As required by

The Washington State Administrative Procedures Act

Chapter 34.05 RCW

CONCISE EXPLANATORY STATEMENT
AND
RESPONSIVENESS SUMMARY
FOR THE ADOPTION OF
Chapter 173-333 WAC
Persistent Bioaccumulative Toxins

January 2006

Publication: 06-07-006

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CHAPTER 173-333 WAC,
Persistent Bioaccumulative Toxins

Prepared by:

Washington State Department of Ecology

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Concise Explanatory Statement
Persistent Bioaccumulative Toxins (PBT) Regulation
Chapter 173-333 WAC

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Chapter 1 Introduction

Purpose of the Document

This document constitutes the concise explanatory summary for the Persistent, Bioaccumulative Toxins Regulation (Chapter 173-333 WAC). The Washington Administrative Procedures Act (APA) requires that an agency prepare a concise explanatory statement of the rule that:

i. Identifies the agencies reasons for adopting the rule;

ii. Describes the differences between the text of the proposed rule and the text of the rule as adopted, other than editing changes, stating the reasons for differences; and

iii. Summarizes all comments received regarding the proposed rule and provides responses to the comments by category or subject matter, indicating how the final rule reflects agency consideration of the comments, or why it fails to do so. (RCW 34.05.325(6)(a))

The concise explanatory statement must be prepared prior to final rule adoption and must be provided to any person upon request or from whom the agency received comment (RCW 34.05.325(6)(a) and (b).

1.2 Background Information

A wide range of activities result in the production and release of persistent bioaccumulative toxins (PBTs) into the Washington environment. These activities include highly visible sources (e.g. large industrial processes) that have been the traditional focus of pollution control strategies. However, there are also numerous smaller sources of PBTs that may release (on a cumulative basis) an equal or greater amount of PBTs. These smaller sources include automobiles, consumer products, etc. Releases from these sources (both ongoing and historical) have resulted in measurable levels of PBTs being found in the air, water, soils, and sediments throughout Washington State.

Although many chemicals can have toxic effects on humans and the environment, PBTs pose special challenges because of their chemical properties. Unlike many chemicals, PBTs do not readily break down or react with other chemicals in the environment (e.g. they are persistent). They also tend to be absorbed into the tissues of living organisms. In many cases, the concentrations of these chemicals can increase as PBTs are passed up the food chain (e.g. bioaccumulate) where they can pose threats to human health and the environment.

Ecology and other agencies currently implement a wide range of programs to protect human health and the environment. These programs have been in place for many years and have produced significant reductions in the uses, releases and environmental concentrations of several PBTs. However, a new and growing body of information reveals that PBTs remain in our environment and may pose a greater threat to health and the environment than previously thought. Consequently, Ecology and other agencies are faced with answering the following question:

> *What is a reasonable approach for responding to the threats to human health and the environment posed by persistent bioaccumulative toxins (PBTs) that are used, released or present in Washington (either now or in the future) given:*
>
> – *Current understanding of the potential threats to human health and the environment posed by PBTs and the uncertainties surrounding those threats;*

- *Current understanding of the sources of PBTs and the behavior of PBTs once released into the environment;*
- *Current understanding of the effectiveness of current programs to prevent threats to human health and the environment associated with PBTs;*
- *The benefits associated with the uses of PBTs; and*
- *The availability of technically feasible and cost-effective alternatives for reducing or eliminating uses and releases of PBTs (and the uncertainties associated with estimating economic and social costs of current uses and alternatives).*

Over the last decade, Ecology has worked to devise an effective response to the problems and challenges associated with PBTs. This has resulted in a series of proposals and actions by Ecology to develop an approach for addressing this issue.

- August 1998 Announcement: In August 1998, Ecology announced plans to develop a long-term strategy to reduce and eliminate certain chemicals that accumulate in human and animal tissues. As a starting point, Ecology proposed to focus on the 27 substances identified by the Province of Ontario's Ministry of Environment. Ecology held a series of public meetings in late 1998 and early 1999 and numerous organizations and individuals submitted comments on that proposal.
- August 2000 Draft Strategy (Ecology 2000a): Ecology distributed a draft PBT strategy for public review and comment in August 2000. In developing the draft strategy, Ecology considered the wide range of issues and concerns identified during the public meetings held in late 1998 and early 1999. The August 2000 draft approach contained: (1) an initial PBT list (i.e. Starter List) that included nine of the twelve chemicals included on EPA's National PBT List; (2) a proposal to develop a process for identifying and listing additional PBT chemicals; and (3) a number activities that Ecology proposed to undertake to facilitate the reduction and elimination of PBT chemicals from existing sources, the cleanup of PBT chemicals released from historical sources and prevention of new sources of PBT chemicals. Ecology held a series of public meetings and received numerous public comments on the August 2000 Draft Strategy.
- December 2000 Proposed Strategy (Ecology, 2000b): After evaluating the public comments, Ecology elected to modify the draft strategy and submitted the proposed strategy to the Washington Legislature. Specifically, Ecology decided to move forward to develop a process for identifying and ranking PBT chemicals using a four-step process: (1) Identify candidate chemicals; (2) Screen candidate chemicals using information on environmental concentrations, uses, and/or source releases in order to determine which of the candidate chemicals should be included on Washington's PBT list; (3) Rank the chemicals on the PBT list using available information on PBT characteristics, environmental levels and potential sources; and (4) Prioritize the chemicals on the PBT list using the chemical rankings and information on costs, programmatic concerns and opportunities for reductions.
- PBT Working List (Ecology, 2002): Ecology reviewed the comments on the proposed listing and ranking process described in the December 2000 Proposed Strategy. In mid-2002, Ecology distributed the PBT Working List and a document that summarized the comments on the December 2000 proposal, Ecology's response to those comments and the technical and policy rationale for the PBT Working List. The PBT Working List included 22 chemicals or groups of chemicals.

1.3 Reasons for Adopting the Rule

This rulemaking builds upon past Ecology actions and is being adopted in response to directives in early 2004 from then-Governor Gary Locke and the Washington Legislature. Specifically:

- Executive Order 04-01: In January 2004, then-Governor Gary Locke signed an executive order that included several findings and directives regarding persistent toxic chemicals. As part of that executive order, the Governor directed Ecology to establish, through rule, specific criteria for use in identifying persistent toxic chemicals that pose human health and environmental impacts in Washington State and a clear process for developing chemical action plans to address those impacts. Executive Order 04-01 includes the following directive:

  3. The Department of Ecology shall establish, through rule, specific criteria for use in identifying persistent, toxic chemicals that pose human health or environmental impacts in Washington State, and a clear process for developing chemical action plans to address those impacts.

- Legislative Direction: In March 2004, the Washington Legislature directed Ecology to develop a PBT rule that includes (1) specific criteria by which chemicals may be included on a persistent bioaccumulative toxins list, (2) a specific list of persistent, bioaccumulative toxins and (3) criteria for selecting chemicals for chemical action plans. The Legislature further specified that registered pesticides or fertilizers regulated under the Washington Fertilizer Act should not be included on the PBT list developed as part of the rulemaking process. Section 301 of House Bill 2459 includes the following directive:

  (ii) $83,000 is provided solely for rulemaking to develop specific criteria by which chemicals may be included on a persistent bioaccumulative toxins list, develop a specific list of persistent bioaccumulative toxins and establish criteria for selecting chemicals for chemical action plans. The department shall develop the criteria and list consistent with the administrative procedure act provided under chapter 34.05 RCW and shall not adopt the rule prior to the adjournment of the 2005 legislative session. The department shall make recommendations to the legislature by December 31, 2004, regarding future funding alternatives to address persistent bioaccumulative toxins.

  Any pesticide with a valid registration on or after the effective date of this act issued by the environmental protection agency under the federal insecticide, fungicide and rodenticide act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington fertilizer act, chapter 15.54 RCW, shall not be included in a persistent bioaccumulative toxin rulemaking process, list, or chemical action plan undertaken by the department of ecology.

This rule, known as Chapter 173-333 WAC – Persistent Bioaccumulative Toxins was filed with the Washington State Code Reviser's Office on January 13, 2006. This rule becomes effective on February 13, 2006.

1.4 Ecology's Rulemaking Objectives

Ecology considered and balanced a number of issues and concerns during the rule development process. Ecology's efforts to develop this rule were guided by five broad objectives: These include:

- Protection of Human Health and the Environment: The rule should promote efforts to protect human health and environment.
- Scientific Foundation: The rule should promote decisions that are based on current scientific information. However, the lack of full scientific consensus should not be used as

justification for delaying reasonable measures to prevent harm to human health and the environment.

- Efficient Decision-making Approach: The rule should promote timely and rationale decisions using decision-making processes that minimize transaction costs. The rule should promote coordination with other programs and agencies.
- Balancing Predictability and Flexibility: The rule should include well-defined criteria and processes that enable interested parties to understand Ecology actions, timelines and opportunities to provide input to Ecology decisions. However, the rule should also provide the flexibility to address new information and circumstances.
- Meaningful Opportunities for Public Participation in Decision-making Processes: The processes for developing and implementing the PBT rule should provide meaningful opportunities for the public to review and provide comments on Ecology decisions. Toward that end, the rule should be logically organized and written in language that is clear, concise and understandable. Ecology should clearly describe the basis for decisions associated with developing and implementing the PBT rule.

1.5 Public Involvement During the Rule Development Process

PBT Rule Advisory Committee

During the Summer of 2004, Ecology formed the PBT Rule Advisory Committee to advise the Department on issues associated with developing the PBT rule. The committee included representatives from academia, agricultural groups and communities, businesses, environmental groups, health organizations and local government agencies. The committee met eight times between August 2004 and September 2005. As part of the committee process, Ecology developed and distributed draft rule language for review and discussion.

