EVERETT SMELTER SITE

Everett,Washington

INTEGRATED
FINAL CLEANUP ACTION PLAN
and
FINAL ENVIRONMENTAL IMPACT STATEMENT
for the
UPLAND AREA

Volume II

Puget Sound Reduction Works facility looking east. December 10, 1895.
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by

Washington State Department of Ecology

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Appendix B

RESPONSIVENESS SUMMARY for the INTEGRATED DRAFT CLEANUP ACTION PLAN and DRAFT ENVIRONMENTAL IMPACT STATEMENT for the UPLAND AREA

INDEX TO
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This document consists of four volumes.

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List of Acronyms and Abbreviations

ARARs	Applicable or Relevant and Appropriate Requirements
Asarco	ASARCO Incorporated
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act – The federal Superfund law
CFR	Code of Federal Regulations
CPM	Community Protection Measures
DCAP/DEIS	Integrated Draft Cleanup Action Plan and Draft Environmental Impact Statement
DOH	Department of Health
Ecology	Department of Ecology
EIS	Environmental Impact Statement
EPA	U.S. Environmental Protection Agency
FCAP/FEIS	Integrated Final Cleanup Action Plan and Final Environmental Impact Statement
GMA	Growth Management Act
GQ	Generalized Question
id.	idem (*Latin*, meaning the same; used in citations to refer to previous cites of statutes and regulations)
IEUBK model	Integrated Exposure Uptake Biokinetic model
MDL	Method Detection Limit
mg/Kg	milligrams per kilogram (same as ppm)
mg/L	milligrams per liter
MTCA	Model Toxics Control Act
NPDES	National Pollutant Discharge Elimination System
NRC	National Research Council
OCF	On-Site Containment Facility
PAC	Policy Advisory Committee
PLP	Potentially Liable Person
ppm	parts per million (same as mg/Kg)
PSAPCA	Puget Sound Air Pollution Control Authority
RCRA	Resource Conservation and Recovery Act
RCW	Revised Code of Washington
RME	Reasonable Maximum Exposure
RI/FS	Remedial Investigation/Feasibility Study
ROD	Record of Decision
SEPA	State Environmental Policy Act
TCLP	Toxicity Characteristic Leaching Procedure
TSCA	Toxic Substances Control Act
TWG	Technical Work Group
µg/dL	micrograms per deciliter
µg/Kg	micrograms per Kilogram
WAC	Washington Administrative Code

Executive Summary

In January 1999 the Washington Department of Ecology (Ecology) issued the preliminary cleanup decision for the Upland Area of the Everett Smelter Site for public comment in the "Integrated Draft Cleanup Action Plan and Draft Environmental Impact Statement for the Upland Area of the Everett Smelter Site" (DCAP/DEIS, Ecology, 1999c). The DCAP/DEIS explained Ecology's reasons for proposing to select the cleanup actions described therein. As required by the Model Toxics Control Act (MTCA), the DCAP/DEIS was the subject of a public comment period to afford the public a meaningful opportunity to provide input into Ecology's decision-making process. Ecology has reviewed all comments made on its draft cleanup decision.

The primary purpose of this Responsiveness Summary is to document and explain Ecology's evaluation of the comments made on the agency's draft cleanup decision. After careful consideration and review of those comments, Ecology has selected the cleanup actions proposed in the DCAP/DEIS: removal and containment of contaminated soil in the Peripheral Area, removal of highly contaminated soil in the Former Arsenic Trioxide Processing Area, and construction of a Consolidation Facility in the Former Arsenic Trioxide Processing Area for disposal of less contaminated soil from the Peripheral Area. Cleanup will be accomplished in accordance with cleanup standards and standards of performance set forth in the DCAP/DEIS and carried forward in the FCAP/FEIS. Adjustments in cleanup standards and standards of performance from those proposed in the DCAP/DEIS have been made in the FCAP/FEIS for surface water (See GQ 4.4.1), for storm water entering the City of Everett's Treatment Plant (See GQ 4.4.3), and for storm drain sediment (See GQ 4.5.1). Institutional controls will be implemented for the site as described in the FCAP/FEIS.

Based on the suggestions made by several commentors, Ecology has also revised various aspects of the plan for implementing the selected cleanup actions. The final cleanup action plan for the Upland Area of the Everett Smelter Site is presented in this FCAP/FEIS. The FCAP/FEIS also contains land use analyses performed by the City of Everett during the public comment period and preparation of this Responsiveness Summary. These analyses are presented in FCAP/FEIS Section 3.3.5 and discussed in this Responsiveness Summary under GQ 5.2.1 and GQ 6.2.6.

Several commentors indicated the integration of the cleanup action plan and the environmental impact statement was confusing. Ecology believes this is due to titling DCAP/DEIS Appendix A "Draft Environmental Impact Statement," when in fact it was meant primarily to document the evaluation of environmental elements identified during the SEPA scoping process. In the FCAP/FEIS, Appendix A has been re-titled "Evaluation of SEPA Scoping Elements." The Summary chapter has been eliminated because it was confused with the Environmental Summary called for in WAC 197-11-440(4), which is presented with the front matter of the document. These changes are discussed under GQ 5.1.1.

Chapter B1 Introduction

The Washington State Department of Ecology (Ecology) received public comment on the Everett Smelter Site Integrated Draft Cleanup Action Plan and Draft Environmental Impact Statement for the Upland Area (DCAP/DEIS, Ecology, 1999c) from January 26, 1999, through February 26, 1999. This Responsiveness Summary addresses the comments received during the public comment period.

A number of meetings during the comment period provided the opportunity for people to discuss the proposed cleanup actions. A public meeting was held in Everett at the Hawthorne Elementary School on February 11, 1999. Forty people attended the public meeting. Informal workshops were held on February 16 and 20, 1999, to engage people in the detail of the proposed cleanup action plan. Six people took advantage of the workshops to talk individually.

Comments were received in writing, summarized from discussions with people in public meetings and workshops, and compiled from continued discussions between Ecology and stakeholders. Ecology received comments from 90 citizens and other interested persons, including several local governments and ASARCO Incorporated (Asarco). Ecology reviewed these comments and identified 490 separate comments. Please note that these comments incorporate by reference any attachments.

The Responsiveness Summary responds to the identified comments in a question and answer format. The 490 comments were numbered and grouped into 136 generalized questions**.** Each of the generalized questions corresponds to a section in the DCAP/DEIS and reflects a particular issue raised by one or more of the commentors. The numbered comments addressed by each of the generalized questions are listed in parentheses below the respective question. Ecology's response to those comments follows. Note that some comments are addressed by and appear under more than one generalized question.

Attachment B1 presents Ecology's review of comments and additional items submitted to Ecology by Asarco in February 1999. Asarco requested Ecology consider as these comments and materials as new scientific information while developing the FCAP/FEIS.

Attachment B2 (Volume III) provides the text of the numbered comments addressed by each generalized question (GQ). The attachment is organized by GQ number. The attachment should be used as a companion document to the text of the Responsiveness Summary. Since some comments appear under more than one generalized question, some comments appear more than once in the attachment. Tables at the beginning of Attachment B2 correlate commentor, comment numbers, and generalized question numbers.

Attachment B3 (Volume IV) presents the numbered original comments letters. Tables at the beginning of Attachment B3 correlate comment number, commentor, and page number in the attachment where the original comment may be found.

Chapter B2 Background

GQ 2.1.1
Has Ecology appropriately characterized the history of the Everett Smelter Site?

(48)

Response:
The DCAP/DEIS is one in a series of documents used by Ecology to define remedial actions and to monitor progress of site investigation and cleanup. An outline of these various documents was provided in Section 1.5 of the DCAP/DEIS. The purpose of a Remedial Investigation and Feasibility Study is to investigate the nature and extent of contamination at a site, to assess the risks posed by that contamination, and to evaluate the feasibility of alternative methods of cleaning up the site. The purpose of a DCAP/DEIS is then to describe the cleanup actions proposed to be selected for the site and to set forth the requirements that those cleanup actions must meet.

The purpose of the background section of the DCAP/DEIS, in particular, was to briefly summarize the history of the Everett Smelter Site to provide context for the cleanup actions discussed in the remainder of the document. Language has been added to the FCAP/FEIS to note when the arsenic extraction facilities were constructed, as requested by one commentor. The commentor suggested that addition of the arsenic extraction facility resulted in reduced arsenic emissions (potential effects on lead emissions are not mentioned). Such an inference is neither appropriate in the DCAP/DEIS[1] nor relevant to selection of a remedy for the nature and extent of contamination documented to exist in the Remedial Investigation for the Everett Smelter Site (Hydrometrics, 1995a).

GQ 2.1.2
Has Ecology accurately characterized the current land use and demographics of the Everett Smelter Site?

(335, 360, 362)

Response:
Several comments expressed concern as to whether the DCAP/DEIS accurately characterized the current land use and demographics of the Everett Smelter Site. Each of these concerns has been noted and addressed as appropriate in the FCAP/FEIS. Figures showing land use have been revised. Exhibit 1 has been eliminated. Figure 2-2 showing site zoning remains and a figure in the draft Appendix A (Figure A4-6) showing comprehensive land use designations has been moved to the main text of the FCAP/FEIS

[1] The Remedial Investigation report would be the appropriate document for discussion of the quantity of air emissions and their variation over time. In any case, such a discussion would add nothing to identifying the nature and extent of contamination, which is the key information for selecting a cleanup action.

as Figure 2-3. Clarifying language has been added to Section 2.3 and Table 2.1 of the FCAP/FEIS.

GQ 2.1.3
Has Ecology appropriately characterized and evaluated the Remedial Investigation and the extent of contamination at the Everett Smelter Site?

(32, 49, 51, 52, 53, 385)

Response:
The purpose of the Remedial Investigation report (Hydrometrics, 1995a) was to investigate the nature and extent of contamination at the Everett Smelter Site and to assess the risks posed by that contamination. Ecology's evaluation and summary discussion of the Remedial Investigation report in the context of developing cleanup action plans for the Upland Area of the Everett Smelter Site was presented in Section 2.4 of the DCAP/DEIS. Ecology received several comments regarding various aspects of that evaluation and discussion, including soil contamination, slag, surface water contamination, and ground water contamination.

Ecology's evaluation and summary discussion of soil contamination and the respective portions of the Remedial Investigation report were presented in Section 2.4.1 of the DCAP/DEIS. Commentors expressed various concerns regarding the interpretation of and reliance on the soil concentration data and contour maps developed from that data. As discussed in Section 2.4.1of the DCAP/DEIS, the concentration contour maps provided in Exhibits 2 and 3 are useful for presenting a general overview of the pattern of soil arsenic contaminant distribution across the Upland Area of the Everett Smelter Site. As Ecology also discussed, the "highest concentrations of contaminants in soil exist on and immediately adjacent to the original smelter property," and that "[i]n most cases, contaminant concentrations decrease with increased distance from the original smelter." The contour maps clearly show both the arsenic soil concentrations and the general decrease of such concentrations with increased distance from the smelter site. The highest soil arsenic concentration measured of 727,000 mg/Kg was presented to provide a maximum value that is not apparent from the contour maps.

To address the concerns raised by the commentors, the following clarifying text has been added to Section 2.4.1 in the FCAP/FEIS:

> *Locations at which samples were collected are shown on each map. Property-by-property sampling will provide detailed data needed for cleanup decisions. Although these maps provide a good indication of the general distribution of contamination, variations on a property-specific basis may be expected to occur.*

An additional paragraph has also been added to note that in the Peripheral Area, the distance at which contamination decreases below regulatory standards, and hence the final site boundary, will be defined by further sampling during the cleanup process.

Ecology's evaluation and summary discussion of slag existing at the Everett Smelter Site was presented in Section 2.4.2 of the DCAP/DEIS. While one commentor recommended that the FCAP/FEIS expand on the scope of contamination associated with slag, vegetation, and other materials, as well as the means of addressing such contamination, another commentor recommended that the FCAP/FEIS should not separately address slag within the Upland Area. Section 3.2 of the FCAP/FEIS has been revised to include a description of slag sampling results. Slag will be removed as it is encountered on the site. Section 6.2.1.2 of the FCAP/FEIS has been revised to provide that accessible slag is to be removed if encountered. The soil disposal and management programs, Sections 6.7.5 and 6.7.6 of the FCAP/FEIS, have also been revised to provide for the subsequent management of slag, storm drain sediment, vegetation, building materials, and any other debris or material that exceeds MTCA cleanup levels for the contaminants of concern. Text has been added to Section 6.7.9 of the FCAP/FEIS which provides that environmental investigations may be conducted to respond to finding of slag beyond the site boundaries which is believed to have originated from the Everett Smelter.

Ecology's evaluation and summary discussion of surface water contamination and the respective portions of the Remedial Investigation report was presented in Section 2.4.3 of the DCAP/DEIS. One commentor suggested that Ecology's characterizations are misleading in that they do not acknowledge that there is no indication that runoff causes any exceedance of water quality standards in the Snohomish River. Ecology disagrees. The purpose of the summary of surface water contamination in DCAP/DEIS Section 2.4.3 was simply to summarize the data collected during remedial investigation activities, not to evaluate its impacts in the Lowland Area or on the Snohomish River. Impacts to the Lowland Area and to the Snohomish River will be evaluated in a separate remedial investigation report for the Lowland Area.

Ecology's evaluation and summary discussion of ground water contamination and the respective portions of the Remedial Investigation report (Hydrometrics, 1995a) was presented in Section 2.4.4 of the DCAP/DEIS. One commentor suggested that the ground water sampling provides an insufficient basis to conclude that there are "impacts to both Fill/Till and the Advance Outwash hydrogeological units." As was discussed in the DCAP/DEIS, ground water sampling from wells completed in both the Fill/Till and Advance Outwash hydrogeologic units did have measured arsenic concentrations exceeding regulatory standards. While Ecology acknowledged in the DCAP/DEIS that the Remedial Investigation report concluded that "ground water ... does not appear to have been adversely affected…," Ecology also recognized that the actual measured values indicate impacts to both the Fill/Till and Advance Outwash hydrogeologic units. Again, this section provided a summary of investigation results. Ecology believes that it would have been misleading to omit from the discussion either those measured values exceeding cleanup levels or that any such exceedance is an impact to the hydrogeologic units.

The commentor also suggested that Ecology's characterizations are misleading in that the observed effects are located only at the eastern edge of the Upland Area. Ecology disagrees. Monitoring wells exist only east of the Former Arsenic Trioxide Processing Area with the exception of one monitoring well upgradient (west) of the Former Arsenic Trioxide Processing Area. The upgradient well is completed in the Fill/Till aquifer. No monitoring wells are located, and hence no information is available, throughout most of the Upland Area. The information presented discusses effects where monitoring wells are located.

GQ 2.1.4
Has Ecology appropriately characterized and evaluated the Feasibility Study?

(54, 55)

Response:
Ecology's evaluation and summary discussion of the Feasibility Study report (Hydrometrics, 1995b) was presented in Section 2.5 of the DCAP/DEIS. One commentor asserted that Ecology's characterization of the report is misleading and incomplete because Ecology allegedly failed to recognize that the report concluded that the selection of a 20 mg/Kg soil arsenic cleanup level would violate the MTCA Cleanup Regulation because the cost is allegedly disproportionate to the benefit. Ecology is unaware of where the Feasibility Study report reaches such a conclusion. Even if the report had reached such a conclusion, Ecology would have disagreed with it. The selection of the 20 mg/Kg soil arsenic cleanup level is required by threshold regulatory requirements and, therefore, is not subject to the substantial and disproportionate analysis. Please refer to the discussion in FCAP/FEIS Section 6.2 and the discussion under ***GQ 5.2.2*** *of this Responsiveness Summary.*

The commentor also disagreed with Ecology's conclusion that the Sediment Cleanup Standard Users Manual is inappropriate for use in soil cleanups involving human health. In particular, the commentor asserted that the referenced guidance is applicable to the general evaluation process and provides an appropriate method to evaluate whether cost differences between soil cleanup actions for the Upland Area of the Everett Smelter Site are significant.

Ecology disagrees with this assertion. As discussed in Ecology's comments on the Feasibility Study (Ecology, 1995),

- *"[T]he FS's substantial and disproportionate analysis relies inappropriately on a statement in the Sediment Cleanup Standards Users Manual SCSUM that cost differences become significant in sediment cleanups when, for large cleanups, '... the cost of cleanup to the SQS_O is more than 1.1 times the cost of cleanup to the $MCUL_{10}$' (See SCSUM, p. 8-15, ¶3)."*

- *"Some points regarding the inappropriateness of using the SCSUM are as follows:*

  - *"The fundamental use of the guidance is to select a cleanup level for marine sediments between SQS_O (57 ppm for As) and $MCUL_{10}$ (93 ppm for As); there are not equivalent limits in MTCA, and in particular there is no equivalent upper limit.*

  - *"The guidance manual is discussing cleanup to protect benthic fauna, not humans. The Sediment Management Standards state in WAC 173-204-520(4), 'Puget Sound marine sediment cleanup screening levels and minimum cleanup levels human health criteria. Reserved: The department may determine on a case-by-case basis the criteria, methods, and procedures to meet the intent of this chapter.'*

  - *"The guidance manual is for sediments, not residential soil; sediments involve only a few cleanup options. The guidance is not meant to be applied to a comprehensive remedial action under MTCA, but rather only for sediment undergoing cleanup pursuant to WAC 173-340-760."*

GQ 2.1.5
Has Ecology appropriately characterized the mediation process?

(56)

Response:
The purpose of the DCAP/DEIS was to summarize data collected to characterize the nature and extent of contamination at the site and to select a remedy from among those presented in the Feasibility Study. The primary purpose of discussing the mediation process was to identify and explain the context of the source of additional analyses of data pertaining to the nature and extent of contamination and evaluation of alternatives. Presentation of detailed technical arguments which pertain to regulatory development rather than selection of cleanup actions under current regulations and of detailed legal arguments which were presented during mediation is well beyond the scope of the DCAP/DEIS, the FCAP/FEIS, and this Responsiveness Summary.

GQ 2.1.6
Has Ecology accurately stated the goals identified by the Land Use Task Committee for redevelopment of the Former Arsenic Trioxide Processing Area?

(341)

Response:
As noted by the commentor, the DCAP/DEIS did misquote one of the five goals identified by the Land Use Task Committee for redevelopment of the Former Arsenic Trioxide

Processing Area. The statement in the FCAP/FEIS has been revised to provide the following: "The City of Everett is not interested in maintaining a park on this site."

Chapter B3 Regulatory Requirements

B3.1 MTCA Requirements

GQ 3.1.1
Has Ecology correctly interpreted and applied Chapter 173-340 WAC, the MTCA Cleanup Regulation, in specifying the cleanup levels and selecting the cleanup actions for the Upland Area of the Everett Smelter Site?

(440, 441, 443)

Response:
Ecology's interpretation and application of the MTCA Cleanup Regulation in the specification of cleanup levels and selection of cleanup actions for the Upland Area of the Everett Smelter Site was set forth throughout the DCAP/DEIS. Chapter 3 discussed the provisions considered in the specification of cleanup levels and the selection of cleanup actions. Chapter 4 discussed the application of those provisions in the specification of cleanup levels. Chapters 5 and 6 discussed the application of those provisions in the selection and development of cleanup actions.

Based on a differing interpretation of the MTCA Cleanup Regulation, one commentor expressed concern regarding whether Ecology appropriately applied the provisions of the regulation in the specification of cleanup levels and selection of cleanup actions. Ecology has reviewed the comments and determined that it has properly interpreted and appropriately applied the requirements set forth in the MTCA Cleanup Regulation.

In particular, Ecology disagrees with the conclusion made by the commentor that the MTCA Cleanup Regulation provides sufficient flexibility either to specify a soil arsenic cleanup level other than 20 mg/Kg for residential land use or to select a cleanup action for the Peripheral Area that does not include treatment, removal, and/or containment of soil with arsenic concentrations greater than that cleanup level. With respect to both the establishment of cleanup standards and the selection of cleanup actions, the MTCA Cleanup Regulation provides that "[it] is intended to constrain the range of decisions needed to be made on individual sites to promote expeditious cleanups." WAC 173-340-700(7)(b). With respect to the selection of cleanup actions in particular, the regulation further provides that "[a] remedy that leaves hazardous substances on a site in excess of cleanup levels may qualify as a cleanup action [only if] the remedy is protective of human health and the environment [and] meets cleanup levels at specified points of compliance…." WAC 173-340-700(7)(i). The specification of a soil arsenic cleanup level for residential land use is discussed under ***GQ 4.2.1****. The selection of cleanup actions for the Peripheral Area is discussed under* ***GQ 5.2.2.***

Ecology also disagrees with the commentor that Ecology has failed to utilize the flexibility afforded by the MTCA Cleanup Regulation in the selection of the cleanup actions for the Upland Area of the Everett Smelter Site. Throughout the process of *selecting and developing cleanup actions, Ecology utilized flexibility where afforded by the regulation and where appropriate for the site. Examples include the following:*

- *selecting the Consolidation Facility alternative instead of the Off-Site Disposal alternative for the Former Arsenic Trioxide Processing Area, resulting in the construction of a problem waste landfill within, and immediately adjacent to, an urban residential area on a portion of the site most amenable to complete cleanup to a depth of 15 feet;*

- *selecting a combined soil removal and containment remedy instead of a complete soil removal remedy for the Peripheral Area and limiting the required containment barrier to only one-foot in thickness, allowing for the continued presence of contaminated soils beneath the one-foot barrier when the point of compliance is throughout the site to a depth of 15 feet; and*

- *allowing the use of alternate statistical methods for performance monitoring in the Peripheral Area.*

GQ 3.1.2
Has Ecology conducted a periodic review of the cleanup standards pursuant to WAC 173-340-702(3) and appropriately considered whether to update the cleanup standards?

(130)

Response:
Some cleanup standards, and the process for selecting some cleanup standards, have been the subject of much focus in recent years. Some of this review has been in response to the Policy Advisory Committee (PAC) recommendations (PAC, 1996) Ecology expects to propose an amendment to the MTCA Cleanup Regulation in November 1999. The proposal will embody some changes to some cleanup standards.

In addition, for both the lead and arsenic residential soil cleanup standards, Ecology has conducted recent reviews and made some changes. One such change with respect to arsenic was the 1996 revision to Ecology's CLARCII database to make the cancer potency factor correspond to EPA's 1995 changes (Ecology, 1996a). Also, Ecology's new science review of both standards is documented in Attachment B1 and, as described therein, resulted in a change to the soil lead cleanup standard.

B3.2 Applicable, Relevant and Appropriate, and Local Permitting Requirements

Minimum Functional Standards for Solid Waste Handling

GQ 3.2.1
What is the arsenic concentration at which soil is classified as a problem waste? What is the basis for determining the arsenic concentration at which soil is classified as a problem waste?

(133, 134)

Response:
Classification of soil located in the Upland Area of the Everett Smelter Site as various types of solid waste was discussed in Section 3.2 of the DCAP/DEIS. As noted in that discussion, since arsenic is the chemical upon whose concentration cleanup decisions primarily will be based, the classification of soil is also primarily based on the arsenic concentration. Pursuant to Chapter 173-304 WAC, "problem wastes" include "soils removed during the cleanup of a remedial action site…and which contain harmful substances but are not designated dangerous wastes." WAC 173-304-100(61). In accordance with that definition, Ecology determined that "[s]oils containing arsenic concentrations between the cleanup level for soil (20 mg/Kg), and the dangerous waste concentration (3,000 mg/Kg), are problem waste if removed during the cleanup."

One commentor asserted that soils containing arsenic concentrations above the cleanup level of 20 mg/Kg should not necessarily be considered "hazardous substances" and therefore problem wastes. Ecology disagrees. The soil arsenic cleanup level represents the point at which soils containing arsenic become "harmful substances."

GQ 3.2.2
Should certain provisions of the Minimum Functional Standards for Solid Waste Handling (Chapter 173-304 WAC) be relevant and appropriate requirements applicable to the Upland Area of the Everett Smelter Site?

(135, 436, 437, 439, 445)

Response:
Ecology's consideration of whether selected requirements from the Minimum Functional Standards for Solid Waste Handling, Chapter 173-304 WAC, may be applicable or relevant and appropriate to soil and other material in the Upland Area of the Everett Smelter Site was presented in Section 3.3.1 of the DCAP/DEIS. Ecology determined that certain requirements applicable to the design of a solid waste landfill, WAC 173-304-460, are relevant and appropriate to the construction and closure of a solid waste landfill for problem waste in the Upland Area of the Everett Smelter Site. One

commentor asserted that those requirements are neither applicable nor relevant and appropriate to such a solid waste landfill. More specifically, the commentor asserted that to be relevant and appropriate, a regulatory requirement must also be legally applicable. Ecology disagrees.

The MTCA Cleanup Regulation, Chapter 173-340 WAC, requires that all cleanup actions comply with applicable state and federal laws, and specifically emphasizes that "the term 'applicable state and federal laws' ***shall include*** *legally applicable requirements* ***and*** *those requirements that the department determines…are relevant and appropriate requirements." WAC 173-340-710(1)(a) (emphasis added). The MTCA Cleanup Regulation further specifies that "[r]elevant 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." WAC 173-340-710(3) (emphasis added). Hence, contrary to the assertion by the commentor, a regulatory provision may be relevant and appropriate even if it is not otherwise legally applicable.*

Even though the provisions of WAC 173-304-460 are not legally applicable to the construction and closure of a solid waste landfill containing problem wastes, Ecology determined that certain of those provisions are nonetheless relevant and appropriate. WAC 173-340-710(3) sets forth the criteria that Ecology must consider when determining whether certain requirements are relevant and appropriate for a cleanup. The following discussion provides an evaluation of those criteria.

(a) Whether the purpose for which the statute or regulation under which the requirement was created is similar to the purpose of the cleanup action.

Construction of a Consolidation Facility for problem waste in the Upland Area of the Everett Smelter Site is similar to the purpose for which Chapter 173-304 WAC was adopted – to set minimum functional performance standards for the proper handling of all solid waste material originating from residences, commercial, agricultural, and industrial operations and other sources. WAC 173-304-010(1).

(b) Whether the media regulated or affected by the requirement is similar to the media contaminated or affected at the site.

The media being addressed in the Upland Area of the Everett Smelter Site is a problem waste as defined at WAC 173-304-100; hence, it is one of the media regulated by Chapter 173-304 WAC.

(c) Whether the hazardous substance regulated by the requirement is similar to the hazardous substance found at the site.

The hazardous substance being addressed in the Upland Area of the Everett Smelter Site is exactly the type of problem waste included in the definition of problem waste at WAC 173-304-100(58): an arsenic-contaminated soil being removed during the cleanup of a remedial action site. While it is true the section governing problem waste landfills in the regulation, WAC 173-304-463, is reserved, the fact that problem waste was defined in the regulation as including, "soils removed during the cleanup of a remedial action site…," and the reservation of a section for regulation of such waste indicates that the requirements of Chapter 173-304 WAC are intended to "address problems or situations sufficiently similar to those encountered at the site that their use is well suited to the particular site." WAC 173-340-710(3). Hence the requirements of Chapter 173-304 WAC must be reviewed and those which are relevant and appropriate identified and applied to 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.

The entities and interests protected in the Upland Area of the Everett Smelter Site by the selected provisions of Chapter 173-304 WAC are those entities and interests intended to be protected by those provisions: people living in residences surrounding the problem waste landfill and ground water and surface water in the vicinity of the landfill. That is, as stated in WAC 173-304-010, Authority and Purpose, "This regulation is promulgated to protect public health, to prevent land, air, and water pollution…." The provisions of Chapter 173-304 WAC selected as relevant and appropriate are required to be followed specifically to protect public health and to prevent land, air, and water pollution by the problem waste which will remain in the Everett neighborhood in a Consolidation Facility.

(e) Whether the actions or activities regulated by the requirement are similar to the cleanup action contemplated at the site.

Construction of a Consolidation Facility for problem waste in the Upland Area of the Everett Smelter Site is one of the actions regulated by Chapter 173-304 WAC – landfilling.

(f) Whether any variance, waiver, or exemptions to the requirements are available for the circumstances of the site.

No variances, waivers, or exemptions are available for the relevant and appropriate provision of Chapter 173-304 WAC for construction of a problem waste landfill in a residential neighborhood. WAC 173-304-700 *discusses variances for solid waste facilities. To obtain such a variance, jurisdictional health department approval is required, and only after notice of a public hearing if requested. A variance may only be granted if the solid waste handling practices or location do not endanger public health, safety, or the environment and compliance with the regulation would produce hardship without equal or greater benefits to the public. Ecology has consulted with the Snohomish County Health District about solid waste handling practices necessary to protect public health, safety, and the environment in identifying the provisions of Chapter 173-304 WAC which are relevant and appropriate to construction of a Consolidation Facility in the Upland Area of the Everett Smelter Site. The Consolidation Facility has been selected as part of the remedy at the site specifically to alleviate the expense of complete removal of all contaminated soil exceeding cleanup levels and hence alleviate an alleged hardship. Failure to properly construct the facility would imperil public health, safety, and the environment; compliance with the relevant and appropriate provisions of Chapter 173-304 WAC will produce benefits to the public which would not accrue if a variance to proper construction design was granted.*

(g) Whether the type of place regulated is similar to the site.

The type of place which will be created by construction of a Consolidation Facility within the Peripheral Area – a landfill site – is exactly the type of place regulated by Chapter 173-304 WAC.

(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.

The type of structure proposed for the Upland Area of the Everett Smelter site – a landfill – is the type of structure regulated by Chapter 173-304 WAC.

(i) Whether any consideration or use or potential use of affected resources in the requirement is similar to the use or potential use of resources affected by the site or contemplated cleanup action.

Construction of a Consolidation Facility will use land resources within residential neighborhoods of the City of Everett. This use of land resources is the type of resource which Chapter 173-304 WAC is intended to regulate. The selected relevant and appropriate provisions for the site are intended to regulate the manner in which the land resources are used. In addition, the provisions will protect air and water resources.

In conclusion, based on the analyses discussed above, Ecology identified those provisions of Chapter 173-304 WAC that were relevant and appropriate to the construction of a Consolidation Facility for problem waste in the Upland Area of the Everett Smelter Site.

Dangerous Waste Regulations

GQ 3.2.3

What is the arsenic concentration at which soil is classified as a dangerous waste? What is the basis for determining the arsenic concentration at which soil is classified as a dangerous waste? Is this dangerous waste concentration subject to modification based on further testing? Is the Compliance Monitoring Plan for identifying the occurrence of dangerous waste appropriate?

(24, 42, 120, 132, 151, 166, 372, 373)

Response:
Classification of soil located in the Upland Area of the Everett Smelter Site as various types of solid waste was discussed in Section 3.2 of the DCAP/DEIS. As noted in that discussion, since arsenic is the chemical upon whose concentration cleanup decisions primarily will be based, the classification of soil is also based primarily on the arsenic concentration. Ecology determined pursuant to Chapter 173-303 WAC (Dangerous Waste Regulations) that soils containing arsenic concentrations greater than 3,000 mg/Kg are dangerous wastes. The 3,000 mg/Kg soil arsenic concentration is an estimate of the upper 95% confidence limit on the mean concentration at which soil fails the Toxicity Characteristic Leaching Procedure (TCLP) test[2]*. (See also the discussion in Asarco, 1998, Section 7.2.)*

A 95% upper confidence limit is also being used in the compliance monitoring to ensure that, on average, soil with arsenic concentrations exceeding 3,000 mg/Kg is removed from the site. This applies only once to the concern that high concentration material is removed from the site for the protection of human health. Moreover, the distribution of high concentration material is expected to be sharply defined, as contrasted to the gradational nature of contamination in the Peripheral Area. In effect, using a stringent standard ensures that almost all of the most contaminated material will be removed while not causing significant removal of lesser-contaminated material. This is because results of investigations within the Former Arsenic Trioxide Processing Area indicate high-level contamination is sharply bounded, and once it is excavated, the surrounding material will have significantly lower arsenic concentrations and excavation of such material is very unlikely to be triggered by the performance monitoring scheme.

As noted in DCAP/DEIS Section 6.3, "Flue dust, arsenic trioxide, and any other material with arsenic concentrations exceeding 3,000 mg/Kg shall be excavated and sent to an off-

[2] The TCLP test is one regulatory test for determining whether material classifies as a dangerous waste. WAC 173-303-090(8).

site facility permitted to accept such waste." Hence, even if a particular batch of soil with an arsenic concentration exceeding 3,000 mg/Kg arsenic does not fail the TCLP test during compliance monitoring, it is still required to be excavated and sent off site. This requirement addresses the threshold requirement to be protective of human health and the environment and the other requirements to consider community concerns while balancing those concerns with cost effectiveness.

A batch of excavated soil with an arsenic concentration exceeding 3,000 mg/Kg arsenic which passes the TCLP test upon further testing performed during cleanup of the Former Arsenic Trioxide Processing Area, and hence does not classify as dangerous waste, would not necessarily have to be handled as dangerous waste and sent to a dangerous waste landfill if a facility permitted to accept problem waste would accept the material. Concurrence of the jurisdictional local health district may be required in such a case.

GQ 3.2.4
Should certain provisions of the Dangerous Waste Regulations (Chapter 173-303 WAC) be relevant and appropriate requirements applicable to the Upland Area of the Everett Smelter Site?

(136, 137, 151, 436, 438, 439, 446)

Response:
Ecology's consideration of whether selected requirements from the Dangerous Waste Regulations, Chapter 173-303 WAC, may be applicable or relevant and appropriate to soil and other material in the Upland Area of the Everett Smelter Site was presented in Section 3.3.2 and Section 5.4 of the DCAP/DEIS. Specifically, because one of the alternative cleanup actions considered would have contained soils and other materials designating as dangerous waste in an On-Site Containment Facility in the Former Arsenic Trioxide Processing Area, Ecology reviewed the Dangerous Waste Regulations to determine construction and closure requirements for such a containment facility. Ecology determined that while the Dangerous Waste Regulations were not automatically triggered, they were relevant and appropriate to the construction and closure of such a facility. One commentor asserted that those requirements are neither applicable nor relevant and appropriate to such a facility. More specifically, the commentor argued that to be relevant and appropriate, a regulatory requirement must also be legally applicable. Ecology disagrees.

*The MTCA Cleanup Regulation, Chapter 173-340 WAC, requires that all cleanup actions comply with applicable state and federal laws, and specifically emphasizes that "the term 'applicable state and federal laws' **shall include** legally applicable requirements **and** those requirements that the department determines…are relevant and appropriate requirements." WAC 173-340-710(1)(a) (emphasis added). The MTCA Cleanup Regulation further specifies that "[r]elevant 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." WAC 173-340-710(3) (emphasis added). Hence, contrary to the assertion by the commentor, a regulatory provision may be relevant and appropriate even if it is not otherwise legally applicable.*

Furthermore, Ecology's authority to determine that any substantive requirement of the Dangerous Waste Regulations is relevant and appropriate is not limited by the conditional exemption of RCW 70.105.035 because the waste proposed for disposal in the On-Site Containment Facility designates as hazardous waste under federal law. Even if the waste did not designate as hazardous waste, the exemption would not apply because the conditions of the exemption could not be met. In particular, the conditional exemption applies only to waste generated pursuant to a consent decree. Moreover, even if the exemption would otherwise apply, any "waste treated or disposed of on-site [would have to] be managed in manner determined by [Ecology] to be as protective of human health and the environment as clean-up standards pursuant to [MTCA]." RCW 70.105.035(4).

Finally, Ecology's Area of Contamination (AOC) Policy expressly provides for the retention by Ecology of the ability to determine that any substantive requirement of the Dangerous Waste Regulations is a relevant and appropriate requirement. Specifically, the AOC Policy states that,

> *[i]n any situation where the AOC approach is used, the department may determine portions of the Dangerous Waste Regulations to be relevant and appropriate using criteria established in WAC 173-340-710. If such a determination is made, the substantive portions of these relevant and appropriate requirements must be implemented.*

The AOC Policy identifies those situations in which excavation and movement of contaminated materials at sites being remediated under MTCA or CERCLA, through an order or decree, would not be considered generation or disposal of hazardous waste. Even if movement of contaminated materials is not considered generation or disposal of hazardous waste triggering the requirements of the Dangerous Waste Regulation, the AOC Policy recognizes that there are several substantive requirements of the Dangerous Waste Regulation which should be considered at almost every cleanup site. These include, among others, waste designation and landfill requirements for final disposal of wastes on site.

Consequently, even though the dangerous waste siting criteria set forth in WAC 173-303-282 may not constitute legally applicable requirements,[3] *Ecology is not precluded from determining that they are nonetheless relevant and appropriate. WAC 173-340-710(3) sets forth the criteria that Ecology must consider when determining whether certain requirements are relevant and appropriate for a cleanup. Ecology's evaluation of those criteria was presented in Section 5.4 of the DCAP/DEIS.*

[3] WAC 173-303-282(2)(b) provides that "[t]his section does not apply to…[p]ersons at facilities conducting on-site cleanup of sites under…[MTCA], provided the cleanup activities are being conducted under a consent decree, agreed order or enforcement order, or is being conducted by the department."

Chapter B4 Establishment of Cleanup Standards

B4.1 New Science

GQ 4.1.1
Should Ecology establish soil cleanup standards for arsenic and lead different than those determined under either Method A or Method B?

(43, 44, 45, 59, 69, 89, 104, 112, 130, 138, 139, 149, 154, 155, 158, 161, 171, 172, 244, 246, 247, 252, 325, 327, 383, 395, 398, 406, 407, 408, 409, 410, 411, 412, 413, 415, 416, 425, 426, 443, 444, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 477, 481, 482, 483, 484, 485, 486, 487, 488)

Response:
*In July 1998, prior to the development of the DCAP/DEIS, Asarco submitted materials to Ecology requesting review under WAC 173-340-702(6) as new scientific information relevant to the establishment of cleanup levels for the Upland Area of the Everett Smelter Site. Asarco requested that, based on those materials, Ecology establish soil cleanup levels for arsenic and lead in the Upland Area different from those specified under Method A or B. Ecology, in collaboration with the Washington State Department of Health, reviewed and analyzed the information submitted by Asarco. Ecology's evaluation of Asarco's submittal was documented in two memoranda, "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999a – See Attachment B1-1) and "Decision Memorandum, Arsenic Concentrations at Depth and Considerations of Acute Toxicity" (Ecology, 1999b – See Attachment B1-2). Both documents were listed as supporting documents in DCAP/DEIS Section 1.4 and further discussed in DCAP/DEIS Sections 4.1 and 6.2. Based on a reasoned review of the information submitted (Ecology, 1999a), Ecology announced its preliminary decision that a **change in the soil arsenic cleanup level of 20 mg/Kg was not warranted**. The review did indicate, though, that setting lead cleanup levels for residential sites could be based on the Integrated Exposure Uptake Biokinetic (IEUBK) model, developed by the EPA. As discussed in Section 4.1 of the DCAP/DEIS, Ecology announced its preliminary decision to apply that model and allow for an **increase in the soil lead cleanup level from 250 mg/Kg to 353 mg/Kg**.*

In February 1999 Asarco submitted comments on the DCAP/DEIS. Included with that submittal were comments on Ecology's evaluation of Asarco's July 1998 "new science" submittal, Ecology's preliminary decision regarding soil cleanup levels for lead and arsenic, and some additional materials for Ecology's consideration. Asarco requested that, based on those submitted materials, Ecology establish soil cleanup levels for arsenic and lead different from those proposed in Section 4.1 of the DCAP/DEIS. Ecology, again in collaboration with the Washington State Department of Health, conducted a thorough and reasoned review of all the information presented by Asarco, *including both the July 1998 and February 1999 submittals. Based upon that review, Ecology has determined that Asarco did not submit clear and convincing scientific data regarding either toxicity or exposure parameters to warrant the establishment of a soil cleanup level for either arsenic or lead for the Upland Area of the Everett Smelter Site, different from those specified in Section 4.1 of the DCAP/DEIS.* ***Accordingly, neither the soil arsenic cleanup level of 20 mg/Kg nor the soil lead cleanup level of 353 mg/Kg specified in the DCAP/DEIS have changed.***

The comments and information submitted by Asarco and its consultants regarding arsenic can be divided into three general categories:

1. *Opinions on policies contained in the MTCA Cleanup Regulation such as the allowable risk levels;*
2. *Information concerning various aspects of arsenic toxicity; and*
3. *Information concerning human exposure to contaminated soil.*

MTCA Policy Choices: *The selection of an allowable risk level is policy decision – a risk-management decision. The risk-management decision for Washington State is set forth in the MTCA Cleanup Regulation, which prescribes a maximum allowable cancer risk of one in one million(1 x 10^{-6}) for a single chemical and a total maximum site cancer risk of one in one hundred thousand (1 x 10^{-5}). That risk-management decision was made after extensive public review and comment. The legislatively mandated MTCA Policy Advisory Committee (PAC), which was assigned the responsibility of reviewing and recommending changes to MTCA, did not recommend the risk levels set forth in the current MTCA Cleanup Regulation be changed (PAC, 1996). In contrast with federal law, which provides a range of allowable risk levels in the establishment of site-specific cleanup levels, the MTCA Cleanup Regulation provides no such flexibility. This risk-management decision has a significant impact on the establishment of any cleanup level for any site.*

Asarco proposed alternative approaches to selecting soil cleanup levels, including: changing the acceptable risk level; back-calculating from urinary arsenic levels; comparing soil exposures to dietary exposures; and using precedents for action levels from Superfund sites. However, such other methods cannot be used for the Everett Smelter Site under the MTCA Cleanup Regulation. Even if such dramatically different approaches to selecting cleanup levels were available under MTCA, Asarco has failed to demonstrate that they would fulfill the requirements of the regulation for protection of human health (specifically, providing for a cleanup that will reliably result in a cancer risk of one in one million or less, and no non-cancer health effects).

Toxicity: *With respect to toxicity parameters, Ecology has determined that Asarco did not submit clear and convincing information to warrant the establishment of a soil cleanup level for either arsenic or lead different from those specified in Section 4.1 of the DCAP/DEIS. There are divergent opinions regarding various issues pertaining to the* *science surrounding arsenic toxicity, including exactly how arsenic causes cancer and whether there is a threshold dose below which arsenic does not cause cancer.*

An evaluation of arsenic-induced adverse effects and arsenic exposures was recently performed by the National Research Council (National Research Council, 1999). This evaluation was performed at the request of the EPA to evaluate available scientific information on arsenic toxicity, with particular regard to arsenic in drinking water. The evaluation was performed by a subcommittee chosen for their special competencies and with regard for appropriate balance. The NRC evaluations, recommendations, and conclusions are compatible with and support Ecology's decisions regarding the cleanup for the Upland Area of the Everett Smelter Site. (See Attachment B1 for additional discussion of the National Research Council's evaluation of arsenic toxicity.)

Ecology requested that the Washington State Department of Health (DOH) assess potential hazards of acute exposure to arsenic contaminated soil found in many areas of the state. In January 1999, the DOH published "Hazards of Short-Term Exposure to Arsenic Contaminated Soil" (DOH, 1999, See Attachment B1-3). Ecology wanted to know what concentrations of arsenic in soil could cause adverse health effects in people and what concentrations are unlikely to be harmful. The DOH information was used by Ecology in establishing soil arsenic remediation levels for the Upland Area of the Everett Smelter site. (See ***GQ 5.2.2*** *for further discussion regarding the selection of remediation levels.)*

Exposure: *With respect to exposure parameters, Ecology has determined that Asarco did not submit clear and convincing information to warrant the establishment of a soil cleanup level for either arsenic or lead different from those specified in Section 4.1.2 of the FCAP/FEIS. Scientific studies describe and estimate exposure parameters such as, for example, how frequently children are exposed to arsenic, the amounts of soil children ingest during such exposures, and even who is the susceptible individual and/or susceptible population to protect. Policy choices must then be made regarding the use of the ranges of exposure parameters identified by scientific studies to develop cleanup levels which are considered protective. Although Asarco made general comments regarding exposure parameters, Asarco's comments neither made specific proposals for changes in any of the parameters nor provided any site-specific data to consider regarding those parameters. In the absence of such proposals and site-specific data, Ecology reviewed available information and performed sensitivity analyses. From this work, Ecology concluded that the combined effects of changing several exposure parameters (seasonal changes in soil contact, different arsenic concentrations in house dust and outside soils, and relative arsenic bioavailability from soils and house dusts) are unlikely to change the selected 20 mg/Kg cleanup level for soils in the Upland Area of the Everett Smelter Site.*

Please refer to Attachment B1 of this Responsiveness Summary, entitled "New Science Review," for specific responses to and technical analyses of the issues raised and materials presented by Asarco.

B4.2 Soil Cleanup Standards

GQ 4.2.1
Does the MTCA Cleanup Regulation allow for the establishment of soil cleanup levels for residential areas, as well as for childcare facilities and schools, in accordance with Method C cleanup levels?

(130, 149, 172, 243, 248, 249, 250, 251, 327, 407, 440, 441, 443, 476, 477, 478, 479)

Response:
The specification of soil cleanup levels for residential areas, as well as for childcare facilities and schools, was discussed in Section 4.1.2 of the DCAP/DEIS. In accordance with the MTCA Cleanup Regulation, Ecology specified soil cleanup levels for such areas in accordance with Method B as opposed to Method C.

*Pursuant to the MTCA Cleanup Regulation, Method C cleanup levels do not provide sufficient protection of human health and the environment for certain site uses. The regulation specifically provides that "Method C cleanup levels represent concentrations which are protective of human health and the environment **for specified site uses**." WAC 173-340-706(1) (emphasis added). Compare with WAC 173-340-705(1), which provides that "Method B is applicable to all sites."*

*More specifically, pursuant to the MTCA Cleanup Regulation, Method C cleanup levels do not provide sufficient protection of human health and the environment for either residential areas or for childcare facilities and schools. For residential areas, the regulation provides that "soil cleanup levels…**shall** be established in accordance with **method A or method B** cleanup levels." WAC 173-340-740(1)(a) (emphasis added). For childcare facilities and schools, the regulation similarly provides that "[s]oil cleanup levels…**shall** be established in accordance with **method A or method B** cleanup levels." WAC 173-340-740(1)(d)(i) (emphasis added). Compare with WAC 173-340-740(1)(c-d), which describes the process and criteria for establishing soil cleanup levels for certain non-residential areas other than in accordance with Method A or Method B cleanup levels.*

Hence, the MTCA Cleanup Regulation does not allow for the establishment of soil cleanup levels either for residential areas or for childcare facilities and schools in accordance with Method C cleanup levels.

GQ 4.2.2
Should Ecology establish soil cleanup levels for commercial areas in accordance with residential land use?

(40, 111, 141, 142, 376, 414)

Response:
The selection of soil cleanup levels for commercial areas was discussed in Section 4.1.2 of the DCAP/DEIS. Pursuant to the MTCA Cleanup Regulation, Ecology determined that soil cleanup levels for commercial areas should be established in accordance with residential land use and, consequently, in accordance with Method B.

*For commercial land uses, the MTCA Cleanup Regulation specifically provides that "soil cleanup levels **shall** be established in accordance with residential areas unless it can be clearly demonstrated that this is inappropriate." WAC 173-340-740(1)(c). To demonstrate that this is inappropriate, it must be clearly demonstrated that:*

> *(A) [t]he property is currently zoned for or otherwise officially designated for industrial/commercial use;*
> *(B) [t]he property is currently used for industrial/commercial purposes or has a history of use for industrial/commercial purposes;*
> *(C) [the] properties adjacent to and in the general vicinity of the property are used or are designated for use for industrial/commercial purposes; **and***
> *(D) [t]he property and properties adjacent to and in the general vicinity are expected to be used for industrial/commercial purposes for the foreseeable future due to site zoning, statutory or regulatory restrictions, comprehensive plans, adjacent land use, and other relevant factors."*

WAC 173-340-740(1)(c)(i) (emphasis added). No such demonstration was made or even attempted in either the Feasibility Study (Hydrometrics, 1995b) or the Technical Work Group documents (TWG, 1998a and 1998b).

Selection of soil cleanup levels for commercial areas in accordance with residential land use recognizes that the commercial land uses in the Upland Area of the Everett Smelter Site are adjacent to and in the general vicinity of residential land uses, not industrial or commercial uses. As emphasized in the MTCA Cleanup Regulation, "[Ecology] expects that only industrial/commercial properties located in the interior portion of a large industrial/commercial area will qualify for other than method A or method B cleanup levels…." WAC 173-340-740(c)(v). Rather than being located in the interior of a large commercial/industrial area, the Community Business Zone along Broadway is situated immediately adjacent to residential areas.

Selection of soil cleanup levels for commercial areas in accordance with residential land use also recognizes the undesirability of restricting future land use. This concern was specifically addressed in the development of the MTCA Cleanup Regulation. Responding to concerns by citizens regarding "the potential for uncontrolled land use changes and the creation of 'sacrifice zones,'" Ecology revised the proposed rule to limit the application of WAC 173-340-745 to industrial sites (See Ecology, 1991, pp. 228-230). "Commercial sites, which are frequently located in or immediately adjacent to residential areas," Ecology noted, "will be considered potential future residential sites" (Ecology, 1991, p. 230).

GQ 4.2.3
Should Ecology establish soil cleanup levels for recreational areas in accordance with residential land use?

(29, 40, 111, 142, 376, 414)

Response:
The selection of soil cleanup levels for recreational areas was discussed in Section 4.1.2 of the DCAP/DEIS. Pursuant to the MTCA Cleanup Regulation, Ecology determined that soil cleanup levels for recreational areas should be established in accordance with residential land use and, consequently, in accordance with Method B.

For recreational areas, the MTCA Cleanup Regulation provides that "soil cleanup levels ***shall*** *be established on a case-by-case basis." WAC 173-340-740(1)(d)(ii) (emphasis added). Ecology's selection of soil cleanup levels for recreational areas in accordance with residential land use recognizes that these areas are adjacent to or within the general vicinity of residential areas. Selection of the specified soil cleanup levels also recognizes the undesirability of restricting future land use.*

As with commercial areas, neither the Feasibility Study (Hydrometrics, 1995b) nor the Technical Work Group documents (TWG, 1998a and 1998b) presented any evaluations that soil cleanup levels for recreational areas within the Upland Area of the Everett Smelter Site should be set at other than Method A or Method B cleanup levels.

GQ 4.2.4
Is the selection of the soil arsenic cleanup level of 20 mg/Kg consistent with Ecology's evaluation of risk from drinking water?

(140)

Response:
It should be recognized that arsenic is a ubiquitous element in the environment and that there are concurrent exposures from a number of sources. The Model Toxics Control Act is intended to address, among other things, ***excess*** *cancer risk from releases of hazardous substances into the environment due to human activities. The comment notes that people ingest arsenic from drinking water. The fact that people ingest arsenic from drinking water and sources other than soil is not a reason to accept additional ingestion of arsenic present in soil due to industrial contamination. The effects are additive.*

Drinking water is regulated by the DOH. The current drinking water standard of 50 mg/L is recognized by many as not low enough to sufficiently protect public health. It should be noted that the 50 mg/L concentration was adopted in 1943, and was not based on cancer risk. Ecology does not accept the commentor's contention that the amount of *arsenic that could be ingested at the 50 mg/L concentration is necessarily acceptable from a public health perspective.*

Ecology notes that the current Maximum Contaminant Level for arsenic in drinking water of 50 mg/L was set by the United States Public Health Service in 1943 based on short-term exposure effects. A recent National Research Council report indicated, "The current EPA MCL for arsenic in drinking water of 50 mg/L does not achieve EPA's goal for public-health protection and, therefore, requires downward revision as promptly as possible" (National Research Council, 1999, p. 7). Ecology understands EPA will make recommendations for this revision by January 2000.

GQ 4.2.5
Is the arsenic cleanup level of 20 mg/Kg for residential soils in the Upland Area of the Everett Smelter Site consistent with cleanup levels chosen at other sites? Are the soil removal and containment levels selected for the Upland Area of the Everett Smelter Site consistent with action levels used at other sites?

(39, 49, 244, 325, 405, 415)

Response:
Several comments sought information regarding how cleanup levels and soil removal action levels proposed for the Upland Area of the Everett Smelter Site compare to levels used at other sites, particularly to the cleanup levels and soil removal action levels being used at the Commencement Bay Nearshore/Tideflats Operable Unit 04, Ruston/North Tacoma Study Area, Ruston and North Tacoma, Washington. This site is commonly referred to as Ruston.

At the outset of this discussion it is important to note that review of cleanup levels and cleanup actions selected at other sites is not required by or part of the MTCA remedy selection process. This is not to say, however, that Ecology does not strive to implement MTCA in a consistent fashion at similar sites. Indeed, because the selection of cleanup levels and cleanup actions for all sites cleaned up under MTCA is guided by the applicable MTCA regulations, application of those regulations to cleanup decisions made at similar sites is expected to yield consistent decisions. Consistent, of course, does not mean identical. Remedy selection decisions are made in part by reference to site-specific factors. Therefore, while Ecology expects application of the MTCA regulations to facilitate consistent decision-making at similar sites, Ecology does not expect application of its regulations to produce identical decisions as no two sites are identical.

It is also important to note that where decisions at cleanup sites (similar or not similar sites) were made under a different regulatory framework (e.g., the federal cleanup law and regulations or another state's cleanup law or regulations), a comparison of such decisions with decisions proposed or made under MTCA may be of little or no value in light of the different decision-making requirements and/or decision-making criteria. Nevertheless, because inquiries were made regarding how Ecology's proposed decisions *for the Upland Area of the Everett Smelter Site compare with cleanup decisions made elsewhere, Ecology will describe herein its review of past cleanup decisions for sites nationwide and in Washington State.*

Ecology reviewed approximately 60 sites nationwide (Ecology, 1996b) and found that arsenic concentrations at which soil excavation or other active measures were required ranged from 0.0004 to 250 mg/Kg, with a median of 20 mg/Kg, which is Ecology's Method A cleanup level and is also the value required to be achieved in the top 12" of residential soils to accomplish final cleanup in the Upland Area of the Everett Smelter Site.

Many of the reviewed sites were federal Superfund sites.[4] *The federal Superfund program allows a cancer-risk range of one in one million (*1×10^{-6}*) to one in ten thousand (*1×10^{-4}*) (40 CFR Chapter 1 §300.430). However, EPA Region X allowed a cancer risk of one in two thousand (*5×10^{-4}*) at Ruston for residential cleanup (EPA, 1992, Section 7.3).*

In contrast, MTCA's maximum allowable cancer risk is one in one million (1×10^{-6}*) for a single chemical and a total maximum site cancer risk of one in one hundred thousand (*1×10^{-5}*). Many of the sites with arsenic contamination being addressed under federal law had arsenic soil removal action levels in the higher end of the federal range of allowable cancer risk, particularly mining and smelter sites being addressed by EPA Region VIII.* *Ecology understands this is not because federal and state scientists assess the carcinogenicity of arsenic differently, but rather because federal law makes a different risk management decision than state law – it allows the populace at such sites to face a greater cancer risk after final cleanup is accomplished than Washington State law allows. Other states also have lower allowable carcinogenic risk levels than federal law. For example, Florida and New Jersey have a maximum allowable cancer risk of one in one million and Massachusetts of one in one hundred thousand.*

Had decisions for sites remediated under federal law used a carcinogenic risk of one in one million (1×10^{-6}*), allowable arsenic concentrations requiring soil excavation would have ranged from about 0.5 to 3 mg/Kg. (Under MTCA, the cleanup level would have been raised to Ecology's estimate of an upper limit on natural soil arsenic background concentrations of 20 mg/Kg).*

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[4] Ecology notes that one of the most recent federal Superfund sites involving soil arsenic contamination is Barber's Orchard, North Carolina. This 500-acre orchard is being converted to residential use and pesticide contamination has been found in the soil (as well as in the residential well water). Arsenic derived from lead arsenate pesticide is the contaminant driving the cleanup. At this site, EPA is conducting an emergency removal action (October 1999) for all soils in which the arsenic concentration exceeds 40 mg/Kg (approximately 24 houses on the approximately 100-acre portion of the orchard which has been developed to date). The removal action is being performed to address short-term health risks to residents. The cleanup goal is 20 mg/Kg, which EPA considers protective in the long term.

Ecology also reviewed sites in Washington State (B&L Woodwaste, PACCAR, Yakima Plating) addressed under Ecology oversight using the Model Toxics Control Act. In all cases, arsenic cleanup levels were set at 20 mg/Kg and remedial actions at least as protective as containment beneath a soil cover were required.

Some comments reveal confusion over the cleanup level and soil removal remediation level used for residential areas at Ruston. The cleanup level selected at Ruston is 20 mg/Kg. Above this arsenic concentration, some action is required. For soils containing arsenic concentrations between 20 mg/Kg and 230 mg/Kg, the required "action" is employment of institutional controls. For soils within 18" of the surface containing arsenic exceeding 230 mg/Kg, the required cleanup action is excavation and placement of clean soil over underlying contaminated soils.

In comparing the cleanup decisions made by EPA for Ruston with Ecology's proposed cleanup decisions for the Upland Area of the Everett Smelter Site, it is important to note that Ruston is an EPA lead site; that means the cleanup decision was made by the EPA under the federal cleanup law and federal cleanup regulations. EPA's final decision for the site is documented in EPA's Record of Decision[5]. The Everett Smelter Site, on the other hand, is a site over which Ecology has lead responsibility. All decisions made for the Everett Smelter Site are governed by MTCA and its implementing regulations. Questions have been raised regarding Ecology's concurrence with the EPA's decision-making process for Ruston (Ecology, 1993). Indeed, at least one comment contends that Ecology's decision to concur with EPA's decision for Ruston area amounts to a determination by Ecology that the cleanup actions selected by EPA for Ruston meet all MTCA requirements. At the outset of addressing this topic, it is important to note that Ecology's letter indicating the agency's concurrence with EPA's cleanup decision specifically indicated that the concurrence was based on factors specific to Ruston.

Prior to addressing the questions that have been raised regarding Ecology's concurrence with the Ruston Record of Decision (ROD) as it relates to Ecology's cleanup decisions for the Upland Area of the Everett Smelter Site, it is important to again reference some of the bases for Ecology's decisions at Everett. As noted in other responses herein, the rationale for Ecology's cleanup decisions for the Everett Smelter Site (including Ecology's identification of 20 mg/Kg as the residential soil cleanup level for arsenic and Ecology's specification of soil removal and containment levels at surface and at various depths) is fully explained in the Chapters 4, 5, and 6 of the DCAP/DEIS and of the FCAP/FEIS. Some of the key regulatory provisions cited by Ecology as part of the bases for making the cleanup decisions at Everett include ensuring that the cleanup meets threshold requirements specified in MTCA, WAC 173-340-360(2), including that the cleanup decision assures compliance with cleanup standards; that a cleanup of residential soils utilize removal and containment measures, WAC 173-340-740(1)(a); and that containment and institutional controls alone are not permanent solutions, WAC 173-340-360(5)(c).

[5] The EPA Record of Decision is the administrative equivalent of Ecology's Cleanup Action Plan.

Upon reviewing Ecology's concurrence with EPA's decision for Ruston, it does not appear that Ecology's concurrence letter addressed the MTCA requirements referenced by Ecology in its Cleanup Action Plan for the Upland Area of the Everett Smelter Site. The letter does not indicate how the cleanup actions selected by EPA for Ruston would meet the requirements of MTCA cited in the FCAP/FEIS for the Upland Area of the Everett Smelter Site, specifically those requirements referenced and applied by the agency in Chapters 4, 5, and 6 of the FCAP/FEIS. Thus, at the present time, it is Ecology's conclusion that Ecology's concurrence with the Ruston ROD does not represent a conclusion that the cleanup requirements specified by EPA for residential properties at the Ruston site meet the MTCA requirements discussed at length in the FCAP/FEIS for the Upland Area of the Everett Smelter Site.

B4.3 Ground Water Cleanup Standards

GQ 4.3.1
How should the ground water cleanup standards, including both cleanup levels and points of compliance, be established? Is the establishment of ground water cleanup standards for the Upland Area dependent on the characterization of ground water and surface water in the Lowland Area?

(143, 147)

Response:
The selection of ground water cleanup standards for the Upland Area of the Everett Smelter Site, which includes both the cleanup levels and the points of compliance, was discussed in Section 4.1.3 of the DCAP/DEIS.

Ground water cleanup levels were set in accordance with WAC 173-340-720. The MTCA Cleanup Regulation provides that "[g]round water cleanup levels shall be based on estimates of the highest beneficial use and the reasonable maximum exposure expected to occur under both current and potential future site use conditions." WAC 173-340-720(1)(a). The regulation further notes that for most sites, drinking water is the beneficial use requiring the highest quality of ground water, and that exposure to hazardous substances via ingestion of drinking water and other domestic uses represents the reasonable maximum exposure. Id. The regulation further provides that the cleanup of ground water is to be conducted consistent with this use ***unless*** *it can be demonstrated that (1) the ground water does not serve as a current source of drinking water and (2) the ground water is not a potential future source of drinking water. Id.*

Ecology determined that ground water serves neither as a current nor potential future source of drinking water. Ecology selected ground water cleanup levels for the Upland Area of the Everett Smelter Site based on protection of surface water and consideration of ground water natural background concentration. The relevant cleanup levels Ecology reviewed were presented in DCAP/DEIS Table 4-1. In reviewing surface water standards while considering the comments received on the DCAP/DEIS, Ecology determined that surface water cleanup levels should be changed to standards set for water flowing to the City of Everett's Treatment Plant or standards to protect freshwater wetlands in the Lowland Area of the Everett Smelter Site. These changes were made in FCAP/FEIS Section 4.1.4, which discusses surface water cleanup standards. FCAP/FEIS Section 4.1.3, which discusses ground water cleanup standards, was revised to reflect these changes. (Further discussion of the change to surface water cleanup standards is presented under ***GQ 4.4.1*** *of this Responsiveness Summary.)*

Utilizing the flexibility afforded by the MTCA Cleanup Regulation, WAC 173-340-720(6), Ecology also approved a conditional point of compliance at the receiving surface water body rather than throughout the site from the uppermost level of the saturated zone *extending vertically to the lowest most depth which could potentially be affected by the site.*

One commentor suggested that it is premature to establish ground water cleanup levels prior to the completion of the storm water and storm drain characterization program and the associated supplemental investigation of the Lowland Area. Ecology disagrees. Cleanup levels and points of compliance are not dependent on the characterization of ground water and surface water being performed in the Lowland Area investigation.

The commentor also noted that Ecology did not address large areas of ground water with arsenic concentrations above cleanup levels at the Weyerhaeuser Mill E/Koppers facility. Again, cleanup levels and points of compliance for the Upland Area are not dependent on the characterization of ground water and surface water being performed in the Lowland Area investigation. Regarding the Mill E/Koppers facility in particular, note that arsenic contamination at the site was addressed only within a contained area. Arsenic contamination outside of the contained area was specifically left outside the scope of the Mill E/Koppers facility consent decree. Ecology specifically reserved its right to require further cleanup of arsenic outside the containment area. Accordingly, the Mill E/Koppers facility has not undergone a complete final cleanup for arsenic at the site.

GQ 4.3.2
Has Ecology accounted for background concentrations of arsenic in area ground water in the selection of a ground water cleanup level?

(400)

Response:
The selection of ground water cleanup standards for the Upland Area of the Everett Smelter Site, which includes both the cleanup levels and the points of compliance, was discussed in Section 4.1.3 of the DCAP/DEIS. The ground water cleanup level specified for arsenic of 5 mg/L is based on background concentrations for the State of Washington and is reflected by the Method A cleanup level in WAC 173-340-720(2). The standard background level of 5 mg/L is used at MTCA cleanup sites unless background issues arise on a site-specific basis. If such issues arise, site-specific studies should be undertaken. No such issues have arisen in the Upland Area of the Everett Smelter Site.

Note that dissolved arsenic concentrations in monitoring well EV-1, located southwest and upgradient of the Former Arsenic Trioxide Processing Area, were all less than 5 mg/L (Hydrometrics, 1995a, Table 3-18 on page 3-73).

In any case, the change in ground water cleanup levels made in FCAP/FEIS Section 4.1.3 to reflect the change in surface water cleanup levels made in FCAP/FEIS Section 4.1.4 renders issues regarding background concentrations of arsenic in ground water beneath the Upland Area of the Everett Smelter Site moot.

GQ 4.3.3
Has Ecology accounted for the potential beneficial use of ground water for irrigation at Legion Memorial Park and Legion Memorial Golf Course in the selection of ground water cleanup levels?

(356)

Response:
Ecology has accounted for the potential beneficial use of ground water for irrigation at Legion Memorial Park and Legion Memorial Golf Course in the selection of ground water cleanup levels. As discussed in Section 4.1.3 of the FCAP/FEIS, ground water cleanup levels are considered protective for surface water. The cleanup levels are as protective as if surface water meeting regulatory standards were being diverted for irrigation use.

GQ 4.3.4
Has Ecology sufficiently defined the terms ground water, surface water, and storm water?

(355)

Response:
The terms ground water and surface water are defined in WAC 173-340-200. For terms not defined in the MTCA Regulation or other regulations, Ecology has tried to use terms which occur in a standard collegiate dictionary. Ecology has provided definitions of terms where appropriate. Where such definitions are provided, they occur where the term is first used in the FCAP/FEIS.

B4.4 Surface Water Cleanup Standards

GQ 4.4.1
How should the surface water cleanup standards, including both cleanup levels and points of compliance, be established for water which either flows directly to freshwater wetlands in the Lowland Area or enters the City of Everett's storm water collection system and flows to the City's treatment plant? Is the establishment of surface water cleanup standards for the Upland Area dependent on the characterization of ground water and surface water in the Lowland Area?

(144, 145, 147, 324)

Response:
The selection of surface water cleanup standards for the Upland Area of the Everett Smelter Site, including both the cleanup levels and the points of compliance, was discussed in Section 4.1.4 of the DCAP/DEIS.

Surface water cleanup levels were set in accordance with WAC 173-340-730. The MTCA Cleanup Regulation provides that "[s]urface water cleanup levels are based on estimates of the highest beneficial use and the reasonable maximum exposure expected to occur under both current and potential future site use conditions." WAC 173-340-730(1)(a). The regulation further provides that "[t]he classification and the highest beneficial use of a surface water body shall be determined in accordance with chapter 173-201 WAC, as amended." Id.

In the DCAP/DEIS, Ecology determined that some surface water in the Upland Area ultimately flows to the Snohomish River. The classification and highest beneficial use of the Snohomish River was discussed in Section 4.1.4 of the DCAP/DEIS. The cleanup levels for surface water which flows to the Snohomish River were established in accordance with Method B. Ecology selected surface water cleanup levels based on protection of water quality for wetlands in the Lowland Area and ultimately Snohomish River water quality. Ecology also considered surface water natural background concentration in the selection of cleanup levels. The relevant cleanup levels Ecology reviewed were presented in DCAP/DEIS Table 4-1.

