argument is fallacious because neither condition comports with economic theory. The first condition lacks merit because few commodities can be directly traded across time periods without the mediating function of the price system. Any requirement of direct trading imposes an arbitrary constraint that denies the price system's capacity to reduce the transactions costs of exchange. Prices established through the market provide a convenient "scale" that allows individuals to balance one intertemporal consumption path against another based on their particular preferences for current and deferred welfare. This commenter would arbitrarily deny the legitimacy of intertemporal exchange except in cases where there are explicit market prices.

The commenter's second condition (that the commodities in question must be amenable to monetization) is satisfied at least conceptually for all goods of finite value. If it were not satisfied, we would observe individuals devoting their entire wealth to the pursuit of certain infinitely valued goods. Of course, such an observation is counterfactual. Individuals behave in accordance with real prices where prices exist, and *as if* prices exist in areas where they do not. The relevant distinction between monetizable and nonmonetizable effects is really one of the ease with which one can estimate their value.

Because all commodities are of finite value, analysis requires that they be treated consistently regardless of the ease with which they can be explicitly monetized. To do otherwise would distort the allocation of regulatory resources in favor of nonmonetized goods and services that can be enjoyed in any future time period at the expense of goods and services whose value in that time period is determinate.

Of course, policymakers may wish to weigh certain effects differently than others. However, arbitrarily treating effects differently through the discounting procedure denies decisionmakers that option. As we indicated earlier in our discussion of distributional concerns, the RIA should present the undiscounted streams of costs and benefits as well as their discounted present values in situations where decisionmakers are unusually concerned about nonmonetized effects.

The failure to discount nonmonetized benefits can lead to the absurd result that society will always be better off by deferring an action (and its associated benefits) indefinitely. To argue that a nonmonetized benefit should not be discounted implies that its value is the same whether it occurs today or at any time in the future. Suppose that the resources that would otherwise be used today to achieve a given result could be invested at a positive rate of return (that is, at the discount rate). By forgoing the expense this year and investing the resources at the discount rate, society could spend more next year (by a proportion equal to the discount rate) and achieve a higher level of welfare. As long as society places the same value on a unit of future benefits as a unit of current benefits (i.e., it does not discount), it will be better off by delaying the action ad infinitum.

Finally, there is empirical evidence indicating that individuals behave as if they discount future effects that do not carry explicit prices. In the context of compensating differentials for occupational risks, for example, analysts have estimated a real discount rate of 10 to 12 percent. This implies that the willingness-to-pay today for a 1-year life extension for an individual who expects to live only 5 years is about 40 times as great as that of an individual who expects to live 35 more years. A policy decision based on undiscounted effects in this instance could result in an allocation of resources that is grossly inconsistent with this revealed willingness-to-pay.

While costs and benefits must be compared as if they occurred simultaneously, it is not necessary to discount benefits to accomplish this kind of comparison. As an equivalent alternative to discounting nonmonetized benefits, for example, the RIA may use the discount rate to amortize costs over a period that corresponds to the occurrence of the benefits. Cost estimates will be greater under this method, because they will reflect the forgone investment potential of expenditures that must be made now rather than contemporaneously with the benefit stream.

Estimating Benefits and Costs Based on Steady-State Conditions

Some agencies derive benefit and cost estimates in steady-state equivalents instead of net present value terms. This procedure may be useful for examining regulatory actions when benefits and costs are purely contemporaneous. However, steady-state analysis may obscure the full ramifications of regulatory actions by focusing too much attention on the snapshot view. It is similar in this respect to problems with benefit-cost ratios, which focus attention on relative totals but fail to disclose the magnitude of a contemplated action.

Problems also arise with steady-state analyses when benefits and costs accrue over different time periods. The steady-state outcome may give a distorted impression of the true consequences of a regulatory action. For example, the costs imposed by a particular action may be borne in roughly equal annual increments, whereas the benefits obtained from these expenditures may increase at a declining annual rate until the steady state is achieved many years hence. The net present value of the action will be considerably less than the apparent net benefit in the steady state.

An example of the misuse of steady-state analysis is the practice of "annualizing" health benefits that actually accrue in the latter part of a lifetime. These analyses typically assume that changes in environmental or occupational conditions are instantaneously translated into reduced human health risks. In practice, such changes may take many years to achieve their full protective effect. Analyses that assume instantaneous transmission overstate actual benefits and impart a systematic bias in favor of regulatory action.

Choice of Discount Rates

Rather than specify a single discount rate to be applied in all circumstances, the draft guidance offered two alternatives: (1) a before-tax real rate of 10 percent, consistent with OMB Circular A-94; and (2) an after-tax real rate of 4 percent, consistent with how much consumers must be compensated to defer consumption. In addition, the draft guidance suggested that departments and agencies might want to develop a regulation-specific discount rate based on the "shadow price of capital" and compare the results against the other two rates, using sensitivity analysis.

Some commenters suggested that the guidelines should provide for the use of other discount rates. As the draft guidance makes clear, however, departments and agencies are free to apply a variety of alternative discount rates in sensitivity analyses and make their best case in favor of an alternative rate. However, the need for consistency across regulations demands that RIAs include at least one common discount rate. In any event, the final RIA guidance has been modified to require departments and agencies to provide the full stream of benefits and costs. This allows for any number of alternative discount rates to be applied by policymakers and independent analysts, thus yielding a more useful document in every respect.

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ECOLOGY

September 15, 1990

Dave Bradley
Department of Ecology
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COMMENTS ON PROPOSED CLEANUP STANDARDS

There are very few environmental decisions which are thoroughly based on science. Uncertainty surrounds the assessments even when those assessments are expressed in numbers which imply accuracy. We cannot wait for science to give us certainty but we must make decisions based on our limited knowledge and the concerns of the public. It is misleading to characterize what are really policy decisions as "scientific" or "scientifically defensible."

The purpose of cleanup at historic sites is to rectify practices made without concern for public health and the environment. We must, in spite of our limited knowledge and understanding, decide what risk is acceptable. In deciding on a risk level we will be faced with wide margins of uncertainty. Hazardous waste sites often present even more uncertainty than most toxicological assessments by nature of their complex mixture of chemicals and routes of exposure. If, in our cleanups, we aim for a risk of increased cancer at 10^{-6}, we could be off by several orders of magnitude; we could be accepting 10^{-5} or 10^{-4}. Therefore, we should be conservative with our risk level and not allow it to drop below 10^{-5} or we may, in actuality, be accepting actions which are only slightly protective.

The WEC supports cleanup standards aimed at an increased cancer risk of 10^{-6}.

General Comments

It is difficult to envision how these regulations will "play out" because some basic concepts (feasible and practicable) are intertwined and the overriding considerations (protective risk levels) are tempered with undercutting provisions (cost considerations).

WHEN CAN CLEANUPS OCCUR WITHOUT MEETING THE STANDARDS?

The proposed rules contain the concept that cleanup standards will be fixed within the risk range of 10^{-6} down to 10^{-5} when conditions apply. However, there are escapes which will allow cleanups to fall below 10^{-5}:

1. Move the point of compliance.
2. Slip the time of compliance.
3. Construct a risk assessment with a lower exposure opportunity, i.e. cap, fence, site use restrictions. "Institutional controls" can substitute for actual cleanup.
4. Argue cost. There is some attempt to bound cost considerations, but it is not clear under which decisions those boundaries will apply and exactly when cost will drive the decision. (Just count the number of times "practicability" is used!)

WEC feels that standards should be set without regard to costs. Costs may be considered when choosing between remedial actions which meet the goals (the standards and the priority for permanent solutions). This meets the widely accepted practice of "cost-effective analysis" as opposed to "benefit-cost analysis."

Cost versus technical feasibility. These are two different but important factors in cleanups. They should be dealt with separately and in a straightforward manner so that anyone can clearly tell which factor is influencing a decision. The current draft mixes these two factors together in the definition of "technically practicable".

Suggested change:
360 (2) (a) list (i), (ii) and (iii) should be inclusive; insert "and".

360 (2) (b) (i) as is.
(ii) "Be technically feasible at the site."

Suggested change: definitions:
"Technically feasible" as is

"Technically practicable"...delete

"Practicable or practicability" A remedial action is assumed to be practical unless the following criteria are met:

(a) If the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action;

(b) costs considered shall include present and future direct and indirect capital, operation and maintenance costs and other foreseeable costs;

(c) protection shall include effectiveness, the value of the resources, the potential use of the property, potential costs of further action, all measured in the near term and long term; and

(d) for cleanup action alternatives which are protective of human health and the environment, including complying with cleanup standards and which have an equivalent order of preference as permanent solutions, preference **may** be given to the cleanup action which costs the least.

MOVING FROM COMPLIANCE STANDARDS TO CONDITIONAL STANDARDS.

Suggested change:
700 (5) (d) (iv) delete "below technically practicable levels" and insert "not practicable" .

(v) delete completely. It is a mitigation approach and will be argued continually. Not appropriate to the goals or policy of the cleanup law.

SELECTION OF CLEANUP ACTION.

It should be made more explicit that cleanup standards must be met in addition to ARARS. Therefore the reasonable test of AKARTS or BACT is applied only if standards are met.

GROUNDWATER TREATMENT

page 12, 360 (4) (ii) AKARTs. This statement incorporates the concept of reasonable. The cleanup must still meet the other requirements. Reasonable becomes a test only if the requirement for AKART takes you below the standard. Reference to policy stated in water pollution law should define "reasonable" in that situation. Avoid confusing this with the "practicable" tests specific for these rules. (A),(B) should be deleted here as they imply that the standard (10^{-5} or better) will not be met and cost will determine the degree of control. The remaining sections discussing responsibilities while groundwater standards are being attained should be in institutional controls section.

MOVING POINT OF COMPLIANCE

The point of compliance should be throughout the site if it is technically feasible, if there is no shift or increase in risk and if the "practicable" test is met. Language should be added to require a finding that these criteria cannot be met if the department is to allow a conditional point of compliance.

HAZARD INDEX

The hazard index for non-carcinogens should be adjusted for the fact that exposure from drinking water accounts for only a portion of the total exposure. In recent proposals on federal standards under the Safe Drinking Water Act the approach is to assign a relative contribution from drinking water at 0.2. **WEC urges that the hazard index for non-carcinogens be set at 0.2 rather than 1.0.**

SENSITIVE POPULATIONS

The risk assessment framework spelled out in these rules is not adequately protective of sensitive populations. The more conservative estimates of 70 years of exposure and children's weights should be the normal factors unless there is strong proof that these should not apply.

ENVIRONMENTAL PROTECTION

The rules mainly address risk to public health with not enough attention to risk to ecosystems, wildlife and biological resources. It was a strong intent of the Initiative that cleanups be protective of not only public health but of the environment in total.

MULTIPLE SUBSTANCES AND MULTIPLE EXPOSURES

Under the proposed rules, method A allows for the use of lists and tables to establish cleanup standards. These tables are calculated assuming single chemicals and single routes of exposure, which is seldom the case in actual sites. There needs to be more careful constraints on the use of these tables so that they will ONLY be applied in very simple cleanups with few chemicals and no possibility of synergistic effects or multiple exposure opportunities.

PROTECTION OF NATURAL RESOURCES

Within these rules, the determination of the future value of resources, notably land use and ground water, is too restricted to current practices. We must recognize that, particularly with the growth that the state is experiencing, we need cleanups which will allow wide options. What is currently urban-industrial use may soon be desirable as residential or recreational. Where we are currently obtaining drinking water from distant watersheds, we may need to tap groundwater for increased populations.

Statement of Appreciation:

How clean is clean? is a question which is not easily answered. The Washington Environmental Council recognizes the serious effort that has been dedicated to these rules by the Ecology staff. There is nothing simple about writing rules which can be easily understood, are specific enough and yet allow for a multitude of site differences. We have been critical of draft language and we have expressed our complaints on the proposed rules above, but we have never doubted the process or the effort. We hope these rules will be modified and adopted and that cleanups can proceed swiftly.

Elizabeth Tabbutt

Elizabeth Tabbutt, Director for Public Policy

SMC
Seafab Metal Corporation

SEP 1? 1990
OLOGY

Mr. David Bradley
Toxics Cleanup Program
WDOE
Mail Stop PV-11
Olympia, WA 98504-8711

By FAX to 438-3050
Sept. 17, 1990

Re: Proposed MTCA clean up standards

Dear Mr. Bradley,

While hardly an expert in the field, I have attempted to review the regs in an effort to assist DOE in reaching workable procedures and have the following comments.

1. It is difficult to read the regs. Simple sentences and the use of examples would help.

2. If possible, it would be desirable to have a greater range of risk levels, depending on site conditions. I think this would make it easier to reach final clean up.

3. While the use of interim status may be desirable in some circumstances, I am afraid that it's use to avoid final determination may greatly increase both the cost to the parties and the cost to the agency in supervision manpower. Whatever you can do to make final clean up easier to reach would appear to benefit all concerned. Ultimately, if it were determined that final clean up did not solve critical problems, I am sure there is plenty of legal authority to support a new clean up action.

4. We feel that the restrictions on using cost as a significant item in determining clean up may result in:
   a. hardship on the parties, possibly resulting in productive economic operations being shut down and/or curtailed, thus costing jobs and tax revenue.
   b. extensive "transaction costs" as parties use all available methods to avoid truly burdensome and perhaps fatal cost consequences.
   c. great time delay in effecting clean up.

5. Many and, perhaps, novel, clean up methods should be encouraged to help develop methods that would be cost and time effective to achieve the goal: clean up.

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If I can make any further contribution to this process, please let me know.

Sincerely,

GEORGE O. TAMBLYN

The Boeing Company
P.O. Box 3707
Seattle, WA 98124-2207

4-1241-KJH-441
September 17, 1990
FACSIMILED

Mr. Dave Bradley
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

Subject: Proposed Chapter 173-340 WAC

BOEING

Dear Mr. Bradley:

The Boeing Company ("Boeing") herein provides its comments to the proposed rules published in WSR 90-15-066. Boeing has been an active participant in all available opportunities for involvement in the Model Toxics Control Act ("MTCA"), RCW 70.105D, implementation process. We appreciate the Department of Ecology ("Ecology") efforts to seek broad based participation and consensus in development of MTCA rules. It is unfortunate that greater consensus was not reached with respect to the cleanup standards portion of the rules, but we commend Ecology for its persistence in seeking consensus and encourage Ecology to continue to approach rulemaking in this fashion. In the long run it will lead to much more effective programs, greater understanding of key issues and less likelihood of challenge. Boeing will continue to be a willing participant in such efforts.

General Comments

While the proposed cleanup standards reflect considerable struggle with many key issues of a complicated subject and generally have the potential for being workable and meeting MTCA goals, there are a number of improvements needed. First, the complexity of the rules threatens their workability. Unless appropriate administrative principles are expressed in the rules, application of the rules will be a cumbersome and confusing process. We sense broad support for such a rule addition. Specific language amendments are desirable in a number of areas for clarity and to prevent application of standards inconsistent with MTCA goals and unnecessary conflict with established areas of the federal Superfund program. Boeing's comments will focus more upon concepts and principles that should be recognized and incorporated in the rules.

In addition, Boeing strongly urges Ecology to work with various interest groups to develop guidance materials to enable Ecology staff and PLPs to consistently and effectively apply the rules toward cleanup completion. We believe the legislature and the public, including industry, want to see cleanups completed. Public and private parties and members of the scientific community who have attempted to apply the proposed rules to realistic site examples have generally recognized the need for administrative principles in the rule, further language changes and guidance. Boeing continues to support a state program that is consistent with the MTCA, encourages responsible parties to undertake cleanup and learns from the delays and inefficiencies experienced by the federal program.

BOEING

Specific Comments

1. The MTCA has a widely perceived although somewhat inartfully worded purpose. At face value the statute's purpose is to raise money to clean up sites and prevent the creation of new sites which may require cleanup. MTCA 70.105D.010(2). Read as a whole the broad based purpose is generally recognized as protection of human health and the environment. E.g., MTCA 70.105D.010(2), .030(2) (c). It is unfortunate that concept has been clouded somewhat by the proposed rules, even though expressed in the general procedures and elsewhere. WAC 173-340-700(2); 173-340-360(20) (d). This concern leads to several subcomments.

Perhaps the best way to observe this concern is through the debate over acceptable risk ranges. In many respects that debate has been avoided by the rules through a preference for cleanup levels based upon concentrations first and risk second. As to risk, the focus for carcinogens is 10^{-6} with limited ability to go to 10^{-5}. Such a limited risk "range" approach is of dubious scientific validity to the extent it focuses on reducing concentrations rather than risk and differs markedly from the federal program. It precludes approved federal levels deemed protective of human health and the environment, if they reflect a 10^{-4} risk.