PBT Rule Advisory Committee included the following individuals:

Dr. Kate Davies	Physicians for Social Responsibility
Dave Galvin	King County Hazardous Waste Management
Dr. Steven Gilbert	Institute of Neurotoxicology and Neurological Disorders
Dr. Diana Graham	American Chemistry Council
Heather Hansen	Washington Friends of Farms and Forests
Pete Hildebrandt	Representative for Oil & Aluminum industry
Dr. Jeff Louch	National Council for Air and Stream Improvement
Llewellyn Matthews	Northwest Pulp & Paper Association
Mo McBroom	WashPIRG/Washington Environmental Council
Scott McKinnie	Far West Agribusiness Association
Grant Nelson	Association of Washington Business
Randy Ray	Pacific Seafood Processors Association
Ivy Sager-Rosenthal	People for Puget Sound/Washington Toxics Coalition
Gary Smith	Independent Business Association
Pam Tazioli	The Breast Cancer Fund
Laurie Valeriano	Washington Toxics Coalition

First Public Comment Period (June 1 – July 29, 2005)

Ecology filed the CR-101 (Preproposal Statement of Inquiry) on November 9, 2004. Since Ecology was directed in the 2004 legislation not to *adopt* the PBT Rule prior to the end of the 2005 legislative session, Ecology did not have a public comment period until June 2005. Ecology filed the CR-102 (Proposed Rule Making) and the draft PBT Rule language on May 18, 2005. Notice was published in the June 1, 2005 Washington State Register. The public comment period lasted from June 1 to July 29, 2005. Ecology received comments from representatives of the following groups and from several individuals. These groups and individuals offered diverse opinions on the PBT rule language and related issues.

A list of the comment letters Ecology has received on the draft PBT Rule during Public Comment Period of June 1, 2005 to July 29, 2005 is as follows:

Organizations

1- National Council for Air and Stream Improvement – Dr. Jeff Louch
2- Northwest Pulp & Paper Association - Llewellyn Matthews
3- Breast Cancer Fund - Pam Tazioli
4- Mercury Awareness Team - Mary Ann Newell, Ann Clifton
5- League of Women Voters - Elizabeth Davis
6- Toxic-Free Legacy Coalition - Sybil Diver
7- Puget Sound Keeper Alliance - Sue Joerger
8- City of Seattle - Office of Sustainability & Environment - Steve Nicholas
9- Sierra Club - Rachael Paschal Osborn
10- Weyerhaeuser Company - Ken Johnson
11- American Chemistry Council - Michael P. Walls & Clifford T. "Kip" Howlett
12- North American Metals Council - Dr. William J. Adams
13- Puget Sound Action Team - John Dohrmann
14- Kate Davies (Antioch University)
15- Olympic Environmental Council - Darlene Schanfald
16- Independent Business Association - Gary Smith
17- Washington Refuse and Recycling Association - Brad Lovaas
18- Bromine Science & Environmental Forum – Drs. David Sanders & Raymond Dawson
19- King County Hazardous Waste Management Program - Dave Galvin
20- Washington Toxics Coalition - Ivy Sager-Rosenthal
21- Chlorinated Paraffins Industry Association – Robert J. Fensterheim
22- People for Puget Sound - Heather Trim
23- Association of Washington Business - Grant Nelson

Citizens

1- Alice Romero - Citizen (Seattle)
2- Catherine Farrar, PhD - Citizen (Seattle)
3- John Roberts (retired engineer and house dust expert)
4- Jill Silver - Citizen (Port Townsend)
5- Melinda Honn - Citizen (comments specific to fabric softeners)
6- Paul Allen, MD - Citizen (Olympia)
7- Jamie Donatuto - Citizen (has worked for various Tribes for a number of years)

In addition, Ecology received 371 comments from individual citizens that were submitted by e-mail. These included 211 e-mails submitted directly to Ecology and 160 e-mails attached to comments from the Washington Toxics Coalition. These e-mails contained the following text.

EXAMPLE:

Dear Mr. Gallagher,

I am concerned about the increasing levels of persistent toxic chemicals, such as mercury, dioxin, and flame retardants that are found in our bodies and the environment, and I urge you to issue a strong rule for the Persistent Bioaccumulative Toxics (PBT) Program.

Evidence shows that persistent toxic chemicals, such as mercury, PBDEs, and dioxins, are not going away. Recent studies have found these chemicals in our bodies, house dust, fish, and breast milk.

It is critical that the new rule strengthen the PBT Program's ability to safeguard public health and the environment. The PBT rule must:

* Contain a broad list of persistent toxic chemicals to be phased out. This list must be based on science, not politics, and include chemicals that currently are a problem in Washington state or have the potential to cause a problem in Washington state.
* Include phthalates on the list of chemicals to be phased out. These chemicals were recently linked to reproductive problems in male infants.
* Incorporate the goals of Ecology's 2000 PBT Strategy, including more emphasis on preventing the use and release of persistent toxic chemicals.
* Specifically incorporate the precautionary principle, which calls for taking action to prevent harm when the best scientific evidence available shows harm may occur.
* Ensure that the goal of a phase-out plan (or chemical action plan) is to eliminate the chemical. Each phase-out plan must study and recommend safer substitutes to using the chemical and also include clear timelines for completion.

Also, it is an outrage that pesticides and fertilizers have been exempted from the rule. I have lots of lead and mercury in my cells. These elements are both neurologically damaging. I vote, and the companies whose products have received these exemptions do not. Ecology should request immediately that the Legislature remove the exemption for these dangerous chemicals so that they can be addressed as part of the PBT Program.

Thank you

On July 13, 2005, Ecology held a public hearing on the draft PBT Rule at the Seattle Best Western Hotel, located at 200 Taylor Avenue North in Seattle. 34 people attended the public hearing and 21 provided testimony during the hearing. The following is a list of those who provided testimony during the July 13th public hearing.

1- Nancy Morris
2- Michael Ramos, Church Council of Greater Seattle
3- Robert Pregulman, WashPIRG
4- John Roberts, Engineering Plus
5- Pam Tazioli – Breast Cancer Fund
6- Dr. Steven Gilbert, Institute for Neurotoxicology and Neurological Disorders
7- Bruce Herbert, Newground Social Investment
8- Dr. Sunil Aggarwal, Washington Physicians for Social Responsibility
9- Karen Bowman, Washington Nurses Association
10- Heather Trim, people for Puget Sound
11- Ivy Sager-Rosenthal, Washington Toxics Coalition
12- Dr. Kate Davies
13- Elizabeth Davis, League of Women Voters
14- Eldon Ball
15- Dr. Barry Lawson, Washington Chapter of the American Academy of Pediatrics
16- Matthew Cacho, Healthy Building Network
17- Sibyl Diver – Toxic-Free Legacy Coalition
18- Suellen Mele, Washington Citizens for Resource Conservation
19- Elaine Willey
20- Nancy Dickeman, Washington Physicians for Social Responsibility
21- Laurie Valeriano, Washington Toxics Coalition

Second Public Comment Period (October 19 – November 18, 2005)

Based on public comments received during the June 1 – July 29, 2005 public comment period, Ecology determined that several changes were needed to the draft PBT Rule language. Ecology made these changes and re-filed the draft PBT Rule on September 29, 2005 with the Washington State Code Reviser's Office. Notice of the re-filed PBT Rule was published in the October 19, 2005 Washington State Register. The second public comment period was from October 19th to November 18, 2005.

The following is a list of the comment letters Ecology has received on the draft PBT Rule during Public Comment Period of October 19, to November 18, 2005:

Organizations

1 - People for Puget Sound - Heather Trim
2 - Bromine Science & Environmental Forum – Drs. David Sanders & Raymond Dawson (specific to Deca-BDE)
3 – National Council for Air and Stream Improvement – Dr. Jeff Louch
4 - Bromine Science & Environmental Forum – Drs. David Sanders & Raymond Dawson (specific to Hexabromocyclododecane)
5 - Bromine Science & Environmental Forum – Drs. David Sanders & Raymond Dawson (specific to Tetrabromobisphenol A)
6 - Kinross Gold Corporation – Clyde D. Gillespie

7 - American Chemistry Council Phthalate Esters Council – Courtney M. Price
8 - Weyerhaeuser - Ken Johnson
9 – Dr. Diana Graham
10 – The Boeing Company – Kirk Thomson
11 - North American Metals Council – Dr. William J. Adams
12 - Washington Toxics Coalition – Ivy Sager-Rosenthal
13 - Alkylphenols and Ethoxylates Research Council – Barbara Losey
14 - American Chemistry Council/Chlorine Chemistry Council -
15 - Northwest Pulp and Paper Association – Llewellyn Matthews
16 - Washington Physicians for Social Responsibility – Nancy Dickeman
17 - Association of Washington Business – Grant Nelson

Individual Citizens

1 - Rhonda Turner
2 - Linda Greene
3 - Erin Zamzow
4 - Bob Jacobs

In addition, Ecology received 85 e-mail comments from Washington citizens. These e-mails contained the following text.

EXAMPLE

```
Dear Department of Ecology,

I am concerned about the increasing levels of persistent toxic
chemicals, such as mercury, dioxin, and flame retardants, found in our
bodies and the environment and urge you to issue a strong rule for the
Persistent Bioaccumulative Toxics (PBT) Program.

Thank you for making changes to the rule to include several additional
chemicals, including phthalates, on the list of chemicals to be phased
out. Phthalates were recently linked to reproductive problems in male
infants and are found in many
everyday consumer products, including cosmetics and children's toys.

There are, however, several areas where the rule still MUST be
strengthened if we are to achieve Washington state's goal of
eliminating persistent toxic chemicals.

Specifically, the rule should:

1. Include metals that are classified as PBTs, such as lead, on the
list of chemicals to be phased out. Numerous scientific studies show
that lead bioaccumulates in our bodies and causes learning, behavioral,
and intelligence problems in children.
2. Include the toxic flame retardant, deca-BDE, on the list of
chemicals to be phased out.  Deca breaks down into more toxic forms of
PBDEs that have been shown to affect memory, learning, and behavior in
laboratory animals at very low levels.
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3. Ensure that the goal of the PBT Program and phase-out plan (or
chemical action plan) is to eliminate the uses and releases of a
chemical.
4. Require that each phase-out plan study and recommend safer
substitutes to using the chemical and also include clear timelines for
completion of the plan.

Sincerely
```

On November 9, 2005, Ecology held a public hearing on the re-filed draft PBT Rule at St. Benedict School (school auditorium), located at 4811 Wallingford Avenue North in Seattle. 7 people attended the public hearing and 3 provided testimony during the hearing. The following is a list of those who provided testimony during the November 9th public hearing.