In reviewing surface water standards while considering the comments received on the DCAP/DEIS, Ecology determined that surface water cleanup levels should be changed to standards set for water flowing to the City of Everett's Treatment Plant or standards to protect biota in the Upland Area on the surface water's path to freshwater wetlands in the Lowland Area and biota in the wetlands, rather than biota in the Snohomish River.

The FCAP/FEIS has been revised to provide that surface water in the Upland Area of the Everett Smelter Site, which flows to the storm water sewer system and ultimately to the City of Everett's treatment plant, must meet the requirements of City Pretreatment

Ordinance No. 2034-95, as amended (See FCAP/FEIS Section 4.1.4), rather than the requirements for surface water in the Upland Area which flows directly to the Snohomish River.

Cleanup levels for surface water in the Upland Area of the Everett Smelter Site which flows directly to freshwater wetlands in the Lowland Area have also been revised (See FCAP/FEIS Section 4.1.4). The cleanup levels are set to protect biota in the Upland Area on the surface water's path to the wetlands and biota in the wetlands, rather than for protection of biota in the Snohomish River per Chapter 173-201A WAC. With respect to arsenic, the cleanup level has been increased from the 0.0982 mg/L concentration specified in the DCAP/DEIS to 360 mg/L (acute) and 190 mg/L (chronic).

One commentor suggested that it is premature to establish surface water cleanup levels prior to the completion of the storm water and storm drain characterization program and the associated supplemental investigation of the Lowland Area. Ecology disagrees. Cleanup levels and points of compliance in the Upland Area are not dependent on the characterization of ground water and surface water being performed in the Lowland Area investigation.

GQ 4.4.2
Has Ecology accounted for background concentrations of arsenic in area ground water and in Puget Sound in the selection of a surface water cleanup level?

(146, 400)

Response:
*As noted in **GQ 4.3.2**, the change in surface water cleanup levels made in FCAP/FEIS Section 4.1.4 render issues regarding background concentrations of arsenic in ground water beneath the Upland Area of the Everett Smelter Site moot. This is also true for background concentrations of arsenic in Puget Sound, since surface water standards have been set to protect any freshwater in the Upland Area and the wetlands in the Lowland Area, rather than the marine water of the Snohomish River mouth.*

With respect to background arsenic concentrations in Puget Sound, Ecology notes that data presented by Crecelius, 1998, indicate the upper 90th percentile estimate for natural background arsenic concentrations in Puget Sound is 1.1 mg/L, not 2 mg/L as suggested by one commentor.

B4.5 Storm Drain Sediment Cleanup Standards

GQ 4.5.1
Should the storm drain sediment cleanup levels be established in accordance with the stricter standards imposed by the Snohomish Health District on the City of Everett?

(334, 357)

Response:
The selection of storm drain sediment cleanup standards for the Upland Area of the Everett Smelter Site, including both the cleanup levels and the points of compliance, was discussed in Section 4.1.5 of the DCAP/DEIS. Ecology determined that the storm drain sediment cleanup levels should be established in accordance with the soil cleanup levels established for the site. One commentor suggested that the storm drain sediment cleanup levels should be established in accordance with the stricter standards currently imposed on the City of Everett by the Snohomish Health District. Ecology agrees. Section 4.1.5 of the FCAP/FEIS has been revised accordingly.

Ecology recognizes that the storm drain sediment cleanup levels for cadmium, lead, and mercury, established in accordance with the Snohomish Health District standards, are lower than the cleanup levels established for residential soils in the Upland Area of the Everett Smelter Site. The differential is based on the method for selecting the cleanup levels. While the Snohomish Health District standards were established in accordance with Method A, the soil cleanup levels were established in accordance with Method B. The flexibility afforded by the MTCA Cleanup Regulation under Method B permitted Ecology to increase cleanup levels for residential soils as follows: cadmium, from 2 to 80 mg/Kg; lead, from 250 to 353 mg/Kg; and mercury from 1 to 24 mg/Kg.[6] *To meet the stricter substantive requirements of a local governmental agency, however, Ecology has chosen to establish storm drain sediment cleanup standards in accordance with the Snohomish Health District's guidelines and standards.*

Text has been added to FCAP/FEIS Section 3.3.4 noting that the Snohomish Health District has advised Ecology that Method A cleanup levels apply to storm drain sediments.

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[6] As noted by one commentor, the cleanup level of 1 mg/Kg for mercury listed in Table 4-1 of the DCAP/DEIS was incorrect. The cleanup level for mercury was accurately stated in Section 4.1.5 of the DCAP/DEIS as 24 mg/Kg (the Method B cleanup level). As a result of revision described above, the cleanup levels listed in Section 4.1.5 and Table 4-1 of the FCAP/FEIS have been revised in accordance with the standards required by the Snohomish Health District.

GQ 4.5.2
Does storm drain sediment contain other urban sources of arsenic which could contribute to above-background levels?

(334)

Response:
Ecology's task in selecting a cleanup (which involves establishing cleanup levels and selecting remedial actions) is to specify cleanup requirements for addressing the contamination found at a particular site. The task is not aimed at attributing the contamination to various sources. Whether or not the source of storm drain sediment contamination is entirely attributable to historical smelter operations would not change remedy decisions made by Ecology. The purpose of the FCAP/FEIS is to describe the cleanup actions selected for the Upland Area of the Everett Smelter Site and to set forth the requirements that those cleanup actions must meet.

*See also the discussion under **GQ 7.1.5** of this Responsiveness Summary.*

Chapter B5 Selection of Cleanup Actions

B5.1 Consideration of Environmental Impacts – EIS

Note that the chapters in Appendix A of the FCAP/FEIS have been renumbered. The Summary, Chapter 2, has been eliminated to avoid confusion with the Environmental Summary presented with the front matter of the integrated document. Following chapter numbers have changed accordingly (i.e., Chapter 3 of Appendix A in the DCAP/DEIS has become Chapter A2 of Appendix A in the FCAP/FEIS).

General Comments

GQ 5.1.1
Does the DCAP/DEIS satisfy State Environmental Policy Act (SEPA) requirements as they relate to actions taken under the Model Toxics Control Act (MTCA) for cleanup of a site?

(173, 174, 218, 237, 238, 239, 363, 365)

Response:
Several commentors indicated the integration of the cleanup action plan and the environmental impact statement was confusing. Ecology believes this is due to titling Appendix A "Draft Environmental Impact Statement," when in fact it was meant primarily to document the evaluation of environmental elements identified during the SEPA scoping process – referred to herein as the SEPA Scoping Elements. In the FCAP/FEIS, Appendix A has been retitled "Evaluation of SEPA Scoping Elements." All section numbers in Appendix A have been preceded by an "A" to prevent duplication of section numbers within the main text of the FCAP/FEIS. The Summary in Appendix A has been eliminated because it was confused with the Environmental Summary called for in WAC 197-11-440(4). The Environmental Summary information required by WAC 197-11-440(4) was included in the Executive Summary which preceded the main text of the DCAP/DEIS.

*Note that elimination of the Summary has caused a renumbering of Appendix A chapters, so that the material in DCAP/DEIS Section A**4**.1.1, for example, is presented in the FCAP/FEIS as FCAP/FEIS Section A**3**.1.1. In addition, in referring to Appendix A sections from the DCAP/DEIS, the reference will be made to DCAP/DEIS Section **A**4.1.1, for example, even though the "A" did not precede the Appendix A section number in the DCAP/DEIS. Hence, a response may say, for example, "The text in DCAP/DEIS Section A4.1.1 has been changed in FCAP/FEIS Section 3.1.1 to read…."*

In addition, redundant material and figures have been eliminated from Appendix A. DCAP/DEIS Chapter A3 has been revised as FCAP/FEIS Chapter A2. Detailed *descriptions of alternatives redundant with material presented in the Feasibility Study (Hydrometrics, 1995b) have been eliminated. The identification of the three action alternatives, which was discussed in DCAP/DEIS Chapter 5, has been eliminated from FCAP/FEIS Chapter A2 as redundant with the discussion in FCAP/FEIS Chapter 5. Chapter A2 of the FCAP/FEIS, however, retains the presentation of assumptions necessary for the comparative evaluation of the alternatives, and includes a no action alternative. These assumptions are retained in Appendix A to emphasize they are assumptions made only for comparative evaluation of the SEPA Scoping Elements.*

The cover letter and fact sheet required by WAC 197-11-430 and meeting the criteria set forth in WAC 197-11-435 and -440 have been bound as the first items in the FCAP/FEIS, as they were in the DCAP/DEIS, immediately following the title page and historic photograph of the smelter.

One commentor requested a discussion of the timing of the draft EIS in relationship to the RI/FS and draft CAP, as well as a discussion of how the determination of significance was made. With respect to timing, the SEPA Rules provide that a draft EIS shall be issued no sooner than the issuance of the RI/FS and not later than issuance of the draft cleanup action plan. The final EIS is to be issued no sooner than the issuance of the draft cleanup action plan and no later than the final cleanup action plan. WAC 197-11-262(6). Ecology decided to issue the draft EIS at the same time as the draft CAP and to issue them as a single integrated document, the DCAP/DEIS, to fully inform decision-making.[7] *The final EIS is being issued with the final CAP as a single integrated document, the FCAP/FEIS.*

With respect to the determination of significance, Ecology determined that cleanup of the Upland Area of the Everett Smelter Site would have probable significant adverse environmental impacts and issued a determination of significance pursuant to WAC 197-11-310, -315, and -330 in February 1998. Note that WAC 197-11-330(5) provides that, "[a] threshold determination shall not balance whether the beneficial aspects of a proposal outweigh its adverse impacts, but rather shall consider whether a proposal has any probable significant adverse environmental impacts under the rules stated in this section. For example, proposals designed to improve the environment, such as sewage treatment plants or pollution control requirements, may also have significant adverse environmental impacts."

Scoping of the environmental impact statement was performed according to WAC 197-11-408, which provides that "[t]he lead agency shall narrow the scope of every EIS to the probably significant adverse impacts and reasonable alternatives, including mitigation measures." Ecology reviewed the environmental checklist of WAC 197-11-315 and developed a list of SEPA Scoping Elements from the checklist in coordination

[7] Note that the final RI/FS was issued in September 1995, only four months after the SEPA Rules were amended in May 1995 to provide for the integration of the relevant procedural requirements and documents. The RI/FS process for the Upland Area of the Everett Smelter Site began in 1992, three years prior to the amendments.

with the City of Everett and Asarco. Following the development of the SEPA Scoping Elements, a public meeting was held on February 23, 1998, to obtain public comment. The SEPA Scoping Elements were also presented to the City of Everett Planning Commission on March 3, 1998. The public comments received were organized by Asarco and reviewed by Ecology prior to preparation of the DCAP/DEIS. (See Attachment B3 and Ecology Files: Everett Smelter/SIT7.8)

Finally, one commentor suggested that the fact sheet should indicate whether the EIS is part of a phased review. This FCAP/FEIS is not part of a phased review. The purpose of the cleanup actions is to clean up the site. Part of that plan involves leaving the Former Arsenic Trioxide Processing Area in a condition such that appropriate development may occur in the future. However, no future development has been proposed. If such development is proposed, the proponent of that development would be responsible for meeting SEPA requirements.

GQ 5.1.2
Does the DCAP/DEIS satisfy SEPA requirements as they relate to actions taken under the Growth Management Act (GMA) for proposed redevelopment of the Former Arsenic Trioxide Processing Area? Has the Endangered Species Act been adequately considered?

(337, 339, 363, 365, 404)

Response:
After reviewing and commenting on the DCAP/DEIS, the City of Everett assisted Ecology in preparing information to address its concerns regarding actions which will need to be taken under the GMA for proposed redevelopment of the Former Arsenic Trioxide Processing Area. This information has been incorporated into the FCAP/FEIS as Section 3.3.5. The analysis presented in Section 3.3.5 discusses substantive requirements of City zoning codes and the City's comprehensive plan under the Growth Management Act which prohibit siting of an On-Site Containment Facility; zoning and comprehensive plan land use designation changes that the City commented are necessary to site a Consolidation Facility within the Former Arsenic Trioxide Processing Area; and measures which must be taken to mitigate the environmental impacts of the Consolidation Facility. This analysis will allow the City to make decisions regarding changes to its comprehensive plan and land use designations.

The City of Everett also commented that the FCAP/FEIS should address possible impacts of the proposed action in light of the Endangered Species Act (ESA). Potential impacts to endangered species were considered during the SEPA scoping process; no potential impacts were identified. The SEPA Environmental Checklist prepared by Asarco for the home demolition conducted within the Former Arsenic Trioxide Processing Area in 1999 did not identify any endangered species inhabiting the area (Ecology, 1997, Exhibit E-1, p. 7, Item 5b).

Ecology presumes the comment is made with specific reference to the recent ESA listings of several regional salmon and trout species as endangered or threatened species. Ecology has elected not to engage in any formal SEPA analysis of possible impacts to these species. The applicable SEPA rules allow the scope of the EIS to be determined in part by reference to "the extent to which the adverse impacts are attributable to the applicant's proposal[.]" WAC 197-11-060(4)(e). The rules also indicate that an EIS need only analyze "the probable adverse environmental impacts that are significant." WAC 197-11-402(1). Finally, the SEPA rules indicate that a "probable" impact is one that is reasonably likely to occur, as opposed to an impact that is remote or speculative. WAC 197-11-782.

It is Ecology's belief that the possibility that the proposal (remediation activities in the Upland Area of the site) could impact listed salmon and trout species is remote and speculative as opposed to probable. Since any remediation efforts in the Upland Area of the site will improve existing ground water conditions, any impacts to fish habitat in the Snohomish River would not be attributable to Ecology's cleanup decision.

Specific Comments

Volume Estimates

GQ 5.1.3
Does the DCAP/DEIS underestimate the volume of soil that would be excavated from the Peripheral Area, including the volume from commercial and recreational areas?

(156, 240)

Response:
For the purposes of the environmental analysis, Ecology estimated the volumes of soil that would be excavated and transported to and from the site for the Off-Site Disposal alternative, the On-Site Containment alternative, and the Consolidation alternative. The FCAP/FEIS discusses those volume estimates in Section A2.4.

The volume estimate in the DCAP/DEIS was calculated using the results of a previous volume estimate study conducted for Ecology by SAIC in 1996. The 1996 study estimated soil volumes that would be removed for a wide range of cleanup profiles (i.e., cleanup levels at depth) based on projected soil concentration contours that Ecology had received from Asarco. The volume estimate for the Peripheral Area was calculated by extracting the most appropriate volumes from the 1996 study that best corresponded to the cleanup profile specified in the DCAP/DEIS. Since the cleanup profiles in the 1996 study were not exactly the same as the profile specified in the DCAP/DEIS, the appropriate volumes were extracted from the 1996 study in a conservative manner. For example, the remediation level specified in the DCAP/DEIS for the 12-24 inch soil depth interval was 60 mg/Kg arsenic, whereas the 1996 study made volume estimates for 50 *and 100 mg/Kg arsenic concentrations. In this case, the DCAP/DEIS estimate used the volume in the 1996 study for 50 mg/Kg rather than 100 mg/Kg, and since 50 mg/Kg is conservative compared with 60 mg/Kg, this approach would tend to overestimate (rather than underestimate) the volume. This conservative approach was also used for the other soil depths. As stated in Appendix A, the volume estimates were calculated assuming that soils below four feet would not be excavated in the Peripheral Area.*

The 1996 study was performed before the data from the 1997 boundary study were available. The 1997 boundary study resulted in a modest expansion of the Community Protection Measures (CPM) boundary which is reflected in the DCAP/DEIS. To account for the additional volume from expansion of the CPM area, Ecology adjusted the volume estimate by taking the appropriate volumes from the 1996 study and then increasing them in proportion to the increased number of properties.

The volume estimate included volumes for non-residential areas, but those volumes, based on the 1996 study, were not very large in comparison to the residential volume estimates (the non-residential volume was only about 12% of the total estimated for the Peripheral Area). The 1996 study accounted for soils at Wiggums Hollow Park, Denney Youth Center, the Legion Memorial Park and Golf Course, the mausoleum, the SR 529 cloverleaf, and commercial areas. The DCAP/DEIS soil volume estimate accounted for the soils from each of those areas identified in the 1996 study except for the Legion Memorial Golf Course. The volume estimate did not account for the golf course soils because that area is the subject of an independent cleanup.

There are several variables in the proposed alternatives which can affect the actual volume of soil that will be removed, but which can only be estimated at the present time. For example, the proposed actions involve excavation and removal of only the accessible soils rather than all contaminated soils above the remediation profile in the Peripheral Area. The volume estimate accounted for this factor by estimating the accessible area as the difference between the total area and the area covered by buildings and city streets. However, areas covered by driveways, sidewalks, steep slopes, and landscaping were not counted as inaccessible, even though in many cases they will be. In particular, the DCAP/DEIS allowed for case-by-case decisions to be made at each residence regarding whether or not mature landscaped areas and sloped areas would be excavated, in consultation with the property owner. By not counting these areas as "inaccessible," the volume estimates may actually be overstated, since a significant portion of most yards falls in these categories. Another key variable is that the sampling data to be obtained during implementation to define the areas and depths of contamination at each property will be much more detailed than currently available data, and will likely result in substantial refinement of current concentration contours.

With these variables in mind, it should be recognized that there is considerable uncertainty inherent in any estimate of excavation volumes that can be made prior to implementation. Given this situation, Ecology has judged that the volume estimate is reasonable and adequate for comparing environmental impacts among alternatives, *which is the primary purpose of the SEPA analysis, and that refining the estimate at the present time is not justified. Such refinements in the estimated volumes would not be expected to substantially change the conclusions regarding potential differences in environmental impacts among the alternatives.*

The impact of soil volume estimates on the projected cleanup schedule is discussed in DCAP/DEIS Section A4.10.2, FCAP/FEIS Section A3.10.2 and under ***GQ 5.1.24*** *of this responsiveness summary. The impact of soil volume estimates on transportation risks is discussed in DCAP/DEIS Section A4.10.2, FCAP/FEIS Section A3.10.2, and under* ***GQ 5.1.23*** *of this responsiveness summary.*

Earth

GQ 5.1.4
Should the Earth Section address impacts other than topographic impacts, such as those caused by natural disasters, including earthquakes and floods?

(175, 185)

Response:
The Earth Section (Section A4.1) was limited to evaluating the topographic impacts of the alternatives. Discussion of soil and geology is not necessary for describing topographic impacts, and is not appropriate in this section. A natural disaster (i.e., earthquake or flood) could have an impact on the topography of the area, but the impact would not be the result of the cleanup actions. This section evaluated the impacts of the various remedial alternatives. Under both the On-Site Containment and Consolidation Facility alternatives, the constructed facility would be required to meet applicable seismic and run-on/run-off requirements during facility design and permitting.

GQ 5.1.5
Should the Earth Section address how the topographic impacts of each of the remediation alternatives might impact future land use?

(175, 176)

Response:
The selection of either the On-Site Containment alternative or the Consolidation alternative will impact future land uses within the Former Arsenic Trioxide Processing Area. Those impacts are discussed under the Land Use Section (DCAP/DEIS Section A4.6 and FCAP/FEIS Section A3.6). An analysis of future land use issues and recommendations for changes to land use designations have been developed by the City of Everett Planning Department staff and are presented in FCAP/FEIS Section 3.3.5.

GQ 5.1.6
What are the topographical impacts of the On-Site Containment alternative and the Consolidation alternative, and how may those impacts be mitigated?

(150, 175, 177, 178, 179, 265)

Response:
The Earth Section discussed the topographical impacts of the On-Site Containment alternative and the Consolidation alternative in DCAP/DEIS Sections A4.1.2.3 and A4.1.2.4 (FCAP/FEIS Sections A3.1.2.3 and A3.1.2.4). While view-shed impacts cannot be eliminated under the two alternatives, Ecology has proposed mitigation measures for minimizing those view-shed impacts, particularly for homes just to the south and west of the Former Arsenic Trioxide Processing Area. Mitigation measures were discussed in DCAP/DEIS Section A4.1.2.5 (FCAP/FEIS Section A3.1.2.5). A gradual taper for the soil cover is one such measure. The soil cover along the east side of Hawthorne Street would be tapered and kept to less than 2 feet above the street level. This confused one commentor because the soil pile is stated to be 4 feet deep elsewhere. The 2-foot depth along Hawthorne Street is possible because the site terrain drops off quickly as one moves east from Hawthorne Street. Because of the downward slope, the 4-foot depth of fill would be reached further into the site without causing additional impacts to the view-shed of nearby residences.

One commentor was specifically concerned that limiting grade increases to 2 feet in the Hawthorne area would not allow a sufficient depth of clean material for utility trenches. At other sites, clean backfill has been placed in specific areas to allow for utility placement. This is accomplished by digging the trench in the contaminated material, placing a barrier cloth, then backfilling the trench with clean backfill. This requires identifying utility corridors within the area of concern prior to final covering of the containment or consolidation facility.

It should be noted that limiting grade increases to 2 feet was an assumption made in order to evaluate the relevant SEPA Scoping elements. In the FCAP/FEIS, final grading of the Former Arsenic Trioxide Processing Area for the Consolidation Facility will be determined by a Final Site Restoration Plan which is to be included in the Engineering Design Report for the project.

The text of DCAP/DEIS Section A4.1.2.3 has been corrected in FCAP/FEIS Section 3.1.2.3 to reflect the fact than the On-Site Containment alternative includes both problem waste and dangerous waste.

GQ 5.1.7
Is the environmental analysis of topographical impacts in Section A4.1 of the DCAP/DEIS consistent with the summary and comparison of those impacts in Section 5.3 of the DCAP/DEIS?

(150)

Response:
The environmental analysis of topographical impacts in Section A4.1 is consistent with the summary and comparison of those impacts in Section 5.3. However, to address any potential confusion, FCAP/FEIS Section 5.3.2.1 has been modified to indicate the mitigation measure is minimizing grade changes in appropriate areas of the Former Arsenic Trioxide Processing Area, particularly in the area of Hawthorne Street.

Air Quality

GQ 5.1.8
Are the estimated air quality impacts described in DCAP/DEIS Section A4.2.4 directly related to the transportation analysis described in DCAP/DEIS Section A4.10?

(180)

Response:
Emissions from transport of soil from the site were calculated based directly on the transportation scenarios described in DCAP/DEIS Sections A3.3 (Description of EIS Alternatives) and A4.10 (Transportation). For off-site transport, emissions were calculated for the Central Puget Sound Air Basin (Snohomish, King and Pierce counties), as described in DCAP/DEIS Section A4.2.4.

Surface Water & Ground Water

GQ 5.1.9
What is the source of information upon which the environmental analyses presented in DCAP/DEIS Section A4.3 (Surface Water) and DCAP/DEIS Section A4.4 (Ground Water) were based? What is the source of information contained in DCAP/DEIS Table A4-1?

(181)

Response:
Some of the information presented in DCAP/DEIS Section A4.3.1 was summarized from previous work, specifically the Storm Water and Storm Drains Sediment Characterization and Controls Work Plan, prepared by Hydrometrics in 1998. This work plan is referenced several times within the section and is clearly referenced in the text as the source of the data in DCAP/DEIS Table A4-1. However, in order to make the source of the information presented clearer, DCAP/DEIS Section A4.3.1 has been revised so that it is more apparent which material was derived from the Hydrometrics report. In addition, DCAP/DEIS Table A4-1 has been modified to include a note indicating that the data source was the Hydrometrics work plan.

Some of the information presented in DCAP/DEIS Section A4.4.1 is summarized from previous work (i.e., the remedial investigation report, the feasibility study report, and the supplemental lowland report, all prepared by Hydrometrics). These reports are referenced several times within the section; however, in order to make the source of the information presented clearer, DCAP/DEIS Section A4.4.1 has been revised so that it is more apparent which materials were derived from the Hydrometrics reports.

GQ 5.1.10
Should the Surface Water and Ground Water sections identify potential impacts to the Snohomish River and to the surface water bodies in the Lowland Area?

(181)

Response:
DCAP/DEIS Section A4.3 identified potential impacts to the Snohomish River and to surface water bodies in the Lowland Area. It is necessary and appropriate to identify those potential impacts because they result from remedial actions in the Upland Area.

DCAP/DEIS Section A4.4 identified potential impacts to ground water, wherever they may occur. Again, it is necessary and appropriate to identify those potential impacts because they result from remedial actions in the Upland Area.

GQ 5.1.11
Should the Surface Water and Ground Water sections address the environmental health impacts caused by natural disasters, including earthquakes and floods?

(185)

Response:
DCAP/DEIS Sections A4.3 (Surface Water) and A4.4 (Ground Water) have been revised to discuss natural disasters (such as floods and earthquakes) in a manner consistent with such discussions in Section A4.5 (Environmental Health). Specifically, text has been added to FCAP/FEIS Sections A3.3.2.3 and A3.3.2.4, as well as to FCAP/FEIS Sections A3.4.2.3 and A3.4.2.4, to indicate that natural disasters, in addition to human action or inaction, may be the cause of failure of the impermeable waste caps.

Environmental Health

GQ 5.1.12
Should the Environmental Health Section provide a more comprehensive explanation of assumptions and substantiation of analyses?

(183, 184, 219)

Response:
Ecology does not believe it is either essential or appropriate to present the MTCA default risk assessment assumptions in the environmental analysis. Nevertheless, references have been added to Section A4.5.2.1 as appropriate, including references to applicable sections of MTCA.

One commentor questioned whether the following statement in DCAP/DEIS Section A4.5.2.3 was adequately substantiated:

> *[C]onstruction of an on-site containment facility for dangerous waste within the fenced area would leave arsenic in the neighborhood at concentrations that could cause permanent and potentially lethal health effects.*

The Washington Department of Health (DOH) recently evaluated the hazards of short-term exposure to arsenic-contaminated soil (DOH, 1999). It evaluated a scenario involving atypical exposure of a child to relatively inaccessible areas of arsenic-contaminated soil. Based on best estimate exposure assumptions (i.e., body weight of 13 kg, soil ingestion rate of 20 g/day, bioavailability of 40%, and a lethal dose of 1 mg arsenic/kg body weight), the DOH concluded that acute exposure to a soil arsenic concentration of 1,625 mg/Kg could cause a child's death. Since the On-Site Containment Facility would contain soils containing 3,000 to 20,000 mg/Kg, acute exposure under the conditions described in the DOH report (possibly as a result of long-term human activity or a natural disaster) could result in permanent and potentially lethal health effects.

One comment suggested that certain mitigation measures listed in DCAP/DEIS Section A4.5.2.5 are not related to any identified impacts in DCAP/DEIS Section A4.5.1. DCAP/DEIS Section A4.5.1 identified "maintenance workers who may frequent crawl spaces under residences..." as a potentially exposed population. Signs in crawl spaces and basements would notify people that residual arsenic contamination remains in those areas and, hence, mitigate the chances of exposure.

GQ 5.1.13
Is the environmental analysis in the Environmental Health Section consistent with the analysis in the Surface Water, Ground Water, and Earth sections?

(182, 185)

Response:
*As discussed in the response to **GQ 5.1.11**, the Surface Water and Ground Water sections have been revised to discuss natural disasters (such as floods and earthquakes) in a manner consistent with such discussions in the Environmental Health Section. The potential environmental impacts and mitigation measures for alternative remedial actions with respect to surface water and ground water are discussed in FCAP/FEIS Sections A3.3.2 and A3.4.2 respectively. As discussed in the response to **GQ 5.1.4**, the*

Earth Section is limited to evaluating the topographical impacts of the various remedial alternatives, not the impacts of natural disasters.

Land Use

GQ 5.1.14

Does the analysis in the Land Use Section require further clarification? Is the analysis presented in the Land Use Section both internally consistent and consistent with the analysis presented in other sections of the DCAP/DEIS?

(220, 221, 222, 223, 224)

Response:
Several comments were made regarding both the internal consistency of the analysis presented in the Land Use Section and the consistency of that analysis with the analysis presented in other sections of the DCAP/DEIS. The text of FCAP/FEIS Section A3.6 has been revised to ensure that the section is both internally consistent and consistent with other sections of the FCAP/FEIS.

One commentor expressed confusion regarding whether this project is subject to the Shoreline Management Act. The DCAP/DEIS did not state the project is subject to the Shoreline Management Act; rather, the document simply listed the Shoreline Management Act as one of the laws for which a procedural exemption is provided under MTCA. The Shoreline Management Act has not been triggered by any of the proposed remedial actions in the Upland Area of the site because those actions are not proposed to occur within 200 feet of the shoreline as defined in the Shoreline Management Act, nor within the Snohomish River floodplain.

The same commentor also expressed confusion as to whether the Former Arsenic Trioxide Processing Area is zoned as R-2. The Former Arsenic Trioxide Processing Area is currently zoned as R-2. While the source of the apparent confusion is not clear, Ecology believes the commentor may have been referring to DCAP/DEIS Figure A4-6. That figure listed comprehensive land use designations, not zoning codes.

GQ 5.1.15

Should the Land Use Section contain a more comprehensive analysis of the land use plan changes that would be necessary to accommodate the range of land uses considered for the site?

(338, 339, 340)

Response:
A more comprehensive analysis of the land use plan changes that would be necessary to accommodate the range of land uses considered for the site has been provided by the City of Everett and has been incorporated into the FCAP/FEIS as Section 3.3.5.

Housing

GQ 5.1.16
How do the various remedial action alternatives impact the availability of housing and how could those impacts be avoided?

(225, 226, 227, 228)

Response:
Based upon comments received, the analysis provided under DCAP/DEIS Section A4.7 (Housing) apparently requires some additional clarification. Under both the No Action and On-Site Containment alternatives, the Former Arsenic Trioxide Processing Area could not be redeveloped for residential use. The resulting loss of housing would be a small adverse impact. Under the Off-Site Disposal alternative, and possibly the Consolidation alternative (multi-family only), the Former Arsenic Trioxide Processing Area may be redeveloped for residential use. Such redevelopment would avoid the loss of housing. Ecology recognizes that siting a Consolidation Facility and subsequent redevelopment may require changes in zoning and comprehensive plan land use designations. The need for such changes is addressed under FCAP/FEIS Section 3.3.5.

Aesthetics, Light and Glare

GQ 5.1.17
Is the description of view-shed impacts in the Aesthetics, Light and Glare Section consistent with the description in the Earth Section?

(229)

Response:
The Earth and Aesthetics, Light and Glare sections have been revised in FCAP/FEIS Appendix A. These revisions are believed to have resolved any potential inconsistencies between the these two sections regarding view-shed impacts.

GQ 5.1.18
Would the No Action alternative have a negative impact on the aesthetics of an area?

(230)

Response:
As discussed in Section A4.8.2.1, compared to the ***existing*** *aesthetics of both the Former Arsenic Trioxide Processing Area and the Peripheral Area, the No Action alternative would have no positive or negative impacts. The existing unsightly condition of the area and the tendency for it to attract vagrants, and hence require security guards, would continue.*

GQ 5.1.19
What impacts do the mitigation measures presented in the Aesthetics, Light and Glare Section address?

(231)

Response:
DCAP/DEIS Section A4.8.2.5 discussed the mitigation measures that address the impacts identified in the previous sections. One commentor noted that certain mitigation measures did not clearly address an identified impact. The impact is that until redevelopment occurs within the Former Arsenic Trioxide Processing Area, the property will remain vacant. Such vacant property might attract undesirable uses.

Parks and Recreation

GQ 5.1.20
Does the Parks and Recreation Section accurately reflect arsenic contamination within the boundary of Legion Memorial Park? Does Figure A4-7 correctly show the boundaries of Legion Memorial Park?

(232, 366)

Response:
As discussed in DCAP/DEIS Section A4.9.1, there are three parks located within the CPM boundary: Wiggums Hollow Park, Viola Oursler Overlook, and Legion Memorial Park. DCAP/DEIS Figure A4-7 incorrectly excluded a portion of the Legion Memorial Park from both the park and the CPM area. FCAP/FEIS Figure A3-7 has been revised to correctly show the boundaries of both the Legion Memorial Park and the CPM area.

The environmental analysis presented under the Parks and Recreation Section assumes that remediation would be required within the Legion Memorial Park. DCAP/DEIS Section A3.4 (Volume Estimates) discussed the extent of contamination and estimates of volume throughout the CPM area. Those estimates were derived from prior studies. While those studies indicated that arsenic was not detected in Legion Memorial Park at concentrations exceeding 20 mg/Kg, there were not enough sample points to determine that no areas of the park have concentrations exceeding 20 mg/Kg. The actual areas and volumes to be remediated are expected to vary as additional property-specific sampling data is analyzed during implementation. Consequently, the Legion Memorial Park remains within the current CPM boundary.

GQ 5.1.21
Is the proposed remediation of parks in winter practical and cost-effective?

(378)

Response:
DCAP/DEIS Section A4.9.2.3 proposed that remediation of parks in winter would mitigate impacts on public use of those facilities. The desirability of this mitigation would have to be balanced against the potential problems of earthwork during the wetter winter months. This balancing would be done during the engineering design phase when detailed remediation requirements are developed on a property-specific basis.

GQ 5.1.22
Does Ecology plan to develop remediation and mitigation plans for the parks in cooperation with the City of Everett?

(361)

Response:
The implementation of cleanup actions within the Peripheral Area is discussed in Section 6.2 of the FCAP/FEIS. Property-specific plans, including mitigation measures, will be developed in cooperation with the Everett City Parks Horticultural Department.

Transportation

GQ 5.1.23
Does the environmental analysis in the Transportation Section underestimate the potential impacts of the project, including both the number of traffic accidents and the number of fatalities or serious injuries resulting from such accidents?

(149, 233, 240, 246, 248, 249, 250, 443, 476, 477, 478, 479)

Response:
As a preliminary matter, since many of the comments on this topic are presented in the context of comments on the transportation analyses done pursuant to SEPA requirements, it is important that Ecology clarify its understanding of the types of comparisons involved in an EIS. An EIS identifies a project and various alternatives thereto, and then involves comparisons of impacts to various elements of the environment. Thus, the EIS in this case described the proposed cleanup remedy and various alternatives thereto. Then, the EIS identified specific elements of the environment that would be impacted by the project. Next, the EIS compared the differences in duration, quality, and other aspects of each type of impact for the project and each alternative. So, for example, when evaluating transportation impacts, the EIS identified the types of transportation impacts associated with the project as proposed and compared those to the transportation impacts associated with the alternatives. The EIS analyses did not involve a comparison of different types of impacts; for example, it did not compare transportation system impacts against impacts to air quality. The primary reason this was not done is that SEPA does not contemplate such comparisons.

Other comments are provided in the context of arguments that Ecology should perform a comparative risk analysis in the context of selecting a Method C cleanup standard. As explained in the response to ***GQ 4.2.1****, the use of Method C is not available for soils at a residential site like the Everett Smelter Site.*

Nevertheless, Ecology provides the following response to the substance of the comments regarding the results of Asarco's comparison of various types of risks described above. However, Ecology notes that these discussions do not have pertinence in the context of SEPA analyses or for purposes of selecting a residential soil cleanup level for the reasons just described.

At the outset, Ecology also notes that it previously responded to qualitative comments on remediation risks in a memorandum entitled, "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999a – See Attachment B1-1). The document was listed as a supporting document in DCAP/DEIS Section 1.4 and further discussed in DCAP/DEIS Sections 4.1 and 6.2.

Asarco submitted additional comments that presented quantitative estimates for components of the comparative risk argument contrasting remediation risks with risks from soil contamination. In support of its comments, Asarco presented a calculation of residual risk at a cleanup level of 67 mg/Kg soil arsenic, attempting to show that at that cleanup level risks would be small (an expectation of only one case of skin cancer in 1000 "generations" of exposed children), thereby suggesting that a 67 mg/Kg cleanup level is adequately protective. (Ecology notes that this is a calculation of residual risk, not of risk reduction attributable to cleanup actions.) The risk to remediation workers is calculated by Asarco to be 1.7×10^{-3}*, which Ecology understands to be an expected incidence of worker fatalities (calculated based on 1,425 worker-days for cleanup actions, a fatality risk of* 3×10^{-4} *per worker-year (see Cohen et al., 1997), and 250 worker-days per worker-year). The risk (probability of occurrence) for a fatality accident involving truck transport of soils associated with the cleanup actions is calculated by Asarco at about 1 in 12. The commentors conclude that a comparison of these calculated risks supports a conclusion that the proposed actions will cause significantly more harm than good, and that the proposed actions are therefore not justified under MTCA. Ecology disagrees with this conclusion.*

Before addressing the substance of these comments, it is important to reiterate one of the key observations made in Ecology's previous review of "new science" submittals (Ecology, 1999a). A comparison of different types of risks from different types of circumstances or activities is fraught with difficulties and is not a simple matter. In addition, Ecology rejects Asarco's suggestion that risks of cancers and other illnesses associated with arsenic exposure are any less "real" than risks of construction or traffic accidents. Ecology observes that risk projections on both topics begin with real life data. Risk projections regarding cancers and other illnesses are based on observations that arsenic exposures have caused those illnesses in humans in many settings. Thus, any suggestion that Ecology seeks to address only "theoretical" risks is simply wrong.

Turning to the substance of the comments, Ecology first offers comments on each of the risk calculations identified above. Those comments are followed by a discussion of the basis for risk comparisons, the lack of consistency in numerical risks across many types of activities, and the importance of non-numerical characteristics in comparing specific risks.

Residual (post-cleanup) risks ***should*** *be small to be acceptable. As Slovic (1999) points out, however, what is small can depend on how you measure. The estimation of residual risks in the comments, based on a calculation of incidence (expected number of cases in an exposed population), is presented to support the assertion that they are small. As also noted in the comments, however, the calculated individual lifetime cancer risk at 67 mg/Kg is one in ten thousand, or 100 times the acceptable individual risk under MTCA. This individual risk is the primary criterion for protectiveness under MTCA. It is on that basis that Ecology does not accept an alternate soil arsenic cleanup level of 67 mg/Kg as meeting MTCA's protectiveness requirements. There are several different measurements of risk that can be calculated, and as Ecology has noted previously, they are not interchangeable. Ecology's MTCA Cleanup Regulation, after an extensive public comment process, adopted individual lifetime cancer risk as the criterion for assessing cancer risks rather than other risk metrics such as incidence or years of lifetime lost. The choice of risk metric was discussed in the SEPA EIS prepared for the MTCA Cleanup Regulation.*

Ecology also believes that the calculation as presented is incomplete and flawed. For example, it assumes that 10 children (equivalent to 5% of a population of 200 children at the site) are exposed according to the reasonable maximum exposure (RME) scenario, but inappropriately assumes that exposures and risks for all other children are zero. It focuses only on skin cancer and does not consider the extensive "new science" information on other types of cancer (e.g., bladder, kidney, lung) from arsenic exposure, which could add to cancer risks. The calculation of residual risks also does not provide a measure of risk reduction from cleanup actions, which would be more relevant if a comparative risk analysis was to be conducted.

Calculations of expected cancer incidence are complex when, as in the Upland Area of the Everett Smelter Site, contaminant concentrations vary with location and exposure parameters and contaminant sensitivities vary among individuals. Moreover, the variation in contaminant concentration with location is unrelated to the variation in exposure parameters and contaminant sensitivity among individuals.

A simple illustrative approximation for such a calculation can assume that the population is divided into two classes (e.g., RME and "average" groups), that each class is randomly distributed with respect to the spatial pattern of soil contamination, and that the amount of reduction in soil arsenic concentration is relatively large for a small proportion of each group (e.g., a 150 mg/Kg reduction for 10% of RME and 10% of "average" children) and relatively small (e.g., 30 mg/Kg) for the remainder of each *group. For a population of 200 children (5% at RME and 95% at "average"), assuming reductions of 150 mg/Kg and 30 mg/Kg in soil arsenic for 10% and 90%, respectively, of each group, assuming a relative bioavailability factor for soil arsenic of 40%, and assuming that the "average" group has risk (due to variability in exposures and sensitivity) of only one-fifth the RME group, a simple calculation shows that expected incidence is about 1.2 x 10^{-3} cases of skin cancer. Given the expected highly skewed distribution for exposures, this may well be an underestimate (i.e., a small number of cases with large risk reduction would be expected to contribute disproportionately to total risk reduction). If all other internal cancers related to arsenic are considered, as discussed in the recent National Research Council report (1999), the calculated total lifetime cancer incidence for the 200 children could approach 1 x 10^{-2}, under the assumptions used for this simple illustrative calculation. Since the soil arsenic concentration is expected to persist over time, these risks would also grow over time absent site remediation.*

The calculated incidence of 1.7 x 10^{-3} fatalities for remediation workers presented in the comments is at worst of the same order of magnitude as the cancer risk reduction among one "generation" of site residents, and may well be considerably smaller. This assumes that both the estimated number of worker days for cleanup actions and the fatality rate used in the calculation are applicable to Everett cleanup activities. Ecology notes that the depth of excavations and the size of equipment used for residential site cleanups in Everett will be limited, and that the cleanup activities will occur mostly in periods of better weather and extended daylight. Such factors may the accident and fatality rate for site cleanup activities are overestimated by the use of generic risk statistics.

The calculation of a fatality accident risk from transportation activities associated with site remediation depends on the estimated total number of vehicle miles traveled and the fatality accident rate. Ecology believes the calculation in the comments of vehicle miles traveled is likely to be biased high. The estimate of total vehicle miles traveled is dependent on estimates of soil volumes to be excavated and on estimates of distance and mode of transport. The methodology used by the commentors to estimate soil volume excavated involves comparing the cleanup criterion for ***average*** *soil arsenic concentration in residential yards against the projected concentrations at each residence derived from interpolation from* ***maximum point*** *soil arsenic concentrations from site investigations to date. This methodology is very likely to overestimate the degree of cleanup needed; given the observed variability at small spatial scales in soil arsenic concentrations, the maximum value is expected to be much higher than (and an inaccurate surrogate for) the average concentration within a residential yard or decision unit. Ecology's experience with cleanup of 10 of the most contaminated yards in the summer of 1999, if projected to the estimated total number of yards requiring cleanup, also suggests that the volume of soil to be excavated is substantially overestimated by the commentors.*

A substantial fraction of total miles for transporting excavated soils by road is also attributed to use of excavated soils at the Tacoma Smelter site as subgrade fill. That *option may no longer be viable, given the schedules for both projects. In any event an option exists for eliminating such truck hauls by using the rail transport option to take soils from Everett to a regional landfill (e.g., at Roosevelt, WA), as described in the DCAP/DEIS. Ecology also believes the fatality accident rate may vary from the national rate used in the commentors' calculations, in part because of specific work practices (no night truck hauls, limitation of cleanup actions to months with better weather and prolonged daylight hours, inspection of trucks and screening of driver qualifications) that can be imposed for this project. As a result of these factors, the calculated fatality accident risk of 1 in 12 may overstate actual risks by a factor of two or more. Ecology acknowledges that transportation risks cannot be avoided entirely.*

Whether the expected risk of a fatality accident associated with cleanup program transportation requirements is 1 in 12, 1 in 20, or less, the most likely outcome is that no fatal accidents will occur. In this sense, the transportation risks cited by the commentors are not large in any absolute sense.

The degree of risk associated with many types of activities and occupations varies widely (over orders of magnitude). If risks were judged solely on their numerical values, it would be hard to understand the broad range of apparently acceptable risks. Extensive research has demonstrated that many ***non-quantitative*** *factors affect how risks are viewed and are used to justify disparate levels of acceptable risk for different activities or occupations (see Slovic, 1999). Ecology reasserts its comments made in its previous review of "new science" submittals (Ecology, 1999a) that not only the magnitude but also the characteristics of different risks need to be considered when comparing risks. Among other characteristics, the risks to community residents from site contamination are involuntary, confer no benefits to residents, are unfamiliar (even marked by dread) and unobservable, and are not easily controlled by the individual. These characteristics contrast markedly with the risks to site remediation workers, who benefit from their employment, receive health and safety training (both for their equipment and with respect to site contamination), whose employment is voluntary, and whose own actions can control the risk of site accidents. Similar characteristics apply to transportation risks, both for drivers employed as part of site remediation and for the general public.*

All of the expected incidence numbers are small in the comparative risk evaluation proposed by Asarco for remediation risks versus site cleanup benefits (risk reduction). Ecology rejects a simple ratio of small (and uncertain) calculated incidence numbers as an appropriate measure of comparative risk. Ecology believes the evaluation of the significance of remediation risks, which are real and cannot be reduced to zero, must consider the magnitude and nature of both site health risks and remediation risks. Ecology concludes that remediation risks, which should be controlled to the extent feasible, do not significantly outweigh the benefits of site cleanup actions.

GQ 5.1.24
Does the environmental analysis in the Transportation Section underestimate the level of disruption within the community caused by the projected schedule? Is the projected cleanup schedule practicable?

(240, 241, 242, 243, 377)

Response:
For the purposes of conducting a comparative environmental analysis, a cleanup schedule for the project was projected in DCAP/DEIS Section A4.10.2. The cleanup schedule was based on the assumption that five separate work areas would be established and would be remediated simultaneously. Because the site covers a large area, the properties undergoing cleanup at any one time will be far apart. Hence, in any given portion of the community undergoing cleanup, only one work area will be operating at any given time.

Based on the experience gained in cleaning up 10 homes in the summer of 1999, Ecology has determined that an average rate of only one home per week per construction team is a realistic expectation. Assuming that five work crews will work for 26 weeks each construction season, then 130 homes will be cleaned up each year. This estimate is somewhat less than Asarco's projected cleanup rate for residential areas at Ruston, which varies from 150 to 175 properties per year for the years 2000 to 2004 (Aldrich, 1999b).

For the estimate of 595 homes assumed to require cleanup for comparative purposes, cleanup would take approximately 5 years to complete. Appendix A has been revised to reflect a 5-year schedule for the physical remediation. Mobilization and demobilization activities are estimated to take a year each for an overall cleanup duration of seven years.

Noise

GQ 5.1.25
Is the impact of the remedial action alternatives on the level of noise compared to background levels significant?

(275)

Response:
DCAP/DEIS Section A4.11 discussed the impact of the various alternatives on the level of noise compared to background levels. Temporary noise impacts of active remediation of the site will be significantly greater than background levels in the vicinity of remedial activities.

GQ 5.1.26
Should the reference to California in the third paragraph of DCAP/DEIS Section A4.11.1.1 regarding the methods of characterizing sound be deleted?

(399)

Response:
Yes. This reference to California was included from another report as part of a basic description of characterizing sound used in many reports. It has been deleted in FCAP/FEIS Section A3.11.1.1.

Public Services and Facilities

GQ 5.1.27
What specific public services or facilities could be impacted and how might those impacts be mitigated?

(234)

Response:
DCAP/DEIS Section A4.12.2 describes the impacts to public services and facilities caused by the various alternatives. That section has been revised in FCAP/DEIS Section A3.12.2 to better define the current and potentially impacted public service or agency. Temporary revisions to traffic signals may be required for all of the alternatives if primary haul routes are identified on city streets. These changes would have to be coordinated with the City of Everett.

Funding mechanisms for public services and facilities needed to implement institutional controls will be developed along with development of the institutional controls.

Maintenance

GQ 5.1.28
What is the purpose of the environmental analysis in the Maintenance Section? How may the identified impacts be mitigated?

(235)

Response:
DCAP/DEIS Section A4.13 (Maintenance) describes the ongoing maintenance requirements for the Consolidation Facility and On-Site Containment Facility alternatives and for sod and landscaping in the Peripheral Area. This section has been revised and expanded as FCAP/FEIS Section A3.13 to describe the maintenance requirements for replaced sod and landscape plants.

Other Government Services or Utilities

GQ 5.1.29
Why are the impacts of implementing institutional controls on governmental agencies and utilities discussed separately in DCAP/DEIS Section A4.14 (Other Government Services or Utilities)?

(236)

Response:
The SEPA scoping process indicated that the impact of institutional controls on governmental agencies and utilities should be discussed in a separate section.

GQ 5.1.30
Should the environmental analysis provided in DCAP/DEIS Section A4.14 (Other Government Services or Utilities) contain a more comprehensive discussion of the impacts on the City of Everett from implementing the program of institutional controls?

(364)

Response:
DCAP/DEIS Section A4.14.2.1 discussed the impacts on the City of Everett of implementing the program of institutional controls. The City of Everett has provided further input on the impacts of the institutional controls on City government. Those additional impacts are discussed in the FCAP/FEIS. Ecology will work with the City during development of the institutional controls to mitigate these impacts.

B5.2 Consideration of Threshold and Other Requirements

GQ 5.2.1
Has Ecology appropriately considered threshold and other requirements in the selection of cleanup actions for the Former Arsenic Trioxide Processing Area? Why did Ecology not select either the On-Site Containment alternative or the Off-Site Disposal alternative?

(7, 10, 27, 41, 153, 254, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 287, 290, 368, 369, 440, 441, 443)

Response:
Ecology believes that it appropriately considered threshold and other regulatory requirements in selecting the cleanup actions for the Former Arsenic Trioxide Processing Area. Ecology's explanation of this decision is set forth in Chapter 5 of the DCAP/DEIS and is also described below.

Selection of the cleanup action alternative is a risk management decision. The decision is made by evaluating the proposed cleanup action alternatives with reference to the criteria set forth in the MTCA Cleanup Regulation. The decision-making process involves making qualitative judgments using quantitative and qualitative evaluations while ensuring compliance with the mandatory statutory and regulatory requirements.

Consideration of Threshold Requirements

Selecting the cleanup action alternative for the Former Arsenic Trioxide Processing Area from among the Off-Site Disposal alternative, the Consolidation Facility alternative, and the On-Site Containment Facility alternative required careful consideration of the threshold and other requirements established by the MTCA Cleanup Regulation. Based on those considerations, Ecology determined that while the threshold requirements precluded selection of the On-Site Containment Facility alternative, those requirements did not preclude selection of either the Off-Site Disposal alternative or the Consolidation Facility alternative.

*The MTCA Cleanup Regulation establishes in WAC 173-340-360 certain mandatory requirements applicable to all sites, including certain threshold and other requirements. The threshold requirements require that all cleanup actions conducted under the MTCA Cleanup Regulation **shall**:*

> *(1) protect human health and the environment;*
> *(2) comply with cleanup standards;*
> *(3) comply with applicable state and federal laws; **and***
> *(4) provide for compliance monitoring.*

WAC 173-340-360(2) (emphasis added). Only those cleanup actions which met these threshold requirements were given further consideration.

The On-Site Containment Facility alternative would result in the containment of highly contaminated soil in the Former Arsenic Trioxide Processing Area that classifies as dangerous waste with arsenic concentrations between 3,000 mg/Kg and 20,000 mg/Kg. Material with arsenic concentrations greater than 20,000 mg/Kg would be sent off site. Consideration of the threshold requirements revealed that the On-Site Containment Facility alternative is neither sufficiently protective of human health and the environment nor compliant with applicable or relevant and appropriate provisions of the Dangerous Waste Regulation regarding siting requirements for landfills containing federally-designated hazardous waste.

First, Ecology determined that the On-Site Containment Facility alternative would not be protective of human health and the environment. In making this determination, Ecology considered both arsenic toxicity and the risk of exposure. The On-Site Containment Facility alternative would result in the disposal of highly contaminated soil with arsenic concentrations between 3,000 mg/Kg and 20,000 mg/Kg within a densely populated residential area. Review of arsenic toxicity by the Department of Health (DOH, 1999) indicated that permanent or even lethal health effects in sensitive populations begin to be seen when those populations are exposed to material with arsenic concentrations in the range of 1,500 to 5,000 mg/Kg. Any breach of containment could expose material with much higher arsenic concentrations than 5,000 mg/Kg, material that could pose an immediate threat to health. While Ecology recognizes that the probability of exposure by a sensitive individual is relatively low, Ecology also recognizes that the risk of exposure will remain for the indefinite future because the toxicity of the arsenic-contaminated soil will persist for the indefinite future. Based on these considerations, Ecology determined that leaving arsenic concentrations greater than 3,000 mg/Kg within a densely populated residential area would not be protective of human health and the environment.

Ecology also determined that leaving less contaminated material in place within the Former Arsenic Trioxide Processing Area and constructing a Consolidation Facility to contain the lesser-contaminated soil of the Peripheral Area was sufficiently protective of human health and the environment when combined with an effective program of institutional controls. Ecology recognizes that there will be a low residual risk of exposure of a sensitive individual to material with arsenic concentrations of up to 3,000 mg/Kg if the containment is breached. The risk of such an exposure scenario is considered sufficiently low that leaving material with arsenic concentrations at depth in a Consolidation Facility is considered sufficiently protective of human health and the environment.

Second, Ecology determined that the On-Site Containment Facility would not be compliant with relevant and appropriate provisions of the Dangerous Waste Regulation, including siting requirements for landfills containing federally-designated hazardous *waste.*[8] *As noted in Section 5.4 of the DCAP/DEIS, the most pertinent of those siting criteria require that:*

- *land-based facilities must be located such that the dangerous waste management unit boundary is at least five hundred feet from the nearest point of the facility property boundary; and*
- *the dangerous waste management unit boundary [must be] at least one-quarter mile from residences or public gathering places.*

WAC 173-303-282(7)(a)(ii) & -282(7)(c)(ii). The proposed site of the On-Site Containment Facility clearly meets neither of these requirements.

Based on consultations with the City of Everett, it has also been determined that the On-Site Containment Facility would not be compliant with the applicable substantive requirements of either the Everett comprehensive plan or the Everett zoning code (See FCAP/FEIS Section 3.3.5 for a complete discussion). While MTCA provides an exemption from the procedural requirements of any laws requiring or authorizing local government permits or approvals for remedial actions, that exemption does not extend to the substantive provisions of those laws. RCW 70.105D.090(1). In particular, MTCA provides that "[Ecology] shall ensure compliance with…the substantive provisions of any laws requiring or authorizing local government permits or approvals." Id. The City of Everett determined that while provisions of the Everett comprehensive plan and the Everett zoning code did not preclude the siting of the Consolidation Facility if appropriate land use designations and zoning changes were made, they did preclude the siting of the On-Site Containment Facility (See FCAP/FEIS Section 3.3.5.4.1).

Consideration of Other Requirements

As discussed above, Ecology determined that while the threshold requirements precluded selection of the On-Site Containment Facility alternative, those requirements did not preclude selection of either the Off-Site Disposal alternative or the Consolidation Facility alternative. Selecting a remedy for the Former Arsenic Trioxide Processing Area from among those alternatives that meet the threshold requirements required careful consideration of the other requirements established in the MTCA Cleanup Regulation.

[8] Ecology's determination that these siting requirements are relevant and appropriate requirements applicable to the Everett Smelter Site is discussed in Section 5.4 of the FCAP/FEIS and under **GQ 3.2.4** of this responsiveness summary.

In particular, the MTCA Cleanup Regulation requires that any cleanup action conducted ***shall****:*

> *(1) use permanent solutions to the maximum extent practicable;* [9]
> *(2) provide for a reasonable restoration time frame;* ***and***
> *(3) consider public concerns raised during public comment on the DCAP.*

WAC 173-340-360(3) (emphasis added). Determining whether a cleanup action satisfies the requirement to use "permanent solutions to the maximum extent practicable" requires consideration of a number of factors, including the following:

> *(1) Overall protectiveness of human health and the environment,*
> *(2) Long-term effectiveness,*
> *(3) Short-term effectiveness,*
> *(4) Permanent reduction of toxicity, mobility, and volume,*
> *(5) Ability to be implemented,*
> *(6) Cleanup costs,* ***and***
> *(7) Community concerns.*

WAC 173-340-360(5)(d) (emphasis added).

Selecting between the Consolidation Facility alternative and the Off-Site Disposal alternative required careful consideration of whether the Consolidation Facility alternative satisfies the requirement to use "permanent solutions to the maximum extent practicable." As noted in DCAP/DEIS Section 5.2, discussion among stakeholders during the mediation effort resulted in the conclusion that complete removal of all contaminated soils from the site was not practicable. See WAC 173-340-360(5)(d).

In summary, it was concluded that the incremental costs of excavating contaminated soil within the Former Arsenic Trioxide Processing Area to the soil profiles required in the Peripheral Area, and incurring the expense of sending this soil off site for disposal as well as the expense of sending all of the soil excavated in the Peripheral Area off site (rather than consolidating as much of it as possible within the Former Arsenic Trioxide Processing Area), was disproportionate to the incremental increase in protection of human health and the environment which would occur by such off-site disposal.

Hence, the Consolidation Facility alternative was chosen by Ecology over the Off-Site Disposal alternative.

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[9] The MTCA Cleanup Regulation defines a permanent solution as "one in which cleanup standards can be met without further action being required." WAC 173-340-360(5)(b). The regulation further states that "[c]ontainment of hazardous substances and/or institutional controls alone are not permanent solutions." WAC 173-340-360(5)(c).

GQ 5.2.2
Has Ecology appropriately considered threshold and other requirements in the selection of cleanup actions for the Peripheral Area?

(9, 28, 46, 47, 54, 112, 130, 131, 148, 149, 152, 153, 154, 155, 156, 157, 172, 245, 247, 253, 263, 288, 327, 329, 368, 369, 371, 374, 375, 376, 407, 428, 429, 430, 431, 432, 433, 434, 435, 440, 441, 443, 480)

Response:
Ecology believes it appropriately considered threshold and other regulatory requirements in selecting the cleanup actions for the Peripheral Area. Ecology's explanation of this decision is set forth in Chapter 6 of the DCAP/DEIS and is also described below.

Consideration of Threshold Requirements

*The MTCA Cleanup Regulation establishes in WAC 173-340-360 certain mandatory requirements applicable to all sites, including certain threshold and other requirements. The threshold requirements require that all cleanup actions conducted under the MTCA Cleanup Regulation **shall**:*

> *(1) protect human health and the environment;*
> *(2) comply with cleanup standards;*
> *(3) comply with applicable state and federal laws; **and***
> *(4) provide for compliance monitoring.*

WAC 173-340-360(2) (emphasis added). Only those cleanup actions which met these threshold requirements were given further consideration.

*Therefore, to select a remedy for the Peripheral Area, Ecology's first step was to identify those cleanup actions which meet the threshold requirements. The MTCA Cleanup Regulation prescribes the type of cleanup actions that are required wherever soil cleanup levels are based on residential land use. Soil cleanup levels throughout the Peripheral Area are based on residential land use.[10] The regulation specifically requires that "in the event of a release of a hazardous substance, treatment, removal, and/or containment measures **shall** be implemented for those soils with hazardous substance concentrations which exceed the soil cleanup levels based on [residential land] use." WAC 173-340-740(1)(a) (emphasis added). Consequently, any remedy that Ecology selects for the Peripheral Area must at least include measures to contain soils with hazardous substance concentrations which exceed the soil cleanup levels based on residential land use.*

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[10] Ecology's selection of residential soil cleanup levels for commercial and recreational areas within the Peripheral Area is in accordance with the MTCA Cleanup Regulation and is discussed under **GQ 4.2.2** and **GQ 4.2.3**.

Further selection of a remedy for the Peripheral Area required Ecology to identify those cleanup actions that would be sufficiently protective of human health and the environment to meet threshold requirements. To be sufficiently protective, any containment measure must protect against threats to human health caused by each of the following:

(1) chronic exposure to existing contaminated surface soils;
(2) chronic exposure to recontaminated surface soils, caused by any breach of containment;
(3) acute exposure to existing contaminated subsurface soils, caused by any breach of containment; and
(4) acute exposure to recontaminated surface soils, caused by any breach of containment.

To provide such protection, the containment measure must prevent direct contact with contaminated surface soils and prevent recontamination by and direct contact with contaminated subsurface soils caused by any breach of containment.

For a containment remedy to be sufficiently protective of human health and the environment to meet threshold requirements, Ecology determined that all accessible soils with average arsenic concentrations exceeding the cleanup level of 20 mg/Kg must be removed and replaced with clean soils to a depth of at least 12 inches. Selection of the containment depth was based on several considerations. As clarified in the Responsiveness Summary for the MTCA Cleanup Regulation:

> *If containment is the preferred cleanup action, the soil is still contaminated and compliance [with the cleanup standard] will be based on maintaining the integrity of the containment system in a manner that eliminates the potential for direct contact with contaminated soils (Ecology, 1991, p. 246).*

*In considering what constituted sufficient containment, Ecology considered the fact that the Minimum Functional Standards for Solid Waste Handling, Chapter 173-304 WAC, requires a one foot cover thickness for inert waste landfills. WAC 173-304-461(6). Through discussions with residents, Ecology also identified those residential activities that might result in either direct contact with contaminated surface or subsurface soils or recontamination of the surface soils. Those activities and their respective depths were identified in Table 6-1 of the DCAP/DEIS. Ecology found that many common residential activities occur within the first foot of soil which are not amenable to prevention by institutional controls and which, in any case, would unreasonably restrict people's use of their yards. Such activities included digging by children and pets, gardening (which often penetrates beneath one foot), and soil mixing by biological activity. As discussed further under **GQ 5.2.3** of this Responsiveness Summary, Ecology has also determined that grass covers alone do not meet threshold requirements because grass covers do not provide sufficient containment of underlying contaminated soils to ensure the long-term protection of human health and the environment.*

For the identified containment remedy to be sufficiently protective in the event containment is breached, the underlying soil arsenic concentrations must be sufficiently low to be protective against acute health effects which could occur upon exposure to the underlying soil and against chronic health effects which could occur due to recontamination of surface soils. Ecology is particularly concerned that short-term exposures to arsenic-contaminated soils resulting from a breach of containment and the failure of institutional controls may result in acute health effects, particularly in children. Ecology estimated the range of soil arsenic concentrations which are protective against both transient effects (based on a reasonable maximum exposure of a child) and permanent effects (based on a maximally exposed child) (Ecology, 1999b).[11] *These estimated ranges are presented in Table 6-2 of the DCAP/DEIS. As noted below, these concentrations were used as a check on maximum concentrations that could remain at selected depths beneath a 12-inch thick containment barrier of clean soil.*

Consideration of Other Requirements

Selecting the remedy for the Peripheral Area from among those cleanup actions that meet the threshold requirements required careful consideration of the other requirements established in the MTCA Cleanup Regulation. In particular, the MTCA Cleanup Regulation requires that any cleanup action conducted ***shall****:*

> *(1) use permanent solutions to the maximum extent practicable;* [12]
> *(2) provide for a reasonable restoration time frame;* ***and***
> *(3) consider public concerns raised during public comment on the DCAP.*

WAC 173-340-360(3) (emphasis added). Determining whether a cleanup action satisfies the requirement to use permanent solutions to the maximum extent practicable is based upon consideration of a number of factors, including the following:

> *(1) Overall protectiveness of human health and the environment,*
> *(2) Long-term effectiveness,*
> *(3) Short-term effectiveness,*
> *(4) Permanent reduction of toxicity, mobility, and volume,*
> *(5) Ability to be implemented,*
> *(6) Cleanup costs,* ***and***
> *(7) Community concerns.*

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[11] For further discussion of the DOH's evaluation of the hazards of short-term exposure to soils contaminated with arsenic and any comments pertaining to that evaluation, please refer to Attachment B1-1 of this Responsiveness Summary.

[12] The MTCA Cleanup Regulation defines a permanent solution as "one in which cleanup standards can be met without further action being required." WAC 173-340-360(5)(b). The regulation further states that "[c]ontainment of hazardous substances and/or institutional controls alone are not permanent solutions." WAC 173-340-360(5)(c).

WAC 173-340-360(5)(d) (emphasis added).

Examination of these requirements reveals that cleanup cost is only one of several factors to be considered when selecting cleanup actions from among those actions which meet the threshold requirements. In fact, the MTCA Cleanup Regulation specifically "constrain[s] the role that cleanup costs may play in evaluating whether a cleanup action is practicable" (Ecology, 1991, p. 145). That role was clarified by Ecology in the Responsiveness Summary for the MTCA Cleanup Regulation (Ecology, 1991, p. 145):

> *First, …costs can never be the sole reason for a finding that a permanent solution is impracticable. Cost comes into play only when there are substantial concerns over the engineering feasibility, effectiveness, and other relevant factors.*
> *…*
> *Second, a finding that a permanent solution is impracticable can be made only if it is demonstrated that the incremental costs of the permanent solution are substantial and disproportionate to the incremental degree of permanent protection provided by a cleanup action relying on containment and engineering controls.*

Based upon a consideration of these requirements and a balancing of the identified factors, Ecology selected and developed a soil removal and containment remedy for the Peripheral Area that is permanent to the maximum extent practicable. A full discussion of how this balancing was achieved is provided in FCAP/FEIS Section 6.2.1.1 and further summarized in FCAP/FEIS Figure 6-7. The following discussion provides an overview.

As discussed above, for the containment remedy to be sufficiently protective of human health and the environment to meet threshold requirements, all accessible soils with average arsenic concentrations exceeding 20 mg/Kg must be removed and replaced with clean soils to a depth of at least 12 inches. However, such a containment remedy would only be sufficiently protective if the underlying soil arsenic concentrations are sufficiently low to be protective against acute health effects which could occur upon exposure to the underlying soil and against chronic health effects which could occur due to recontamination of surface soils. Ecology recognized, though, that removal of all accessible soil that exceeds the cleanup level of 20 mg/Kg arsenic to a depth of fifteen feet is not practicable. Hence, Ecology selected a combined soil removal and containment remedy for the Peripheral Area.

In the development of that soil removal and containment remedy, Ecology recognized that the statutory and regulatory preference for permanence requires that arsenic-contaminated soil be removed to the maximum extent practicable. Further recognizing that cost is directly related to the soil volume excavated and that cancer risk is directly related to arsenic concentration per WAC 173-340-740(3)(a)(iii)(B), Ecology balanced costs by maximizing the removal of soil containing the highest soil arsenic concentrations (thereby reducing risk) while minimizing the amount of soil removal, and *therefore, cost. In its comments, Asarco affirmed Ecology's approach (Aldrich, 1999a, Tab H-2, p.3), stating:*

> *Since there is a linear relationship between the number of residences requiring soil removal and replacement, corresponding soil volumes, and total costs, the estimates of number of residences and soil volumes requiring remediation at a given action level can serve the same purpose [as total cost] in terms of evaluating the disproportionality between differing action levels.*

To determine the point at which the incremental increase in soil volume (and hence cost) would become substantial and disproportionate to the incremental reduction in risk, Ecology first estimated the volume of soil that would require removal for each 6- inch depth increment for average and maximum arsenic concentration levels varying from 0 to 10,000 mg/Kg. The soil volume estimates for each depth increment were based on the data provided by Asarco.[13] Each depth increment was evaluated individually to minimize soil removal, and thereby cost.[14] The estimated soil volumes, expressed as a percentage of the total volume in the respective depth increment, were presented in Figures 6-1 through 6-5 of the DCAP/DEIS. For each depth increment, Ecology then selected remediation levels at or above arsenic concentrations where the curve showed rapidly increasing soil volume (and hence cost) for incremental reductions in arsenic concentrations (and hence risk).[15] Those remediation levels were then checked against acute toxicity evaluations provided by the Department of Health to ensure that the concentrations remaining at depth would be sufficiently protective against acute health effects to meet threshold requirements.