Furthermore, the use of 10^{-6} and refusal to go below 10^{-5} reflects a rigidity for numerical purity at the expense of exceeding what is necessary to protect human health and the environment. This threatens to misuse limited government and private dollars. We specifically recommend that you use existing federal MCLs, which have been determined to be protective of human health, even though they may reflect a 10^{-4} risk. WAC 173-340-700(B). Also, in WAC 173-340-700(5), the repeated reference to "but in no case greater than concentrations specified in subsection (8)" should be deleted.

BOEING

In order to avoid the implication that cleanup levels can be set at levels more stringent than those protective of human health and the environment, which does not have a valid statutory or public policy basis, WAC-340-360(2) (a)(i) should be amended by deleting "including complying with cleanup standards." That addition is at best redundant and potentially ambiguous or in excess of statutory authority.

Boeing recommends a clearly stated administrative principle:

Notwithstanding any other provision of this rule, no cleanup standard or level or remedy selected shall be approved which leads to a net increase of environmental risk.

This concept has already been recognized in the Ecology 2010 program and the point seems intuitively obvious, but the potential exists for rigid adherence to cleanup levels without this caution.

Finally on this point, the proposed regulations have the announced goal of establishing cleanup levels as close as possible to natural background levels. WAC 173-340-700(2). Such an expression leaves ambiguous the relationship between protection of human health and the environment, risk and natural background levels. We recommend that protection of human health and the environment be clearly stated as the overarching goal. That may or may not mean natural background depending upon risk under the circumstances.

2. Another conceptual problem closely related to the first but worthy of separate mention is the potential that treatment for treatment's sake will be the driving force in cleanup rather than protection of human health and the environment. An example is WAC 173-360(4) (b) (ii) (A) where "and" should be replaced with "or". See also WAC 173-340-360(6)(e)(v). Also, if the cleanup levels are exceeded, treatment or removal sometimes becomes the only option. It is important that cleanup standards create a range of alternative actions. This area of concern perhaps arises from a lack of clarity between "cleanup levels" and "cleanup standards". Cleanup standards should encompass both cleanup levels and the hierarchy of cleanup actions. We draw your attention to the National Contingency Plan which directs the thinking of participants toward the importance of treatment, but more clearly avoids the potential for treatment for treatment's sake alone. 40 C.F.R. 300.430.

BOEING

3. Boeing believes that establishment of soil cleanup standards for industrial sites is sound public policy. WAC 173-340-745. However, it does not go far enough. Ecology can and should recognize other uses, such as agricultural and recreational, with alternative compliance levels. Appropriate safeguards can be included to protect against usage changes.

Furthermore, Ecology should recognize an alternative compliance cleanup level for groundwater that, while useable, is extremely unlikely to ever be used as drinking water. For example, certainly this applies in various tidal areas where alternative water supplies are well established and the drinking water aquifer is truly marginal at best.

Similarly, the definition of drinking water should not be based on the criteria of 10,000 mg/l of total dissolved solids. WAC 173-340-720. Cleanup to more stringent levels than health based drinking water standards leads to imprudent use of resources.

4. Boeing is aware of little scientific basis for soil cleanup standards based upon one hundred times the groundwater compliance cleanup level. Such cross media guidelines are of dubious validity.

5. The administrative principles that Boeing proposes should affirm the Ecology bias for action and finality at sites even though appropriate reviews or reopeners may sometimes be necessary.

BOEING

6. Boeing opposes the failure of the proposed rules to recognize dilution when applying surface water standards to groundwater cleanups. WAC 173-340-720(6)(d). We believe this position is indefensible on numerous grounds. Even in a permit context, the use of a dilution zone is done on a case by case basis depending upon parameters such as flow volume, receiving water volume and receiving water flow.

7. WAC 173-340-720(3)(a)(iii)(B) should reflect that concentrations are measured in the surface water where groundwaters with no specific beneficial use other than flow to the surface water is involved. It is surface water impacts which matter in this instance.

8. The proposed new section on administrative principles should clearly express a preference for containment or isolation as the cleanup action for indestructible substances. See 40 C.F.R. Section 300.430(a)(1)(iii). In other words, they should clearly recognize the appropriateness of a lower level of hierarchy in some instances. WAC 173-340-360(6)(b).

9. The definition of "applicable state and federal laws" should not include relevant and appropriate requirements. WAC 173-340-200. This is an unwarranted and confusing departure from the federal Superfund program.

BOEING

Conclusion

The foregoing is indicative of areas of concern for Boeing but is not an exhaustive list. We urge Ecology to carefully reflect on all comments received and not permit the urgency for cleanup standards, which we incidentally agree with, to jeopardize the workability of this important program. We believe that much of the concern which will be raised by commentors is not so much based upon policy differences as it is upon workability and meaningful progress under the MTCA. Boeing is willing to devote the appropriate resources to assist you in developing workable rules and appreciates this opportunity to comment.

Very truly yours,

CORPORATE SAFETY, HEALTH AND ENVIRONMENTAL AFFAIRS

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Your statewide
business advocate

September 17, 1990

David Bradley
Toxics Cleanup Program
Department of Ecology
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Olympia, Washington 98504-8711

Dear Dave:

Attached are the comments of the Association of Washington Business on the proposed clean up standards for the Model Toxics Control Act.

If you have any questions, please call. (206) 943-1600.

Sincerely yours,

Roger

Roger L. von Gohren
Director of Natural Resources

COMMENTS ON PROPOSED AMENDMENTS TO CHAPTER 173-340 WAC

FROM THE ASSOCIATION OF WASHINGTON BUSINESS SEPTEMBER 17, 1990

MANY IMPROVEMENTS

Many improvements have been noted when this version of the WAC is compared to earlier versions. Examples include recognition of combined technologies in clean up actions and greater flexibility in the application of alternative clean up standards.

READABILITY

Reading the regulation is difficult. Perhaps such difficulty is inherent in such a complex document; however some improvements may be possible. For example, the many citations back and forth within the regulation make following an idea through to its regulatory answer very difficult. Repeating some of the text in full, in place of citations may be a case where longer equals better.

We encourage adding a preface to the regulation which illustrates, perhaps through examples, how some of the most complex procedures are to operate, and identifying assumptions or presumptions utilized.

Publication of the regulation on computer disk would greatly facilitate reference and analysis by those who are so equipped with computers.

INCENTIVES FOR ON-SITE MANAGEMENT OF WASTE

We continue to have concern with the rigidity of the risk levels through use of the 10-6 level generally and the 10-5 for conditional clean up levels. A greater range of acceptable risk values should be allowed, depending on site conditions. A range such as EPA has used in the NCP will facilitate clean up actions which might otherwise take much longer and/or leave off-site disposal as the only alternative.

INCENTIVES TO SEEK FINAL CLEAN UP STATUS

We share the goal of many responsible parties: to have a final clean up Owners are motivated by desires to assure public health and safety and to make a site available for reuse or sale. However, the proposed regulation may produce a high percentage of interim actions because the final clean up standards cannot be met. While complete removal of contamination is good public policy by itself, a long term interim status for a large percentage of otherwise usable industrial sites generates a negative impact on the public welfare. It costs jobs and tax revenues. It encourages conversion of virgin, often non-urban, sites for industrial use. We urge the Department to make final clean up status a reachable goal and offset the adverse effects cited above.

COST CONSIDERATIONS

The continued restrictions on considerations of cost may result in clean up costs which are beyond reach in an unacceptable number of cases. The result can include unnecessary bankruptcies, litigation, and cost burdens upon state clean up funds.

The cost impacts of a clean up have been viewed as a punishment factor, to punish the "responsible" parties and to deter future violations. Such a view of cost is not consistent with the public policy of seeking rapid clean up of toxic sites, nor does it take into consideration the somewhat arbitrary procedures for determining who are "responsible" parties. If punishment is the objective, it should be clearly stated as a goal and the issue of fairness and consistency with other goals addressed head-on.

USE OF METHOD A

The potential for community leaders, lenders and buyers and sellers of real estate to focus on the numbers in method A is of concern. The great reliance that could be placed on these levels, used out of their context in the regulation, could threaten business transactions. We suggest including a statement that use of the tables is expressly limited to method A clean ups and shall not be used for decisions relating to the listing or the potential need for remedial actions.

RANGE OF CLEAN UP ALTERNATIVES

It is desirable that the standards produce clean up plans which recommend a range of reasonable alternatives, each of which meets the goals of the law. This is particularly important given the consideration of cost is deferred until the stage of selecting from alternatives. If there are no or limited alternatives, there is no or limited consideration of cost.

Why should cost - or a variety of alternatives - be an issue of public policy, rather than a private problem of the responsible party? Consider the following reasons:

A. "Responsibility" is determined arbitrarily, without a serious consideration of "guilt".

B. Responsible parties in many cases will be governments, such as owners of landfills and vehicle maintenance facilities.

C. Excessive costs lead to private bankruptcies, costing workers their jobs, and lenders and creditors their resources. Vacant sites in prime industrial areas result; while at the same time a public policy of restricting urbanization in out-lying areas is being implemented.

D. Strategies to defer costs, such as litigation or interim clean up, are pursued, which may increase costs and environmental burdens on public resources, and will not meet the goal of permanent clean up.

PRESTON
THORGRIMSON
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ATTORNEYS AT LAW

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SEP 18 1990
ECOLOGY

September 14, 1990

Ms. Carol Fleskes
Program Manager and
Responsible Official
Toxics Cleanup Program
Washington State Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

BY FAX

Re: Request for Extension for Comments

Dear Ms. Fleskes:

We have been active participants in the development of the Model Toxics Control Act Regulations on behalf of the Public Private Cleanup Coalition, a group of major public and private entities in Washington State.

The Coalition's goals and objectives, which have been plainly stated at meetings and in formal testimony in your rulemaking record, focus on achieving prompt, fair and effective cleanups under the Act. From the outset, we have been convinced that there is considerable common ground among various interests, including business, environmental, and governmental, for these goals and for workable procedures to achieve these goals. There have been real successes.

Two years of hard work by a broad range of interests resulted in a general consensus on rules for the cleanup process. Although there were many difficult issues, much common ground was able to be found. We recognize that differences may be more pronounced on the specifics of cleanup standards than on the process of planning and approving cleanup actions. Nonetheless, it is essential that the state's cleanup standards at least be understandable and usable and that as much willingness to try the fundamental approach be reached as is possible. If not, as Director Gregoire recently pointed out, the rule will fail because it will both discourage parties from coming forward to initiate cleanups and discourage citizens from informed participation in the process.

As you may know from our comments in the advisory process and our formal testimony in Spokane, it appears, assuming we understand it accurately, that the basic structure of the proposed cleanup standard rule makes sense. As drafted, however, a number of provisions are not readily understandable or workable. We are trying to work with various interests in finding common ground on key comments and on proposing specific language to Ecology. We are very concerned about proposing revisions and polarizing different groups' positions until we have had more of an opportunity to consult with each other. Key participants will be unavailable over the next two weeks. Consequently, we are requesting an extension for our comments on the rule and associated documents until October 5.

We realize the September 17 deadline is not the end of the rulemaking process. We appreciate Dave Bradley's commitment for Ecology staff to consult and work with us after September 17 on the text of the rule. For this reason, we have limited our request to the earliest time we could provide the kind of written comments we hope could provide a constructive basis for improving key parts of the proposed rule. Please do not hesitate to call if you have any questions regarding this request.

We do not make this request lightly, but we also realize if an extension will increase the chances of consensus on some important issues, it will have been well worthwhile. We have taken the initiative to consult with members of the environmental community who have been active in the rulemaking process, and they do not object to this request. Too much has been accomplished to see the progress to date jeopardized.

Very truly yours,

PRESTON THORGRIMSON
SHIDLER GATES & ELLIS

Kenneth S. Weiner

cc: Christine Gregoire
Pete Kmet
Dave Bradley
Elena Guilfoil

KSW7235

STATE OF WASHINGTON
DEPARTMENT OF ECOLOGY
Mail Stop PV-11 • Olympia, Washington 98504-8711 • (206) 459-6000

September 19, 1990

Mr. Kenneth S. Weiner
Preston, Thorgrimson, Shidler,
Gates and Ellis
5400 Columbia Center
701 Fifth Avenue
Seattle, WA 98104-7078

Dear Mr. Weiner:

The purpose of this letter is to acknowledge your request for additional time to submit comments on the proposed amendments to the Model Toxics Control Act Cleanup Regulation. Although the official comment period closed September 17, the Toxics Cleanup Program will accept your comments no later than October 5, 1990. Under our current rulemaking schedule, it will be extremely difficult to address comments received after that date.

This approval is based on our understanding that you intend to utilize the additional time to meet with representatives from various interest groups to prepare specific comments or proposed language revisions. We expect that these will be far more detailed than the general concerns you have raised during the official public comment period.

Although granting this time extension complicates Ecology's efforts to finalize the proposed amendments by the end of this year, we appreciate your efforts to improve and/or clarify portions of the proposed rule. If you have additional questions, please contact Dave Bradley at (206) 438-3026.

Sincerely,

Carol L. Fleskes

Carol L. Fleskes, Manager
Toxics Cleanup Program

CLF:df

cc: Christine Gregoire
Pete Kmet
Dave Bradley
Elena Guilfoil

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October 5, 1990

Ms. Carol Fleskes
Toxics Cleanup Program Manager
Department of Ecology
Mail Stop PV-11
Olympia, Washington 98504-8711

BY FAX

RECEIVED
OCT 09 1990
ECOLOGY

Subject: Comments on Model Toxics Control Act Cleanup Standards Proposed Rule

Dear Ms. Fleskes:

We appreciate your telephone message and letter extending the comment period for the comments of the Public Private Cleanup Coalition, a group of several major public bodies and private companies who are committed to the effective implementation of the state cleanup program. We especially acknowledge your encouragement for us to seek a consensus approach by October 5 on some key concepts and specific revisions to the proposed Model Toxics Control Act Cleanup Standards Rule.

We have been doing this since the rule was proposed, working informally with members of the environmental, business, local government and technical communities, including drafters of Initiative 97 and members of Ecology's Cleanup Process and Cleanup Standards Workgroups. We have spent a lot of time and energy to put together specific revisions within this timeframe and without undercutting other comments by these groups.

The bottom line of our comments is: *everyone who uses the rules needs to understand the basic gist of how Ecology will set cleanup standards and select remedies*, even if they do not need to be experts in the inevitably more complicated, technical portions of the rule. We have not found a single person who has read Section 700 as currently drafted, for example, who will say it meets this test. We seriously wonder if the Director or the Ecological Commission members have tried.

All interests agree on this fundamental point, one repeated in every public hearing you held and in the written comments you received from every constituency. If the most basic concepts in the cleanup cannot be read or understood by the people who must use the rules – citizens and news media, environmental professionals, staff and lawyers in your agency, decisionmakers in the companies and public agencies you expect to perform and pay for cleanups, not to mention the judges who are required to approve every cleanup – the rules will:

- discourage effective cleanups from being proposed and carried out.
- discourage informed citizen participation in the cleanup process, one of the basic tenets of Initiative 97.
- reverse the cooperative approach of the cleanup process rule by forcing Ecology to pursue most cleanups by enforcement and litigation, which will waste taxpayer and private dollars and throw the law back into a controversial legislative arena.

We do not want that, and we don't think the public, members of the Legislature, Governor Gardner, Director Gregoire and Ecology staff do either. For better or worse, the problem needs to be addressed in the adoption of the final cleanup standards rule itself. The rule, not possible future guidance policies or handbooks, is the law and the document that defines the cleanup process.

We are pleased to be able to propose relatively limited but crucial revisions in the proposed rule. Representatives from a variety of interests believe these revisions will improve and strengthen the rule. Naturally it would be desirable to meet with you and various other commenters to discuss the revisions and refine the text further as necessary. Without these kinds of changes, however, we believe the cleanup standards rule will directly undermine the goals of the Model Toxics Control Act and the consensus cleanup process rule adopted earlier this year.

As typified by the cleanup standards themselves, there are few guarantees and many risks in life. No one can say whether the methods and levels set out in the proposed cleanup standards will in fact avoid these problems.

We can say that, with the revisions we have proposed and with a concerted effort by Ecology to address remaining inconsistencies and comments on methodologies, a diverse and substantial part of the community is willing to acknowledge Ecology's hard work and tough policy calls and to try to use these cleanup standards with an open mind before reaching conclusions on whether they are really working. This would be a significant step on so divisive an issue.

FUNDAMENTAL PROBLEMS ADDRESSED BY THE REVISIONS

1. Lack of a Basic Rule on the Standard Setting Process

The proposed rules do not provide a cogent explanation of how cleanup levels are set. The two logical sections, 700 (General Procedures) and 705 (General Principles) are almost entirely devoted to detailed provisions on how to conduct risk assessments. Some people's eyes might not glaze over, but not many. These provisions are important, but, like the cleanup process rule, the provisions belong *after* the user knows how they fit into the basic system for setting the standards.