1- Dr. Kate Davies –
2 - Randy Ray – Pacific Seafood Processors Association
3 - Ivy Sager-Rosenthal – Washington Toxics Coalition

Public notice for both the June 1 – July 29, 2005 and October 19 – November 18, 2005 public comment periods was provided in the:

1) Washington State Register;
2) Ecology's PBT Rule web page (http://www.ecy.wa.gov/programs/eap/pbt/rule/index.html); and
3) Ecology's Public Involvement Calendar (http://apps.ecy.wa.gov/pubcalendar/calendar.asp).

1.6 Organization and Format of the Concise Explanatory Statement

The rest of this Concise Explanatory Statement is organized into five main chapters with a sixth chapter providing a list of references cited by Ecology in responding to particular issues:

Chapter 2: General Rulemaking Issues
Chapter 3: General Provisions (Part I)
Chapter 4: Definitions (Part II)
Chapter 5: The PBT List and Criteria and Procedures for Revising the List (Part III)
Chapter 6: Chemical Action Plans (Part IV)
Chapter 7: References.

The Concise Explanatory Summary responds to comments received on both the June 2005 proposal and the October 2005 proposal. Comments were received in writing and transcribed from oral testimony provided at public hearings.

The Concise Explanatory Summary responds to the identified comments in a question and answer format. Ecology reviewed the public comments and grouped them into a series of questions. Each of the questions reflects a particular issue or set of issues raised by one or more commenters. The following format is used for each question:

- Proposed Rule: This subsection includes a brief summary of relevant provisions in the October 2005 proposal and any differences between the June 2005 proposal and the October 2005 proposal.

- Public Comments and Concerns: This subsection provides a summary of the public comments and concerns raised on the issue during the June and October 2005 comment periods. Where multiple comments were received on a particular issue, Ecology summarized the major concerns and provided examples of individual comments.
- Ecology's Review and Response to Public Comments: This subsection provides Ecology response to each issue.

References to written comments are designated by the name of the individual providing the comment and, where appropriate, whether the comment was submitted during the first or second public comment period (e.g. (Dave Galvin, p. 2 of July 2005 written comments). References to public testimony provided at one of the public hearings include the persons name and the hearing date (e.g. Randy Ray, testimony at November 9th Public Hearing).

The following appendices are attached to this document:

Appendix A: Initial PBT Rule language filed on May 18, 2005

Appendix B: PBT Rule language highlighting differences between the initial draft PBT Rule language and the re-filed draft PBT Rule language – filed on September 29, 2005

Appendix C: PBT Rule language highlighting differences between the re-filed draft PBT Rule language and the final adopted PBT Rule (January 13, 2006).

Appendix D: Comments on the June 2005 Proposed Rule (Available Upon Request).

Appendix E: Comments on the October 2005 Proposed Rule (Available Upon Request).

Chapter 2 General Rulemaking Issues

Issue 2-1: Was Ecology correct in it's determination that the PBT rule is not a significant legislative rule as defined in Washington's Administrative Procedures Act?

Proposed Rule

The Washington Legislature directed Ecology to develop the PBT criteria and list consistent with the Washington Administrative Procedures Act (APA) . Early in the rulemaking process, Ecology considered whether the proposed rule should be considered a "significant legislative rule" [1]. Based on that review, Ecology determined that the PBT rule was a rule "...relating only to internal government operations that are not subject to violation by a nongovernmental party..." Based on that determination, Ecology proposed to adopt the PBT rule as a "procedural rule"[2].

Public Comments and Concerns

Several organizations and individuals provided comments on this issue. Some organizations disagreed with Ecology's determination that the rule is a procedural rule. They stated that the publication of the PBT List could produce indirect impacts on the production and use of PBT chemicals. For example:

> *We understand that Ecology has taken the view that the proposed rule is strictly procedural under RCW 34.04.328(5,c,i), in that it is only intended to address the internal operations of the agency, i.e. making decisions on how an agency prioritizes its work in dealing with persistent bioaccumulative toxins in the environment. The CP industry vehemently disagrees.*
>
> *The designation of a substance as a PBT, whether made by the federal EPA, the federal Environment of Canada or the State of Washington, will trigger a shift away from the use of these substances. There are sufficient examples throughout history of chemical control programs where either governmental or voluntary programs have resulted in the shift from one substance to another, only to find that the replacement substance is more toxic than the substance that is being replaced. While we recognize that Ecology is not directing industry to shift from listed substances to unlisted substances, it must be recognized that the mere inclusion of a compound on the list will drive some companies to shift without adequate consideration of the properties of the substitute compound. For these reasons we believe it is important that Ecology proceed carefully in designating a substance as a PBT.*
>
> *In our view, if Ecology's intention is to adopt purely a procedural rule, it should remove reference to any specific list of PBT substances, as it is the designation of a substance as a PBT that renders the rule a significant legislative action. Instead we suggest that Ecology focus its rulemaking on defining*

[1] RCW 34.05.328(5)(c)(iii) includes the following definition: A "significant legislative rule" is a rule other than a procedural or interpretive rule that (A) adopts substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction; (B) establishes, alters, or revokes any qualification or standard for the issuance, suspension, or revocation of a license or permit; or (C) adopts a new, or makes significant amendments to, a policy or regulatory program.

[2] RCW 34.05.328(5)(c)(i) includes the following definition: A "procedural rule" is a rule that adopts, amends, or repeals (A) any procedure, practice, or requirement relating to any agency hearings; (B) any filing or related process requirement for making application to an agency for a license or permit; or (C) any policy statement pertaining to the consistent internal operations of an agency.

the process for declaring a substance a PBT and associated actions, and not the incorporation of an initial list of PBT substances. ***(Robert Fensterheim, p. 4 of July 2005 written comments)***

While it is Ecology's and WRRA's desire to reuse and recycle as much of the waste stream as possible, this proposed rule may result in less recycling of materials that are currently recycled today. ***(Brad Lovaas, p. 1 of July 2005 written comments)***

Other organizations and individuals appeared to agree with Ecology's determination and rationale, but recommended that Ecology clarify how the CAP process might be used to establish requirements for nongovernmental parties and how the process for establishing those requirements will comply with the Administrative Procedures Act. For example:

*IBA is willing to accept the conclusion of the Department that the proposed new rule will not have an economic impact on small businesses and thus no Small Business Economic Impact Statement is required for this proposed rule if one clarification is made...We believe one additional clarification is needed to clearly notify all parties that a CAP's recommendations are truly voluntary actions and someone or some entity who does not follow a CAP's recommendations will not be subject to any citation or sanction****....(Gary Smith, p. 1 of July 2005 written comments)***

During the stakeholder process, Ecology took the position that the proposed rule is "administrative," meaning that the rule applies to Ecology operations and does not pose new regulatory burdens as would a "significant legislative" rule. The thinking was that the proposed rule sets out the process for identifying chemicals to be included in the PBT list, the criteria for selecting those warranting chemical action plans (CAPs) and the process for determining the scope of the CAPs. The additional steps of selecting PBTs or groups of PBTs and the CAP will be subject to public notice and opportunity for comment pursuant to the Administrative Procedures Act.....

- *Given the extensive concern on this subject, NWPPA requests Ecology to clarify this issue in the response to comments.*
- *WAC 173-333-120(2) describes the opportunity for public involvement with respect to this rule. NWPPA recommends a cross reference to WAC 173-333-410(3)(c-d) and WAC 173-333-430 (6-7) to clarify these separate public involvement opportunities for the next steps in the process****. (Llewellyn Matthews, pp. 1-2 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that the PBT rule is a "procedural rule" as defined in the APA. WAC 173-333-120 clearly states that the chapter applies to the Department of Ecology and does not impose new requirements on persons using or releasing PBT chemicals. In addition, all of the stated purposes in WAC 173-333-110 are related to the internal operations of the agency (i.e., making decisions on how Ecology will prioritize activities to address PBT chemicals in the environment, etc.). Normally, Ecology does not prepare rules describing on how the Department manages and prioritizes day-to-day environmental work. Nor does the APA require that these types of activities and priorities be set forth in a rule.

The PBT rule contains policy statements that pertain to the consistent internal operations of the agency (e.g. identification of PBT chemicals, content and processes for selecting and preparing chemical action plans). Ecology recognizes that the preparation of chemical action plans will produce recommendations for certain types of actions by nongovernmental parties.

- Chemical action plans may include recommendations to establish regulatory requirements that would be implemented through existing regulatory programs and processes. Ecology and other applicable agencies will comply with applicable rulemaking, permitting or other

administrative requirements when establishing regulatory requirements to implement particular recommendations. For example, if a chemical action plan includes a recommendation for Ecology to establish a rule to limit certain PBT uses or releases, Ecology will comply with the applicable APA rulemaking requirements when preparing such rules.

- Chemical action plans may include recommendations that require new statutory authority for Ecology or other implementing agencies. Implementation of these recommendations will require action by the Washington Legislature.
- Chemical action plans may include recommendations to reduce/phase-out PBT uses and releases through voluntary actions. Ecology will implement these recommendations in a manner that is similar to other Ecology voluntary programs. Since these are voluntary programs, persons electing not to implement the recommended measures will not be subject to penalties and sanctions.
- Chemical action plans will include performance measures to evaluate progress in implementing actions using regulatory and voluntary approaches. Ecology may decide to modify the initial approaches if they prove to be ineffective in reducing and phasing-out PBT uses and releases. For example, Ecology may decide to establish regulatory requirements for certain uses and releases if voluntary programs are found to be ineffective.