As was shown in Figure 6-6 of the DCAP/DEIS, the selection of those remediation levels (the less permanent remedy) instead of the soil arsenic cleanup level of 20 mg/Kg (the more permanent remedy) for depths below 12 inches reduced the estimated volume of soil to be removed from the Peripheral Area below 12 inches by about 80%. At the same time, each of the remediation levels selected was within the range of arsenic concentrations considered sufficiently protective against acute health effects, according to the Department of Health, to meet the threshold requirements.

To summarize, for the Peripheral Area, Ecology determined that a clean containment barrier at least 12 inches in thickness is required to meet threshold requirements. Beneath that barrier, soils with higher arsenic concentrations are to be excavated and

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[13] These data are described in Asarco's comments as the GIS Linear Average and GIS Linear Maximum data files (Aldrich, 1999a, Tab H-2, p.3).

[14] Because significantly more contaminated soil is located above a depth of 24 inches than below, the incremental cost of removing contaminated soil from the lower depths would be comparatively low.

[15] For depths below 24 inches, Ecology selected a remediation level of 500 mg/Kg for maximum arsenic concentrations, even though Ecology's analyses of soil volume estimates would likely support a lower concentration of 300 mg/Kg. Ecology's decision was based on the decreased likelihood of penetrating below 24 inches, the evaluation from the Department of Health that 500 mg/Kg was within a range considered protective against permanent health effects, and cost balancing.

soils with lower arsenic concentrations are to remain and be managed using engineering controls. In addition, permanent structures and pavement will not be excavated and contaminated soil beneath them will remain and be managed by institutional controls.

GQ 5.2.3
Do grass covers alone provide sufficient containment of underlying contaminated soils to ensure the long-term protection of human health and the environment to meet threshold requirements?

(253, 331)

Response:
In July 1998 prior to the development of the DCAP/DEIS, Asarco submitted materials to Ecology requesting review under WAC 173-340-702(6) as new scientific information relevant to the establishment of cleanup levels for the Upland Area of the Everett Smelter Site. As part of that submittal, Asarco included comments and materials regarding whether grass could provide an effective cover over contaminated soils. Ecology, in collaboration with the Washington State Department of Health (DOH), reviewed and analyzed the information submitted by Asarco. Ecology's evaluation of Asarco's submittal was documented in a memorandum entitled "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999a). The document was listed as a supporting document in DCAP/DEIS Section 1.4 and further discussed in DCAP/DEIS Sections 4.1 and 6.2. Based on a reasoned review of the information submitted, Ecology determined that grass covers alone do not meet threshold requirements, because grass covers do not provide sufficient containment of underlying contaminated soils to ensure the long-term protection of human health and the environment (Ecology, 1999a).

For a more detailed discussion of this prior review, please refer to Attachment B1-1 of this Responsiveness Summary, pages 56-57.

In February 1999 Asarco submitted comments on the DCAP/DEIS (Aldrich, 1999a). Included with that submittal were comments on Ecology's evaluation of Asarco's July 1998 "new science" submittal and some additional materials for Ecology's consideration. The comments identified several published studies which Asarco interpreted as supporting the conclusion that grass cover mitigates exposures from soil contaminants. Asarco also included statements interpreting the EPA's preamble discussion within the proposed rules for reducing lead hazards under TSCA, Title X. (Aldrich, 1999a, comments by Beck, pp. 14-15 and Tsuji, p. 10) Ecology, again in collaboration with the DOH, conducted a thorough and reasoned review of all the information presented by Asarco, as well as other literature. Based on that review, Ecology reaffirms its prior conclusion that grass covers alone do not meet threshold requirements because grass covers do not provide sufficient containment of underlying contaminated soils to ensure the long-term protection of human health and the environment.

The relevant issue with respect to grass covers, in the context of new science reviews, is not whether they improve matters or are (partially) effective in reducing exposures, but rather whether they are sufficient to meet the target acceptable exposure and risk levels under MTCA. As Ecology stated previously, "the fact that with bare soils things could be worse is not in and of itself particularly relevant." The commentors appear to focus on defending the "effectiveness" of grass covers, defined as their ability to reduce exposures compared to conditions with bare soils. Ecology is instead focused on the "sufficiency" of grass covers to meet the requirements for long-term protectiveness under MTCA, including the degree of protectiveness (acceptable risk) required. Ecology previously commented that the soil ingestion studies supporting the reasonable maximum exposure (RME) soil contact rate for children used in MTCA, and by EPA, include studies where grass covers clearly were present. The RME parameter estimate therefore already assumes the existence of grass cover; that is, soil contact continues to occur even with grass covers present. No comments to rebut this finding were offered.

EPA's proposed rulemaking under TSCA (EPA, 1998a) includes an extensive preamble discussion. In Ecology's opinion, a reading of the entire preamble shows that EPA recognizes the limitations for long-term performance of temporary measures such as grass covers. The proposed use of grass covers in the TSCA program is a response to the specific goals of that program and nationwide conditions leading to potential lead exposures, and does not reflect a determination, as a matter of scientific analysis, that grass covers are effective at reducing soil contact for the long-term.

Two soil lead concentrations are identified in the preamble of the TSCA rulemaking: a standard for soil lead hazards at 2,000 mg/Kg and a soil lead level of concern at 400 mg/Kg. The soil lead hazard value is part of the proposed rule; the soil lead level of concern is not. These different values are developed based on differences in the level of certainty regarding their association with adverse health effects, a distinction made by EPA in response to the specific statutory language and requirements of the legislation. The commentors point to the following section (quoted more extensively here than in the comments) in an introductory summary of the rulemaking (EPA, 1998a, p. 30303):

> *In addition, this document proposes to identify a soil lead level of concern of 400 mg/Kg based on a yard-wide average, which represents a level at which risk should be communicated to the public as compared to the more active risk reduction measures recommended for hazards. This level will not be included in the regulation because it would impose no legally recognizable requirements on any person or entities subject to this regulation. Nevertheless, if a soil lead hazard is not present, but lead in soil exceeds the level of concern, EPA recommends that low cost measures, which may be sufficient to reduce exposure, be implemented. These measures include but are not limited to covering bare soil, placement of washable doormats, more frequent washing of hands and toys, and access restrictions.*

EPA also notes that "soil-lead hazards should be eliminated. Currently available options include soil removal and permanently covering the soil (i.e., paving)." Ecology believes that a reading of the entire preamble makes it clear that EPA's recommendations for low-cost measures to address exceedances of the soil lead level of concern are limited in scope and should not be taken out of the context of the TSCA rulemaking.

EPA notes that the TSCA rulemaking applies to millions of homes built prior to 1978 that could contain lead-based paint. Residential lead hazard reduction activities at such properties would often occur without oversight by any government agency, and the proposed standards therefore focus on providing practical advice widely applicable to residential properties. Setting priorities for the very large population of affected properties, cost-balancing and resource allocation (on a national scale), and consistency with the specific statutory language of TSCA Title X are identified as important factors for the development of proposed rules; as EPA notes, "for a framework to be workable, it needs to be based on realistic goals, goals that are achievable with available resources and feasible with available technology" (EPA, 1998a, p. 30313). EPA discusses the relevance of this TSCA proposed rulemaking for CERCLA and RCRA corrective actions in the preamble and summarizes its position as follows: "the TSCA Section 403 standards are being developed for different purposes and audiences" (EPA, 1998a, p. 30345). EPA specifically comments that TSCA, unlike CERCLA and RCRA, does not have any stated preferences for permanent remedies but instead recognizes the important role of temporary control measures (i.e., interim control measures) in the context of the goals of the TSCA program. EPA identifies grass cover as an interim (i.e., temporary) measure in previous guidance for lead-based paint remediation (EPA, 1994). The incorporation of cost-balancing (prior to protectiveness evaluations) and acceptance of temporary (interim) cleanup measures in the TSCA rulemaking approach are both quite different than the comparable provisions of MTCA. EPA concludes that "the action levels, cleanup goals, and remedies selected at CERCLA and RCRA sites may differ from those being proposed in [this rulemaking]" (EPA, 1998a, p. 30345).

Additional comments by EPA in the preamble support Ecology's conclusion that grass covers do not reliably provide long-term protectiveness. With respect to the cost-benefit analyses conducted in support of the rulemaking, EPA states that "due to the lack of data about the effectiveness of interim controls to reduce exposure to lead in soil, the Agency did not include these interventions in its analyses" (EPA, 1998a, p. 30322). Regarding the decision on a standard to define soil lead hazards, EPA notes that benefits from soil abatement (i.e., permanent actions) accrue "not only for the child immediately protected when the abatement is performed but also for children who may reside in that residence in the future" (EPA, 1998a, p. 30329). EPA also states that in deciding on a standard for soil lead hazards "interim controls were not considered because EPA lacks data to estimate the effectiveness of those controls" (EPA, 1998a, p. 30329). The definition of lead-contaminated soil in TSCA refers to bare soil (and none of the proposed rules therefore apply to areas with grass cover). In considering whether or not to include a de minimis area of bare soil as part of the lead hazard criteria, EPA comments that it decided not to adopt a de minimis criterion, since "EPA has no analysis or data that *relate the amount of bare soil to risk and, therefore, no basis upon which to select the de minimis," and "if a soil lead hazard is present, the property owner or other decisionmaker should take action to control the hazard and this action should address all soil where lead levels exceed the hazard standard whether or not it is bare" (EPA, 1998a, p. 30338). Finally, as cited previously by Ecology, EPA notes that its concerns extend beyond the bare soils covered under the TSCA rulemaking: "Although Title IV of TSCA restricts the standard for soil lead hazards to bare soil, EPA is concerned that the presence of soil cover, such as grass, may not reduce exposure to lead sufficiently" (EPA, 1998a, p. 30338).*

Ecology notes that the goal for remedial actions for soil lead is to maintain blood lead levels in children below 10 mg/dL. This may not result in a requirement for the same degree of effectiveness in reducing exposures as in the case of soil arsenic; the "allowable increment" for arsenic, based on risk-equivalent calculations, may be much smaller than for lead.

Ecology concludes that the proposal to use temporary, interim measures such as grass covers for "low-level" soil lead contamination in the proposed TSCA rulemaking is a function of the goals and framework for that program, which differ in important respects from the MTCA framework (e.g., role of cost and preference for permanent remedies). Ecology believes EPA, in the preamble, recognizes the limitations and uncertainties regarding long-term performance of temporary measures such as grass covers.

The use of grass covers as a temporary, interim cleanup action is most reasonable where there are ongoing sources that have not yet been controlled and that could result in soil recontamination. For lead, such sources as deteriorating or improperly removed lead-based paints and ongoing air emissions sources (e.g., lead smelters) could negate the benefits of soil removal and replacement through recontamination. Ecology points out that the situation for arsenic in Everett is different; there are no significant sources for air emissions of arsenic and nothing comparable to the lead-in-paint problem. The occurrence of arsenic in treated wood, some local gravel sources, pesticides, or other products has not been shown to have significant potential for affecting residential yard soils or for producing yard-wide recontamination. The residual arsenic in soils in Everett yards is the dominant remaining source. Interim controls are therefore not justified by recontamination concerns. The emphasis on establishing grass cover in Trail, British Columbia (Hilts, 1996) is reasonable when it is recognized that the local smelter was continuing to emit 120 tons of airborne lead per year. Grass cover may also be reasonable where movement (e.g., resuspension or erosion) of contaminants from soils over a large area is a primary concern. This approach has been used at the Bunker Hill, Idaho Superfund site for valley-wide remediation; even at that site, however, remediation of residential soils has been accomplished by excavation and replacement of contaminated soils and not the use of grass cover. Ecology is not aware of sites where grass cover alone has been used as other than a temporary measure for residential soils.

Madhavan et al. (1989) considered the relationship between soil lead and blood lead levels in children. They recommended different maximum permissible soil lead concentrations depending on whether or not soils were bare. Ecology notes that the recommended maximum permissible level for areas with grass cover is much lower than EPA's proposed soil lead hazard level of 2,000 mg/Kg. Their recommended maximum of 600 mg/Kg is in fact close to EPA's proposed soil lead level of concern of 400 mg/Kg, and this reflects a conclusion that soil contact can still occur even if grass covers are in place. The recommended maximum level for bare soils, 250 mg/Kg, is well below EPA's soil lead level of concern from the TSCA preamble.

Ecology previously raised the concern that soil contaminants contained below a grass cap could move vertically upwards and become more available for contact. Jenkins et al. (1988) provide some interesting information relevant to this concern. They report that soil replacement to a depth of 15 cm (about 6 inches, or somewhat more than is typically installed with new sod) occurred at properties with lead-contaminated soil in Toronto in 1977. Measurements of the replacement soils one year later showed recontamination. Although local secondary lead smelters were still operating, raising the possibility of recontamination from airborne deposition, the authors note that lead concentrations increased from the surface to the replacement depth. Based on comparisons with unreplaced soils seven years later, the authors concluded that "the most feasible current explanation speculates that mixing of the replaced soils occurred through: a) the action of removal/replacement equipment; b) activities such as gardening; c) annual freezing and thawing; or d) earthworm activity" (Jenkins et al., 1988, p. 241). The authors recommended soil removal to a depth of 30 cm to minimize "the potential for re-contaminating the replacement soil from underneath."

Several studies have also concluded that the presence of pets allowed outside is an important factor for predicting indoor contamination levels and human exposures (body burdens) of contaminants. Berny et al. (1994) studied blood lead levels in pets in relation to environmental lead levels in an Illinois community with a secondary lead smelter. The authors stated that there were no differences in blood lead concentrations in pets spending most of their time on a grass-covered soil, concrete, sand, or bare ground soil. There was, however, a statistically significant positive relationship between pets' blood leads and soil lead concentrations (composite of four soil cores including front and back yards). Thus, grass cover was not protective or predictive for pet exposures, which in turn may be related to potential human exposures. The authors note that the likelihood of having one or more persons in a home with higher blood leads (> 10 mg/dL), given that a pet in that home had higher blood lead (also > 10 mg/dL), was significantly increased.

Ecology lacks any reliable evidence that grass covers can be maintained over a long time period, or that they can be sufficiently protective over the long term against contact with contaminated soils. The studies cited in the comments indicate that grass cover may reduce potential contact compared to bare soils, measured on a study population basis (e.g., regression slope relating average change in blood lead level versus change in soil *lead concentration). They do not, in Ecology's opinion, support the long-term performance of grass covers, the effectiveness for individuals (RME case) versus average or population-wide effectiveness, or the reduction of potential exposures to acceptable levels as defined under MTCA.*

GQ 5.2.4
Has Ecology considered other disposal options, including soil treatment processes?

(318)

Response:
The Everett Smelter Site Feasibility Study (Hydrometrics, 1995b) developed information regarding potential methods of site cleanup, assembled fourteen different alternatives for cleaning up the site from those methods, and evaluated the degree to which each alternative met MTCA requirements. The Feasibility Study report concluded that treatment of contaminated soils was not a viable, cost-effective solution for the site. Further investigation by Asarco of the various stabilization, soil washing, and metals recycling options for addressing dangerous waste also indicated that those options were not viable (Asarco, 1998d and e). Ecology concurred in that judgment.

Chapter B6 Implementation of Selected Cleanup Actions

B6.1 Soil Cleanup Actions – Peripheral Area

Areas Not Covered by Permanent Structure or Paving

GQ 6.1.1
Under what circumstances should the containment barrier extend to a depth below 12 inches to ensure that human health is sufficiently protected?

(69, 104, 116, 401)

Response:
Ecology recognizes that some areas of high activity and comparatively deeper and more frequent soil disturbance, such as gardens, justifiably require a containment barrier that extends to a depth of 18 inches. Section 6.2.1.2 of the DCAP/DEIS specified that "vegetable gardens" should be excavated to a depth of 18 inches if arsenic concentrations exceed an average of 20 mg/Kg or a maximum of 40 mg/Kg in the 12 to 18-inch depth interval. Recognizing that many people work extensively with gardens containing many varieties of plants that frequently involve turning over soil to a depth of 18 inches, Ecology has revised Section 6.2.1.2 of the FCAP/FEIS to extend application of the provision to any "existing garden." Note that this provision applies only to existing gardens. If a homeowner wishes to install a garden in the future, contaminated soil below a depth of 12 inches may be handled under the Institutional Control Program. This decision to extend application of this provision to any existing garden was made both to protect children playing in the garden and to protect against the spread of soil containing arsenic concentrations exceeding 20 mg/Kg into other areas of the yard when brought to the surface.

GQ 6.1.2
What is an appropriate marker to delineate contaminated soil at depth?

(113, 257)

Response:
Section 6.2.1.2 of the DCAP/DEIS provided the flexibility to use either coarse gravel or a durable, permeable geofabric at the base of clean soil as a warning that there exists contaminated soil at depth. One commentor was concerned about the appropriateness of gravel, indicating that it would not give as clear a warning as a geofabric. Gravel was specified as an option because it is considered more permanent. Geofabrics have a use history of, at most, several tens of years. Gravel has lasted in the environment for thousands to millions of years. The use of either marker requires statements in property records about what the gravel layer or geofabric signifies. The flexibility to use either marker has been retained in the FCAP/FEIS.

GQ 6.1.3
Should Ecology determine whether a structure constitutes a permanent structure based on whether the structure was built under permit from the City of Everett?

(4, 216)

Response:
Section 6.2.1.2 of the FCAP/FEIS defines what constitutes a permanent structure. The definition has been changed from that provided in the DCAP/DEIS to permit a more flexible decision on what constitutes a permanent structure. Specifically, the text has been modified to provide the following:

> *Existing houses, detached garages, and similar buildings will be considered permanent structures. Sheet metal garden storage sheds, children's "forts" or "playhouses," and similar structures will not be considered permanent. Property-specific decisions will be made by Ecology regarding whether a structure is permanent or not. As a general guidance, if a structure has a concrete foundation poured into the soil, it is probably permanent. If a structure can be readily moved, it is probably not permanent.*

GQ 6.1.4
Should Ecology require the replacement of nonpermanent structures?

(216)

Response:
One commentor expressed the concern "that the integrity of many of the nonpermanent structures will not allow them to be moved for remediation. Therefore, it is not appropriate ... to move temporary structures, remediate beneath them, then replace them with new nonpermanent structures." Ecology believes this is a decision to be made on a property-specific basis during development of the cleanup plans for that property. Certainly, temporary structures such as metal garden sheds can be easily moved, the underlying ground cleaned up, and the shed replaced. Others may be of a nature that disassembly and rebuilding, either using the original material or using new material, is a simple matter within the context of the cleanup and is the most efficient approach. It is particularly important that temporary structures be addressed because removal of these structures to expose soil is considered one of the most common and difficult to control activities that may be undertaken by residents, particularly new residents.

GQ 6.1.5
Should Ecology determine whether paving provides sufficient containment based on whether the paving meets the standards set by the American Society for Testing Materials (ASTM) appropriate for the service and any standards set by the City of Everett? For pavement that does not provide sufficient containment, who should be responsible for the required upgrades?

(114, 326)

Response:
Section 6.2.1.2 of the DCAP/DEIS provided that asphalt or concrete would not be considered sufficient containment unless it met standards set by the ASTM appropriate for the service and any standards set by the City of Everett. Ecology has revised Section 6.2.1.2 to permit a more flexible approach in evaluating whether asphalt or concrete provides a sufficient cover. Specifically, the text has been modified to provide the following:

> *Existing asphalt or concrete pavement will be inspected visually to assess whether it will provide containment for a period of at least five years. If not, it will be repaired or removed and replaced. Replacement pavement must meet relevant standards. Property-specific decisions will be made by Ecology regarding whether a pavement is permanent or not. (Remaining pavement will be inspected during 5-year periodic reviews.)*

Responsibility for repairing or removing and replacing asphalt or concrete will be specified in legal instruments governing implementation of the cleanup action plan.

GQ 6.1.6
Should Ecology require areas with existing pavement not meeting ASTM standards to be remediated and upgraded while permitting areas without pavement to be paved without remediation?

(15, 115, 326)

Response:
Ecology acknowledges the inconsistency in Section 6.2.1.2 of the DCAP/DEIS of requiring areas with existing pavement not meeting ASTM standards to be remediated prior to upgrading to meet ASTM standards while permitting areas without pavement to be paved without remediation. To remove this inconsistency, Ecology could either require areas without pavement to be remediated prior to being paved or allow areas with non-standard pavement to be upgraded without remediation. Ecology has decided to allow areas with non-standard pavement to be upgraded without remediation. Determining whether non-standard pavement must be upgraded to provide sufficient containment is discussed above under ***GQ 6.1.5*** *of this Responsiveness Summary. Irrespective of whether remediation is required, any contaminated soil removed to*

maintain an appropriate grade or for other reasons during pavement repair or removal and replacement must be disposed of properly.

GQ 6.1.7
Should Ecology require removal of decks impeding soil removal and replacement of such decks with construction of equal or better quality?

(326)

Response:
Ecology required in Section 6.2.1.2 of the DCAP/DEIS that where decks impede soil removal, the deck must be removed, the soil removed and/or contained, and the deck replaced with construction of equal or better quality. One commentor noted that decks provide sufficient containment of contaminated soil. Ecology disagrees. However, to address this concern, Ecology has revised Section 6.2.1.2 so that decks do not need to be removed and replaced, so long as the area beneath the deck is enclosed to prevent entry by pets and other animals which could result in the spreading of contaminated soil remaining beneath the deck.

GQ 6.1.8
Should the imperiling of a structure or pavement or the necessity of shoring preclude excavation of soil throughout the remainder of the contaminated property? Where contaminated soil cannot be excavated without shoring, should homeowners be afforded a buyout option?

(31, 336)

Response:
As provided in Section 6.2.1.2 of the FCAP/FEIS, where contaminated soil exists below the depth that can be excavated without shoring or imperiling the integrity of a structure or pavement, Ecology will address the contamination on a site-specific basis. The fact that shoring is required does not necessarily preclude excavation. However, where shoring is required, excavation may not necessarily be practicable. Such a determination must be made on a site-specific basis. Ecology must balance the degree to which the soil exceeds the applicable cleanup or remediation level and the benefit associated with excavation of such soils with the practicability of such excavation. Ecology is particularly concerned that driving shoring may imperil structures, pavement, and utilities. Where Ecology determines that contaminated soils cannot be excavated due to such concerns, Ecology will develop property-specific plans to address the remediation of those contaminated soils.

During the Summer 1999 Cleanup, Ecology did not encounter contamination at depth which justified shoring, although contamination in steeply sloping areas at one residence required construction of landscaping walls to properly restore the site during backfilling. Because the homes included in this cleanup were among the most contaminated, it is *unlikely that shoring would be required in the remainder of the Peripheral Area. If contamination requiring excavation is encountered at depths which would require shoring (or landscaping walls), it will be addressed on a property-specific basis. Purchase of such a home, as suggested by one commentor as a "buy-out option," is not under consideration.*

GQ 6.1.9
What are the applicable soil concentration limits for backfill? What is the appropriate soil arsenic concentration limit for backfill?

(330, 389)

Response:
Section 6.2.1.2 of the DCAP/DEIS provided that excavations shall be backfilled with soil having "no concentrations of any hazardous substance exceeding MTCA Method B standards and shall come from a source approved by Ecology." Comments indicated that some ambiguity exists regarding the applicable soil concentration limits for backfill, particularly for arsenic. To resolve that apparent ambiguity, Section 6.2.1.2 has been revised to provide the following:

> *Functional requirements for backfill are that it contains no concentrations of any hazardous substance exceeding the greater of MTCA Method A concentrations, MTCA Method B concentrations, or concentrations set for the Upland Area of the Everett Smelter Site, and that it have engineering, drainage, and agricultural characteristics suitable for its intended use.*

To ensure that the requirements for backfill are met, Section 7.2.1.3 of the FCAP/FEIS provides for quality assurance testing of granular backfill for priority pollutant metals and topsoil for priority pollutant metals, PCBs, organochlorine pesticides, semivolatile organic compounds, and volatile organic compounds.

The comments also suggested that the 20 mg/Kg soil arsenic concentration limit for backfill is inappropriate. In particular, one commentor suggested that Ecology identify a lower limit based on the availability of soils with lower arsenic concentrations. Another commentor suggested that the limit is not practicable because the incremental cost of replacing marginally contaminated soil with marginally clean soil is substantial and disproportionate to the incremental degree of protection it would achieve. These comments are addressed below.

First, as indicated, the soil arsenic concentration limits are based on the cleanup levels established in accordance with the MTCA Cleanup Regulation. Second, as a practical matter, the arsenic concentration of clean backfill is anticipated to be considerably below the 20 mg/Kg cleanup levels specified for the Upland Area of the Everett Smelter Site. The 20 mg/Kg arsenic concentration is an upper bound on natural background concentration, not an average concentration. Moreover, Ecology has estimated that over

90% of uncontaminated soils in the Puget Sound area have an arsenic concentration of less than 20 mg/Kg arsenic.[16]

Furthermore, Ecology's own experience has indicated that clean backfill often has arsenic and lead concentrations considerably below the 20 mg/Kg and 353 mg/Kg concentrations specified for the Upland Area of the Everett Smelter Site. For example, backfill testing by Asarco and the Environmental Protection Agency in connection with their remediation of homes in Ruston, Washington found arsenic concentrations in the backfill were generally less than 10 mg/Kg (where 10 mg/Kg was the method detection limit). Ecology testing of granular backfill sources during the Summer 1999 cleanup found arsenic concentrations ranging from 1.2 to 3.2 mg/Kg (Pearman, 1999). Ecology tested four topsoil sources as well during the Summer 1999 cleanup. While one source had concentrations of carcinogenic polyaromatic hydrocarbons above MTCA cleanup levels and was rejected for use as replacement topsoil, the three other sources had no concentrations of harmful substances exceeding regulatory levels. The arsenic concentrations in these four sources ranged from 2.4 to 7.8 mg/Kg (four samples, the highest concentration being in the rejected source). Hence, the concerns raised by the commentors may be substantially addressed in practice simply due to available sources of backfill and topsoil having arsenic concentrations well below the 20 mg/Kg cleanup level.

GQ 6.1.10
Should Ecology allow "three-in-one" soils containing biosolids to be used as topsoil? Should homeowners have the option of not accepting soils containing biosolids?

(11, 118, 389)

Response:
As discussed in the previous response, Ecology is requiring quality assurance testing of topsoil to ensure it does not contain concentrations of harmful substances above regulatory levels. Topsoil which will be used as replacement soil is manufactured from feedstock from a variety of sources, one of which may be biosolids.[17] *Quality assurance testing of imported soil is discussed in FCAP/FEIS Section 7.2.1.3.*

GQ 6.1.11
Will property-specific cleanup plans be developed in consultation with individual property owners?

(13, 31, 107, 108, 109)

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[16] It is estimated that 90% of soils in the Puget Sound area have an arsenic concentration of less than 7 mg/Kg arsenic (Ecology, 1994).
[17] Biosolids means municipal sewage sludge that is a primarily organic, semisolid product resulting from the wastewater treatment process that can be beneficially recycled.

Response:
As was discussed in Section 6.2.1.2 of the DCAP/DEIS, "property-specific cleanup plans will be developed in consultation with individual property owners and Ecology" to protect each property during remediation. Affected individuals, including owners, property managers, and renters, will be contacted individually when the time for remediation of their property approaches. Access agreements signed by the owner or other responsible individual must be obtained before any work will be done on site. Public involvement activities will provide advance notice on scheduling of cleanup of properties in individual neighborhoods of the site, on when property owners and tenants will be contacted, on requesting access permission and permission to clean up the site if cleanup is found to be necessary, and on developing property-specific cleanup plans.

As part of developing property-specific plans, underground utilities and oil tanks will be located and addressed. Contingency plans will also be developed for repairing underground utilities and oil tanks in case damage does occur.

GQ 6.1.12
Will Ecology provide a "disturbance coordinator" during the cleanup process?

(14)

Response:
Ecology staff contacts will be provided whom residents may contact regarding cleanup of their property. Ecology will have representatives in the field during the remediation as appropriate. It is anticipated that an Ecology representative will be on site frequently or even full-time at the beginning of cleanup activities. As cleanup continues, the time that Ecology staff are present at the site will be adjusted in response to the level of need.

GQ 6.1.13
How will the implementation of the cleanup action plan in the Upland Area of the Everett Smelter Site affect property values both during and after the cleanup?

(57, 67, 99)

Response:
Ecology recognizes the concern that many citizens have regarding how the implementation of the cleanup action plan for the Upland Area of the Everett Smelter Site may affect property values, both during and after cleanup. Property values may be impacted by many factors, including the presence of existing contamination, as well as the remediation of that contamination. Because existing contamination will be remediated as a consequence of implementing this cleanup action plan, Ecology anticipates that cleanup will have a long-term positive impact on property values. While Ecology recognizes the potential for short-term negative impact during cleanup, Ecology also anticipates that as the cleanup proceeds, prospective buyers will see that cleanup is occurring. After cleanup is completed at a property, disclosure of environmental

conditions to a prospective buyer, as required by real estate law, may be done with specific information about environmental conditions and safeguards at the property, as well as a statement that cleanup pursuant to Ecology requirements has been completed.

GQ 6.1.14
What protective measures should Ecology undertake to protect water mains from becoming contaminated with arsenic? What hazard is associated with drinking water contaminated with arsenic?

(106)

Response:
Engineering plans will provide measures to protect water mains during cleanup. As noted earlier, contingency plans will also be developed for repairing underground utilities in case damage does occur. Unless major damage occurs to the water main, Ecology does not expect contamination from surrounding soil, surface water, or ground water to occur. Because water mains are pressurized, leaks of water are outward from the main rather than inward, thereby protecting the main from contamination. If repair to a line causes tap water to be muddy after a repair is completed, the tap should be turned on and the lines flushed until the water runs clear.

Health effects associated with drinking water with elevated levels of arsenic are the same as for ingesting soil with elevated levels of arsenic: increased cancer risk and increased chance of organ damage. Risks increase as arsenic concentrations increase.

Note that the current Maximum Contaminant Limit (MCL) for arsenic in drinking water is 50 mg/L per the Safe Drinking Water Act. This MCL was set by the United States Public Health Service in 1943 based on short-term exposure effects. A recent National Research Council report recommended, "the current EPA MCL for arsenic in drinking water of 50 mg/L does not achieve EPA's goal for public-health protection and, therefore, requires downward revision as promptly as possible" (National Research Council, 1999, p. 7). Ecology's understanding is that the World Health Organization recommends a drinking water standard for arsenic of 10 mg/L, and that this concentration is used in much of Europe. The City of Everett advises Ecology that actual arsenic concentrations in drinking water supplied to the Northeast Everett area are less than the analytical detection limit of 1 mg/L (Mark Weeks, Everett City Water Information Service, personal communication).

GQ 6.1.15
How does Ecology plan to address arsenic that has been incorporated into building materials?

(100, 101, 102)

Response:
Ecology acknowledges the concern that some citizens have with arsenic that has been incorporated from the historic smelter site into building materials. Contaminated building materials will be addressed under the program of institutional controls. In particular, the identification, testing, management, and disposal of contaminated building materials should occur under the Small Quantity Soil Disposal Program and the Large Project Soil Disposal and Management Program. Those programs are discussed respectively in Sections 6.7.5 and 6.7.6 of the FCAP/FEIS. Ecology has specifically revised those two programs to include other materials, including slag, storm drain sediment, vegetation, building materials, and any other debris or material, that exceeds MTCA cleanup levels for the smelter contaminants of concern. When those programs are further developed as part of the engineering design phase, plans will incorporate how to assess when a citizen concern should trigger testing and the nature of that testing.

GQ 6.1.16
Should Ecology consider bioremediation as a viable remedial option in either the Former Arsenic Trioxide Processing Area or the Peripheral Area to address residential soil arsenic contamination?

(105)

Response:
Although various types of plants have been investigated for remediation of metals at contaminated sites, neither the Feasibility Study (Hydrometrics, 1995b) nor the Technical Work Group studies (TWG, 1998a and 1998b) included an evaluation of the use of plants as a viable remedial option. Bioremediation options are usually reserved for open areas that can be planted and left for significant periods. Concentrations within the Former Arsenic Trioxide Processing Area are too high to permit efficient bioremediation. Within the Peripheral Area, planting large areas with the type of vegetation used for bioremediation is not viable.

GQ 6.1.17
Should heating ducts be cleaned as well as carpets?

(283)

Response:
The Snohomish Health District noted that the DCAP/DEIS provided for the cleaning of carpets after remediation of the property, but did not provide for the cleaning of heating ducts. Ecology believes that heating ducts should also be cleaned of dust after remediation is complete to address potential hazards associated with inhalation of dust with elevated arsenic levels. The text of Section 6.2.1.2 has been revised to provide the following:

> *At the conclusion of remediation of a property, the resident will be provided the opportunity to have their carpets shampooed and air ducts cleaned. (Implementation note: It is envisioned that carpet cleaning and duct vacuuming services will be contracted for this work and the resident be provided vouchers valid for some time period. It will then be the residents responsibility to arrange for the cleaning, if they so choose, within that time period and to coordinate with the cleaning contractor.)*

The requirement to wet mop all floors has been removed as this is part of normal house maintenance.

Maintenance Areas Not Normally Occupied

GQ 6.1.18
How should maintenance areas not normally occupied that exceed the cleanup standard be sealed to prevent entry of animals?

(117, 328)

Response:
As was discussed in Section 6.2.3 of the DCAP/DEIS, Ecology recognizes the importance of protecting the health of people who enter maintenance areas not normally occupied, such as crawl spaces and utility access, where arsenic-contaminated soil and dust may be present. Ecology is also concerned that pets and other animals entering such areas may be exposed to arsenic contaminated soil and dust. Those animals could then spread contamination to yards and inside houses. Ecology determined that all maintenance areas not normally occupied which exceed the cleanup standard must be addressed by a program of institutional controls. As part of that program, Ecology determined that such areas must be sealed to prevent entry of animals. In particular, the DCAP/DEIS provided that "[a]nimals should be prevented from entry by a barrier sufficient to prevent entry by rats."

Ecology's highest concern is use of a contaminated area by a household pet that is then played with and cuddled by a young child. This could provide a direct pathway for contaminated dust to a child. Ecology specified rat-proofing because the necessary measures are both effective in preventing entry by household pets and are simple, cheap, and readily available. Routine measures to prevent entry of rats to buildings and other areas are available from the Snohomish Health Department in their pamphlet, "Rats – Lets Get Rid of Them." The pamphlet recommends keeping rats out of the home by keeping food inaccessible, removing potential shelter, and building them out. The rat-proofing Ecology envisions is included in the "Build Them Out" section of the pamphlet, and includes measures such as the following:

> *Close necessary openings such as windows, doors and ventilators with ¼ inch wire mesh (hardware cloth) ... cover all edges subject to gnawing*

> *with sheet metal or hardware cloth ... close unnecessary openings with concrete or sheet metal ... fit pieces of sheet metal around pipes to make a collar through which rodents cannot gnaw.*

These measures are expected to be simple, inexpensive to implement, and effective. Some maintenance will be required over time.

GQ 6.1.19
How did Ecology select the remediation level for maintenance areas not normally occupied?

(158)

Response:
As was discussed in Section 6.2.3 of the DCAP/DEIS, Ecology recognizes the importance of protecting the health of people who enter maintenance areas not normally occupied, such as crawl spaces and utility access, where arsenic-contaminated soil and dust may be present. Ecology selected the Method A industrial soil cleanup level of 200 mg/Kg arsenic in soil and dust as the maximum arsenic concentration allowable for short-term entry for brief inspections and repair without personal protective equipment (Ecology, 1999b). Ecology determined that institutional controls would not be sufficiently protective where contamination exceeds that remediation level.

GQ 6.1.20
How should the soil or dust located in maintenance areas not normally occupied that exceeds the remediation level be contained or removed?

(258)

Response:
As was discussed in Section 6.2.3 of the DCAP/DEIS, Ecology determined that a program of institutional controls alone would not be sufficiently protective where contamination exceeds 200 mg/Kg. Consequently, the cleanup action plan requires the following:

> *All maintenance areas not normally occupied containing soil or dust exceeding [200 mg/Kg] will have the soil contained or removed in some manner, such as by placement of a durable plastic barrier and/or application of materials to the soil surface which will prevent dust generation during work activities. The maintenance areas not normally occupied will be thoroughly cleaned of dust. Procedures to address maintenance areas not normally occupied on a site-specific basis will be developed in the Engineering Design Report.*

In other words, specific procedures to clean dust from maintenance areas not normally occupied will be developed during the engineering design phase.

One commentor noted that proper installation of any protective lining is important and that "all seams should be well lapped, taped and sealed to adjoining foundation walls." Specific installation procedures will be developed in the Engineering Design Report.

Independent Cleanup Actions

GQ 6.1.21
Should the independent cleanup actions conducted by the City of Everett on Marine View Drive and Legion Memorial Golf Course be acknowledged in and incorporated into the Cleanup Action Plan? Should Ecology issue a "No Further Action" letter for these projects?

(349)

Response:
FCAP/FEIS Section 6.2.4 discusses conducting independent cleanups on properties within the Upland Area of Everett Smelter Site and describes the status of independent cleanup reports submitted by the City of Everett regarding Marine View Drive and Legion Memorial Golf Course as of the date of issue of the FCAP/FEIS.

GQ 6.1.22
Should the independent cleanup actions conducted by Snohomish County at the Denney Youth Center be acknowledged in and incorporated into the Cleanup Action Plan? Should Ecology issue a "No Further Action" letter for this project?

(255)

Response:
FCAP/FEIS Section 6.2.4 discusses conducting independent cleanups on properties within the Upland Area of the Everett Smelter Site and describes the status of the independent cleanup report submitted by Snohomish County regarding the Denney Youth Center as of the date of issue of the FCAP/FEIS.

GQ 6.1.23
Under what circumstances may citizens implement cleanup actions on their property and be reimbursed?

(62, 490)

Response:
Property owners may conduct independent cleanup actions at their own expense and at their own risk at any time. While Ecology cannot reimburse property owners for independent cleanup actions, property owners may bring a private right action under

MTCA against any person liable under RCW 70.105D.040 for the recovery of remedial action costs. RCW 70.105D.080.

B6.2 Soil Cleanup Actions – Former Arsenic Trioxide Processing Area

Disposal of Problem Waste in the On-Site Consolidation Facility

GQ 6.2.1
Will Ecology develop the engineering design plans for the Consolidation Facility in cooperation with the Snohomish Health District?

(281)

Response:
Ecology will coordinate review of engineering design plans for the Consolidation Facility with the Snohomish Health District. Ecology will also consider the points raised by the District in the development of those plans.

GQ 6.2.2
Should the bottom liner of the Consolidation Facility consist of clay bedding?

(259)

Response:
Section 6.3 of the DCAP/DEIS required that the Consolidation Facility (problem waste landfill) be constructed and designed in accordance with the relevant and appropriate requirements of Chapter 173-304 WAC, Minimum Functional Standards for Solid Waste Handling. More specifically, in accordance with WAC 173-304-460(3)(c)(iii), Ecology determined that the "till will function as the bottom liner." One commentor suggested that till might not provide sufficient protection for the community. Ecology acknowledges the commentor's concern and has revised Section 6.3 to provide for the testing of the permeability of the till. If the till does not have sufficiently low permeability, installation of a low permeability bottom liner (such as clay or a geomembrane) shall be required.

GQ 6.2.3
Should the least-contaminated peripheral soils be placed in the Consolidation Facility to the extent possible? How could this be implemented?

(17, 23, 123, 331, 397)

Response:
Ecology agrees that the least-contaminated peripheral soils should be placed in the Consolidation Facility to the extent possible. This is reflected in Section 6.3 of the FCAP/FEIS, which states:

> *While short-term effectiveness dictates that problem waste from the Peripheral Area be consolidated to the degree possible within the Former Arsenic Trioxide*

> *Processing Area, long-term effectiveness dictates that problem waste with the lowest level of contamination be the waste brought to the Consolidation Facility.*

The general schedule set forth in Chapter 8 of the FCAP/FEIS also reflects that concept. In particular, the FCAP/FEIS states that subsequent to the Summer 1999 Cleanup,

> *[the] cleanup will continue outward from the Former Arsenic Trioxide Processing Area, the entire area within the Community Protection Measures boundary will be sampled, the Former Arsenic Trioxide Processing Area will be cleaned up and the Consolidation Facility constructed.*
>
> *Once the Consolidation Facility is constructed, cleanup of the least contaminated homes will be begun so that the least contaminated soil on site will be placed in the Consolidation Facility. Cleanup moving outward from the Former Arsenic Trioxide Processing Area will continue, with that soil being sent off site.*

Clarifying language has been added to Chapter 8, which states:

> *The Consolidation Facility can hold only a portion of the contaminated soil in the Peripheral Area. It is Ecology's intent and a requirement of this cleanup action plan that work be sequenced so that soils in the Peripheral Area farthest from the Former Arsenic Trioxide Processing Area and with the lowest concentrations of contaminants requiring remediation be placed within the Consolidation Facility.*

Note that cleanup will begin by removing and disposing off site the highly contaminated soil from the Former Arsenic Trioxide Processing Area. While cleanup of the Former Arsenic Trioxide Processing Area and construction of the Consolidation Facility progresses, the entire area within the Community Protection Measures boundary will be sampled. Once construction of the Consolidation Facility is completed, cleanup of the least-contaminated properties will begin. The concept is to work from the Former Arsenic Trioxide Processing Area outward and from the site boundary inward simultaneously, with as many crews as can be worked without causing undue impacts to the community. Construction operations should be sequenced so that crews work in different areas, so that the impact of multiple crews is minimized.

One commentor offered the opinion that grass grown in contaminated soil provides the same level of protection against contact as a cover which meets the minimum standards of Chapter 173-304 WAC, <u>Minimum Functional Standards for Solid Waste Handling</u>, a cover which requires at least two feet of soil.[18] *WAC 173-340-460(e)(i). Ecology disagrees. As discussed under **GQ 5.2.3** of this Responsiveness Summary, grass covers alone do not meet threshold requirements because grass covers do not provide sufficient containment of underlying contaminated soils to ensure the long-term protection of human health and the environment.*

[18] Except for inert waste, for which a one foot cover is required [WAC 173-304-461(6)].

Disposal of Problem and Dangerous Waste Off Site

GQ 6.2.4
Has Ecology evaluated landfill options for off-site disposal of problem and dangerous wastes other than the landfills at Roosevelt (for problem waste) and Arlington (for dangerous waste)? Has Ecology determined whether dangerous wastes might require stabilization prior to disposal at the designated sites?

(119, 384)

Response:
Disposal of problem waste at the Roosevelt Landfill and dangerous waste at the Arlington Landfill was assumed in the DCAP/DEIS in order to evaluate environmental impacts associated with the various alternatives proposed for cleaning up the site. The landfill in Arlington, Oregon was sited as a regional dangerous waste landfill to accept dangerous waste from throughout the Northwest. Ecology recognizes that alternative off-site disposal sites may be available. Ecology's reference to the Arlington or Roosevelt facilities was solely for the purpose just described. The FCAP/FEIS does not specify any particular destination for off-site disposal of contaminated materials removed during cleanup. The FCAP/FEIS simply specifies that disposal shall be at a facility permitted to receive such materials.

Ecology recognizes that dangerous waste may require stabilization prior to placement in a dangerous waste landfill. The need to stabilize dangerous waste will be evaluated as part of engineering design. Ecology anticipates that samples will be collected and sent to the proposed dangerous waste landfill to determine whether successful stabilization can be achieved and whether the landfill can accept the various waste materials. Ecology anticipates that any required stabilization will be performed at the proposed landfill.

Ecology also recognizes that the unit costs of disposal of dangerous waste materials off site may depend on whether those materials can be stabilized and disposed of at the proposed landfill without prior processing. Yet, while stabilization may entail additional cost beyond those costs evaluated in the Feasibility Study (Hydrometrics, 1995b), cost considerations arise only after the MTCA Cleanup Regulation's threshold requirements are met. Application of those threshold requirements requires the removal of dangerous waste from the site. In particular, off-site disposal is required to ensure the long-term protection of human health in a residential neighborhood. Materials that actually require stabilization, if any, are the ones most likely to contain high concentrations of hazardous substances. Consequently, they are precisely the materials that must be removed from the site to protect human health in a residential neighborhood.

GQ 6.2.5
Has Ecology adequately addressed the viability of disposing of non-soil materials within the Former Arsenic Trioxide Processing Area?

(159)

Response:
Section 6.3 of the DCAP/DEIS required the excavation and off-site disposal of all non-soil material, including identifiable smelter debris, housing foundation material, road and driveway material, utility pipes, rubbish, vegetation and wood debris, regardless of its arsenic concentration. One commentor suggested that such material should not be disposed of off site, regardless of its arsenic concentration. Ecology disagrees. These materials will be excavated along with the soil being excavated from within the Former Arsenic Trioxide Processing Area prior to construction of the Consolidation Facility. Disposal of all of these contaminated materials at a properly permitted off-site facility would be simpler and more efficient than stockpiling these materials until construction of the Consolidation Facility is completed. In addition, from an engineering design standpoint, disposal of such materials in the Consolidation Facility would reduce the amount of space available for the less contaminated soil from the distant Peripheral Area, requiring the less contaminated soil from the far Peripheral Area to be sent off site.

Future Land Use

GQ 6.2.6
What types of land use should be allowed within the Former Arsenic Trioxide Processing Area?

(7, 27, 42, 260, 338, 339, 340)

Response:
The City of Everett provided Ecology an analysis of land use and required changes to zoning and comprehensive plan designations as part of our ongoing discussions regarding the site. This analysis provides substantive local government requirements for land use changes within the Former Arsenic Trioxide Processing Area and has been incorporated into the FCAP/FEIS as Section 3.3.5.

In brief, the analysis indicates that the Off-Site Disposal alternative could be accomplished without changes in zoning and the comprehensive plan, but that construction of Consolidation Facility would require changes in zoning and the comprehensive plan. Siting an On-Site Containment Facility to contain dangerous waste and soil with high arsenic concentrations (>3,000 mg/Kg) does not meet substantive local requirements and cannot be allowed.

Construction of the Consolidation Facility will require the zoning and comprehensive plan designations to be changed from single-family, medium density use to mixed-use-commercial/community business use. It is expected that the City will take action in the future to implement these changes.

The land use analysis also included environmental impact mitigation measures required during construction of the Consolidation Facility and upon site re-use after the Facility is constructed. Specifically, during construction of the Consolidation Facility, a construction and traffic management plan must be developed and implemented, a landscape buffer installed to screen the construction site, a final site restoration plan must be developed and implemented, and institutional controls and monitoring must be developed and implemented.

After the Consolidation Facility is constructed, consideration of site re-use requires that the site be left oriented toward East Marine View Drive functionally in terms of access and visually in terms of similar land uses (commercial and industrial), that a substantial separation and sight obscuring landscaped buffer between building pads for future commercial/mixed use and the adjacent residential neighborhood must be installed and maintained, and that the necessary infrastructure to serve future redevelopment be installed and maintained. Any property-specific zoning changes would be processed at a later time.

Please refer to Section 3.3.5 of the FCAP/FEIS for more details.

GQ 6.2.7
How should future land use within the Former Arsenic Trioxide Processing Area be restricted to assure the continued protection of human health and the environment and the integrity of the cleanup actions? May Ecology restrict who may purchase or exert control over property?

(333)

Response:
Pursuant to the MTCA Cleanup Regulation, Ecology must impose restrictive covenants on property owned by a person who either has been named as a potentially liable person or meets the legal criteria for being named a potentially liable person in the following circumstances:

- *(a) where a cleanup action results in residual concentrations of hazardous substances which exceed method A or method B cleanup levels;*
- *(b) if conditional points of compliance have been established; or*
- *(c) where Ecology determines such controls are required to assure the continued protection of human health and the environment or the integrity of the cleanup action.*

WAC 173-340-440(1), -440(4)(a). With respect to the Former Arsenic Trioxide Processing Area, where construction of the Consolidation Facility will result in leaving problem wastes with arsenic concentrations of up to 3,000 mg/Kg within a densely populated residential area, institutional controls, in form of restrictive covenants or other administrative mechanisms, are necessary to assure the continued protection of human health and the environment and the integrity of the cleanup actions. Zoning and comprehensive plan designations will specify appropriate future land use within the Former Arsenic Trioxide Processing Area.

Language on page 93 of the DCAP/DEIS called for restricting future control of the Former Arsenic Trioxide Processing Area to control by either a single or a small number of organizations. The intent of this restriction was to ensure institutional controls are properly implemented and the Consolidation Facility properly maintained. As the commentor pointed out, there is no authority in MTCA for limiting those groups who may purchase or exert control over properties in the Former Arsenic Trioxide Processing Area, so long as any institutional controls and other ongoing requirements that Ecology may have the authority to impose are carried out by successors-in-interest. This language has been struck from the FCAP/FEIS.

GQ 6.2.8
Has Ecology accounted for the fact that future development of the Former Arsenic Trioxide Processing Area may be significantly constrained by the decisions of the current property owner?

(367)

Response:
Ecology recognizes that future development of the Former Arsenic Trioxide Processing Area will be constrained not only by the zoning decisions, comprehensive plan designations, and permit approvals of the City of Everett, but also by the decisions of the current and future property owners. Nonetheless, Ecology selected and developed cleanup actions for the Former Arsenic Trioxide Processing Area to ensure that the widest possible range of redevelopment options that are compatible with the zoning and comprehensive plan designations are available.

GQ 6.2.9
Has Ecology considered whether the disposal of problem waste in the Consolidation Facility would result in the abandonment of streets and utility easements?

(25, 122, 370)

Response:
Construction of a Consolidation Facility will require development of a detailed plan for final site grading and access. The plan may require abandonment of streets and existing utility easements, and potentially, development of new right-of-ways and utility easements. These considerations will be developed in detail in the Engineering Design Report and in coordination with the City of Everett.

GQ 6.2.10
Should the cleanup action plan for the Former Arsenic Trioxide Processing Area include a program of physical institutional controls to assure both the continued protection of human health and the environment and the integrity of the cleanup actions?

(18, 42, 332)

Response:
Section 6.3 of the DCAP/DEIS provided for a program of institutional controls that included physical measures to limit activities that that may result in exposure to hazardous substances at the site. One commentor suggested that such physical measures are "not part of a health-based cleanup." Ecology disagrees.

The MTCA Cleanup Regulation specifically provides that:

> *[Institutional controls]* ***shall*** *be required to assure both the continued protection of human health and the environment and the integrity of an interim action or cleanup action…[w]here a cleanup action results in residual concentrations of hazardous substances which exceed method A or method B cleanup levels…; [i]f conditional points of compliance have been established; or [w]hen [Ecology] determines such controls are required to assure the continued protection of human health and the environment or the integrity of the cleanup action.*

WAC 173-340-440(1) (emphasis added). The cleanup actions selected for the Former Arsenic Trioxide Processing Area include a problem waste landfill (Consolidation Facility) resulting in the disposal of problem wastes on site which exceed, potentially significantly, the applicable Method A or Method B cleanup levels. Because the Consolidation Facility is located in the middle of a residential neighborhood, Ecology has also determined that such controls are required to assure the continued protection of human health and the integrity of the cleanup action.

The MTCA Cleanup Regulation further provides that institutional controls specifically include "physical markers, such as fences and signs to limit activities that may interfere with the cleanup action or result in exposure to hazardous substances at the site." WAC 173-340-440(3)(a). To limit activities that may interfere with the integrity of the cleanup action and result in exposure to hazardous substances at the site, Section 6.3 of the DCAP/DEIS provided for the construction of an aesthetically pleasing fence meeting the approval of citizens and the placement of a granite monument on the site with a record of its former use, its current condition, and a reference of where to obtain further information.

To address citizen concerns with respect to the implementation of institutional controls within the Former Arsenic Trioxide Processing Area, Section 6.3 has been revised in the FCAP/FEIS to provide the following:

> *If no use has a planned construction start date within one year of closure, the site will be left in a condition and maintained in a manner which meets the approval of Ecology. Ecology shall consult with interested parties, including the Community Advisory Committee established as part of the Institutional Control Program, prior to giving such approval.*

This allows discussion among interested parties to attempt to arrive at mutually acceptable conditions for the condition and maintenance of the property.

As part of the overall program of institutional control measures for the Former Arsenic Trioxide Processing Area, the granite monuments play an essential role. They will provide a comparatively permanent record of the site's former use and a reference of where to get further information. Granite monuments are purchased regularly to serve as permanent signs. They are comparatively inexpensive,[19] *durable, and maintenance-free. Ecology does not intend that the monuments be obtrusive; rather, Ecology simply intends that they be placed where they can be noticed and have sufficient information on them to guide people to further information regarding the site, such as a reference to Ecology and Snohomish Health Department records. Ecology has revised Section 6.3 in the FCAP/FEIS to provide the following:*

> *Granite monuments shall be placed at each corner of the Consolidation Facility area with a record of its former use and a reference of where to get further information. The monuments will be placed at locations where they will be likely to be seen by future users of the land within the Former Arsenic Trioxide Processing Area.*

[19] Ecology contacted Flintoff's Monuments, 425-747-8989, for the purposes of obtaining an estimate and discovered that a granite slab 3" thick x 32" wide x 20" high could be purchased for prices ranging from $509 (Georgia gray granite) to $1072 (blue pearl granite). These prices include up to 34 engraved letters. Additional letters are $1.00 each. For more letters, a paragraph could be set as a design for a $75 to $100 charge. The gentleman providing the estimate said signs made of granite are often placed on a cinder-block base, then surrounded by rockery or bricks. Engraving a simple phrase such as "Northwest Corner of a portion of the former site of the Everett Smelter – Contact Snohomish Health District or the Washington State Department of Ecology for information on environmental conditions at this site" would alert people to check on site conditions. The cost of such monuments is insignificant in terms of overall project costs and in any case is cost effective compared to less durable types of signs.

B6.3 Ground Water Protection Measures

GQ 6.3.1
Has Ecology adequately considered and addressed the long-term pathways for contaminant movement, both downward through the till and laterally along the till, as part of the long-term design for the consolidation area? Should Ecology adopt an enhanced ground water monitoring system?

(26, 121, 386, 387)

Response:
In the selection of cleanup actions for the Former Arsenic Trioxide Processing Area, Ecology considered and addressed the long-term pathways for contaminant movement through ground water. Pathways for ground water migration from the Upland Area are downward from the surface to the till and then either horizontally along the fill-till contact or downward through the till to the advance outwash aquifer. In both cases, ground water eventually either emerges as springs to form surface water or flows to ground water underlying the Lowland Area. The FCAP/FEIS addresses contamination in the Upland Area. The Cleanup Action Plan requires that ground water which emerges as surface water must meet the cleanup levels based on protection of surface water (See FCAP/FEIS Section 4.1.3). Ground water flowing from the Upland Area to ground water in the Lowland Area will be addressed by actions taken to address contamination in the Lowland Area.

Performance and confirmational monitoring will ensure surface water is being protected. The detailed ground water performance monitoring plan will be developed as the cleanup actions are implemented. Section 7.2.4 of the FCAP/FEIS provides the following specifications:

> *The ground water performance monitoring plan will include installation of at least three sampling locations at the fill/till contact and at least three sampling locations in the advance outwash aquifer downgradient from the Consolidation Facility. The sampling locations will be monitored to see if any water is present and, if so, to evaluate its quality.*
>
> *In addition, sampling locations will be installed in the Peripheral Area to verify that ground water is not impacted by contamination remaining on site. Three sampling locations will be sited initially, one each on the north, west, and east sides of the Former Arsenic Trioxide Processing Area within Zone B as shown on Figure 7-1. Wells will be completed at the Fill/Till contact and in the advance outwash aquifer. If monitoring of these wells finds hazardous substances above cleanup levels, additional monitoring wells will be installed to evaluate the nature and extent of the contamination.*

Section 6.4 of the FCAP/FEIS provides that contingency plans will be developed so that remediation measures may be implemented in a timely manner if compliance monitoring detects ground water contamination. To further clarify this point, Section 7.2.4 has been further revised to provide the following:

> *If monitoring indicates that ground water impacts are occurring, contingency plans to remediate the impacts will be implemented. Such remediation may include additional soil removal, using all practicable methods of treatment of ground water where it emerges as surface water, and/or use of institutional controls.*

B6.4 Surface Water Protection Measures

GQ 6.4.1
Has Ecology adequately considered and addressed the impacts of ground and surface water contamination on the City of Everett's treatment facilities, including those impacts caused by the cleanup process itself?

(354)

Response:
Ground water cleanup levels are specified in Section 4.1.3 of the FCAP/FEIS. Surface water cleanup levels are specified in Section 4.1.4 of the FCAP/FEIS. Ground water cleanup levels have been set based on protection of surface water. Surface water cleanup levels for surface water entering the City of Everett's storm drain system have been set based on City of Everett standards for water influent to its system. These standards are set by the City of Everett to ensure that unacceptable impacts to their treatment system do not occur.

To address concerns of the City of Everett regarding the potential for lowering of pretreatment standards in the future due to requirements of the Endangered Species Act or any other requirement, Section 4.1.4 has been revised to provide the following:

> *If the City of Everett lowers pretreatment standards for the storm water sewer system in the future these lower standards must be met and additional remediation may be required. This requirement is the same as would be applied to any facility discharging to the storm sewer system upon lowering of pretreatment standards.*

Engineering controls will be developed during the engineering design phase of the cleanup to prevent unacceptable impacts due to the cleanup process itself. Ecology will work with the City to develop these controls.

GQ 6.4.2
Has Ecology adequately considered and addressed the impacts of the proposed Consolidation Facility's ground water interceptor trench on the City of Everett's treatment facilities?

(358, 359)

Response:
Water from both the ground water collection trench and from the Consolidation Facility's leachate collection trench is expected to discharge into the City of Everett's wastewater treatment system. Since the ground water collection trench will be upgradient from the Consolidation Facility, Ecology expects that the quality of water

discharging from that source will be acceptable for discharge into the City's wastewater treatment system. However, to ensure that water from both of these discharge points is acceptable for input into the City of Everett's wastewater treatment system, Ecology is revising Section 7.2.3 to provide for monitoring of these discharges.

In both cases, if monitoring indicates discharge water quality is such that it should not be allowed to enter the City's wastewater treatment system, pretreatment or other appropriate measures will be taken to ensure the water quality is acceptable at the point of discharge.

GQ 6.4.3
What control measures will be undertaken during the cleanup process to prevent surface water from recontaminating properties already cleaned up?

(103, 110)

Response:
Detailed planning for property remediation will include measures to prevent such recontamination from happening. This will include such considerations as remediating upslope properties first where practicable, and controlling runoff from properties being remediated.

B6.5 Storm Drain Sediment Cleanup Actions

GQ 6.5.1
How does Ecology plan to monitor compliance with the storm drain sediment cleanup standards?

(357)

Response:
Section 6.6 and Sections 7.2.5 and 7.3 of the FCAP/FEIS provide for the development of a performance monitoring plan for storm drain sediments. The plan will be developed in cooperation with the City of Everett and the Snohomish Health District during the engineering design phase of the cleanup. The purpose of the plan will be to evaluate whether cleanup actions at the site have adequately addressed storm drain sediment contamination or whether additional actions are required. This evaluation will also ensure that storm drain sediment will be managed in a manner that does not cause unacceptable impacts to the City of Everett's wastewater treatment facilities. As indicated in Section 6.6, storm drain sediment will be sampled beginning with cleanout points and points where sediment discharges from the storm sewer system nearest the Former Arsenic Trioxide Processing Area, then moving outward.

GQ 6.5.2
How does Ecology plan to manage and dispose of the contaminated storm drain sediment? Who will be responsible and financially liable for such disposal?

(357)

Response:
Where performance monitoring determines that sediment exceeds the cleanup levels specified in Section 4.1.5 of the FCAP/FEIS, Section 6.6 of the FCAP/FEIS requires that it be removed and sent to a properly permitted facility for disposal. Such a disposal facility can only be identified after the degree of contamination is determined. Responsibility for managing contaminated storm drain sediment, as well as determinations of financial responsibility, will be discussed in the legal instruments governing implementation of the cleanup. Again, storm drain sediment will be managed in a manner that does not cause unacceptable impacts to the City of Everett's wastewater treatment facilities.

Section 6.7.5 and Section 6.7.6 of the FCAP/FEIS provide the conceptual framework, respectively, for a small quantity soil disposal program and a large project soil disposal and management program. These programs have been revised in the FCAP/FEIS to include storm drain sediment. Detailed plans for implementing the soil disposal and management programs will be developed during the engineering design phase of the cleanup. The plans for implementing the program will be developed in cooperation with the City of Everett, the Snohomish Health District, and any interested citizens. All *material collected during the program will be sent to a facility permitted to accept soil with the levels of contamination found.*

B6.6 Institutional Controls

General Comments

GQ 6.6.1
Does the Cleanup Action Plan for the Upland Area of the Everett Smelter Site include a program of institutional controls that ensures both the continued protection of human health and the environment and the integrity of the cleanup action?

(18, 160, 263, 287, 381)

Response:
Section 6.7 of the DCAP/DEIS provided for a program of institutional controls that includes both physical and legal and administrative measures to limit or prohibit activities that may interfere with the integrity of a cleanup action or result in exposure to hazardous substances at the site. Though the commentors generally supported implementation of the proposed program, commentors also expressed various concerns that the program proposed by Ecology was, on the one hand, not sufficiently protective or, on the other hand, not reasonably related to the protection of human health and the environment. The program of institutional controls proposed by Ecology is necessary to ensure both the continued protection of human health and the environment and the integrity of the cleanup actions, as required by the threshold requirements of the MTCA Cleanup Regulation.

The MTCA Cleanup Regulation specifically provides that:

> *[A program of institutional controls]* ***shall*** *be required to assure both the continued protection of human health and the environment and the integrity of an interim action or cleanup action…[w]here a cleanup action results in residual concentrations of hazardous substances which exceed method A or method B cleanup levels; [i]f conditional points of compliance have been established; or [w]here [Ecology] determines such controls are required to assure the continued protection of human health and the environment or the integrity of the cleanup action.*

*WAC 173-340-440(1) (emphasis added). Those institutional controls, however, "****shall not*** *be used as a substitute for cleanup actions that would otherwise be technically possible." WAC 173-340-440(2) (emphasis added).*

For the Upland Area of the Everett Smelter Site, institutional controls are necessary to assure the continued protection of human health and the integrity of the selected cleanup actions.[20] *Selection of the Consolidation Facility alternative for the Former Arsenic Trioxide Processing*

[20] Discussion of Ecology's consideration of threshold and other requirements in the selection of cleanup actions for the Upland Area of the Everett Smelter Site is provided under **GQ 5.2.1 and GQ 5.2.2**.

Area will result in leaving problem wastes on the site with arsenic concentrations of up to 3,000 mg/Kg, which significantly exceeds the applicable cleanup levels. Moreover, because the problem waste landfill will be located in the middle of, and in close proximity to, a residential neighborhood, institutional controls are necessary to assure the continued protection of human health and the integrity of the cleanup action. Selection of the soil removal and containment remedy for the Peripheral Area will also result in residual contamination being left at depth both beneath the ground surface and in relatively inaccessible areas (e.g., beneath permanent structures and pavement) on site. Such contamination also requires the implementation of control measures to ensure the continued protection of human health.

To address the residual contamination in the Upland Area of the Everett Smelter Site, Ecology has developed a program of institutional controls that includes both physical measures and legal and administrative mechanisms. Each component of the program is reasonably related to ensuring both the continued protection of human health and the environment and the integrity of the cleanup actions. Physical measures, such as fences or signs, are designed to limit activities that may interfere with the cleanup actions or result in exposure to hazardous substances at the site. WAC 173-340-430(3)(a). Legal and administrative mechanisms are designed to limit site use or activities and to ensure that any physical measures are maintained over time. WAC 173-340-430(3)(b). The physical components of Ecology's proposed program of institutional controls primarily apply to the Former Arsenic Trioxide Processing Area and are discussed in Section 6.3 of the FCAP/FEIS and under ***GQ 6.2.10*** *of this Responsiveness Summary. The legal and administrative components of the program are discussed in Section 6.7 of the FCAP/FEIS, as well as in the following responses.*

GQ 6.6.2
Does the program of institutional controls proposed by Ecology provide the most cost-effective means of ensuring both the continued protection of human health and the environment and the integrity of the cleanup actions?

(160)

Response:
Ecology has determined that each of the institutional control measures or mechanisms proposed is necessary to ensure both the continued protection of human health and the environment and the integrity of the cleanup actions. Because the implementation plans for each of the controls has not yet been developed, the actual implementation cost for each control cannot presently be ascertained. However, as Ecology develops these plans in cooperation with citizens, the City of Everett, and the Snohomish Health District, Ecology will consider the cost-effectiveness of various implementation alternatives. It should be noted that the program of institutional controls proposed by Ecology in the FCAP/FEIS also does not assume that a particular entity will pay the costs. Determinations of financial responsibility will be discussed in the legal instruments governing implementation of the cleanup.

Again, the physical components of the program are discussed in Section 6.3 of the FCAP/FEIS and in the response to ***GQ 6.2.10*** *of this Responsiveness Summary. The legal and administrative components of the program are discussed more specifically in Section 6.7 of the FCAP/FEIS, as well as in the following responses.*

GQ 6.6.3
How does Ecology plan to implement the proposed program of institutional controls? Does Ecology intend to develop the plans and agreements necessary to implement the program in cooperation with the City of Everett, the Snohomish Health District, and citizens?

(18, 19, 124, 342, 343)

Response:
The FCAP/FEIS is a conceptual document that determines the components of the Cleanup Action Plan and their functional objectives. To the degree that detail is necessary to ensure that those functional objectives are met or that detail is known, such detail has been provided. However, more specific plans and agreements are required before the institutional controls can be implemented. These specific plans and agreements will be developed in cooperation with citizens, the City of Everett, and the Snohomish Health District during the engineering design phase of the cleanup. Ecology anticipates that interested parties will have representatives on the Community Advisory Committee, which is discussed in Section 6.7.11 of the FCAP/FEIS. Responsibility for operating, maintaining, and implementing the institutional controls will be discussed in legal instruments governing implementation of the cleanup. Chapter 8 of the FCAP/FEIS has been revised to include additional information regarding the further development of Ecology's program of institutional controls.

GQ 6.6.4
What is the implementation area for the program of institutional controls?

(98, 344)

Response:
Ecology's program of institutional controls will be implemented, as appropriate, throughout the area circumscribed by the Community Protection Measures boundary. However, that boundary may change as additional sampling data are collected and arsenic concentrations defined in greater detail. Where appropriate, institutional controls will differ for different areas of the site. For example, the physical measures will primarily apply to the Former Arsenic Trioxide Processing Area. Details of the Institutional Control Program will be developed during the engineering design phase of the project.

Specific Comments

Deed Covenants

GQ 6.6.5
Under what circumstances should restrictive covenants be placed in the deeds of properties?