Solution. Insert a page which provides an overview on how the standard setting process works, similar to WAC 173-340-120 on the cleanup process. Specific text is attached as revised WAC 173-340-700 - OVERVIEW OF CLEANUP STANDARDS. The reasons for some of the subsections in this overview should be apparent from the specific concerns in our testimony in the Spokane public hearing and from comment letters as diverse as those from the Association of Washington Business and the Washington Environmental Council.

Combine all of the subsections of Sections 700 and 705 dealing with risk assessment assumptions and procedures into a single Section 709, after the sections explaining the basic structure and three methods, since these procedures are mainly used in applying Methods B and C.

We would be glad to elaborate orally or in writing at your request.

2. Lack of a Basic Rule on How to Carry Out the Standard Setting Process

The proposed rules do not provide any basic direction on key items required for the cleanup standards and process to be implemented as intended by the statute, the existing rule, and the briefings from Ecology staff at public meetings and hearings. As noted above, the two logical sections, 700 (General Procedures) and 705 (General Principles) are almost entirely devoted to detailed provisions on how to conduct risk assessments.

Furthermore, the purpose statement in subsection 700(1) refers to explaining how the process of setting cleanup standards relates to the selection of cleanup actions, but the section is essentially void of any such explanations. This is crucial because, as discussed below, one of the fundamental problems with the proposed rule is its persistent confusion of these two central concepts. We should emphasize that we agree with Ecology that these concepts are different and should be kept relatively distinct, even though they need to work in tandem to develop and approve cleanup action plans. This is an area where the proposed rule could be better than federal superfund if the internal inconsistencies in the proposed rule are eliminated.

We have therefore urged, along with commenters from every interest, that the administrative principles are needed to address the most common concerns – ones where there is in fact quite a broad level of consensus.

Solution. Insert a page which provides administrative principles, similar to WAC 173-340-130 on the cleanup process. Specific text is attached as revised WAC 173-340-702 - ADMINISTRATIVE PRINCIPLES FOR CLEANUP STANDARDS. As noted above, the reasons for the subsections should be apparent from the specific concerns we have previously stated and from comment letters as diverse as those from the Association of Washington Business and the Washington Environmental Council. The revised national contingency plan also recognizes the value of articulating key implementation principles. We would be glad to elaborate orally or in writing at your request.

Retain the general policies for setting cleanup standards as Section 704, adding points of compliance from Section 700(11) and indicator chemicals from Section 700(3). They do not appear to be appropriate for Section 709 as they are not limited to risk assessment procedures.

3. Use of Basic Terms that Defy Common Understanding

The proposed cleanup standard rule is premised on a few bedrock elements. Two of these use terms that are so foreign to common understanding and to consistency with the rule itself that, at best, they confuse the user. At worst, they will be constantly misinterpreted, leading to unnecessary delay and litigation in getting cleanups accomplished.

Not surprisingly, members of the environmental, business, local government, and technical communities have all complained about them.

We want to stress at the outset that people will write rules differently and use words they prefer. This is not a case of personal preference for a given term. In fact, we know how Ecology staff have struggled to find appropriate terms. It is a problem that results from trying to find words from fundamental conceptual problems.

Conditional and Compliance

The basic problem is that *all* remedial actions that qualify as cleanups are *both* conditional and compliance. As we stated in our public hearing testimony, all cleanups must comply with cleanup standards, and all cleanups are conditioned upon monitoring results (see both proposed and revised Section 360(2) and attached sheets).

By intent and definition, this means that a remedial action that implements cleanup standards identified under *any* of the three methods in part 7, as well as meeting applicable laws, qualifies as a "cleanup action". Although the rule creates a special burden of proof on so-called conditional cleanups, it does not change the basic fact that if a cleanup meets these standards, it could then be selected if the criteria in Section 360 (Selection of Remedy) are met.

Likewise, regardless of whether a remedial action implements cleanup standards identified under Method A or B, compliance monitoring is required and other conditions, ranging from the need to obtain permits to operation and maintenance actions or site restrictions may be involved.

Solution. Keep it simple and consistent. The proposed rule already uses "Method A" and "Method B". Simply use "Method C", and get rid of the modifiers "compliance and conditional." Each method is an alternate method, depending on which is appropriate to use, as substantively defined in the rules. Under each method, there is an additional safety net because a cleanup is also required to be protective of human health and the environment and meet applicable state and federal laws. In fact, the proposed revisions (Sections 700 and 702) make this clearer.

The rule should just be direct: (1) cleanup standards for particular substances and pathways are figured out by using methods A, B, or C and applying applicable state and federal law; (2) if a remedial action meets these levels, it is presumed to be protective of human health and the environment; and (3) protectiveness is the overriding criteria regardless of cost or whether the specific levels are met.

Each method should also have its own section (see attached revised text), especially since there are quite a few provisions dealing with Method C. Both the criteria for using Method C and the procedures for using it should be next to each other. These are not only very difficult to follow in Section 700, where they are separated, but they are in the middle of a number of other subjects in the same section.

Technically Feasible and Technically Practicable

If conditional and compliance are confusing, it is largely because they are inconsistent with the Act and the rules. As we discussed in our public hearing testimony, the terms "technically feasible" and "technically practicable" are inconsistent with common English usage. Not only are these synonymous, but is inconsistent with case law, where the modifier "technical" generally excludes cost. Equally important, the confusion reflects some basic conceptual problems in the statement of the balancing criteria in Section 360.

There are two basic concepts that need definition in order to be applied in the currently proposed rule: (1) methods or alternatives that can actually be done, regardless of whether they are easy, hard, affordable or desirable – in other words, is something "technically possible"; and (2) methods or alternatives that can be done and should be done – in other words, is something "reasonable" or "feasible". Since the latter term is already used to evaluate options (remedial investigation/*feasibility* study), it seemed to be an appropriate term.

Solution. As the concept is already intended by the rule, as we understand it, it would appear that you need only substitute "technically possible" for "technically feasible", and substitute "feasible" for "technically practicable." As noted above, this is not just a matter of drafting preferences. If there are other words that work for these concepts, we are certainly open to them.

This also solves the problem of inconsistency between sections 350 and 360, because with minor re-ordering of the criteria in 350(6)(e), the last three all relate to the feasibility of a remedial action, while the first seven criteria all relate to actual performance and the environmental risk and impact of the action itself.

It is essential to include an overall environmental quality criterion to address remedial actions that meet cleanup standards and otherwise improve environmental quality such as habitat and cross-media considerations. This is in practice, and is clearly mandated to be, part of Ecology's decisionmaking, whether you consider the basis to be MTCA, CERCLA, SEPA, Environment 2010 goals, or other laws. Please note that we did not use the "environmental benefit" language that has caused concern in the past. With the other revisions, it is clear that this criterion cannot outweigh the requirement to meet cleanup standards and is not part of "feasibility."

4. Mixing Up Cleanup Standards and Selection of Remedy

Dave Bradley, other Ecology staff, and the Attorney General's office have consistently maintained that one set of factors is used for setting cleanup levels, and another for selecting among cleanup action alternatives. We agree, but the rule fails to maintain this distinction. To the contrary, both Section 360 and 700 of the proposed rule mix up these two concepts, which has, in part, led to considerable problem in trying to understand and interpret what criteria apply to each.

Solution. Separate out these concepts again and use administrative principles (discussed above) to explain their relationship. The particulars of how to do this should be apparent from the specific revisions.

For example, Section 360(3) on "Protection" is solely about how to determine whether cleanup standards are met, not about which alternative to select (it also repeats Section 705(5)), and we reached a consensus that it should be revised as indicated and as discussed on page four of this letter. As another example, Subsection 360(4) on applicable state and federal laws belongs with Section 710 on applicable state and federal laws. The former explains what conditions need to be part of specific remedial actions in order to meet the cleanup standard of compliance with these laws, not unlike the provisions on whether and how to use so-called conditional (Method C) cleanup standards.

5. Lack of Distinctions in Other Key Concepts

Both cleanup standards and selection of remedy are based on some key elements that are likewise mixed up in the proposed rule. Without these distinctions, which Ecology has plainly acknowledged in briefings, advisory committee meetings, and in practice, the rules create irreconcilable problems.

Hazardous Substances and Exposure Pathways

Cleanup standards are premised on setting levels for two different elements: (1) the particular *hazardous substances* released or threatened to be released; and (2) the specific *pathways* that will cause environmental exposure to these hazardous substances. This is why there are cleanup levels for both specified substances and for land, water, and so on. The rule as currently drafted never makes this distinction clear, a problem which is aggravated by the next point.

Methods of Treatment and Cleanup Action Alternatives or Plans

Selection of remedy is also premised on two different elements: (1) the specific *methods* or technologies by which hazardous substances will be treated for each pathway (the two distinct elements noted above); and (2) the *overall plan* or package of methods for addressing a release or threatened release at a site, which often involves a combination of treatment methods at different locations, or alternative cleanup action plans.

The RI/FS is intended to develop different packages that will meet cleanup standards ("feasible alternatives") and are therefore available for selection. It does this by identifying, evaluating and screening methods of treatment. The methods of treatment for both substances and pathways that can meet cleanup standards are then put together into alternative cleanup action plans, which again must meet cleanup standards in order to be selected. The RI/FS then evaluates these alternatives under the criteria in Section 350. These criteria are -- or at least should be -- the same criteria in Section 360 for selecting a remedy. The draft cleanup action plan identifies the preferred alternative or alternatives, and the final cleanup action plan selects one.

Putting it all together, *cleanup action plans are typically a combination of treatment methods for particular substances and pathways.* In order for the preferences for selecting remedies to be applied, there are two steps:

1. Maximizing use of higher preference treatment methods for particular substances and pathways.

2. Maximizing the extent of the overall cleanup action that gets done with higher preference methods.

Compliance with the first step is much more capable of being ascertained. With the second step, the combination of methods may make the overall plan difficult to categorize (is it by volume, toxicity, sensitive environmental areas, and so on).

Solution. Rather than create impossible conundrums, these four elements should be clearly stated in the rule. Because these concepts appear to be what Ecology has intended but not included in the proposed rule, it actually takes very little revision to accomplish this (see Sections 702 (1) and (2) and 360(4)).

In addition – and we have not fully explored this idea but believe it ties in with subsection 360(9)(a)(vi) – recognizing that overall cleanup plans may not be so easily classified, it is important to create accountability and an action-forcing mechanism for selecting higher preference approaches. This revision would require specific findings if cleanup actions are mainly accomplished by methods of treatment that are lower than the top three priorities.

CONCLUSION

As we testified in Spokane, we think the basic structure of the rule makes sense – assuming one can make sense of it.

In our comments, we have maintained *virtually all* of the existing text of part 7 on cleanup standards. Tempted as we may have been to fiddle with the writing, we knew that our effort needed to be focused on *the most basic problems with all users understanding the rule*, and not with stylistic concerns on the one hand, or with basic methodological differences such as risk assessment levels on the other.

You are aware of serious concerns from many quarters, including our Coalition members, and we strongly urge you to give genuine consideration to the excellent set of written comments you have received, which overall are unusually thoughtful for so difficult a subject. We have appended a list of comments we hope will get particular attention as we share many of the concerns raised in them. We regret that neither the draft environmental impact statement nor the economic impact statement adequately addressed the kind of adverse impacts in general or specific that would result from the proposed rule, such as those we note on page one. We were also disappointed that the examples in the DEIS and appendix did not provide adequate information to understand how the standard setting and the selection of remedy would work in practice. Fortunately, a number of technical consultants were willing to volunteer unpaid time to develop examples that assisted our analysis of the rules and development of these proposed revisions. We have not devoted our comment letter to Sections 720 through 750 because we have been working with many of the commenters, wished to avoid duplication, and wanted to emphasize our commitment to you to focus our comments on the most important conceptual problems that could be resolved on a consensus basis by October 5.

I would also like to emphasize, as you and I discussed on the telephone this afternoon, that there is a consensus among several of the individuals from very different groups who have been active in this rulemaking process for the past three years (it's painful just to say that!) on the concepts in this letter and in the attached text. While we have a good comfort level with the organizational revisions, we have generally focused more on agreeing on the solutions by the October 5 deadline than on the precise text. There are certainly involved individuals in Ecology and the various communities with whom we would like to discuss this. We hope you would give us that opportunity, as we discussed today, so that our comments are not rejected over misunderstandings or concerns that could be allayed.

The following materials are attached:

1. Cross-section of comments on the ability to read and understand the proposed rules.

2. Basic definitions and meanings of key terms (submitted at the public hearing).

3. Section 360 in legislative markup style, with key explanatory notes bracketed in boldface type.

4. A clean version of Section 360, so that it can be read more easily.

5. Section 700 - OVERVIEW.

6. Section 702 - ADMINISTRATIVE PRINCIPLES FOR CLEANUP STANDARDS.

7. General outline of how the beginning of part 7 is re-organized.

8. Sections 704 through 710 in legislative markup style, with key explanatory notes in boldface type. The text for these sections were previously in Sections 700, 705, and 710. We have tried to indicate where text has been moved from.

9. List of other comment letters as noted above.

In order to expedite and assist your ability to use this material, we are enclosing with the hard copy of this letter a computer disc of the revised text. We have appreciated your providing material in this format to us on the cleanup process rule and found it very helpful. Please let us know if you would like it in another format or different size disc. We also apologize for not conforming every section to the basic proposed changes, but we are prepared to submit a legislative style markup which does this if you would like.

We would request an opportunity to meet with you, Terry Husseman, Dave Bradley, Jay Manning or whomever you think appropriate within the next week or so to discuss the substance and process for incorporating these comments into the rule. We would be most concerned and would like to know immediately if you think that the planned decisionmaking schedule limits the inclusion of these revisions in the rule.

As we said at the public hearing, we recognize and appreciate the hard work and professionalism your staff has put into these proposed cleanup standards. The basic structure appears sound if the risk assessments are well done and the regulation is applied thoughtfully and consistent with its administrative principles.

Thank you again for your encouragement to develop these comments. With these revisions, several of us are at least optimistic that a person picking up the cleanup standard rule has a fighting chance to understand what it's about and how to use it.

Respectfully submitted,

PRESTON THORGRIMSON
SHIDLER GATES & ELLIS

Kenneth S. Weiner

Attachments

KSW7249

cc: Rod Brown
Betty Tabbutt
Dan Ballbach
Don Cordell
Et al.
Public Private Cleanup
Coalition Steering Committee

Cross-Section of Comments by Experienced Commenters from
Diverse Interests on the Difficulty of Being Able to Read and Understand
Basic Sections and Concepts in the Rules and on the Need for Improvements

Sweet-Edwards/EMCON

We recognize that Ecology has added text and revised text (e.g., added definitions to make the regulation more readable and hopefully more consistent. However, the regulation is still difficult to read and understand. This is especially the case in determining the selection of cleanup actions and in determining which cleanup levels apply.

Washington Public Ports Association

One of the comments that has been made by many individual ports as they have reviewed this rule is that it is far too complex and difficult to understand. Several experienced port environmental planners and analysts have great difficulty understanding this rule as it is written.

The rule would [also] be immeasurably improved by the addition of a clear section of administrative principles, which puts forth in simple language the general administrative cleanup policies of the Department.

Washington Environmental Council/Betty Tabbutt

oral: Key sections are difficult to read and understand.

written: <u>Cost versus technical feasibility.</u> These are two different but important factors in cleanups. they should be dealt with separately and in a straightforward manner so that anyone can clearly tell which factor is influencing a decision. The current draft mixes these two factors together in the definition of "technically practicable."

Boeing

First, the complexity of the rules threatens their workability. Unless appropriate administrative principles are expressed in the rules, application of the rules will be a cumbersome and confusing process.

Association of Washington Business

Reading the regulation is difficult. Perhaps such difficulty is inherent in such as complex document; however some improvement may be possible.

WEBSTERS DICTIONARY

<u>feasible</u> 1. capable of being done or carried out; <u>practicable</u>; possible [a feasible scheme] 2. within reason; likely; probable [a feasible story] 3. capable of being used or dealt with successfully; suitable [land feasible for cultivation]

<u>practicable</u> 1. that can be done or put into practice; <u>feasible</u> [a practicable plan] 2. that can be used, usable; useful [a practicable tool]

in compliance with in accordance with; comply: to act in accordance (with a request, order, rule, etc.)

ALL CLEANUPS REQUIRE COMPLIANCE: See 173-340-360, 700
All cleanup actions shall be protective of human health and the environment, meet applicable standards, etc.

conditional 1. containing, implying, or dependent on a condition or conditions; qualified; not absolute

ALL CLEANUPS ARE CONDITIONAL: See 173-340-360, 410
Compliance monitoring shall be required for all cleanup actions;
RCW 70.105D.040(4)(c) -- Any covenant not to sue shall contain a reopener clause...