Ecology believes the language in Section 120 of the draft rule is sufficient to address concerns that the PBT rule itself is not imposing a new requirement on persons using or releasing PBTs. However, Ecology does agree that the concern that "…*the shift from one substance to another, only to find that the replacement substance is more toxic than the substance that is being replaced*." is a valid concern. In fact, Ecology is addressing a similar issue as the agency (along with the Washington State Department of Health) has developed recommendations for further action on the PBDE Chemical Action Plan (to be finalized in December 2005). As Ecology and Health have examined possible alternatives to the current use of Deca-BDE, most of the possible alternatives have even less information than Deca-BDE. Ecology sees this issue, instead as a short-coming of U.S. federal chemical policy. Currently, under the federal Toxic Substances Control Act (TSCA) requirements, chemical companies are not required to test new chemicals before they are submitted to EPA for review. On average, over 700 new chemicals are introduced into commerce each year and currently approximately 60,000 chemicals are currently in commercial use. EPA does not routinely assess the risk of these chemicals to human health and the environment because TSCA puts the expensive and time consuming burden of obtaining data on EPA instead of the companies that developed and manufactured the chemicals. Often, chemical companies claim that information about their chemicals is "confidential business information". Ecology believes that US chemical policy needs to be changed to address this problem.

Issue 2-2: Is the proposed rule confusing and difficult to understand?

Proposed Rule

Ecology published proposed PBT rules in June 2005 and October 2005. Each version of the proposed rule was divided into four parts with a total of fifteen sections.

Public Comments and Concerns

Several people expressed concerns that the regulation was confusing and difficult to understand. For example, several people found that the format used in the table of PBT chemicals was difficult to read and understand. For example:

> *...the extensively footnoted table format is difficult to read and understand. Please consider a new presentation format for the list and the detailed and important technical information that accompanies it* ***(Dave Galvin, p. 3 of July 2005 written comments)***

Several organizations and individuals recommended that Ecology use a standard set of terms and avoid using different phrases for the same term. For example:

> *Different phrases are used throughout the draft regulation to describe the fundamental objective of reducing the exposure of PBTs to humans, plants and animals. .... In some instances the policy intent and regulatory context requires slightly different action phrases or words. Where possible, standard language should be used to avoid variable interpretations of the regulation. We generally prefer "reducing exposure" to phrases using "threat," "harm" or "impact." "Phase out" seems better than "eliminate."* ***(Ken Johnson, p. of July 2005 written comments)***

Several organizations and individuals expressed concerns that the process for selecting chemicals for CAP preparation is unclear and confusing. For example:

> ***There is no clear process for selecting chemicals from the PBT list for development of CAPs.*** *Based on the language in the proposed rule, it appears that Ecology is proposing the following:*
>
> - *Chemicals on the PBT list will be placed in one of three categories based on available information/data, and only Category 1 chemicals will be targeted for CAPs.*
> - *Chemicals in Category 1 will be ranked according to the criteria given in 173-333-410(2), and those with soil/sediment half-lives >180 days and BAFs or BCFs >2000 in combination with some toxicity score (see comment 3) will be given priority for CAP development.*
>
> *As described, this is a logical approach to ranking/prioritizing chemicals for CAPs. Is this what Ecology intends? If so, the language in the proposed rule should be modified to clearly express this. If not, Ecology needs to modify the rule by incorporating some clearly defined scheme for ranking chemicals on the PBT list for use in prioritizing CAPs [1,2]****.(Jeff Louch, p.3 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed these comments and made several changes to the rule format and language prior to republishing the proposed rule in October 2005. These changes include:

- List Format: Ecology initially proposed a PBT list that included 26 chemicals and chemical groups. Individual chemicals in various chemical groups were identified in explanatory footnotes. After reviewing the public comments on the June proposal, Ecology decided to integrate the table and explanatory notes into a single table that clearly identifies the individual chemicals meeting the PBT criteria. Ecology made these changes in order to reduce the confusion on the relationship between the table and explanatory notes. The revisions are also designed to more clearly identify which chemicals within broader chemical groups or categories are included on the list.
- Terminology: Ecology decided to revise the rule in order to incorporate more consistent terminology. Revisions include: (1) revising WAC 173-333-100 to clarify that the goal of the PBT rule is to "reduce and phase-out PBT uses, releases and exposures"; (2) removing or

modifying statements in other parts of the rule that include different wording; and (3) adding language to clarify that a variety of factors (health impacts, economic costs, availability of safer substitutes, technical feasibility and regulatory consistency) will be considered when evaluating whether and when the overall goal can be achieved. These changes are being made in response to public comments urging Ecology to use a consistent set of terms throughout the rule. Ecology agrees that the use of different phrases in different parts of the proposed PBT rule was confusing and increased the chances of multiple interpretations of particular provisions.

- Process for Selecting Chemicals for Development of Chemical Action Plans: Ecology revised the process for selecting chemicals from the PBT List for the development of chemical action plans. Revisions include: (1) streamlining the process by eliminating the criteria for identifying candidates for CAP development (WAC 173-333-410(2)); (2) incorporating the concepts underlying the three list categories identified in WAC 173-333-310(3) of the proposed rule into the CAP selection process in WAC 173-333-410; and (3) revising the selection process to replace the chemical-by-chemical selection process with a multi-year schedule for CAP preparation.

Issue 2-3: Should Ecology use a science-based approach or a precautionary approach or a combination of the two approaches to develop and implement the PBT rule?

Proposed Rule

The PBT Rule Advisory Committee discussed the role of scientific information in the development and implementation of the PBT rule. Based on those discussions, Ecology identified three main principles important to the development and implementation of the PBT rule: (1) decisions should be based on credible scientific information; (2) full scientific consensus or certainty is not necessary to justify actions to prevent harm; and (3) decisions associated with the development and implementation of the PBT rule represent a combination of scientific and policy determinations. Ecology included the following statement in the proposed PBT rules published in June and October 2005:

> ***(140)(1) Scientific information.*** *Ecology will base decisions on PBTs on sound public policy and credible scientific information. However, ecology believes that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.*

Public Comments and Concerns

Several organizations and individuals expressed support for basing decisions on credible scientific information. For example:

> *The integrity of the PBT rule is dependant on the evaluation of credible scientific information.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

> *As a policy matter, NWPPA advocates that the role of science in the listing process cannot be over emphasized. The listing decisions lend themselves to evaluation of objective science in a systematic manner. NWPPA recognizes that the decisions as to whether CAPs are needed, while still based on credible science, are inherently more subjective and will likely involve policy considerations.* ***(Llewellyn Matthews, p. 1 of November 2005 Written Comments)***

Contain a broad list of persistent toxic chemicals to be phased out. This list must be based on science, not politics, and include chemicals that currently are a problem in Washington state or have the potential to cause a problem in Washington state. ***(Allisa Berteig, p.1 of July written comments)***[3]

Some organizations and individuals providing comments on the June 2005 proposed rule expressed the opinion that the proposed rule represented a science-based approach. For example:

*Ecology should continue to take a science-based approach to their assessment of chemicals. The proposed Rule is appropriately guided by sound science and risk assessment, rather than utilizing a purely precautionary approach based on hazard characteristic alone..... .****(Michael Walls and Clifford Howlett, p. 2 of July 2005 Written Comments)***

However, other organizations questioned whether decisions on certain chemicals were consistent with the principle of basing decisions on credible scientific information. For example:

Ecology Needs to Follow Its Principles of Good Science and Clear Documentation. The CP industry believes that Ecology has incorporated in the draft rule an important set of principles to be followed in order to establish a credible, scientifically based program. We fully endorse these principles and as such regret that, at least with regards to the inclusion of SCCPs on the draft PBT list, several of the principles were not followed. For example, several of these principles were not followed. For example, two of the principles address the need to base decisions on credible scientific information and the need for clear descriptions of rationale... ***(Robert Fensterheim, pp. 1-2 of July 2005 written comments)***

Ecology's decision to include di-n-hexyl phthalate (DnHP), di-iso-decyl phthalate (DIDP) and nonylphenol also prompted comments on Ecology's implementation of this principle. These include comments on Ecology's decisions on those three chemicals and, more broadly, Ecology's consideration of scientific information when making decisions on whether to include a chemical on the PBT. In general, many organizations expressed the opinion that Ecology's decision to include these three chemicals on the proposed PBT List was not consistent with current credible scientific information on the persistence, bioaccumulation and toxicity. For example:

PBT decisions, including the first "starter list," should be based on credible science, not ad hoc politics. Chemicals recently added reflect ad hoc considerations, not scientific rigor, and should be deleted. *The most important objective of the proposed rules is to provide a clear, predictable and scientifically driven process to identify and list PBTs. To the greatest extent possible, credible science should drive Ecology decisions as which of the listed chemicals warrant Chemical Action Plans. The alternative is the undesirable reality, already unfolding in Washington, whereby various interest groups seek ad hoc Executive Orders or legislative directives regarding the "chemical of the day."* ***(Llewellyn Matthews, p. 1 of November 2005 written comments)***

Some of the organizations who expressed support for basing decisions on credible scientific information also expressed concerns that the second sentence in subsection (1) was unnecessary and potentially in conflict with a science-based approach. For example:

WAC 173-333-140(1) Scientific Information *– The second sentence in this subsection announcing a decision-making bias based on a precautionary principle is unnecessary and should be removed.....This regulation will be useful, credible, accepted and actively supported primarily because it has a science-based foundation. Physical, chemical and biological criteria will be defined in rule to identify PBTs. The CAP development process will reveal the effective and reasonable*

[3] Ecology received 371 e-mails recommending that the Department incorporate the precautionary principle into the PBT rule.

measures that can be taken to reduce human health and environmental exposures. This logical and transparent approach would be undercut should Ecology reserve to itself an ability to impose a decision based on inconclusive science. ***(Ken Johnson, p. 2 of July 2005 written comments)***