(125, 402)

Response:
Restrictive deed covenants were discussed in Section 6.7.1 of the DCAP/DEIS. Commentors expressed some confusion with respect to the applicability of restrictive covenants. The following discussion is an attempt to clarify the issue.

The MTCA Cleanup Regulation provides the following:

> *For properties owned by a person who has been named as a potentially liable person or who has not been named a potentially liable person by the department but meets the criteria in RCW 70.105D.040 for being named a potentially liable person, appropriate institutional controls* ***shall*** *be described in a restrictive covenant on the property. The covenant shall be executed by the property owner and recorded with the register of deeds for the county in which the county is located. This restrictive covenant shall run with the land, and be binding on the owner's successors and assigns.*
>
> *For properties containing hazardous substances where the owner does not meet the criteria in RCW 70.105D.040 for being a potentially liable person, the department* ***may*** *approve cleanup actions which include restrictive covenants or other legal and/or administrative mechanisms. The use of legal or administrative mechanisms which do not include restrictive covenants is intended to apply to situations where the release has affected properties near the source of the release not owned by a person potentially liable under the act. Examples of such mechanisms include zoning overlays, placing notices in local zoning or building department records or state lands records, public notices and educational mailings.*

WAC 173-340-440(4)(a-b) (emphasis added).

Pursuant then to the MTCA Cleanup Regulation, restrictive covenants must be included in the deeds of properties owned by Asarco because Asarco has been named a potentially liable person. Ecology has not identified other persons as meeting the criteria for being named a potentially liable person. For those not meeting the criteria for being a potentially liable person – a category which is expected to include almost all land owners in the Peripheral Area – Ecology anticipates applying the legal and administrative *institutional control mechanisms described in the FCAP/FEIS to manage contamination left on site.*

The specific language of the deed covenants will be included in legal instruments governing the cleanup. WAC 173-340-440(5) describes what those covenants must include.

Permit Overlay

GQ 6.6.6
How does Ecology plan to implement the permit overlay program?

(90, 91, 345)

Response:
Section 6.7.2 of the FCAP/FEIS provides the conceptual framework for a permit overlay program. A detailed plan for implementing the permit overlay program will be developed during the engineering design phase of the cleanup. The plans for implementing the program will be developed in cooperation with the City of Everett, the Snohomish Health District, and any interested citizens.

GQ 6.6.7
For those redevelopment activities requiring permits, what are the applicable sampling requirements, and what agency has the responsibility for monitoring and ensuring compliance with those requirements?

(346, 347)

Response:
Applicable sampling requirements will be defined during the engineering design phase of the cleanup. Responsibility for monitoring and ensuring compliance will be discussed in the legal instruments governing implementation of the cleanup.

GQ 6.6.8
Under what circumstances are permits not required for redevelopment activities? For those activities not requiring permits, what institutional controls are applicable to ensure that the soil contamination profile does not exceed relevant standards?

(346)

Response:
Whether or not a permit is required for redevelopment activities can only be identified once the nature of the redevelopment activities are known. Institutional controls to ensure that the soil contamination profile does not exceed relevant standards will be

developed during the engineering design phase of the cleanup. The institutional controls will consider both redevelopment activities which require permits and those which do not.

Worker Protection Program

GQ 6.6.9
How does Ecology plan to implement the worker protection program?

(33, 350)

Response:
Section 6.7.4 of the FCAP/FEIS provides the conceptual framework for a worker protection program. A detailed plan for implementing the worker protection program will be developed during the engineering design phase of the cleanup. The plans for implementing the program will be developed in cooperation with the Community Advisory Committee, which will include the City of Everett and the Snohomish Health District.

GQ 6.6.10
Does Ecology plan on developing a health and safety plan?

(282)

Response:
A detailed health and safety plan will be developed during the engineering design phase of the cleanup.

Soil Disposal and Management Programs

GQ 6.6.11
How does Ecology plan to implement the soil disposal and management programs?

(35, 94, 351)

Response:
Section 6.7.5 and Section 6.7.6 of the FCAP/FEIS provide the conceptual framework, respectively, for a small quantity soil disposal program and a large project soil disposal and management program. Detailed plans for implementing the soil disposal and management programs will be developed during the engineering design phase of the cleanup. The plans for implementing the program will be developed in cooperation with the Community Advisory Committee, which will include the City of Everett and the Snohomish Health District.

GQ 6.6.12
Should the soil disposal and management programs also apply to slag and contaminated vegetation encountered in the Peripheral Area?

(32, 35)

Response:
Ecology recognizes that both citizens and local public entities may encounter slag deposits within the CPM boundary. To ensure that such materials are properly managed and disposed, Ecology has revised both the Small Quantity Soil Disposal Program (Section 6.7.5) and the Large Project Soil Disposal and Management Program (Section 6.7.6) so that they apply not only to contaminated soil, but also to slag and contaminated vegetation. Both sections have been modified to provide the following:

> *In addition to soil, the program shall include other materials, including slag, storm drain sediment, vegetation, building materials, and any other debris or material, that exceeds MTCA cleanup levels for the smelter contaminants of concern.*

Both programs are applicable to public entities, as well as private citizens. These programs will be further developed as part of the engineering design phase.

GQ 6.6.13
Should Ecology establish a soil testing program to provide information to employers, workers, and homeowners planning soil excavation and vegetation removal projects?

(34)

Response:
One of the first tasks which will be performed during a comprehensive implementation of the FCAP/FEIS is detailed sampling of the entire site, including sampling to finalize the site boundary. This program will provide information to those planning projects in the study area.

Public Education Program

GQ 6.6.14
How does Ecology plan to implement the public education program?

(261)

Response:
Section 6.7.7 of the FCAP/FEIS provides the conceptual framework for a public education program. Detailed plans for implementing the public education program will be developed during the engineering design phase of the cleanup. The plans for

implementing the program will be developed in cooperation with the Community Advisory Committee, which will include the City of Everett and the Snohomish Health District.

Effectiveness Evaluation

GQ 6.6.15
How does Ecology plan to evaluate the long-term effectiveness of the institutional controls?

(3, 88, 126, 284, 289, 380, 381)

Response:
Section 6.7.10 of the FCAP/FEIS provides the conceptual framework for an evaluation of the long-term effectiveness of institutional controls as part of the confirmational monitoring program. Specificity has been added to the conceptual framework regarding property resampling to evaluate the effectiveness of institutional controls in preventing recontamination due to site development or landscaping. Detailed plans for evaluating the long-term effectiveness of institutional controls will be developed during the engineering design phase of the cleanup. The plans will be developed in cooperation with the City of Everett, the Snohomish Health District, and any interested citizens.

Community Advisory Committee Program

GQ 6.6.16
How does Ecology plan to implement the community advisory committee program?

(80, 352, 379)

Response:
Section 6.7.11 of the FCAP/FEIS provides the conceptual framework for a Community Advisory Committee. Note that the name has been changed from the Citizen's Advisory Committee in the DCAP/DEIS to the Community Advisory Committee in the FCAP/FEIS to better reflect the composition of the committee, which will include local government representatives as well as citizens. Detailed plans for implementing the community advisory committee program will be developed during the engineering design phase of the cleanup.

Section 6.7.11 has been revised to provide further guidance regarding the composition of the committee, as follows:

> *It is anticipated the Community Advisory Committee will be comprised of representatives of local government, community groups, potentially liable persons, and Ecology. Those who participated in the mediation effort will be contacted by Ecology to ascertain if they wish to participate in the committee's initial efforts. These organizations are ASARCO Incorporated, City of Everett, Ecology, Everett Housing Authority, Northeast Everett Community Organization, Northwest Everett Neighborhood Association, Snohomish County, Snohomish Health District. Participation by any other interested organizations will be considered by Ecology.*

Financial Assurances

GQ 6.6.17
Who is responsible for funding the operation, maintenance, and implementation of the various institutional controls?

(92, 93, 127, 256)

Response:
Section 6.7.14 of the FCAP/FEIS requires financial assurances to ensure that continued funds are available for the operation, maintenance, and implementation of the various institutional controls. Determination of financial responsibility and the development of financial assurances will be discussed in the legal instruments governing implementation of the FCAP/FEIS.

GQ 6.6.18
Who is responsible for funding the operation, maintenance, and implementation of the various institutional controls prior to obtaining financial assurances?

(353)

Response:
At present ASARCO Incorporated is funding implementation of a Community Protection Measures Program as directed by Ecology Enforcement Order No. DE97TC-N119. As cleanup actions proceed, the specification of who pays for cleanup actions will be spelled out in the legal instruments governing implementation of the FCAP/FEIS.

Chapter B7 Compliance Monitoring

B7.1 Performance Monitoring

Community Protection Measures Boundary

GQ 7.1.1
What does Ecology currently know about the distribution of contamination within the Community Protection Measures boundary and what residential areas will be covered by property-specific testing?

(60, 64, 66, 95, 96, 207, 211)

Response:
Several citizens were interested in what is currently known about the distribution of contamination within the CPM boundary and whether property-specific sampling would occur on their property. Knowledge regarding the distribution of contamination within the top 18 inches of soil is summarized in Exhibits 2 and 3 of the DCAP/DEIS (revised to Exhibits 1 and 2 of the FCAP/FEIS). Residents may refer to those maps for summary information on the arsenic distribution. The complete database of all samples collected to date is kept by both Ecology and the Snohomish Health District. If you have questions on data on or in the vicinity of your home, contact Mike Young of the Snohomish Health District. Please be advised that because the current data is not based on property-specific testing, neither the database of samples nor the graphical representation of those samples may accurately reflect contamination at depth for any specific property.

Property-specific sampling will occur on all properties within the CPM boundary. As discussed under ***GQ 7.1.3*** *of this Responsiveness Summary such testing may also occur outside the current boundary as part of the site boundary study. There will be no charge to the homeowner/residents for this testing.*

GQ 7.1.2
Should the golf course be included in the Community Protection Measures boundary?

(58, 68)

Response:
Contamination has been identified at the Legion Memorial Golf Course. The golf course has been recently remodeled, and contamination issues were addressed during the remodeling. Much of the contamination is being managed on site. Hence, the golf course is included in the Community Protection Measures boundary.

GQ 7.1.3
Does Ecology plan to conduct a site boundary study to determine whether contamination extends beyond the current Community Protection Measures boundary? How does Ecology plan to conduct the site boundary study?

(1, 12, 167, 382)

Response:
As discussed in Section 7.2.1.1.6 of the FCAP/FEIS, a site boundary study will be conducted to determine whether contamination extends beyond the current CPM boundary. The final site boundary will determine where the cleanup actions required in the FCAP/FEIS are applicable. The site boundary will be defined by property-specific soil sampling conducted during implementation of the cleanup action plan. The specific plan outlined in Section 7.2 of the DCAP/DEIS has been revised based on comments received and subsequent discussions with interested parties. The plan outlined in the FCAP/FEIS Section 7.2.1.1.6 reflects those changes. If contamination is found farther from the site at a later time, it will be addressed in a separate action.

Plan for the Peripheral Area

GQ 7.1.4
What is the appropriate sampling methodology to identify those decision units in the Peripheral Area where soil arsenic concentrations exceed the cleanup and remediation levels?

(128, 162, 163, 165, 390, 391, 392, 393, 394, 396, 403)

- discrete sampling versus composite sampling (162, 163)
- variable sampling densities (392)
- variable number of decision units (392)
- variable depth intervals (396)
- property-specific testing (391)
- determination of decision unit boundary (390)
- exclusion zones to prevent confounding effects (393)
- analytical detection limit for soil arsenic samples (394, 128)
- alternate decision rule based on arithmetic mean (403)
- calculation of average concentration (165)

Response:
Comments on the sampling methodology concerned the details of the soil sampling plan. Subsequent to receipt of the comments, additional discussion was held with commentors. In addition, results of soil sampling conducted during the cleanup of the most contaminated homes in the Peripheral Area by Ecology in the summer of 1999 were considered. A draft overall soil sampling and analysis plan for the Peripheral Area was developed by Asarco under Ecology Enforcement Order No. DE97TC-N119 (Asarco,

1999), and comments on that draft plan were returned to Asarco by Ecology (Ecology, 1999d). Additional detail on sampling and decision rules based on these discussions, considerations, plans, and comments has been incorporated into the FCAP/FEIS at Section 7.2.1.1.

The site was divided into zones, and sampling depth and sampling density decrease outward from the historic plant boundary. Discrete samples are required to look for hot spots for homes within the historic plant boundary and in the zone just outside the historic plant boundary. In zones further out decisions are based on average values only. Review of data indicate that that the combination of the chances of having a hot spot exceeding remediation levels and the maximum concentration of hot spots which may be missed is acceptably low.

Samples collected in a decision unit will be composited by depth interval (0-6 inch, 6-12 inch, etc.). Decisions will be based on whether arsenic concentrations in composite samples exceed cleanup levels and remediation levels based on average arsenic concentrations. Compositing samples will provide a direct reading of average values (sample mean in statistical terms) and avoid the need to deal with samples in which arsenic was not detected. Within and adjacent to the historic plant boundary, if the average arsenic concentration in a composite sample is below the cleanup level or remediation level based on an the average value but high enough that hot spots cannot be ruled out, discrete samples will be collected and analyzed.

The overall soil sampling plan for the Peripheral Area included in the FCAP/FEIS represents a balancing of the chances of cleaning up a clean property, the chances of failing to cleanup a contaminated property, expressed citizen concerns to begin sampling as soon as possible, and cost of sampling.

See FCAP/FEIS Section 7.2.1.1 for a description of the plan.

GQ 7.1.5
Does the performance monitoring plan consider the potential for other urban sources of arsenic to influence residential soil concentrations?

(45, 50, 164, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427)

Response:
Ecology responded to previous comments on background soil arsenic issues in a memorandum entitled, "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999a – See Attachment B1-1). Those previously submitted comments used the Puget Sound regional soils data from Ecology's statewide background study (Ecology, 1994) to statistically estimate false positive error rates[21] for cleanup decisions, under certain sampling design and decision rule assumptions. Ecology noted that 5 of 52 values in the extracted Puget Sound regional data set, including the 4 highest values, were from a location significantly affected by Tacoma Smelter emissions (at Point Defiance Park). The range of soil arsenic concentrations in the 47 remaining samples was 1.1 to 11.3 mg/Kg, well below the MTCA Method A cleanup standard of 20 mg/Kg. Those regional data, omitting the biased Tacoma values, do not support the claim that there will be a significant false positives problem or that natural background arsenic concentrations exceed 20 mg/Kg. Ecology further noted that no site-specific soil background study had been performed for the Everett Smelter Site; that remains true.

Ecology's statewide soil background study did not target urban areas or developed parcels. Asarco submitted additional comments on background issues, noting several potential anthropogenic sources, other than smelter emissions, with elevated arsenic levels that could affect urban soils and in particular soils in Everett. Such urban sources would probably not have been reflected in Ecology's statewide background study. General "urban sources" identified included wood treated with chromated copper arsenic (CCA), arsenical pesticides and herbicides, and some soil nutrient amendments. A potential source affecting Everett in particular was identified, namely the past use of gravel mined in east Snohomish County that has elevated arsenic levels from naturally occurring arsenic geochemistry in the mining area. Asarco provided no data or analyses (e.g., from a sampling program in urban background area residential yards) to demonstrate how these potential urban sources might affect typical urban residential yard soils.

In the absence of a site-specific background study for the Everett Smelter Site, Ecology has compiled some relevant soils data and evaluated how typical yard soils might be affected by the other potential arsenic sources suggested in the comments. Ecology concludes that their effects are limited and that properly designed soil sampling protocols and decision rules will minimize cleanup of contamination that might be present at the site solely as a consequence of non-smelter related activities.

[21] The false positive error rate is the chance of cleaning up a property whose true average arsenic concentration is below the relevant cleanup level or remediation level, but for which sampling data, by chance, gives a sample average greater than the relevant cleanup level or remediation level. There is also a false negative error rate – the chance of failing to clean up a property at which remediation is required because, by chance, the samples collected at the property yield a sample average lower than the relevant cleanup level or remediation level whereas the true population average is actually higher than the relevant cleanup level or remediation level. Reducing one error rate increases the other.

Ecology acknowledges that arsenic occurs in various products and sources in consumer use, such as those identified in the comments. Ecology knows of no site-specific information which shows that any of these sources have, in fact, impacted the soils within the CPM boundary. Nonetheless, Ecology has evaluated the spatial scale of impacts from such potential sources. Available information strongly suggests that the spatial effects from those sources are limited, especially within the residential yard areas typically considered as an "exposure unit." Some of the identified sources are restricted in areas of application by their potential uses. Gravel, for example, has been used mostly on road shoulders and alleys, not in residential yards. Treated wood is typically used for fences, decks, or other structures that are present only in limited areas (and in many cases the areas under decks are inaccessible or little used). Studies have demonstrated that movement of arsenic from these sources into adjacent soils is limited. Stilwell and Gorny (1997) report that soil arsenic levels decreased by 85% only 15 cm from the perimeter of a treated wood deck and state that "the soil contamination can decrease to a great extent a short distance from the deck." Preliminary tests of soil beneath gravels with elevated arsenic concentrations in Everett showed there was "not a significant contribution...to underlying soil." An EPA study (for the Ruston/North Tacoma Superfund Site) of the mobility of arsenic from smelter slag used to cover residential driveways also noted that contamination of yard soils from the slag was not significant. These results suggest that the identified potential urban sources for arsenic, other than widespread application of arsenical pesticides or herbicides, are unlikely to cause significant increases in arsenic levels across a residential yard.

Ecology has also reviewed available data from urban soil monitoring programs. Carey et al. (1980) report the results of testing soils for arsenic (among other constituents) in five U.S. cities and their surrounding Standard Metropolitan Statistical Areas (SMSA). Samples were collected in 1972; the number of samples per community ranged from 51 to 189. The arithmetic and geometric mean soil arsenic concentrations are all well below 20 mg/Kg. Maximum concentrations are up to 158 mg/Kg, and exceed 100 mg/Kg in 3 of the 5 communities tested. However, the much lower arithmetic mean values suggest that the higher concentrations occur infrequently (complete data listings are not provided in the cited reference). A similar EPA study in the Tacoma, WA SMSA reported a maximum value in a rural sample of over 1,000 mg/Kg arsenic, perhaps the result of use of an arsenical pesticide or herbicide. These results suggest that occasional soil samples could be affected by an arsenic source such as the ones listed in the comments. It does not appear, however, that a significant fraction of samples is so affected. Other industrial sources for arsenic releases may also exist in these other cities (e.g., glass manufacturing, pesticide/herbicide production), contributing to the infrequent elevated values.

Ecology has identified several western Washington data sets that provide useful information for evaluating urban soil arsenic levels, including any effects from the suggested urban sources identified in the comments. General urban sources for arsenic such as treated wood, soil amendments, and pesticides and herbicides are as likely to occur in other western Washington cities as in Everett. Thus, soil arsenic data from *other communities without a dominant smelter source for arsenic provide relevant information on the frequency of elevated community soil arsenic levels. A recent study in Port Angeles (EPA, 1998b) included sampling in 21 residential areas; the range for soil arsenic was 1.2 to 16.2 mg/Kg (the ITT Rayonier site itself had some soil arsenic results at several hundred mg/Kg, and thus could have been a minor source of arsenic releases). Background soil samples were collected for the South Tacoma Field Superfund site in Tacoma (Kennedy/Jenks Consultants, 1992); 11 samples had a range of <1.3 to 12.6 mg/Kg (arsenic was elevated in soils at the South Tacoma Field site itself). The University of Washington Exposure Pathways Study (Polissar et al., 1987) included sampling in Bellingham to provide comparative "background" information; soil sampling at 10 residential yards resulted in a range for arsenic concentrations of 1.7 to 10.1 mg/Kg. The City of Seattle (Herrera Environmental Consultants, 1994) tested residential yard setouts ("clean green" recycling materials) from several different neighborhoods in Seattle; analyses for arsenic in 24 samples of root soils and loose soils in these yard setout materials showed a range of 6.9 to 18.6 mg/Kg (and precipitation chemistry studies by University of Washington researchers in the 1970s showed impacts on Seattle rainwater chemistry, including elevated arsenic levels, from Tacoma Smelter emissions). Thus, the 64 samples from these 4 studies show an overall range of about 1 to 19 mg/Kg soil arsenic (ignoring for the moment possible high bias in the results), all less than the MTCA Method A cleanup level of 20 mg/Kg. These results are consistent with the Puget Sound regional results from Ecology's statewide soil background study, as well as other available data (e.g., pre-application testing at biosolids application sites). None of these data sets indicates a significant frequency of residential yard soils elevated above 20 mg/Kg.*

Ecology also finds the results of the SAIC "peripheral soils" monitoring study at the Everett Smelter Site (SAIC, 1997) interesting with respect to urban soil arsenic levels. The SAIC study includes sampling in areas most distant from the former smelter facilities at Everett, among all available studies; it is not, however, a background study. Although the effects from other urban sources are likely to be confounded with effects from Everett Smelter releases in these data, Ecology notes that almost 90% of the 300 reported results are below 20 mg/Kg. The prevalence of low arsenic concentrations in the SAIC results suggests that the effects of other potential urban arsenic sources on residential soils are limited.

The comments note that historic use of arsenic herbicides has been proposed as the principal source for elevated residential soil arsenic levels in a community in Denver, Colorado, being studied for possible designation as a Superfund Site. Source identification issues there are under review by the regulatory agencies. Both the magnitude and spatial patterns in soil arsenic levels and historic research on the sale and use of arsenic herbicides in the community are advanced by Asarco as supporting the identification of arsenic herbicides rather than a nearby metals smelter as the source of the observed residential soil arsenic at the Denver site. Absent site-specific information for the Everett Smelter Site, the findings in Denver do not indicate that arsenical herbicides or pesticides have any significant effect on residential soil arsenic *levels in Everett. In fact, Ecology believes the available soils data for Everett suggest there is no widespread, significant effect from such sources; the available data are generally consistent with spatial patterns and gradients expected if the Everett Smelter was the primary source for currently observable soil arsenic.*

The comments also proposed that the other sources of urban soil arsenic will confuse the definition of a site boundary for a 20 mg/Kg cleanup standard. To the extent that their spatial impact is limited and general urban soils still do not exceed 20 mg/Kg (as suggested by the data reviewed above), this concern is of no practical importance. A site-specific background study would provide additional information to support the selection of a site boundary. Ecology also believes that it is typically the cumulative spatial pattern in soil arsenic results, rather than individual sample results, that support source identification and establishment of a site boundary. Thus, occasional results above 20 mg/Kg can be assessed with respect to their pattern of occurrence in considering boundary questions.

The comments noted that "clean" replacement soils at the Bunker Hill Superfund Site in Idaho are allowed to have up to 100 mg/Kg arsenic, indicating that the MTCA cleanup standard of 20 mg/Kg is inappropriate. It is important to note that the backfill soil quality criterion for arsenic at Bunker Hill was established soon after adoption of the 230 mg/Kg soil arsenic action level for the Ruston site, and considered that action level. That backfill soil criterion is now being re-evaluated and consideration is being given to the question of redoing soil cleanups at some residential properties at the Bunker Hill site because of soil arsenic concentrations (Ian von Lindern, TerraGraphics, personal communication with Gregory Glass). Ecology believes the available soils data for Washington do not support background arsenic levels higher than 20 mg/Kg; indeed, they may support lower levels. Ecology also notes that decisions made by EPA at Superfund sites have a different acceptable risk range than MTCA cleanup decisions, which can directly affect acceptable soil contaminant levels.

The comments also proposed that replacing soils marginally above 20 mg/Kg at Everett with backfill soils nearly at 20 mg/Kg arsenic would result in no appreciable benefits with respect to potential exposures. Commercial topsoils are available from a number of sources and are not generally regulated or required to be tested. Commercial topsoils include materials that are removed from sites undergoing development or redevelopment (not suitable for structural fill, or required to be removed due to grade requirements); some of those materials may have elevated concentrations of several constituents. It is also the case that some soil amendments used in developing commercial topsoils, including biosolids and compost derived from urban "clean green" programs, can have modestly elevated arsenic levels. However, Ecology's experience in conducting residential yard cleanup actions in Everett in the summer of 1999 demonstrated that backfill soils with arsenic concentrations well below 20 mg/Kg, and without significant concentrations of other contaminants, can be obtained at reasonable costs for use as backfill for excavated soils. Arsenic concentrations below 10 mg/Kg, consistent with Puget Sound regional background levels (Ecology, 1994), should be available. At those *levels, potential exposures from soils marginally above 20 mg/Kg arsenic would be reduced by more than 50 to 75%.*

The protocols for soil sampling selected for the Upland Area of the Everett Smelter Site (See FCAP/FEIS Section 7.2.1) will lead to cleanup decisions that minimize cleanup of contamination that might be present in the Upland Area solely as a consequence of non-smelter activities. For example, areas within a few feet of chromated copper arsenic (CCA) treated wood can be excluded from soil sampling, and information can be sought from residents on the use of herbicide or pesticide products or soil amendments that might contain arsenic. With respect to decision rules, Ecology notes the adoption of a simple arithmetic average (not a geometric mean, as stated in the comments) rather than a one-sided upper confidence level on the mean at this site as a statistic for determining whether cleanup actions are needed. This statistical approach has the result of reducing false positive error rates (the arithmetic average is always less than or equal to the UCL on the mean) compared to the standard MTCA statistics approach. Therefore, consideration of the effects of other "urban sources" for arsenic begins from a lower-than-normal false positive error rate for cleanup decisions.

GQ 7.1.6
How does Ecology propose to implement the sampling plan in the maintenance areas not normally occupied?

(129)

Response:
Performance monitoring for the Peripheral Area, including for maintenance areas not normally occupied, is discussed in Section 7.2.1.1 of the FCAP/FEIS. In maintenance areas not normally occupied – principally crawl spaces – up to four samples will be collected to a depth of 2" and composited. The resulting average arsenic concentration will be used to evaluate worker protection and remedial actions needed in crawl spaces.

GQ 7.1.7
What is the appropriate sampling methodology in non-residential areas to identify those decision units where soil arsenic concentrations exceed the cleanup and remediation levels? How does Ecology propose to implement the sampling plan in non-residential areas?

(21, 142, 376)

Response:
Performance monitoring for the Peripheral Area, including both commercial and recreational areas, is discussed in Section 7.2.1.1 of the FCAP/FEIS. The sampling plan for commercial and recreational areas is essentially the same as the plan for residential areas since each of these areas has been subject to soil disturbance caused by development. For commercial areas, the sampling density is the same as for residential

areas. For recreational areas, however, the sampling density will decrease because accessible soil in public areas is typically associated with open grassed or landscaped areas which have not undergone development activities as heterogeneous as residential and commercial areas.

Where property has not been disturbed by development, both sampling density and sampling depth will be less than that for residential, commercial, or recreational areas. In addition, because soil has not been disturbed on those properties, depth intervals will be 0-2" and 2-6" in the top 6 inches of soil. These depth intervals account for the greater potential for the 0-2" depth interval to contain greater concentrations of arsenic.

GQ 7.1.8
Does the performance monitoring plan for the Peripheral Area provide for the testing of all media of concern?

(283)

Response:
The Performance Monitoring Plan provides for monitoring of soil, ground water, surface water, and storm drain sediment. These are the environmental media of concern at the site. If other material such as that suggested by the commentor – vegetative waste, food harvested in the area – is of concern, it may be tested as part of the environmental monitoring program included in the institutional controls. This concern can be addressed by the Community Advisory Committee. Note that as discussed under ***GQ 6.6.12*** *of this Responsiveness Summary, the soil disposal and management programs, Sections 6.7.5 and 6.7.6 of the FCAP/FEIS, have also been revised to provide for the subsequent management of slag, storm drain sediment, vegetation, building materials, and any other debris or material that exceeds MTCA cleanup levels for the contaminants of concern.*

The commentor also suggests testing carpets and dust after house cleaning. Ecology considered testing the carpets and dust ***prior*** *to house cleaning and decided that simply performing the cleaning would likely be less expensive than the sampling. Ecology also judged that such cleaning would be sufficiently effective that further testing would not be necessary. If, during development of institutional controls, the Community Advisory Committee believes additional carpet and dust testing is necessary, such testing can also be incorporated into the environmental monitoring program.*

Air monitoring will be conducted as appropriate during cleanup as part of the Health and Safety Plan.

Plan for the Former Arsenic Trioxide Processing Area

GQ 7.1.9
How does Ecology plan to determine the limits of excavation within the Former Arsenic Trioxide Processing Area?

(2, 22, 217, 388)

Response:
The area within the Former Arsenic Trioxide Processing Area with arsenic concentrations exceeding 3,000 mg/Kg, as shown on FCAP Figure 2-3, will be excavated. Performance monitoring sampling will be conducted at a frequency of one location every 400 square feet. Sampling outside the area excavated will not be required, although sampling of excavation walls will be done and the excavation extended if contamination exceeding remediation levels is found.

This sampling program, combined with earlier results, is considered sufficient to define the area of arsenic concentrations exceeding 3,000 mg/Kg within the Former Arsenic Trioxide Processing Area which must be excavated. As with any statistical sampling program, some spots may be missed. However, the Consolidation Facility will cover the remaining soils with soils from the far Peripheral Area having some of the lower arsenic concentrations in the area and these contaminated soils will in turn be covered by a cover which meets the minimum standards of Chapter 173-304 WAC, Minimum Functional Standards for Solid Waste Handling.

One commentor noted that, "[d]ata from an interim action sampling site (IA-1; see RI report, Table 1-13, page I-30) near SAIC-S26 show increasing concentrations with depth, to a maximum of 3,100 mg/Kg arsenic at 23-25 inches; that location also appears to be beyond the intended excavation area." Asarco has reviewed the data and advises Ecology that sample IA-1 was a composite of five discrete samples collected around the residential property, inside and outside the area of smelter debris delineated in the Smelter Area Investigation Report. A single point was subsequently shown on maps developed for the project, indicating only the property sampled, rather than an exact sampling location. The value of 3,100 mg/Kg arsenic is believed due to collection of one of the samples used to make up the composite within the area of smelter debris.

Plan for Surface Water, Ground Water, and Storm Drain Sediment

GQ 7.1.10
Does the performance monitoring plan consider the potential for other urban sources of arsenic to influence surface water concentrations?

(168)

Response:
No such influences were described in the Remedial Investigation (Hydrometrics, 1995a) for the site. If surface water monitoring indicates there is a potential that urban sources of arsenic not related to contamination from the Everett Smelter are influencing surface water concentrations of contaminants, a program will be developed to evaluate whether such influences are indeed occurring.

GQ 7.1.11
Does the performance monitoring plan consider the potential for other urban sources of arsenic to influence storm drain sediment concentrations?

(169)

Response:
No such influences were described in the Remedial Investigation (Hydrometrics, 1995a) for the site. If storm drain sediment monitoring indicates there is a potential that urban sources of arsenic not related to contamination from the Everett Smelter are influencing storm drain sediment concentrations of contaminants, a program will be developed to evaluate whether such influences are indeed occurring.

B7.2 Confirmational Monitoring

GQ 7.2.1
How does Ecology plan to implement the confirmational monitoring program to ensure the long-term effectiveness of the selected remedies?

(3, 88, 126, 284, 289, 380, 381)

Response:
Section 7.3 of the FCAP/FEIS provides the conceptual framework for a confirmational monitoring program. Detailed monitoring plans will be developed during the engineering design phase of the cleanup in cooperation with the Community Advisory Committee. Any such plan must be in accord with WAC 173-340-820 and -830 and any other relevant and appropriate regulatory requirements or standards.

Several commentors were particularly concerned with whether the selected cleanup actions for the Upland Area of the Everett Smelter Site would be sufficiently protective of human health and the environment. Ecology recognizes that selection of the Consolidation Facility for the Former Arsenic Trioxide Processing Area and the soil removal and containment remedy for the Peripheral Areas requires an extensive set of robust institutional controls and monitoring to ensure long-term community protection from residual on-site contamination. Ecology considers those institutional controls and site monitoring as essential components of the overall protectiveness of the selected cleanup actions. Those controls should be subject to the same standards for demonstrating long-term effectiveness as any engineering measures would be. The Compliance Monitoring Program will be developed in consideration of these factors.

Moreover, site monitoring will continue as long as hazardous substances remaining on site exceed the specified cleanup levels. The cleanup levels are identified in Chapter 4 of the FCAP/FEIS, and are not to be confused with the remediation levels discussed in Chapter 6. Hazardous substances (arsenic, lead, cadmium, antimony, mercury, and thallium) which remain on site in concentrations above the specified cleanup levels, even though below an applicable remediation level, must be monitored to ensure containment continues to adequately protect human health and the environment.

GQ 7.2.2
Should the confirmational monitoring program consider the potential for new urban sources of arsenic to influence concentration levels?

(170)

Response:
If confirmation monitoring identifies new urban sources of arsenic as a potential influence on monitoring results, a program will be developed to evaluate whether such influences are indeed occurring.

GQ 7.2.3
What are the consequences of discovering through confirmational monitoring concentrations in excess of the applicable cleanup or remediation level?

(210)

Response:
To the extent that the contamination is identified during confirmational monitoring that was not identified earlier, it will be addressed as required by the provisions of the FCAP/FEIS.

Chapter B8 Schedule

GQ 8.1
What cleanup actions occurred during the summer of 1999 as part of the interim cleanup action?

(13, 63, 65, 75, 97)

Response:
During the summer of 1999 the most contaminated homes were cleaned up by Ecology. These homes included nine homes north of Broadway which were located within the historic plant boundary and one home south of Broadway on East Marine View Drive, which is just outside the southeast corner of the Former Arsenic Trioxide Processing Area. One homeowner within area north of Broadway declined remediation. The work was completed in September 1999.

GQ 8.2
Should Ecology provide pursuant to WAC 173-340-360(10)(a)(iv) a more comprehensive schedule of implementation of the cleanup action plan?

(16, 38, 285, 291, 348, 489, 491)

Response:
Legal instruments governing implementation of the cleanup actions will provide additional detail regarding the schedule for implementing the cleanup action plan.

GQ 8.3
How should the cleanup actions within the Former Arsenic Trioxide Processing Area be implemented and coordinated with the implementation of cleanup actions in the Peripheral Area?

(17, 23, 123, 331, 397)

Response:
The least-contaminated peripheral soils should be used as consolidation materials to the maximum extent practicable. This will require coordination of cleanup actions within the Former Arsenic Trioxide Processing Area and the Peripheral Area. This concept is reflected in Section 6.3 of the FCAP/FEIS, where Ecology states:

> *While short-term effectiveness dictates that problem waste from the Peripheral Area be consolidated to the degree possible within the Former Arsenic Trioxide Processing Area, long-term effectiveness dictates that problem waste with the lowest level of contamination be the waste brought to the consolidation facility.*

The general schedule set forth in Chapter 8 of the FCAP/FEIS also reflects that concept. In particular, the FCAP/FEIS states that subsequent to the Summer 1999 Cleanup,

> *[the] cleanup will continue outward from the Former Arsenic Trioxide Processing Area, the entire area within the Community Protection Measures boundary will be sampled, and the Former Arsenic Trioxide Processing Area will be cleaned up and the Consolidation Facility constructed.*
>
> *Once the Consolidation Facility is constructed, cleanup of the least contaminated homes will be begun so that the least contaminated soil on site will be placed in the Consolidation Facility. Cleanup moving outward from the Former Arsenic Trioxide Processing Area will continue, with that soil being sent off site.*

Clarifying language has been added to Chapter 8, which states:

> *The Consolidation Facility can hold only a portion of the contaminated soil in the Peripheral Area. It is Ecology's intent and a requirement of this cleanup action plan that work be sequenced so that soils in the Peripheral Area farthest from the Former Arsenic Trioxide Processing Area and with the lowest concentrations of contaminants requiring remediation be placed within the Consolidation Facility.*

Note that cleanup will begin by removing and disposing off site the highly contaminated soil from the Former Arsenic Trioxide Processing Area. While cleanup of the Former Arsenic Trioxide Processing Area and construction of the Consolidation Facility progresses, the entire area within the Community Protection Measures boundary will be sampled. Once construction of the Consolidation Facility is completed, cleanup of the least-contaminated properties will begin. The concept is to work from the Former Arsenic Trioxide Processing Area outward and from the site boundary inward simultaneously, with as many crews as can be worked without causing undue impacts to the community. Construction operations should be sequenced so that crews work in different areas, so that the impact of multiple crews is minimized. Because the Consolidation Facility can hold only a portion of the contaminated soil in the Peripheral Area, the FCAP/FEIS requires that work be sequenced so that soils in the Peripheral Area farthest from the Former Arsenic Trioxide Processing Area and with the lowest concentrations of contaminants requiring remediation be placed within the Consolidation Facility. The Consolidation Facility will be closed when it is full. Cleanup will continue until all properties within the Upland Area are addressed.

GQ 8.4
What is a reasonable restoration time frame? Has Ecology adequately considered those factors that might effect the restoration time frame?

(6, 30, 241, 242, 285)

Response:
There are about 600 residential properties within the CPM boundary. It is estimated that about 130 properties can be remediated during the construction season each year. This estimate is in accord with the rate at which Ecology found that homes could be remediated in Ecology's cleanup of ten properties in the summer of 1999. It is somewhat less than Asarco's projected residential cleanup rate at Ruston, which varies from 150 to 175 properties per year for the years 2000 to 2004 (Aldrich, 1999b).

Based on this rate, it would take about five years to clean up all residential properties within the CPM boundary. Of course, not all properties may need to be cleaned up.

Commercial areas have little accessible soil and cleanup of public areas should be comparatively rapid as they have little infrastructure on them compared to residential areas.

Other activities would be occurring during soil excavation, backfilling, and re-landscaping, including construction and filling of the Consolidation Facility, development and implementation of institutional controls, and other activities necessary to fulfill cleanup requirements. It is anticipated, however, that excavation, backfilling, and re-landscaping of accessible contaminated soils will be the activity that controls the length of time it takes to complete the cleanup.

As noted above, Ecology estimates that about five years will be required to excavate, backfill, and re-landscape accessible soils which require it. Allowing one year at the beginning for start-up activities and one year at the end for wrapping up the work, Ecology believes a reasonable restoration time frame from project start to finish is about seven years. This time frame assumes a coordinated, comprehensive approach to the project.

Chapter B9 General Support

Several commentors expressed general support for the DCAP/DEIS. These comments are presented in Attachment B2 under GQ 9.0. Typical of the comments were statements which supported the MTCA risk management decisions and statements requesting timely implementation of the cleanup actions.

(5, 8, 20, 36, 37, 61, 70, 71, 72, 73, 74, 76, 77, 78, 79, 81, 82, 83, 84, 85, 86, 87, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 208, 209, 210, 212, 213, 214, 215, 256, 262, 286, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 319, 320, 321, 322, 323)

Thank you for your comments. They are appreciated and noted.

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Everett Smelter Site
Integrated Final Cleanup Action Plan and Final Environment Impact Statement

Appendix B
Responsiveness Summary

Attachment B1

New Science Review
November 19, 1999

Table of Contents

<u>Note:</u> Comments relating to Topic 12 – *Risk of Remediation*, Topic 20 – *Grass as an Effective Cover*, and Topic 14 – *The Three Part Rule* from the previous review have been addressed in the main text of the Responsiveness Summary under GQ 5.1.23, GQ 5.2.3, and GQ 7.1.5, respectively.

List of Acronyms and Abbreviations

Asarco	ASARCO Incorporated
ATSDR	Agency for Toxic Substances and Disease Registry
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act – The federal Superfund law
DCAP/DEIS	Integrated Draft Cleanup Action Plan and Draft Environmental Impact Statement
DOH	Washington State Department of Health
Ecology	Washington State Department of Ecology
EPA	U.S. Environmental Protection Agency
FCAP/FEIS	Integrated Final Cleanup Action Plan and Final Environmental Impact Statement
IEUBK	Integrated Exposure Uptake Biokinetic model
MCL	Maximum Contaminant Level
MTCA	Model Toxics Control Act
mg/Kg	milligrams per kilogram (same as ppm)
ng/g	nanograms per gram
NRC	National Research Council
PAC	Policy Advisory Committee
ppb	parts per billion (same as µg/Kg and µg/L)
ppm	parts per million (same as mg/Kg and mg/L)
RCRA	Resource Conservation and Recovery Act
RME	Reasonable Maximum Exposure
SEPA	State Environmental Policy Act
TSCA	Toxic Substance Control Act
µg/Kg	micrograms per kilogram (same as ppb)
µg/L	micrograms per liter (same as ppb)
UW	University of Washington
WAC	Washington Administrative Code

Chapter B1-1 Introduction

B1-1.1 Overview and Conclusion

In July 1998, prior to the development of the DCAP/DEIS, Asarco submitted materials to Ecology requesting review under WAC 173-340-702(6) as new scientific information relevant to the establishment of cleanup levels for the Upland Area of the Everett Smelter Site. Asarco requested that, based on those materials, Ecology establish soil cleanup levels for arsenic and lead in the Upland Area different from those specified under Method A or B. Ecology, in collaboration with the Washington State Department of Health, reviewed and analyzed the information submitted by Asarco. Ecology's evaluation of Asarco's submittal was documented in two memoranda, "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999a – see Attachment B1-1) and "Decision Memorandum, Arsenic Concentrations at Depth and Considerations of Acute Toxicity" (Ecology, 1999b – see Attachment B1-2). Both documents were listed as supporting documents in DCAP/DEIS Section 1.4 and further discussed in DCAP/DEIS Sections 4.1 and 6.2. Based on a reasoned review of the information submitted (Ecology, 1999a), Ecology announced its preliminary decision that a **change in the soil arsenic cleanup level of 20 mg/Kg was not warranted**. The review did indicate, though, that setting lead cleanup levels for residential sites could be based on the Integrated Exposure Uptake Biokinetic (IEUBK) model, developed by the EPA. As discussed in Section 4.1 of the DCAP/DEIS, Ecology announced its preliminary decision to apply that model and allow for an **increase in the soil lead cleanup level from 250 mg/Kg to 353 mg/Kg**.

In February 1999 Asarco submitted comments on the DCAP/DEIS. Included with that submittal were comments on Ecology's evaluation of Asarco's July 1998 "new science" submittal, Ecology's preliminary decision regarding soil cleanup levels for lead and arsenic, and some additional materials for Ecology's consideration. Asarco requested that, based on those submitted materials, Ecology establish soil cleanup levels for arsenic and lead different from those proposed in Section 4.1 of the DCAP/DEIS. Ecology, again in collaboration with the Washington State Department of Health, conducted a thorough and reasoned review of all the information presented by Asarco, including both the July 1998 and February 1999 submittals. Based upon that review, Ecology has determined that Asarco did not submit clear and convincing scientific data regarding either toxicity or exposure parameters to warrant the establishment of a soil cleanup level for either arsenic or lead for the Upland Area of the Everett Smelter Site, different from those specified in Section 4.1 of the DCAP/DEIS. **Accordingly, neither the soil arsenic cleanup level of 20 mg/Kg nor the soil lead cleanup level of 353 mg/Kg specified in the DCAP/DEIS have changed.**

B1-1.2 MTCA Goals and History

The Model Toxics Control Act (MTCA) and the MTCA Cleanup Regulation provide that a safe environment is a fundamental right of individuals and that even sensitive individuals are to be protected from illness due to site-related contaminants. The statute was enacted by popular vote by the people of Washington State. The regulation was crafted by Ecology to enforce the principles of the law, and was adopted after extensive public comment. The goals, principles and, for the most part, framework of MTCA were recently reaffirmed through a legislatively-mandated re-evaluation by the MTCA Policy Advisory Committee (PAC), a broad-based group of stakeholders with many members representing groups responsible for causing and cleaning up environmental pollution.

B1-1.3 The Main Concern at the Everett Smelter Site

The main concern at the Everett Smelter Site is that people's health could be degraded and people could get sick (exhibit clinical illness) from exposure to the arsenic-contaminated soil. Whether or not a person will get sick depends on three things:

- how sensitive the person is to the effects of arsenic;
- how much exposure the person has to contaminated soil; and
- the arsenic concentrations in the soils to which the person is exposed.

Available information on the toxicity of arsenic, the amount of exposure people are expected to have to the soil, and the concentrations of arsenic in the soil suggests that illness could occur in people exposed to soil in the Upland Area of the Everett Smelter Site.

B1-1.4 Scientific Uncertainty

In order to provide effective public health protection at the Everett Smelter Site, it is important to determine how clean the soil should be before it is considered safe for people to live on. Cleanup is expected to protect thousands of people over thousands of years, each person with an unpredictable combination of susceptibility to the harmful effects of arsenic and behaviors leading to exposure. However, available scientific data pertaining to arsenic and lead toxicity and soil exposure have limitations that lead to uncertainty when applying them to the Everett Smelter Site.

In order to develop measures that effectively and reliably meet the goal of protecting public health, it is important to address this uncertainty. This involves policy choices that go beyond available science. The MTCA Cleanup Regulation contains policies that address scientific uncertainties, incorporating standard methods of using scientific information on toxicity and exposure to reliably protect public health. These methods are similar to those used by EPA and have undergone extensive scientific review. According to the MTCA Cleanup Regulation, different methods could be used if there are clear and convincing scientific data that these standard methods are inappropriate and that support an alternative approach to establishing cleanup levels. Scientific data submitted to Ecology, in support of changing the standard methods and assumptions, are judged according to this clear and convincing standard.

B1-1.5 Specification of the Soil Cleanup Level for Arsenic

Applying the MTCA Method B equations and incorporating the applicable toxicity and exposure information, as well as the acceptable cancer-risk of one in one million, Ecology determined that the risk-based soil cleanup level for arsenic would be 0.67 mg/Kg. However, this risk-based concentration is below background soil arsenic concentrations in Washington State. Accordingly, as discussed in Section 4.1.2 of the main text of the FCAP/FEIS, Ecology specified a soil arsenic cleanup level of 20 mg/Kg, the MTCA Method A cleanup level, which is based on background soil arsenic concentrations. Note that the background-based Method A cleanup level is 30-fold higher (and thus less protective) than the risk-based Method B cleanup level. Selection of the Method A cleanup level is appropriate because MTCA does not require contaminants to be cleaned up to below-background concentrations.

B1-1.6 Science and the Cleanup Level: Framing the Question

As discussed above, the soil arsenic cleanup level specified in Section 4.1.2 of the main text for the Upland Area of the Everett Smelter Site is 20 mg/Kg, which is based on an upper bound estimate of soil arsenic background concentrations in Washington State (Method A cleanup level), not the risk-based Method B equations. Several of the comments received questioned whether currently available scientific information relating to arsenic toxicity and soil exposure supports the use of the specified cleanup level of 20 mg/Kg. Note that the scientific information pertaining to arsenic toxicity and soil exposure is used to calculate the risk-based Method B cleanup level of 0.67 mg/Kg, not the 30-fold higher specified cleanup level of 20 mg/Kg. Accordingly, the appropriate baseline reference is the Method B cleanup level of 0.67 mg/Kg, not the Method A cleanup level of 20 mg/Kg. To demonstrate that the 20 mg/Kg cleanup level is overprotective, therefore, one must demonstrate with clear and convincing evidence that the exposure and/or toxicity values used by Ecology in the calculation of the Method B cleanup level are more than 30-fold overprotective. With this in mind, Ecology carefully evaluated the scientific basis for 20 mg/Kg as an appropriate soil arsenic cleanup level for meeting the goals of MTCA.

B1-1.7 Science and Policy in MTCA

As mentioned above, determining cleanup levels under MTCA (as well as in EPA's Superfund Program) is an inseparable mixture of science and public policy. The science consists of information related to toxicity and exposure. Science clearly shows that arsenic causes many different health effects at low doses and that exposure through soil ingestion does occur. Science can also be used to provide quantitative estimates of the hazards, although the estimates have a wide range. How the science is interpreted and used to derive these estimates is influenced by MTCA policies. With respect to cleanup levels, policy guides how to deal with uncertainties in scientific information, discusses the protection of individuals and not just populations (an important consideration when mathematically evaluating how protective to be), and sets the acceptable cancer risk level of one in one million. There is some flexibility in the science under MTCA, but little flexibility with respect to the risk level.

B1-1.8 Consequences of One in One Million Cancer Risk as a Surrogate for "Safe"

Some comments claim that several epidemiological studies (measuring either health effects or urinary arsenic levels in populations) have not found significantly increased hazards from arsenic in soil. One of the consequences of the one in one million excess cancer risk level is that data from available epidemiological studies cannot demonstrate that conditions are as safe as required by MTCA. The epidemiological studies are not powerful enough to detect a cancer risk of the size specified in MTCA and are not particularly responsive to the question of safety. Further, epidemiological studies to date have only evaluated one or a few of the multitude possible health effects of arsenic, and it is hard to draw reliable conclusions about harmful effects if they haven't been looked for. While sufficiently powerful epidemiological studies can be useful for identifying hazards, they are not particularly useful for demonstrating that conditions are safe from the cancer risks specified in MTCA. Quantitative risk assessment is better suited to evaluate whether or not conditions are safe.

The one in one million acceptable cancer risk level also explains why cleanups at a few EPA Superfund sites, such as the Ruston and Anaconda Smelters, did not require removal of soil until arsenic concentrations were well above 20 mg/Kg. Cleanup levels at Ruston and Anaconda were higher only because acceptable risk under Superfund can be higher than the one in one million specified under MTCA.

B1-1.9 Balancing of Uncertainties

The comment has been made that all available scientific evidence indicates that a cleanup level of 20 mg/Kg would be overprotective. This is not true. Although some assumptions or choices embodied in the MTCA Cleanup Regulation are conservative in nature, as described in the detailed responses, other assumptions or choices embodied in MTCA may underestimate risk.

B1-1.10 Lack of Site-Specific Data

One way to reduce scientific uncertainty is to gather reliable site-specific data. To the best of Ecology’s knowledge, this has not been done at the Everett Smelter Site. It is MTCA policy to make protective assumptions when using uncertain data. For example, the assumption by Ecology that relative bioavailability of arsenic from soil is 100% doesn’t necessarily mean that Ecology knows that to be the case. It means that, lacking reliable site-specific information (or a reliable method to obtain such information), it is a prudent assumption that will ensure the protection of public health.

B1-1.11 Quantitative Analyses

Asarco has cited certain information related to soil exposure and arsenic toxicity as indicating that the cleanup level should be well above 20 mg/Kg. The company neglected, however, to specify how the information should be applied to the Everett Smelter Site and by how much it indicates the cleanup level should be raised. While Ecology judged this information preliminary and less than clear and convincing, an exercise was conducted to evaluate whether the issues raised might result in a cleanup level exceeding 20 mg/Kg. Specifically, Ecology evaluated how factors related to soil exposure (seasonality, dust loading, and bioavailability) might influence the cleanup level. Further, since Asarco suggested that the best way to estimate arsenic toxicity would be to use EPA’s 1996 draft cancer guidelines, Ecology performed the actual calculations using EPA's guidelines. As detailed in the responses below, none of these assessments suggested that the cleanup level should be greater than 20 mg/Kg.

B1-1.12 Background Exposure to Arsenic

Some commentors pointed out that people are normally exposed to arsenic that is found in food, water and soil and speculated that exposure to the levels in such natural sources cannot possibly be harmful. Asarco provided no compelling evidence that background exposures are harmless. On the contrary, background levels of naturally occurring sunlight contribute to hundreds of thousands of cases of skin cancer in the United States every year. In any event, MTCA is concerned with the potential additional cancer risk, above the risk from background exposure, that exposure to elevated levels of arsenic in soil could cause.

B1-1.13 Specification of the Soil Cleanup Level for Lead

In contrast to most of the arsenic-related issues listed above, lead-contaminated soil poses its own, though much smaller, set of issues and challenges. Asarco requested an increase in the soil lead cleanup level. Ecology evaluated the non-site specific information submitted. Using EPA’s lead exposure model that is appropriate for the Everett Smelter Site, Ecology increased the cleanup level from 250 mg/Kg to 353 mg/Kg. Without site-specific data (Asarco did not provide any), Ecology used the model's default values when developing the cleanup level for the site.

B1-1.14 New Science Review Process and Procedures

In response to Asarco's prior request for Ecology to review materials submitted by Asarco as new scientific information, Ecology assembled a team of people to conduct a thorough and reasoned review of the company's submittal. That team consisted of two Ecology staff, one person from the Washington State Department of Health, and an independent environmental consultant. Attachment B1-1 of this Responsiveness Summary presents the results of the review of that prior submittal. In February 1999 Asarco submitted additional materials for Ecology's consideration, including comments on Ecology's evaluation of Asarco's July 1998 "new science" submittal, Ecology's preliminary decision regarding soil cleanup levels for lead and arsenic, and some additional materials for Ecology's consideration. The same Ecology team conducted the review of Asarco's February 1999 "new science" submittal. In addition to the review by the team, consultations were also made with regional and headquarters science and policy staff from the Environmental Protection Agency and other agencies.

The format and issues of this review are similar to the format and issues of Ecology's prior review. Based on the comments received, Ecology re-addressed many of the same issues presented by Asarco in July 1998 as well as addressing a few new ones. Similar to the manner in which comments were consolidated into generalized questions in the main text of the Responsiveness Summary, this review consolidates the comments received into general topics and provides a response. As noted in the Table of Contents, three issues were integrated with the main text of this Responsiveness Summary.

Asarco raised the issue of why Ecology has not taken this matter to its own Science Advisory Board (SAB). According to the MTCA Cleanup Regulation, the Board should be consulted on how to use new scientific information, not whether to use it. Ecology has and continues to consult with the Science Advisory Board when developing or amending the MTCA Cleanup Regulation and risk based cleanup levels, among other things. It should be noted that in the context of the soil cleanup for lead, Ecology consulted with the SAB in the context of a different site. The SAB consultation in that setting was drawn upon in selecting the soil cleanup level for lead for the Everett Smelter Site.

Ecology's review standard for the February 1999 submittal is the same as for the July 1998 submittal and is reiterated below:

The "New Science Review Team" has evaluated the issues submitted by Asarco by asking the following basic questions:

Is the information submitted by Asarco of a quantity and/or quality sufficient to persuade Ecology to select soil cleanup levels different than the levels identified *above (in background section) as the expected cleanup levels for lead and arsenic? Is the submitted information clear and convincing to make changes about what is protective?*

Evaluating the issues also involved consideration of additional factors, such as:

- *Is the information "new"? (i.e., is it information that was developed since the adoption of the cleanup standards in 1991?)*
- *Is the information "science" or "policy"?*
- *Where the information is "science," has the "scientific approach" advanced with respect to a particular issue been endorsed elsewhere? By other state regulatory agencies? By the EPA? By science advisory boards, such as Ecology's Model Toxics Control Act Science Advisory Board?*
- *Where the information is "policy," was a policy choice regarding how to use such information made by the agency when it promulgated its regulations in 1991?*
- *If yes, has new information been presented that suggests that the original policy choice should be revisited?*

B1-1.15 Conclusion

Ecology's calculation of cleanup levels is a combination of exposure factors, toxicity values, and acceptable risk. Ecology's cleanup level evaluation process is very similar to EPA's. Ecology's departure from EPA is the level of acceptable risk for carcinogens, which is defined in the MTCA Cleanup Regulation as one in one million. EPA's policy choice in Superfund is to allow for a risk range from one in one million up to one in ten thousand.

Scientific information and opinions were submitted by Asarco in an attempt to support the company's request for a change to the soil arsenic cleanup level of 20 mg/Kg. The quality of the scientific data submitted has been evaluated. MTCA requires a high degree of confidence that cleanups will result in safe conditions. The submitted scientific data had significant limitations and uncertainties. When evaluated and interpreted with an eye toward public health protection, the data did not show, in a clear and convincing fashion, that a soil arsenic cleanup level exceeding 20 mg/Kg would fulfill the goals of MTCA and adequately protect public health at the site. Information and opinions were also submitted to support an additional increase to the soil lead cleanup level of 353 mg/Kg. No site-specific data were submitted to support additional changes to the soil lead cleanup level.

Finally, it should be noted that this review of Asarco's February 1999 submittal supplements Ecology's review of Asarco's July 1998 submittal. For the purposes of addressing Asarco's February 1999 comments, this review encompasses some discussion and analyses similar to that discussed in the prior review. Hence, Ecology's review, evaluation, and ultimate decision on Asarco's “new science” submittal is documented by the discussions contained in both reviews.

Chapter B1-2 Toxicity Parameters for Arsenic

Asarco's Contention: Numerous aspects about arsenic's toxicity were not properly considered or evaluated by Ecology including: mode of action, uncertainties in epidemiological studies, difference between Taiwanese and U.S. populations, essentiality, and methylation.

B1-2.1 Introduction

In its comment letter of February 25, 1999, and attachments (Asarco, 1999), Asarco reiterated its assertions related to arsenic toxicity made in its July 1998 submittal. Based on its interpretation of certain scientific information Asarco states that EPA's cancer slope factor, the measure of arsenic toxicity used by Ecology and EPA to develop cleanup levels for hazardous waste sites, "cannot be used for quantitative risk assessment." As was discussed in Section 4.1.2 of the DCAP/DEIS, the soil arsenic cleanup level specified for the Upland Area of the Everett Smelter Site is 20 mg/Kg, which is based on background concentrations in Washington State (Method A cleanup level), not the risk-based Method B equations. The Method B soil arsenic cleanup level of 0.67 mg/Kg calculated using the cancer slope factor is below the established background concentration and 30-fold more protective.

Asarco has not specified what it believes to be an appropriate measure of toxicity for arsenic, but instead suggests only that EPA's cancer slope factor is overprotective and should not influence cleanup of the Everett Smelter Site. Asarco's main contentions related to arsenic toxicity have not changed from those in its July 1998 submittal. An evaluation of Asarco's comments and submitted information has not changed Ecology's conclusion that EPA's cancer slope factor for arsenic is an appropriate measure of arsenic toxicity on which to base decisions regarding a residential soil cleanup level for the Everett Smelter Site. Previous comments contained in Ecology's document "Review of Asarco's 'New Science' Submittals Regarding Arsenic and Lead" (Ecology, 1999) still apply. Ecology's conclusion find further support in the conclusions documented in a report issued by the National Research Council (NRC) in 1999, entitled "Arsenic in Drinking Water" (NRC, 1999).

The NRC report was the result of a request by EPA to evaluate available scientific information on arsenic toxicity, which included many of the same scientific articles that Asarco provided to Ecology in its July 1998 submittal. As explained in the report: "The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters." "The

National Research Council was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purpose of furthering knowledge and advising the federal government." (NRC, copyright page) With respect to the subcommittee on arsenic in drinking water, "[t]he members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance." (NRC, copyright page) The subcommittee was composed of 16 members (including Kenneth G. Brown who was one of six experts contributing to Asarco's July 1998 submittal), and the report was reviewed by 13 individuals (including Joyce Tsuji, who also contributed to Asarco's July 1998 submittal) to "assist the NRC in making the report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge." (NRC, p. xii) As detailed below, the subcommittee made many of the same general conclusions as made by Ecology.

The responsibilities of the subcommittee were described in the report. "In 1996, EPA's Office of Water requested that the National Research Council (NRC) independently review the arsenic toxicity data base and evaluate the scientific validity of EPA's 1988 risk assessment for arsenic in drinking water. The NRC assigned this project to the Committee on Toxicology (COT), which convened the Subcommittee on Arsenic in Drinking Water, whose membership includes experts in toxicology, pharmacology, pathology, chemistry, nutrition, medicine, epidemiology, risk assessment, and biostatistics. The subcommittee was charged with the following tasks: (1) review EPA's characterization of human health risks from ingestion of arsenic compounds found in food and drinking water and the uncertainties associated with that characterization; (2) review available data on cancer and non-cancer health effects from exposure to arsenic compounds in drinking water and the implications of these effects on the assessment of the human health risks from arsenic exposure; (3) review data on the toxicokinetics, metabolism, and mechanism or mode of action of arsenic and ascertain how these data could assist in assessing human health risks from drinking-water exposures; and (4) identify research priorities to fill data gaps. EPA did not request, nor did the subcommittee endeavor to provide, a formal risk assessment for arsenic in drinking water." (NRC, pp. 1-2)

"The subcommittee evaluated data relating to key elements of the risk-assessment process - hazard identification, dose response, and risk characterization - that addresses the protective nature of the current maximum contaminant limit (MCL) specified in the Safe Drinking Water Act for arsenic in drinking water. Specifically, the subcommittee reviewed information on the health effects of arsenic exposure and data on the disposition and the mechanism or mode of action of arsenic. The subcommittee also evaluated other information that could affect the risk assessment, such as variations in human susceptibility, and current capabilities to measure arsenic in various media, including biological tissue." (NRC, p. 2)

As with most problems involving human health, the estimation of arsenic toxicity is extremely complex. The available scientific information addressing this problem is somewhat limited in scope and this results in numerous data gaps and uncertainties. These uncertainties are acknowledged and discussed throughout the NRC report. Despite these uncertainties, the subcommittee determined that there is sufficient evidence that exposure to low levels of arsenic represents a significant public health concern and should be addressed.

The comments and information submitted by Asarco that relate to arsenic toxicity can be summarized into the following categories:

- mode of action;
- uncertainties in epidemiological studies;
- differences between the Taiwanese and U.S. populations;
- essentiality; and
- methylation/detoxification.

The exact toxicity of arsenic at low doses is not known, but can be estimated from toxicity observed at higher doses. The issues raised by Asarco, as well as other issues it did not raise, could be important because they might influence how arsenic toxicity is estimated at low doses. Asarco states that "all of the evidence points to a lesser rather than greater risk from arsenic." As discussed below, this is not the case. Further, when the NRC subcommittee performed sample calculations to quantify arsenic toxicity, it did not incorporate the type of evidence cited by Asarco, mostly due to scientific uncertainties and inadequacies in the information.

Summarized below are Asarco's comments on specific factors related to its evaluation of arsenic toxicity, and corresponding comments by the NRC subcommittee and Ecology on the same topics. The comments chosen from the NRC report are brief and not intended to cover the full range of discussion presented in the report on these issues. However, Ecology believes that these comments reflect overall consensus conclusions reached by the subcommittee.

B1-2.2 Mode of Action

Asarco comment: "Arsenic is not a cancer initiator and does not cause inheritable DNA damage. There is no known biological mechanism by which arsenic could have the linear no-threshold effect that Ecology and the Method B formula assume."

Related NRC comments: "Data on the modes of action for carcinogenicity can help to predict the shape of cancer dose-response curves below the level of direct observation of tumors. For arsenic carcinogenicity, the mode of action has not been established, but the several modes of action that are considered most plausible (namely, indirect mechanisms of mutagenicity) lead to a sublinear dose-response at some point below the level at which a significant increase in tumors is observed. However, because a specific mode (or modes) of action has not been identified at this time, it is prudent not to rule out the possibility of a linear response." (NRC, pp. 213-214) "Information on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity. Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity cannot be ruled out. In vitro studies of the genotoxic effects of arsenic indicate that changes in cellular function related to plausible modes of carcinogenesis can occur at arsenic concentrations similar to the current MCL. However, the subcommittee believes that those data and the confidence with which they can be linked to arsenic-induced neoplasia are insufficient to determine the shape of the dose-response curve in the low-dose range (point of departure)." (NRC, pp. 7-8) "In vitro studies of human and animal cells show that the genotoxic effects occur at submicromolar concentrations of arsenite that are similar to those found in urine of humans consuming drinking water at about the current MCL." (NRC, p. 214) "Studies of lung cancer among workers exposed to airborne arsenicals indicate a linear dose-response over a broad range of exposure." (NRC, p. 130)

Ecology response: There are several different modes of action that may operate alone or together to produce arsenic induced cancers. Proposed modes of action include:

- Genotoxic effects including chromosomal abnormalities and arsenic induced aneuploidy;
- Arsenic induced abnormalities in the methylation of DNA;
- Arsenic induced oxidative stress with the production of reactive oxygen species;
- Arsenic induced effects on cell proliferation; and
- Concurrent exposures to other carcinogens (e.g., cigarette smoke and ultraviolet irradiation) may result in a co-carcinogenic response.

While some, all of the above, or other modes of action yet to be discovered may contribute to the development of arsenic induced cancer, the mode or modes of action for arsenic carcinogenicity has not been conclusively established (NRC, 1999; ERG, 1997). The Toxics Cleanup Program will continue to rely on information from EPA, supported by the National Research Council and others, to help select technically supportable and protective cleanup standards for arsenic. For risk based decisions related for the protection against arsenic-induced cancers, the Toxics Cleanup Program will continue to rely on the Integrated Risk Information System and use the Cancer Potency Factors as appropriate. EPA maintains that "there is no convincing evidence that a threshold exists."

(Gibb, 1997) If a threshold did exist then the threshold would have to occur within a very narrow range of exposure. (Gibb, 1997) While the dose-response curve for arsenic could have a threshold and/or nonlinear regions, it is not clear whether, or how this would affect calculated arsenic toxicity at doses relevant to the Everett Smelter Site. The statements in the NRC document suggest that an assumption of linearity remains a scientifically valid choice given current scientific evidence.

B1-2.3 Uncertainties in Epidemiological Studies

Asarco comment: "The assumed levels of exposure and rate of cancer incidence are now understood to be inconsistent with actual exposures and cancer incidence experienced among the Taiwanese population on which the calculations are based." (Asarco, p. 27)

Related NRC comments: "New information related to EPA's estimate of lifetime risk of skin cancer from arsenic, however, has added additional uncertainty to the sources used in the EPA report. In particular, it has been learned that arsenic exposure among persons and villages grouped together in the data reported in the Tseng study is more variable than previously realized. This variability might be largely accounted for by Tseng's creation of an undetermined category, but the specifics are unclear." (NRC, p. 25)

Ecology response: Ecology agrees that there is some degree of uncertainty with respect to exposure in the Taiwanese studies. While this may make estimates of toxicity based on these data less certain, it does not necessarily indicate that they are incorrect. The information presented by Asarco may add to the uncertainty, but it doesn't provide a clear indication of whether estimates of toxicity derived from the studies are too high or too low, or by how much.

B1-2.4 Differences between Taiwanese and U.S. Populations

Asarco comment: "In addition, the database indicates that the Taiwan data is likely inapplicable to the U.S. population because of differences in diet between the populations and exposure to other chemicals in Taiwanese drinking water." (Asarco, pp. 27-28)

Related NRC comments: "No information is available on how responses to arsenic toxicity are modulated by the nutritional status of individuals. For example, there is disagreement among investigators concerning the nutritional status of arsenic-exposed subjects with blackfoot disease, mainly because of the lack of proper studies (Yang and Blackwell, 1961; Engel and Receveur, 1993; Hsueh et al., 1995)." (NRC, p. 238) "It is plausible, but not proved that poor diet substantially exacerbates the toxicity of arsenic. Much more work is needed to draw any definitive conclusions about the role of specific dietary components in the manifestations of arsenic toxicity." (NRC, p. 243) "Human susceptibility to adverse effects resulting from chronic exposure to inorganic arsenic is likely to vary based on genetics, nutrition, sex, and other possible factors. Some factors, such as poor nutrition and arsenic intake from food might affect assessment of risk in

Taiwan or extrapolation of results in the United States." (NRC, p. 8) "The contribution to arsenic intake from dietary sources could not be factored into the dose-response assessment for Taiwan or the extrapolation to the United States because of insufficient information on arsenic in food. Limited data on dietary arsenic intake in the blackfoot-disease region now available suggests that arsenic intake from food is higher in Taiwan than in the United States, although more data and improved quantification are needed for confirmation." (NRC, p. 24)

Ecology response: The information provided by Asarco on differences between the Taiwanese and U.S. populations is speculative with respect to its effect on arsenic toxicity. More and better information is needed to establish whether and how these differences influence the hazards of arsenic.