AMENDATORY SECTION

WAC 173-340-360 SELECTION OF CLEANUP ACTIONS.

(1) *Purpose.* This section describes the requirements for selecting ~~and implementing~~ cleanup actions. This section is intended to be used in conjunction with the administrative principles for the overall cleanup process (WAC 173-340-130) and for cleanup standards (WAC 173-340-702).

(2) *Threshold* ~~*General*~~ *Requirements.* ~~The general requirements for cleanup actions are as follows:~~ (a) All cleanup actions conducted under this chapter shall~~:~~ meet cleanup standards (Part VII) and shall ~~(i) Be protective of human health and the environment, including complying with cleanup standards; (ii) Comply with all applicable state and federal laws; (iii) P~~ provide for compliance monitoring (WAC 173-340-410).

(3) *Other Requirements.* ~~When evaluating alternative cleanup actions that meet requirements of (a) of this subsection~~ In addition, the cleanup action selected shall:

(a) Use permanent solutions to the maximum extent practicable (WAC 173-340-360(4) and (6));

(b) Be feasible (WAC 173-340-360(5) and (7)) ~~technically practicable at the site~~; and

(d) Provide for a reasonable restoration time frame. ~~; and~~

~~(e) Consider public concerns.~~ **[NOTE: this could be added to (b) if necessary, but then we get into adding other items, like cost]**

~~(3) *Protection.* Cleanup actions that comply with the cleanup levels determined under Methods A, B, or C (as applicable) and to applicable state and federal laws under WAC 173-340-700 achieve compliance cleanup levels shall be presumed to be protective of human health and the environment demonstrate compliance with subsection (2)(a)(i) of this section unless the person undertaking the cleanup action can demonstrate that conditional cleanup levels are protective in accordance with WAC 173-340-700 through 173-340-760.~~ **[belongs in adminstrative principles for cleanup standards; moved as revised to 702; nonrevised text is already stated in Burden of Proof paragraph in 705(5), now 705(5)]**

[NOTE: Paragraph (4) on applicable state and federal laws belongs in 710 of cleanup standards (which has the same title). Its inclusion here is part of the persistent problem of not recognizing that either a cleanup action meets cleanup standards (and hence can be selected) or it doesn't (and hence, can't). It says how you have to condition a remedy in order to be considered to meet cleanup standards and belongs in Part VII.]

MOVE DON'T DELETE:

~~(4) *Applicable State and Federal Laws.* (a) To demonstrate compliance with subsection (2)(a)(ii) of this section, all cleanup actions shall comply with all applicable state and federal laws.~~

~~(b) The following are selected applications of specific applicable state and federal laws to cleanup actions.~~

~~(i) Hazardous substances which are directly or indirectly released or proposed to be released to waters of the state shall be provided with all known, available and reasonable methods of treatment consistent with the requirements of chapters 90.48 and 90.54 RCW and the regulations that implement these statutes.~~

~~(ii) All known, available and reasonable methods, consistent with the policy stated in RCW 90.48.010 and 90.54.020 to insure the highest possible quality of all waters of the state, shall be used to protect and restore the quality of ground water affected by a release from a site.~~

~~(A) Ground water treatment to achieve the standards in WAC 173-340-720 throughout the ground water shall be required where such treatment is practicable or in the public interest.~~

~~(B) When treatment within an existing ground water plume is not practicable the following measures shall be taken:~~

~~(i) All practicable source control measures shall be implemented to prevent additional releases to the ground water.~~

~~(ii) Containment, including barriers or hydraulic control through ground water pumping or both, shall be implemented to the maximum extent practicable to avoid lateral and vertical expansion of the ground water volume affected by the hazardous substance;~~

~~(iii) Adequate ground water monitoring to demonstrate control and containment of the hazardous substance shall be conducted;~~

~~(iv) If the ground water has been rendered unusable because of exceedances of cleanup standards in WAC 173-340-720 resulting from releases from a site, the potentially liable person shall provide an alternative water supply or point of use treatment to persons with water supplies rendered unusable by the release; and~~

~~(v) The practicability of treating the ground water affected by the release shall be reevaluated during the periodic review under WAC 173-340-420.~~

~~(C) Appropriate restrictions on the use of ground water shall be placed under WAC 173-340-440 until cleanup standards established under WAC 173-340-720 are achieved.~~

~~(D) The integrity and continued operation of any treatment or containment system shall be assured in accordance with WAC 173-340-440.~~

~~(iii) Best available control technologies consistent with the requirements of chapter 70.94 RCW and the regulations that implement this statute shall be applied to air emissions from a site, including air emissions resulting from cleanup actions at a site.~~

~~(iv) Where the department determines that either chapter 173-303 or 173-304 WAC are applicable state and federal laws for a site, in addition to any other requirements in this chapter, the requirements of that portion of the rules determined to be applicable shall be the minimum requirements for the site.~~

~~(5) *Compliance Monitoring.* In demonstrating compliance with subsection (2)(a)(iii) of this section, the cleanup actions selected shall provide for monitoring in accordance with WAC 173-340-410.~~ **[repetition of paragraph (2) above and circular statement besides:]**

(4) *Order of Preference for Selection of Remedy.* ~~(a) A permanent solution is one in which the cleanup standards under WAC 173-340-700 through 173-340-760 are achieved without further action being required at the original site or any other site involved with the cleanup action, such as an off-site landfill.~~ **[NOTE: this paragraph has been revised and moved to (6) below, which directly addresses what permanent solutions are]**

(a) Selection of remedy involves selection among both: (i) alternative methods of treatment for hazardous substances in specific locations; and (ii) alternative cleanup action plans for an entire site (see WAC 173-340-702(2)).

(b) In selecting among alternative methods of treatment, ~~demonstrating compliance with subsection (2)(b)(i) of this section, the technology and method or combination of technologies and methods for site cleanup~~ the following methods shall be selected in ~~the following~~ order of decreasing preference in order to promote permanent solutions:

(i) Reuse or recycling;

(ii) Destruction or detoxification;

(iii) Separation or volume reduction with approved treatment or management of the hazardous substance;

(iv) Immobilization of hazardous substances;

(v) On-site or off-site disposal, isolation or containment with attendant engineering controls; and

(vi) Institutional controls and monitoring.

(c) A combination of technologies from more than one of the categories under (b) of this subsection may be used at a site. For example, the source of the hazardous substance may be recovered and recycled or destroyed, while containment is used to stop migration of hazardous substances that have reached the ground water.

(d) Because cleanup action plans will often involve a combination of methods of treatment, preference shall be given to developing and selecting cleanup action plan alternatives that maximize use of higher preference methods.

(5) *Balancing Criteria.* ~~Selection of a lower preference technology and method or combination of technologies and methods shall only be allowed where it can be justified based on a balancing of t~~ The following balancing criteria shall be considered in selecting among alternative cleanup actions and in deciding whether a lower preference method is justified. The weight given to each factor may vary as appropriate to specific sites. These criteria are addressed in the remedial investigation/feasibility study (see WAC 173-340-350(6)(e)(i) through (x)). The first seven criteria address the environmental impacts, and the last addresses the public and regulatory impacts of a potential cleanup action:

(i) Overall protectiveness of human health and the environment ~~including consideration of the factors in WAC 173-340-350(6)(e)(i)~~;

(ii) The degree the cleanup action may perform to a higher level than specific standards in Part VII of these rules;

(iii) Short-term effectiveness ~~including consideration of the factors in WAC 173-340-350(6)(e)(iii)~~;

(iv) Long-term effectiveness ~~including consideration of the factors in WAC 173-340-350(6)(e)(iv)~~;

(v) Permanent reduction of toxicity, mobility and volume of the hazardous substance; ~~including consideration of the factors in WAC 173-340-350(6)(e)(v); and~~

(vi) The decree to which recycling, residue, and waste minimization are employed;

(vii) Overall environmental quality;* and

(viii) Feasibility, ~~Practicability~~ in accordance with subsection (7) of this section.

*** [NOTE: to ensure consistency with this section, the recycling criterion would be moved up from (6)(e)(ix) to (6)(e)(vi) in 350 and the overall environmental quality criterion (note the avoidance of the problemmatic term environmental "benefits") would be added as (vii) and would read along the following lines: "(vii) overall environmental quality, including the degree the alternative leaves the environment or its natural or human communities in a better condition or addresses cross-media environmental problems."**

(6) *Policies to Promote Permanent Solutions.*

(a) A permanent solution is one in which ~~the~~ cleanup standards ~~under WAC 173-340-700 through 173-340-760 are achieved~~ can be met without further action being required at the original site or any other site involved with the cleanup action, other than confirmational monitoring or the approved disposal of any residue from preferred treatment methods under paragraph (4)(b)(i) through (iii) of this section ~~such as an off-site landfill~~. **[NOTE: the definition in 173-340-200 needs to be conformed to this paragraph]**

~~(e)~~ (b) To ensure a bias toward permanent solutions, the cleanup action selected based on the balancing under ~~(d) of this~~ subsection (5) of this section must comply with the following requirements.

(i) The cleanup action shall prevent or minimize present and future releases and migration of hazardous substances in the environment;

(ii) The cleanup action shall provide for a net reduction in the amount of a hazardous substance being released from the site;

(iii) The cleanup actions shall not rely solely on dilution and dispersion of the hazardous substance;

(iv) Long-term monitoring and appropriate site use restrictions and institutional controls shall be required when on-site isolation, containment or a nonpermanent treatment technology or method is part of the selected cleanup action.

(v) A cleanup action plan relying only on isolation or containment of hazardous substances shall not be used if a cleanup action alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is feasible ~~technically practicable~~;

(vi) A cleanup action relying solely on institutional controls and monitoring shall not be used if a cleanup action alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is feasible ~~technically practicable~~; and

(vii) A cleanup action involving off-site transport and disposal of hazardous substances without treatment shall not be used if a ~~practicable~~ treatment technology or method exists which will attain cleanup standards ~~meets the requirements of subsection (2)(a) of this section~~ and is feasible ~~technically practicable~~;

(viii) A cleanup action mainly accomplished through methods of treatment that are a lower priority than the top three preferences in this section shall not be selected unless the cleanup action plan includes findings explaining how the plan is consistent with this subsection.

(7) *Feasibility* ~~Practicability~~. ~~In determining whether a cleanup action meets the requirement of subsection (2)(b)(ii) of this section, t~~ The following factors shall be considered in determining feasibility (see WAC 173-340-200* and 350(6)(e)(viii) through (x)):

(a) Whether the method or alternative is technically possible* ~~Technical feasibility~~;

(b) The ability of the method or alternative to be implemented ~~including consideration of the factors in WAC 173-340-350(6)(e)(vi)~~;

(c) The nature and extent of community concerns and how these may be addressed; and

(d) Whether the method or alternative is cost effective, which shall be evaluated ~~Cost~~ in accordance with the following:

(i) A cleanup action shall not be considered feasible ~~technically practicable~~ if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action;

(ii) For cleanup actions ~~alternatives which meet the requirement of subsection (2)(a) of this section and which~~ that have an equivalent order of preference under subsection (~~6~~ 4)(b) of this section, preference shall be given to the cleanup action which cost the least; and

(iii) Costs considered shall include present and future direct and indirect capital, operation and maintenance costs, and other foreseeable costs.

***[NOTE: The definitions of "technically feasible" and "technically practicable" -- neither of which are commmonly understandable -- would be replaced. The former would become "technically possible" with a definition similar to the current one, but removing the ambiguity of the modifiers "reliable and effective" (i.e., "capable of being designed, constructed, and implemented in an engineering and not theoretical sense, regardless of cost"). The latter would simply become "feasible", defined along the following lines: "Feasible or feasibility means capable of being accomplished (including being technically possible) and reasonable and appropriate under the circumstances, as further described in WAC 173-340-360(7). For purpose of compliance with this Act, the identification of feasible alternatives shall be synonymous with the identification of reasonable alternatives under the State Environmental Policy Act."**

(8) *Restoration Time Frame.*

(a) ~~In demonstrating compliance with subsection (2)(b)(iii) of this section t~~ The following factors shall be considered:

(i) Potential risks posed by the site to human health and the environment;

(ii) Feasibility ~~Technical practicability~~ of achieving a shorter restoration time frame;

(iii) Current use of the site, surrounding areas, and associated resources that are or may be affected by releases from the site;

(iv) Potential use of the site, surrounding areas, and associated resources that are, or may be, affected by releases from the site;

(v) Whether providing an alterative water supply to water users that may be affected by releases to ground water or surface water is technically possible ~~feasible~~;

(vi) Effectiveness and reliability of institutional controls;

(vii) Ability to control and monitor migration of hazardous substances from the site;

(viii) Toxicity of the hazardous substances at the site; and

(ix) Natural degradation processes which will affect the concentration of the hazardous substances at

(b) A longer period of time may be used for the restoration time frame for a site to achieve cleanup standards at the point of compliance if higher preference cleanup technologies in accordance with subsection 4 ~~(6)(b)~~ of this section are selected instead of on-site or off-site disposal or containment options.

(c) When area background concentrations would result in recontamination of the site to levels which exceed cleanup standards, that portion of the cleanup action which addresses cleanup below area background concentrations may be delayed until the off-site sources of hazardous substances are controlled. In these cases the remedial action shall be considered an interim action.

(d) Where ~~conditional~~ cleanup levels determined under Method C in WAC 173-340-707 result in a need to achieve concentrations that are not ~~are below~~ technically possible ~~feasible concentrations, technically feasible~~ concentrations that are technically possible to ~~shall be~~ achieve~~d~~ shall be met within a reasonable time frame ~~in~~ considering ~~ation of~~ the factors in (a) of this subsection. In these cases the remedial action shall be considered an interim action.

(e) Extending the restoration time frame shall not be used as a substitute for active cleanup actions, when such actions are technically practicable.

(9) *Draft Cleanup Action Plan.* The department shall issue draft cleanup action plan for cleanup actions conducted by the department or under an order or decree. The level of detail in the draft cleanup action plan shall be commensurate with the complexity of the site and proposed cleanup action.

(a) The draft cleanup action plan shall include the following:

(i) A general description of the proposed cleanup action including compliance monitoring;

(ii) A brief summary of other alternative cleanup actions evaluated in the state remedial investigation/feasibility study or comparable documents;

(iii) Site cleanup standards for each media of concern and the point of compliance for the standards where these have been established at this step in the cleanup process;

(iv) The schedule for implementation of the cleanup action plan including, if know, restoration time frame;

(v) Required institutional controls and site use restrictions, if any, for the proposed cleanup action;

(vi) Justification for selecting a cleanup action that is less preferred than other cleanup actions listed in subsection 4 ~~(6)~~ (b) of this section, when applicable;

(vii) Applicable state and federal laws for the proposed cleanup action, when these are known at this step in the cleanup process (this does not preclude subsequent identification of applicable state and federal laws); and

(viii) A preliminary determination bythe department that the proposed cleanup action will comply with subsection (2) of this section.

(b) For routine actions the department may use an order or decree to fulfill the requirements of a cleanup action plan, provided that the information in (a) of this subsection is included herein. the scope of detail for the required information shall be commensurate with the complexity of the site an proposed cleanup action.

(10) *Public Participation.* The department will provide public notice and opportunity for comment on the draft cleanup plan as described in WAC 173-340-600.

(11) *Final Plan.* After completion of the public comment period the department, after review and consideration of the comments received, shall issue a final cleanup action plan and publish its availability in the site register and by other appropriate methods.

(12) *Determinations under Other Laws.* The fact that a draft or final cleanup action plan selects a preferred alternative based on a remedial investigation/feasibility study or comparable document that contains more than one feasible alternative shall not preclude a determination that there are no feasible, reasonable, or practicable alteratives if such a determination is required under another applicable law, regulation, or policy.

(13) *Federal Cleanup Sites.* A record of decision prepared under the Federal Cleanup Law may be used by the department to meet the requirements of this section provided:

(a) The cleanup action provided by the record of decision meets the requirements in subsection (2) of this section;

(b) The state has concurred with the record of decision; and

(c) An opportunity was provided for the public to comment on the cleanup action.

7247A/10/5

AMENDATORY SECTION

WAC 173-340-360 SELECTION OF CLEANUP ACTIONS.

(1) *Purpose.* This section describes the requirements for selecting cleanup actions. This section is intended to be used in conjunction with the administrative principles for the overall cleanup process (WAC 173-340-130) and for cleanup standards (WAC 173-340-702).

(2) *Threshold Requirements.* All cleanup actions conducted under this chapter shall meet cleanup standards (Part VII) and shall provide for compliance monitoring (WAC 173-340-410).

(3) *Other Requirements.* In addition, the cleanup action selected shall, as specified in this section:

(a) Use permanent solutions to the maximum extent practicable;

(b) Be feasible; and

(c) Provide for a reasonable restoration time frame.