On the other hand, many organizations and individuals expressed support for Ecology's statement "...that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment..." For example:

The Local Hazardous Waste Management Program in King County supports the concept expressed in this proposed rule "...that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment ***(Dave Galvin, p. 3 of July written comments)***

We support WAC 173-333-140 (1) Scientific information. We believe that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.... ***(John Dohrmann, p. 1 of July 2005 written comments)***

Many of these organizations and individuals urged Ecology to incorporate the precautionary principle into the PBT rule. For example:

...Further, we believe that whenever possible the precautionary principle should be invoked to protect Puget Sound's marine resources. Specifically, we ask you to consider incorporating the precautionary principle approach into WAC 173-333-420 (1)(f). ***(John Dohrmann, p. 1 of July 2005 written comments)***

Incorporate the precautionary principle ***(Heather Trim, p. 2 of July 2005 written comments).***

Specifically incorporate the precautionary principle, which calls for taking action to prevent harm when the best scientific evidence available shows harm may occur. ***(Allisa Berteig, p.1 of July written comments)***[4]

Several organizations and individuals provided comments related to Ecology's statement that decisions to develop and implement the PBT rule represent a combination of scientific and policy determinations. For example:

Ecology should continue to take a science-based approach to their assessment of chemicals. The proposed Rule is appropriately guided by sound science and risk assessment, rather than utilizing a purely precautionary approach based on hazard characteristic alone. Importantly, a science and risk-based approach is not at odds with precaution because risk assessment practices, including the use of conservative safety factors, reflect precaution. Risk assessment is the essential component in making "precautious" decisions and will allow Ecology to most effectively manage potential risks to human health and the environment by providing a means to set priorities. It is a well-established process to combine knowledge about hazard, use and exposures to make decisions about risks in context.

The public interest dictates that policy-making must follow a thorough, objective examination of all available scientific evidence. Science helps take the guesswork out of policy making, increases knowledge, reduces uncertainty, and is a critical component of the public's right to know.

In making PBT chemical management decisions, sensible precaution should include a full assessment of the level of uncertainty and the benefits that might be sacrificed if the products and technologies in question are restricted or otherwise called into question. The assessment process should also factor the uncertainties and risks that accompany potential alternatives into any decisions. The proposed

[4] Ecology received 371 e-mails recommending that the Department incorporate the precautionary principle into the PBT rule.

Rule rightly incorporates necessary elements of science and risk prioritization. ***(Michael Walls and Clifford Howlett, p. 2 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and believes that PBT rule incorporates both a "science-based approach" and a "precautionary approach". This reflects the fact that agency decisions on PBT chemicals are complicated by the fact that many gaps remain in our scientific understanding of the exact relationships between exposure to PBT chemicals and the adverse health or environmental effects resulting from such exposures. Given the limitations in scientific information and knowledge, Ecology recognizes that it will often be necessary to take action where there is some evidence of hazard, but before that evidence has reached the point that scientists would universally regard as conclusive. Ecology believes it would be inconsistent with its statutory obligations to delay actions in the hope that science will provide definitive answers to questions on health and environmental hazards.

Ecology's rulemaking efforts have been directed towards constructing a rational and efficient decision-making framework that recognizes the fluid and developing nature of scientific knowledge. The Department believes that the PBT rule creates such a decision-making framework that reflects Ecology's position that decisions on PBTs represent a combination of scientific and policy determinations (see WAC 173-333-140(1)).

In reviewing the public comments on this issue, there appears to be general agreement that (1) Ecology's decisions on developing and implementing the PBT rule should be based on credible scientific information; and (2) There are significant uncertainties associated with characterizing the adverse health threats associated with the use and release of PBT chemicals and our level of understanding on those threats will rarely, if ever, rise to point that scientists would uniformly regard as conclusive.

However, the public comments also indicate some disagreement (or confusion) on whether those decisions are scientific decisions or decisions informed by science. This is not surprising given that the proposed rule establishes a decision-making process where scientific information plays a central role – but one in which scientific information is used in a decision-making process that also reflects a series of values and policy choices for dealing with scientific uncertainty. The central role played by scientific information in evaluating health hazards and the complexities associated with evaluating and interpreting scientific information was discussed by Dr. Douglas Weed of the National Cancer Institute (NCI) in a recent review article:

At the center of the RA [risk assessment] process is science and at the center of science are methods: the study methods used to generate scientific evidence and the methods used to summarize and interpret that evidence. Anyone familiar with this practice would likely agree that improvements in the interpretative methods are needed. These methods are used to summarize and synthesize evidence across several dimensions: large studies and small; strong studies and weak; old studies and new; human and animal studies, and studies involving human populations and studies of cellular systems. In addition to these obvious challenges, applying these methods involves values, both scientific and extra-scientific, values that are not always made explicit. Uncertainty and underdetermination – the lack of definitive proof or disproof in science – are constant companions (2). Not uncommonly, claims about a purported hazard – e.g. a chemical, medication or consumer product – can differ sharply even when the evidence is not in dispute. Examples abound: the carcinogenicity of polychlorinated biphenyls (PCBs), the health risks of environmental tobacco smoke (or diesel fumes), and the role of moderate alcohol consumption in breast cancer, to name a few. Risk assessors in these situations typically use a decision process involving some combination of scientific evidence,

interpretative methods, and expert judgment. When the evidence itself is not in dispute, then either the interpretative methods or expert judgment (or both) are responsible for disparate claims. Improvements in the interpretative methods of risk assessment could improve the situation. Better science and a better understanding of the role of expert judgment are also needed, but for this article, we focus on the interpretative methods of risk assessment, the so-called weight of evidence methods. ***(Weed, 2005, p. 1546)***

While science plays a central role in the decision-making process, Ecology believes it would be misleading to characterize decisions on whether to include a particular on the PBT list as a purely scientific decision. Over the last 20 years, many agencies and expert committees have highlighted the distinction between scientific information/evaluation and regulatory decision-making. For example:

Scientific methods in themselves lead only to new information and cannot convey "good or bad" values. Human judgments attribute positive or negative values, and the scientists using these phrases are expressing their judgments on regulatory polices rather than on scientific studies. Rowe uses the term "trans-science" to describe the area where judgments must be made but the science is limited: "The judgments involved are about science, but are not science in themselves"...Science can provide the scale, but doesn't draw the line. Most practitioners would agree with Victor Hugo's comment: "Science has the first word on everything, and the last word on nothing." ***(Tomboulian, P. 1989, pp. 1041 and 1045)***

Ecology's policies tend towards protecting human and environmental health by preferring an approach that does not underestimate health threats in the face of scientific uncertainty and variability. As noted above, Ecology incorporated the concept of "precaution in the face of scientific uncertainty" into WAC 173-333-140(1). Ecology's experience with other regulations indicates that many disagreements that are framed in terms of scientific-basis for decisions are actually disagreements on the methods and policies for dealing with scientific uncertainty and variability (e.g. the degree of precaution). [See Issue 5-29].

Consequently, Ecology believes that scientific information and precaution in the face of scientific uncertainty both play central roles in Ecology's decisions on whether to include a particular chemical on the PBT List. However, Ecology believes there are several broad issues that relate to how this combined approach is actually implemented. These issues are related to what Dr. Weed refers to as "interpretative methods" and how those "interpretative methods" interact with agency decision-making that also incorporates consideration of expert judgment, values and policy choices. For purposes of review, Ecology has organized these implementation issues around the four questions which are addressed in later sections of this document.

- Issue 3-8: Should the PBT rule include a statement on the precautionary principle and, if so, what should that statement say?
- Issue 5-27: Should Ecology use a "weight of evidence" approach when making decisions on whether to include a chemical on the PBT List?
- Issue 5-28: How should Ecology take into account the quality of different types of scientific information when making decisions on whether to include a chemical on the PBT List?
- Issue 5-29: How should Ecology taken into account scientific uncertainty and variability when making decisions on whether to include a chemical on the PBT List?

Issue 2-4: Is the proposed PBT rule consistent with Ecology's December 2000 Proposed PBT strategy?

Proposed Rule

Ecology published the *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* in December 2000. Then-Governor Locke referenced the proposed strategy in Executive Order 04-01. However, the budget proviso language directing Ecology to prepare the PBT rule did not include a similar reference. This issue was discussed with the PBT Rule Advisory Committee. Based on those discussions, Ecology decided not to include a reference to the proposed PBT strategy in the PBT rule.

Public Comments and Concerns

Several organizations and individuals provided comments that explicitly or implicitly reflected the viewpoint that one of the main purposes of the PBT rule is to implement the proposed strategy and that this should be clearly stated in the rule. For example:

> ***Better Define Goals and Purpose of PBT Program and Eliminate WAC 173-333-300 (a)*** *We are extremely concerned that the current draft rule does not reflect the goals and purpose of the PBT program as outlined in the 2000 Strategy to Continually Reduce and Eliminate Persistent Bioaccumulative Toxins in Washington State (Strategy). To demonstrate how much the rule has departed from the Strategy, we have attached a comparison of the Strategy and the proposed rule. As you will see, several important pieces of the Strategy have been dropped from the rule, including the goal of significant reductions in PBTs by 2020 and the commitment to reduce and phase out all of the chemicals on the PBT list. While we recognize that it may not make sense to include every piece of the Strategy in the rule, we firmly believe that the overarching goal of reducing and phasing out ALL of the chemicals on the PBT list must clearly be reflected in the goal and purpose of the rule.* ***(Ivy Sager-Rosenthal, p. 1-2 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology believes that the proposed PBT rule is consistent with Ecology's proposed PBT strategy and the Department's early implementation of that strategy: Although there are differences on specific issues, Ecology believes that a critical review of the proposed PBT strategy and Ecology's early implementation (e.g. preparation of the mercury action plan) indicates a high degree of consistency on several broad points:

- Environmental Goal: The two proposed documents identify similar environmental goals. The proposed PBT rule states that "...[t]he goal of this chapter is to reduce and phase-out PBT uses, releases and exposures in Washington...". This goal is consistent with the proposed PBT strategy which includes an overall vision (...continually reducing risks to human health and the environment from exposures to PBTs, by the year 2020...) and several goals associated with achieving that vision including reducing and, where possible, phase-out existing sources of PBTs, clean up PBTs from historical sources and prevent new sources of PBTs.
- Phased Decision-Making Process: The two proposed documents both envision a phased decision-making process. The proposed PBT rule establishes a decision-making process for evaluating what actions should be taken to reduce and phase-out PBT uses, releases and exposures. Identification of PBTs is the first step in that process. This represents a preliminary determination that actions are needed with a preference being given to

actions that achieve the overall goal. However, that presumption can be overcome at later stages in the decision-making as additional factors are considered as part of the processes for selecting and preparing chemical action plans. The proposed PBT strategy (in the discussion of the precautionary principle) describes a similar process:

> *New and Existing Sources of PBTs: Once a substance has been identified as a PBT, a full range of response options (e.g. control, prevention, use reduction, phase-out) need to be identified and evaluated. Consistent with many current environmental laws, applying the precautionary principle creates a preference for using safer alternatives. However, that presumption can be overcome by considering the technical, economic, and social circumstances surrounding the specific activity.* ***(Ecology, 2000b, p. 16)***

- Chemical Action Plans: Both proposed documents establish a central role for chemical action plans. The proposed PBT rule establishes a decision-making process where chemical action plans are the primary vehicle for decisions on actions to reduce and phase-out uses, releases and exposures. Although the proposed PBT strategy identified a number of potential implementation mechanisms, Ecology proposed that "...*Chemical action plans*, to be developed by Ecology in collaboration with others for specific high-priority chemicals, will be the primary means by which specific reduction actions and activities will be developed and implemented..." (Ecology 2000b, p. 6).

Issue 2-5: Is Ecology's proposed approach consistent with other federal and international programs?

Proposed Rule

Ecology worked with a rule advisory committee (PBT Rule Advisory Committee) to develop the proposed PBT rule. As part of the rule development process, Ecology considered approaches being used by other state, federal and international organizations to address PBT chemicals.

Public Comments and Concerns

Several organizations and individuals emphasized the importance of establishing an approach that is consistent with other state, federal and international efforts. Some of these organizations concluded that Ecology's proposed approach was at odds with other federal and international efforts to address PBT chemicals. For example:

> *AWB believes that Ecology has proposed PBT criteria that are overly conservative and inconsistent with established internationally recognized criteria for PBTs. Comments submitted by ACC/CCC, NCASI and BSEF provide rationale and documentation for the department to consider on this subject.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

The American Chemistry Council/Chlorine Chemistry Council (ACC/CCC) discussed the importance of consistency and provided several recommendations for improving consistency with international programs:

> *WAC 173-333-320 sets out the criteria by which Ecology will identify PBTs of possible interest to the State of Washington. Under these criteria, however, Ecology will likely identify a much larger group of priority chemicals than under comparable regional or international programs, creating a significant management burden on the State both in terms of assessment and diversion of limited resources with little marginal impact on health or the environment. As outlined below, ACC and CCC recommend that Ecology amend the criteria for persistence and bioaccumulation.*

A. ***The persistence criteria for soil and sediment should be consistent with other PBT programs****. Ecology has established a half-life of 60 days in water, soil and sediment as the single criteria by which persistence is established. The North American Commission for Environmental Cooperation's Sound Management of Chemicals (SMOC) Initiative,1 under which the U.S., Canadian and Mexican governments have agreed to address priority PBT issues and develop Regional Action Plans (RAPs) on select chemicals, adopts persistence criteria of six months (180 days) in soil or water, and 1 year in sediment. The Stockholm Convention on Persistent Organic Pollutants (POPs)2, a global legally-binding instrument to control emissions of the PBT-subset that are transported in air or water, adopts persistence criteria of 60 days in water, and 180 days in soil or sediment. ACC and CCC recommend that Ecology adopt persistence criteria for soil and sediment that are consistent with the North American regional program and internationally agreed programs. In the case of the Stockholm Convention, for example, the criteria were adopted after lengthy negotiations on the criteria that would assure the identification of potential chemicals of concern, and have a well-accepted scientific basis.*

B. ***Ecology should adopt a bioaccumulation or bioconcentration factor of 5,000****. The rule establishes that a bioaccumulation (BAF) or bioconcentration factor (BCF) of 1,000 identifies a chemical as bioaccumulative. In the absence of such data, an octanol-water partition coefficient (LogK_{0w}) of 5 establishes the bioaccumulative characteristic under the rule. ACC and CCC believe the BAF and BCF criteria should more properly be 5,000. Ecology should be aware that a LogK_{0w} of 5 is very closely associated with BAFs and BCFs of 5,000, not 1,000. In the context of the negotiations on the Stockholm Convention, the International Council of Chemical Associations (ICCA), of which ACC is a member, reviewed the technical basis for concluding that LogK_{0w} 5 is equivalent to a BCF of 5,000. A copy of that paper, developed for the Criteria Expert Group (CEG) that met during the Stockholm Convention negotiations, is contained in Appendix 2. Further, in both the North American SMOC initiative and the Stockholm Convention BCF and BAF values of 5,000 are used to identify chemicals as bioaccumulative. Again, there is a strong scientific basis for setting bioaccumulation values at 5,000. Setting BCF and BAF factors at the low level of 1,000 risks identifying substantially more chemicals as potential candidates for Washington's PBT program – particularly chemicals that do not pose a risk to human health or the environment.*

C. ***Ecology should modify the language for degradation products****. In the proposed Rule, section 173-333-320(3) on degradation products reads:*

> *"Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will be considered in the development of a CAP for those derivative chemicals."*

The Advisory Committee agreed that if a chemical was not a PBT, but degraded into a PBT, the degredate would be listed, but the parent would not be listed (but could be considered for regulation in the CAP). To better reflect the recommendation of the Advisory Committee, this section should be clarified to read as follows:

> *"Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will not be listed as a PBT but will be considered in the development of ~~a~~ CAP**s** for those ~~derivative chemicals~~* ***degradation products that do meet the criteria in this section for a PBT and are on the PBT list."***

Dr. Diana Graham (a member of the PBT Rule Advisory Committee) expressed the opinion that the criteria used by several international agencies were more appropriate than the Toxics Release Inventory criteria because Ecology's program objectives were more closely aligned with the international programs than the TRI objectives:

> *My biggest concern is the apparent continuing disconnect between the objectives and the criteria. According to the goals and objectives section, this rule is not going to be used to collect information or to manage chemicals but to reduce and where feasible phase out or ban chemicals.*
>
> *The WMPT does indeed use 60 days for water, soil or sediment half-lives. The reference is to the TRI reporting revision in 64 FR 688. According to that citation "However, EPCRA section 313 is an information collection and dissemination program. EPA believes that persistence criteria consistent with the criteria applied to chemicals that are of global or regional (e.g., Europe and the Great Lakes) concern and that are targeted for ban, restriction, or phase-out are inappropriate for such a program. Chemicals that meet the persistence criteria used in the international agreements are the extremely persistent chemicals. Applying these strict criteria to EPCRA section 313 would result in a very narrow list of chemicals that would focus on only extremely persistent chemicals. This is inconsistent with one of the fundamental tenets of right-to know which is to provide the public with information on toxic chemicals that have the potential to cause adverse effects in their community. Further, persistence criteria of half-lifes of 6 months and 5 days have not been used to establish whether a chemical is a PBT chemical but rather whether a chemical should have restrictions on its uses. The Agency stated in the proposal its belief that half-life criteria of 2 months for water, sediment, and soil and 2 days for air will include a better representative sample of chemicals that persist in the environment. Therefore, EPA used a half-life criterion of 2 months for water, sediment, and soil and a half-life of 2 days for air for the purposes of determining under EPCRA section 313 whether a toxic chemical is persistent in the environment. Under these criteria, if a toxic chemical meets any one of the media-specific criteria, it is considered to be persistent." Since this rule is targeting chemicals for "ban, restriction, or phase-out" it would seem that the persistence criteria should be similar to those programs with similar regulatory goals referenced above rather than the TRI criteria.*
>
> *The issue is particularly important with soil and sediment because of actual bioavailability. The methods used to determine half-lives in these media are those required to extract all of the residue from the soil or sediment. The procedures necessary are determined using radioactive material and may include such things as boiling with nitric acid. This rule has no place for expert judgment as to whether chemicals are actually available to target organisms.* ***(Diana Graham, p. 1 of written comments on November 10, 2004 draft rule distributed for review by the PBT Rule Advisory Committee)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the approaches used by the other federal and international programs to address PBT chemicals. Programs have been developed for a wide range of purposes using a several different sets of evaluation criteria. Given the variety of program goals, methods and criteria, Ecology concluded that it would be impossible to achieve absolute consistency with every single one of these other approaches. For example, several international programs have identified Lindane as a PBT chemical while the Washington Legislature has directed Ecology not to include registered pesticides on the PBT list.

However, Ecology has made an effort to promote consistency and believes that the approach used to develop the PBT List is generally consistent with approaches being used by other states, EPA and various international organizations. Specifically:

- General Framework*:* The general framework being used by Ecology to identify PBT chemicals is similar to those being used by other programs and agencies. Specifically, Ecology has chosen to focus on chemicals that are persistent, bioaccumulative, and toxic. This is consistent with all of the other federal and international programs reviewed by Ecology (see Table 1).
- Criteria for Identifying PBT Chemicals*:* As shown in Table 1, other federal and international agencies have developed PBT criteria. In general, the criteria used to develop the PBT List fall within the range of PBT criteria being used by other programs to evaluate persistence, bioaccumulation, and toxicity. The similarities and differences between the PBT criteria in WAC 173-333-320 and criteria used by other agencies are discussed in Chapter 5 (Issues 5-20 through 5-26).
- Range of Chemicals*:* The range of chemicals being considered by Ecology is similar to the range of PBT chemicals being considered by other programs and agencies. The vast majority of chemicals on the proposed PBT List are included on one or more other PBT list or being considered for inclusion on one or more other lists.