B1-2.5 Essentiality

Asarco comment: "Arsenic is a demonstrated essential element in animals and there is strong evidence that it is likely essential to humans as well." (Asarco, p. 28)

Related NRC comment: "Arsenic has not been tested for essentiality in humans, nor has it been found to be required for any essential biochemical processes. Arsenic supplementation at very high concentrations (e.g., 350-4,500 nanograms per gram (ng/g)) in the diet has been shown to affect growth and reproduction in minipigs, chicks, goats, and rats." (NRC, p. 3) "Future studies on the beneficial effects of arsenic in experimental animals should carefully monitor the amount and speciation of arsenic in diets and water, use biomarkers to assess arsenic exposure and bioavailability, and use techniques that assess the toxicity and benefits of arsenic in a more specific manner than is possible through measurement of growth and reproductive success. In humans, the concentration of arsenic in total parenteral nutrition (TPN) should be determined by validated analytical methods and related to the health status of patients on long-term TPN." (NRC, p. 3)

Ecology response: Lacking appropriate studies in humans and a demonstrated requirement for an essential biochemical process, the information provided by Asarco cannot be considered clear and convincing evidence that arsenic is an essential element in humans.

B1-2.6 Methylation

Asarco comment: "Humans methylate inorganic arsenic to organic forms that are quickly excreted through urine. Current science views this as a de-toxifying mechanism that is inconsistent with the view that any arsenic exposure is potentially harmful, the assumption built into the Method B formula." (Asarco, p. 28)

Related NRC comments: "Humans and some animals methylate inorganic arsenic to forms that are less acutely toxic and more readily excreted…. The methylation of ingested arsenic is not inhibited or overloaded, unless acutely toxic doses are ingested. Substantial variations in the fractions of methylated forms of arsenic in urine are also known to occur among different populations and individuals within the same exposed population. Such variations might be indicative of genetic differences in the enzymes responsible for the methylation of arsenic. Methylation of arsenic might also be influenced by such factors as the arsenic species absorbed, high acute doses, nutrition, and disease. The extent to which variation in arsenic methylation affects its toxicity, including carcinogenicity, is not known." (NRC, p. 4)

Ecology response: The effect of methylation on the shape of the dose-response curve for arsenic cannot be predicted for arsenic doses relevant to the cleanup of the Everett Smelter Site.

B1-2.7 Important Issues Not Raised by Asarco

Two important factors that could bear on any evaluation of arsenic toxicity are the finding that arsenic causes bladder and lung cancer (not just skin cancer, the only effect quantified in the EPA's cancer slope factor) and the variability in peoples' susceptibility to the adverse effects of arsenic. Consideration of these factors, not discussed by Asarco in its "New Science Submittal," could lead to the conclusion that EPA's cancer slope factor could underestimate arsenic toxicity.

B1-2.7.1 Internal cancers caused by arsenic

NRC comments: "Ingestion of inorganic arsenic is an established cause of skin cancer. Recent studies strengthen the evidence that ingestion of arsenic can also cause cancers of the lung and the urinary bladder. Based on findings of increased risk of bladder- and lung-cancer mortality in three countries (Taiwan, Argentina, and Chile), the subcommittee believes that the evidence is now sufficient to include bladder and lung cancer among the cancers that can be caused by ingestion of inorganic arsenic." (NRC, p. 130)

Ecology comment: Ecology raised this issue in its previous response. (Ecology, 1999) EPA's current cancer slope factor considers only skin cancer. It could be underprotective if all forms of arsenical cancer were considered.

B1-2.7.2 Variability

NRC comments: "A wider margin of safety might be needed when conducting risk assessments of arsenic because of variations in metabolism and sensitivity among individuals or groups." (NRC, p. 244) "Variability in response to arsenic might have its origin in one or a number of intrinsic or extrinsic factors, many of which affect the body's ability to methylate and eliminate arsenic. Other factors, such as nutrition, life stage, preexisting health conditions, or recreational habits, might play a role in the response to arsenic but have not been studied extensively." (NRC, p. 243) "Studies of the potential differences in arsenic methylation efficiency between young children and adults need to be validated and considered in the risk assessment of arsenic." (NRC, p. 244)

Ecology comment: Susceptibility to the harmful effects of arsenic appears to be highly variable from person to person, and the full extent of this variability is not well defined. This variability will be considered to protect the health of the susceptible individuals as required by the MTCA Cleanup Regulation.

B1-2.8 Risk characterization

The NRC subcommittee did not conduct a formal quantitative risk assessment for ingested arsenic, but it did perform a number of analyses of arsenic toxicity for illustrative purposes. While the subcommittee cautions that it does not endorse the analyses as a formal risk assessment, the results are revealing in that the estimates of carcinogenic potential are consistently similar to or greater than the current cancer slope factor across many scientifically valid approaches. The subcommittee was evaluating the carcinogenicity of arsenic doses in the range of the current MCL, or approximately 1.4 micrograms per kilogram per day for a 70 kilogram adult drinking 2 liters of water per day containing 50 micrograms per liter (the current MCL). This dose is very similar to that expected for a 16 kilogram child at the Everett Smelter Site (specifically, 0.25 microgram per kilogram per day) who ingests 200 milligrams of soil containing 20 mg/Kg arsenic. From a toxicity standpoint, the doses are similar enough that the toxicity evaluations conducted by the NRC subcommittee for arsenic exposures around the MCL would be applicable to the Everett Smelter Site.

"In the context of its task, the subcommittee was asked to consider whether cancer or non-cancer effects are likely to occur at the current MCL. No human studies of sufficient statistical power or scope have examined whether consumption of arsenic in drinking water at the current MCL results in an increased incidence of cancer or non-cancer effects. Therefore, the subcommittee's characterization of risks at the current MCL is based on observed epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variation in human susceptibility." (NRC, p. 7)

"In the absence of a well-designed and well-conducted epidemiological study that includes individual exposure assessments, the subcommittee concluded that ecological studies from the arsenic endemic area of Taiwan provide the best available empirical human data for assessing the risks of arsenic-induced cancer. The cultural homogeneity of this region reduces concern about unmeasured confounders, although the potential for bias still exists due to considerable uncertainty about the exposure concentrations assigned to each village. Ecological studies in Chile and Argentina have observed risks of lung and bladder cancer of the same magnitude as those reported in the studies in Taiwan at comparable levels of exposure." (NRC, p. 7)

Data on bladder cancer in Taiwanese males was evaluated using a number of different statistical models. "The subcommittee also concludes that the choice of model for statistical analysis can have a major impact on estimated cancer risks at low-dose exposures, especially when the model accounts for age as well as concentration. Applying different statistical models to the Taiwanese male bladder cancer data revealed that a more stable and reliable fit is provided by Poisson regression models that characterized the log relative risk as a linear function of exposure. The estimation of risk at low doses using those models is substantially higher than that using the multistage Weibull model." (NRC, p. 8)

In both its July 1998 submittal and in its February 1999 submittal, Asarco suggested that it would be more appropriate to evaluate arsenic toxicity using draft guidelines published by EPA in 1996. The NRC subcommittee determined that "[i]nformation on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are inconclusive and do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity. Of the several modes of action that are considered most plausible, a sublinear dose-response curve in the low-dose range is predicted, although linearity cannot be ruled out. In vitro studies of the genotoxic effects of arsenic indicate that changes in cellular function related to plausible modes of carcinogenesis can occur at arsenic concentrations similar to the current MCL. However, the subcommittee believes that those data and the confidence with which they can be linked to arsenic-induced neoplasia are insufficient to determine the shape of the dose-response curve in the low-dose range (point of departure)." (NRC, pp. 7-8) The NRC subcommittee, as an illustrative exercise, evaluated Taiwanese bladder cancer data according to its interpretation of the guidelines. "As an alternative to model-based estimates of risk, the subcommittee finds that the point-of-departure methods discussed in the 1996 draft EPA guidelines for cancer risk assessment give much more consistent low-dose estimates across a wide range of dose-response models. For male bladder cancer, a straight-line extrapolation from the 1% point of departure yielded a risk at the MCL of 1 to 1.5 per 1,000. Because some studies have shown that excess lung cancer deaths attributed to arsenic are 2-5 fold greater than the excess bladder cancer deaths, a similar approach for all cancers could easily result in a combined cancer risk on the order of 1 in 100." (NRC, p. 8)

Using a linear extrapolation, and assuming a combined cancer risk of 1 in 100 at the MCL (equivalent to a dose of 1.4 micrograms per kilogram body weight per day for a 70 kilogram person drinking 2 liters of water per day for a lifetime), the calculated cancer risk for a 20 mg/Kg cleanup level at the Everett Smelter Site would be 140 in one million (assuming a dose of 0.25 micrograms per kilogram per day for six out of 75 years). Two of the 16 members of the subcommittee did not agree with the 1 in 100 estimate pending further analysis of the risk of lung cancer. Thus, a similar calculation for bladder cancer alone gives a risk estimate for the Everett Smelter Site of 14 in one million. Thus, an evaluation of arsenic toxicity according to the method recommended by Asarco suggests that the cancer risk for a cleanup level of 20 mg/Kg arsenic in soil exceeds Ecology's target risk level of one in one million by 140-fold for combined cancers and 14-fold for bladder cancer alone. Note that the calculated risk would be even greater if exposure occurred for more than 6 years.

B1-2.9 Conclusions

Asarco has failed to provide clear and convincing evidence that Ecology should not apply EPA's cancer slope factor for arsenic to determine the appropriate soil arsenic cleanup level for the Upland Area of the Everett Smelter Site. The NRC subcommittee evaluated the strength of currently available scientific evidence related to the concerns raised by Asarco. If the current evidence were clear and convincing, it would be expected that the NRC committee would have strongly suggested that it should be used to evaluate arsenic toxicity. Instead of strong recommendations for using these factors, the subcommittee noted the uncertainties in the information and provided recommendations for further clarifying research.

In addition, alternative cancer risk calculations by the NRC subcommittee suggest that EPA's cancer slope factor for arsenic may underestimate total cancer risk in the region of the arsenic dose-response curve pertinent to Ecology's Method A cleanup level of 20 mg/Kg.

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Chapter B1-3 Cancer Potency Factor for Arsenic

Asarco's Contention: Recently published papers presenting the results of meta-analyses of epidemiological studies on arsenic health effects (in the U.S. and worldwide) provide evidence that EPA's Cancer Potency Factor overestimates cancer risk for ingested arsenic.

EPA's cancer risk assessment for ingested arsenic is based on the results of selected epidemiological studies in exposed human populations. In this respect, arsenic is unlike most other chemicals, for which risk estimates are typically derived from the results of animal experiments, where extrapolation from animals to humans is required. Additional epidemiological studies of arsenic exposures and health effects are available that are not used by EPA to develop the cancer potency factor for ingested arsenic. The idea of examining the results of those additional studies for their consistency with the derived potency factor is attractive. For most of these additional studies, the study population is quite small, estimates of exposure are relatively less certain, or other methodological issues are noted that led EPA not to use the studies as the basis for development of the cancer parameter in the first place. Individually, the power of many of the additional studies is too small to provide meaningful comparisons. Meta-analysis is a technique for combining the results from multiple independent studies in statistical evaluations, and by so doing including a larger total study population and increasing the power of statistical tests.

The comments note that two meta-analyses for arsenic skin cancer effects have recently been published (Guo and Valberg, 1997; Valberg et al., 199[8]), one looking at U.S. studies and the other including worldwide studies. As new research papers incorporating the results of a number of previous studies and performing statistical modeling with the necessary supporting assumptions to allow calculations, these publications may not have been extensively peer reviewed to date. Ecology notes that they do not include any information on other internal organ cancers, such as bladder cancer (see National Research Council, 1999); those non-skin cancers are being evaluated by EPA as part of current review efforts for arsenic risk assessment. The meta-analysis studies on skin cancer are known to EPA, but have not been used by EPA to date to revise the ingested arsenic cancer potency factor (Herman Gibb, USEPA/ORD, personal communication).

Ecology has reviewed the meta-analysis papers identified in the comments. For the reasons discussed below, Ecology concludes that the meta-analysis results do not justify the use of an alternate cancer potency factor in risk estimates under MTCA.

Epidemiological studies in human populations, while avoiding troublesome animal-to-human extrapolation issues, typically suffer from significant questions about individual exposure levels, the lack of a reasonable mass balance for arsenic intakes and outputs, loss of subjects (e.g., due to migration, non-participation in the study, and other causes), and other issues. Meta-analyses based on epidemiological studies do not escape these issues; numerous assumptions must be made in order to complete statistical analyses. In the meta-analysis for U.S. studies (Valberg et al., 199[8]), the cumulative total number of subjects from four groups in three studies is 329. The total predicted number of arsenic-caused skin cancers is 0.805 (note that the authors use EPA's then-current cancer potency factor of 1.75, not the more recent IRIS-listed value of 1.5), of which almost 80% comes from one of the four study groups. For three of the four groups, the calculated likelihood ratio (the ratio of the probability of observing the reported data under two alternate hypotheses, EPA's cancer potency factor is true or the cancer potency factor is zero) is only marginally less than 1, and the predicted number of arsenic-caused skin cancers in each study is less than 0.1 (i.e., a single case would be expected to be observed only once in ten or more repetitions of the "experiment," and 0 cases would be observed in all of the remaining repetitions). Thus, the cited result that "the assumption of no additional skin cancer risk from arsenic was 2.2 times more likely than the [EPA] predicted rate of skin cancers" is dominated by the result from a single study in Utah. In this sense, the meta-analysis is not significantly stronger than analysis of just the one Utah study. Moreover, the reporting of zero cases where less than 0.1 cases are predicted is more or less the result one would expect; even in three successive studies, such a null finding would be more likely than not.

The authors note several factors that could bias the likelihood ratio lower; one such factor is the assumption that individuals had exposures from birth to their age in the study (i.e., lifetime-to-present exposures). The study in Alaska (Harrington et al., 1978), however, reports that 85% of the subjects had lived in the study area for less than 10 years. This clearly does bias the calculation of the number of predicted cancers from arsenic and the likelihood ratio for this study in the paper. Given the latencies for skin cancer effects, exposures of less than 10 years also may well have been too short to observe any arsenic-related cases. This finding underscores the importance of examining the circumstances in each epidemiological study and the assumptions used in meta-analysis calculations. Assumptions used to provide missing information (e.g., age distributions of subjects, estimated from statewide distributions but applied to very small study populations) can introduce significant variability into the calculations.

Confidence in the results of any statistical analysis is increased if the results are robust. With small populations and a small number of predicted cases (less than 1 for all studies combined in the Valberg et al. paper), the U.S. meta-analysis results are not robust. This can be seen by assuming that instead of zero cases, a single case (reflecting misclassification, loss of subject, latent effect not yet visible, or other similar effects) was observed in any of the individual epidemiological studies. Three of the four studies would then result in likelihood ratios greater than 1, that is, in favor of the EPA risk estimate versus the alternative of no additional risk from arsenic. Thus, the meta-analysis results change substantially with only minor assumed changes in the observed data, and are not robust.

Valberg et al. (199[8]) append to their paper a statistical derivation of a cancer potency factor distribution for ingested arsenic. Ecology notes with interest that the median cancer potency value (50:50 chance of exceeding or not) for that derived distribution is 1.5 $[mg/Kg/day]^{-1}$, which is exactly the current value in EPA's IRIS listing and is the value used by Ecology within MTCA for calculation of a risk-equivalent soil cleanup standard for arsenic. The distributional analysis by Valberg et al. therefore appears to support rather than negate the validity of using EPA's current IRIS-listed cancer potency factor for estimating risks from ingested arsenic.

The paper by Guo and Valberg (1997) reviews worldwide studies using a similar meta-analysis approach. Power calculations are included in this paper (although Ecology has been unable to reproduce the cited results for study power, given the data and equations for power calculation listed in the paper). The authors note that any study powerful enough to detect risks at relatively low exposures (less than 50 ug/L arsenic in drinking water) will have to be very large (hundreds of thousands of subjects). For the key finding of the authors that studies with arsenic exposures in drinking water above 50 ug/L (and especially above 170 ug/L) show results inconsistent with EPA's risk estimate, it is again the case that the results are dominated by a single study (Wu et al.) which includes most of the cumulative number of subjects in all studies combined. Omitting that one study (as well as Tseng et al. which may share subjects with the Wu et al. study), the likelihood ratio for other studies with drinking water arsenic above 50 ug/L is about 1:7.61 (1 case observed, 0.81 baseline cases, 4.57 predicted cases; total number of subjects 805). However, if a single additional case is assumed, that likelihood ratio would drop to only 1:1.35; for 2 additional cases, it drops to only 1:0.24. Thus, the results for all studies except the Wu et al. study are far from robust. The same issue of residence time and exposure duration noted above for the Harrington et al. study (included among the group with drinking water exposures above 50 ug/L) is also applicable for the Guo and Valberg analysis.

Although the Guo and Valberg (1997) paper quantifies likelihood ratios and study power only for the case of the cancer potency factor as derived by EPA, the same approach should be applicable for alternative cancer potency estimates. It would be interesting to determine what degree of change in cancer potency factor estimates would result in likelihood ratios dropping to only marginally less than 1 (see, for example, Table 5 in the paper). Preliminary analysis by Ecology suggests that this occurs when the cancer potency factor is reduced by a factor that is small in comparison to the factor of 30 between the MTCA Method A soil arsenic cleanup standard of 20 mg/Kg and the risk-equivalent value (1 in 1,000,000 assuming 100% relative bioavailability) of 0.67 mg/Kg. This, in turn, would indicate that the meta-analysis results - absent any further evaluations of potential bias in all of the assumptions included in the calculation - do not strongly support alternative risk-equivalent soil cleanup values above the Method A value of 20 mg/Kg.

References

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Chapter B1-4 Bioavailability of Arsenic in Soil

Asarco's Contention: Ecology initially assumed that 40% of the arsenic in soil was bioavailable and then, in the draft CAP, changed the assumption to 100% bioavailability. Neither figure has any adequate scientific basis and Ecology provides none in the draft CAP or in its Review of "New Science." Recent studies indicate that a better estimate of the bioavailability of arsenic in soil is approximately 20%.

Ecology chose to assume that relative bioavailability of arsenic from soil at the Everett Smelter Site was 100% for the following two reasons:

- there are no site-specific data on bioavailability for the site (lacking such data, 100% is an appropriate assumption for protection of human health); and
- the data from other sites have not been shown to reliably predict bioavailability in humans under the exposure conditions present at those sites, let alone been shown to be applicable to the Everett Smelter Site.

Certain comments suggest that Ecology should choose a very low bioavailability value based on some studies of questionable reliability performed at other hazardous waste sites. Ecology does not believe that those studies provide clear and convincing data supporting a bioavailability value of less than 100% for the Everett Smelter Site. Studies of the bioavailability of arsenic from soil have been performed at a number of other sites, using a variety of different animal and artificial models, and using many different experimental protocols. There are few useful scientific data that can be used to evaluate the degree to which the results are influenced by the experimental procedures, and there is little evidence that any of the results are reliable estimates of bioavailability in humans. Reported results from these studies ranged from 98% to minus 8% bioavailability. Lack of consistency in experimental protocols and lack of information on the reproducibility of the results make it impossible to choose which results, if any, accurately reflect bioavailability in humans from Everett Smelter soils.

It remains to be demonstrated that bioavailability studies performed in animals or artificial systems can accurately and reliably predict bioavailability of arsenic from soil in humans. Absorption by the gut of arsenic from contaminated soil is a complex process. Bioavailability of arsenic from soil depends mostly on two general factors: first, the amount of arsenic that is removed from the soil particles in the stomach and intestines; and second, how much of this dissolved arsenic is absorbed into the body through the intestines (including how quickly the absorption occurs). Ecology previously pointed out that available data from bioavailability studies suggest that the animals used in soil bioavailability studies absorb purified arsenic more poorly than humans. Dr. Schoof contends that such differences in absolute bioavailability between animals and humans are "irrelevant for estimation of relative bioavailability." While this may be true for some differences in absorption, it may not be true for differences in solubility and or for differences in overall rate of absorption. There are no data regarding how well arsenic dissolves from soil particles in the human gastrointestinal tract compared to the gastrointestinal tracts of the various animals used in bioavailability studies. Differences in absolute bioavailability between humans and animals is an indicator that the physiological processes involved in arsenic bioavailability are different between humans and animals and that animal studies may not accurately reflect bioavailability in humans.

Another concern is that prior studies have tested the bioavailability of arsenic from soil under conditions that are different from conditions at the Everett Smelter Site, and it remains to be demonstrated that these differences are unimportant when predicting bioavailability. One difference (soil dose) was evaluated previously by Ecology and appears to influence the results of the study. Ecology is concerned that such differences compromise the reliability with which the results could be used for the site. Dr. Schoof discusses two studies performed in swine (Casteel et al., 1997; Rodriguez et al., 1999) and suggests that they demonstrate that the concerns of Ecology related to the reliability of bioavailability results are unfounded. As previously noted by Ecology, an examination of the data from the Casteel et al. study showed that more than half of the arsenic administered to the animals could not be accounted for, suggesting a serious problem with either the technique or the experimental system. Because of this problem, it is impossible to draw any reliable conclusions from the data. The second swine study (Rodriguez et al., 1999) referenced by Dr. Schoof was performed in the same laboratory, apparently using the same protocol as the first study. Original data from this study were not provided to Ecology, only highly summarized information about bioavailability, and it is impossible to judge the quality of the work from the data provided. Given the problems with the first study, Ecology is concerned about potential technical problems with the second study that may not have been reported by the authors. Other recent publications cited by Dr. Schoof also do not provide enough information for proper evaluation of the stated findings. Data from a recent study in an artificial system (Hamel et al., 1998) suggest that study conditions can affect results for some soils.

Ecology is not aware of any attempts to measure bioavailability of arsenic from soil at the Everett Smelter Site. While certain comments suggest that bioavailability could be determined based on site-specific factors, those comments do not provide any site-specific data pertinent to the conditions at the Everett Smelter Site. Over the past nine years interested parties have had ample opportunity to work with Ecology to try to develop a reliable method for determining arsenic bioavailability at the Everett Smelter Site, but they have failed to take advantage of that opportunity.

In conclusion, Ecology has not been provided with site-specific data on the bioavailability of arsenic from soil for the Everett Smelter Site. Further, as previously stated, "it remains to be demonstrated that the results of any soil arsenic bioavailability study accurately represent bioavailability for humans, or whether the results are more dependent on study conditions as opposed to actual differences in bioavailability" (Ecology, 1999). Lacking reliable site-specific information, Ecology will assume that bioavailability is 100%, an upper-bound estimate that will ensure protection of human health. As pointed out in the introduction and response number 9, the chosen cleanup level would not be changed even if the relative bioavailability were shown to be somewhat less than 100%, since there is already a 30-fold difference between the chosen cleanup level (20 mg/Kg) and the Method B cleanup level (0.67 mg/Kg) to which a bioavailability factor would be applied.

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Chapter B1-5 Urinary Arsenic Data and Cleanup Levels

Asarco's Contentions: Urinary arsenic is a valid biomarker of arsenic exposure. It is inconsistent for Ecology to propose using urinary arsenic monitoring as part of a long-term Community Protection Measures Program yet reject the use of urinary arsenic data for deriving a protective soil arsenic level.

Site-specific urinary arsenic data at the Everett Smelter Site show that no significant exposures are occurring, even without extensive cleanup actions. This supports a conclusion that extensive soil cleanup actions are not needed. Studies show that soil arsenic levels do not appreciably affect urinary arsenic levels when soil arsenic is less than a few hundred mg/Kg.

The distribution of urinary arsenic levels in children in a population not exposed to elevated environmental concentrations of arsenic can be used to derive an appropriate and protective soil arsenic cleanup standard. Data from a urinary arsenic study in Bingham Creek, Utah show that an appropriate soil cleanup standard should be considerably higher than the current MTCA standard.

In its prior “new science" responses (Ecology, 1999), Ecology responded to comments proposing the use of urinary arsenic data to back-calculate a soil arsenic cleanup level for the Everett Smelter Site. Ecology provided a fairly detailed response which remains relevant to evaluation of the commentors proposal. Additional comments were submitted addressing several related facets of the urinary arsenic argument. Ecology briefly addresses each of these additional comments here.

In its prior response, Ecology noted that it was unaware of the acceptance by any regulatory agency of the proposed approach to derive soil cleanup levels from urinary arsenic data. No rebuttal comments to this finding were submitted as part of Asarco's February 1999 submittal.

The commentors claim that it is inconsistent and contradictory for Ecology to propose the use of urinary arsenic monitoring in a Community Protection Measures Program while rejecting the use of urinary arsenic data to derive soil cleanup levels. Ecology disagrees. Urinary arsenic measurement is a useful, but imperfect and limited, approach to assessing arsenic exposures. Ecology believes it is consistent and appropriate to use urinary arsenic monitoring for those purposes where it can provide meaningful information and avoid its use where it cannot. Ecology notes that public health criteria for "elevated" urinary (total) arsenic levels include no statements about the magnitude of potential cancer risks; they are "normative" (derived from the distribution of observed values) rather than risk-derived numbers. In just such a "normative" sense, urinary arsenic monitoring within a Community Protection Measures Program can identify significantly elevated urinary arsenic levels (sum of speciated arsenic compounds indicating inorganic arsenic exposures) that could be indicative of ongoing arsenic exposures. Ecology believes in such circumstances followup through case study investigations would be warranted at the Everett Smelter Site to determine if significant environmental arsenic sources exist (e.g., recently exposed soils from construction at a home) which could be controlled. Urinary arsenic monitoring is not similarly capable of detecting incremental exposures above risk-based cleanup standards. Using MTCA exposure assumptions (without relative bioavailability, which does not enter into this calculation of absorbed dose) and EPA's cancer potency factor (1.5 $[mg/Kg/day]^{-1}$), a daily childhood dose over 6 years of only 0.133 ug/day is calculated to result in a one in one million increment in lifetime cancer risk. Considering laboratory detection limits and measurement errors and variability from typical dietary/drinking water exposures, urinary arsenic monitoring is unable to be used effectively to target such low incremental exposures. As Ecology notes in a separate response on background dietary/drinking water arsenic exposures, there is no compelling information that the measurable background exposures and resulting typical urinary arsenic levels are free of health risks. (Considering the power or sensitivity of a tool is an important part of deciding for what purposes to use that tool. We would readily use a 100-power telescope to count large craters on the moon, but not to search for the Lunar Rover during a manned moon landing.)

The commentors claim that data collected at the Everett Smelter Site by the Agency for Toxic Substance and Disease Registry (ATSDR) indicate that urinary arsenic levels are not elevated above normal, suggesting that excessive exposure is not occurring. Ecology notes several reasons why that is not a valid conclusion. The monitoring program had the limited purpose of providing some residents a spot check of their levels to determine whether anyone had very high exposure that could suggest an immediate health threat. It was not designed to detect small changes in urinary arsenic levels, as indicated by the high analytical detection limits (typically about 10 micrograms per liter) and by the high reference value (100 micrograms per liter) used to classify people into “exposed” and “normal” categories. In the context of the monitoring program, “normal” did not necessarily mean “unexposed.” The program involved relatively few site residents and reflected potential exposures over a period of only a few days, and would be a very poor indicator of the potential for exposure over the long term. The results may have reflected lower than expected exposure to contaminated soil since the monitoring program occurred after years of community meetings about site contamination and extensive community education efforts, including distribution of written public health advisory information to all households at the site. The long-term effectiveness of such community education efforts in controlling children’s exposures from soil arsenic is questionable. They are likely, however, to have had a greater short-term impact on area residents, especially considering the large amount of information associated with the monitoring program. For these reasons, Ecology does not consider this study to be a reliable basis on which to conclude that no significant soil arsenic exposures are possible at the site. Ecology notes that, of about 90 people tested, one had elevated urinary arsenic and six had elevated hair arsenic, suggesting that some people at the site are highly exposed. The families of these people received personal counseling from Washington State Department of Health (DOH) and ATSDR on ways to reduce their exposure.

The commentors propose that issues of variability in individual person-day measurements of urinary arsenic levels are resolved by including large populations in urinary arsenic studies. Ecology disagrees. Ecology previously noted that for health effects concerns from chronic exposures (e.g., cancer risks), it is the long-term pattern of an individual's exposure to arsenic (e.g., annual average exposure) that is most relevant, and that the effect of day-to-day fluctuations in an individual's urinary arsenic concentration should be considered in evaluating short-term monitoring data. Ecology disagrees with the commentors that increasing the study population size in a short-term study design resolves this concern regarding variability in person-day measurements and the proposal to derive a soil cleanup standard from urinary arsenic monitoring data. The statistical issue here is "regression to the mean." An analogy may help in understanding why study population size does not resolve the variability issue. Consider baseball players' batting averages. An individual player's yearly average reflects performance over a 162 game season. If "baseball hitting monitoring" is conducted by sampling the weekly averages of some players, the results may range widely from .000 (a player mired in a hitting slump) to .600 or more (a player with a very hot bat). This does not, of course, mean that any player is expected to have a yearly average anywhere close to either extreme value for weekly batting statistics. By analogy to the Reasonable Maximum Exposure (RME) scenario under MTCA, what we are seeking is an estimate of the 90th or 95th percentile annual batting average among baseball players. Increasing the number of players for whom we monitor batting performance in a one-week study may provide a better estimate of the average batting performance over all players (which may approximate the median annual average), but it clearly will not produce a reliable estimate of the 95th percentile annual average among players. As the period of monitoring lengthens, the range of observed individual player averages will "regress toward the mean" because of day-to-day fluctuations in performance (e.g., the player hitting .600 will cool off). Thus, estimated upper percentiles for batting averages based on short-term monitoring will be biased high, and so will the increments between two upper percentile values. By similar reasoning, "longitudinal studies" that consist of only one or two days of monitoring per quarter (reflecting only a few days exposures per quarter) are likely not to have enough measurements to provide reliable estimates of annual average values. It is reasonable to expect that daily diets vary with respect to arsenic content, given the variability in arsenic concentrations across foods and food groups and the fact that an individual's daily diet represents a small sample from all available foods. Ecology previously noted that substantial daily fluctuations in urinary arsenic levels "within-individual" are observable (e.g., in the Bellingham control group from the UW Exposure Pathways Study). The annual average dietary exposures should show a regression to the mean from short-term monitoring studies in the same way that baseball batting averages do.

The proposal to derive a soil arsenic cleanup standard from urinary arsenic data starts with an estimation of the increment in urinary arsenic levels between two upper-percentile values from the highly skewed "background" distribution. Ecology has evaluated how that estimated increment would be affected by using person-day urinary arsenic measurements versus longer-term individual averages (e.g., annual averages calculated from short-term quarterly sampling). As would be expected from the regression-to-the-mean analysis above, the use of longer-term averages instead of person-day values is shown to result in smaller estimated increments. Data from the UW Exposure Pathways Study (Polissar et al., 1987) for Vashon Island and Census Tract 604, where urinary arsenic data were determined by the authors not to be significantly elevated, were used for this illustrative evaluation.

The commentors claim that available studies show little effect of soil arsenic on urinary arsenic levels. The Hwang et al. (1997) report on a study at the Anaconda, Montana site is representative of these studies; Figure 3 in that paper, reproduced below, provides a log-log scatter plot of urinary arsenic concentrations versus soil arsenic concentrations, along with a best-fit regression line. The commentors have focused on the regression line as summarizing the results for the relationship between soil arsenic and urinary arsenic in the study population, ignoring the extensive scatter of points around that line. As Ecology previously noted, it is important to ask how RME cases are represented in such data plots and regression lines. One commentor states that the best-fit regression line for the Anaconda data suggests an increment of about 700 mg/Kg in soil arsenic is required to increase urinary arsenic levels by 5 ug/L, proving Ecology's comments that such an increment could result from soil arsenic of about 20 mg/Kg unreasonable. Ecology believes that these comments are based on a superficial and incorrect interpretation of the data as reflected in the Hwang et al. (1997) scatter plot. The best-fit regression line provides a summary of all of the data across the entire study population, most of whom would (by definition) be characterized by exposure parameters (e.g., soil contact rates) well below RME assumptions. In the language of EPA as presented in Walker and Griffin (1998), the regression line reflects a "central tendency" estimate and not a "reasonable maximum exposure" estimate. If the RME soil ingestion rate is 5 or 10 times higher than the median or typical soil ingestion rate, then the RME slope would also be 5 or 10 times higher, all other factors being equal. This is equivalent to noting that the RME scenario would be reflected in the data points above the regression line in the scatter plot (see Hwang et al., 1997, Figure 3, reproduced below). The Anaconda data viewed in this way show an increment of more than 5 ug/L from an increase of considerably less than 100 mg/Kg soil arsenic (with very few data points to represent soils at under 50 mg/Kg). In Ecology's view, it is unwarranted to simply assume that the scatter plot variability around the regression line reflects only variations among individuals from dietary and drinking water contributions to urinary arsenic levels; differences in soil exposures (e.g., variability in soil contact rate) are as likely to be involved. If data relating urinary arsenic and soil arsenic concentrations are used to evaluate potential exposures, it is critical to understand the differences between central tendency and RME exposure scenarios and how they are reflected in the data plot. Ecology also notes that the recent Kavanaugh et al. (1998) study in the United Kingdom shows mean urinary arsenic levels (adjusted for creatinine) increasing by a factor of almost three and one-half for an increase in mean soil arsenic levels of only 328 mg/Kg between exposed and control sites. That result appears inconsistent with the Hwang et al. results for Anaconda.

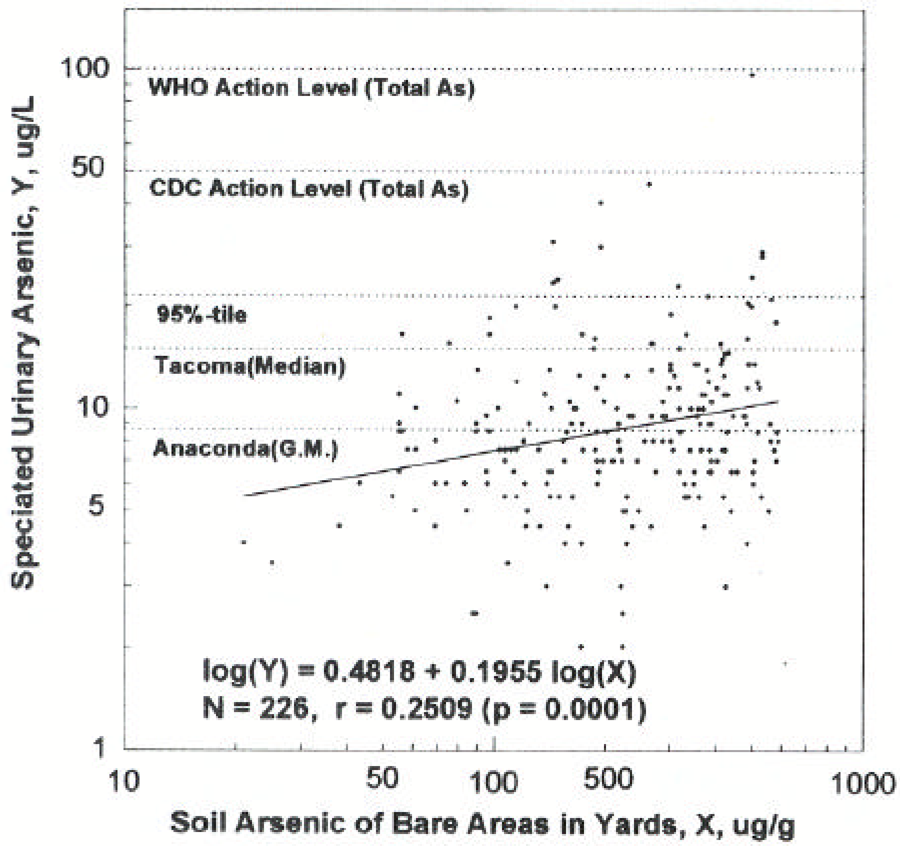

FIG. 3. Scatter plot of speciated urinary arsenic against soil arsenic level of bare areas in yards.

Reproduction of Hwang, et al, 1997, Figure 3 – G.M = geometric mean, µg/g = mg/Kg.

The Bingham Creek urinary arsenic data are proposed by the commentors as a sufficient basis to establish a higher soil cleanup standard for the Everett Smelter Site. Ecology has performed additional review of the Bingham Creek data since the initial "New Science" responses. Ecology does not accept the proposal to establish an alternate soil arsenic cleanup standard from these data, on both technical and policy grounds. As Ecology previously noted, the data are not site-specific for Everett or Washington and their representativeness is unknown. Moreover, the children included in the study reside in a community with areas of substantially elevated soil arsenic, and it cannot be established that the urinary arsenic data (especially upper percentile values) reflect "background" exposure conditions. Ecology notes that the expected relationship between drinking water and urinary arsenic concentrations is not reproduced in the data. In many cases, from drinking water versus urinary arsenic data alone (i.e., ignoring soils and house dusts), derived dietary arsenic contributions would be negative, an impossibility. The use of person-day measurements does not address the "regression to the mean" for estimated individual annual average values, as discussed above. Ecology has noted elsewhere in these responses that there is no compelling evidence that "background" dietary and drinking water arsenic exposures are free from risk. The use of an increment in urinary arsenic levels among those with highest values (upper percentiles in the population distribution) may therefore result in a substantial de facto increase in the acceptable risk level for site cleanup.

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Chapter B1-6 Soil-Arsenic Exposures versus Food and Water

Asarco's Contention: Lifetime exposures to arsenic at Everett are trivial compared to the "background" exposure to arsenic in diet and drinking water. Even if the soil arsenic cleanup level was 100 mg/Kg, the incremental exposure from soils would be lost in the "noise" of the normal variability in the intake of inorganic arsenic from food and water. If Ecology believes that arsenic in soil above 20 mg/Kg presents an unacceptable health risk, it must also believe that the entire food and water supply of the United States presents a very large risk.

Ecology responded to comments comparing lifetime inorganic arsenic exposures from diet and drinking water versus exposures from contaminated soils in the initial "New Science" responses. These comments are largely restated in the most recent comments on Ecology's DCAP/DEIS and New Science documents. The two main themes in the comments are: 1) that potential soil arsenic exposures represent small increments over unavoidable background exposures; and 2) that estimates of health effects from the unavoidable background exposure levels based on EPA's cancer potency factor or Ecology's risk estimates under MTCA lead to inconsistencies and contradictions, suggesting the risk estimates are incorrect.

In its January 1999 document, Ecology pointed out several issues that it concluded were not adequately addressed by Asarco in its July 1998 comments comparing soil and diet/drinking water arsenic exposures. These were: the relative bioavailability of dietary inorganic arsenic; age differences in dietary intakes; the variability of dietary arsenic intakes (e.g., regionally) and the reliability of market basket survey approaches versus other methods for estimating dietary intakes (see also MacIntosh et al., 1997 on this issue); the relative bioavailability of soil arsenic; and the effect of assuming more than a six-year exposure period for soils. Ecology notes additionally that the comparison in the comments is based on the use of total (cumulative) amount of arsenic ingested as the exposure metric. The more common exposure metric, and the one on which EPA bases the cancer slope factor, is dose adjusted for body weight (i.e., µg arsenic/Kg body weight). If the arsenic doses in the commentors calculation were translated to µg/Kg units, the relative importance of childhood soil arsenic exposures would increase by a factor of three or more, since most dietary and drinking water exposures over a lifetime would be diminished in relative magnitude because of much larger adult body weights.

Ecology previously noted that the incremental exposures from soil arsenic are not obviously de minimis as Asarco contends. At 20 mg/Kg soil arsenic and at the RME soil ingestion rate of 200 mg/day, arsenic intake for a child would be 4 ug/day, as noted by the commentors. Even if the relative bioavailability of soil arsenic was as low as 20 percent, the soil arsenic pathway could still contribute 10 to 20% or more of typical childhood dietary plus drinking water arsenic doses. Ecology does not consider this to be a de minimis contribution to total arsenic doses. At 100 mg/Kg soil arsenic, the RME absorbed arsenic dose, even at a relative bioavailability approaching 20 percent, could easily equal or exceed dietary plus drinking water exposures for some children. Drinking water arsenic exposures can be controlled (and are the subject of current EPA rulemaking); dietary arsenic exposures are much less controllable. Both food and drinking water, which could also incidentally contribute to arsenic exposures, convey nutritional and life-sustaining benefits by their very nature. It is Ecology's view that soil arsenic exposures are controllable (through remedial actions) and unlike food and water are accompanied by no significant benefits to those exposed, and that these characteristics of the potential exposures by different pathways are relevant to any comparison of food and drinking water versus contaminated soil arsenic exposures.

While Ecology has noted several issues concerning the magnitude, variability, and uncertainty of arsenic exposures via diet and drinking water, Ecology agrees with the commentors that typical dietary and drinking water sources contribute to some measurable level of arsenic exposures. Ecology is aware of no compelling argument that these background exposures, especially at the higher end of the normal range, or incremental exposures above those typical dietary levels, are free of health risks as Asarco contends in its comments. The recent epidemiological study by Kurttio et al. (1999) on cancer risks in Finland in relation to background levels of arsenic in drinking water on the contrary shows an apparent risk of bladder cancer (especially in association with smoking) related to extremely low arsenic exposure levels.

The commentors state that if EPA's cancer potency factor is accepted as true, the risks from dietary plus drinking water arsenic exposures would be very large and would result in an observable "epidemic" of skin cancer cases. EPA has previously evaluated the potential magnitude of U.S. health risks from normal dietary plus drinking water arsenic exposures (see USEPA, 1988, pp. 31-32). The nature of the analyses of this issue has not changed significantly since then (personal communication with Herman Gibb, USEPA, September 27, 1999). The proportion of U.S. skin cancer cases that would be contributed by dietary plus drinking water arsenic exposures is likely in the neighborhood of 0.1%. Unlike systematic population surveys with active pursuit of cases (e.g., the Taiwanese studies), cases of skin cancer from typical dietary or background drinking water exposures would only be seen based on self-referral by individuals or their primary physicians. Cases would not be accompanied by any information to alert clinicians to potential arsenic exposures as a cause. Assuming relatively invariant background dietary exposures regionally across the U.S., the cases would occur randomly throughout the country (at a general rate of far less than one per county per year, ignoring variations in population) rather than in clusters that might elicit greater interest from clinicians. Treatment (e.g., removal) may be provided in many cases without great concern over causes. The observable characteristics of arsenical skin lesions may be less distinguishable at low exposure levels versus the much higher levels from Taiwan or similar studies (personal communication with Herman Gibb, USEPA, September 27, 1999). Ecology concludes that the risks from typical background dietary and drinking water arsenic exposures could be consistent with estimates derived from EPA's cancer potency factor without observable consequences for national skin cancer rates or occurrence. Those risks may be large in comparison to a one in one million risk level (e.g., up to 100-fold higher), but they do not appear to be large in an epidemiologically detectable context.

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Chapter B1-7 Medicinal Use of Arsenic

Asarco's Contention: Ecology also fails to comment on the recent publication in the New England Journal of Medicine and other journals of peer-reviewed studies showing that arsenic is an effective treatment for certain kinds of leukemia at doses that produce only mild side-effects. No objective evaluation of this chemical can ignore, as Ecology does, this striking new development. (Asarco letter of February 25, 1999, p. 60)

While the finding that arsenic can be an effective treatment for some cases of promyelocytic leukemia is an interesting medical development, the relevance of this finding to an evaluation of the toxicity of arsenic is unclear to Ecology. The fact that a substance may be used for certain medicinal purposes does not necessarily mean that the substance cannot cause harmful side-effects. Medicines are used cautiously to treat illness because, in addition to their therapeutic actions, they often have adverse side-effects. The patients treated with arsenic were very ill, and other forms of treatment had failed. Noted side effects included nerve damage and fluid retention (Huang, et al., 1998, and Soignet et al., 1998) which Ecology does not consider "mild."

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Chapter B1-8 Background Soil-Arsenic Concentrations and Risk

Asarco's Contention: The calculation of a risk-equivalent soil cleanup standard using the MTCA Method B equation results in a soil arsenic concentration well below typically occurring background values in the United States. This irrational result demonstrates that the calculated soil cleanup standard is incorrect, since naturally occurring soil arsenic concentrations do not pose unacceptable risk.

The calculated Method B soil cleanup level under MTCA, based on an acceptable risk of one in one million for cancer and a reasonable maximum exposure (RME) scenario, is indeed less than typical naturally occurring soil arsenic concentrations in Washington State and other parts of the United States. Arsenic is one of a very few substances for which this is true in MTCA. The commentors suggest that the Method B calculation can be interpreted as showing that background soil arsenic levels pose unacceptable risks, presumably for everyone. Ecology notes that the RME calculation is not assumed to be characteristic of all individuals equally, since both the behaviors leading to exposure (e.g., amount of soil ingestion) and individual sensitivity to arsenic toxicity may vary greatly among individuals. This is embedded in the concept of a "reasonably maximally exposed individual" and the MTCA objective to protect most individuals, not just the typical individual. As a result, the commentors interpretation that the calculated MTCA Method B soil cleanup level for arsenic shows that all individuals are assumed to be at unacceptable cancer risk from background soil arsenic concentrations is incorrect.

The estimated 90th percentile value for typical Puget Sound background soil arsenic concentrations (Ecology, 1994) is about 7 mg/Kg, or about 10 times the lowest MTCA Method B cleanup standard of 0.67 mg/Kg (assuming 100% relative bioavailability). Individual variability is likely to result in many individuals showing more than a 10 fold difference from the RME case. As a result, many individuals would have a (bounding) risk estimate for most background soil concentrations (at least 90 percent) of less than one in one million. Calculations of potential incidence from background soil exposures must take account of this population distribution, rather than applying the MTCA soil cleanup level as though every person was at the RME. Ecology believes that any correctly calculated estimate of incidence in the U.S. population from background exposures would be too small to be detectable in epidemiological investigations. Ecology notes that EPA has not used this approach of assuming background soil concentrations are risk-free to set a "floor" for arsenic toxicity calculations.

This set of comments can be characterized as "the evolutionary argument": since humans evolved in the presence of naturally occurring arsenic in the environment, evolution and natural selection have resulted in an adaptation that minimizes any potential toxicity from "natural" arsenic. The selective advantage of a mutation that allowed humans to "detoxify" arsenic from environmental exposures would be expressed through the greater birth and survival of offspring from those individuals with the mutation than those without. The primary health effect of concern from naturally occurring environmental levels of arsenic would have been cancer; concentrations are too low to cause direct mortality or significant morbidity. Because of the long latency for cancer effects (which may not have been lethal in many cases, from skin cancers), impacts in individuals without the mutation would not have appeared at younger, child-bearing ages, and the "selective pressure" from reduced numbers of offspring, or even from less effective child rearing (the so-called "grandparent effect"), would probably have been exceedingly small, if an advantage existed at all. Evolutionary models could provide quantitative estimates for such processes, but only with a large number of assumptions for model parameters. Qualitatively, there is no reason to assume that all humans have become adapted to naturally occurring arsenic concentrations (personal communications with Dr. Jon Herran, UW and Dr. Joel Kingsolver, UW). The apparent diversity in present-day human sensitivity and response to arsenic (see, for example, Bettley and O'Shea, 1975 and National Research Council, 1999), including variability in methylation capacity (Weinshilboum, 1988), is a significant factor to be considered in assessing the "evolutionary argument." Thus, even if evolution has played a role in human responses to arsenic, current understanding suggests that the entire population has not achieved a similar degree of protection.

Ecology knows of no scientific evidence adequate to demonstrate that background soil arsenic levels are free of risk. A recent epidemiological analysis of cancer risks in Finland in relation to drinking water arsenic levels (Kurttio et al., 1999) shows an apparent increase for bladder cancer risks (especially among smokers) related to extremely low arsenic exposure levels, comparable in magnitude to estimated RME exposures from soil background arsenic levels. The use of an upper percentile value background arsenic concentration for a cleanup level in MTCA, instead of the lower calculated Method B (risk-based) value, does not correspond to an assumption that lower level exposures are free of risk. Since the selected cleanup level for the Everett Smelter Site of 20 mg/Kg is well above typical background soil arsenic concentrations in Washington, however, the comments disputing calculated risks at lower background concentrations are of little relevance to the cleanup decision.

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Chapter B1-9 Exposure Parameters for Arsenic

Asarco's Contention: MTCA's exposure calculations are biased high, and cleanup standards are therefore biased low, because the MTCA Method B equation for soil exposures does not account for: 1) seasonal variations in soil/dust contact rates, and 2) lower contaminant concentrations in indoor dusts compared to outdoor soils. WAC 173-340-740(3).

The calculation of a soil cleanup level under MTCA is derived from choices for exposure parameters, toxicity parameters, and acceptable risk levels. WAC 173-340-740(3). The comments claim that conservative assumptions on exposure parameters such as soil ingestion rate and relative bioavailability, the lack of consideration of seasonal factors reducing soil contact rates, and the assumption that indoor dusts have the same contaminant concentration as outdoor soils all result in the generation of unrealistically low soil cleanup levels. The comments also state a general conclusion that the choices on exposure variables have less impact on the calculation of a cleanup level than do the assumptions made for toxicity values. Ecology agrees with that conclusion, and would add that the exposure variable choices also have less effect than the selection of alternate acceptable risk levels would have.

The comments do not provide relevant site-specific information from which to develop alternate choices for exposure parameters, nor do they suggest a quantitative measure of potential high bias in estimated exposures or propose an alternate numerical calculation for a soil arsenic cleanup level. In evaluating these comments, Ecology has assessed additional information from the literature, as well as some data from Washington State relevant to the seasonality issue, and has performed a number of alternate sensitivity calculations for a soil cleanup level using a more complicated exposure model including variables to address the issues raised in the comments. The critical question for the New Science review, in the context of the Everett Smelter Site Cleanup Action Plan, is whether there is scientific support for changing the selected soil arsenic cleanup level from 20 mg/Kg (a background-based rather than a risk-based value) to a higher value. Based on its review and sensitivity calculations, presented below, Ecology concludes that the exposure parameter issues raised in the comments do not support a higher cleanup level.

Ecology's default value for an RME soil ingestion rate, 200 mg/day, is identical to the value used by EPA and is developed from a review of available studies. The MTCA approach using a single annual parameter value for soil ingestion rate is consistent with current EPA practice, in particular in the absence of site-specific data to support an alternate approach. Ecology notes that studies of childhood soil ingestion rates (which include soil contributions to indoor house dusts) include results with estimated 95th percentile daily soil ingestion values greater than 200 mg/day for some selected tracer elements (see, for example, Calabrese et al., 1996). Ecology also notes that there are still significant methodological and data interpretation issues for all soil ingestion studies (see, for example, Simon, 1998). The soil contact rate parameter is not among those listed in the MTCA Cleanup Regulation that can be changed based on site-specific data. WAC 173-340-708(10)(b). Ecology concludes based on its review of available studies that there is not clear and convincing scientific evidence to change the 200 mg/day RME value as the MTCA default for all sites. WAC 173-340-702(6).

Ecology points out that the MTCA Policy Advisory Committee report also provided recommendations on the ability to change exposure parameters (MTCA PAC, 1996). In those recommendations, the PAC distinguished between parameters for which site-specific values could be reliably measured, and which could therefore be modified if sufficient site-specific data were provided, and those which should not be changed on a site-by-site basis. The reasonable maximum exposure (RME) soil ingestion rate is identified by the PAC as an example of a parameter that is a function of human behavior and population characteristics and which therefore should not be changed on a site-by-site basis.

The comments regarding seasonal variability in soil/dust ingestion rates and differences between soil and indoor dust contaminant concentrations are addressed below. Relative bioavailability issues are addressed in a separate response to "new science" comments. The potential combined effect of all three exposure parameters on a soil arsenic cleanup standard in comparison to the MTCA Method A value of 20 mg/Kg is, however, considered here.

EPA provides information on exposure parameters for use in human health risk assessments in its Exposure Factors Handbook. Ecology contacted EPA to discuss the issue of seasonality in soil/dust contact rates. EPA stated that in its current guidance the RME soil/dust ingestion rate of 200 mg/day is recommended to be used as an annual value, which a site project manager could adjust for seasonality given adequate site-specific information (Jacqueline Moya, EPA/DC, personal communication, August 10, 1999).

The commentors claim that reduced soil/dust ingestion rates in winter have been demonstrated in recent studies at other sites. Ecology believes that there are significant questions regarding the generalizability and representativeness of results from studies in areas where winter temperatures are much colder, winter snow pack is much more common and prolonged, and frozen ground is more likely than in the Puget Sound region, which is characterized by relatively mild and wet winters. These climatic factors can influence human behavior and soil exposures differently under different site conditions, making it inappropriate to generalize broadly across sites with different climates. As a result, Ecology has considered available information for the Puget Sound region in assessing the potential for seasonal variation in soil/dust ingestion rates in children.

Exposures of children to arsenic from Tacoma Smelter emissions have been monitored using urinary arsenic measurements in a series of studies over a period of about 15 years. Mass calculations of potential arsenic exposures via an inhalation pathway showed fairly early on that inhalation could not account directly for most of the detected increase in urinary arsenic levels. The extensive University of Washington Exposure Pathways Study (Polissar et al., 1987) indicated that ingestion pathway exposures (perhaps mediated by high arsenic concentrations in dustfall of airborne particulates during the period of smelter operations) were likely to account for high urinary arsenic values in young children living near the smelter. The urinary arsenic data therefore offered a possible means of looking at seasonality issues for the soil/dust ingestion pathway.

Wicklund and Harter (undated; 1985?) compiled and statistically evaluated urinary arsenic data from many studies of people living near the Tacoma Smelter; most of the data were for young children. Neither univariate nor multivariate (regression) statistical analyses showed season of sampling (data assigned to one of four calendar quarters) to be a significant factor for the overall variance in the data set. Unfortunately, most of the samples were collected in only two of the four seasons, and there may have been other confounding factors affecting the seasonality analysis. This comprehensive review of data through 1983 does not provide support for assigning seasonal variation to exposure parameters.

Polissar et al. (1987) collected data over four quarters (not matching calendar quarters; the first three-month quarter began with February) for a large number of subjects near the Tacoma Smelter. The authors also performed detailed statistical analyses of the results. Seasonality was not a significant factor accounting for the variability in urinary arsenic results, and the authors described seasonal variations as small in relation to variation on other factors (e.g., age and distance from the smelter). Most subjects did not show significantly elevated urinary arsenic levels; the seasonality analysis may therefore have been limited in its ability to detect any effects over the entire study population.

The UW's Exposure Pathways Study included sampling of a "control" population in Bellingham. Ecology considered looking at the urinary arsenic data for that group to examine seasonality issues. However, the urinary arsenic values in Bellingham were low and likely reflected mostly dietary and drinking water exposures (air and soil arsenic concentrations were low), and there were relatively few samples collected. These factors make it impossible to examine the soil/dust contributions on a seasonal basis. Ecology decided instead to look at the subset of subjects in the Exposure Pathways Study that had the most elevated urinary arsenic values: children in the Ruston census tract. The data evaluations by Polissar et al. (1987) lead to the conclusion that soil and dust ingestion exposures were dominant for this group; the relative influence of dietary and drinking water arsenic exposures are proportionally small. Ecology reviewed the reported urinary arsenic values by quarter within individual subjects to examine seasonality trends. A review of air quality data, while not conclusive, suggests that ambient air arsenic levels are not a serious confounding factor for this simple assessment.

A total of 20 subjects 12 years of age or younger living in Ruston are included in the Exposure Pathways Study data set. Of those, 15 had a maximum reported urinary arsenic level (single day measurement) of at least 40 ug/L, and the evaluations focus on that group to minimize confounding by dietary arsenic intakes. (The five excluded subjects included all four subjects over the age of 10, consistent with our understanding that younger children are most at risk for elevated soil/dust contact, and one two-year old subject.) Thirteen of the 15 children had the highest quarterly urinary arsenic levels (average of two daily measurements in most cases) in one of the two "summer" quarters, that is, in the period May through October. Assuming this seasonal variation reflects primarily soil/dust ingestion exposures, the ratio of "summer" to "winter" urinary arsenic levels can be used as an initial indicator of the potential degree of seasonal variation in soil/dust exposures (involving the combined effects of ingestion rates and arsenic concentrations in soils versus dusts). The median ratio based on reported urinary arsenic concentration is 1.81 (range: 0.74 to 3.34). If dietary plus drinking water contributions are assumed to account for about 5 to 10 ug/L in urinary arsenic, and those amounts are subtracted from all reported values, the median ratio is relatively unaffected, becoming 1.96 to 2.18 (assuming 5 or 10 ug/L, respectively, from dietary sources). Thus, this preliminary analysis of some Puget Sound regional exposure monitoring data suggests a seasonality factor of about 2.

It might be argued that this factor of about 2 actually underestimates the degree of seasonal variability in soil/dust exposures. The urinary arsenic monitoring data for the Exposure Pathways Study included the period surrounding closure of the Tacoma Smelter, with continuing emissions and elevated ambient air arsenic levels (i.e., relatively high arsenic concentrations in airborne particulate matter). The relative indoor dust arsenic concentrations, and contributions from soil to house dusts, might be lower in the absence of recent smelter operations (e.g., in the case of Everett). In the absence of suitable data to examine this issue, a reasonable upper bound ratio of 5 (summer:winter) for seasonality of exposures from soil/dust is used for sensitivity analyses.

The soil-to-dust "transfer factor" (ratio of dust: soil concentrations) has been evaluated in a number of studies using different protocols (see, for example, Rutz et al., 1997 and Allott et al., 1992. See Glass, 1997 for a review and general discussion). Ecology notes that there are substantial methodological issues in studies of indoor dusts, among which is the question of what measurement or measurements are most representative of potential human exposures. Ecology recently considered the question of relative contaminant concentrations in outdoor soils versus indoor dusts for another MTCA site (the Former DuPont Works Site, DuPont, WA) where the soil-to-dust pathway rather than the air-to-dust pathway was of primary interest. Ecology concluded that the literature suggested a range of approximately 0.2 to 0.5 for the soil-to-dust transfer factor, and adopted a value at the upper end of this range for site-specific use in (lead) exposure modeling at the DuPont site. The lower end of the range approximates the median dust-to-soil arsenic concentration ratio in a limited ATSDR study of homes at the Everett Smelter Site.

With these exposure parameter evaluations in hand, Ecology performed sensitivity analyses of potential soil and dust exposures using a more complicated exposure model, including parameters for the issues raised by the commentors, than the MTCA Method B equation. Comparisons with current MTCA calculations (the "baseline case") initially focus only on the seasonality and dust versus soil arsenic concentration parameters for exposure calculations.

For the baseline case, using the MTCA Method B equation, the parameters are an annual 200 mg/day contact rate and the soil arsenic concentration (dust assumed equal in concentration to soil). The results of all other sensitivity analyses are compared to this "200 x soil" baseline (the units, mg/day-mg/Kg, are unimportant for the comparison and are dropped in the following discussion). The more complex exposure model includes additional parameters: the length of "summer" versus "winter" seasons, with a default value of 6 months each in Puget Sound; the allocations of total soil/dust contact rate to soil versus dust, by season; and the relative contaminant concentrations in dust versus soils, by season. Thus, the more complicated model estimates annual exposures by adding and averaging summer and winter exposures, each of which is calculated using an allocation of the ingestion rate between soil and house dusts that can vary in concentration. The seasonality factor for exposures, as described above, actually sets the relative exposure levels for summer versus winter, and that is all that is needed for calculating annual exposures (see examples below); the overall seasonality factor is a "higher order" parameter that includes the effects of the winter allocation of soil/dust contact rates and winter dust versus soil concentrations. It can be shown that reasonable choices for the individual winter parameters (e.g., starting with an assumption that indoor dust contact rates are no lower in the winter than in the summer, since more time is spent indoors in the winter) will produce the seasonality factor used. Some studies have shown increased lead loadings in house dusts in winter and wetter weather versus summer and drier weather (Al-Radady et al., 1994; Laxen et al., 1988). Site-specific data for the seasonal variation in dust:soil arsenic ratios at Everett are lacking, but with use of the overall seasonality factor, such detailed information is not needed for the sensitivity calculations. Ecology notes that the more complicated exposure model includes many more parameters, and therefore requires much more site-specific monitoring data in order to perform detailed calculations directly.

Two sensitivity cases are sufficient to illustrate the main finding: exposure parameter issues do not support changing the selected soil arsenic cleanup level of 20 mg/Kg for the Everett Smelter Site, based on possible revisions to exposure/risk estimates.

> Case I: assume that the summer allocation between soil and dust ingestion is equal (100 mg/day for soil and 100 mg/day for house dusts), that dust concentrations are one-half soil concentrations, and that the seasonality factor (summer exposures/winter exposures) is 2. The summer exposures are then calculated as:
>
> [0.5 yr. x (100 mg/day soil x soil concentration + 100 mg/day dust x (soil concentration x 0.5))] = [0.5 yr. x ("150 x soil")] = "75 x soil."
>
> Winter exposures are just half as much, or "37.5 x soil," making annual exposures "112.5 x soil." Under these assumptions, the annual exposures would be reduced to (112.5/200) = 0.5625 of the baseline case values, and the soil cleanup level

would be increased by (1/0.5625) or a factor of 1.78. This is a very small factor compared to the factor of 30 between the selected cleanup level of 20 mg/Kg and the calculated Method B risk-equivalent value of 0.67 mg/Kg at 100% relative bioavailability. Relative bioavailability would have to be less than 6% to result in a soil cleanup level even marginally above 20 mg/Kg.

Case II: assume the total ingestion rate in summer is allocated 40% to soil and 60% to dust, that dust concentrations in summer are 20% of soil concentrations, and that the seasonality factor is 5. Using the same approach as above, the summer exposures are calculated as:

[0.5 yr. x (80 mg/day soil x soil concentration + 120 mg/day dust x (soil concentration x 0.2))] = [0.5 yr. x ("104 x soil")] = "52 x soil"

Winter exposures are one-fifth as much or "10.4 x soil," and the annual exposures are "62.4 x soil." Compared to the baseline case, exposures are reduced by a factor of (62.4/200) = x0.312, and the soil cleanup level would be increased by (1/0.312) or a factor of 3.21. This is again a small factor compared to the factor of 30 already present in the selected cleanup level of 20 mg/Kg. Relative bioavailability would have to be less than 11% to result in a cleanup standard even marginally above 20 mg/Kg.

Ecology notes that these preliminary evaluations of both the seasonality factor for soil/dust exposures and the soil-to-dust transfer factor are not adequately defined by site-specific information for the Everett Smelter Site. For general adoption of changes in the way MTCA calculates soil/dust exposures [WAC 173-340-702(6)] and in the Method B equations for all sites, any proposed factors for seasonality, allocation of contact rate to soils versus dusts, and dust:soil ratios should be subject to much greater public comment and technical review. Ecology's analyses and sensitivity calculations here support a conclusion that, for the Everett Smelter Site, possible changes in exposure parameters do not scientifically support a change in the selected soil arsenic cleanup level of 20 mg/Kg.

Finally, Ecology notes that the equations adopted within MTCA for calculation of risk-based soil cleanup levels were made relatively simple by design. After review of the prolonged and repetitive debates over all of the risk equation parameters at virtually every site in the EPA Superfund Program, Ecology adopted the approach reflected in MTCA as a better policy alternative, one in which repetitive debates over parameter values would not occur at each site (see Ecology's Responsiveness Summary for the MTCA Cleanup Regulation, February, 1991). Given clear and convincing site-specific information, certain parameters can be modified for a given site. Given clear and convincing scientific information of a general nature, applicable to all sites in a reasonable and unvarying manner, the default parameter values can be modified within MTCA for all sites. Ecology believes that the standard MTCA equation for soil cleanup levels reflects a balanced judgment of both conservative and non-conservative factors, with appropriate but constrained options for flexibility given adequate supporting information. The duration of exposure in the MTCA equation is only 6 years; that is far less than EPA's RME default value, and as a result the MTCA equation results in higher soil cleanup levels than the default EPA equation. Potential exposures from ancillary pathways related to soils - dermal absorption, inhalation (the EPA's Total Exposure Assessment Methodology studies have demonstrated a "personal cloud" of particulates surrounds many human activities, increasing potential exposures), ingestion via home-grown vegetables - are typically not considered at all in deriving soil cleanup levels. The possible conservatism in exposure calculations caused by seasonality and soil versus dust issues, raised by the commentors, is at least partially offset in Ecology's opinion by non-conservative factors such as those noted above.

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Chapter B1-10 Estimation of Risk

Asarco's Contention: All evidence points to actual risks that are less than, rather than greater than, the risks calculated by Ecology. The EPA's cancer potency factor cannot underestimate ingested arsenic toxicity, it can only overestimate it.

A theme in the submitted "new science" comments is that **every** uncertainty and line of reasoning regarding potential risks from ingested arsenic would lead to a reduction in estimated health risks compared to the MTCA risk equation, and that the risk-based cleanup standards under MTCA are therefore conservative in an absolute sense. Ecology disagrees. For the purpose of responding to this set of comments, it is sufficient to illustrate some of the potentially non-conservative elements in the MTCA derivation of a soil cleanup level:

- ❑ Contaminant concentrations in soils are typically measured for that fraction of soils up to 2 mm in size. WAC 173-340-740(7)(a), compliance monitoring provisions. Soil ingestion, however, is dominated by particles considerably smaller than the 2 mm size cutoff for compliance monitoring (as has been noted by some of the same commentors). The arsenic concentration in soils has been shown to increase with decreasing particle sizes. Thus, the soil cleanup standard is likely to be biased high for typical compliance monitoring data, since the arsenic concentration actually ingested is greater than the concentration measured in compliance monitoring data.

- ❑ Exposure duration in the MTCA equation is only 6 years. This is considerably shorter than the duration assumed by EPA for a reasonable maximum exposure (RME) scenario (30 years), based on information reviewed in EPA's Exposure Factors Handbook. The personal experience of many community residents also shows that they live at one location for periods longer than 6 years. As a result, exposures and risks may well be underestimated for an RME scenario in the MTCA equation. EPA's standard risk equation for soil arsenic using a longer default duration of exposure (RME case) results in higher estimated risks than Ecology's MTCA equation.