(4) *Order of Preference for Selection of Remedy.* (a) Selection of remedy involves selection among both: (i) alternative methods of treatment for hazardous substances in specific locations; and (ii) alternative cleanup action plans for an entire site (see WAC 173-304-340(2)).

(b) In selecting among alternative methods of treatment, the following methods shall be selected in order of decreasing preference in order to promote permanent solutions:

(i) Reuse or recycling;

(ii) Destruction or detoxification;

(iii) Separation or volume reduction with approved treatment or management of the hazardous substance;

(iv) Immobilization of hazardous substances;

(v) On-site or off-site disposal, isolation or containment with attendant engineering controls; and

(vi) Institutional controls and monitoring.

(c) A combination of technologies from more than one of the categories under (b) of this subsection may be used at a site. For example, the source of the hazardous substance may be recovered and recycled or destroyed, while containment is used to stop migration of hazardous substances that have reached the ground water.

(d) Because cleanup action plans will often involve a combination of methods of treatment, preference shall be given to developing and selecting cleanup action plan alternatives that maximize use of higher preference methods.

(5) *Balancing Criteria.* The following balancing criteria shall be considered in selecting among alternative cleanup actions and in deciding whether a lower preference method is justified. The weight given to each factor may vary as appropriate to specific sites. These criteria are addressed in the remedial action/feasibility study (see WAC 173-340-350(6)(e)(i) through (x)). The first seven criteria address the environmental impacts, and the last addresses the public and regulatory impacts of a potential cleanup action:

(i) Overall protectiveness of human health and the environment;

(ii) The degree the cleanup action may perform to a higher level than specific standards in Part VII of these rules;

(iii) Short-term effectiveness;

(iv) Long-term effectiveness;

(v) Permanent reduction of toxicity, mobility and volume of the hazardous substance;

(vi) The decree to which recycling, residue, and waste minimization are employed;

(vii) Overall environmental quality; and

(viii) Feasibility, in accordance with subsection (7) of this section.

(6) *Policies to Promote Permanent Solutions.*

(a) A permanent solution is one in which cleanup standards can be met without further action being required at the original site or any other site involved with the cleanup action, other than confirmational monitoring or the approved disposal of any residue from preferred treatment methods under paragraph (4)(b)(i) through (iii) of this section.

(b) To ensure a bias toward permanent solutions, the cleanup action selected based on the balancing under subsection (5) of this section must comply with the following requirements.

(i) The cleanup action shall prevent or minimize present and future releases and migration of hazardous substances in the environment;

(ii) The cleanup action shall provide for a net reduction in the amount of a hazardous substance being released from the site;

(iii) The cleanup actions shall not rely solely on dilution and dispersion of the hazardous substance;

(iv) Long-term monitoring and appropriate site use restrictions and institutional controls shall be required when on-site isolation, containment or a nonpermanent treatment technology or method is part of the selected cleanup action.

(v) A cleanup action plan relying only on isolation or containment of hazardous substances shall not be used if a cleanup action alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is feasible;

(vi) A cleanup action relying solely on institutional controls and monitoring shall not be used if a cleanup action alternative that utilizes a higher preference cleanup technology or method for all or a portion of the site is feasible; and

(vii) A cleanup action involving off-site transport and disposal of hazardous substances without treatment shall not be used if a treatment technology or method exists which will attain cleanup standards and is feasible;

(viii) A cleanup action mainly accomplished through methods of treatment that are a lower priority than the top three preferences in this section shall not be selected unless the cleanup action plan includes findings explaining how the plan is consistent with this subsection.

(7) *Feasibility.* The following factors shall be considered in determining feasibility (see WAC 173-340-200 and 350(6)(e)(viii) through (x)):

(a) Whether the method or alternative is technically possible;

(b) The ability of the method or alternative to be implemented;

(c) The nature and extent of community concerns and how these may be addressed; and

(d) Whether the method or alternative is cost effective, which shall be evaluated in accordance with the following:

(i) A cleanup action shall not be considered feasible if the incremental cost of the cleanup action is substantial and disproportionate to the incremental degree of protection it would achieve over a lower preference cleanup action;

(ii) For cleanup actions that have an equivalent order of preference under subsection (4)(b) of this section, preference shall be given to the cleanup action which cost the least; and

(iii) Costs considered shall include present and future direct and indirect capital, operation and maintenance costs, and other foreseeable costs.

(8) *Restoration Time Frame.*

(a) The following factors shall be considered:

(i) Potential risks posed by the site to human health and the environment;

(ii) Feasibility of achieving a shorter restoration time frame;

(iii) Current use of the site, surrounding areas, and associated resources that are or may be affected by releases from the site;

(iv) Potential use of the site, surrounding areas, and associated resources that are, or may be, affected by releases from the site;

(v) Whether providing an alterative water supply to water users that may be affected by releases to ground water or surface water is technically possible;

(vi) Effectiveness and reliability of institutional controls;

(vii) Ability to control and monitor migration of hazardous substances from the site;

(viii) Toxicity of the hazardous substances at the site; and

(ix) Natural degradation processes which will affect the concentration of the hazardous substances at the site during the period of exposure.

(b) A longer period of time may be used for the restoration time frame for a site to achieve cleanup standards at the point of compliance if higher preference cleanup technologies in accordance with subsection (4) of this section are selected instead of on-site or off-site disposal or containment options.

(c) When area background concentrations would result in recontamination of the site to levels which exceed cleanup standards, that portion of the cleanup action which addresses cleanup below area background concentrations may be delayed until the off-site sources of hazardous substances are controlled. In these cases the remedial action shall be considered an interim action.

(d) Where cleanup levels determined under Method C result in a need to achieve concentrations that are not technically possible, concentrations that are technically possible to achieve shall be met within a reasonable time frame considering the factors in (a) of this subsection. In these cases the remedial action shall be considered an interim action.

(e) Extending the restoration time frame shall not be used as a substitute for active cleanup actions, when such actions are feasible.

(9) *Draft Cleanup Action Plan.* (a) The department shall issue draft cleanup action plan for cleanup actions conducted by the department or under an order or decree. The level of detail in the draft cleanup action plan shall be commensurate with the complexity of the site and proposed cleanup action. The draft cleanup action plan shall include the following:

(i) A general description of the proposed cleanup action including compliance monitoring;

(ii) A brief summary of other alternative cleanup actions evaluated in the state remedial investigation/feasibility study or comparable documents;

(iii) Site cleanup standards for each media of concern and the point of compliance for the standards where these have been established at this step in the cleanup process;

(iv) The schedule for implementation of the cleanup action plan including, if know, restoration time frame;

(v) Required institutional controls and site use restrictions, if any, for the proposed cleanup action;

(vi) Justification for selecting a cleanup action that is less preferred than other cleanup actions listed in subsection (4)(b) of this section, when applicable;

(vii) Applicable state and federal laws for the proposed cleanup action, when these are known at this step in the cleanup process (this does not preclude subsequent identification of applicable state and federal laws); and

(viii) A preliminary determination by the department that the proposed cleanup action will comply with subsection (2) of this section.

(b) For routine actions the department may use an order or decree to fulfill the requirements of a cleanup action plan, provided that the information in (a) of this subsection is included herein. The scope of detail for the required information shall be commensurate with the complexity of the site an proposed cleanup action.

(10) *Public Participation.* The department will provide public notice and opportunity for comment on the draft cleanup plan as described in WAC 173-340-600.

(11) *Final Plan.* After completion of the public comment period the department, after review and consideration of the comments received, shall issue a final cleanup action plan and publish its availability in the site register and by other appropriate methods.

(12) *Determinations under Other Laws.* The fact that a draft or final cleanup action plan selects a preferred alternative based on a remedial investigation/feasibility study or comparable document that contains more than one feasible alternative shall not preclude a determination that there are no feasible, reasonable, or practicable alteratives if such a determined is required under another applicable law, regulation, or policy.

(13) *Federal Cleanup Sites.* A record of decision prepared under the Federal Cleanup Law may be used by the department to meet the requirements of this section provided:

(a) The cleanup action provided by the record of decision meets the requirements in subsection (2) of this section;

(b) The state has concurred with the record of decision; and

(c) An opportunity was provided for the public to comment on the cleanup action.

AMENDATORY SECTION (Amending WSR 90-08-096, filed 4/3/90, effective 5/4/90)

WAC 173-34-700 GENERAL PROCEDURES.*

~~(1) Purpose.* This section defines the decision making process for establishing cleanup under this chapter and how that process relates to the selection of cleanup actions under WAC 173-340-360.~~

~~(2) Protection.* All cleanup actions performed under this chapter shall attain a degree of cleanup of hazardous substances and control of further releases of hazardous substances that assures protection of present and future human health and the environment. The goal is to establish cleanup levels as close as possible to natural background levels.~~

~~(12) Selection of cleanup actions. Cleanup actions which result in compliance with cleanup levels shall be selected in accordance with the requirements in WAC 173-340-360.~~

~~(5) Methods for determining cleanup levels.*~~

~~(a) Compliance cleanup levels are established at concentrations which are protective of human health and the environment and, with the exception of compliance cleanup levels established under WAC 173-340-745, require no restrictions on the use of the site. Compliance cleanup levels shall be established using one of the following two methods.~~

~~(i) Method A; or~~

~~(ii) Method B.~~

*** These subsections are replaced by new sections 700 and 702, Overview and Administrative Principles:**

AMENDATORY SECTION

WAC 173-340-700 OVERVIEW OF CLEANUP STANDARDS

(1) ***Purpose.*** (a) This part provides the methods for identifying the cleanup standards that apply to a release or threatened release of a hazardous substance at a site. In other words, this part specifies how clean a site must be in order to protect human health and the environment. Cleanup standards are identified for the particular hazardous *substances* at the site and the specific areas or *pathways*, such as land or water, where humans or the environment can become exposed to these substances.

(b) The various ways of cleaning up a site are analyzed based on the cleanup standards to be met. Other parts of this rule govern the process for planning and deciding on the cleanup action to be taken at a site. For example, Section 350 (state RI/FS) specifies the studies that are prepared to identify the cleanup standards and alternatives. Section 360 (selection of remedy) specifies the criteria for selecting the best alternative. Section 410 specifies the monitoring required to assure that the remedy is effective.

(2) ***Threshold Criteria for All Cleanup Actions.*** The Act provides two basic cleanup standards: (a) protection of human health and the environment; and (b) compliance with applicable state and federal laws. These are the threshold criteria for cleanups.

(3) ***The Overriding Test: Protectiveness.*** Protection of human health and the environment is the overriding criterion for all cleanups under this chapter. A remedial action must meet this criterion regardless of other factors, including cost or whether the action complies with applicable state and federal standards. The term "protectiveness" is not synonymous with cleanup to the greatest possible degree (see WAC 173-340-702).

(4) ***Three Basic Methods for Determining Cleanup Standards.*** These rules allow three approaches for identifying cleanup standards:

(a) ***Method A: Tables.*** On some sites, the cleanup action may be routine (WAC 173-340-130) or may involve relatively few substances. Method A uses tables which specify cleanup levels for groundwater and soil contamination.

(b) ***Method B: Formulas.*** Sites typically have a mixture of hazardous substances or more complex site conditions. Method B is the standard method for determining cleanup standards and uses formulas for groundwater, surface water, soil, and air. The formulas are based on a risk assessment approach of one person in one million (1×10^{-6}) having the risk of getting cancer over a lifetime of exposure.

(c) ***Method C: Risk Assessments.*** When the Method B formulas are applied to some sites, the cleanup might not be able to be carried out or could produce illogical results. For example, the actions could cause greater environmental harm or might expend a great deal leaving the site cleaner than natural conditions. In these situations, a site specific risk assessment based on a cancer risk of one person in one hundred thousand (1×10^{-5}) is prepared under Method C. Method C also includes other requirements to assure that cleanup results comparable to the other methods are achieved.

(5) ***Other Requirements for Setting Cleanup Standards.*** Several requirements apply to cleanups under any of the three basic methods. Some of these requirements, such as the identification of applicable state and federal laws, describe analyses used *along with* Methods A, B or C in order to set cleanup standards for particular substances at a site. Others describe the technical procedures to be used.

(a) ***Applicable State and Federal Laws.*** RCW 70.105D.030 requires the cleanup standards in these rules to be "at least as stringent as all applicable state and federal laws." In addition to using one of the three basic methods explained above, the state and federal laws that apply to the cleanup alternatives under consideration need to be identified. The cleanup standards under these other laws can then be compared with the cleanup standards identified under one of the three basic methods. This enables Ecology to determine that the cleanup standards being applied are at least as stringent as applicable state and federal laws. The requirements in WAC 173-304-710 are similar to the "ARAR" (applicable relevant and appropriate requirements) approach of the federal superfund law.

(b) ***Measuring Compliance.*** Setting cleanup standards also involves being able to demonstrate that they have been met. Two complicating factors are: *how long* it takes for a site to meet its cleanup standards; and *where* on the site the cleanup standards must be met. The provisions for the time for attaining a cleanup ("restoration timeframe") and for the location where the cleanup must be attained ("points of compliance") are in WAC 173-340-704. The compliance monitoring plan included in each cleanup action plan specifies precisely how these are measured for each site.

(d) ***General Procedures.*** The analyses performed under Methods B and C use several factors for estimating cancer risks. The procedures and assumptions to be used for these factors are specified in WAC 173-340-709. In addition, some hazardous waste sites involve the release of more than one hazardous substance, and others have more than one pathway for the substances to be released. Section 173-340-709 also provides rules for use of indicator chemicals and for estimating cancer risks in these situations.

NEW SECTION

173-340-702 ADMINISTRATIVE PRINCIPLES FOR CLEANUP STANDARDS

(1) ***Cleanup and Interim Actions.*** In order to qualify as a cleanup under the Model Toxics Control Act, a remedial action must meet the cleanup standards set forth in this part. If a remedial action does not meet these standards, it may be considered an interim action (WAC 173-340-430). The Act and these rules are intended to promote prompt and effective cleanup actions, rather than long term interim actions.

(2) ***Cleanup Standards versus Selection of Remedy.*** (a) The determination of cleanup standards and the selection of remedy are different processes. Cleanup standards govern the level of cleanup that must, at a minimum, be met to control or eliminate the release of particular hazardous substances from identified pathways at a site in order to protect human health and the environment. Selection of remedy refers to the overall cleanup action plan selected for a site.

(b) There is usually more than one hazardous substance and more than one pathway at a site for a substance to get into the environment. There may be more than one method to address each of these. A feasible alternative or remedy refers to the combination of methods for addressing the entire site. Except for routine actions, sites typically have a few feasible alternatives. This rule is intended to encourage consideration of feasible alternatives.

(c) Alternatives that do not meet cleanup standards should be screened out in the RI/FS process. Alternatives that meet cleanup standards -- alternative cleanup action plans that are protective of human health and the environment -- may be selected. Each alternative available for selection may include a different combination of methods designed to meet the policy objectives specified in the Act and WAC 173-340-360. Selection of remedy involves a much wider range of factors than the determination of cleanup standards under this part of the rules.

(3) ***Degree of Cleanup.*** The Act does not require sites to be cleaned up to the cleanest possible; rather, the Act requires a site to be cleaned up so that it is protective of human health and the environment. The goal is to estalish cleanup levels as close as possible to natural background levels, recognizing that the rule makes provision for where this goal may not be attainable or appropriate. Alternatives that meet cleanup standards may vary in the degree to which they clean up particular substances, cause environmental impacts or improve environmental quality, have public support, cost more or less, or can be implemented quickly. Although this part provides uniform methods statewide for identifying cleanup standards and requires that all cleanups meet cleanup standards, the actual cleanup levels to be met at each particular site will depend on the cleanup action plan selected for that site.

(4) ***Protection.*** Cleanup actions that comply with the cleanup levels determined under Methods A, B, or C (as applicable) and to applicable state and federal laws under WAC 173-340-700 shall be presumed to be protective of human health and the environment.

(5) ***Role of Cost.*** Cost may not be used to determine if a remedial action is protective of human health or the environment (see WAC 173-340-700); consideration of cost is appropriate:

(a) To determine a cleanup standard under an applicable state or federal law, where that law uses cost as a factor in setting standards, such as "all known, available, and reasonable methods of treatment";

(b) To determine whether Method C may be used (WAC 173-340-707) and conditional points of compliance may be established (WAC 173-340-704);

(c) To select a remedy (WAC 173-340-360);

(d) To decide whether additional analysis will provide sufficiently useful information to warrant its preparation (WAC 173-304-130(5).

(6) ***Compliance and Monitoring.*** In general and as provided more specifically by these rules, cleanup standards must be met throughout a site before a remedial action may be approved as a cleanup action. A remedy that leaves hazardous substances on a site, uses innovative technologies or institutional controls, or involves continued operation and maintenance, monitoring or periodic review may qualify as a cleanup action as long as the remedy is protective of human health and the environment. The department's determination of permanence or that cleanup standards have been attained will be based on performance monitoring. Confirmational monitoring may be used if necessary to assure that cleanup standards continue to be met.

RE-STRUCTURING OF OPENING PROVISIONS OF PART VII

This is an outline of where the sections in 700 and 705 get moved to group similar provisions together and add two brief new sections (700 and 702).

700 OVERVIEW OF CLEANUP STANDARDS
basic purpose and protection requirements from 700(1)
providing a new overview of the cleanup standard reg, similar to Sec. 100/120 for the process rule

702 ADMINISTRATIVE PRINCIPLES FOR CLEANUP STANDARDS
provide a guiding set of principles similar to 130 in the process rule

704 GENERAL POLICIES
use current 705(1) - (6) and add 700(11) on points of compliance
add "indicator chemicals" from 700(3)

705 METHOD A
consolidate existing text and use 700(5)(b) and 700(6) on Method A
add caution about misuse of tables as arars or for financing or insurance

706 METHOD B
use 700(7)

707 METHOD C
this really needs its own section because its disjointed now and has two distinct parts: the hurdles you have to jump to use it (700(5)(d)), and then what it is (700(8))

709 RISK ASSESSMENT PROCEDURES
risk analyses formulas currently and inappropriately found in "General Principles" (705(7) - (12)).
move the reasonable maximum expoure (RME) paragraph from 700(4), so it can join its risk assessment buddies in this section (or put in definitions section on RME)
add the multiple hazardous substances and multiple pathways sections (700 (9) and (10)) which also belong here, as they are about risk assessment methods

[NOTE: REMAINING SECTIONS NEED TO HAVE COMPLIANCE/CONDITIONAL LANGUAGE CHANGED TO BE CONSISTENT WITH METHODS A,B,C, CORRECTED CROSS REFERENCES, AND SIMILAR CONFORMING CHANGES]

NEW SECTION

WAC 173-340-704 ~~705~~ GENERAL POLICIES ~~PRINCIPLES~~. (1) *Purpose.* This section defines the policies and principles that the department shall utilize to ensure that cleanup standards under this chapter are established and implemented in a scientifically and technically sound manner.

(2) **Relationship to federal cleanup law.** When evaluating cleanup actions performed under the federal cleanup law, the department shall consider WAC 173-340-360 and 173-340-700 through 173-340-760 to be a legally applicable requirement under Section 12(d) of the federal cleanup law. **[NOTE: this needs revision, esp. re table 1 and sediments]**

(3) **Regulation update.** The department shall review and, as appropriate, update WAC 173-340-700 through 173-340-750 no less frequently than once every five years.

(4) **Restrictions on site use.** Appropriate site use restrictions including institutional controls under WAC 173-340-440 shall be required whenever conditional cleanup levels or conditional points of compliance are approved by the department under WAC 173-340-720 through 173-340-750. Site use restrictions, including institutional controls, shall also be required when cleanup levels are established under WAC 173-340-745. **[NOTE: these terms are used inconsistently in rule and need to be clarified, as not all institutional controls require recorded covenants, etc.]**

(5) **Burden of proof.** Any person responsible for undertaking a cleanup action under this chapter who proposes to establish a ~~conditional~~ cleanup level under Method C or a conditional point of compliance shall have the burden of demonstrating to the department that requirements in this part have been met in order to assure ~~are~~ protection~~ive~~ of human health and the environment ~~and that such requirements are allowable under this chapter~~. The department shall only approve ~~conditional~~ cleanup levels under Method C or conditional points of compliance when it determines that the person undertaking the cleanup actions met this burden of proof.

(6) **New scientific information.** The department shall consider new scientific information when establishing cleanup levels for individual sites. In making a determination on how to use this new information, the department shall, as appropriate, consult with the science advisory board, the department of health, and the United States Environmental Protection Agency.

(7) ~~(11)~~ **Points of compliance.** (from 700(11))

(a) The point of compliance is the point or points where cleanup levels established in accordance with WAC 173-340-720 through 173-340-750 shall be attained.

(b) The point of compliance under this chapter shall be established throughout the site. Under certain circumstances a conditional point of compliance may be established under WAC 173-340-720 through 173-340-750.

(c) A conditional point of compliance shall not be established unless the person undertaking the cleanup action can demonstrate that all feasible ~~practicable~~ methods of treatment shall be or have been utilized at the site.

(8) ~~(3)~~ **Selection of indicator hazardous substances.**

(a) When defining cleanup requirements at a site that is contaminated with a large number of hazardous substances, the department may eliminate from consideration those hazardous substances that contribute a small percentage of the overall threat to human health and the environment. The remaining hazardous substances shall serve as indicator hazardous substances for purposes of defining site cleanup requirements.

(b) If the department considers this approach appropriate for a particular site, at a minimum, the following factors shall be evaluated when eliminating individual hazardous substances from further consideration:

(i) The toxicological characteristics of the hazardous substance that influence its ability to adversely affect human health or the environment relative to the concentration of the hazardous substance at the site;

(ii) The chemical and physical characteristics of the hazardous substance which govern its tendency in the environment relative to other hazardous substances at the site;

(iii) The chemical and physical characteristics of the hazardous substance which govern its tendency to move into and through environmental media;

(iv) The natural background concentrations of the hazardous substance;

(v) The thoroughness of testing for the hazardous substance at the site;

(vi) The frequency that the hazardous substance has been detected at the site; and

(vii) Degradation by-products of the hazardous substance.

(c) When the department determines that the use of indicator hazardous substances is appropriate for a particular site, it may also require biological testing to address potential toxic effects associated with hazardous limits on the hazard index and total excess cancer risk shall also apply to sites where there is exposure to a single hazardous substance by one exposure pathway.

(4) ~~(e)~~ If there are any inconsistencies between this ~~sub~~section and any specifically referenced sections, the referenced section shall govern.

NEW SECTION

WAC 173-340-707 USE OF METHOD C. **(from 700(5)(d) and (8))**

(d) Conditional cleanup levels represent concentrations which are protective of human health and the environment under restricted site use conditions. Conditional cleanup levels may be established where the person undertaking the cleanup action can demonstrate that such levels are consistent with applicable state and federal laws, that all practicable methods of treatment are utilized, that institutional controls are implemented in accordance with WAC 173-340-440, and that one or more of the following conditions exist:

(i) Where compliance cleanup levels established by methods A or B are below area background concentrations, conditional cleanup levels may be established at concentrations that are equal to area background concentrations, but in no case greater than concentrations specified in subsection (8) of this section;

(ii) Where attainment of compliance cleanup levels established using methods A or B has the potential for creating a significantly greater overall threat to human health or the environment than attainment of conditional cleanup levels established under this chapter, conditional cleanup levels may be established at concentrations which minimize those overall threats, but in no case greater than concentrations specified in subsection (8) of this section. At a minimum, the following factors shall be considered in making this determination:

(A) Results of a site-specific risk assessment;

(B) Duration of threats;

(C) Reversibility of threats;

(D) Magnitude of threats; and

(E) Nature of affected population.

(iii) Where compliance cleanup levels established using methods A or B are below technically feasible concentrations, conditional cleanup levels may be established at the technically feasible concentrations, but in no case greater than levels specified in subsection (8) of this section; or

(iv) Where compliance cleanup levels established by methods A or B are below technically practicable levels, conditional cleanup levels may be established at concentrations which are at least as stringent as concentrations specified in subsection (8) of this section if the person undertaking the cleanup action can demonstrate all of the following:

(A) The incremental cost of attaining the compliance cleanup level is substantial and disproportionate to the incremental reduction in the threat to human health and the environment; and

(B) Neither containment or isolation of hazardous substances nor institutional controls are a principal component of the cleanup action.

(v) Where attainment of compliance cleanup levels will limit a person's ability to respond to other environmental threats at the site in question or other facilities owned or operated by the person undertaking the cleanup action, conditional cleanup levels may be established at concentrations which are at least as stringent as concentrations specified in subsection (8) of this section if the person undertaking the cleanup action can demonstrate all of the following:

(A) The incremental cost of attaining the compliance cleanup level is substantial and disproportionate to the incremental reduction in the threat to human health and the environment; and

(B) Neither containment or isolation of hazardous substances nor institutional controls are a principal component of the cleanup action.

(C) Financial benefits resulting from the approval of a conditional cleanup level will be utilized to fund actions that are not otherwise required under applicable state and federal laws to eliminate or substantially reduce other environmental threats; and

(D) Requirements for performing such actions are included in an enforceable document with the department.

(e) Cleanup levels shall not exceed concentrations established under subsections (6), (7), (8), (9), and (10) of this section except where the natural background concentration is greater than cleanup levels established under those subsections. In such situations, the cleanup level shall be established at a concentration equal to the natural background concentration.

(f) When a hazardous substance is not detected or is detected below the practical quantitation limit utilizing sampling and analytical procedures approved by the department and the practical quantitation limit is higher than the cleanup levels established under subsections (6), (7), (8), (9), and (10) of this section, the cleanup level shall be considered to have been attained only when the more stringent of the following conditions has been met:

(i) The practical quantitation limit is no greater than ten times the method detection limit; or

(ii) The practical quantitation limit for a particular hazardous substance, medium, and analytical procedure is no greater than the practical quantitation limit

NEW SECTION

WAC 173-340-705 USE OF METHOD A **(from 500(5)(2)(b) and (6))**

(1) ~~(b)~~ Method A may be used to establish cleanup levels at the following types of sites:

(a) ~~(i)~~ Sites undergoing routine cleanup actions as defined in WAC 173-340-130; or

(b) ~~(ii)~~ Sites where numerical standards are available in this chapter or applicable state and federal laws for all indicator hazardous substances in all media of concern.

~~(6) *Method A compliance cleanup levels.*~~

(2) ~~(a)~~ Method A compliance cleanup levels shall be established in accordance with the procedures in WAC 173-340-720 through 173-340-760. If there are any inconsistencies between this subsection and any specifically referenced sections, the referenced section shall govern. Method A compliance cleanup levels shall be at least as stringent as all of the following:

(a) ~~(i)~~ Concentrations of individual hazardous substances listed n the tables in WAC 173-340-720, 173-340-740, or 173-340-745.

(b) ~~(ii)~~ Concentrations of individual hazardous substances established under applicable state and federal laws; and

(c) ~~(iii)~~ Any other concentrations which the department determines are necessary to protect human health, and the environment.

~~(b) If there are any inconsistencies between this subsection and any specifically referenced sections, the referenced section shall govern.~~

(3) *Caution on Misusing Method A Tables.* (a) Method A tables shall not be misused for purposes for which they were not intended. They are not site specific and are not intended to define cleanup levels that must be met for financial, real estate, insurance, due diligence or similar purposes.

(b) Because conservative values have been used in order for the tables to be suitable for their intended purpose, they are not applicable, relevant or appropriate requirements under state or federal law except for the type of sites specified in subsection (1) of this section or except where a potentially liable or responsible party voluntarily wishes to have them applied to another type of site.

[NOTE: need to add similar cautionary note as 3(a) about misuse of tables directly onto Tables 1, 2, and 3]

NEW SECTION

WAC 173-340-706 USE OF METHOD B **(from 700(5)(c) and (7))**

(1) ~~(c)~~ Method B is applicable to all sites. It shall be used to develop compliance cleanup levels unless one or more of the conditions for using method A are demonstrated to exist and the person conducting the cleanup action elects to utilize method A.

~~(7) *Method B compliance cleanup levels.*~~

(2) ~~(a)~~ Method B compliance cleanup levels shall be established in accordance with the procedures in WAC 173-340-720 through 173-340-760. Method B compliance cleanup levels shall be at least as stringent as all of the following.

(a) ~~(i)~~ Concentrations of individual hazardous substances established under applicable state and federal laws;

(b) ~~(ii)~~ Concentrations which are expected to result in no adverse effects on the protection and propagation of aquatic and terrestrial life;

(c) ~~(iii)~~ For hazardous substances for which health-based standards have not been established under applicable state and federal laws, those concentrations which protect human health and the environment as determined using the following methods:

(i) ~~(A)~~ Concentrations which are anticipated to result in no acute or chronic toxic effects on human health as determined using a hazard quotient of 1.0 and the procedures specified in WAC 173-340-720 through 173-340-750;

(ii) ~~(B)~~ For known or suspected carcinogens, concentrations which are anticipated to result in an excess cancer risk less than or equal to 1 in 1,000,000 as determined using the procedures specified in WAC 173-340-720 through 173-340-750; and

(iii) ~~(C)~~ Concentrations which eliminate or substantially reduce the potential for food chain contamination; and

(d) ~~(iv)~~ Any other concentrations which the department determines are necessary to protect human health and the environment.

(3) ~~(b)~~ Concentrations of individual hazardous substances established under (a) of this subsection, including those based on applicable state and federal laws, shall be adjusted downward to take into account exposure to multiple hazardous substances and/or exposure resulting from more than one pathway of exposure. These adjustments shall be made in accordance with subsections (9) and (10) of this section. In making these adjustments, the hazard index shall not exceed 1.0 and the total excess cancer risk shall not exceed 1 in 100,000. These overall

established by the United States Environmental Protection Agency and published in 40 CFR 136, 40 CFR 141 through 143, or 40 CFR 260 through 270.

(g) The department shall consider the availability of improved analytical techniques when performing periodic reviews under WAC 173-340-420. Subsequent to those reviews, the department may require the use of improved analytical techniques with lower practical quantitation limits.

(8) Conditional cleanup levels.

(a) Conditional cleanup levels shall be established in accordance with the procedures in WAC 173-340-720 through 173-340-760. Conditional cleanup levels shall be at least as stringent as all of the following:

(i) Concentrations established under applicable state and federal laws;

(ii) Concentrations which are expected to result in no significant adverse effects on the protection and propagation of aquatic and terrestrial life;

(iii) For hazardous substances for which no health based standard has been established under applicable state and federal laws, those concentrations which are protective of human health as determined by the following methods:

(A) Concentrations which are expected to result in no significant adverse acute or chronic toxic effects on human health as estimated using a hazard quotient of 1.0 and the procedures defined in WAC 173-340-720 through 173-340-750;

(B) For known of suspected carcinogens, concentrations which are anticipated to result in a total excess cancer risk less than or equal to 1 in 100,000 as determined using the procedures defined in WAC 173-340-720 through 173-340-750; and

(C) Concentrations which eliminate or minimize the potential for food chain contamination; and

(iv) Any other concentration which the department determines are necessary to protect human health and the environment.

(b) Concentrations of individual hazardous substances established under (a) of this subsection, including those based on applicable state and federal laws, shall be adjusted downward to take into account exposure to multiple hazardous substances and/or exposure resulting from more than one pathway of exposure. These adjustments shall be made in accordance with subsections (9) and (10) of this section. In making these adjustments, the hazard index shall not exceed 1.0 and the total excess cancer risk shall not exceed 1 in 100,000. These overall limits on the hazard index and total excess cancer risk shall also apply to sites where there is exposure to a single hazardous substance by one exposure pathway.

(c) If there are any inconsistencies between this subsection and any specifically referenced sections, the referenced section shall govern.

NEW SECTION

WAC 173-304-709 RISK ASSESSMENT PROCEDURES **(from 700(9) and (10) and 705(7) - (11))**

[NOTE: Add purpose statement (1)]

(2) ~~(4)~~ Reasonable maximum exposure.

(a) Cleanup levels shall be based on estimates of current and future resource uses and reasonable maximum exposures expected to occur under both current and potential future site use conditions.

(b) The reasonable maximum exposure is defined as the highest exposure that is reasonably expected to occur at a site under current and potential future site use. Sections WAC 173-340-720 through 173-340-760 define the reasonable maximum exposures for ground water, surface water, soil, and air. These reasonable maximum exposures will apply to most sites where individuals or groups of individuals are or could be exposed to hazardous substances. For example, the reasonable maximum exposure for most ground water is defined as exposure to hazardous substances in drinking water and other domestic uses.

(c) Persons performing cleanup actions under this chapter may utilize the evaluation criteria in WAC 173-340-720 through 173-340-760 to demonstrate that the reasonable maximum exposure scenarios specified in those sections are not appropriate for a particular site. The use of an alternate exposure scenario shall be documented by the person performing the cleanup action. Documentation for the use of alternate exposure scenarios shall be based on the results of investigations performed in accordance with WAC 173-340-350.

(d) Individuals or groups of individuals may be exposed to hazardous substances through more than one exposure pathway. For example, a person may be exposed to hazardous substances from a site by drinking contaminated ground water, eating contaminated fish, and breathing contaminated air. At sites where the same individuals or groups of individuals are or could be consistently exposed through more than one pathway, the reasonable maximum exposure shall represent the total exposure through all of those pathways. At such sites, the cleanup levels derived for individual pathways under WAC 173-340-720 through 173-340-760 shall be adjusted downward to take into account multiple exposure pathways.