- ❑ Soil cleanup levels under MTCA are typically based on an equation that considers only direct (incidental) soil (or soil/dust) ingestion. Other pathways and routes of exposure are not considered, such as eating garden vegetables grown in contaminated soil, dermal contact, or inhalation (personal cloud of resuspended particulates from an individual's activities). This is in contrast to the practice in a detailed Superfund risk assessment, where all pathways and routes of exposure can be estimated quantitatively (with much greater complexity). By ignoring other pathways and routes of exposure, the MTCA soil risk equation can underestimate total exposures.

- Soil (or soil/dust) contact rate in the MTCA risk equation is 200 mg/day. However, the studies of childhood soil ingestion rates using element tracer methodology show variable results among different tracers, and none of the studies includes long-term monitoring. The reported 95th percentile values for daily soil ingestion rates across elemental tracers include multiple estimates that exceed 200 mg/day, depending on the tracer element being considered. This suggests that the RME soil contact rate could exceed the 200 mg/day default value.

- EPA's cancer potency factor for ingested arsenic is based only on skin cancer effects. Since the EPA's 1988 reanalysis of the Taiwanese data that supports the current cancer potency factor estimate, a great deal of information has been developed from additional epidemiological studies that shows risks of internal organ cancers from ingested arsenic exposures. Those internal organ cancers have a much greater case-fatality rate than arsenical skin cancers. Those internal organ cancers present additional health risks. The MTCA risk equation using only the skin cancer potency factor does not account for any additional risk from non-skin cancers, and discounting of risks (e.g., in making risk management decisions) because of low case-fatality rates for arsenical skin cancers should not apply to risks for internal organ cancers.

- EPA's cancer potency factor for ingested arsenic was developed using maximum likelihood statistical estimation techniques. Unlike the use of upper confidence limits on dose-response slopes from animal studies, the maximum likelihood estimation approach reflects a "best-fit" approach and not a conservative upper bound. Maximum likelihood estimators can certainly underestimate parameter values, and may do so to a greater degree when the likelihood response function is relatively flat.

- EPA's cancer potency factor is developed from statistical analysis of an ecological study design of a large population group. Under MTCA, individual risks rather than group or population incidence are the primary focus (MTCA's declaration of policy begins: "Each person has a fundamental and inalienable right to a healthful environment...," not "No group or community shall exhibit increased adverse health effects caused by environmental contamination..."). Available information leads Ecology to conclude that it is reasonable to expect significant individual differences in both exposure and sensitivity to arsenic (i.e., toxicity). Applying the cancer potency factor derived from analysis of group incidence of effects as though it represented individual risks probably underestimates the risks for more sensitive subgroups or individuals of a population. (EPA's cancer potency factor also averages results for males and females, and thereby discounts the higher risks shown for males in the Taiwanese study). In Ecology's opinion, the comments do not appropriately distinguish between individual and population risk estimates.

In evaluating "new science" claims regarding risks from arsenic exposures, Ecology concludes that it is appropriate and necessary to consider factors that could lead to underestimation of risks as well as overestimation of risks. Ecology has also focused on the question of whether there is clear and convincing scientific information to modify the selected 20 mg/Kg soil arsenic cleanup level, not just the question of whether the calculated risk-equivalent soil arsenic concentration could be modified. The proposed soil arsenic cleanup level in Everett is not, in the end, based on the risk-equivalent concentration calculated in MTCA; it is 30-fold higher (assuming a 100% relative bioavailability factor for the purpose of calculating a risk-equivalent value). Ecology has performed sensitivity analyses on issues raised in the comments, in the absence of any submitted site-specific data or quantitative estimates within the comments, to evaluate possible cleanup levels in light of this factor of 30.

Ecology believes that the comments that risks are overestimated also embrace and are intertwined with a fundamentally different viewpoint on what risks are acceptable; that is, the issue is as much a challenge to the level of acceptable risks under MTCA as it is a matter of how to quantitatively estimate risks. In pointing to precedents for higher soil arsenic cleanup levels at several Superfund sites, the comments should emphasize that the target risk levels at those sites are orders of magnitude higher than the one in one million cancer risks in MTCA. The comments portray a viewpoint that risks become "significant" when they are "observable," and criticize the acceptable cancer risk target under MTCA precisely on the grounds that no scientific (epidemiological) study could make those risks observable. Ecology does not have to read between the lines on this matter. The comments include the following clear statement: "Ecology should have developed a more realistic cleanup level for arsenic by...selecting a less restrictive target cancer risk level." This is a determination of policy, not of science, and MTCA has adopted a policy on acceptable risks (after much public comment) which the recent MTCA Policy Advisory Committee did not recommend changing. Ecology holds to the position that the policy issue of acceptable risks and the scientific issues involved in quantitatively estimating risks must be carefully distinguished and treated separately, not commingled.

Chapter B1-11 Calculating Risk and Developing Soil Cleanup Levels

Asarco's Contention: Walker and Griffin (1998) modified EPA's default risk model at the Anaconda, Montana Superfund site to account for site-specific study results. They concluded that a 250 mg/Kg soil arsenic cleanup level would be protective of human health.

At the Anaconda, Montana Superfund site, unlike the Everett Smelter Site, the owner of the site collected extensive site-specific data in a series of studies including biological (urinary arsenic) and environmental variables (Walker and Griffin, 1998). This information is used by Walker and Griffin to modify EPA's default exposure model through changes based on site-specific study results for parameters such as house dust versus soil arsenic concentrations, the bioavailability of ingested soil and dust arsenic, and children's urinary excretion volumes. The authors then compare the measured distribution of children's urinary arsenic levels at the site to the modeled distribution using the modified exposure equation. Walker and Griffin (1998) conclude that the modified exposure equation reasonably matches and predicts the measured urinary arsenic data for this site. On the basis of this agreement, the calculated risk estimates using the modified exposure equation are supported. EPA's cleanup decision for the site is still based on calculated risks; urinary arsenic data are used in the validation of a site-specific alternate exposure model and in risk management judgments with respect to EPA's acceptable risk range. The calculated risks reflect the use of modified rather than default values for exposure parameters, based on site-specific studies.

To evaluate the comment that the Anaconda decision shows that the 250 mg/Kg soil arsenic level is protective of human health, it is important to understand how protective has been defined for the Anaconda site. In other words, a comparison of Anaconda and Everett decisions requires recognition of what EPA calculates the lifetime cancer risks from ingested arsenic to be at 250 mg/Kg at the Anaconda site. EPA uses the modified exposure equation to calculate lifetime cancer risks under a (modified) reasonable maximum exposure (RME) scenario. The result is 8×10^{-5}, a value acceptable under EPA's risk management approach in Superfund but far exceeding the one in one million acceptable risk level under MTCA. Thus, what is "protective" under Superfund decision making at Anaconda is not "protective" under MTCA. If the 250 mg/Kg soil arsenic level and associated lifetime cancer risk calculated by EPA for Anaconda are used to extrapolate a one in one million risk-equivalent soil arsenic concentration, the result is 3 mg/Kg, much less than the 20 mg/Kg background-based cleanup level selected for the Everett Smelter Site. This is equally true of EPA's 230 mg/Kg soil arsenic cleanup action level for the Ruston/North Tacoma (Tacoma Smelter) site, which had a (bounding) lifetime cancer risk estimate of 5×10^{-4} using the EPA default soil ingestion exposure equation plus an 80% relative bioavailability factor. Extrapolating a one in one million risk-equivalent soil arsenic concentration from the Ruston/North Tacoma site, the result is 0.5 mg/Kg.

This analysis shows that all of the site-specific evaluations at Anaconda, if applied equally to the Everett Smelter Site, would not affect the selected 20 mg/Kg soil arsenic cleanup level as long as the acceptable risk target remains one in one million. Ecology notes that the results from studies at another site such as Anaconda do not provide site-specific information for the Everett Smelter Site. Thus, the results should not be used in making a cleanup decision for the Everett Smelter Site, a position consistent with the recent MTCA PAC recommendations. The selection of a 250 mg/Kg soil arsenic level at Anaconda reflects primarily the higher acceptable risk range under Superfund compared to MTCA. It is not correct to state that the site-specific modifications in exposure parameters at Anaconda imply that a 250 mg/Kg soil arsenic cleanup level would meet MTCA's requirements for protectiveness, which differ substantially from EPA's under Superfund.

References

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Chapter B1-12 Acute Exposures To Arsenic-Contaminated Soil

Asarco's Contention: The Washington State Department of Health prepared a paper entitled, *Hazards of Short-Term Exposure to Arsenic-Contaminated Soil*. Within that paper, the Department of Health overestimated many exposure factors and/or included unrealistic scenarios. Those issues related to toxicological endpoints, soil ingestion rates, and the safety factor.

When the Washington State Department of Health (DOH) evaluated the hazards of acute exposure to arsenic-contaminated soil, available information related to five factors was evaluated:

- the dose of arsenic reported to cause health effects in people after a single or, at most, a few exposures by ingestion;
- body weights of potentially exposed people;
- the amount of soil people might occasionally ingest over a short period;
- the bioavailability of arsenic from soil ingested by people; and
- a safety factor to estimate a safe level of arsenic in soil from a harmful one.

With the exception of body weights, Asarco stated its disagreement with the DOH evaluation for all of these factors. However, most of Asarco's statements lacked scientific data to support them (the exception being a small amount of new information on bioavailability, which is discussed by Ecology elsewhere in this Responsiveness Summary). Brief responses to Asarco's comments about acute arsenic toxicity, soil ingestion rates, and safety factor are provided below.

B1-12.1 Toxicity

Asarco comment: "Scenarios 1 and 3 are based on avoiding transient health effects that include such symptoms as nausea and diarrhea, but which do not result in permanent injury or harm to human health. These toxicological endpoints are too insignificant and the likelihood of their occurrence too small to justify the costs of achieving these levels of protection."

Ecology response: What Asarco considers "toxicological endpoints [which] are ... insignificant," Ecology considers illnesses that MTCA was adopted to address. Other agencies, such as OSHA, address transient adverse health effects such as eye irritation and dizziness when setting regulatory levels and actions for occupational exposures. Specifically, the OSHA regulation for inorganic arsenic (29 CFR Standard Number 1910.1018(m)(6)) states that "[t]he employer shall assure that no employee is exposed to skin or eye contact with arsenic trichloride, or to skin or eye contact with liquid or particulate inorganic arsenic which is likely to cause skin or eye irritation." It should be noted that Scenarios 1 and 3 were developed to prevent many adverse health effects, including altered electrocardiogram, enlarged liver, edema of the face, and conjunctivitis, not just gastrointestinal problems.

Asarco comment: "Ecology's Scenario 2 analysis for "lethality" results in calculation of an acceptable soil level of 162.5 mg/Kg…. As noted in Asarco's Comments on Ecology's Review of New Science, a number of studies reveal that arsenic in soil at this level has no effect at all on urinary arsenic levels. To suggest that this concentration in soil presents an unreasonable risk of lethality is an absurd and unsubstantiated conclusion."

Ecology response: Ecology believes that Scenario 2 represents conditions that, although unlikely, could occur at the site. The consequences of this scenario (death or permanent serious injury) are not acceptable, and it is Ecology's intent that they be prevented. Given that such an exposure is expected to be rare, it is not surprising that it would not be detected by examining average urinary arsenic levels in a couple of limited studies. Any large individual exposure, if it had even occurred during the one or two days when urine was collected for the study, would likely not be detected by examining the combined average for all subjects.

Asarco comment: "Ecology has misinterpreted and misused the underlying studies on which its toxic effects conclusions were calculated. It had to assume body weights with no supporting data, for example, to calculate the concentration per kilogram of body weight at which toxic effects supposedly occurred; it had to assume that exposure levels were accurately measured, even though some of the data dates back more than 70 years; and it took examples of continuing exposures to arsenic over multiple days and assumed that the same toxic effects would occur from a single incident of exposure. Much of the data relied upon can only be described as anecdotal. Moreover, as explained in Dr. Schoof's statement, it ignored more reliable modern data that contradicts its conclusions."

Ecology response: As stated in the DOH document, "[t]he dosage data for medicinal arsenicals may be the best human exposure estimates available, given the widespread use of the drugs, consistent formulations, and standard treatment regimens. Data in the other studies appear to be reliable." Ecology agrees that there is some inherent uncertainty with respect to exposure doses. While the exposure doses could have been either underestimated or overestimated to some extent, the assumptions related to exposure doses were explained in the DOH report and appear to be well justified. Asarco offers no data to suggest otherwise. Contrary to Dr. Schoof's assertion that "[i]n many cases, exposure to arsenic occurred for a week or more, and therefore does not truly represent acute exposures," health effects appear to have occurred after a day's exposure or less in all but one study. Asarco suggests that recent studies on the treatment of certain leukemia patients with arsenic provide "more reliable modern data that contradicts [Ecology's] conclusions." If anything, the studies support Ecology's conclusions since adverse health effects consistent with arsenic exposure were reported in six of seven patients (Huang et al., 1998) and at least 3 of 12 patients (Soignet et al., 1998) at doses similar to those identified in the DOH document as causing adverse health effects. However, it is unclear that these studies are particularly useful for evaluating the hazards of acute arsenic exposure since the studies were very small, the patients had a myriad of preexisting health problems, and arsenic was administered for extended periods of time intravenously, not orally for short periods.

B1-12.2 Soil Ingestion Rate

Asarco comment: The soil ingestion rates are not realistic. The Scenario 3 ingestion value of 2,000 mg/day for an adult is by no means "common." This exceeds by 10 times the 95 % UCL value used by Ecology for children, who clearly are more prone to soil ingestion than adults. It is unrealistic to assume that any adult would deliberately eat that much soil, unless the person was deranged, and it is silly to suggest that this consumption could occur on a "relatively common" basis from soils lying below 2 feet down to 15 feet.

Ecology response: The DOH document details the scientific bases for the choices of soil ingestion rates for the three acute exposure scenarios. The 95% UCL referenced by Asarco is based on continuous exposure, not acute exposure events, and its relevance to the discussion of acute exposure is not clear. Pica behavior (the ingestion of non-food items, including soil) is a well-documented phenomenon in both children and adults. Asarco provides no data to show that "the soil ingestion rates are not realistic."

Asarco comment: "Ecology's assumptions of a soil ingestion by a child of 20,000 mg/day in Scenario 2, resulting in lethality, is extraordinary. It is based on one reported incident of one child's behavior."

Ecology response: Soil ingestion rate has been measured in only a small number of children, and yet two of those children repeatedly ingested 20,000 mg/day or more (Calabrese et al., 1997). Ecology agrees that ingestion of 20,000 mg/day or more by a child is likely to be uncommon. Nonetheless, available scientific information demonstrates that some individuals do ingest that amount of soil and more, and Ecology believes that cleanup of the site should protect such individuals from serious illness and death.

Asarco comment: Moreover, the soil ingestions assumed are so high it is likely that the same symptoms would occur from soil ingestion alone wholly apart from any arsenic content.

Ecology response: Ecology made its cleanup decisions at the Everett Smelter Site to protect people against the full spectrum of potential health effects caused by arsenic. While it is possible that ingestion of one or two grams of soil could cause nausea and diarrhea in some people, there is no evidence to suggest that ingestion of uncontaminated soil can cause the other adverse health effects associated with ingestion of small amounts of arsenic (i.e., edema of the face, conjunctivitis, anemia, enlarged liver, abnormal electrocardiograms).

B1-12.3 Safety Factor

Asarco Comment: There is no justification for imposing a 10-fold safety factor to protect against such transient effects, particularly given the extraordinarily conservative assumptions used for soil ingestion and bioavailability. These factors, in effect, already have a safety factor built in, and Ecology's selected cleanup levels have redundant layers of protection built in to avoid insignificant and temporary effects.

Ecology Response: Based on available information of acute arsenic toxicity, Ecology believes that a 10-fold safety factor is justified and the minimum that can reasonably be considered in developing a protective soil arsenic concentration for acute exposure. When EPA estimates "safe" doses of noncarcinogenic chemicals, a safety factor of 10 is almost universally used to account for differences among humans in sensitivity to a chemical, and another safety factor of 10 used to estimate a safe dose from a harmful dose. These are to help compensate for uncertainties in toxicological knowledge. Greater uncertainty about the toxicity of a chemical is generally correlated with the use of a larger safety factor. There is significant uncertainty with respect to toxicity of arsenic from acute exposures, and this uncertainty would justify the use of a safety factor of 100, in keeping with the EPA paradigm. However, as stated in the DOH document, "[f]or the three scenarios a safety factor of 10, to derive a no-effect level from an effect level, was considered adequate to calculate soil arsenic concentrations protective of public health. This choice was based on consideration of documented variability in human sensitivity to the toxic effects of arsenic…as well as consideration of likelihood of occurrence of the various scenarios." The underlying basis for Asarco's comment (i.e., that the exposures described in the scenarios are somewhat unlikely) was already considered by DOH in the document, and contributed to the choice of a safety factor of 10 instead of 100.

It should be noted that in choosing a safety factor, consideration was given to the extent of knowledge regarding toxicity, amount of exposure, and likelihood of exposure. The scenarios evaluated all involve exposure to subsurface soil, and the choice of a safety factor of 10, instead of a larger one, was partially based on the reduced likelihood of exposure to subsurface soil compared to soil that is at the ground surface, which may occur daily. Therefore, while a safety factor of 10 is considered adequate for exposure to subsurface soil, it may not be adequate for exposure to contaminated surface soil where exposure is expected to be more frequent. Thus, the more frequent contact associated with surface soil versus subsurface soil may require a safety factor greater than 10 to be equally protective of the health of the children at the site.

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Chapter B1-13 Soil-Lead Cleanup Levels

Asarco's Contention: The assumptions used by Ecology to calculate a soil lead cleanup level are too conservative. The soil lead cleanup level should be increased above Ecology's newly revised value of 353 mg/Kg.

Several of the outside experts hired by Asarco commented in their declarations that the soil lead cleanup level of 353 mg/Kg, while higher than the 250 mg/Kg cleanup level originally considered by Ecology, was still too stringent. They commented that the most conservative assumptions in EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) must have been used by Ecology. The Model Toxic Control Act Method A soil lead cleanup level is 250 mg/Kg. WAC 173-340-740. Based on the earlier request and comments received from Asarco, Ecology agreed to use EPA's child exposure model, the IEUBK model, to establish a soil lead cleanup level for the Everett Smelter Site. Asarco provided no site-specific information to Ecology as a rationale to vary any of the inputs to the IEUBK model. Ecology therefore selected the model's standard default exposure assumptions in developing a soil lead cleanup level of 353 mg/Kg for residential properties. (See below for the default assumptions used by Ecology.)

Asarco commented that EPA uses 400 mg/Kg as their screening level for soil lead cleanups. A policy decision by EPA has established 400 mg/Kg as their screening level for CERCLA cleanups. That policy decision was outlined in an EPA Directive (OSWER Directive 9355.4-12 dated July 14, 1994) and again in an EPA memorandum dated August 1998 (OSWER Directive 9200.4-27P). EPA's Office of Solid Waste and Emergency Response (OSWER) recommends that the IEUBK model be used as the primary tool to generate risk-based soil cleanup levels at lead sites for current or future residential land use. OSWER also recommends that cleanup level at lead sites be designed to reduce risk to a typical or individual child receiving exposures at the residence to meet their guideline - no greater than a 5% chance of exceeding a 10 ug/dl blood-lead level for a child 6 months to 84 months old. (Note: If the 400 mg/Kg screening level is input into the IEUBK model and is "run backwards," the model predicts that there is a 7.28% chance of a child exceeding the 10 ug/dl blood lead level.) EPA 1998 OSWER Directive reaffirmed: the use of the IEUBK model to establish site-specific residential risk-based soil cleanup levels; that blood-lead data not be used alone to assess risk from lead exposure; and a preference for permanent remedies and the use of engineering controls for long-term cleanup actions versus a reliance on education and intervention programs to mitigate risk.

In developing a soil lead cleanup level for the Everett Smelter Site, Ecology is using the same guidelines (5%, 10 ug/dl, 6 to 84 months) as EPA uses. Ecology has made a policy choice to use the IEUBK model and to use the model's predicted soil lead cleanup level. (See discussion in Ecology's New Science Review dated January 1999.) Could other site-specific or region-specific input parameters be used in the IEUBK model for the Everett

Smelter Site? Yes. Would alternate input parameters change the soil lead cleanup level? Yes. Did Asarco propose site-specific input parameters to Ecology for use in the IEUBK model? No. Will the site-specific soil lead cleanup level for the Everett Smelter Site remain at 353 mg/Kg? Yes.

The IEUBK input parameters (model defaults) used by Ecology are as follows:

1. Outdoor air lead concentration = 0.1 $\mu g/m^3$ (micrograms per cubic meter)
2. Indoor air lead concentration = 30% of outdoor air concentration
3. Drinking water concentration = 4.0 µg/l (micrograms per liter)
4. Soil/dust ingestion weighting factor = 45% (soil)
5. Mother's blood lead concentration at birth = 2.5 µg/dl (micrograms per deciliter)
6. Contribution of soil lead to indoor household dust-lead = 70%
7. Soil lead gastrointestinal bioavailability = 30%
8. Total soil and dust intake rate (grams/day) = ranges from 0.085 to 0.135 g/day
9. Other input variables are also the standard defaults (IEUBK model - Version 0.99D).

Everett Smelter Site
Integrated Final Cleanup Action Plan and Final Environment Impact Statement

Appendix B
Responsiveness Summary

Attachment B1
New Science Review

Attachment B1-1

Review of Asarco's "New Science" Submittals Regarding Arsenic and Lead
January 1999
Washington State Department of Ecology

DEPARTMENT OF ECOLOGY
TOXICS CLEANUP PROGRAM
JANUARY 26, 1999

To: Tim Nord
David L. South
Mary Sue Wilson

From: Mike Blum

Subject: Review of Asarco's New Science Submittal for the Everett Smelter Site

This brief cover memo outlines the conclusions reached by the New Science Review Team (Mike Blum, Craig McCormack, Jim White, & Greg Glass) in our review of the July 1998 Asarco submittal to Ecology. Basically, the submittal was a regurgitation of existing information (journal articles and EPA documents) and declarations from six experts hired by Asarco. Little to none of the information was site-specific to the Everett Smelter site. No actual new science was generated, only some limited reinterpretation of the existing science. Asarco did not offer any new specific cleanup levels with the science to back it up, but rather mostly criticism of Ecology's Model Toxics Control Act cleanup regulation, including the science and policy aspects of that regulation.

The New Science Review Team is recommending that no changes be made to Ecology's soil cleanup levels for arsenic. We are however recommending that EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) be used to establish soil-lead cleanup levels for residential properties. To be protective of 95% of the population of children (6 to 84 months) from exceeding a blood lead level of 10 ug/dl (micrograms per deciliter), the residential soil-lead cleanup level would be 353 ppm. That value is in contrast to the current Model Toxics Control Act Method A residential soil-lead value of 250 ppm.

If you have any questions regarding this memo or the New Science Review document that will follow very soon, please give me a call at 407-6262. Thank you for the opportunity to participate in this most interesting project.

cc: Craig McCormack, Ecology
Jim W White, State Health
Greg Glass, Greg Glass Consulting

Review of Asarco's "New Science" Submittals Regarding Arsenic and Lead

By the Washington State Department of Ecology

January 1999

Team Leader: Mike Blum, Ecology
Co-authors: Dr. Jim W. White, State Health
Dr. Craig McCormack, Ecology
Greg Glass, Environmental Consultant

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Introduction

Background.

Under the Model Toxics Control Act (MTCA) regulations, chapter 173-340 WAC, the Washington State Department of Ecology (Ecology) establishes cleanup levels for particular sites pursuant to WAC 173-340-700 through -750. The regulations currently include three methods for determining cleanup levels, methods A, B, and C. WAC 173-340-700(3).

With respect to soil cleanup levels for the Everett Smelter Site, Ecology indicated in early discussions with interested parties, including Asarco, that it expected to use 20 parts per million (ppm) as the arsenic soil cleanup level and 250 ppm as the lead soil cleanup level. The analysis done by Ecology in determining that these cleanup levels were likely to be the levels that would be used at the Everett Site is explained below.

Ecology reasoned that establishing soil cleanup levels for arsenic and lead for residential portions of the site would involve the use of Method A or B. WAC 173-340-740(1)(a). For arsenic, the Method B cancer equation yields a 1.67 ppm value. *See* WAC 173-340-740(3)(a)(iii)(B).[1] However, the regulations indicate that where the natural background concentration is greater than a cleanup level derived under this method, the cleanup level shall be established at the natural background concentration. WAC 173-340-700(4)(d). The 20 ppm soil cleanup level for arsenic is the concentration identified in the Method A table as the arsenic concentration based on natural background. WAC 173-340-740, table 2 note b. Thus, based on these regulatory provisions Ecology indicated to interested parties that it expected to use 20 ppm as the soil cleanup level for arsenic.

The soil cleanup level Ecology expected to use for lead at the Everett Smelter Site was 250 ppm, the valued identified in Table 2 of WAC 173-340-740. Because lead is not a known carcinogen, use of the Method B cancer equation was not appropriate. The Method A value is a value identified by Ecology, when it adopted the regulations in 1991, as based on preventing unacceptable blood lead levels. *See, generally,* discussion in 1991 Responsiveness Summary (Pages 231-233).

The Asarco Submittal

Asarco Incorporated requested that Ecology review their proposal to consider new scientific information that is relevant to the Everett Smelter site cleanup. That request was sent on July 13, 1998 and received on July 14th by Ecology. The 12-page request cover

[1] [1] For the reasons explained in Ecology 1999a, Ecology has recently decided to use 100% for the bioavailability input for the cancer equation. Here, 1.67 ppm is the value yielded when 40% bioavailability is used. If 100% is used, the resulting value is 0.67 ppm.

letter included sworn declarations from six outside experts hired by Asarco Incorporated (Asarco) and thirteen three-ring binders of additional supporting documentation.

The Model Toxics Control Act regulations (WAC 173-340-702(6)) states, *"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."* Asarco requested Ecology to consider changing the soil cleanup levels for both arsenic and lead, the two primary contaminants at the former Everett Smelter site.

This document outlines the "new science" review conducted by Ecology, responses to the questions, issues, and statements contained in the submitted declarations, and the decisions reached following the review of the information submitted. In summary, Asarco was requesting Ecology to increase the soil cleanup levels for lead and arsenic. Based on a reasoned review of the information submitted, Ecology has decided not to make any changes to the soil cleanup level for arsenic. Ecology has decided to make changes to the way it evaluates the risks associated with lead in soil, thereby increasing the soil-lead cleanup level. Ecology will also be setting remediation levels for the Everett Smelter site. What is the difference between a cleanup level and a remediation level? A cleanup level is the concentration of a hazardous substance in soil, water, air, or sediment that is determined to be protective of human health and the environment under specified exposure conditions. A remediation level is the concentration, or other means of identification, of a hazardous substance in soil, water, air, or sediment above which a particular cleanup action component will be required as part of a cleanup action at a site. The draft Cleanup Action Plan for the Everett Smelter site identifies cleanup levels and remediation levels.

So what was included in the thirteen three-ring binders, sometimes referred to as "the thirteen volumes", that Asarco submitted to Ecology? In general, the three-ring binders included photocopies of selected articles from technical journals and copies of EPA documents and guidance manuals. (Asarco's submittal can be reviewed at Ecology's Northwest Regional Office in Bellevue or the Everett Information Center repository.) The binders did not include any information developed specifically for the Everett site. The declarations of the six outside experts (Dr. Barbara Beck, Dr. Kenneth Brown, Dr. Daniel Menzel, Dr. Joseph Rodricks, Dr. Rosalind Schoof, and Dr. Joyce Tsuji) raised issues and concerns about how Ecology and EPA evaluate risk, both from the science perspective and from a policy standpoint. They did not recommend any specific cancer potency factor that Ecology should use in the Model Toxics Control Act risk formulas when establishing a soil cleanup level for arsenic. Asarco did not request or recommend any specific soil cleanup levels for arsenic and lead.

Ecology has consulted extensively with the Washington State Department of Health (Health) who's been involved in the evaluation and assessment of the public health risks associated with the Everett smelter site for several years. Consultations between the U.S. Environmental Protection Agency (EPA) and Ecology about arsenic risks have been less extensive, however the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) has been involved in health risk assessments at the Everett site in conjunction with Health. In the recent past, Ecology has consulted with the Model Toxics Control Act Science Advisory Board, EPA, and Health on soil-lead cleanup and exposure modeling at another state cleanup site. The input from these consultations is applicable to the Everett site as well as other similar sites around the state.

Lead does not fit the standard risk formulas contained in the Model Toxics Control Act cleanup regulation. The EPA has developed two approaches for evaluating risks associated with lead in soil. They are both interim approaches, but are usable until a final exposure model is developed, which will be known as the All Ages Model. One model is known as the Integrated Exposure Uptake Biokinetic Model (IEUBK) and is applicable for exposures by young children. The other model, which is applicable for adults, is known as the Adult Lead Model. The adult lead model is only applicable for sites where adults are the only exposed individuals, such as industrial sites. For the Everett site, the surrounding land uses are primarily residential so children are the exposed population, therefore the IEUBK model is applicable for establishing soil-lead cleanup levels for the site.

Arsenic is a different story altogether. There is no exposure model developed specifically for arsenic. There is however, the necessary information to evaluate the risk of exposure to arsenic like there is for many other chemicals. Arsenic is a known carcinogen and EPA has developed a cancer potency factor. Arsenic also has non-carcinogenic properties, and EPA has also established an oral reference dose. This is in contrast to lead. Lead is a currently identified as a probable carcinogen and its non-carcinogenic properties are measured by its concentration in the bloodstream. Lead has no established cancer potency factor or oral reference dose. Lead, in contrast to arsenic, does not "fit" the Model Toxics Control Act risk formulas, because these formulas require a cancer potency factor or an oral reference dose.

Decisions regarding risk that are made at cleanup sites, including the Everett Smelter site, are based on a mix of science and policy. Science helps to inform the many policy decisions. Risk assessment relies more on science while risk management is much more heavily dependent on policy decisions. Ecology's Model Toxics Control Act cleanup regulation is a mix of science and policy. As the science changes, Ecology makes modifications to its cleanup standards as appropriate. New scientific information can address global changes to cleanup standards that effect all cleanup sites or be uniquely site specific. The Asarco request was not site-specific.

Human health risk assessments include many uncertainties. This is due in part to gaps in scientific knowledge regarding hazardous substances and their long and short-term impacts on humans. In the face of uncertainty, Ecology chooses to be protective of human health and the environment. Does that mean that Ecology is overly protective? Possibly. As a regulatory agency, Ecology will and should err on the side of protectiveness. To do otherwise is not prudent nor does it meet the basic tenant in the Model Toxics Control Act law wherein it states,

> *"Each person has a fundamental and inalienable right to a healthful environment, and each person has a responsibility to preserve and enhance that right. The beneficial stewardship of the land, air, and waters of the state is a solemn obligation of the present generation for the benefit of future generations."* (Chapter 70.105D.010 RCW)

No reasonable and responsible agency or individual should choose to do otherwise.

So how is this document organized and how has Ecology evaluated Asarco's New Science submittal? Ecology has reviewed all of the key issues and questions raised in Asarco's cover letter and the six declarations. In an attempt to explain our evaluation as concisely as possible, we have consolidated the multitude of comments and questions raised by Asarco into twenty issues and presented discussions of our assessment of each one. During the review of the declarations, the thirteen three-ring binders functioned as a library of reference documents. Ecology appreciated having that library, albeit selective, close at hand. Ecology believes that it has conducted a reasoned review of the Asarco submittal. Ecology has also provided answers to the two basic requests contained within Asarco's submittal: Change (increase) the soil-arsenic cleanup level - no; change (increase) the soil-lead cleanup level - yes.

<u>Review Standard.</u>

The "New Science Review Team" has evaluated the issues submitted by Asarco by asking the following basic questions:

Is the information submitted by Asarco of a quantity and/or quality sufficient to persuade Ecology to select soil cleanup levels different than the levels identified above (in background section) as the expected cleanup levels for lead and arsenic? Is the submitted information clear and convincing to make changes about what is protective?

Evaluating the issues also involved consideration of additional factors, such as:

* Is the information "new"? (i.e., is it information that was developed since the adoption of the cleanup standards in 1991?)
* Is the information "science" or "policy"?
* Where the information is "science," has the "scientific approach" advanced with respect to a particular issue been endorsed elsewhere? By other state regulatory agencies? By the EPA? By science advisory boards, such as Ecology's Model Toxics Control Act Science Advisory Board?
* Where the information is "policy," was a policy choice regarding how to use such information made by the agency when it promulgated its regulations in 1991?
* If yes, has new information been presented that suggests that the original policy choice should be revisited?

"Nature of Uncertainty - Uncertainty can be defined as a lack of precise knowledge as to what the truth is, whether qualitative or quantitative. That lack of knowledge creates an intellectual problem - that we do not know what the 'scientific truth' is; and a practical problem - we need to determine how to assess and deal with the risk in light of that uncertainty." (Science and Judgement in Risk Assessment, 1994)

Comments and Questions Raised by Asarco

The following are the comments and questions raised by Asarco in their July 13, 1998 New Science submittal to Ecology. As noted in the introduction, this consolidated list was generated after review of Asarco's cover letter and attached declarations and identifies the major issues raised. The individual comment(s) and/or question(s) can also be found at the beginning of each of the following sections. The authors of the comment are at the end in brackets. Some statements, in italics, are direct quotes while others are a summarization. We recognize some comments were made by multiple authors and possibly only attributed to one or two of them.

1. **Use of a linear threshold model for arsenic is not appropriate** - *"EPA's IRIS cancer slope factor for arsenic, which Ecology's Method B formula incorporates as a cancer potency factor, is invalid." "The cancer slope factor bears no reasonable relation to arsenic's actual cancer potency and both overstates risk at low dose and understates risk at high dose, thus rendering extrapolation to the U.S. population inappropriate." (Thorp) "When such [mechanistic] data are available EPA reveals, in the new [Cancer] Guideline, how they will be used for risk assessment in place of the "default" (which is to be used when data support it or when no significant data are available to demonstrate that it is incorrect)." (Rodricks)*

2. **The slope factor most likely overestimates cancer for the U.S.** - *"[S]tudies conducted in U.S…. suggest that arsenic does not induce skin cancer at rates comparable to those predicted by EPA's CSF [cancer slope factor], and that a threshold for these effects might exist." (Rodricks)*

3. **Uncertainties in exposure analysis in Taiwanese study** - *"EPA's calculation assumed levels of exposure which are inconsistent with the actual exposures in Taiwan." (Thorp)*

4. **Other questions about the validity of the Cancer Slope Factor (CSF) and the application of the Taiwan study to the U.S. population** - *"The Taiwan data are inapplicable to the U.S. population.…because of significant differences between the Taiwanese and U.S. populations. These differences include elevated arsenic levels and protein deficiency in the Taiwan diet (which may affect the ability of those persons to methylate arsenic) and significant exposures to other carcinogens in the Taiwanese drinking water studied by Tseng." (Thorp)*

5. **200 mg soil ingestion rate is too high** – *"In deriving the Method B cleanup level, Ecology assumes that a child ingests 200 mg of soil every day for 6 years. This assumption is flawed for a variety of reasons. They include: a) the failure to consider the impact of climatological factors on soil ingestion. Significant soil ingestion is prevented during the fraction of the year that the ground is frozen, and climate can be highly variable in Washington, which clearly affects actual exposures to chemicals*

in soils; b) the failure to consider site and chemical-species differences in bioavailability of chemicals in soil that would limit the uptake of the chemicals into the body; c) the fact that much of the soil taken into the body is ingested indirectly as dust, which typically has a lower concentration of metals than soil. This overall uptake of metal, causing the formula to overstate risk." [Beck]

6. **Arsenic bioavailability in MTCA Method B is too high** - *The WDOE's use of a bioavailability factor of 40% likely resulted in an overestimation of the soil arsenic dose available for potential carcinogenic effects and an overly restrictive cleanup level for arsenic in soil. (Rodricks)*

7. **Arsenic exposure from soil is minimal compared to that from food and water** - *"The likely significance of exposures to arsenic in soil is diminished in comparison to background exposures to arsenic from other sources, particularly diet and drinking water." (Schoof)*

8. **Suggested alternative for calculating a cleanup level** - *In addition to the numerous epidemiological studies such as at Ruston and Anaconda which have not found health effects associated with environmental arsenic exposure….two additional epidemiological studies of residential exposure to smelters in Utah….likewise did not find an association between environmental arsenic exposure and lung cancer incidence. (Schoof)*

9. **There is no evidence that residing in a home surrounded by soil containing concentrations of arsenic far in excess of the 20 ppm standard poses any public health threat or a significant risk to individuals residents** - *In the absence of a clear alternative to the EPA's unsupportable CSF [Cancer Slope Factor] for arsenic, the problem of soil cleanup at Everett might be approached in the following way...the following question can be posed: what total lifetime exposure to arsenic will be incurred if all the soils are cleaned up to 20 ppm?...[versus] what total lifetime exposure to arsenic will be incurred if all the soils are cleaned up to 100 ppm?...the calculations [presented in the comment] demonstrate that the ranges of total lifetime arsenic intakes...will be affected only slightly if soils are cleaned up to 20 ppm rather than to 100 ppm [Rodricks].*

10. **Studies show that children living in communities w/ soil arsenic concentrations far in excess of Ecology's 20 ppm cleanup level do not have arsenic exposures (as demonstrated by no significantly increased urinary arsenic concentrations) from soil that pose a health threat** - *New studies of exposure to arsenic in soil indicate that absorbed doses are much lower than assumed by the agencies ... Recent exposures to arsenic in environmental media may be evaluated by means of studies that use urinary arsenic as an exposure marker ... even for children residing in a community with widespread and marked elevations in soil arsenic concentrations, the exposures from soil were still relatively insignificant ... [in another community] the lack of an increase in mean urine concentrations indicates that increasing arsenic*

concentrations in soil are not causing a detectable increase in arsenic exposures above background exposures in most of these children ... Taken together these new studies provide documentation that children living in communities with soil arsenic concentrations far in excess of WDOE's 20 ppm cleanup level do not have arsenic exposures from soil that pose a health threat. The distribution of urinary arsenic levels for a population with typical background exposures to arsenic provides an indication of the distribution of background exposures...The best available data set for a population with background exposures to arsenic is from a comprehensive study...in young children living near the Bingham Creek Channel site in Salt Lake County, Utah...From this data set, the 90th and 99th percentile values for background absorbed daily doses of arsenic for young children is estimated to be approximately 12 and 22 ug/day, respectively...The distribution of background arsenic exposures in the entire U.S. population is expected to be even broader than this distribution...If a small fraction of an exposed population has an increased exposure to arsenic of 10 ug/day or less, there will be no discernible public health risk to that population...based on the fact that an additional 10 ug dose would not cause 90 percent of the population to exceed the 99th percentile background exposure value...Using WDOE's assumptions for deriving risk-based soil cleanup levels, an allowable incremental 10 ug/day intake of arsenic yields an acceptable soil concentration of 125 ppm. [Schoof].

11. **Arsenic is an essential nutrient** - *"Arsenic is a demonstrated essential element in animals and the evidence indicates in is likely essential to humans as well." (Thorp)*

12. **Risk of remediation is greater than the risk of leaving the contaminant in place** – *Risks are created by soil cleanup activities that could be more significant from a public health perspective than the risks eliminated by removal of arsenic or lead from soil. The stricter the cleanup level, the higher the remediation risk becomes. At the levels of arsenic in soil under consideration here, this is an important consideration...Ecology apparently does not consider the fact that the soil cleanup itself may create new risks...For example, soil excavation and transport of contaminated soil by truck can result in accidental injuries and fatalities. Remediation itself creates risks to workers...Moreover the fatalities from accidents typically occur at younger ages than fatalities resulting from cancer, resulting in more "years of potential life lost". It is important to note that these estimates of injuries and fatalities are based on actual data. In contrast, the risk from arsenic in soil is ... based on a theoretical model [Beck].*

13. **Method A level for lead is too low and inconsistent with current scientific evidence** – *"The regulation does not state the blood lead model used, or any of the assumptions, such as the soil ingestion rate, lead bioavailability, amount of lead from other sources and population blood lead distribution, that went into the derivation of the 250 ppm level. Nonetheless, the level is inconsistent with the 400 ppm level used*

by EPA as a screening level for lead in soil." [Beck] "The 250 ppm Method A cleanup level for lead is inconsistent with the current scientific evidence on health protective levels for lead in soil." [Tsuji]

14. **<u>The 3-part rule is overly conservative</u>** *"Ecology's three-part decision rule, coupled with application of a cleanup level of 20 ppm based on Method A, could result in as many as 48% of the Everett residential properties requiring remediation <u>based solely on the influence of background levels of arsenic</u> [Thorpe]. The three-part rule is overly conservative. Cleanups should be based only on the average concentrations at a property; meeting the three-part rule would in fact result in an even more restrictive result than implied by the cleanup value itself" [Beck].*

15. **<u>Reviewed 12 vs. 18 inch cleanup depth for the Sandy smelter and concluded that an 18 inch removal depth would not provide measurable additional protection</u>** - *"Regarding depths of soil cleanup, I have reviewed the relative health protectiveness of 12 versus 18 inch depths for soil remediation for the Sandy Smelter site in Utah. This evaluation….concluded that based on the likelihood and magnitude of soil contact and decisions at other sites, an 18-inch soil removal depth would not provide measurable additional protection relative to a 12-inch remediation depth. The conclusions of this evaluation are also applicable to the Everett site." (Tsuji)*

16. **<u>Lack of consideration of site-specific exposure differences doesn't represent sound scientific principles</u>** – *"The Method B approach is generically flawed in that it does not consider a range of factors. These include: 1) Site-specific differences in exposure due to climate and other variables across sites that will result in different doses at the same cleanup level; 2) Differences in dose/response relationships among carcinogens which would require the use of different dose/response models, rather than the single model sued by Ecology." and "Overall, the MTCA cleanup levels for lead and arsenic in soil are inconsistent with current scientific knowledge regarding exposure, toxicology and risks of these substances. Moreover, the use by Ecology of a formula with unvarying input assumptions for all chemicals at all sites to develop cleanup levels does not represent the use of sound scientific principles." [Beck]*

17. **<u>Opinion that 10^{-6} cancer risk is inappropriate</u>** – *"Ecology uses an inflexible risk target of 10^{-6} for all carcinogens. This decision does not consider factors such as the size of the population exposed or the relative importance of soil as an exposure pathway for a particular chemical in selection of the risk target. Such factors are normally considered by regulatory agencies in setting permissible risk levels and should be considered by Ecology." [Beck] "Consequently, EPA site managers may use higher target risks and cleanup levels when they believe arsenic exposures at a site are low enough that no pulic health hazard exists." [Schoof]*

18. **<u>Assumption of 6-year childhood exposure in MTCA Method B equation is unwarranted scientifically and statistically</u>** - *"The Ecology Method B formula ... assumes that a six year childhood exposure creates a lifetime cancer risk directly*

proportionate to the risk from a lifetime exposure, i.e. that the childhood risk is 6/75 of the lifetime risk. This is an unwarranted assumption...In general, since the available evidence is that arsenic is more likely a promoter or progressor than initiator, the lifetime risk from exposure during the first six years of life should be lower than the proportionate method assumed by Ecology" [Brown].

19. **EPA is moving away from point estimates to distributions for exposure estimates** - *The EPA has ... moved forward on the issue of human exposure estimation. It recognizes that a simple "point estimate", derived without an understanding of the fraction of the population having exposures at or below it, provides a poor profile of actual human exposures. The agency is now attempting to make fuller use of exposure-related data to derive quantitative profiles of the distribution of exposures in populations...The EPA...is thus moving away from undefined "point estimates"... as a basis for decision-making [Rodricks].*

20. **Grass as an effective cover** – *" Vegetation is an effective containment methodology that minimizes exposure to arsenic in soils." [Thorp]*

[1] Comment - The use of a linear threshold model for arsenic is not appropriate.
"EPA's IRIS cancer slope factor for arsenic, which Ecology's Method B formula incorporates as a cancer potency factor, is invalid." "The cancer slope factor bears no reasonable relation to arsenic's actual cancer potency and both overstates risk at low dose and understates risk at high dose, thus rendering extrapolation to the U.S. population inappropriate." (Thorp) "When such [mechanistic] data are available EPA reveals, in the new [Cancer] Guideline, how they will be used for risk assessment in place of the "default" (which is to be used when data support it or when no significant data are available to demonstrate that it is incorrect)." (Rodricks)

Response - In order to protect public health, it is important to estimate the potential for arsenic to cause harmful health effects at exposures below those where health effects have been measured. This is due to the goal of preventing health effects in members of the population who may be especially sensitive to the effects of arsenic and the known or suspected limitations of studies of the health effects of arsenic. While toxicity below the measured range is not known, there are a number of ways to estimate it by extrapolating from data in the measured range. However, different methods of extrapolation can produce different estimates of toxicity using the same data. Choosing an extrapolation method, and determining how the method will be used for an individual chemical, are policy decisions based on an evaluation of the limitations and uncertainties of available toxicity data, of the degree of protectiveness desired, and of the plausibility that the method is appropriate.

For carcinogens, WAC 173-340-708(8)(a) states that the EPA cancer potency factor on EPA's IRIS database will be used in Method B calculations to determine cleanup levels unless there is clear and convincing scientific data which demonstrates the use of this value is inappropriate. EPA develops a cancer potency factor, a measure of the potency of a chemical to cause cancer, using models that assumed a linear dose-response with no threshold for effect. For low-dose extrapolation for arsenic, EPA chose to use a linear quadratic model to provide an estimate of toxicity that could be used to ensure the protection of public health. The cancer potency factor was developed using data from a large population in Taiwan (Tseng et al., 1968; Tseng, 1977). The ability of the model to predict skin cancer prevalence rates in a Mexican population (Cebrian et al.) was tested, and the differences between observed prevalence rates and those predicted using the Taiwanese data was negligible (U.S. Environmental Protection Agency, 1988).

Uncertainty in mechanism of action of arsenic was discussed in a 1988 EPA document (U.S. Environmental Protection Agency, 1988):

- "After evaluating several factors that might aid in selecting an extrapolation model for cancer risk, the available evidence is not persuasive as to any particular approach, and certain considerations seem to point in different directions. Some considerations suggest that a conservative approach – e.g., methods assuming that there is no threshold for carcinogenic response – is necessary to adequately predict arsenic risks for humans, while others suggest that nonthreshold assumptions will overestimate the risk to humans." (p. 27)

- "Scientists at EPA and elsewhere, faced with uncertainty about mechanisms of chemical carcinogenesis, often analyze chemical carcinogens as though simple genetic changes initiate a carcinogenesis process that is linear at low levels of exposure. Extrapolation procedures from high to low doses then depend on models that are also linear at low doses. Since for arsenicals, as for a number of other carcinogens, there is no evidence of point mutations in standard genetic test systems, the single-hit theory for chemical carcinogenesis may not be applicable. Similarly, the structural chromosomal rearrangements that have been implicated in some cases of carcinogenesis would be expected to require at least two "hits", if not more. In addition, the known toxic effects of the inorganic arsenicals are not inconsistent with the idea that multiple interactions are involved in producing adverse cellular effects. While consideration of these data on the genotoxicity, metabolism, and pathology of arsenic has provided information on the possible mechanism by which arsenic may produce carcinogenic effects, a more complete understanding of these biological data in relation to carcinogenesis is needed before they can be factored with confidence into the risk assessment process." (p. 7)

Many studies, discussions, and opinions regarding arsenic carcinogenicity have been published since the 1988 EPA document was released. None have provided convincing evidence that the EPA cancer potency factor is inappropriate for use in protecting public health.

As discussed in EPA's Expert Panel Report on Arsenic Carcinogenicity (U.S. Environmental Protection Agency, 1997), there are currently several different theories of the mechanism by which arsenic causes cancer, all highly speculative and unproven. Some studies suggest that arsenic does not damage DNA through direct interaction, an assumption that forms part of the basis for EPA's linear, nonthreshold model. This raises the possibility that the dose-response curve for arsenic at doses below the measured range could be nonlinear, with a possible threshold for effect. Arsenic could appear to be less hazardous if the toxicity of arsenic were estimated using the assumption that the dose-response curve is sublinear at low doses, and/or using the assumption that there is a threshold for arsenical carcinogenesis.

While certain studies could be interpreted as suggesting that the dose-response curve for arsenic carcinogenicity may be nonlinear, they provide no information about the actual shape of the curve useful for accurately estimating toxicity. While some studies suggest that there may be a threshold for arsenical carcinogenesis, they provide no information about the location of the threshold point. The studies provide little guidance to establish a quantitative dose-response curve that is demonstrably more accurate for the purpose of protecting public health. Even if the unknown segment of the dose-response curve is, as a whole, nonlinear, portions of it, including the portions at doses of interest for the Everett Smelter site, may be linear. Further, nonlinear portions may be difficult to distinguish from linear. There are no data to enable the accurate quantification of how far from linear the possibly nonlinear portions might be, or what quantitative effect this might have on the estimate of toxicity. The true shape of the line cannot be determined without more information. Lacking additional data of proven reliability, the true carcinogenic potency can only be estimated through a process that involves policy choices regarding how to be protective despite information deficiencies.

While some studies suggest that the model EPA used to calculate the cancer slope factor could overestimate the carcinogenic potency of arsenic, they provide little guidance for choosing the “correct” model. Choosing a model is a policy choice, influenced by the goal of the analysis. In its Proposed Guidelines for Carcinogen Risk Assessment (U.S. Environmental Protection Agency, 1996), EPA suggests a general approach for estimating carcinogenicity for chemicals that appear to have a nonlinear dose-response, but provides little specific guidance. As part of the proposed approach, the degree of protectiveness is not determined scientifically, but "the risk manager decides whether a given margin of exposure is acceptable under applicable management policy criteria." The guidelines are currently in draft form and EPA has not used them to develop a carcinogenic toxicity factor for arsenic. The cancer potency factor remains on the Integrated Risk Information System (U.S. Environmental Protection Agency, 1998), EPA’s official list of endorsed toxicity factors, and is still available for use by EPA (and Ecology) for regulatory purposes. EPA and Ecology acknowledge that there is a degree of uncertainty in the cancer potency factors and reference doses listed on the IRIS database. This is inevitable, considering the limitations of studies on toxicity and the potentially large variability in response to chemicals within the population. However, the numbers, and the information on which they are based, have undergone a great degree of review to ensure they will fulfill the purpose of protection of public health.

It is important to note that the cancer potency factor addresses only skin cancer, one of at least five types of cancer strongly associated with arsenic exposure (cancer of the skin, bladder, lung, liver, and kidney). If the potency of arsenic to cause all these forms of cancer were considered, the current cancer potency factor could significantly underestimate total cancer risk.

The previous discussion notwithstanding, the cancer potency factor can still be considered an appropriate indicator of the carcinogenic toxicity for arsenic. Asarco asserts that, based on mechanistic data, it is likely that arsenic has a threshold for carcinogenicity and that the dose-response curve for arsenic carcinogenicity is nonlinear. Asarco argues that, if true, these assertions invalidate the use of the model EPA used to calculate the cancer potency factor for arsenic, which assumes no threshold and a nonlinear dose-response. However, these arguments, even if true, are based on the premise that arsenic is the only chemical acting to cause cancer in humans, an assumption used by the model. But when the carcinogenic impact of other chemicals to which humans are exposed, and the variation in peoples’ predisposition to develop cancer are considered, the model used by EPA is a scientifically plausible measure for protecting public health. The following paragraph from a standard textbook of toxicology (Casarett and Doull, 1996), discusses the concept of thresholds for developmental toxicity, although the statements are equally valid for other classes of toxicity, including carcinogenicity:

> "In the context of risk assessment for human health, it is also important to consider the distinction between individual thresholds and population thresholds. There is a wide variability in the human population, and a threshold for a population is defined by the threshold for the most sensitive individual in that population (Gaylor et al., 1988). Indeed, even though the biological target of a developmental toxicant may be a threshold phenomenon, background factors such as health status and concomitant exposures may render an individual at or even beyond the threshold for failure of that biological process. Any further toxic impact on that process, even one molecule, would be expected to increase risk." Pp. 309-310

If Ecology ignored this possibility and used a different method of calculating risk, the excess cancer risk could be underestimated. Cleanups under MTCA must address carcinogenic hazards in terms of excess cancer risks (WAC 173-340-700(3)(b)), and the cancer potency factor is a plausible and appropriate value to use to calculate these risks.

Cleanup decisions must still be made in the face of uncertainty. The cancer potency factor for arsenic, as a protective estimate of toxicity, is valid and remains on EPA’s official list of endorsed toxicity factors (IRIS). It is still available for use by EPA (and Ecology) for regulatory purposes, and has been used recently by EPA to determine cleanup activities for the Ruston Smelter site (U.S. Environmental Protection Agency, 1993), the Sandy Smelter site (U.S. Environmental Protection Agency, 1995a), and the Anaconda Smelter site (U.S. Environmental Protection Agency, 1995b).

It should be noted that the soil arsenic cleanup remedy chosen by Ecology for the Everett Smelter site already allows 30 times the cancer risk that would be permitted if the cancer potency factor were used to develop a cleanup level. Using the MTCA Method B equation for carcinogens, the soil arsenic cleanup level calculated to cause one in one million excess cancer risk is 0.67 milligrams of arsenic per kilogram of soil (mg/kg). This assumes that bioavailability of arsenic from soil is 100%. (*See* Ecology 1999a) Because this is below the background concentration for arsenic in soil, Ecology plans to use the MTCA Method A value of 20 mg/kg as the cleanup level for the Everett Smelter site. A cleanup level of 20 mg/kg is equivalent to a calculated cancer risk of 3 in one hundred thousand, or 30 times the risk normally allowed under MTCA. Therefore, even if the dose-response curve were sublinear with a threshold, an alternative method for calculating carcinogenic potency would have to result in an estimate that is 30 times less than the cancer potency factor currently listed on the IRIS database before the cleanup level chosen by Ecology for arsenic-contaminated soil at the Everett Smelter site would be raised.

[2] Comment - The slope factor most likely overestimates cancer for the U.S.
"[S]tudies conducted in U.S.…. suggest that arsenic does not induce skin cancer at rates comparable to those predicted by EPA's CSF [cancer slope factor], and that a threshold for these effects might exist." (Rodricks)

Response - The cancer potency factor for arsenic, listed on EPA's IRIS database, was calculated using data from a study of approximately 40,000 people in Taiwan who were exposed to arsenic in their drinking water. The application of Taiwanese data to people in the United States has been questioned based on possible differences in the two populations. Studies have been performed in the United States to evaluate effect of arsenic-contaminated drinking water on skin cancer occurrence (Lewis et al., 1998). However, because the populations examined were small, the results of these studies cannot be considered reliable enough to confirm or deny the possibility that differences between the Taiwanese and U.S. populations affect the usability of the cancer potency factor to protect public health in the U.S.

It is important to note that the cancer potency factor doesn't addresses total cancer risk, only the risk of skin cancer, one of at least five types of cancer strongly associated with arsenic exposure (cancer of the skin, bladder, lung, liver, and kidney). If the potency of arsenic to cause all these forms of cancer were considered, the current cancer potency factor could significantly underestimate total cancer risk. While the U.S. studies didn't show statistically significant increases in skin cancer, one study found that arsenic exposure was associated with increased bladder cancer in smokers (Bates et al., 1995). As with the U.S. skin cancer studies, the reliability of the results of this investigation needs to be adequately confirmed in larger populations.

[3] - Uncertainties in exposure analysis in Taiwan Study - *"EPA's calculation assumed levels of exposure which are inconsistent with the actual exposures in Taiwan." (Thorp)*

Response - EPA developed the oral reference dose and oral potency factor for arsenic using information from epidemiological studies of about 40,000 people in Taiwan who were exposed to arsenic in their drinking water. The original data are no longer available, so the reference dose and cancer slope factor were calculated using summarized data contained in two published documents (Tseng et al., 1968; Tseng, 1977).

In order to develop the cancer potency factor and reference dose, it was necessary for EPA to estimate exposure doses for the Taiwanese subjects (U.S. Environmental Protection Agency, 1988). Some of the information needed to do this (water ingestion rates and body weights) were not measured by the original investigators and had to be estimated. Asarco suggests that EPA underestimated the amount of water consumed. EPA acknowledged that it was a hot climate and assumed that people drank large amounts of water. The issue of water intake rates has been discussed in detail (Mushak and Crocetti, 1995, 1996; Slayton et al., 1996), and adequate evidence that intake rates were underestimated has not been presented.

Asarco suggests that the original researchers did not properly classify some of their subjects with respect to the concentration of arsenic in the water they were drinking. However, there is no way to know today whether the classifications were correct or incorrect, and what effect any possible misclassifications actually had on the results.

Asarco has also questioned the use of group (versus individual) exposure estimates as well as the way the groupings were chosen and the accuracy of the exposure estimates. It is theoretically possible to reanalyze the data using different data groupings and different statistical techniques. This could result in different interpretations of the findings. However, the original data are no longer available and such reanalyses are not possible.

Some reassessments of the people, arsenic concentrations, and exposure conditions in Taiwan have been published 30 years after the original studies. It is difficult to prove that such reanalyses, involving speculation about arsenic concentrations and well usage, are more accurate than the findings reported by the original investigators during the original study.

In all epidemiological studies there is some degree of uncertainty with respect to the actual dose of contaminant to which individuals were exposed over time. This uncertainty can be acknowledged when the data are analyzed, but the way in which it affects the accuracy of the interpretation of the results (i.e., how close the interpretation is to the truth) is unknowable. It cannot be determined whether the uncertainty has had no effect on the accuracy of the conclusions, or whether it has resulted in the conclusions overestimating or underestimating the actual effect, or by how much (i.e., the degree and direction of the inaccuracy of the conclusion).

It is important to note that, although EPA based the cancer potency factor and reference dose for arsenic on results from the Taiwanese study, the results of numerous similar studies conducted in many parts of the world are very similar to those of the Taiwanese study. Specifically, the amount of exposure found to cause adverse health effects in populations living under many different conditions in many parts of the world was similar to that estimated by EPA to cause effects in the Taiwanese population. Although a dose-response curve could not be derived for many of these populations (since they were only exposed to a single water arsenic concentration) the lowest estimated chronic dose of arsenic in each study causing health effects bracketed the lowest dose from the Taiwanese study. This suggests that the exposures estimated for the Taiwanese population were not significantly underestimated (if at all). The following list compares drinking water arsenic concentrations and estimated doses causing adverse health effects in many populations around the world.

Country	Water Concentration (mg/L)	Dose (mg/kg/day)
Taiwan	0.17 (U.S. EPA, 1988)	0.014 (U.S. EPA, 1998)
India	< 0.1 (Mazumder et al., 1998)	0.032-0.0149 (Mazumder et al., 1998)
Chile	0.6 (Zaldivar, 1978)	0.01 (ATSDR, 1998)
Mexico	0.411 (U.S. EPA, 1988)	0.022 (ATSDR, 1998)
China	0.6 (Yue-zhen et al., 1985)	
Mongolia	0.12-0.199 (Luo et al., 1997)	

One recent study examined health effects in 7683 people exposed to arsenic-contaminated drinking water in West Bengal, India (Mazumder et al., 1998). Many of the concerns voiced by Asarco regarding uncertainties in exposure were addressed in this study, since exposure to arsenic in drinking water was estimated on an individual basis by surveying members of the population and measuring the arsenic content of the wells from which water was consumed. Health effects were observed at doses between 3.2 and 14.9 micrograms per kilogram per day, similar to the dose of 0.014 mg/kg/day estimated by EPA for the Taiwanese population.

Ecology agrees that the data from the Taiwanese study are not perfect and that there are uncertainties in exposure estimates. All scientific studies have some associated uncertainties and limitations. The Taiwanese data are currently the best data available for the purpose of evaluating the hazards of arsenic to humans. The oral reference dose and cancer potency factor for arsenic are on EPA's IRIS database for use by EPA and other agencies such as Ecology. While Asarco asserts that the uncertainties result in overestimation of the toxicity of arsenic, their evidence is weak. Uncertainties cut both ways, and it is also possible that the uncertainties may result in underestimation of risk. One of the goals of the Model Toxics Control Act is to protect human health, and this would not be accomplished by delaying cleanup of the Everett Smelter site until perfect data become available.

[4] Comment - Other questions about the validity of the Cancer Slope Factor (CSF) and the application of the Taiwan study to the U.S. population - *"The Taiwan data are inapplicable to the U.S. population.…because of significant differences between the Taiwanese and U.S. populations. These differences include elevated arsenic levels and protein deficiency in the Taiwan diet (which may affect the ability of those persons to methylate arsenic) and significant exposures to other carcinogens in the Taiwanese drinking water studied by Tseng." (Thorp)*

Response: The potential for these factors to affect the toxicity estimates derived from the Taiwanese study has been debated (Mushak and Crocetti, 1995, 1996; Slayton et al., 1996). The effect of the humic substances is unknown and likely not relevant to the analysis. Cancer and other health effects have been observed in numerous populations around the world where arsenic levels in drinking water were similar to those in Taiwan, but where no humic substances were present (see response #3).

The effect of a possibly nutritionally deficient diet is not known, but the possibility exists that it could have some effect on the dose-response curve (either positive or negative). The direction and degree of effect is not possible to predict from the current knowledge base. One theory suggests that malnourishment leads to a shortage of methyl donors that some believe are important for the detoxification of arsenic. Mushak and Crocetti (1995, 1996) cite evidence that the diets of the Taiwanese were not deficient in methyl donors. Increased bladder cancer has been associated with arsenic intake in at least one well-nourished population (Hopenhayn-Rich et al., 1996). In India, it was found that, while severe malnourishment may be a risk factor for arsenical health effects, the increased risk wasn't very large (Mazumder et al., 1998).

In EPA's estimate of arsenic toxicity, arsenic from food intake was considered, and assumed to be 2 µg/day. This was discussed in 1988 by EPA (U.S. Environmental Protection Agency, 1988). EPA said "For a realistic adjustment of the risk estimates, one would need the information on the arsenic content and the composition of the diet taken by the studied population whose diet content was certainly different from the population currently living in the same area." Some argue that this was an underestimate. A recent paper described arsenic levels in modern-day samples of food that were thought to be dietary staples of the Taiwanese populations more than three decades ago (Schoof et al., 1998). The modern food samples (rice and dried yams) were found to contain significant levels of "inorganic" arsenic. However, it cannot be shown that the food samples analyzed were representative of the diet of the 40,000 Taiwanese during the period from 1910 to 1960. Further, is not clear that the "inorganic" arsenic in the food samples is biologically or toxicologically active (see Response to Comment #7).

[5] Comment - The 200 milligram (mg) soil ingestion rate is too high. *"In deriving the Method B cleanup level, Ecology assumes that a child ingests 200 mg of soil every day for 6 years. This assumption is flawed for a variety of reasons. They include: a) the failure to consider the impact of climatological factors on soil ingestion. Significant soil ingestion is prevented during the fraction of the year that the ground is frozen, and climate can be highly variable in Washington, which clearly affects actual exposures to chemicals in soils; b) the failure to consider site and chemical-species differences in bioavailability of chemicals in soil that would limit the uptake of the chemicals into the body; c) the fact that much of the soil taken into the body is ingested indirectly as dust, which typically has a lower concentration of metals than soil. This overall uptake of metal, causing the formula to overstate risk." [Beck]*

Response - Asarco has raised a concern that the soil ingestion rate in the Model Toxics Control Act (MTCA) is too high. The soil ingestion rates listed in MTCA are as follows:

1. Section 173-340-740 WAC (Soil Cleanup Standards) states that residential land use is generally the site use requiring the most protective cleanup levels and that exposure to hazardous substances under residential land use conditions represents the reasonable maximum exposure scenario. The reasonable maximum exposed (RME) individual in a residential setting is a young child. With that assumption, the soil ingestion rate has been set at 200 mg/day. Under a commercial land use, the soil ingestion rate is set at 100 mg/day. Again, the young child is the maximally exposed individual.
2. Section 173-340-745 WAC (Soil Cleanup Standards for Industrial Properties) states that this section shall be used to establish soil cleanup levels where industrial land use represents the reasonable maximum exposure. The maximally exposed individual in an industrial setting is an adult. With that assumption, the soil ingestion rate has been set at 50 mg/day.

The MTCA residential soil ingestion rate for young children was established in 1991. The 200 mg/day value was based on several studies and EPA guidance documents. (See February 1991 MTCA Responsiveness Summary) More recent EPA guidance, such as the August 1997 *Exposures Factor Handbook*, summarizes numerous soil intake studies. EPA's recommended values for soil ingestion by children are a mean value of 100 mg/day and an upper percentile value of 400 mg/day. The EPA handbook lists seven (7) key studies and nine (9) relevant studies. The mean values ranged from 39 to 271 mg/day with an average of 146 mg/day for soil ingestion and 191 mg/day for soil and dust ingestion. This group of mean values is consistent with the 200 mg/day value that Ecology and EPA programs have used as a conservative reasonable maximum exposed estimate.

Climate factors can play a role in terms of soil ingestion rates. In areas where the ground is frozen and or covered with snow for a fraction of the year, soil ingestion rates are probably lower in the winter. Rain and cooler temperatures generally characterize winters in Everett Washington. The ground is rarely frozen or covered with snow. Children still play outside during the winter and are potentially exposed to contaminated soil. Also due to the wet weather, mud is often tracked into homes. That wet soil dries and then becomes part of the household dust - another route of exposure to contaminants.

EPA's overall "confidence" rating in the soil intake recommendations (August 1997 *Exposure Factors Handbook*) is "medium". Their rationale for that rating are: studies were well designed; results were fairly consistent; sample size was adequate for children and very small for adults; accuracy of methodology is uncertain; variability cannot be characterized due to limitation in data collection period; insufficient data to recommend upper percentile estimates for both children and adults.

It should be noted that the soil ingestion rates contained in MTCA are based on chronic exposures. The MTCA cleanup levels are not based on acute exposures. In consideration of all the above factors, Ecology should not deviate from the 200 mg/day soil ingestion rate contained in MTCA. As noted above, there is nothing site-specific that would support another soil ingestion rate for the Everett Asarco site.

[6] Comment - Arsenic bioavailability in MTCA Method B is too high. *The WDOE's use of a bioavailability factor of 40% likely resulted in an overestimation of the soil arsenic dose available for potential carcinogenic effects and an overly restrictive cleanup level for arsenic in soil. (Rodricks)*

Response: Site-specific data for bioavailability of arsenic from soil are not available and a demonstrably reliable system for measuring soil arsenic bioavailability in a way that is relevant to humans has yet to be developed. As described below, studies performed in animals have found values of bioavailability of arsenic from soil ranging from less than 10% up to 78%. The 78% value was for soils at the former Ruston Smelter, which has conditions very similar to those at Everett. However, it remains to be demonstrated that the results of any soil arsenic bioavailability study accurately represent bioavailability for humans or whether the results are more dependent on study conditions as opposed to actual differences in bioavailability.
Based on the following information, Ecology believes that an assumption of 40% bioavailability for arsenic from soil at the Everett Smelter site is too low (Ecology, 1999a).