(3) ~~(9)~~ Multiple hazardous substances.

(a) Cleanup levels for individual hazardous substances established under subsections (7) and (8) of this section shall be adjusted downward to take into account exposure to multiple hazardous substances. Adverse effects resulting from exposure to two or more hazardous substances with similar types of toxic response are assumed to be additive unless scientific evidence is available to demonstrate otherwise.

(b) Cancer risks resulting from exposure to two or more carcinogens are assumed to be additive unless scientific evidence is available to demonstrate otherwise.

(c) For purposes of establishing cleanup levels for noncarcinogens under subsections (7) and (8) of this section, the health threats resulting from exposure to two or more hazardous substances with similar types of toxic response may be apportioned between those hazardous substances in any combination as long as the requirements of subsections (4), (7), and (8) of this section are met and the hazard index does not exceed 1.0.

(d) For purposes of establishing cleanup levels for carcinogens under subsections (7) and (8) of this section, the cancer risks resulting from exposure to multiple hazardous substances may be apportioned between hazardous substances in any combination as long as the requirements of subsections (4), (7), and (8) of this section are met and the total excess cancer risk does not exceed 1 in 100,000.

(e) The department may require biological testing to assess the potential interactive effects associated with chemical mixtures.

(4) ~~(10)~~ Multiple pathways of exposure.

(a) Estimated doses of individual hazardous substances resulting from more than one pathway of exposure are assumed to be additive unless scientific evidence is available to demonstrate otherwise.

(b) Cleanup levels based on one pathway of exposure shall be adjusted downward to take into account exposures from more than one exposure pathway. The number of exposure pathways considered at a given site shall be based on the reasonable maximum exposure scenario as defined in WAC 173-340-700(4).

(c) For purposes of establishing cleanup levels for noncarcinogens under subsections (7) and (8) of this section, the health threats associated with exposure via multiple pathways may be apportioned between exposure pathways in any combination as long as the requirements of subsections (4), (7), and (8) of this section are met and the hazard index does not exceed 1.0.

(d) For purposes of establishing cleanup levels for carcinogens under subsections (7) and (8) of this section, the cancer risks associated with exposure via multiple pathways may be apportioned between exposure pathways in any combination as long as the requirements of subsections (4), (7), and (8) of this section are met and the total excess cancer risk does not exceed 1 in 100,000.

[NOTE: REMAINDER OF SECTION FROM 705:]

(5) ~~(7)~~ Reference doses.

(a) The chronic reference dose and the developmental reference dose shall be used to establish cleanup levels under this chapter. Cleanup levels shall be established using the value which results in the most protective concentration.

(b) Inhalation reference doses shall be used in WAC 173-340-750. Where the inhalation reference dose is reported as a concentration in air, that value shall be converted to a corresponding inhaled intake (mg/kg-day) using a human body weight of 70 kg and an inhalation rate of 10 m^3/day.

(c) A subchronic reference dose may be utilized to evaluate potential noncarcinogenic effects resulting from exposure to hazardous substances over short periods of time. This value may be used in place of the chronic reference dose where it can be demonstrated that a particular hazardous substance will degrade to negligible concentrations during the exposure period.

(d) For purposes of establishing cleanup levels for hazardous substances under this chapter, a reference dose established by the United States Environmental Protection Agency and available through the "integrated risk information system" data base shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of this value is inappropriate.

(e) If a reference dose is not available through the "integrated risk information system" or is demonstrated to be inappropriate under (d) of this subsection, a reference dose shall be established utilizing the methods described in Risk Assessment Guidance for Superfund. Human Health Evaluation Manual, Part A. (October 1989).

(f) In estimating a reference dose for a hazardous substance under (e) of this subsection, the department shall consult with the science advisory board, the department of health, and the United States Environmental Protection Agency.

(g) Where a reference dose other than those established under (d) of this subsection is used to establish a cleanup level at individual sites, the department shall summarize the scientific rationale for the use of those values in the cleanup action plan. The department shall provide the opportunity for public review and comment on this value in accordance with the requirements of WAC 173-340-360.

(6) ~~(8)~~ Carcinogenic potency factor.

(a) For purposes of establishing cleanup levels for hazardous substances under this chapter, a carcinogenic potency factor established by the United States Environmental Protection Agency and available through the "integrated risk information system" data base shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of this value is inappropriate.

(b) If a carcinogenic potency factor is not available through the "integrated risk information system" or is demonstrated to be inappropriate under (a) of this subsection, one of the following methods shall be utilized to establish a carcinogenic potency factor:

(i) The carcinogenic potency factor may be derived from appropriate human epidemiology data on a case-by-case basis; or

(ii) The carcinogenic potency factor may be derived from animal bioassay data using the following procedures:

(A) All carcinogenesis bioassays shall be reviewed and data of appropriate quality shall be used for establishing the carcinogenic potency factor.

(B) The linearized multistage extrapolation model shall be utilized to estimate the slope of the dose-response curve unless the department determines that there is clear and convincing scientific data which demonstrates that the use of an alternate extrapolation model is more appropriate;

(C) All doses shall be adjusted to give an average daily dose over the study duration; and

(D) An interspecies scaling factor shall be used to take into account differences between animals and humans. This scaling factor shall be based on the assumption that milligrams per surface area is an equivalent dose between species unless the department determines there is clear and convincing scientific data which demonstrates that an alternate procedure is more appropriate. The slope of the dose response curve for the test species shall be multiplied by this scaling factor to obtain the carcinogenic potency factor. Where adequate pharmacokinetic and metabolism studies are available, data from these studies may be utilized to adjust the interspecies scaling factor.

(c) In estimating a carcinogenic potency factor for a hazardous substance under (b) of this subsection, the department shall consult with the science advisory board, the department of health, and the United States Environmental Protection Agency.

(d) Where a carcinogenic potency factor other than that established under (a) of this subsection is used to establish cleanup levels at individual sites, the department shall summarize the scientific rationale for the use of that value in the cleanup action plan. The department shall provide the opportunity for public review and comment on this value in accordance with the requirement of WAC 173-340-360.

<u>(7)</u> ~~(9)~~ Bioconcentration factors.

(a) For purposes of establishing cleanup levels for a hazardous substance under WAC 173-340-730, a bioconcentration factor established by the United States Environmental Protection Agency and utilized to establish the ambient water quality criterion for that substance under section 304 of the Clean Water Act shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of an alternate value is more appropriate.

(b) When utilizing a bioconcentration factor other than that utilized to establish the ambient water quality criterion, the department shall consult with the science advisory board, the department of health, and the United States Environmental Protection Agency.

(c) Where a bioconcentration factor other than that established under (a) of this subsection is used to establish cleanup levels at individual sites, the department shall summarize the scientific rationale for the use of that factor in the draft cleanup action plan. The department shall provide the opportunity for public review and comment on the value in accordance with the requirements of WAC 173-340-360.

<u>(8)</u> ~~(10)~~ Exposure parameters.

(a) As a matter of policy, the department has defined the exposure parameters to be used when establishing cleanup levels under this chapter. With the exception of the parameters identified in (b) of this subsection, these parameters shall not be modified for individual hazardous substances or sites in a manner which results in a less stringent cleanup level. The scientific and technical basis for these parameters shall be reviewed when updating WAC 173-340-700 through 173-340-760 under subsection (3) of this section.

(b) The department may approve the use of values other than those specified in WAC 173-340-720 through 173-340-760 where there is clear and convincing scientific data which demonstrates that one or more of the following parameters should be modified for an individual hazardous substance or site:

(i) Gastrointestinal absorption rate;

(ii) Inhalation correction factor; or

(iii) Bioconcentration factor.

(c) Where exposure parameters other than those established under WAC 173-340-720 through 173-340-760 are used to establish cleanup levels at individual sites, the department shall summarize the scientific rationale for the use of those parameters in the cleanup action plan. The department shall provide the opportunity for public review and comment on those values in accordance with the requirements of WAC 173-340-360.

<u>(9)</u> ~~(11)~~ Methods for defining background concentrations.

(a) Sampling of hazardous substances in background areas may be conducted to distinguish site-related concentration from nonsite related concentrations of hazardous substances or to support the development of a conditional cleanup level under the provisions of WAC 173-340-700 (5) and (8). For purposes of this chapter, two types of background may be determined. Natural background and area background concentrations.

(b) For purposes of defining background concentrations, samples shall be collected from areas that have the same basic characteristics as the medium of concern at the site and have not been influenced by releases from the site and, in the case of natural background concentrations, other than localized human activities.

(c) The statistical method used to evaluate available data shall be appropriate for the distribution of each hazardous substance. If the distribution of the hazardous substance data is inappropriate for statistical methods based on a normal distribution, then the data may be transformed. If the distributions of individuals hazardous substances differ, more than one statistical method may be required at a site. In general, appropriate statistical methods include the following:

(i) A tolerance interval procedure in which an interval for each hazardous substance is established from the distribution of background data and the cleanup level of each hazardous substance is compared to the upper tolerance limit; and

(ii) Other statistical methods proposed by the person undertaking the cleanup action and approved by the department.

(d) If a tolerance interval approach is used to evaluate natural background data, the tolerance interval shall have a coverage of ninety-five percent and a tolerance coefficient of ninety-five percent. When determining natural background concentrations, sample size of ten or more background samples shall be required. When determining area background concentrations, a sample size of twenty or more samples shall be required.

(e) For purposes of estimating background concentrations, values below the method detection limit shall generally be assigned a value equal to one-half of the method detection limit. Measurements above the method detection limit but below the practical quantitation limit shall generally be assigned a value equal to the method detection limit. The department may approve the use of alternate statistical procedures for handling data below the method detection limit or practical quantitation limit.

(10) ~~(12)~~ **Analytical considerations.**

(a) Analytical methods used to evaluate the effectiveness of a cleanup action shall be approved by the department. Approved analytical methods shall include methods identified in WAC 173-340-830.

(b) If a hazardous substance is not detected or is detected at a concentration below the practical quantitation limit utilizing sampling and analytical procedures approved by the department and the practical quantitation limit is higher than the cleanup level for that substance, the cleanup level shall be considered to have been attained only when the more stringent of the following conditions are met:

(i) The practical quantitation limit is no greater than ten times the method detection limit; or

(ii) The practical quantitation limit for the particular hazardous substance, medium, and analytical procedure is no greater than the practical quantitation limit established by the United States Environmental Protection Agency and used to establish requirements in 40 CFR 136, 40 CFR 141 through 143, or 40 CFR 260 through 270.

(c) In cases where a cleanup level required by this chapter is less than the practical quantitation limit using an approved analytical procedure, the department may also require one or more of the following:

(i) Use of surrogate measures of hazardous substance contamination;

(ii) Use or development of specialized sample collection or analysis techniques to improve the method detection limit or practical quantitation limit for the hazardous substances at the site; or

(iii) Monitoring to assure that the concentration of a hazardous substance does not exceed detectable levels.

(d) The department shall consider the availability of improved analytical techniques when performing periodic reviews under WAC 173-340-420. Subsequent to those reviews, the department may require the use of improved analytical techniques with lower practical quantitation limits.

NEW SECTION

WAC 173-340-710 APPLICABLE STATE AND FEDERAL LAWS. (1) Applicable state and federal laws. For purposes of this chapter, the term "applicable state and federal laws" shall include both legally applicable and relevant and appropriate requirements. The person undertaking a cleanup action shall identify all applicable state and federal laws. The department shall make the final interpretation on whether these requirements have been correctly identified and are legally applicable or relevant and appropriate.

(2) Legally applicable requirements. Legally applicable requirements include those cleanup standards, standards of control, and other environmental protection requirements, criteria, or limitations promulgated under state or federal law that specifically address a hazardous substance, cleanup action, location or other circumstances at the site.

(3) Relevant and appropriate requirements. Relevant and appropriate requirements include those cleanup standards, standards of control, and other environmental requirements, criteria, or limitations established under state or federal law that, while not legally applicable to the hazardous substance, cleanup action, location, or other circumstance at a site, address problems or situations sufficiently similar to those encountered at the site that their use is well suited to the particular site. The following criteria shall be evaluated, where pertinent, to determine whether a requirement is relevant and appropriate.

(a) Whether the purpose for which the statute or regulations under which the requirement was created is similar to the purpose of the cleanup action;

(b) Whether the media regulated or affected by the requirement is similar to the media contaminated or affected at the site;

(c) Whether the hazardous substance regulated by the requirement is similar to the hazardous substance found at the site;

(d) Whether the entities or interests affected or protected by the requirement are similar to the entities or interests affected by the site;

(e) Whether the actions or activities regulated by the requirement are similar to the cleanup action contemplated at the site;

(f) Whether any variance, waiver, or exemption to the requirements are available for the circumstances of the site;

(g) Whether the type of place regulated is similar to the site;

(h) Whether the type and size of structure or site regulated is similar to the type and size of structure or site affected by the release or contemplated by the cleanup action; and

(i) Whether any consideration of use or potential use of affected resources in the requirement is similar to the use or potential use of the resources affected by the site or contemplated cleanup action.

(4) Variances. For purposes of this chapter, a regulatory variance or waiver provision included in an applicable state and federal law shall be considered potentially applicable to interim actions and cleanup actions and the department may determine that a particular regulatory variance or waiver is appropriate if the substantive conditions for such a regulatory variance or waiver are met. In all such cases, interim actions and cleanup actions shall be protective of human health and the environment.

(5) New requirements. The department shall consider new applicable state and federal laws as part of the periodic review under WAC 173-340-420. Cleanup actions shall be evaluated in light of these new requirements to determine whether the cleanup action is still protective of human health and the environment.

[added from 360(4); needs to made consistent with methods, technically possible, and feasible language]

<u>(4) Applicable State and Federal Laws.</u>

(a) To demonstrate compliance with subsection (2)(a)(ii) of this section, all cleanup actions shall comply with all applicable state and federal laws.

(b) The following are selected applications of specific applicable state and federal laws to cleanup actions.

(i) Hazardous substances which are directly or indirectly released or proposed to be released to waters of the state shall be provided with all known, available and reasonable methods of treatment consistent with the requirements of chapters 90.48 and 90.54 RCW and the regulations that implement these statutes.

(ii) All known, available and reasonable methods, consistent with the policy stated in RCW 90.48.010 and 90.54.020 to insure the highest possible quality of all waters of the state, shall be used to protect and restore the quality of ground water affected by a release from a site.

(A) Ground water treatment to achieve the standards in WAC 173-340-720 throughout the ground water shall be required where such treatment is practicable or in the public interest.

(B) When treatment within an existing ground water plume is not practicable the following measures shall be taken:

(I) All practicable source control measures shall be implemented to prevent additional releases to the ground water.

(II) Containment, including barriers or hydraulic control through ground water pumping or both, shall be implemented to the maximum extent practicable to avoid lateral and vertical expansion of the ground water volume affected by the hazardous substance;

(III) Adequate ground water monitoring to demonstrate control and containment of the hazardous substance shall be conducted;

(IV) If the ground water has been rendered unusable because of exceedances of cleanup standards in WAC 173-340-720 resulting from releases from a site, the potentially liable person shall provide an alternative water supply or point of use treatment to persons with water supplies rendered unusable by the release; and

(V) The practicability of treating the ground water affected by the release shall be reevaluated during the periodic review under WAC 173-340-420.

(C) Appropriate restrictions on the use of ground water shall be placed under WAC 173-340-440 until cleanup standards established under WAC 173-340-720 are achieved.

(D) The integrity and continued operation of any treatment or containment system shall be assured in accordance with WAC 173-340-440.

(iii) Best available control technologies consistent with the requirements of chapter 70.94 RCW and the regulations that implement this statute shall be applied to air emissions from a site, including air emissions resulting from cleanup actions at a site.

(iv) Where the department determines that either chapter 173-303 or 173-304 WAC are applicable state and federal laws for a site, in addition to any other requirements in this chapter, the requirements of that portion of the rules determined to be applicable shall be the minimum requirements for the site.

Comment Letters

We urge Ecology to pay particular attention to the following comments, a large portion of which are shared by each other and the Public Private Cleanup Coalition:

Sweet-Edwards/EMCON, all comments; particular emphasis on page five, which we also addressed in our public hearing testimony

Golder Associates

ReTec

Hart-Crowser, especially page one

Washington Environmental Council, page two

U.S. Environmental Protection Agency/Chuck Findley

Washington Public Ports Association and Port of Tacoma

Association of Washington Business

The Boeing Company

Lynda Brothers

CWMNW/Donald Haagensen

Dan Syrdal, pages one and two

ASARCO, particularly documents one and two

SIERRA CLUB
WASHINGTON STATE CONSERVATION OFFICE

2631 TWELFTH COURT SOUTHWEST, SUITE A
OLYMPIA, WASHINGTON 98502 (206) 754-2386

September 12, 1990

Mr. Dave Bradley
Hazardous Waste Investigations
and Cleanup Program
Department of Ecology
Mail Stop PV-11
Olympia, WA 98504-8711

RE: Proposed Cleanup Standard Amendments to MTCA Regulation

Dear Dave:

After having reviewed the final draft of the cleanup standards regulation, I would like to offer the following comments on behalf of the Sierra Club.

I. The Role of Cost in Designing a Cleanup Action

As you know, during the legislative debate over the issue of toxic waste cleanup, the central issue was the role of cost in the cleanups. Since the legislature was unable to resolve the question, environmental groups put the issue up for a vote by placing Initiative 97 on the ballot in 1988.

The central theme in our campaign was "make the polluters pay" for the cost of cleaning these sites. When the voters affirmed this theme at the polls, they assumed that a program would be created to clean sites to levels protective of human health and the environment without much regard to cost.

Unfortunately, the Department has ignored this message in drafting rules for the cleanup program. Throughout the rule, you use the term "practicable" to cost modify decisions made on the cleanups. The point of compliance, the type of remediation, the timing of the cleanup, even the standards themselves are subject to cost considerations. This language will, in many cases, limit the ability of the Department to achieve cleanups which are protective of human health and the environment.

We strongly suggest that you remove language of this sort as it is inconsistent with the overall intent of the law.

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ECOLOGY

If the term "practicable" is used, then it should be defined in the definition section so that it is clear that any cost modification that occurs weigh the cost of the decision against the environmental benefits of the decision. The cost should be a determining factor only in instances in which the cost is "substantial and disproportionate" to the benefits. If you choose to retain the very broad definition of cost found in 173-340-360(7), then the benefits of such decisions should be defined broadly, including short and long-term benefits.

II. Conditional Point of Compliance [173-340-700(11)(c)]

The determination of the point of compliance is without a doubt one of the most significant decisions made in the process. As you know, the Sierra Club has maintained that the point of compliance should be throughout the site; we do not support the use of a "conditional point of compliance."

If you should choose to adopt a conditional point of compliance procedure, then the cost effectiveness analysis approach described above should be utilized. In addition, we would strongly recommend that, in instances in which a conditional point of compliance is utilized, the Department issue findings which demonstrate that the cost is clearly substantial and disproportionate to the benefits of adopting a point of compliance throughout the site.

In short, we believe that the use of the conditional point of compliance should be limited to sites in which there is no other real option. Despite the fact that these sites will be dealt with as "final" cleanups, they will not be clean. The rule should work to severely limit this approach.

III. Cleanup Standards

We believe that the cleanup standard sections of the law are seriously flawed and will permit cleanups which are not protective of human health and the environment.

(A) Conditional Cleanup Levels [173-340-700(5)(d)]

This section allows for deviations from the 1 in a million standard adopted under the compliance cleanup standard section. Again, we feel that this section should be narrowly drawn so as to limit the number of cleanups which fail to meet that standard. With the exception of a few select situations, we do not accept the 1 in 100,000 level as an acceptable alternative.

1. Area Background Deviations

Subsection (i) allows for a deviation when it can be shown that "area background" is below the 1 in a million standard. We urge you to substitute "natural background" for "area background." There can be no justification for deviating from acceptable cleanup levels simply due to the fact that a neighboring property is also contaminated with the same toxic compounds (e.g.-two oil refineries on adjacent properties). A possible exception might be carved out for situations in which recontamination is an issue. This exception, however, should be narrowly drawn, with the burden on the responsible party to demonstrate that recontamination is likely. The exception should only be applied to an interum cleanup.

2. Technically Practical Deviations

Subsection (iv) allows for deviations from compliance cleanup levels based on cost considerations. We object to this language for the reasons outlined above. Standards should be based on science and not economics.

3. Mitigation Deviation

The Sierra Club strongly objects to subsection (v) which allows for lower standards if the savings incurred would be used to address other environmental threats. While, in principle, this would seem to be a reasonable approach, we believe it would be extremely difficult to administer. It could, for example, require the Department to weigh the benefits of a wetlands mitigation against the human health benefits of a cleanup that attains compliance cleanup standards. Even within the same general area of concern this balancing would be problematic. How can one compare the effects of benzene in water to carbon monoxide in the air?

(B) Compliance Cleanup Levels

1. Industrial Soil Standards

We do not believe the use of industrial or commercial soil standards is justified. This is not a narrow exemption; almost all sites will fit into either the industrial or commercial category.

The pressure to convert industrial and commercial areas into residential and recreational areas has never been greater (e.g.- Seattle's Gas Works Park). By allowing for a less stringent standard for industrial areas, the Department will create "sacrifice zones" which cannot be converted short of a second cleanup.

Moreover, the establishment of less stringent standards in these areas does not take into account the fact that many industrial and a large percentage of commercial sites border on residential areas. Why should a service station cleanup in a residential area in which children play be allowed to achieve a less stringent soil standard simply because the site is located on property zoned "commercial ?"

In addition, while the standard applies only to soils, by leaving contaminated soils in place at the end of the cleanup, leachate from those soils will continue to effect groundwater after the so-called "cleanup" is completed (i.e.-not all these sites will be capped, and many will not be monitored).

2. Risk Assessment Assumptions

We believe that many of the assumptions made under "method B" risk assessments will not work to insure that standards are protective of human health and the environment. Most notably, the standards do not factor in: synergistic effects; inhalation and dermal exposure routes; impacts on the environment (non-human impacts); average lifetime exposure (i.e.-the rule does not utilize a 70 year exposure assumption). See Comments on Draft EIS for Multimedia Cleanup Standards (Monroe Toxicology Professional, Oct. 1989).

These ommissions and others will result in the establishment of cleanup standards which fall far below the 1 in 100,000 level for carcinogenic chemicals, and below what we consider acceptable for non-carcinogens.

While we recognize that this is a difficult area due to the number of unknowns, we feel very strongly that the Department should err on the conservative side until we are more certain as to the effects of these chemical and more confident that we understand exposure pathways.

From our perspective, this approach represents the most significant "loophole" in the entire regulation. We are extremely disappointed that you have chosen to gamble with human health in this fashion. [See: Roberts, "Is Risk Assessment Conservative?" Science (March 24, 1989)].

IV. Choice of Remediation (173-340-360)

The use of the term "practicable" throughout this section could place significant limitations on the Department's ability to require more sophisticated forms of treatment. While we do not object to cost being considered when a choice is made as between two or more equally protective types of remediation, we do not support the use of cost to discriminate against more protective technologies. We are especially disturbed by the use of the word "practicable" in relation to groundwater treatment. This language should be eliminated.

You also seem to indicate that final cleanups could be accomplished by simply instituting institutional controls and monitoring (173-340-360(6)(b)(vi). We do not accept that this type of action would serve as a "cleanup" in any sense of the word. We ask that you remove this language and clarify that cleanups must involve physical actions on site which are protective of human health and the environment.

V. Periodic Review (173-340-420)

When we wrote Initiative 97, we did so with the intent of eliminating the need of secondary cleanups. The Department, by in its rulemaking, has almost assured that we will indeed require secondary cleanups on a wide variety of sites. For this reason, the site review process becomes far more important.

As it now stands, this section contains little information on how the review will be conducted. We strongly suggest that you make public monitoring data and other pertinent information at the time of the review (and at all times) and provide for some type of process to allow for public comment. Without this component, you can not expect the public to have any confidence in your program.

In summary, the rule is very disappointing to the Sierra Club as well as to the literally thousands of people who actively participated in the Initiative 97 campaign. The public wants some assurance in the rule that the Department will get serious about cleanups, and that it will not bend to special interest pressure on sites. We ask you to make the changes which are outlined above before the rule is adopted.

Thank you for considering our comments.

Sincerely,

Bruce Wishart
Director
State Conservation Office
Sierra Club

TECHNICO
ENVIRONMENTAL SERVICES

• • •

201 West 33rd Avenue
Kennewick, WA 99336 (509) 582-7447

September 17, 1990

Mr. David Bradley
Department of Ecology
Toxic Cleanup Program
MS PV-11
Olympia, WA 98504-8711
(206) 438-3050

REF: AMMENDMENTS TO THE MODEL TOXICS CONTROL ACT, CLEANUP REGULATION - CHAPTER 173-340 WAC

Dear Mr. Bradley:

My concern with the subject regulation is that the wording seems to be very strict in relationship to the clean-up standards. The groundwater standards are particularly important because the point of compliance shall be established throughout a site. If groundwater is contaminated above drinking water standards my interpretation of the present wording indicates that it requires soil cleanup since soil cleanup standards are based upon not violating groundwater cleanup standards. Does this require cleanup at a site where groundwater contamination would never be above drinking water standards off the owners property? I presume all of this depends upon Section 173-340-720, "removal or containment measures shall be implemented to reduce the concentration of the hazardous substances and groundwater to concentrations consistent with this use unless the following can be demonstrated: I. The groundwater does not serve as a current source of drinking water; II. the groundwater is not a potential future source of drinking water; III. the department determines it is unlikely that hazardous substance will be transported from the contaminated groundwater to groundwater that is a current or potential source of drinking water ...... at concentrations which exceed groundwater quality criteria published in chapter in 173-200 WAC. I am also concerned about the point of compliance in that an alternate point of compliance can not be established unless all practicable methods of treatment have be utilized at the site. As I read this document this too would require cleanup of a site, once again even if the groundwater contamination would not exceed drinking water standards off the owners property. I do not see how the risk assessment comes into play here. I believe a risk assessment should be an important part of any cleanup decisions, if there is no exposure there is no risk. <u>PERHAPS THE MOST USEFUL THING TO BE ADDED WOULD BE A FLOW CHART TO ILLUSTRATE HOW THE DECISION MAKING PROCESS PROCEEDS</u>. Without a flow chart I can't tell how one section of the regulation relates to another section.

I do believe there should be time frames associated with DOE responses to all portions of these regulations and their associated studies. I suspect the main driving force behind the initiative for cleaning up hazardous waste sites was because of the publics feeling of a lack of progress at many of these sites. I think the lack of progress at times is due to the Department of Ecology's reluctance to make decisions. The following time frames provide a case in point for one of my clients sites. July 1986 a cleanup report was submitted after March and April cleanups. February 2, 1987 DOE stated that we need a new closure plan. August 10, 1987 DOE finally issues an order for a groundwater assessment. February 1988 closure and post-closure plans where resubmitted along with the groundwater assessment results. August 8, 1990 the Environmental Protection Agency finally issued a letter defining clean closure of this site. August 27, 1990 our response was provided with data demonstrating clean closure. DOE never did decide what clean closure was. I believe DOE could act more directly on these sites and not be so heavily concerned about EPA oversite.

I appreciate the chance to comment on this act and I would like to have you place me on your mailing list for all future correspondence.

Sincerely,

John A. Zillich

John A. Zillich

JAZ/mrb

Ken Weiner
9/11/90
Spokane Hearing

WEBSTERS DICTIONARY

feasible 1. capable of being done or carried out; practicable; possible [a feasible scheme] 2. within reason; likely; probable [a feasible story] 3. capable of being used or dealt with successfully; suitable [land feasible for cultivation]

practicable 1. that can be done or put into practice; feasible [a practicable plan] 2. that can be used, usable; useful [a practicable tool]

Ken Weiner
9/11/90
Spokane Hearing

<u>in compliance with</u> in accordance with; <u>comply</u>: to act in accordance (with a request, order, rule, etc.)

<u>ALL</u> CLEANUPS REQUIRE COMPLIANCE: See 173-340-360, 700

<u>All</u> cleanup actions shall be protective of human health and the environment, meet applicable standards, etc.

<u>conditional</u> 1. containing, implying, or dependent on a condition or conditions; qualified; not absolute

<u>ALL</u> CLEANUPS ARE CONDITIONAL: See 173-340-360, 410

Compliance monitoring shall be required for all cleanup actions;

RCW 70.105D.040(4)(c) -- Any covenant not to sue shall contain a reopener clause...

Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

AUG 30 1990

Mr. Norm Buske
SEARCH Technical Services
HCR Box 17
Davenport, Washington 99122

Dear ~~Mr. Buske~~ Norm:

REQUEST FOR ACCESS, VEGETATION STUDY OF THE HANFORD SHORELINE

Thank you for your letter of July 14, 1990, describing the state's actions regarding your request for access to the Hanford Site for the purpose of vegetation sample collection. There appears to be some misunderstanding concerning the circumstances surrounding your request for access to portions of the river bank adjacent to Hanford property. Under a grant provided to the State of Washington on March 8, 1990, the State Department of Health has assumed responsibility for all non-federal oversight of environmental monitoring activities at the Hanford Site. In this role, the State determines how to conduct independent environmental monitoring oversight activities. Your request for access to conduct oversight environmental monitoring was referred to the State under this agreement. The decision on whether or not your proposal will be included in their oversight activities is theirs.

We appreciate your offer of assistance in identifying areas containing low levels of contamination; however, the Hanford Site is being remediated under the Tri-Party Agreement. Site characterization will identify the areas and extent of contamination. The subsequent remedial action will remove contamination to levels directed by the Environmental Protection Agency with recommendations from the Washington Department of Ecology.

Quarterly public meetings are held under the Tri-Party Agreement. I have enclosed a recent newsletter which discusses the cleanup of Hanford. If you are interested in being placed on the mailing list for this newsletter, please complete and mail the coupon which appears in it.

Should you have any questions concerning this matter, please call Randall F. Brich of the Safety and Environment Division at (509) 376-9031.

Sincerely,

Tom Bauman

Tom Bauman, Acting Director
Office of Communications

SED:RFB

Enclosure

cc w/o encl:
John Erickson, DOH

Department of Energy
Richland Operations Office
P.O. Box 550
Richland, Washington 99352

AUG 28 1990

Mr. Norm Buske
SEARCH Technical Services
HCR Box 17
Davenport, Washington 99122

Dear Mr. Buske:

MULBERRY JAM

Your letter of August 6, 1990, to Secretary Watkins was forwarded to me for a response along with the container of mulberry jam for analysis. I have asked scientists at Battelle's Pacific Northwest Laboratory to analyze the jam for strontium-90 and other radionuclides.

Since 1981, the annual environmental report for the 100 Area has indicated measurable concentrations of strontium-90 in vegetation growing in the vicinity of the 100 N-Springs area. According to the 1988 report, the levels of strontium-90 are decreasing. A copy of the 1988 report is enclosed for your information. The 100 N-Springs area was posted in 1981 to restrict access to the public.

The 100 N-Springs area is part of the 100-NR-1 Operable Unit that will be remediated under the Comprehensive Environmental Response, Compensation and Liability Act, as amended. Site characterization will identify the areas and extent of contamination. The subsequent remedial action will remove contamination to levels directed by the Environmental Protection Agency with recommendations from the Washington Department of Ecology.

Should you have any questions concerning this matter, please call Mr. Randall F. Brich of my staff at (509) 376-9031.

Sincerely,

R. A. Holten

R. A. Holten, Director
Safety and Environment Division

SED:RFB

Enclosure

Proposed Amendments to the Model Toxics Control Act Cleanup Regulation Chapter 173-340 WAC (WSR 90-15-066) and the Draft Environmental Impact Statement (July 1990)

Written Comments Submitted By:

1. Thomas L. Aldrich
   Asarco Incorporated
   Post Office Box 1677
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2. Jeff Belfiglio
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   10500 NE 8th Street
   Bellevue, WA 98004-4300

3. Lynda L. Brothers
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   Seattle, WA 98101-1688

4. E. R. "Skip" Burch
   Department of Transportation
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   Olympia, WA 98504-5201

5. Anthony S. Burgess and
   Douglas S. Dunster
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   4104 148th Avenue NE
   Redmond, WA 98052

6. Leonard J. Butler[1]
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7. Joan Cabreza
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13. Lee Fortier
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    18912 North Creek Parkway,
    Suite 210
    Bothell, WA 98011

[1] Article not included here is available upon request. Starr, "Risk Management, Assessment, and Acceptability," Risk Analysis, Vol. 5, No. 2, 1985, pp. 97-102.

27. Dennis F. Stefani
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[3] Article not included here is available upon request. Office of Management and Budget, Regulatory Program of the United States Government (April 1, 1990 - March 31, 1991), pp. 1-41.

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20. Bonnie Orme[2]
Wetlands Chair, Magnolia
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21. Clayton R. Patmont and
M. Marian Wineman
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22. Don Peterson
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23. Dan W. Reicher and
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24. John R. Ryan
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25. Leslie Sacha
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Tacoma, WA 98401

26. Science Advisory Board
(Department of Ecology)
Dr. Henry Landau, Chair
Dr. David Eaton
Dr. KNona Liddell
Dr. Thomas Sibley
Dr. Donald Wood

[2] Six attachments not included here are available upon request.

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Public Hearing Testimony

Seattle, September 6, 1990

1. Jack Roberts
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Spokane, September 11, 1990

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No one testified.