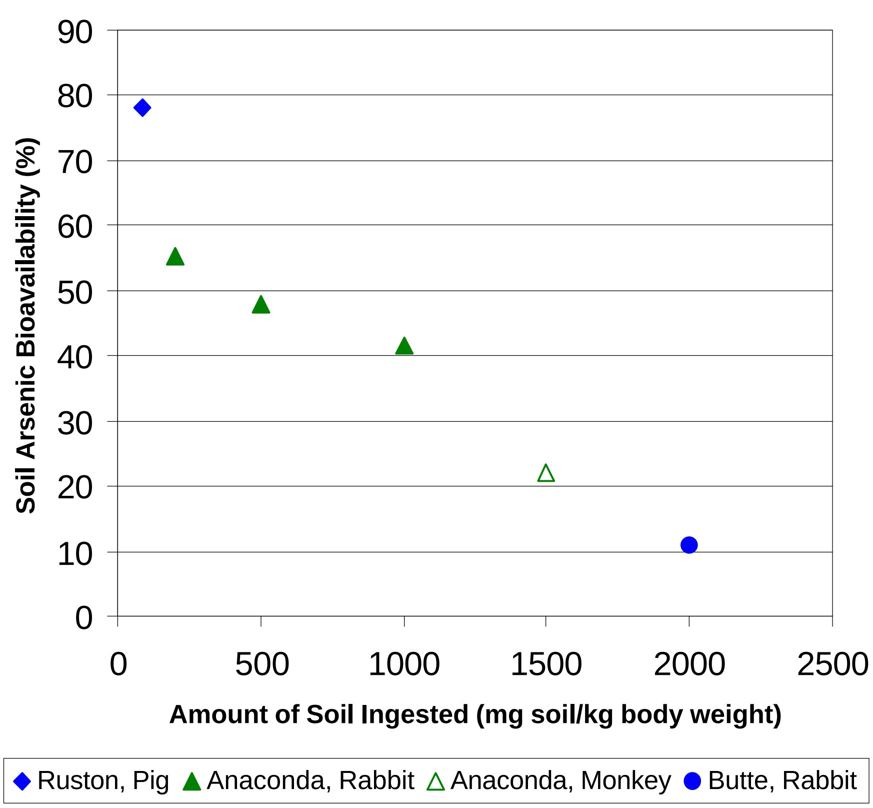
B1-13.1.1 Human and animal studies

In most studies of the absorption of ingested arsenic, humans or animals ingest arsenic and the amount of arsenic excreted in urine and feces is measured for five to ten days. Frequently, a significant percentage of the original dose of arsenic is not recovered in either the urine or feces, and appears to be retained in the body. A study in humans using radioactive arsenic supports this conceptual model (Pomroy et al., 1980). The sum of the arsenic excreted in urine and retained by the body reflects the arsenic that was absorbed, while the arsenic in feces represents the unabsorbed fraction. An analysis of this type may underestimate the absorbed fraction, since some absorbed arsenic may be excreted in the bile (Klaassen, 1974) and appear in the feces.

Studies in humans have found that arsenic, in the form of purified compounds such as arsenic trioxide, arsenic acid, and lead arsenate, is almost completely absorbed (94-99%) when ingested (Bettley and O'Shea, 1975; Pomroy et al., 1980; Fairhall, 1938). Essentially complete absorption (98%) was also observed in one study in monkeys (Charbonneau et al. 1978). However, based on fecal excretion, significantly less absorption of purified arsenic compounds (75%) was observed in a different study in monkeys (Freeman et al., 1995), as well as studies in swine (variable, but roughly estimated as 25-30%) (Casteel et al., 1998) and rabbits (48-55%) (Freeman et al., 1993). In the swine study, a large portion of the administered arsenic “disappeared,” and could not be found in the urine, feces, or tissues of the animals. Based on this finding, it is difficult to support the use of this study in evaluating bioavailability. In another swine study(U.S. Environmental Protection Agency, 1996b), estimated absorption was variable from animal to animal (49 to greater than 100%). Since absorption of arsenic in most of the animal studies was significantly less than absorption in humans, it is questionable whether any of the animal studies are appropriate for use in estimating bioavailability in humans.

Arsenic in soil may be in the form of mixtures of a number of arsenical compounds bound to soil particles and it has been suggested that arsenic in contaminated soil may not be as bioavailable as the purified compounds used in the human studies. Studies have been conducted to measure the bioavailability of arsenic from soil, based on the hypothesis that bioavailability may vary depending on the specific contaminated soil sample. Mean bioavailability of arsenic from soil, relative to the bioavailability of purified compounds, has been reported as 20% in monkeys (Freeman et al., 1995), 48% in rabbits (Freeman et al., 1993), 78% in immature swine(U.S. Environmental Protection Agency, 1996b), and 8.3% in dogs(Groen et al., 1994). While these results could be interpreted as supporting the hypothesis, the differences in bioavailability reported in the studies may instead reflect differences in animal models and study conditions and not actual differences among soils. For example, different amounts of contaminated soil were fed to the animals in four different studies, and the apparent differences in bioavailability may actually be due to the volume of soil ingested. A trend is observed when bioavailability is compared to the amount of soil ingested. See Figure 1.

FIGURE 1
Soil Arsenic Bioavailability vs Amount of Soil Ingested



The trend demonstrated in Figure 1 is consistent for soil at a single hazardous waste site, since the four data points in the middle of the curve all represent bioavailability results from the Anaconda, Montana site (three points from a study in rabbits (Freeman et al., 1993), one from a study in monkeys(Freeman et al., 1995)). The data point at the far left of the curve is from a study on soil at the Ruston, Washington smelter site (U.S. Environmental Protection Agency, 1996b), and the data point at the far right is from a study on soil at a site in Butte, Montana(Davis et al., 1992).

For reference, a 13 kilogram child who ingested 1 gram of soil would receive a soil dose of 77 milligrams of soil per kilogram of body weight, or less than the left-most point on the above graph. A 13 kilogram child who ingested 20 grams of soil would receive a soil dose of 1538 milligrams of soil per kilogram of body weight.

Studies in animals suggest that arsenic in soil is less bioavailable that purified arsenic compounds. However, due to uncertainties and limitations of the studies, these findings could be due to the animal model, experimental conditions, and protocols, and not actual decreases in bioavailability. The data appear to be highly uncertain and can be explained by other hypotheses. It remains to be demonstrated that the results of these animal studies accurately and reliably reflect bioavailability in humans.

13.1.1.1 In Vitro Leaching/Solubility Tests

A study to investigate leaching of lead and arsenic from contaminated soil, as a surrogate measure of bioavailability, was published in 1996 (Ruby et al., 1996). An *in vitro* system designed to mimic the actions of the human stomach and intestines on solubilizing arsenic from contaminated soil was constructed. Soil samples weighing 0.4 g were placed in 40 milliliters (ml) of solution similar to gastric juice (at either pH 1.3 or pH 2.5) and incubated for 1 hour. The solution was then neutralized to pH 7 and the samples allowed to incubate for 3 more hours to simulate passage through the small intestine. Arsenic concentrations were measured in samples withdrawn at specific time points. Bioavailability was estimated by comparing the amount of arsenic in solution in the final aliquot with the total amount added to the reaction vessel. At the end of the experiment, approximately 44 - 50% of the soil-bound arsenic was in solution when the simulated gastric juice was pH 1.3, and approximately 30 - 32% solubilized when the gastric juice was pH 2.5.

There are four potential problems with using this system as a model for human bioavailability. First, the volume of artificial gastrointestinal solutions used versus the amount of soil added was significantly less than would be expected in a human who swallowed soil. The total daily volume of liquid that is excreted and resorbed by the adult human gastrointestinal tract is typically 8.5 liters (Hendrix, 1974), or 212 times the volume used in this extraction procedure. The authors provided no evidence to clarify whether the arsenic that remained bound to the soil was simply not extractable or whether it had reached an equilibrium between the soil and liquid phases. Increasing the volume of extraction solution might result in greater release of arsenic from the soil.

Second, the concentration of sodium chloride in the test system was significantly below physiological concentrations. In a study published in 1939, the solubility of lead arsenate in different fluids was measured (Fairhall, 1939). Although lead arsenate was poorly soluble in water, solubility was significantly greater when placed in saliva, gastric juice, serum, or isotonic sodium chloride. The *in vitro* system could underpredict solubility of soil-bound arsenical compounds due to the low ionic strength of the solutions.

Third, during the course of the test, 2 ml aliquots were removed for analysis at 5 time points and replaced with 2 ml of fresh solution. When the final aliquot was removed and analyzed to estimate bioavailability, the reaction vessel would still contain 40 ml of solution, but only 81.35% of the original material. Thus, bioavailability would be underestimated when the authors compared the arsenic concentration in this aliquot to the original amount added. There is no indication that the authors corrected for this reduction in material.

Fourth, it is believed that many factors not modeled by the *in vitro* system could play a role in the solubility of substances in the gastrointestinal tract (Whitehead et al., 1996). For example, when the pH of the artificial gastric fluid was raised from 2.5 to 7, it was observed that arsenic solubility decreased by 25-29%, possibly due to precipitation reactions. The formation of precipitates may be less likely *in vivo* due to the presence of small organic molecules that would tend to keep the arsenic in solution.

In a poster entitled "Development of a physiologically based extraction test to predict arsenic bioavailability from soil" by Michael V. Ruby, Rosalind Schoof, and Chris Sellstone, presented at the Third International Conference on Arsenic Exposure and Health Effects in San Diego, California, July 12-15, 1998, it was stated: "Comparison of relative bioavailability (in swine) and bioaccessibility values for a set of 10 substrates (Figure 2), suggests that although a correlation exists between these two measurements (p=0.049), it is not well defined at this time ($r^2 = 0.40$). This probably results from uncertainty associated with both the *in vivo* and *in vitro* estimates."

In conclusion, since the extraction test appears to ignore a number of potentially significant features of human digestive system physiology, the results of the test may not accurately model bioavailability in humans.

Conclusions

No human studies of the bioavailability of arsenic from contaminated soil have been published. Studies in animals suggest that bioavailability of arsenic from contaminated soil is less than bioavailability of purified compounds. However, results of arsenic bioavailability studies in animals appear to be greatly influenced by the choice of animal model and test conditions. It remains to be demonstrated whether differences in bioavailability reported in these studies reflect actual soil-specific differences in bioavailability or were due to differences related to animal models, study conditions and protocols. Limitations of these studies, as well as findings in animals that differ from humans, suggest that the animals and experimental protocols used may not be appropriate models of human response. Studies of soil arsenic bioavailability to date have not been shown to accurately and reliably reflect bioavailability in humans. Furthermore, the soils tested came from small areas of specific contaminated sites, and, it remains to be shown that it is appropriate to generalize the results either throughout one site or to soil from other sites.

[7] Arsenic exposure from soil is minimal compared to that from food and water.
"The likely significance of exposures to arsenic in soil is diminished in comparison to background exposures to arsenic from other sources, particularly diet and drinking water." (Schoof)

Response: WAC 173-340-700(3)(b) states, in part, "For individual carcinogens, cleanup levels are based on the upper bound of the estimated excess lifetime cancer risk of one in one million (1×10^{-6})." "For individual noncarcinogenic substances, cleanup levels are set at concentrations which are anticipated to result in no acute or chronic toxic effects on human health or the environment."

Thus, even if the arsenic dose from soil is small compared to that from food and water, the harm caused by the additional exposure is not acceptable under MTCA.

It remains to be determined whether arsenic in food is biologically or toxicologically active. A number of different arsenic-containing compounds have been described in food. Organic forms (MMA, DMA, etc.) are considered to be relatively nontoxic while it is believed that inorganic arsenic compounds are responsible for most or all of the harmful effects. Many foods appear to contain some organic forms and some inorganic forms. The amount of inorganic arsenic in food has come to be viewed by some as if it were all biologically active and potentially harmful. However, this conclusion is questionable. Studies have found that inorganic arsenic in animal tissues is bound to sulfur-containing compounds, primarily glutathione and proteins, and that the arsenic will tend to remain bound until the pH is lowered to 1.5 or 1.0 (Delnomdedieu et al., 1994). When food is ingested, it enters the stomach where the pH, during a meal, is about 3 to 4. In the intestines, the pH is closer to 7. Under these conditions, the fraction of arsenic in food that is generally referred to as "inorganic" is likely already bound and biologically inactive, i.e., not harmful.

When food is analyzed for arsenic, it is first digested in concentrated acid overnight at high temperature. These conditions, which are much more extreme than those in the human body will likely release these bound arsenic ions which are measured as biologically active inorganic arsenic. As noted above, the conditions in the human digestive tract are much milder and may not cause the release of significant amounts of biologically active (harmful) arsenic from food. Thus, it is possible that exposure to arsenic in food, even that measured as "inorganic," may result in little or no harm.

See Comment #8 for a quantitative evaluation of lifetime exposure to arsenic in soil compared to lifetime exposure from food and water.

[8] Comment - Suggested Alternative for calculating a cleanup level. *In the absence of a clear alternative to the EPA's unsupportable CSF [Cancer Slope Factor] for arsenic, the problem of soil cleanup at Everett might be approached in the following way...the following question can be posed: what total lifetime exposure to arsenic will be incurred if all the soils are cleaned up to 20 ppm?...[versus] what total lifetime exposure to arsenic will be incurred if all the soils are cleaned up to 100 ppm?...the calculations [presented in the comment] demonstrate that the ranges of total lifetime arsenic intakes...will be affected only slightly if soils are cleaned up to 20 ppm rather than to 100 ppm [Rodricks].*

Response: This comment uses a number of assumptions to calculate a "lifetime cumulative intake of inorganic arsenic", considering exposures via food, drinking water, and soil pathways. The soil exposures (absorbed doses) are calculated assuming soil arsenic concentrations of 20 ppm or, alternatively, 100 ppm; food exposures (expressed as a range) and water exposures are held constant for the two assumed soil exposure levels. The resulting summation over pathways of inorganic arsenic exposure is described as a lifetime cumulative exposure, and is interpreted as showing that compared to soil arsenic cleanup to 20 ppm, an alternative soil cleanup to 100 ppm arsenic would not significantly affect lifetime exposures. This result appears to be presented as a margin-of-exposure approach to developing a soil cleanup level for the Everett Smelter site. Although different in the particular information it uses, this approach has considerable similarity to the proposal to develop an acceptable soil cleanup level based on an increment, or margin of apparent exposure, in speciated urinary arsenic measurements. The primary difference is that one approach uses a calculation of arsenic exposures (based on pathway calculations) and the other uses a measurement of urinary arsenic (and survey data) as a biomarker of exposure. These "input side" and "output side" assessments reflect essentially the same type of argument.

To evaluate the proposed approach based on calculation and comparison of "lifetime exposures", both the calculations themselves and the interpretation of results need to be considered. (In the calculations that follow, to simplify things, only the high end of the calculated range for food exposures to inorganic arsenic will be referenced. This will be conservative in the sense that it will minimize, or bias low, the consequences of comments that follow).

A number of general discussions of dietary intake of arsenic are available (see, for example, Adams et al., 1994; Borum and Abernathy, 1994; Yost et al, 1998). Some site-specific determinations of dietary arsenic (including speciated forms of arsenic) are also available, as part of comprehensive exposure pathway investigations (see, for example, Cohen et al., 1998). The available information raises a number of questions regarding the calculation of dietary arsenic, the dominant contributor to arsenic intakes, as presented in the comment. First, the estimated dietary intake shown in the calculation is in fact intake (or external dose), in contrast to water and soil "intakes" which include a fractional absorption value. It is clear from a review of Borum and Abernathy (1994), which is the original source cited by the reference (Valberg et al. 1997) used by the commentor for dietary intakes of inorganic arsenic, that the values do not account for less than 100% bioavailability of dietary arsenic. Yost et al. (1998) comments as follows: "Arsenic in food may also have limited bioavailability. To accurately estimate exposure to inorganic arsenic in food, it is necessary to determine the absorption of arsenic from dietary sources". Yost et al. (1998) note that further research on bioavailability of inorganic arsenic in food is needed. In a recent exposure model for inorganic arsenic, Cohen et al. (1998) use a value of 85% for the bioavailability of inorganic arsenic in food, terming that value "a plausible assumption" in the absence of adequate studies. Thus, the dietary intakes should be reduced for fractional bioavailability to be consistent with estimates for other exposure pathways. The values given in the comment are biased high by virtue of ignoring this factor, although studies are lacking to quantify the degree of bias accurately.

A second issue relates to changes in inorganic arsenic intake by age. The calculation as presented in the comment multiplies the estimated daily arsenic intake by 365 days a year and 70 years, effectively assuming a constant exposure level for all ages. Yost et al. (1994) use constructions of typical diets by age group and data on typical total arsenic concentrations by food type and percentages inorganic arsenic to calculate inorganic arsenic intake for infants, toddlers, and adults. The results show a modestly lower intake for younger age groups in comparison to adults. Yost et al. (1998) also note that the statistical estimate for total arsenic concentration in the dairy food group used only detected values; since there was a large percentage of undetected results for the dairy food group, this approach biased the arsenic concentration high. The dairy food group contributes significantly to the calculated inorganic arsenic intakes for infants and toddlers. Thus, the differences by age are in fact likely greater than calculated by Yost et al. Adams et al. (1994) provide estimates of total (unspeciated) arsenic intake for five age groups. For the most recent data cited, reflecting Food and Drug Administration market basket measurements of arsenic concentrations in 1990-1991, a clear age relationship is shown, with total arsenic intakes significantly reduced at least through teenage years. Given the total arsenic intakes shown, the inorganic arsenic intakes are obviously constrained. Thus, the dietary intakes should be reduced to account for variable intakes by age. Absent this adjustment, the results are biased high.

The variability in dietary intakes is also of interest. The data used to estimate dietary arsenic intakes are limited in important respects. Yost et al. (1998) point to the order-of-magnitude variability in arsenic concentrations measured for different foods within a single food group in one Canadian survey. In another Canadian study used as a basis for dietary arsenic intake estimates, only one homogenized sample per food type was analyzed. Another way to estimate dietary arsenic intake is to perform a duplicate diet study, where meals as actually prepared and eaten rather than a reconstructed "typical diet" are evaluated for arsenic content. Data exist to show that duplicate diet measurements for a given population are inconsistent with the estimated dietary arsenic intake reflected in the comment. In a multi-pathway study of arsenic exposures of children in Anaconda, Montana, Cohen et al. (1998) cite average total arsenic intakes of 5.5 ug/day; assuming one-third of total food arsenic is inorganic, the authors used a value of

1.83 ug/day for inorganic arsenic intake in children. This result also further reinforces the conclusion that inorganic arsenic intake is reduced in younger age groups.

Drinking water inorganic arsenic intakes are the second highest contributor to "cumulative lifetime" exposures as calculated in the comment. A value of 2 ppb arsenic in drinking water is assumed based on "average arsenic water concentrations for Washington". Lifetime "intakes" (actually, absorbed doses) are calculated assuming constant consumption of 2 liters per day for 70 years and an absorption factor of 90%. Concerns similar to those discussed for dietary intakes arise for the estimated drinking water intakes. To cite but one example, the actual arsenic concentration in drinking water may differ substantially from the assumed 2 ppb. Polissar et al. (1987), in a multi-pathway exposure study of populations living near the former Asarco Tacoma Smelter, report a median drinking water arsenic concentration of only 0.4 ppb. This one factor alone could reduce the lifetime estimate for drinking water arsenic intake by 80%.

The inorganic arsenic intakes from diet and drinking water are calculated based on daily exposures for 70 years. However, the exposures from soils are calculated based on only 6 years of exposure in childhood, presumably because that exposure duration is used in the MTCA Cleanup Regulation (Chapter 173-340 WAC) to derive risk-based cleanup standards. Ecology has commented elsewhere on the policy basis for using only a six-year exposure period for the purpose of deriving soil cleanup standards. Assuming both food and drinking water exposures would continue regardless of residence location, the lifetime increment between soil arsenic levels of 20 ppm and 100 ppm would depend on the amount of time spent living at the site versus other locations. Many (if not most) community residents will live at the site for more than the six-year period assumed for the calculation of soil cleanup levels under MTCA. Ecology has also commented elsewhere on the uncertainty in the bioavailability from ingested soil arsenic, based on a review of available information (and absent site-specific studies). A series of straightforward calculations can illustrate how these factors affect both the absolute and relative increment from exposures to 20 ppm versus 100 ppm soil arsenic.

For the sake of these calculations to illustrate uncertainties in incremental soil exposures, accept for the moment the high end of the range of dietary intakes and the drinking water exposures as presented in the comment. Thus, none of the issues regarding bias raised in the discussions above are considered here. Assume that soil exposures occur for 70 years, at site concentrations of either 20 ppm or 100 ppm and at 7 ppm for other locations (i.e., "background soils"). Assume that the relative bioavailability of ingested soil arsenic is either 40% or 100% (see Ecology comments elsewhere regarding relative bioavailability factors for ingested soil arsenic). Assume daily soil ingestion of 200 mg/day for ages 0-6 years, and 100 mg/day for 6-70 years. Finally, assume residence at the site starting at birth for either 6 years, 30 years, or 70 years. The resulting incremental arsenic exposures for 100 ppm versus 20 ppm in site soils are as follows:

I. At 40% relative bioavailability for ingested soil arsenic, the lifetime increments for the various periods of site residence are:

a) 6 years: 14,016 ug arsenic, or 3.1%.

b) 30 years: 42,048 ug arsenic, or 9.1%

c) 70 years: 88,768 ug arsenic, or 18.8%

II. At 100% relative bioavailability for ingested soil arsenic, the lifetime increments for the same periods of site residence are:

a) 6 years: 35,040 ug arsenic, or 7.6%

b) 30 years: 105,120 ug arsenic, or 21.6%

c) 70 years: 221,920 ug arsenic, or 43.9%

The relative exposure increments expressed as a percent increase would, of course, be higher if adjustments to dietary and drinking water exposures suggested by the comments above were also incorporated. Ecology also notes that the comparison of pathway exposures by age interval would show a variable pattern; especially with lower age-related dietary exposures for children, the relative importance of soil arsenic exposures would be greater than shown above for young children as a subpopulation.

Ecology concludes that it cannot accept an argument, as proposed in the comment, that the incremental exposure posed by 100 ppm versus 20 ppm soil arsenic at the Everett Smelter site is somehow obviously de minimis, especially for the RME exposure scenario. There are substantial uncertainties in the relevant calculations; both the magnitude of the incremental soil exposures and their relative contribution to total arsenic exposures are uncertain. Finkel (1995) has discussed the problems of comparing two risk values when both are subject to substantial uncertainty. Ecology believes the proposed arsenic exposure comparisons across pathways present an analogous situation.

[9] Comment - There is no evidence that residing in a home surrounded by soil containing concentrations of arsenic far in excess of the 20 ppm standard poses any public health threat or a significant risk to individual residents. In addition to the numerous epidemiological studies such as at Ruston and Anaconda which have not found health effects associated with environmental arsenic exposure….two additional epidemiological studies of residential exposure to smelters in Utah….likewise did not find an association between environmental arsenic exposure and lung cancer incidence. (Schoof)

Response: While well-designed and conducted studies of human populations can be an effective way to screen for the presence of easily identified environmental hazards, they are not very effective for determining whether or not environmental conditions are safe. Small populations, limited ability to detect adverse health effects, and limited ability to accurately determine the cause of the health effects, render most epidemiological studies inadequate for evaluating the potential for occurrence of low-probability events that are important to prevent in order to adequately protect public health. Risk assessment is a more useful technique for evaluating safety of environmental conditions.

No adequate studies have been done to examine health effects in individuals living on arsenic-contaminated soil. All studies to date have only looked at relatively small populations and have only evaluated one or a few of the more than thirty distinct health effects documented to be caused by arsenic. The ability of the studies to detect the occurrence of health effects due to exposure to arsenic-contaminated soil was low.

Epidemiological studies of arsenic toxicity in humans frequently rely on measurements of a few specific health effects: hyperkeratosis, hypopigmentation, and hyperpigmentation, skin cancer, and lung cancer. This is not because these effects have been shown to be the most sensitive indicators of toxicity, but because they are easy to measure and are characteristic lesions of arsenic toxicity. Arsenic is a somewhat nonspecific toxin, affecting many parts of the body and causing a wide variety of adverse health effects. More than thirty adverse health effects have been associated with arsenic exposure (ATSDR, 1998), many of them (such as nausea, vomiting, diarrhea, bronchitis, cirrhosis, etc.) with numerous potential causes. It is questionable to conclude that arsenic is not causing adverse health effects in a population if the full range of potential effects has not been evaluated. Further, arsenic likely causes subtle subclinical effects prior to the appearance of overt symptoms, and until these effects are identified and quantified, it will be difficult to have confidence in the use epidemiological studies to determine whether a given population is at risk of adverse health effects.

[10] Comment - Studies show that children living in communities with soil arsenic concentrations far in excess of Ecology's 20 ppm cleanup level do not have arsenic exposures (as demonstrated by no significantly increased urinary arsenic concentrations) from soil that pose a health threat. *New studies of exposure to arsenic in soil indicate that absorbed doses are much lower than assumed by the agencies ... Recent exposures to arsenic in environmental media may be evaluated by means of studies that use urinary arsenic as an exposure marker ... even for children residing in a community with widespread and marked elevations in soil arsenic concentrations, the exposures from soil were still relatively insignificant ... [in another community] the lack of an increase in mean urine concentrations indicates that increasing arsenic concentrations in soil are not causing a detectable increase in arsenic exposures above background exposures in most of these children ... Taken together these new studies provide documentation that children living in communities with soil arsenic concentrations far in excess of WDOE's 20 ppm cleanup level do not have arsenic exposures from soil that pose a health threat. The distribution of urinary arsenic levels for a population with typical background exposures to arsenic provides an indication of the distribution of background exposures...The best available data set for a population with background exposures to arsenic is from a comprehensive study...in young children living near the Bingham Creek Channel site in Salt Lake County, Utah...From this data set, the 90th and 99th percentile values for background absorbed daily doses of arsenic for young children is estimated to be approximately 12 and 22 ug/day, respectively...The distribution of background arsenic exposures in the entire U.S. population is expected to be even broader than this distribution...If a small fraction of an exposed population has an increased exposure to arsenic of 10 ug/day or less, there will be no discernible public health risk to that population...based on the fact that an additional 10 ug dose would not cause 90 percent of the population to exceed the 99th percentile background exposure value...Using WDOE's assumptions for deriving risk-based soil cleanup levels, an allowable incremental 10 ug/day intake of arsenic yields an acceptable soil concentration of 125 ppm. [Schoof].*

Response: Urinary arsenic measurement is generally recognized as the most useful biomarker for arsenic exposures. It represents a cumulative exposure across multiple pathways. Speciated arsenic measurement (summing the inorganic and mono- and dimethyl- forms of arsenic) is typically used to represent inorganic arsenic exposures, avoiding confounding from other forms of arsenic intakes such as organic arsenic compounds of lesser toxicity. Unless stated otherwise, the comments that follow will refer to the speciated urinary arsenic measurements that reflect inorganic arsenic exposures.

Asarco comments that an exposure-based approach, using urinary arsenic measurements, rather than a risk-based approach should be used to develop soil cleanup criteria for the Everett Smelter site. There are two parts to the proposed approach: 1) using the correlation of speciated urinary arsenic values and soil arsenic values at contaminated sites to show little or no impact from the soil contamination, and 2) using the distribution (variability) of speciated urinary arsenic values in a control population exposed to background levels of environmental arsenic to determine an allowable increment for inorganic arsenic intake, and then back-calculating the soil arsenic concentration that would contribute that level of intake under stated exposure assumptions. Ecology is unaware of the acceptance of the latter approach by any other regulatory agency involved in site cleanup decisions.

Studies that correlate soil arsenic concentrations, measured by a specific soil sampling protocol, and urinary arsenic levels over a study population typically show considerable scatter around any best-fit regression line. The relationship summarized by the statistical regression line usually accounts for a relatively small proportion of the variance in urinary arsenic measurements. If the regression relationship is the best summary of the relationship between soil and arsenic concentrations for the population as a whole, it is nonetheless important to recognize the scatter around the regression line. The variability around the regression line may in part reflect methodological issues related to the representativeness of the data; it may also reflect individual differences in the nature of the relationship between the soil and urinary arsenic measurements. From Ecology's point of view, where under MTCA protection of individuals and not just the typical exposed population member is the objective, it is important to ask where the RME individual occurs within the correlation plot. It seems apparent that it is in the "outliers" and not in the summary regression line itself. Thus, the regression findings in these correlation studies are not themselves particularly informative toward the objective of determining a soil cleanup standard.

The strength and reliability of urinary arsenic measurements also need to be considered. At least three concerns are noted here, related to individual differences, alignment of known intakes and urinary measurements, and time variability. Differences among individuals are increasingly being recognized as important for understanding distributions of risks and identifying sensitive populations. With respect to urinary arsenic, for example, differences in methylation (genetic polymorphisms) are well recognized (see, for example, Weinshilboum, 1988). There is some evidence that individual differences may play a role in sensitivity to adverse effects from arsenic exposures. Subjects who had known prior arsenical skin cancers were shown to retain significantly more of a given oral dose of arsenic than control subjects (Bettley and O'Shea, 1975). If the sensitive populations show lower urinary arsenic excretion for a given dose, then there are some obvious limitations to the use of urinary arsenic data as biomarkers of exposure.

The alignment between urinary arsenic levels and known sources of arsenic exposure may also be imperfect, especially at the level of individual daily measurements of urinary arsenic. Where known dietary and drinking water arsenic intakes (generally deemed the two most important exposure pathways for arsenic, absent site-specific contamination) are not commensurate with measured urinary arsenic values, there is a suggestion of "missing sources" or other factors affecting how urinary arsenic levels should be interpreted. The sometimes large differences in urinary arsenic measurements between siblings of similar ages living together, whose drinking water and dietary intakes may be similar, is interesting to note. Absent strong evidence that urinary arsenic measurements do align with known intakes, at a scale corresponding to the data being used (e.g., individual person-day measurements), the possibility of imprecision and misalignment should be considered.

Urinary arsenic measurements reflect arsenic exposures only over the previous few days; the "clearance rate" for arsenic is relatively fast. The representativeness of short-term urinary arsenic sampling for long-term patterns is a very important consideration. Many applications of urinary arsenic data collected over a very short period of time (e.g., daily measurements for two consecutive days in a study population) have made an implicit or explicit assumption that those data are representative of long-term exposure patterns. Yet for cancer and other adverse health effects where chronic exposures are relevant, the long-term patterns of exposure are most relevant. There are no good longitudinal studies of urinary arsenic in children, with measurements frequent enough to determine variability over time. In short-term studies, the variability in urinary arsenic levels in the same individual from one day to the next can be quite large. For example, in the small Bellingham, WA population used as a control group for the Exposure Pathways Study (Polissar et al., 1987) related to the Asarco Tacoma Smelter, a 13 year old male and a 9 year old female showed interday variability of 18.8 and 12.6 ug/L, respectively, in urinary arsenic levels. The amount of variability in urinary arsenic data sets may depend on the period over which data are collected (see also the discussion in Walker and Griffin, 1998). Unless individuals have persistently high or low urinary arsenic levels over time, the variability over a study population (based on average levels) is likely to decrease as the duration of sampling gets longer. It is also noted that if the season of highest exposures is targeted for sampling, the apparent variability for short-term results may be greatest and most biased high for long-term patterns.

Asarco proposes use of urinary arsenic data from a sampled population of children in Utah to quantitatively demonstrate that a soil arsenic cleanup level of 125 ppm would be protective. For the same reasons that a soil background study in Utah would be considered not relevant to establishing a site-specific background value for soils at Everett, Ecology would be disinclined to accept urinary arsenic data from Utah as a proper basis for establishing an allowable urinary arsenic increment, and thereby a soil cleanup level, for the Everett Smelter site. The distributions of populations at background exposure levels may not be identical at different locations. A study similar to the one discussed in Asarco's comment could be performed for a population in Washington closer to the Everett Smelter site. Ecology therefore also comments on policy and technical aspects of the use of the proposed approach.

The derivation of a soil cleanup level in the proposed approach starts with identification of a tolerable increment in urinary arsenic level. That tolerable increment as proposed in the comment is based on the difference between the 90th and 99th percentile values in the study population distribution. Ecology views this as a policy rather than a technical choice; Ecology, if it were to consider this approach, may choose a different measure for deriving a tolerable increment. For example, to provide greater protectiveness the increment could be based on the difference between the 95th and 99th percentiles. Alternatively, because of representativeness issues for extreme upper tail percentiles such as the 99th, the increment could be based on the difference between the 90th and 95th percentiles. Population distributions of urinary arsenic are typically lognormal, and may be significantly skewed at the upper percentiles. Relatively large data sets are needed to narrow the uncertainty in estimated upper tail percentiles in such distributions; thus the values are typically subject to significant uncertainty, the magnitude increasing as the upper-tail percentile increases. The proposed increment, it is noted, approaches or exceeds the median urinary arsenic level for the study population and in that sense is far from de minimis. The uppermost values in the distribution may also not be commensurate with expected dietary plus drinking water intakes. It is possible that the high outlier urinary arsenic values reflect other types of arsenic exposures that would not, in Ecology's opinion, qualify as background. In a study population residing close to, but not on, a contaminated site, the possibility that activities have led to contact with site-related contaminants should be considered. Many other sources for idiosyncratic arsenic exposures exist, some of which are identifiable through case reports or evaluations of poisoning incidents (see, for example, Abdelghani et al., 1986; Brayer et al., 1997; Falk et al., 1981; Fuortes, 1988; Geschke et al., 1996; Tay and Seah, 1975). Exclusion of the highest outlier values may be justified where misalignment with known or expected background sources is demonstrated.

The back-calculation of a soil arsenic concentration from a tolerable increment in urinary arsenic levels includes many of the same exposure variables as the MTCA risk-based equation, plus additional variables related to urinary arsenic fractional excretion and urinary volume. The selection of appropriate parameter values to use in the back-calculation thus includes similar considerations of scientific uncertainty and risk-management policy as occur when using the MTCA risk-based equations. Ecology comments elsewhere in this document on issues related to relative bioavailability. The urinary volume excreted by young children has been shown to deviate from standard literature-cited values; in a study of Anaconda children, for example, measured urinary volumes of young children were found to be markedly suppressed (Walker and Griffin, 1998; see also the discussion in Mushak and Crocetti, 1995). There is also a range of values cited and used for the fractional excretion of arsenic in urine. Walker and Griffin (1998) cite and apply a value of 80% rather than the 60% used in Asarco's back-calculation; Walker and Griffin were able to predict measured urinary arsenic values reasonably accurately using this, and other, parameters in a site-specific risk assessment. Hwang et al. (1997) also cite a fractional excretion value of 75%.

A relevant data set that could be considered site-specific for urinary arsenic background values for the Everett Smelter site has not been developed or submitted by Asarco. For policy and technical reasons, Ecology considers it likely that any tolerable increment in urinary arsenic levels that might be estimated would be smaller than the one proposed in Asarco's comment. (Note: this should not be misinterpreted as Ecology approval for this approach to deriving soil cleanup standards). As a hypothetical calculation, assume the tolerable increment is up to 5 ug/L. Further assume that for the back-calculation of a soil cleanup level, urinary volume for young children in 0.5 L/day, fractional arsenic excretion is 80%, relative bioavailability is 100%, soil ingestion rate is

200 mg/day, and the frequency of exposure factor is 1.00. The result would be a soil cleanup level below 20 ppm.

In conclusion, Ecology believes that urinary arsenic measurements can provide useful information and are justifiably proposed as a component of a Community Protection Measures program for the Everett Smelter site. Ecology also believes, however, that there are significant concerns regarding the use of urinary arsenic measurements as a basis for deriving a soil cleanup standard (or remediation level) under MTCA. Finally, even if the approach is used, the back-calculation of a soil cleanup level includes a number of assumptions (similar to other forms of exposure calculation) and is subject to substantial uncertainty. Addressing that uncertainty, and recognizing the goal under MTCA of protecting individuals (including those at the upper tail of a population distribution on exposures), Ecology believes that the range of soil arsenic concentrations that could be back-calculated under the proposed approach would include the 20 ppm soil arsenic cleanup standard already proposed for the Everett Smelter site.

[11] Comment - Arsenic is an essential nutrient. "Arsenic is a demonstrated essential element in animals and the evidence indicates in is likely essential to humans as well." (Thorp)

Response: A discussion of whether arsenic has been established to be an essential nutrient was presented in 1988 in an EPA document, “Special Report on Ingested Inorganic Arsenic.” A summary of the conclusions of the Technical Panel Subcommittee on Essentiality is as follows:

1. Information from experimental studies with rats, chicks, minipigs, and goats demonstrates the plausibility that arsenic, at least in inorganic form, is an essential nutrient. A mechanism of action has not been identified and, as with other elements, is required to establish fully arsenic essentiality.
2. The nutritional essentiality of inorganic arsenic for humans is not established. However, the history of trace element nutrition shows that, if essentiality of an element for animals is established, it is highly probable that humans also require the element. Accordingly, knowing a mechanism of action is needed for full interpretation of the currently available animal data.
3. The group consensus position is that, at this time, it is only possible to make a general approximation of amounts of arsenic that may have nutritional significance for humans.
4. Elucidation of the role of arsenic in human nutrition will depend upon the development of specific information in the following areas:
   - Biochemical and physiological mechanism of action
   - Biological activity and metabolic response to various chemical species of ingested arsenic, and
   - Dose-response relationships between animal species.

The Subcommittee on Essentiality agreed that "the nutritional essentiality of inorganic arsenic in animals has not been established, but is a plausible assumption." "[T]here is insufficient published information available to determine the reproducibility of the arsenic deficiency syndrome." "A mechanism of action has not been identified and, as with other elements, is required to fully establish arsenic essentiality."

Other comments from the report:

- "If arsenic were an essential element, one still does not know how to use that information in an assessment of cancer dose-response. One can say that the risks from arsenic deficiency would increase as a function of reductions in exposure below the threshold of essentiality. One might say that cancer dose-response decreases to the threshold for essentiality, but it does not follow that the cancer risk is zero at that point. It is possible that, at doses below an essentiality threshold, the overall risk to an individual would depend on both the cancer and deficiency-induced effects."
- "The risk of skin cancer is unlikely to be influenced by the *possible* essentiality of arsenic."

It was widely recognized in pharmacological literature from the late 1800s and early 1900s that one of the effects of arsenic in humans is stimulation of the appetite. It is unclear whether this effect was considered in any of the studies that claimed to show the essentiality of arsenic. Food consumption did not appear to be measured or reported for any of the studies. It is possible that malnutrition, due to a low intake of the highly processed diet used in the studies, could be responsible for the effects seen in the "arsenic-deficient" animals. It is also possible that the way in which the diet was produced may have removed nutrients other than arsenic that were important for normal growth and development.

The few studies on arsenic essentiality that have been published since that EPA report was issued have added little, if any, proof that arsenic is essential in either animals or humans. Ecology believes that more information establishing a biochemical function for arsenic in humans is essential to establish the necessity of arsenic for human function.

Even if it were proven that arsenic is required for good health in humans, that finding wouldn't preclude it from having toxic actions at essential doses or just above such doses.

[12] Comment - Risk of Remediation is greater than the risk of leaving the contamination in place. *Risks are created by soil cleanup activities that could be more significant from a public health perspective than the risks eliminated by removal of arsenic or lead from soil. The stricter the cleanup level, the higher the remediation risk becomes. At the levels of arsenic in soil under consideration here, this is an important consideration...Ecology apparently does not consider the fact that the soil cleanup itself may create new risks...For example, soil excavation and transport of contaminated soil by truck can result in accidental injuries and fatalities. Remediation itself creates risks to workers...Moreover the fatalities from accidents typically occur at younger ages than fatalities resulting from cancer, resulting in more "years of potential life lost". It is important to note that these estimates of injuries and fatalities are based on actual data. In contrast, the risk from arsenic in soil is ... based on a theoretical model [Beck].*

Response: Asarco's comment raises the general concern that possible risks from implementing soil cleanup actions be evaluated and considered when selecting cleanup actions for the Everett Smelter site. By the nature of the comment, Asarco appears to believe that soil cleanup actions at the Everett Smelter site should be constrained because of the magnitude of potential risks from cleanup actions. The comment does not provide site-specific analyses of such possible risks for the Everett Smelter site, nor does it provide other scientific information applicable to this site that would determine at what proposed soil remediation level (e.g., for excavation and replacement of contaminated soils) the risks from cleanup actions themselves would become more significant than the protectiveness (risk reduction) imparted by those cleanup actions. A hypothetical case study is presented in Cohen et al. (1997).

MTCA already recognizes the relevance of evaluating potential risks to human health and the environment that may occur as a result of implementing cleanup actions. The MTCA Cleanup Regulation (Ecology, 1996) specifies in several sections that selected cleanup actions and cleanup standards should not result in a significantly greater overall threat to human health and the environment (see, for example, -360(5)(d)(iii), -360(9)(i)). Those sections of the rule make it clear that potential risks to human health and the environment that are a result of cleanup actions should be considered. The concern raised in Asarco's comment is therefore not a new issue, but rather one already incorporated in the MTCA Cleanup Regulation. Site-specific evaluations relevant to this concern can be reflected in the Cleanup Action Plan and/or the incorporated SEPA environmental analyses.

Potential risks from remediation activities include risks to remediation workers and to community residents and the general public (e.g., along routes used to transport excavated soils). MTCA includes provisions for development of a site-specific health and safety plan (see WAC 173-340-810) for worker protection and recognition of site-related hazards. Additional specific worker protection requirements are applicable under regulations of the Occupational Safety and Health Act (OSHA) and the Washington Industrial Safety and Health Act (WISHA), addressing both physical and contaminant-related hazards. Ecology believes these provisions will provide for adequate protection of remediation workers. All cleanup actions undertaken at the Everett Smelter site will be characterized and described in a series of site-specific engineering and planning reports (see WAC 173-340-400). Those documents can and should include discussions of potential risks to community residents and the general public, and specification of specific actions to be taken to minimize those risks. Ecology will review all such plans and can seek additional public comment on the proposed protective measures to be taken. Cleanup actions are subject to Ecology inspection and oversight for conformance with the approved engineering and planning report specifications. Ecology acknowledges that possible risks to community residents and the general public can never be reduced to zero by these measures. Any injuries or deaths caused by site cleanup actions would be a tragedy, and Ecology is committed to working with the community to minimize such risks. Any residual risks associated with cleanup actions are short-term, voluntary risks that citizens will be asked to accept for the benefits of reducing the long-term risks from site contamination.

The analysis and comparison of risks posed by site contamination versus cleanup actions involves multiple factors. Both the magnitude and characteristics of the various risks need to be evaluated, a point that has been discussed in both the SEPA EIS on the MTCA Cleanup Regulation (Ecology, 1990: see section 3) and in evaluations of soil cleanup actions at other sites (see, for example, USEPA, Region 10, 1993). It is emphasized here that more than a simple numerical magnitude of risks is involved in the evaluation process on comparative risks (see Ecology, 1990).

Asarco comments that the risks to workers or from transportation accidents are based on actual data, suggesting that the estimates for those risks are both more accurate and realistic than risk estimates for exposures to site contamination. It is worth noting that even though accident rates or other statistics for worker or transportation risks are fundamentally based on observations (data), there are still likely to be significant uncertainties about the representativeness of those statistics for evaluating site-specific risks. For example, general highway accident or injury statistics are unlikely to take into account factors that may apply to site-specific remediation activities involving transportation of contaminated soils. Worker training, vehicle inspection and maintenance status, limitations on hours of operation and routing, and many other factors may distinguish the appropriate risk factors for remediation activities from general transportation risks. An analysis of the causes of truck accidents (Joshua and Garber, 1992), for example, points to areas where actions to control risks may be effective. Similarly, general worker accident and injury statistics may not appropriately reflect the limited types of worker activities, the seasonal nature of those activities, the requirements for worker health and safety training, and other relevant factors characterizing cleanup actions at a specific site such as the Everett Smelter site. Uncertainties about the representativeness of risk statistics, or failure to appropriately consider the degree to which they can be controlled, certainly affect the accuracy of estimated risks from cleanup actions.

Other aspects of the quantification of risk should also be considered in any comparison of cleanup action risks and site contamination risks. One concern is the choice of how risks should be measured (see Ecology 1990). Thus, the result of a comparison may be affected by whether it is based on number of deaths versus number of years of life lost. A second concern is that estimates of worker or transportation risks be recognized as probabilistic rather than certain. Numerous examples of cleanup actions involving transportation of contaminated materials can be found for which there were no injuries or fatalities, a priori risk estimates notwithstanding.

Worker and transportation risks are also different in kind, not merely different in magnitude, from risks due to exposure to site contamination. Those differing risk characteristics also must be considered in any comparative evaluation. As is amply demonstrated by the remaining soil contamination at the Everett Smelter site, and other similar sites, arsenic and lead contamination that is left in neighborhood soils will remain there for a long time; natural degradation or recovery processes are extremely slow. Therefore, the short-term, one-time risks from transportation or site remediation stand in contrast to community risks that will recur generation after generation. While Cohen et al. (1997) propose a discounting of future human health risks based on the health economics literature, Ecology notes that the statute makes the following declaration of policy: "Each person has a fundamental and inalienable right to a healthful environment, and each person has a responsibility to preserve and enhance that right. The beneficial stewardship of the land, air, and waters of the state is a solemn obligation of the present generation for the benefit of future generations". The non-economic impacts of future human health threats do not support discounting of future risks, especially in light of this declaration of policy. The cumulative risks of residual site contamination should therefore be compared to the one-time risks from cleanup actions.

Worker and transportation risks are also likely to be more amenable to control than community risks from site contamination. The long-term behaviors of area residents, especially young children, may be controllable to only a limited degree, even with community education programs and other institutional controls in place. There are greater opportunities to control worker and transportation risks, for example through training, inspection, and monitoring activities and numerous enforceable work practices. To the degree that controls can be implemented, the risks from cleanup actions may be reduced. Through training, workers and transporters are likely to be more familiar with the risks they face. Workers also accrue direct benefits in association with the cleanup action risks, while community residents do not benefit from residual site contamination. All of the non-numerical characteristics of the risks should be considered in the comparative evaluation under MTCA to determine if cleanup actions pose significantly greater threats to human health and the environment.

[**13] Comment - The Method A Level for Lead is Too Low and Inconsistent with Current Scientific Evidence** *"The regulation does not state the blood lead model used, or any of the assumptions, such as the soil ingestion rate, lead bioavailability, amount of lead from other sources and population blood lead distribution, that went into the derivation of the 250 ppm level. Nonetheless, the level is inconsistent with the 400 ppm level used by EPA as a screening level for lead in soil." [Beck] "The 250 ppm Method A cleanup level for lead is inconsistent with the current scientific evidence on health protective levels for lead in soil." [Tsuji]*

Response - The current Model Toxics Control Act cleanup level for lead, using the Method A tables is 250 mg/kg lead in soil for a residential setting and 1000 mg/kg in an industrial setting. The Model Toxics Control Act regulations and cleanup levels became effective in early 1991. The lead cleanup levels were based on several studies identified in the 1991 Responsiveness Summary. Today, additional lead exposure studies have been completed and peer reviewed/published and EPA also has developed two peer reviewed computer exposure models. Those models are known as the Integrated Exposure Uptake Biokinetic Model (IEUBK) and the Adult Lead Model. The IEUBK model (Version 0.99D) is used to estimate blood-lead exposures in children, generally between birth and 84 months of age. The Adult Lead Model (Interim Approach) is for adults, however it is not clearly defined at what age "adulthood" starts. The Adult Lead Model is based on protection of the fetus, wherein the exposed individual is a pregnant woman. EPA is currently working on an All Ages Model that will eventually replace the two models listed above.

Ecology agrees that the Method A residential soil-lead cleanup level of 250 ppm may be more protective than necessary to achieve the blood-lead goal established by the Centers for Disease Control and Prevention. (It should be noted that there is not universal agreement that the IEUBK model is a good predictor of blood-lead concentrations.) That goal is to protect 95% of the children from having blood-lead levels exceeding 10 ug/dl (micrograms per deciliter). Using the IEUBK model default values and a soil lead concentration of 250 ppm predicts that 98 percent of the children would not exceed the goal of 10 ug/dl. Running the model "in reverse" to determine a soil-lead concentration that still meets the blood-lead goal, results in a concentration of 353 ppm.

EPA issued a directive in 1994 stating that the soil-lead level at which EPA will begin to take action is 500 ppm. The Everett Smelter site is not an EPA Superfund site. Using 500 ppm as the soil concentration in the IEUBK model predicts that approximately 12 percent of the children will exceed the blood-lead goal, which is not acceptable to Ecology. Ecology has gone before the Model Toxics Control Act Science Advisory Board and received their approval to use the IEUBK model at a cleanup site in Southwest Washington. All of the IEUBK default parameters must be used to establish a soil-lead cleanup level for the Everett site, unless site-specific data is available to allow a change to the model defaults.

The Adult Lead Model may also be used in Washington State to establish remediation or action levels for site cleanups, however it should be used at sites where adults are the only exposed population. The adult lead model is neither applicable nor appropriate for residential properties. The concurrence from the Model Toxics Control Act Science Advisory Board to be able to use this model was only received in November 1998. The adult model is not appropriate for developing cleanup levels. As with any other contaminant, if concentrations are left behind in excess of the residential cleanup levels, then institutional controls are required to prevent or reduce exposures.

Ecology believes that the existing residential cleanup level (Method A - Residential) may be more stringent than necessary. When the Model Toxics Control Act regulations and cleanup standards or levels were being developed in the late 1980s and early 1990, the best available science at the time led the agency to make the 250 mg/kg soil cleanup level decision. When in doubt, regulatory agencies will generally err on the side of conservatism (choose to be protective of human health and the environment) rather than be less conservative and find out later that they were wrong.

Should Asarco wish to use site-specific rather than default values in the IEUBK model to establish soil-lead cleanup levels at the Everett site, they should put that request in writing. The request should include the appropriate site-specific data. Moving off the model defaults should not be taken lightly and the quality of information needed to make changes is very high. As noted earlier in this issue discussion, the residential soil-lead cleanup level using the IEUBK model is 353 mg/kg as contrasted to the 250 mg/kg residential Model Toxics Control Act Method A level.

<u>[14] The three-part rule is overly conservative.</u> *Ecology's three-part decision rule, coupled with application of a cleanup level of 20 ppm based on Method A, could result in as many as 48% of the Everett residential properties requiring remediation <u>based solely on the influence of background levels of arsenic</u> [Thorpe]. The three-part rule is overly conservative. Cleanups should be based only on the average concentrations at a property; meeting the three-part rule would in fact result in an even more restrictive result than implied by the cleanup value itself [Beck].*

<u>Response:</u> Ecology adopted a three-part decision rule (i.e., a tandem test statistical approach) for evaluating compliance with soil cleanup standards (see WAC 173-340-740(7)(d)). Asarco comments that application of this three-part decision rule to sites with characteristic soil arsenic concentrations for Puget Sound surficial soils would result in a high rate of false positive results, in which "background" soils would be identified as requiring cleanup actions. The technical basis for Asarco's comments is an analysis (Peterson, 1998) using data from Ecology's statewide study of background concentrations for metals in soils (Ecology, 1994) plus assumptions about the sampling and data evaluation approaches to be included in the Cleanup Action Plan for the Everett Smelter Site.

Asarco and Ecology have discussed performing a site-specific soil background study to provide data most representative of the Everett Smelter site and most relevant to site cleanup decisions. That type of study is consistent with the MTCA cleanup rules and would directly address any questions about proposed cleanup levels in relation to local background conditions. To date, however, Asarco has chosen not to perform such a site-specific background study. The results presented in Peterson (1998) use a surrogate (non-site specific) data set and are a function of that data set selected for analysis, among other factors. Unfortunately, the data set used in the analysis is flawed by inclusion of values that are unrepresentative of general Puget Sound background conditions and specifically unrepresentative for Everett. Peterson (1988) compiles all surficial soils results (within top one foot) for arsenic for sampling locations within the Puget Sound Basin region from Ecology's 1994 report and uses that data set for analysis. The selected values are listed by Peterson in Table 2 of his report. The 52 results for surficial soil arsenic concentrations range from 1.1 to 73.3 ppm. [Note that the individual values in this selected data set represent different degrees of spatial compositing (from 1:1 to 5:1; see Ames, 1994), which affects the statistical evaluations of the data]. Five of the 52 values are from a sampling location designated as Lat 47 18 43 and Long 122 31 57 (see Ecology, 1994, page 10-9); the five results for this location represent uncomposited samples from five locations within a one-acre site. Those five values include the four highest, and five of the six highest, results in the data set used by Peterson (at 73.3, 50.7, 23.5, 19.3, and 11.2 ppm). The sampling location in question can be located on the USGS 7.5 minute Gig Harbor Quadrangle topo map; it is in Point Defiance Park in North Tacoma, approximately 1.5 miles from Asarco's former Tacoma Smelter (the dominant regional source of arsenic emissions, historically). Sampling results from the Remedial Investigation for that Superfund site (Bechtel Environmental, Inc., 1992) include elevated soil arsenic concentrations (to more than 200 ppm) for multiple samples near the entrance to Point Defiance Park, in the same vector heading as the five samples used by Peterson and approximately half way between the former smelter site and the "background" sampling location. Those results confirm that the sampling location in Point Defiance Park should be considered biased (source-related) and unrepresentative of Puget Sound background conditions.

Almost all of the cited 48 percent false positive error rate calculated by Peterson (1998) arises from inclusion of the three highest values in his selected data set (at 73.3, 50.7, and 23.5 ppm arsenic). Exclusion of all of the results from the Point Defiance Park sampling location would therefore result in essentially 0 percent false positives, accepting for the moment all of the assumptions about sampling design included by Peterson (1998). [Note that there appears to be a transcription error in Peterson's paper on page 3, where the total number of possible compliance monitoring data sets should apparently be 15,820,024,220; the calculation of error rates, however, is not affected]. Absent a site-specific background data set for the Everett Smelter site, and recognizing that this revised analysis still uses a surrogate data set that may not be fully representative of site-specific conditions, Ecology is proceeding on the assumption that any false positive error rates due to background conditions are quite small (possibly zero) and insufficient to modify the cleanup level for soil arsenic.

Asarco's comments assume that the three-part rule will be incorporated in the soil sampling design and compliance decision rules in Ecology's Cleanup Action Plan. Ecology is itself interested in the statistical performance of the three-part rule for this site and has been evaluating that performance. The Everett Smelter site presents an atypical issue for MTCA sites; the number of individual decisions for cleanup will be very large, because such decisions will be needed separately for each contaminated property (or multiple decision units within each property), and for multiple soil depth intervals. The very large number of cleanup decisions to be made, based on separate data sets, will make it impractical to substantially improve statistical performance of the three-part rule by increasing the number of samples in each data set, an approach that otherwise would be available. The performance of the three-part rule may therefore be limited by practical constraints in ways that will rarely occur at other (non-residential) MTCA sites. Ecology will be considering these issues, as well as protectiveness objectives, as it develops a sampling design and data evaluation decision rules for the Cleanup Action Plan.

Ecology originally adopted a tandem test approach for compliance monitoring decisions in soils with awareness and intent. The tandem test approach constrains the magnitude and frequency of exceedances of the cleanup standard, even while allowing some exceedances as long as the test based on average concentrations is met. This is in contrast to other proposals for statistical evaluation of "action levels" at concentrations greater than "cleanup levels" as long as the cleanup level is met on average (see, for example, Bowers et al., 1996), which include no such constraints. Thus, Beck's comment does not address the MTCA rules as they were developed and adopted by Ecology. Ecology further notes that the recent MTCA PAC process did not propose any revisions of the three-part rule for evaluating compliance with cleanup standards (MTCA PAC, 1996). That approach is retained in the current proposed revisions to the MTCA Cleanup Regulation. To the extent that the compliance decision is based on an estimate of the average concentration in a decision unit, it incorporates an assumption that there is equal contact with all parts of that decision unit over the period of exposure. Ecology views that assumption as an obvious simplification of human behavior, especially at residential sites where preferential contact areas are likely to occur (e.g., play areas, gardens, etc.) even if they cannot be identified in advance with confidence. If the assumption of equal contact is dropped, the true average concentration for exposure will be a function of the spatial variability in contamination and an individual's pattern of unequal contact over time. The constraints on the maximum magnitude and frequency of exceedances of the cleanup standard will therefore also constrain the maximum individual exposure to a level not substantially greater than the cleanup standard. The potential contaminant migration (from residual "hot spots") and effects from short-term exposures are also reduced by the constraints that result from the tandem test approach.

[15] Comment - Reviewed 12 versus 18 inch cleanup depth for the Sandy Smelter and concluded that an 18 inch removal depth would not provide measuarable additional protection. *"Regarding depths of soil cleanup, I have reviewed the relative health protectiveness of 12 versus 18 inch depths for soil remediation for the Sandy Smelter site in Utah. This evaluation….concluded that based on the likelihood and magnitude of soil contact and decisions at other sites, an 18-inch soil removal depth would not provide measurable additional protection relative to a 12-inch remediation depth. The conclusions of this evaluation are also applicable to the Everett site." (Tsuji)*

Response: A document written by Kleinfelder (Kleinfelder, 1994), discussed 12 inch versus 18 inch remediation depths at the Sandy Smelter site in Salt Lake County, Utah (Kleinfelder). This qualitative analysis described cleanup depths chosen for a number of EPA sites and discussed types of activities that could lead to exposure to subsurface soil at the Sandy Smelter site. The document concluded that removal of soil to a depth of 12 inches would be appropriate for that site. There was little analysis related to potential for harm from acute exposure to arsenic-contaminated soil which is a significant concern at the Everett Smelter site. An evaluation of the acute health hazard of arsenic-contaminated soil was performed by the Washington State Department of Health (DOH, 1999).

Concern for acute toxicity of arsenic-contaminated soil is related to the occasional ingestion of large amounts of soil (e.g., one or more grams during a day). Ingestion of greater than one gram of soil per day has been documented, and is likely to be a relatively common behavior in a population that includes a significant number of children, such as the Everett Smelter site. Contaminants are rarely confined to just the surface layer of soil, but may be present beneath the surface as well as in relatively inaccessible areas such as in crawl spaces of buildings and under structures such as roads, driveways, barns and sheds. While it is not expected that people will have regular contact with this material, it is occasionally brought to the surface where exposure can occur. For example, gardening, digging by children and pets, and other common activities could result in contact with contaminated soil that was previously not available for human exposure. Piles of soil excavated during single or multi-day projects and left at the surface may attract children and could become sources of exposure. Short-term contact with this soil could be hazardous unless contact with the soil is controlled and the soil is handled and disposed of properly.

The following list of activities that could result in exposure to subsurface contaminants is based on consultation with people who live and work in the Everett, Washington area:

- gardening,
- digging by children and pets,
- planting trees and shrubs,
- resodding,
- installing or repairing utility lines and utility poles,
- digging holes for fence posts,

- installing and repairing a sprinkler system,
- removing and installing heating oil tanks,
- bioturbation (disturbance of soil by worms, ants, moles, etc.),
- repairing roads and driveways,
- construction of structures such as decks, sheds, barns, home additions, and
- new home construction.

On a site-wide basis, it is expected that these activities will be commonplace, and many would likely result in disturbance of soil to a depth of 12 to 24 inches. Construction activities and work on utility lines and oil tanks may involve deeper excavations. While it is theoretically possible that contact with subsurface soil can be controlled through institutional control programs, Ecology has little confidence that control of people's activities in a large residential area can be accomplished over the long term.

Since these activities are likely to result in exposure to contaminated soil, Ecology believes that it is important to address arsenic-contaminated soil located at depths below 12 inches. A detailed discussion of remediation levels for subsurface soils at the Everett Smelter site is presented in Ecology's Integrated Draft Cleanup Action Plan and Draft Environmental Impact Statement (Ecology, 1999b).

[16] Comment - Lack of Consideration of Site-Specific Exposure Differences Doesn't Represent Sound Scientific Principals *"The Method B approach is generically flawed in that it does not consider a range of factors. These include: 1) Site-specific differences in exposure due to climate and other variables across sites that will result in different doses at the same cleanup level; 2) Differences in dose/response relationships among carcinogens which would require the use of different dose/response models, rather than the single model sued by Ecology." and "Overall, the MTCA cleanup levels for lead and arsenic in soil are inconsistent with current scientific knowledge regarding exposure, toxicology and risks of these substances. Moreover, the use by Ecology of a formula with unvarying input assumptions for all chemicals at all sites to develop cleanup levels does not represent the use of sound scientific principles." [Beck]*

Response: The Model Toxics Control Act regulations and cleanup standards include several approaches to evaluating risk based on site complexity as well as land use considerations. Basically, for "simple routine sites" with a limited number of contaminants, the Method A tables are appropriate to use. Those are quick and simple lookup tables. The Method B formula values are appropriate for any site and are the most stringent in terms of cleanup levels. Method B is based on young children and a residential exposure scenario. Method C is applicable for adults and an industrial exposure scenario. The Method B and C formulas identify standard exposure assumptions.

"As a matter of policy, the department has defined the exposure parameters to be used when establishing cleanup levels under this chapter." WAC 173-340-708(10)(a) When the Model Toxics Control Act regulation was drafted, Ecology already had several years of experience in working with Federal Superfund sites and site specific risk assessments. The process of evaluating site-specific risk assessments was often a long, cumbersome, and expensive process, sometimes with little apparent benefit. As noted above, Ecology decided to establish default exposure parameters as a matter of policy. That policy choice also set the stage for how Ecology would evaluate, for example, multiple chemicals and their effects on human health. Where there is "clear and convincing scientific information", one or more of the following parameters may be modified: gastrointestinal absorption rate; inhalation correction factor; bioconcentration factor; and inhalation absorption factor.

In an attempt to simplify the data evaluation process and determine the effects of the contaminants on human health and the environment, numerous assumptions were included in the cleanup regulations. These assumptions were instituted to accelerate the investigative and decision making phases to be able to get to the physical cleanup actions sooner. Less talk and more action.

As noted above, the Model Toxics Control Act regulations do allow a certain amount of flexibility in evaluating site-specific exposures. Other flexibility is currently not allowed in the Model Toxics Control Act regulations, however site-specific risk assessments are being contemplated in the new draft version of the Model Toxics Control

Act. Due to very high levels of uncertainty, Ecology has made numerous decisions regarding risk based on policy.

Risk assessment is a combination of both science and policy. There is often a high level of uncertainty in risk assessments. The current Model Toxics Control Act regulations allow a certain amount of flexibility in allowing site and chemical-specific exposure differences from the standard default values. There of course needs to be clear and convincing scientific information presented to Ecology to allow those site-specific changes to be made to the standard exposure assumptions. The greatest degree of flexibility is in the setting of site-specific action or remediation levels, as compared to the setting of cleanup levels. To the best of Ecology's knowledge, there is nothing unique about the Everett Smelter site that would allow one to deviate from the standard MTCA default values. However, should there be site-specific exposure difference that Asarco believes should be considered for the Everett Smelter site, that request should be submitted in writing for review by Ecology. For example, Asarco could have conducted a site-specific soil-arsenic background study. If the background soil concentration for arsenic was determined to be higher than the Method A value of 20 ppm, a higher cleanup level could have been set for the site. To date, Asarco has not submitted any site-specific exposure studies or assessments.

Again, the exposure scenarios contained in the Model Toxics Control Act include various assumptions, all of which are based in science but many are set by policy. The exposure formulas are based on reasonable maximum exposure scenarios. They might be overly protective for some individuals while at the same time being under-protective of others. It is Ecology's opinion that they are reasonable.

[17] Comment - Opinion that 10^{-6} Cancer Risk is Inappropriate *"Ecology uses an inflexible risk target of 10^{-6} for all carcinogens. This decision does not consider factors such as the size of the population exposed or the relative importance of soil as an exposure pathway for a particular chemical in selection of the risk target. Such factors are normally considered by regulatory agencies in setting permissible risk levels and should be considered by Ecology." [Beck] "Consequently, EPA site managers may use higher target risks and cleanup levels when hey believe arsenic exposures at a site are low enough that no public health hazard exists." [Schoof]*

Response - Ecology regards the decision as to whether a risk of a given magnitude is "acceptable" or "unacceptable" as a policy matter rather than a scientific matter. (1991 Responsiveness Summary) The Model Toxics Control Act regulations (173-340-700(3)(b) WAC) states, "For individual carcinogens, cleanup levels are based upon the upper bound of the estimated excess lifetime cancer risk of one in one million ($1 X 10^{-6}$). Where a site involves multiple hazardous substances and/or multiple pathways of exposure… the total excess lifetime cancer risk for a site shall not exceed one in one hundred thousand ($1 X 10^{-5}$)." The 1991 Responsiveness Summary also states, "In selecting a 10^{-6} cancer risk level for individual carcinogens and a 10^{-5} total excess site cancer risk level, Ecology considered (1) requirements under other Ecology regulatory programs, (2) requirements under other state and federal laws, (3) experience on cleanup sites, (4) comparisons with other activities, and (5) public comment on the proposed rule."

The Model Toxics Control Act Policy Advisory Committee (PAC), authorized by the Washington State Legislature in 1995, had as one of their priority issues to discuss "allowable risk/risk range". The PAC requested that the Model Toxics Control Act Science Advisory Board (SAB) revisit the issue of risk values. Several years earlier the SAB expressed some concerns that MTCA risk values were too restrictive. The SAB declined to recommend changing the risk values because they were seen as policy matters. The PAC reached no consensus or broad support recommendation to change the allowable risk and risk range. (12/15/96 Final PAC Report)

While Asarco may disagree with Ecology's choice of acceptable risk, that decision is based on policy and the desire of the citizens of the State of Washington. "Declaration of policy. (1) Each person has a fundamental and inalienable right to a healthful environment, and each person has a responsibility to preserve and enhance that right. The beneficial stewardship of the land, air, and waters of the state is a solemn obligation of the present generation for the benefit of future generations." RCW 70.105D.010

[18] Comment - Assumption of 6-year childhood exposure in MTCA Method B equation is unwarranted scientifically and statistically. *The Ecology Method B formula ... assumes that a six year childhood exposure creates a lifetime cancer risk directly proportionate to the risk from a lifetime exposure, i.e. that the childhood risk is 6/75 of the lifetime risk. This is an unwarranted assumption...In general, since the available evidence is that arsenic is more likely a promoter or progressor than initiator, the lifetime risk from exposure during the first six years of life should be lower than the proportionate method assumed by Ecology [Brown].*

Response: The use of only a six-year childhood duration of exposure in the equation for deriving soil cleanup standards under MTCA (WAC 173-340-740-(3)) is discussed in Ecology's Responsiveness Summary for the cleanup regulation (Ecology, 1991; see pages 244-245). As stated in the Responsiveness Summary, Ecology believes that this approach, in combination with other exposure parameters and with a relatively strict limit on acceptable risks, results in protective soil cleanup levels. Basing the calculation on only childhood exposures should not be misinterpreted as meaning that adult exposures are of no concern to Ecology or have no potential for adverse consequences. Ecology has noted that the childhood-only exposure scenario, using the selected exposure parameters, accounts for about 70 percent of the total exposure in EPA's standard default exposure equation, which assumes a 30-year total exposure (RME case). Thus, even assuming a longer period of exposure as in EPA's default equation, the majority of lifetime exposure still occurs in the childhood period that represents only a small fraction of a total RME exposure duration. This is simply another way of stating that children are a sensitive population for contaminant exposures via the soil ingestion pathway. Ecology remains concerned, however, about potential exposures and health risks for any population, including adults.

Asarco's comments propose that because of the likely mechanisms of carcinogenicity associated with arsenic exposures, childhood exposures pose less of a cancer risk than adult exposures (since fewer initiating events will have occurred at younger ages). Under this assumption, Asarco claims that the equation used to calculate soil cleanup levels based on a six-year childhood exposure is over-protective and unrepresentative. For the purposes of evaluating the consequences of this comment, an alternative cancer risk calculation, similar to the one included in the MTCA cleanup regulation, can be performed assuming only adult exposures. The result is a soil arsenic cleanup level that is modestly higher than the one for childhood exposures calculated according to the equation in WAC 173-340-740-(3), but still well below soil arsenic background concentrations. Therefore, an alternative calculation based on adult exposures would not affect the selection of a soil cleanup level for the Everett Smelter site, which would still be based on soil background levels.

To calculate a soil cleanup level based on adult-only exposures, assume the following parameter values (compare to WAC 173-340-740-(3)):

RISK = 1 in 1,000,000
ABW = 70 kg
LIFE = 75 years
UCF1 = 1,000,000 mg/kg
CPF = 1.5 $[\text{mg/kg/day}]^{-1}$
SIR = 100 mg/day
ABS = 1.0
DUR = 30 years
FOC = 1.0

Then, using the form of the equation in the cleanup regulation,

$$\text{Soil cleanup level} = \frac{\text{RISK} \times \text{ABW} \times \text{LIFE} \times \text{UCF1}}{\text{CPF} \times \text{SIR} \times \text{ABS} \times \text{DUR} \times \text{FOC}}$$

$$= \frac{10^{-6} \times 70 \times 75 \times 10^{6}}{1.5 \times 100 \times 1.0 \times 30 \times 1}$$

= 1.17 mg/kg soil arsenic

This calculated value is only modestly higher than the comparable value of 0.67 ppm for the six-year exposure of a child. (See Ecology comments elsewhere regarding the bioavailability of ingested soil arsenic; both the adult and child exposures here are calculated assuming 100% relative bioavailability).

Ecology still believes that children are a sensitive subpopulation for soil arsenic exposures, by virtue of their behaviors (e.g., see Kissel et al., 1996) and physiology. Arsenic has been associated with a large number of adverse health effects besides cancer, and the relatively higher exposures of children are still of concern with respect to adverse health effects. Even if an adult exposure scenario is used to calculate a risk-equivalent soil cleanup level, based on assumptions about mechanisms of arsenic carcinogenicity, community protection measures and cleanup actions should take note of the importance of childhood exposures to arsenic in soils and dusts.

[19] Comment - EPA is moving away from point estimates to distributions for exposure estimates. *The EPA has ... moved forward on the issue of human exposure estimation. It recognizes that a simple "point estimate", derived without an understanding of the fraction of the population having exposures at or below it, provides a poor profile of actual human exposures. The agency is now attempting to make fuller use of exposure-related data to derive quantitative profiles of the distribution of exposures in populations...The EPA...is thus moving away from undefined "point estimates "... as a basis for decision-making [Rodricks].*

Response: Asarco's comment proposes that MTCA should adopt the use of probabilistic (distributional) risk assessment in place of the existing deterministic approach, as currently reflected in the risk-based equations for determining cleanup levels as set forth in Ecology equations. Asarco does not provide any site-specific analyses or applications of probabilistic risk assessment methods to the Everett Smelter site in its comment.

Ecology is well aware of the development of probabilistic risk assessment methods. Application of probabilistic risk assessment methods was one of the priority issues that was discussed at length within the MTCA Policy Advisory Committee (MTCA PAC) process. Ecology is currently implementing the MTCA PAC recommendation on use of probabilistic risk assessment in the revisions to the MTCA Cleanup Regulation (see MTCA PAC, 1996; Ecology, 1998).

The MTCA PAC recommendations were developed in recognition that there were members with strong support and those with strong reservations regarding the use of probabilistic risk assessment to establish cleanup levels or remediation levels. The final recommendation proposed allowing limited use of probabilistic risk assessment on a pilot basis where initiated by PLPs, with Ecology to perform additional evaluations of the approach and its potential applicability within MTCA. The recommendations also included the following statement: "Such probabilistic techniques should not be used to replace cleanup standards and remediation levels derived using deterministic methods until adequate technical protocols and policies have been derived, including appropriate revisions to the regulation". Thus, at a PLP's option, probabilistic risk assessment can be performed to provide additional information at a site, and that information will be reviewed by Ecology and can be one factor the agency can consider in developing a Cleanup Action Plan for the site. Asarco has in fact submitted a risk assessment evaluation for the Everett Smelter site (Kleinfelder, Inc., 1995); with respect to this comment, Ecology merely notes that Asarco's site-specific risk assessment used a deterministic approach very similar in form (but not in technical details of parameter choices or risk-based equations) to the approach provided in MTCA.

EPA has discussed a distinction that can be drawn between variability and uncertainty (see USEPA, 1992). Ecology believes that distinction has relevance for the evaluation of probabilistic risk assessment methods. EPA defines variability as the receipt of different levels of exposure by different individuals within an exposed population, while uncertainty is the lack of knowledge about the correct value for a specific exposure measure or estimate (e.g., the 95th percentile exposure level within an exposed population) (USEPA, 1992). One of the goals of a probabilistic risk assessment is to provide more information than a deterministic point estimate approach. By characterizing an entire distribution of exposures or risks for a population of interest, a probabilistic risk assessment attempts to fully characterize the variability in exposure or risk levels. Ecology unequivocally supports this goal of more completely characterizing the variability in exposures or risks; there is no doubt that more information of this type will support better risk management decisions (see Finkel, 1994a). However, the quality of the detailed information provided in a probabilistic risk assessment depends on the level of uncertainty associated with each exposure or risk value of interest reported for the output distribution of the assessment. The magnitude of those uncertainties, and the likelihood that the uncertainties can even be adequately characterized, are issues that need to be considered in evaluating a probabilistic risk assessment approach. Research on evaluating both variability and uncertainty in probabilistic risk assessments is ongoing.

EPA has identified several types of uncertainty, for example scenario uncertainty, parameter uncertainty, and model uncertainty (see USEPA, 1992). All types of uncertainty are relevant in evaluating probabilistic risk assessment. Parameter uncertainty is perhaps the most apparent and easily understood issue. The characterization of input distributions for parameters such as soil ingestion rates or contaminant bioavailability from ingested soils, required for using probabilistic risk assessment methods, is subject to substantial uncertainty largely because of limitations in scientific understanding and data gaps. The input distributions for toxicity parameters, including individual (genetic or physiological) differences in sensitivity, are even harder to characterize; thus many probabilistic models may focus on exposure variability rather than risk variability. Additional concerns arise for correctly identifying the dependent relationships among the variables included in a probabilistic model. A fundamental issue for further Ecology assessment is the degree to which probabilistic methods, considering their inherent uncertainties due to limited knowledge, actually provide a better characterization than deterministic methods.

Concerns other than the technical performance of probabilistic risk assessment were also raised in the MTCA PAC discussions, and these additional concerns also merit consideration. Probabilistic risk assessments are complex and can require considerable resources to review and explain. Affected community residents may find it difficult to effectively comment or participate in site cleanup processes where a complex probabilistic risk assessment is used. There is a potential for selective use of probabilistic risk assessments to introduce unwarranted inconsistency among MTCA sites, unless policies and protocols for their use are established (for example, to address the percentiles of interest and how uncertainty issues will be handled) and technical reviews are thorough. Some issues, such as combined exposures to multiple site contaminants and possible interactive effects, will always be omitted from probabilistic risk assessments in any case, limiting their completeness in characterizing site risks.

[20] Comment - Grass as an effective cover. *Grass is an effective cover that will minimize contact with contaminated soils and exposures to community residents. (Thorp)*

Response - Asarco does not provide technical supporting information for the claim that grass is an effective cover minimizing contact with contaminated soils. It may seem a matter of common sense that compared to bare soils, a grass cover in a yard will reduce potential soil contact. Ecology does not believe, however, that this is an appropriate form for the issue of grass cap effectiveness. Potential reasonable maximum exposure (RME) exposures under MTCA are calculated with certain assumptions regarding the amount of soil contact. The relevant question is to what degree, if at all, would a grass cover alone (without a provision for an additional interval of clean soils beneath the grass cover) reduce soil contact compared to the RME assumption. The fact that with bare soils things could be worse is not in and of itself particularly relevant.

Ecology does not agree with Asarco's comment that grass cover, alone, is effective in reducing RME soil contact. Scientific studies of soil ingestion rates in children support a finding that even with grass cover present there is a broad range of soil contact rates; those studies are in fact the basis for the development of the RME assumption for soil contact. To be effective, a grass cover should also provide for long-term protectiveness. Ecology finds that grass covers are easily penetrated by a variety of typical activities, commonly observed in the community, and that they are subject to physical degradation or elimination over time from a variety of causes (i.e., they are not reliably present in the long term). It is also considered likely that the effectiveness of a grass cover is not proportional to the percentage of area that is covered. Even relatively small areas of degraded or absent grass cover may be adequate to contribute to substantially elevated soil contact rates, because those contact rates reflect the confluence of time spent, locations contacted, and types of activities in which individuals engage (see also USEPA, Region 10, 1993, Appendix A: Responsiveness Summary).

Scientific studies using a chemical tracer methodology have provided most of the information for development of an RME (typical residential) soil contact assumption. Information in those studies provides a technical basis for evaluation of the effectiveness of grass cover. In a study by van Wijnen et al. (1990), soil contact rates were estimated using tracer methodology for children in cities, at campgrounds, and in hospitals (i.e., with only indoor exposures). The campground settings are in part described as having "fields that were mostly covered with grass". The children at campgrounds showed substantially increased soil contact rates in comparison to the other two groups. A study of 64 children in Amherst, Massachusetts (see Calabrese et al., 1989; the same data set has been re-evaluated several times by the authors) occurred in a setting in which almost all of the children's yards had well-established and well-maintained grass cover (confirmed in discussions with the lead author). This is one of the most detailed and extensive studies of soil contact rates in children. The most recent evaluations of the Amherst data show variable levels of soil contact across individuals, with the upper end of the range of estimated soil contact rates being consistent with the RME assumption in MTCA. Thus, the studies of soil contact rates in children do not support the claim that grass cover minimizes soil contact.

A grass cover is easily penetrated by any of a large number of actions, intentional or unintentional. As a physical barrier to contact with soils beneath them, grass caps offer little inherent resistance. Typical play activities of children, digging by pets, and many other activities of community residents will penetrate a grass cover. Ecology and Department of Health staff have observed these typical behaviors and activities within the community during site tours. Contaminated soils below a grass cover can be contacted through such activities, or brought to the surface where they will be available for long-term contact at the surface. Natural soil disturbance (e.g., bioturbation by insects and small animals) may also mix contaminated soils originally below a grass cover up into the grass matrix.

Ecology also believes, as a matter of observation as well as analysis, that in the long-term it will be difficult to preserve a grass cover over all areas of contaminated soils. Areas used for home gardening or horticulture, parking areas, and areas that become de facto or intentional primary play areas are examples of yard areas at typical residences where maintenance of a grass cover will be difficult or impossible. Many other factors - insects (e.g., crane flies), burrowing animals, disinterest in lawn maintenance, drought, watering restrictions, among others - are considered likely to degrade the condition of a grass cover over time. Therefore, Ecology does not consider grass covers to be effective over the long-term. EPA has also recently commented on its view of the effectiveness of grass covers. In the discussion of a proposed rule on dangerous levels of soil lead, EPA noted the following: "Although Title IV of TSCA restricts the standard for soil lead hazards to bare soil, EPA is concerned that the presence of soil cover, such as grass, may not reduce exposure to lead sufficiently. Consequently, it may be prudent to test covered soil to determine whether a soil-lead hazard exists." (USEPA, 1998; see page 30338).

The effectiveness of a grass cover in reducing soil contact may be markedly affected by even small areas where the grass cover is degraded, absent, or penetrated. The amount of soil contact will reflect the types of activities occurring, the duration of those activities, and the locations where they occur. Recent research supports the idea that exposures are activity dependent. For example, Kissel et al. (1996) have shown a strong effect of activity on dermal soil loadings. Mielke (1999) reports that children at day care show an order of magnitude greater soil loadings on hands after periods of outdoor play versus indoor play. Therefore, the degree of protectiveness of a grass cap cannot be considered equivalent to the proportion of a yard in which grass is present.

Ecology therefore concludes that grass covers alone do not provide for long-term protectiveness from contaminated soils at the Everett Smelter site.

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Everett Smelter Site
Integrated Final Cleanup Action Plan and Final Environment Impact Statement

Appendix B
Responsiveness Summary

Attachment B1
New Science Review

Attachment B1-2

Decision Memorandum: Everett, Arsenic Concentrations at Depth In Consideration of Acute Toxicities
January 26, 1999
Washington State Department of Ecology

DEPARTMENT OF ECOLOGY

January 26, 1999

TO: Tim Nord
Toxics Cleanup Program

FROM: Craig R. McCormack
Toxics Cleanup Program

SUBJECT: Decision Memorandum: Everett, Arsenic Concentrations At Depth In Consideration of Acute Toxicities

Introduction

This memorandum documents Ecology's evaluation of the human health hazard of subsurface arsenic-contaminated soil at the Everett Smelter site and the process used by a technical and policy review committee to perform this evaluation.

The primary concern at the Everett Smelter site is human health hazards from exposure to arsenic-contaminated soil. Potential health hazards from chronic exposure to arsenic-contaminated surface soil, as well as from acute exposure to subsurface soil resulting from activities involving excavation, are important considerations. The cleanup level for arsenic at the site is 20 milligrams of arsenic per kilogram of soil (mg/kg), which is expected to protect residents and workers from adverse health effects due to chronic and acute exposure to contaminated soil. Because arsenic-contaminated soils are expected to be left on-site above the 20 mg/kg cleanup level, the acute toxicity of arsenic was considered by Ecology to make better site-specific cleanup decisions protective of human health.

For the purpose of cleanup of the Everett Smelter site, the entire area will be considered residential. Ecology recognizes that, within a residential area, the amount and likelihood of exposure to arsenic-contaminated soil could differ depending on the depth of the soil. Ecology decided to evaluate whether an appropriately protective cleanup could be conducted that incorporated the use of different remediation levels for different depths. Selection of these remediation levels would include consideration of acute exposures that would be based on the likelihood of exposure, the amount of exposure, and the potential consequences of exposure. Ecology asked the Washington State Department of Health (DOH) to assess the potential hazards of acute exposure to arsenic-contaminated soil. DOH gathered and evaluated information related to this topic, as summarized in the attached DOH document, *"Hazards of Short-Term Exposure To Arsenic-Contaminated*

Soil." This memorandum documents the discussions and conclusions made by the review committee regarding the potential hazards from acute exposures to arsenic-contaminated soil, and includes an evaluation of the DOH document.

Scenarios

Because arsenic-contaminated soils with arsenic concentrations greater than the 20 mg/kg cleanup level were expected to be left on-site, it was determined that an assessment of acute toxicity would enable Ecology to make better site-specific cleanup decisions protective of human health. DOH was asked to evaluate the potential hazards of short-term exposure to arsenic-contaminated soil for three sets of exposure conditions, or scenarios, consistent with conditions at the Everett Smelter site. Development of these exposure scenarios was a collaborative effort by Ecology and DOH. Exposure scenario development and determinations regarding appropriate degrees of health protections are policy decisions that rely on an integration of science and public health policy.

To address the influence of the location of contaminated soil on exposure, these scenarios incorporated consideration of the likelihood or probability of exposure to soils from different locations. The scenarios also evaluated different exposed populations (children versus adults) and different consequences of exposure (transient adverse health effects versus lethality). The three scenarios, which are expected to address foreseeable acute exposure hazards at the site, are:

1. Children are exposed to arsenic-contaminated soil by playing in piles of dirt excavated in residential yards as a consequence of typical homeowner activities such as gardening, planting trees and shrubs, digging fence posts, and installation and maintenance of a sprinkler system. Digging activity by children, pets, and other animals (moles, gophers, ants, earthworms) could also bring contaminated soil to the surface where exposure could occur. These activities are expected to occur commonly in a residential area.

2. Children are exposed to arsenic-contaminated soil in relatively inaccessible areas or deep beneath accessible areas. Contact with these soils would be expected as a result of activities such as construction of additions for existing homes, new home construction, road repair, and utility repair. These activities are expected to be relatively common in a residential area. Compared to Scenario 1, children are less likely to be exposed since people performing the excavations are expected to follow instructions in proper handling and disposal of these soils. However, this scenario evaluates unlikely conditions under which failure to properly handle highly contaminated soil could result in an exposure leading to death of a child.

3. Adult workers and residents are exposed to arsenic-contaminated soil in relatively inaccessible areas (beneath roads and buildings) or beneath accessible areas such as residential yards. Activities such as gardening, repair work in a crawl space, fence

installation, road repair, utility repair, and home construction could result in exposure. These activities are expected to be relatively common in a residential area. Occasional exposure to this contaminated soil is expected.

WAC 173-340-200 defines the reasonable maximum exposure (RME) as the highest exposure that can be reasonably expected to occur for a human or other living organism at a site under current and potential future site use. The maximally exposed individual (MEI) is an estimate of the highest exposure concentration that might be found among the broad distribution of possible exposures at Everett. Although not specifically defined under WAC 173-340-200, this concept is included as site-specific evaluation necessary to protect human health. Scenarios 1 and 3 evaluate the RME exposures, while Scenario 2 evaluates MEI exposures resulting in death.

Evaluation of the hazards of arsenic-contaminated soil was based on published scientific information related to soil exposure and arsenic toxicity. For each scenario, DOH used ranges or point values for soil ingestion rate, bioavailability, body weight, and acute arsenic toxicity to calculate a range and a best estimate for soil arsenic concentrations protective of public health. As described in the DOH document, scientific studies related to these topics have limitations, and DOH developed reasonable ranges for toxicity and exposure parameters based on an assessment of the quality and reliability of the information and professional judgement.

DOH results

Scenario 1

Relatively common child exposure to arsenic-contaminated soil located in accessible areas, resulting in adverse health effects that are not permanent.

Scenario 1	Body weight (kg)	Soil ingestion rate (mg soil/ day)	Bioavailability (%)	Toxicity (mg arsenic/ kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**13**	**1751**	**100**	**0.05**	**371**
More Protective	13	2000	100	0.035	228
Less Protective	13	1000	100	0.071	923

Scenario 2

Atypical child exposure to deeply buried or relatively inaccessible arsenic-contaminated soil resulting in death.

Scenario 2	Body weight (kg)	Soil ingestion rate (mg soil/ day)	Bioavailability (%)	Toxicity (mg arsenic/ kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**13**	**20,000**	**40**	**1**	**1625**
More Protective	13	50,000	60	0.32	139
Less Protective	13	20,000	20	2.37	7702

Scenario 3

Relatively common adult resident or worker exposure to arsenic-contaminated soil resulting in nonpermanent adverse health effects.

Scenario 3	Body weight (kg)	Soil ingestion rate (mg soil/ day)	Bioavailability (%)	Toxicity (mg arsenic/ kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**70**	**2000**	**100**	**0.05**	**1750**
More Protective	70	2000	100	0.035	1225
Less Protective	70	100	100	0.071	49700

The values in the far right column of each table represent soil arsenic concentrations potentially causing health effects. Since the goal is to prevent adverse health effects, DOH determined that these concentrations should be divided by a safety factor of 10 to calculate soil arsenic concentrations unlikely to cause health effects. A safety factor of 10 was chosen based on consideration of documented variability in human sensitivity to the toxic effects of arsenic as well as consideration of likelihood of occurrence of the various scenarios. After applying this safety factor, the range of soil arsenic concentrations protective of human health for each scenario is:

- Scenario 1: 23 mg/kg to 92 mg/kg,
- Scenario 2: 14 mg/kg to 770 mg/kg, and
- Scenario 3: 122 mg/kg to 4970 mg/kg.

DOH recognized that the limitations in available information on acute arsenic toxicity and soil exposure rates lead to uncertainties in predicting exposure, as well as the consequences of exposure, for people at arsenic-contaminated sites. For each scenario, the range of soil arsenic concentrations bounded by the low estimate and the high estimate reflects a reasonable expression of uncertainty in applying the information to populations.

DOH selected best estimate parameters based on several factors, including quality of the information, uncertainty associated with the information, and likelihood that the scenario would occur. As stated in the DOH document, "The goal of DOH is to protect public health. Therefore, if the information used to estimate public health hazards is of questionable accuracy and reliability, protective assumptions will be made when interpreting the data in order to prevent illness. If a range of possible interpretations is consistent with data from scientific studies (for example, there was a range of responses or a range of behaviors identified in the studies), protective values in the range will be selected for the purpose of estimating public health hazard."

Ecology Conclusions

An Ecology review committee evaluated the quality and appropriate use of information in the DOH document *"Hazards of Short-Term Exposure To Arsenic-Contaminated Soil."* Participants included Tim Nord, Lynn Coleman, Mike Blum, Craig McCormack, and Dave South (all from Ecology), and Greg Glass (Environmental Consultant). The Department of Ecology's review committee considers *"Hazards of Short-Term Exposure To Arsenic-Contaminated Soil"* a thoughtful review of the acute hazards due to arsenic exposure. In addition to summarizing scientific information on acute arsenic toxicity and human exposure through the soil ingestion pathway, the document recognized the uncertainties in applying the information to estimate safe concentrations of arsenic in soil. The review committee found the choice of scenarios to be representative of current and future conditions at the Everett Smelter site. Parameter values are supported by scientific literature and appropriate for use at the site. For each scenario, the range of soil arsenic concentrations between the more protective and less protective estimates represents a reasonable set of health-protective values.

The DOH document reviewed information on arsenic bioavailability and concluded, "*Without accurate information on bioavailability of arsenic from Washington soils, or even a proven and reliable method to obtain that information, it is appropriate to assume that relative bioavailability of arsenic from soil is 100% when small amounts (<5,000 milligrams) of soil are ingested. This value is supported by studies of the absorption of arsenic in humans, and represents a protective choice that considers the limitations of published studies of arsenic bioavailability from contaminated soils.*" The current soil arsenic bioavailability default assumption used by Ecology is 40%. However, based on the discussion in the DOH document, the review committee believes that, in order to be sufficiently protective of human health, it is reasonable for Ecology to assume that soil arsenic bioavailability at the Everett Smelter site is 100% for ingestion of small amounts of soil.

<u>CONCLUSIONS:</u>

The review committee and I conclude that:

1. "*Hazards of Short-Term Exposure to Arsenic-Contaminated Soil*" is a reasonable scientific review of the human health hazards of short-term exposure to arsenic and recognizes limitations of the scientific information;

2. The exposure scenarios used in the DOH document are consistent with current and future use of the site;

3. For each scenario, the ranges of parameter values for acute toxicity and exposure selected by DOH are reasonable and consistent with the current and anticipated future use of the site;

4. The soil arsenic concentration ranges presented in the DOH document are reasonably protective of human health and are appropriate to use to guide cleanup actions where acute exposure to soil is a health concern; and

5. Based on "*Hazards of Short-Term Exposure to Arsenic-Contaminated Soil,*" and subsequent discussions, the assumed bioavailability of arsenic from soil at the Everett Smelter site should be 100% for ingestion of small amounts of soil.

CRM:df

cc: Mary Sue Wilson, AAG
Jim W. White, DOH
Greg Glass, Environmental Consultant

Everett Smelter Site
Integrated Final Cleanup Action Plan and Final Environment Impact Statement

Appendix B
Responsiveness Summary

Attachment B1
New Science Review

Attachment B1-3

Hazards of Short-Term Exposure to Arsenic-Contaminated Soil
January 1999
Washington State Department of Health

Hazards of Short-Term Exposure To Arsenic-Contaminated Soil

January 1999

Office of Environmental Health Assessment Services

Hazards of Short-Term Exposure To Arsenic Contaminated Soil

January 1999

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EXECUTIVE SUMMARY

Arsenic-contaminated soil is a potential public health problem in many areas of Washington. The Washington State Department of Ecology asked the Washington State Department of Health to assess the potential hazards of acute exposure to arsenic-contaminated soil. Information regarding arsenic toxicity and human soil ingestion was evaluated and used to determine soil arsenic concentrations protective of public health for acute exposures. Best estimated soil concentrations of arsenic to protect the public from adverse health effects due to short-term exposure were developed for three scenarios:

1. Relatively common child exposure to contaminated soil from accessible areas, resulting in transient adverse health effects (37 milligrams of arsenic/kilogram soil),
2. Infrequent child exposure to deeply buried or relatively inaccessible, contaminated soil resulting in death (162 milligrams of arsenic/kilogram soil), and
3. Relatively common adult resident or worker exposure to subsurface or relatively inaccessible soil resulting in transient adverse health effects (175 milligrams of arsenic/kilogram soil).

Further work is necessary to determine where in Washington arsenic-contaminated soil may be a hazard and what actions would be appropriate to ensure protection of public health. It will be important to involve a wide range of stakeholders to develop approaches to these problems.

PURPOSE

Soil in many areas of Washington State is contaminated with arsenic from smelter operations or from arsenical pesticides and herbicides. Residential communities are located in some of these contaminated areas, and people are likely to be exposed to arsenic in the soil. This exposure could result in illness.

The Washington State Department of Ecology (Ecology) is responsible for determining whether, and how, to manage arsenic-contaminated soil in many areas of the state. A major consideration in this determination is the potential human health hazard of the soil. Ecology has asked the Washington State Department of Health (DOH) to assess the potential hazards of exposure to arsenic-contaminated soil. Specifically, what concentrations of arsenic in soil could cause adverse health effects in people and what concentrations are unlikely to be harmful. Both short-term (acute) exposure and long-term (chronic) exposure to contaminated soil could result in adverse health effects in people. The purpose of this document is to evaluate information on hazards of short-term exposure to arsenic-contaminated soil and to use the information to calculate soil arsenic concentrations protective of public health. Hazards of chronic exposure to arsenic-contaminated soil will be evaluated in another document.

PUBLIC HEALTH CONCERNS FROM ARSENIC-CONTAMINATED SOIL

The health hazard of arsenic-contaminated soil depends on both the toxicity of arsenic and the amount of arsenic to which people are exposed through contact with the soil. Studies of the toxicity of arsenic and of the potential for people to be exposed to arsenic in soil suggest that arsenic-contaminated soil could be a public health hazard in some contaminated areas. Exposure to arsenic can cause a wide spectrum of adverse health effects.(1) The primary route of exposure is expected to be ingestion of contaminated soil, by direct hand to mouth activity or by swallowing airborne soil and dust particles that enter the mouth and nose.

The potential health hazard of arsenic-contaminated soil is not limited to current populations. Future generations of residents may also be at risk since arsenic remains in soil for hundreds to thousands of years.(2) For example, at the Everett Smelter hazardous waste site in Everett, Washington, an area of contamination that appears to be composed of pure arsenic trioxide is still present 85 years after production was discontinued.(3) One estimate of the residence time for arsenic in soil is 9000 years.(2) Since arsenic is expected to remain in soil for centuries or longer, contaminated soil left at the site must be considered a potential source of exposure throughout this time frame.

APPROACH TO EVALUATING HAZARDS OF ARSENIC-CONTAMINATED SOIL FROM ACUTE EXPOSURE

Use of Scientific Information

Adequate scientific studies that directly assess the hazard of arsenic-contaminated soil to exposed populations have not been conducted. At this time, the hazard can be better evaluated indirectly through a synthesis of information from toxicity and exposure studies that, individually, address pieces of the overall question. To estimate what concentrations of arsenic may be left in soil and be protective of the health of current and future residents and workers, the following types of information are needed:

- How exposure could occur, and to whom,
- How much exposure might occur, and
- The potential consequences of exposure (as reflected by the toxicity of arsenic).

This information can be used in the following equation to calculate the amount of arsenic in soil that is potentially harmful following short-term ingestion:

$$\textit{harmful soil arsenic concentration} = \frac{\textit{acutely toxic dose x body weight}}{\textit{acute soil ingestion rate x bioavailability}}$$

This was adapted from an equation used by Ecology to calculate soil cleanup levels.[(4)]

Exposure Scenarios

Another consideration when evaluating the hazard is the likelihood of exposure, which may depend on the location of the contaminated soil and the types of activities that occur on the contaminated property. Locational factors that could influence the potential for exposure include depth of the contaminated soil, the presence of an overlying structure such as a road or building, and the accessibility of the contaminated property to potentially exposed individuals.

Three scenarios, representing realistic sets of conditions whereby people could be exposed to arsenic-contaminated soil, were developed based on who would be exposed (adults versus children), the likelihood of exposure, and the potential consequences of exposure. The conditions of each scenario guide the choice of appropriate values for parameters in the above equation to calculate potentially harmful soil arsenic concentrations.

The three short-term exposure scenarios that will be considered in this document are:

1. Relatively common child exposure to arsenic-contaminated soil located in accessible areas, resulting in adverse health effects that are not permanent. For example, a child is exposed in a residential yard while playing in a pile of contaminated dirt excavated for a garden or to install a fence post.
2. Atypical child exposure to deeply buried or relatively inaccessible arsenic-contaminated soil resulting in death. For example, a child is exposed while playing in a pile of contaminated dirt excavated to repair a utility pole or install a foundation for a home addition.
3. Relatively common adult resident or worker exposure to arsenic-contaminated soil resulting in nonpermanent adverse health effects. For example, a homeowner or worker is exposed while landscaping or performing plumbing repairs in the crawl space under a home.

In consultation with Ecology, DOH determined that these scenarios could be used to determine appropriate cleanup activities for most currently foreseeable exposure situations where protection of public health from arsenic-contaminated soil is the primary concern.

Addressing Uncertainties and Limitations of Available Scientific Data

For this document, the evaluation of the hazards of arsenic-contaminated soil was based on published scientific information related to soil exposure and arsenic toxicity. However, information on these topics is incomplete, resulting in uncertainties in predicting exposure, as well as the consequences of exposure, for potentially affected populations. Scientific studies have limitations that must be recognized and evaluated before relying on them to protect public health in real-world situations. Limitations of the studies raise concerns such as the following:

- Are study results sufficiently reliable and reproducible to assume that they accurately reflect the real world?
- Can results of toxicity and exposure studies in other groups of people or animals be assumed to accurately reflect results that would be expected in people at the site in question (due, for example, to differences in populations or study conditions)?
- People vary in sensitivity to the toxic effects of arsenic. Do study results adequately reflect the variability in sensitivity that may be present in people at the site in question, now and in the future?
- Individuals have a wide variety of behaviors, habits, and activities that can affect their amount of exposure to contaminated soil. Do study results adequately reflect the variability in exposure that may occur in people at the site in question, now and in the future?
- Do studies evaluate hazards based on the most sensitive indicator of toxicity, or are less sensitive indicators used? Has the most sensitive indicator of toxicity been identified?

Important information deficiencies and uncertainties must be identified and addressed to evaluate the hazards of arsenic-contaminated soil. The goal of DOH is to protect public health. Therefore, if the information used to estimate public health hazards is of questionable accuracy and reliability, protective assumptions will be made when interpreting the data in order to prevent illness. If a range of possible interpretations is consistent with data from scientific studies (for example, there was a range of responses or a range of behaviors identified in the studies), protective values in the range will be selected for the purpose of estimating public health hazard.

Information on toxicity and exposure can be used to estimate harmful concentrations of arsenic in soil. To determine a soil arsenic concentration that is not expected to cause illness, the potentially harmful level will be adjusted with a safety factor.

How Exposure Could Occur

Numerous studies suggest that people ingest soil from their environment [5-17] during daily activities, including soil that forms the surface of their yard. Concern for acute toxicity of arsenic-contaminated soil is related to the occasional ingestion of large amounts of soil.[18-23] When surface soil in a residential area is contaminated, it is expected that chronic exposures to the contaminants will occur and that cleanup of this soil will be based on an evaluation of long-term exposure. However, contaminants are rarely confined to just the surface layer of soil, but may be present beneath the surface as well as in relatively inaccessible areas such as in crawl spaces of buildings and under structures such as roads, driveways, barns, and sheds. While it is not expected that people will have regular contact with this material, it is occasionally brought to the surface where exposure can occur. For example, gardening, digging by children and pets, and other common activities and projects involving an excavation could result in contact with contaminated soil that was previously not available for human exposure. Piles of soil excavated during single or multi-day projects and left at the surface may attract children and could become sources of exposure. Residents and workers who go into crawl spaces and under decks for inspection or repair work could also be exposed to contaminants. Short-term contact with this soil could be hazardous unless contact with the soil is controlled and the soil is handled and disposed of properly.

The following list of activities that could result in exposure to subsurface contaminants is based on consultation with people who live and work in the Everett, Washington area:

- gardening,
- digging by children and pets,
- planting trees and shrubs,
- resodding,
- installing or repairing utility lines and utility poles,
- digging holes for fence posts,
- installing and repairing a sprinkler system,

- removing and installing heating oil tanks,
- bioturbation (disturbance of soil by worms, ants, moles, etc.),
- repairing roads and driveways,
- construction of structures such as decks, sheds, barns, home additions, and
- new home construction.

Many of these activities commonly occur on residential properties and would likely result in disturbance of soil to a depth of 12 to 24 inches. Construction activities and work on utility lines and oil tanks may involve deeper excavations.

SHORT-TERM EXPOSURE RATE

Soil Ingestion Rate

Children 18-24 months of age are generally believed to ingest the most soil per kilogram of body weight.[20] Studies suggest that, over time, the upper 95th percentile for soil ingestion in children 1 to 6 years of age is approximately 200 - 250 milligrams per day.[7] However, these studies found that the amount of soil ingested varied greatly from child to child and also from day to day for each child. On a particular day, a child may ingest significantly more soil than his or her average. An analysis of soil ingestion studies [13] suggests that, over the course of a year, most children will occasionally ingest 1,000 to 2,000 milligrams in a day, and that the upper 95th percentile of the average daily soil ingestion is 1751 milligrams. In a study of 64 children, one child ingested approximately 20,000 milligrams of soil on each of two separate days.[20] Psychological problems and mental retardation may lead to behaviors that include ingestion of large amounts of soil. In one study, a retarded child was estimated to ingest greater than 48,000 milligrams of soil on three out of four days.[20]

Soil ingestion rates in adults have not been well documented. One small study estimated that the upper 95th percentile for adult soil ingestion was 330 milligrams per day, and the maximum one-day ingestion was approximately 2,000 milligrams.[16] Information was not found regarding short-term soil ingestion rates for adults whose work involves significant contact with soil or generation of dust.

For the purposes of this document, the following will be assumed:

- For scenario 1, the range of commonly occurring short-term soil ingestion rates for children is 1000 to 2000 milligrams per day. The upper 95th percentile of 1751 milligrams per day is the best estimate.

- For scenario 2, where atypical children occasionally ingest very large amounts of soil, the range of soil ingestion rates is 20,000 to 50,000 milligrams per day. Because of the expected low probability of occurrence of this scenario, a best estimate of 20,000 milligrams per day was chosen.
- For scenario 3, the range of commonly occurring short-term soil ingestion rates for adults working in the soil is 100 to 2,000 milligrams per day. A best estimate of 2,000 milligrams per day was chosen based on the assumption that this would best reflect exposures in adult workers with significant soil contact, a population of concern that was not specifically targeted in the adult soil ingestion study.[16]

Bioavailability

When a chemical is ingested, some may be absorbed into the body by the gut and enter the blood stream to be distributed throughout the body. The remainder is not absorbed and is excreted in the feces without having a chance to damage the body, except by directly affecting the lining of the gut. The bioavailability of a chemical is the percentage of the ingested amount that is absorbed by the gut.

Many effects of ingested arsenic are due only to the arsenic that is absorbed and not the arsenic that passes through the gut without being absorbed.[1] However, some effects can be caused by direct contact of arsenic with tissues, and absorption is not necessary.[1,24] For example, ingestion of arsenic can lead to irritation of mucous membranes and damage to the gastrointestinal tract leading to diarrhea, vomiting, and abdominal pain.[1,24,25]

Intestinal absorption of purified compounds of arsenic and of arsenic from contaminated soil has been studied. Bioavailability studies in humans show that purified arsenic compounds are absorbed almost completely (90-100%) when ingested.[26-28] Tests of the bioavailability of purified arsenic compounds in animals [29-31] have found that absorption is frequently significantly less than in humans, suggesting that these animals may not be accurate models for arsenic bioavailability in humans.

No human studies of the bioavailability of arsenic from contaminated soil have been published. Studies in animals suggest that bioavailability of arsenic from contaminated soil is less than bioavailability of purified compounds.[28-32] However, as described in Appendix A (Evaluation of Bioavailability Studies) of this report, results of arsenic bioavailability studies in animals appear to be greatly influenced by the choice of animal model and test conditions. It remains to be demonstrated whether differences in bioavailability reported in these studies reflect actual soil-specific differences in bioavailability or were due to differences related to animal models, study conditions and protocols. For example, one possible explanation for the results is that bioavailability may decrease as larger amounts of soil are ingested. These studies represent interesting first steps toward understanding the bioavailability of arsenic from soil. However, limitations of these studies, as well as findings in animals that differ from humans, suggest that the animals and experimental protocols used may not be appropriate models of human response. It remains to be demonstrated that these studies accurately and reliably reflect bioavailability in humans. Furthermore, the soils tested came from small areas of specific contaminated sites, and it has not been shown that it is appropriate to generalize the results to soil from other sites.

Without accurate information on bioavailability of arsenic from Washington soils, or even a proven and reliable method to obtain that information, it is appropriate to assume that relative bioavailability of arsenic from soil is 100% when small amounts (<5,000 milligrams) of soil are ingested. This value is supported by studies of the absorption of arsenic in humans and represents a protective choice that considers the limitations of published studies of arsenic bioavailability from contaminated soils. Lacking adequate data, an assumption of 100% bioavailability for larger amounts of ingested soil (5,000 to 50,000 milligrams) is defensible. Alternatively, based on Figure 1 and the discussion in Appendix A (Evaluation of Bioavailability Studies), it may be reasonable to assume that relative bioavailability is lower, perhaps 20-60%, when larger amounts of soil are ingested. See Appendix A for a more complete discussion of studies of arsenic bioavailability.

For the purposes of this document, the following will be assumed:

- For scenarios 1 and 3, bioavailability is 100%.
- For scenario 2, bioavailability is between 20 and 60%, with a best estimate of 40%. These values were chosen based on the discussion in Appendix A (Evaluation of Bioavailability Studies) and the expected low probability of occurrence of this scenario.

Body Weight

Due to the frequency of mouthing activity, young children are believed to be the population most likely to ingest large amounts of soil. Mouthing activity is reported to be greatest in children 18 to 24 months of age. For calculations in this document the body weight of an 18 to 24 month old child is assumed to be 13 kilograms.[34]

Assumed adult body weight is 70 kilograms.[34]

POTENTIAL CONSEQUENCES OF EXPOSURE (TOXICITY)

Numerous health effects in humans have been documented after short-term exposure to arsenic. The most sensitive reported indicators of toxicity appear to be transient (edema, conjunctivitis, liver enlargement, irritation of the mucous membranes, and gastrointestinal problems such as vomiting, diarrhea, cramps, and pain).[1,25,35,36] Permanent effects such as nervous system damage and death [1,25,35,37] have been documented after several such doses or single higher doses. Information from studies documenting doses of arsenic that caused health effects on short-term exposure is presented in Appendix B (Analysis of Acute

Arsenic Toxicity) of this report.

Transient adverse health effects have been reported in people who ingested 0.035 to 0.071 milligrams of arsenic per kilogram of body weight as a single dose, or over the course of one day.[25,35,36] One reference states that health effects commonly occur when such a dose is ingested.[25] Effects appear to be transient, but this cannot be confirmed from information provided in the publications.

Lethal doses of arsenic have been reported as 0.32 milligrams of arsenic per kilogram of body weight (a single dose in one individual) [25] and approximately 0.37 to 2.37 milligrams of arsenic per kilogram of body weight per day (about one week exposure for two individuals).[37]

For the purposes of this document, the following will be assumed:

- For scenarios 1 and 3, transient adverse health effects commonly occur when doses between 0.035 and 0.071 milligrams of arsenic per kilogram of body weight are ingested. The best estimate is 0.05 milligrams of arsenic per kilogram of body weight.
- For scenario 2, lethality can occur from doses between 0.32 and 2.37 milligrams of arsenic per kilogram of body weight, with a best estimate of 1 milligram of arsenic per kilogram of body weight.

CALCULATING HARMFUL SOIL ARSENIC CONCENTRATIONS FOR SHORT-TERM EXPOSURE

With the information presented in previous sections, it is possible to calculate concentrations of arsenic in soil that could cause adverse health effects in exposed populations under various short-term exposure conditions, or scenarios. Three different exposure scenarios, presented below, represent the exposure conditions of greatest public health concern. The evaluations of soil exposure and arsenic toxicity presented provide ranges of possible values for exposure and toxicity. These ranges reflect documented variability in humans with respect to sensitivity to the toxic effects of arsenic as well as documented variability in behaviors that lead to different amounts of exposure to soil.

For each scenario, ranges and best estimates of arsenic concentrations in soil potentially causing health effects are shown in the associated tables below. For the rows labeled “Best Estimate,” potentially harmful soil arsenic concentrations were calculated using protective values for toxicity and exposure parameters that were chosen based on degree of support in the scientific literature and consideration of likelihood of occurrence of the scenario. In the rows labeled “More Protective,” values from the more protective parts of the published ranges for toxicity and exposure were used. In the rows labeled “Less Protective,” values from the less protective parts of the published ranges for toxicity and exposure were used. For each scenario, the range of soil arsenic concentrations bounded by the more protective and less protective estimates reflects a reasonable expression of uncertainty in applying the information to populations.

Scenario 1

Children are exposed to arsenic-contaminated soil by playing in piles of dirt excavated in residential yards as a consequence of typical homeowner activities such as gardening, planting trees and shrubs, digging fence posts, and installation and maintenance of a sprinkler system. Digging activity by children, pets, and other animals (moles, gophers, ants, earthworms) could also bring contaminated soil to the surface where exposure could occur. These activities are expected to occur commonly in a residential area. Occasional ingestion by children of 1,000 to 2,000 milligrams of this excavated contaminated soil is expected.

Scenario 1	Body weight (kg)	Soil ingestion rate (mg soil/day)	Bioavailability (%)	Toxicity (mg arsenic/kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**13**	**1751**	**100**	**0.05**	**371**
More Protective	13	2000	100	0.035	228
Less Protective	13	1000	100	0.071	923

Scenario 2

Children are exposed to arsenic-contaminated soil in relatively inaccessible areas or deep beneath accessible areas. Contact with these soils would be expected as a result of activities such as construction of additions for existing homes, new home construction, road repair, and utility repair). These activities are expected to be relatively common in a residential area. Compared to Scenario 1, children are less likely to be exposed since people performing the excavations are expected to follow instructions in proper handling and disposal of these soils. However, this scenario evaluates unlikely conditions under which failure to properly handle highly contaminated soil could result in an exposure leading to death of a child.

Scenario 2	Body weight (kg)	Soil ingestion rate (mg soil/day)	Bioavailability (%)	Toxicity (mg arsenic/kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**13**	**20,000**	**40**	**1**	**1625**
More Protective	13	50,000	60	0.32	139
Less Protective	13	20,000	20	2.37	7702

Scenario 3

Adult workers and residents are exposed to arsenic-contaminated soil in relatively inaccessible areas (under roads and buildings) or beneath accessible areas such as residential yards. Activities such as gardening, repair work in a crawl space, fence installation, road repair, utility repair, and home construction could result in exposure. These activities are expected to be relatively common in a residential area. Occasional exposure to this contaminated soil is expected.

Scenario 3	Body weight (kg)	Soil ingestion rate (mg soil/day)	Bioavailability (%)	Toxicity (mg arsenic/kg body weight)	Arsenic concentration in soil causing health effects (mg/kg)
Best Estimate	**70**	**2000**	**100**	**0.05**	**1750**
More Protective	70	2000	100	0.035	1225
Less Protective	70	100	100	0.071	49700

CALCULATION OF SOIL ARSENIC CONCENTRATIONS TO PROTECT PUBLIC HEALTH FOR SHORT-TERM EXPOSURE

The calculated soil arsenic concentrations in the above tables reflect the amount of arsenic that may cause health effects after a single day exposure. Since the goal of DOH is to ensure that health effects are prevented, a no-effect level will be determined to protect public health. A no-effect level is typically estimated by dividing the dose observed to cause health effects by a safety factor. There is little scientific information available to guide the selection of a safety factor for short-term exposure to arsenic in soil. The selection must be based on judgement of the margin of safety desired for protection from the potential adverse consequences of this type of event.

For the three scenarios a safety factor of 10, to derive a no-effect level from an effect level, was considered adequate to calculate soil arsenic concentrations protective of public health. This choice was based on consideration of documented variability in human sensitivity to the toxic effects of arsenic (Appendix B, Analysis of Acute Arsenic Toxicity) as well as consideration of likelihood of occurrence of the various scenarios. Therefore, using the best estimates from the preceding tables, protective concentrations for the three scenarios can be calculated as follows:

Scenario 1 (common child exposure, transient effect)

$$\frac{371\, mg\ arsenic\ per\ kg\ soil}{10} = 37\ mg\ arsenic\ per\ kg\ soil$$

Scenario 2 (atypical child exposure, fatality)

$$\frac{1625\ mg\ arsenic\ per\ kg\ soil}{10} = 162\ mg\ arsenic\ per\ kg\ soil$$

Scenario 3 (common adult exposure, transient effect)

$$\frac{1750\ mg\ arsenic\ per\ kg\ soil}{10} = 175\ mg\ arsenic\ per\ kg\ soil$$

OTHER FACTORS NOT CONSIDERED IN THIS EVALUATION

Other factors that could influence this evaluation were not incorporated into this evaluation. While the qualitative effects these factors would have on the analysis can be assessed, quantification of the effects is problematic.

- Toxicity factors were mostly derived from cases where people were exposed to arsenic for one day or less. However, it is possible that people could have multiple exposures to contaminated soil for several days during some projects. Multiple exposures to a specific concentration of arsenic in soil could result in health effects where a single exposure might not.
- Community protection measures, such as educational efforts and programs that encourage proper handling and disposal of contaminated soil, could help reduce exposure to a portion of the potentially exposed population.

CONCLUSIONS

The hazards of short-term ingestion of large amounts of arsenic-contaminated soil were evaluated. Such exposures may occur to contaminated soil that is located at the ground surface, as well as to soil located in relatively inaccessible areas (such as in crawl spaces under homes) or that has been excavated from beneath the ground surface or from under structures.

Best estimates of concentrations of arsenic in soil to protect the public from adverse health effects due to short-term exposure were estimated for three scenarios:

1. Relatively common child exposure to contaminated soil from accessible areas, resulting in transient adverse health effects (37 mg arsenic/kilogram soil),
2. Infrequent child exposure to deeply buried or relatively inaccessible, contaminated soil resulting in death (162 mg arsenic/kilogram soil), and
3. Relatively common adult resident or worker exposure to subsurface or relatively inaccessible soil resulting in transient adverse health effects (175 mg arsenic/kilogram soil).

To derive these best estimates, parameters were selected from ranges that reflect documented variability in humans with respect to sensitivity to the toxic effects of arsenic and documented variability in behaviors that lead to different amounts of exposure. Another agency, such as Ecology, may choose different values within the ranges depending on what combinations of sensitivities and behaviors are expected in a potentially exposed population, as well as other factors the agency deems appropriate to consider.

Further work is necessary to determine where in Washington arsenic-contaminated soil may be a hazard and what actions would be appropriate to ensure protection of public health. It will be important to involve a wide range of stakeholders to develop approaches to these problems.

APPENDIX A

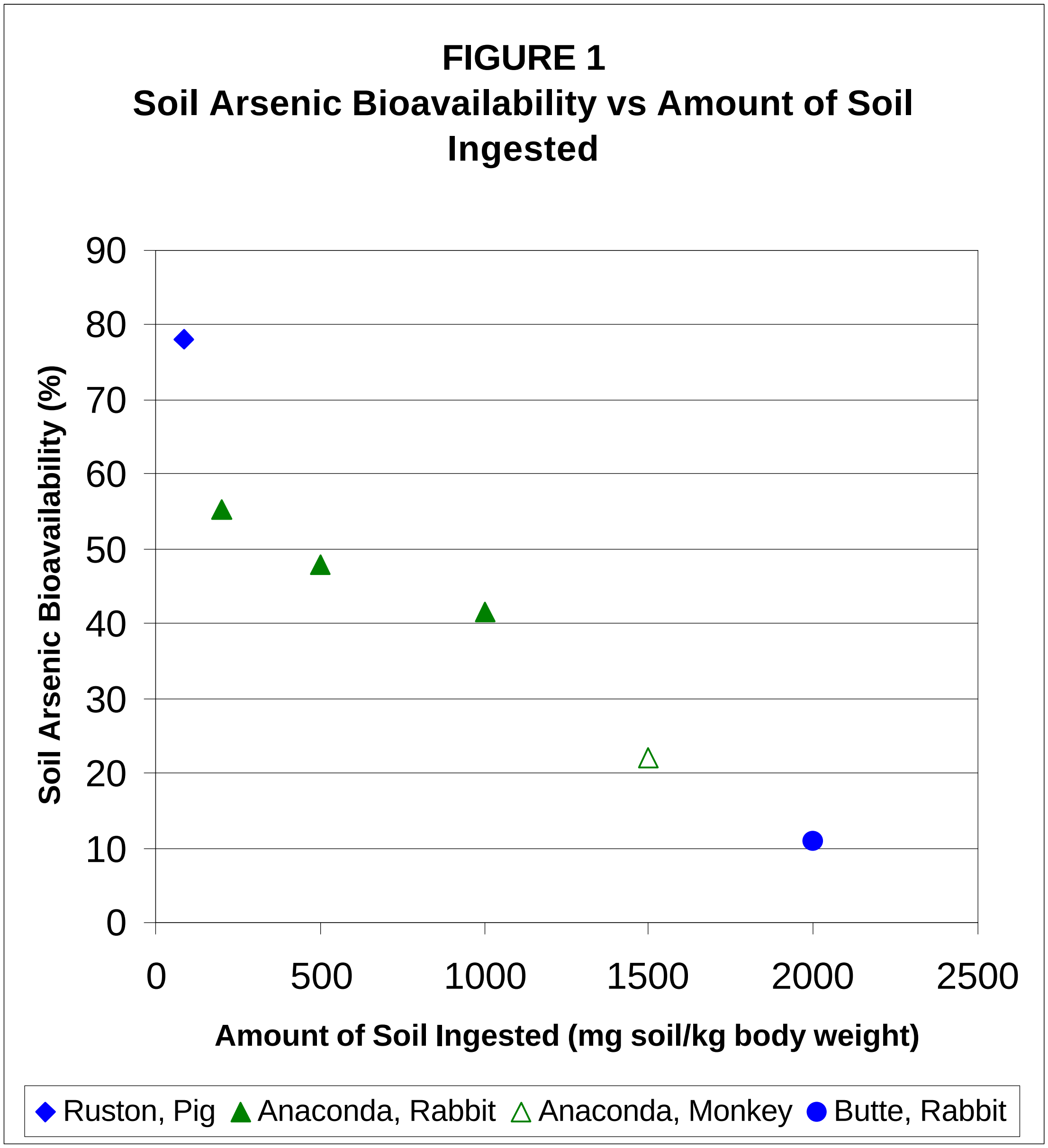
EVALUATION OF BIOAVAILABILITY STUDIES

Human and Animal Studies

In most studies of the absorption of ingested arsenic, humans or animals ingest arsenic and the amount of arsenic excreted in urine and feces is measured for five to ten days (26-31,33). Frequently, a significant percentage of the original dose of arsenic is not recovered in either the urine or feces and appears to be retained in the body. A study in humans using radioactive arsenic supports this conceptual model.(27) The sum of the arsenic excreted in urine and retained by the body reflects the arsenic that was absorbed, while the arsenic in feces represents the unabsorbed fraction. An analysis of this type may slightly underestimate the absorbed fraction, since some absorbed arsenic may be excreted in the bile and appear in the feces.(39)

Studies in humans have found that arsenic, in the form of purified compounds such as arsenic trioxide, arsenic acid, and lead arsenate, is almost completely absorbed (94-99%) when ingested.(26-28) Essentially complete absorption was also observed in one study in monkeys (98%).(40) However, based on fecal excretion, significantly less absorption of purified arsenic compounds was observed in a different study in monkeys (75%) (30), as well as studies in swine (variable, but roughly estimated as 25-30%) (31) and rabbits (48-55%).(29) In the swine study, a large portion of the administered arsenic “disappeared,” and could not be found in the urine, feces, or tissues of the animals. Based on this finding, it is difficult to support the use of this study in evaluating bioavailability. In another swine study (32), estimated absorption was variable from animal to animal (49 to greater than 100%). Since absorption of arsenic in most of the animal studies was significantly less than absorption in humans, it is questionable whether any of the animal studies are appropriate for use in estimating bioavailability in humans.

Arsenic in soil may be in the form of mixtures of a number of arsenical compounds bound to soil particles and it has been suggested that arsenic in contaminated soil may not be as bioavailable as the purified compounds used in the human studies. Studies have been conducted to measure the bioavailability of arsenic from soil, based on the hypothesis that bioavailability may vary depending on the specific contaminated soil sample. Mean bioavailability of arsenic from soil, relative to the bioavailability of purified compounds, has been reported as 20% in monkeys (30), 48% in rabbits (29), 78% in immature swine (32), and 8.3% in dogs.(41) While these results could be interpreted as supporting the hypothesis, the differences in bioavailability reported in the studies may instead reflect differences in animal models and study conditions and not actual differences among soils. For example, different amounts of contaminated soil were fed to the animals in four different studies. A trend is observed when bioavailability is compared to the amount of soil ingested. See Figure 1.



The trend demonstrated in Figure 1 is consistent for soil at a single hazardous waste site, since the four data points in the middle of the curve all represent bioavailability results from the Anaconda, Montana site (three points from a study in rabbits, one from a study in monkeys).[29,30] The data point at the far left of the curve is from a study on soil at the Ruston, Washington smelter site,[32] and the data point at the far right is from a study on soil at a site in Butte, Montana.[33]

For reference, a 13 kilogram child who ingested 1 gram of soil would receive a soil dose of 77 milligrams of soil per kilogram of body weight, or less than the left-most point on the above graph. A 13 kilogram child who ingested 20 grams of soil would receive a soil dose of 1538 milligrams of soil per kilogram of body weight.

Studies in animals suggest that arsenic in soil is less bioavailable than purified arsenic compounds. However, due to uncertainties and limitations of the studies, these findings could be due to the animal model, experimental conditions, and protocols, and not actual decreases in bioavailability. The data appear to be highly uncertain and can be explained by other hypotheses. It remains to be demonstrated that the results of these animal studies accurately and reliably reflect bioavailability in humans.

In Vitro Leaching/Solubility Tests

A study to investigate leaching of lead and arsenic from contaminated soil, as a surrogate measure of bioavailability, was published in 1996.[(42)] An *in vitro* system designed to mimic the actions of the human stomach and intestines on solubilizing arsenic from contaminated soil was constructed. Soil samples weighing 0.4 g were placed in 40 milliliters (ml) of solution similar to gastric juice (at either pH 1.3 or pH 2.5) and incubated for 1 hour. The solution was then neutralized to pH 7 and the samples allowed to incubate for 3 more hours to simulate passage through the small intestine. Arsenic concentrations were measured in samples withdrawn at specific time points. Bioavailability was estimated by comparing the amount of arsenic in solution in the final aliquot with the total amount added to the reaction vessel. At the end of the experiment, approximately 44 - 50% of the soil-bound arsenic was in solution when the simulated gastric juice was pH 1.3, and approximately 30 - 32% solubilized when the gastric juice was pH 2.5.

There are four potential problems with using this system as a model for human bioavailability. First, the volume of artificial gastrointestinal solutions used versus the amount of soil added was significantly less than would be expected in a human who swallowed soil. The total daily volume of liquid that is excreted and resorbed by the adult human gastrointestinal tract is typically 8.5 liters [(43)], or 212 times the volume used in this extraction procedure. The authors provided no evidence to clarify whether the arsenic that remained bound to the soil was simply not extractable or whether it had reached an equilibrium between the soil and liquid phases. Increasing the volume of extraction solution might result in greater release of arsenic from the soil.

Second, the concentration of sodium chloride in the test system was significantly below physiological concentrations. In a study published in 1939,[(44)] the solubility of lead arsenate in different fluids was measured. Although lead arsenate was poorly soluble in water, solubility was significantly greater when placed in saliva, gastric juice, serum, or isotonic sodium chloride. The *in vitro* system could underpredict solubility of soil-bound arsenical compounds due to the low ionic strength of the solutions.

Third, during the course of the test, 2 ml aliquots were removed for analysis at 5 time points and replaced with 2 ml of fresh solution. When the final aliquot was removed and analyzed to estimate bioavailability, the reaction vessel would still contain 40 ml of solution, but only 81.35% of the original material. Thus, bioavailability would be underestimated when the authors compared the arsenic concentration in this aliquot to the original amount added. There is no indication that the authors corrected for this reduction in material.

Fourth, it is believed that many factors not modeled by the *in vitro* system could play a role in the solubility of substances in the gastrointestinal tract.[(45)] For example, when the pH of the artificial gastric fluid was raised from 2.5 to 7, it was observed that arsenic solubility decreased by 25-29%, possibly due to precipitation reactions. The formation of precipitates may be less likely *in vivo* due to the presence of small organic molecules that would tend to keep the arsenic in solution.

In conclusion, since the extraction test appears to ignore a number of potentially significant features of human digestive system physiology, the results of the test may not accurately model bioavailability in humans.

APPENDIX B

ANALYSIS OF ACUTE ARSENIC TOXICITY

Several authors have published estimates of the amount of arsenic that has been observed to cause illness after short-term ingestion (from one dose to week-long exposures).[25,35-37] Information in four reports will be summarized and discussed below.

1. Mizuta et al.[36]

In 1956, more than 400 people in Japan developed health effects from the ingestion of soy sauce contaminated with arsenic. Arsenic concentration in the soy sauce was stated to be 0.1 milligrams per milliliter, and people were thought to ingest approximately 30 ml of soy sauce per day. Affected individuals reported health effects beginning the day after exposure. Observable health effects included edema of the face, enlarged liver, conjunctivitis, anemia, gastrointestinal illness, and abnormal electrocardiograms. The dose was estimated to be approximately 0.05 mg/kg/day of arsenic, assuming a typical Japanese body weight of 60 kilograms.

Urinary arsenic was reported for 5 patients. An inconsistency in this study was the finding that urinary arsenic output appeared too high for the estimated intake 5 to 10 days after exposure ceased. This could be due to an underestimate of the intake for these 5 patients, or for the entire population. Alternatively, these patients could have consumed seafood with significant levels of arsenic prior to the test.

2. Franzblau and Lilis[35]

In September 1987, a couple began to visit a vacant house once or twice a week prior to its purchase. During these visits the wife would drink one or two glasses of water. "Immediately after consumption of well water at the house began, she noted the onset of occasional nausea, diarrhea, and abdominal cramps. These symptoms worsened, and, in addition, she started experiencing occasional vomiting, paresthesias in the lower extremities and right hand (burning and tingling), and a sensation of swelling and irritation of the eyes and sinuses." (page 386)

The husband also consumed water during visits to the house and reported symptoms including abdominal cramps, nausea, headache, nasal congestion, and diarrhea.

The concentration of inorganic arsenic in the water supply was measured on eight occasions and ranged from 9,000 to 10,900 μg/liter. Assuming the wife weighed 70 kilograms and drank 1 to 2 glasses (0.25 to 0.5 liters) containing 10,000 μg/liter, her dose was approximately 0.036 to 0.071 mg arsenic/kilogram body weight.

3. Armstrong et al.[37]

Eight members of a family of nine became ill over the course of approximately one week while drinking arsenic-contaminated well water. Two individuals died and the remaining six affected people had numerous signs consistent with arsenic toxicity.

Arsenic concentration in the well water was 108 mg/liter. Information was gathered on approximate daily consumption of water. Estimated arsenic doses calculated by the authors ranged from 26 to 166 mg/day. Assuming a body weight of 70 kilograms (likely an overestimate, most family members were less than 18 years of age), these doses, adjusted for body weight, become 0.37 to 2.37 mg/kg/day.

Of interest is the finding that output of arsenic in the urine was significantly less than the estimated intake.

4. Pharmacotherapeutics[25]

Arsenical compounds were once used as medicines to treat a variety of conditions. The doses of arsenic causing toxic effects are discussed in this reference book, primarily as they relate to medicinal use.

The following information was used to calculate arsenic doses based on statements in the book:

Compound	Formula	Molecular Weight	Percent Arsenic (by weight)
Potassium metaarsenite	$KAsO_2$	146.02	(51.3% arsenic)
Arsenic trioxide	As_2O_3	197.84	(75.7% arsenic)
Sodium orthoarsenate (mono-H)	$Na_2HAsO_4 \bullet 7H_2O$	312.01	(24.0% arsenic)
“Exsiccated” sodium arsenate	Na_2HAsO_4	185.94	(40.3% arsenic)

1 milligram = 1/60 grain

1 minim = 0.06 milliliter

In addition, the following assumptions were used to calculate arsenic doses from statements in the book:

For the calculations below, it was assumed that "sodium arsenate" refers to the "exsiccated" form (40.3% arsenic) and **not** the hydrated form (24.0% arsenic). If it was assumed that the hydrated form were used, the resulting calculations would suggest that arsenic had greater toxicity.

Fowler's solution is typically referred to as a solution containing 1% potassium arsenite, thus containing 0.513% arsenic. However, the book, "Pharmacotherapeutics" suggests that it is a 1% solution of arsenic trioxide with potassium bicarbonate added, resulting in a solution that contains 0.757% arsenic. In the calculations below, it will be assumed that Fowler's solution contained 0.757% arsenic, and **not** 0.513%. If it were assumed that Fowler's solution contained 0.513% arsenic, the resulting calculations would suggest that arsenic had greater toxicity.

The following excerpts were taken from the specified pages of "Pharmacotherapeutics."[(25)]

page 601:

"From 1/24 to 1/20 grain (2.5 to 3 mgm) of arsenic trioxide or sodium arsenate, or 5 to 6 minims (0.3 to 0.4 cc.) of the official 1 percent (Fowler) solution of potassium arsenite will ordinarily be well borne by an adult not previously habituated of the drug; but symptoms of *intolerance* - irritation of all the mucous membranes - have been induced by a much smaller quantity; as 3 minims of Fowler's solution in one of our cases."

This suggests that 3 minims of Fowler's solution, or 1.36 mg of arsenic (0.18 ml x 10 mg/ml x 0.757), can cause health effects. Assuming body weight was 70 kg, the dose was 0.02 mg/kg.

page 601:

"An initial dose of 1/10 grain (6 mgm) of sodium arsenate or 10 minims of Fowler solution will commonly excite distress; indeed some persons cannot readily acquire tolerance to this quantity, even by gradual approach."

This suggests that 6 milligrams of sodium arsenate, or 2.42 mg of arsenic (6 mg x .403) commonly caused health effects. Further, 10 minims of Fowler's, or 4.54 mg of arsenic (0.6 ml x 10 mg/ml x 0.757) commonly caused health effects and could not be tolerated with a gradual buildup in dose. Assuming body weight was 70 kg, the respective doses were 0.035 mg/kg and 0.065 mg/kg.

page 601:

"In an instance related to us, 3 cc. (45 minims) of Fowler solution, equivalent at most to 30 mgm. (gr. 1/2) of potassium arsenite, proved fatal to an adult."

This suggests that 45 minims of Fowler's, or 22.71 mg of arsenic (3 ml x 10 mg/ml x 0.757) was fatal to an adult. Assuming body weight was 70 kg, the fatal dose was 0.32 mg/kg.

page 606:

"In the absence of habituation, full doses (1/60 to 1/12 grain; 1 to 5 mgm.) excite salivation, nausea, vomiting, epigastric pain, diarrhea, or constipation and, if continued, chronic intoxication. Larger doses (1/6 to 1/3 grain; 0.01 to 0.02 Gm) produce dryness and burning of the tongue, mouth and throat and perhaps epigastric cramp."

Assume this refers to arsenic trioxide. This suggests that the first set of health effects occurs at doses of 0.757 to 3.78 mg of arsenic (1 mg or 5 mg x 0.757), and the second set at doses of 7.57 to 15.14 mg of arsenic (10 mg or 20 mg x 0.757). Assuming body weight was 70 kg, the dose range for these effects was 0.01 to 0.22 mg/kg. If the compound was sodium arsenate, the corresponding dose range of arsenic would have been 0.006 mg/kg to 0.12 mg/kg.

Summary of Information From this Reference

Single doses of inorganic arsenicals used as drugs ranging from 0.035 to 0.065 mg arsenic/kg body were commonly found to cause adverse health effects. In some individuals, single doses caused adverse health effects at even lower doses that ranged from 0.01 to 0.02 mg arsenic/kg body weight. A dose of 0.32 mg arsenic/kg body weight was reported to cause death in an individual. All doses assume that body weight was 70 kg.

Summary of Information on Acute Arsenic Toxicity

The dosage data for medicinal arsenicals may be the best human exposure estimates available, given the widespread use of the drugs, consistent formulations, and standard treatment regimens. Data in the other studies appear to be reliable.

There are some potential data gaps and unexplained inconsistencies in the reviewed studies. In all cases, body weights can only be estimated. Although these publications provided estimates of the amounts of arsenic ingested, none listed the body weights of affected individuals, an important consideration when extrapolating exposure information to other individuals. Urinary outputs do not match up well with estimated inputs in the Mizuta and Armstrong studies.

However, taken together, these publications consistently suggest a small range of doses that produce nonfatal adverse health effects from short-term (often a single) exposure:

Pharmacotherapeutics:[25]	0.035 - 0.065 mg/kg (or sometimes lower)
Mizuta:[36]	0.05 mg/kg
Franzblau:[35]	0.036 - 0.071 mg/kg

Fatal doses reported in these references [25,37] ranged from 0.32-2.37 mg/kg.

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