Table 1
Comparison of PBT Criteria used by Washington and Federal and International Programs

Agreement/Organization	Persistence	Bioaccumulation	Toxicity	Long-Range Transport	Protection Goals & Risk Management
Washington Proposed PBT Rule	Half life in water, sediment, soil > 60 days	BAF/BCF > 1000 or pKow > 5	Carcinogen, developmental or reproductive toxicant or neurotoxicant; or reference dose < 0.003 mg/kg/day; or chronic NOEC < 0.1 mg/L or acute NOEC < 1.0 mg/L	Not applicable	Reduce and phase-out uses, releases and exposures
United States/Canada					
EPA – Water Quality Criteria (1995)	Half life in water, sediment or biota > 56 days	BAF > 1000	Potential to cause adverse effects.	Not applicable.	
Great Lakes Bi-National Toxics Strategy (GLNPO, 1997)	Half life > 56 days (high), 7-56 days (moderate) and < 7 days (low)	BAF > 5000 (high); 1000 – 5000 (moderate); and < 1000 (low)	Substances that appear on one or more existing toxic substance lists.	Not applicable.	
EPA – National PBT Strategy (EPA, 1998a)	Half life > 56 days (high), 7-56 days (moderate) and < 7 days (low)	BAF > 5000 (high); 1000 – 5000 (moderate); and < 1000 (low)	Substances that appear on one or more existing toxic substance lists.	Not applicable.	
EPA – Waste Minimization Program (1998b)	Regional half life > 580 hrs (high); 140 – 580 hrs (medium); and < 140 days (low)	BAF/BCF > 1000 (high); 250 – 1000 (medium); and < 250 (low)	Potential to cause cancer, non-cancer and ecological effects.	Not applicable.	
EPA – Toxics Release Inventory (EPA, 1999a)	Half life in water, sediment, soil > 2 months; air > 5 days	BAF/BCF > 1000	Potential to cause cancer, non-cancer and ecological effects.	Not applicable.	Reporting required for releases. (lower reporting thresholds for PBT chemicals)
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – New Chemicals Policy	Half life in water, sediment, soil > 2 months; air > 5 days	BAF/BCF > 1000	Toxicity data based on level of risk.	Not applicable.	Testing and release control required.
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – Presumption of Ban	Half life in water, sediment, soil > 6 months	BAF/BCF > 5000	Toxicity data based on level of risk.	Not applicable	Commercialization denied unless testing justifies removing from "high risk concern" category.
EPA PBT Profiler	Half-life in water, soil and sediments > 2 months (persistent) or > 6 months (very persistent)	BCF > 1000 (Bioaccumulative) or > 5000 (Very Bioaccumulative)	Fish Chronic Toxicity Value (ChV) < 0.1 mg/L	Not applicable	Screening tool.

Criteria used to identify candidates for bans, phaseouts, or reductions (OME, 1993)	Half life > 2 days air; 6 months water or soil; or 1 year sediment.	BAF/BCF > 5000 or LogKow > 5	Acute and chronic (including toxicity of breakdown products)	Not applicable.	
Environment Canada (1994) – Accelerated Reduction/ Elimination of Toxics (ARET)	Environmental half life > 50 days.	BCF > 500 (Substances with BCF between 250 and 500 flagged for data collection)	Evaluation to produce normalized toxicity score (NTS). NTS > 40 (Max=60)	Not applicable.	
Canada Toxics Substances Management Programme	Half life in air (> 2 days); water or soil (> 6 months); sediments (> 1 year)	BAF/BCF > 5000	Toxicity determined by Canadian EPA	Not applicable.	Risk assessment; if toxic and P &B and primarily anthropogenic – then virtual elimination
International					
UN-ECE POPs Protocol	Half life in water (> 2 months); soil (> 6 months); sediments (> 6 months).	BAF/BCF > 5000 or Log Kow > 5	Potential to adversely affect human health and/or environment.	Vapour pressure < 1000 Pa and half-life in air > 2 days or monitoring data in remote areas	Control, reduce or eliminate discharges, emissions and losses of POPs.
Stockholm Convention	Half life in water (> 2 months); soil (> 6 months); sediments (> 6 months).	BAF/BCF > 5000 or Log Kow > 4 or 5; evidence that substance with lower BCF /BAF is of concern or monitoring indicates concern.	Chronic toxicity or ecotoxicity data indicate a potential for damage human health or the environment due to long-range transport.	Measured levels far from source or monitoring data in remote areas or multi-media modeling evidence or half-life in air > 2 days.	Objective is to protect human health and the environment. Reduce or eliminate releases.
European Union PBT Criteria	Half life in marine water (> 60 days); freshwater (> 40 days); marine sediments (> 180 days); freshwater sediments (> 120 days)	BCF > 2000	Chronic NOEC < 0.01 mg/L or carcinogen, mutagen or reproductive toxicant (CMR) category 1 or 2 or endocrine disrupting effects.	Not applicable.	No risk assessment based on PEC/PNEC ratio. Source inventory and emission reduction w/o risk assessment.
European Union vPBT Criteria	Half life in marine or fresh water (> 60 days); or marine or freshwater sediments (> 180 days)	BCF > 5000	Not applicable	Not applicable	Phase out or ban (may authorize production as intermediate in closed system)
Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)	Half life > 50 days	BCF > 500 or pKow > 4	Acute L(E)C50 < 1.0 mg/L or NOEC < 0.1 mg/L or CMR or chronic toxicity	Not applicable	

Issue 2-6: What is the relationship between the PBT rule and other Ecology programs?

Proposed Rule

The proposed PBT rules published in June 2005 and October 2005 included the following statement:

> *....This chapter establishes a process that Ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations."*

Public Comments and Concerns

The Northwest Pulp and Paper Association recommended that Ecology view the rule as a supplement to existing regulatory programs:

> ***The rules should be viewed as a supplement to Washington's existing regulatory regime and narrowly focus on PBT issues that result from gaps; the PBT program should not be an over-arching umbrella program. ....****The concept of the PBT rules as supplementary to, and designed to enhance, actions taken under other programs is reflected in the introductory section of the proposed rules and was robustly discussed in the advisory committee process. NWPPA continues to endorse this approach.* ***(Llewellyn Matthews, p. 4 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that the chapter is designed to enhance actions being taken under other environmental programs. Indeed, existing environmental programs will serve as important vehicles for implementing measures to reduce and phase-out PBT uses, releases and exposures. Ecology believes that one of the underlying rule objectives is to promote more integrated approaches (e.g. multi-media, multi-agency and multi-pollutant) for addressing PBT chemicals. Consequently, existing programs serve as a baseline for evaluating the need for enhanced actions for particular PBT uses and releases.

Chapter 3 General Provisions (Part I)

3.1. Introduction (WAC 173-333-100)

Issue 3-1: <u>What is the appropriate environmental goal for actions to address PBTs?</u>

Proposed Rule

The Introduction (WAC 173-333-100) in the proposed PBT rule published in June 2005 included the following goal statement:

> *"The goal of this chapter is to reduce and eliminate the uses and releases of PBTs in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. This chapter establishes a process that Ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations."*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following goal statement:

> *The goal of this chapter is to reduce and phase-out PBT uses, releases and exposures in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. These factors include environmental and human health benefits, economic and social costs, technical feasibility, availability of safer substitutes, and consistency with other regulatory requirements. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.*

Public Comments and Concerns

Several organizations and individuals expressed opinions on whether the goal should include the concept of "phasing-out" or "eliminating" PBT uses, releases and exposures. Several groups expressed a preference for one of the other of these terms. For example:

> *Establish that the goal of chemical action plans is to eliminate the toxic chemical. Because chemical action plans are only developed for those chemicals where a problem has been identified, it is crucial that the goal of the plans is to eliminate the chemical for the program to be effective (**Pam Tazioli et. al., p. 2 of July 2005 written comments**)*
>
> ***<u>Clarify the Goal of the Program is to Eliminate PBTs</u>**....As stated in the Strategy several times, the goal of the PBT program is to reduce and where possible eliminate the use and production of PBTs **(Ivy Sager Rosenthal, p. 2 of July 2005 written comments)***
>
> *We would like to reiterate from our previous comments that a strong rule should encompass a goal to phase out persistent toxic chemicals, and be based upon a framework of prevention.... **(Nancy Dickeman, p. 1 of November 2005 written comments)***
>
> *Substituting "phasing out" in place of "eliminating" and adding "feasibility" to the goal of the rule is important. Phasing out implies an elimination over time and represents a reasonable expectation of what is feasible for a company who may be required to discontinue using or install additional pollution prevention or other controls. The "phasing-out" of a chemical is more conducive to*

allowing for the testing of alternatives prior to discontinuing the production or use of a listed chemical. Also, many PBTs are naturally occurring substances and can not be eliminated ***(Grant Nelson, p. 2 of July 2005 written comments****)*

Several organizations and individuals expressed opinions on whether the goal should include the concepts of "reducing" or "minimizing" PBT uses, releases and exposures. Several groups expressed a preference for one of the other of these terms. For example:

Generally speaking, throughout the rule the word "reduce" should be substituted in place of the word "minimize". "Reducing" uses and releases and threats to human health and the environment is a more realistic expectation of what is feasible. During the stakeholder process, committee members agreed that the PBT rule should result in a reduction of threats to human health and the environment. The word "minimize" however, establishes a level of reduction or could mandate an action "at any cost". This is an unrealistic expectation. ***(Grant Nelson, pp. 1-2 of July 2005 written comments)***

Several organizations and individuals recommended that Ecology incorporate the concept of managing uses, releases and exposures into the goal statement. For example:

....With the goals of managing, reducing, or eliminating the chemical, it is important to recognize that eliminating exposure to a particular chemical is not always possible because significant natural sources, or those outside the state, may contribute to a chemical's presence (e.g., dioxins/furans). Ecology's "reduce, manage or eliminate" approach allows for feasible policy options that will result in focused, achievable CAPs to address PBT chemicals considered to pose risks to the State of Washington. ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

Substituting "phasing out" in place of "eliminating" and adding "feasibility" to the goal of the rule is important. Phasing out implies an elimination over time and represents a reasonable expectation of what is feasible for a company who may be required to discontinue using or install additional pollution prevention or other controls. The "phasing-out" of a chemical is more conducive to allowing for the testing of alternatives prior to discontinuing the production or use of a listed chemical. Also, many PBTs are naturally occurring substances and can not be eliminated ***(Grant Nelson, p. 2 of July 2005 written comments)***

Finally, several organizations recommended that Ecology avoid using slightly different phrases for similar terms because this was confusing and increased the potential for multiple interpretations. For example:

Different phrases are used throughout the draft regulation to describe the fundamental objective of reducing the exposure of PBTs to humans, plants and animals. .... In some instances the policy intent and regulatory context requires slightly different action phrases or words. Where possible, standard language should be used to avoid variable interpretations of the regulation. We generally prefer "reducing exposure" to phrases using "threat," "harm" or "impact." "Phase out" seems better than "eliminate." ***(Ken Johnson, p. of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and continues to believe Ecology's rationale for this decision includes the following:

- Executive Order**:** The Executive Order includes the statement "...I, Gary Locke, Governor of the state of Washington, declare my commitment to phasing out persistent, toxic pollution in Washington State..."
- Nature of the Problem Posed by PBTs**:** The nature of PBT sources, releases and environmental behavior argue for a goal that includes the concepts of phasing out or eliminating uses and releases. Specifically, programs have often been unsuccessful in

managing the numerous small PBT sources or uses that result in the release of low or undetectable concentrations of chemicals that can bioaccumulate in the food chain to levels that threaten health and ecosystems.

- Other PBT Strategies: All major national and international PBT strategies include some type of goal statement. Many of these goal statements include the concepts of phasing out and eliminating uses and releases.
- Practical Considerations: State, federal and international efforts are based on the premise that new and more effective approaches are needed to address this class of chemicals. Ecology believes that the goal statement will help promote greater scrutiny of alternatives to the status quo during the CAP process. However, Ecology also believes that the goal statement should acknowledge that there are several real-world considerations that will influence whether, how and when that goal can be achieved **(See Issue 3-2).**

Issue 3-2: What is the relationship between the environmental goal and the decision-making processes established in the PBT rule?

Proposed Rule

The Introduction (WAC 173-333-100) in the June 2005 proposed PBT rule included the following statement:

> *"The goal of this chapter is to reduce and eliminate the uses and releases of PBTs in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. This chapter establishes a process that Ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations."*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following goal statement:

> *The goal of this chapter is to reduce and phase-out PBT uses, releases and exposures in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. These factors include environmental and human health benefits, economic and social costs, technical feasibility, availability of safer substitutes, and consistency with other regulatory requirements. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.*

Public Comments and Concerns

The Washington Toxics Coalition expressed concerns that the proposed goal does not reflect the goals and purpose of the proposed Ecology PBT Strategy and specifically recommended that Ecology remove language that suggests indicates that all uses and releases of all of the chemicals on the PBT list will not be reduced and phased-out:

> *Better Define Goals and Purpose of PBT Program and Eliminate WAC 173-333-300 (a) We are extremely concerned that the current draft rule does not reflect the goals and purpose of the PBT program as outlined in the 2000 Strategy to Continually Reduce and Eliminate Persistent Bioaccumulative Toxins in Washington State (Strategy). To demonstrate how much the rule has departed from the Strategy, we have attached a comparison of the Strategy and the proposed rule. As you will see,*

several important pieces of the Strategy have been dropped from the rule, including the goal of significant reductions in PBTs by 2020 and the commitment to reduce and phase out all of the chemicals on the PBT list. While we recognize that it may not make sense to include every piece of the Strategy in the rule, we firmly believe that the overarching goal of reducing and phasing out ALL of the chemicals on the PBT list must clearly be reflected in the goal and purpose of the rule. WAC 173-333-100 must be amended to eliminate the language indicating the goal of phase out may not be possible.... ***(Ivy Sager-Rosenthal, p. 2 of November 2005 written comments)***

Several organizations recommended that Ecology frame the goal statement in terms of establishing a process. For example:

*Consistent with Ecology's position that the PBT rule is a "procedural rule", the third paragraph of 173-333-100 should make clear that the goal of this chapter is to "establish a process".... (****Grant Nelson, p. 2 of July 2005 written comments****)* [5]

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided not to revise the proposed rule language. Specifically, Ecology believes the proposed rule language captures the correct relationship between the environmental goal and the decision-making processes in other parts of the rule. Ecology believes the inserting the phrase "establish a process" would be redundant and serve to blur the distinction between the stated environmental goal and those processes.

Ecology believes that the phrase "...Ecology recognizes that many factors will influence whether and when this goal can be attained..." is consistent with the phased decision-making process established in the rule. Specifically, the proposed PBT rule establishes a decision-making process for evaluating what actions should be taken to reduce and phase-out PBT uses, releases and exposures. Identification of PBTs is the first step in that process. This represents a preliminary determination that actions are needed with a preference being given to actions that achieve the overall goal. However, that presumption can be overcome at later stages in the decision-making as additional factors are considered as part of the processes for selecting and preparing chemical action plans. As noted above (Issue 2-4), Ecology's proposed PBT strategy envisioned a similar decision-making process.

Issue 3-3: Does the Introduction to the PBT rule prematurely determine that PBTs pose a threat to human health and the environment?

Proposed Rule

The opening paragraphs in the proposed PBT rule published in June 2005 included the following statements:

[5] AWB provided the following suggested language to illustrate how the concept of "feasibility" could be integrated into the goal statement: *The goal of this chapter is to establish a process to manage, and where feasible, reduce or phase-out the uses and releases of PBTs in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.*

WAC 173-333-100 Introduction. *Persistent, bioaccumulative toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, can build up in the food chain, and can be transported long distances and readily move between air, land and water media.*

Because of the unique threat that these PBTs pose, special attention is necessary to identify actions that will minimize or eliminate threats to human health and the environment. While ecology addresses PBTs through existing regulatory and nonregulatory programs, there remains a need for multimedia, cross-program measures that will reduce and eliminate releases and uses of PBTs over time

Public Comments and Concerns

Several organizations recommended that Ecology frame the goal statement in terms of establishing a process. For example:

WAC 173-333-100 Introduction and -110 What is the purpose of this chapter – These sections prematurely conclude that PBTs are, in fact, threatening human health and the environment in Washington. The PBT chemicals listed in the WAC 173-333-320 process will, by definition, have characteristics which threaten HH/E. However, it is not until the Chemical Action Plan development activities in WAC 173-333-410 and -420 are underway that information on the uses, releases, levels and, ostensibly, the HH/E impacts in Washington, are even examined.

WAC 173-333-100 and -110 should be amended to acknowledge this reality. This can be accomplished by adding the word "may" at appropriate locations in sections -100 and -110; i.e., "are chemicals that may pose a unique threat…", "Because of the unique threat that these PBTs may pose,…", "to identify persistent bioaccumulative toxins that may pose human health…". ***(Ken Johnson, p. 1 of November 2005 written comments)***

WAC 173-333-100 Introduction. *PBTs may pose a threat to human health, but not necessarily. This is especially true if their sources, releases and exposure pathways are managed, reduced or when appropriate and feasible, phased out. AWB's suggested changes to this section reflect more accurately this reality and the stated purpose of the PBT rule.* ***(Grant Nelson, p. 1 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided not to revise the proposed language. The introductory paragraph is referring to the broad category of chemicals that meet the definition of persistent bioaccumulative toxins – not individual chemicals that fall within the category. Ecology believes that the proposed language is consistent with current scientific information and statements from federal and international environmental agencies and/or expert scientific panels. For example:

*...More recently, scientists and public leaders have reached a general consensus that the presence of environmentally persistent, bioaccumulative contaminants is a serious environmental threat to the Great Lakes Basin Ecosystem... (****Environmental Protection Agency, Preamble to the Final Water Quality Guidance for the Great Lakes System; Final Rule. Published in the March 23, 1995 Federal Register, 60 FR 15366 at 15367****)*

The U.S. Environmental Protection Agency (EPA) has developed this draft strategy to overcome the remaining challenges in addressing priority PBT pollutants. These pollutants pose risks because they are toxic, persist in ecosystems, and accumulate in fish and up the food chain. The PBT challenges remaining stem from the pollutants' ability to travel long distances, to transfer rather easily among air, water, and land, and to linger for generations, making EPA's traditional single-statute

approaches less than the full solution to reducing risks from PBTs. Due to a number of adverse health and ecological effects linked to PBT pollutants -- especially mercury, PCBs, and dioxins -- it is key for EPA to aim for further reductions in PBT risks. The fetus and child are especially vulnerable. EPA is committing, through this strategy, to create an enduring cross-office system that will address the cross-media issues associated with priority PBT pollutants. ***(Environmental Protection Agency (1998), Page 1 of the Executive Summary of EPA's Multi-media Strategy for Priority Persistent, Bioaccumulative and Toxic (PBT) Pollutants)***

The Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs) POPs are chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to humans and wildlife. POPs circulate globally and can cause damage wherever they travel. In implementing the Convention, Governments will take measures to eliminate or reduce the release of POPs into the environment. ***(Background Statement on the website for the Stockholm Convention on Persistent Organic Pollutants (POPs)***

Issue 3-4: Should Ecology refer to long range transport when discussing the characteristics of persistent, bioaccumulative toxins?

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following introductory sentences:

WAC 173-333-100 Introduction. *Persistent, bioaccumulative and toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, and can build up in the food chain.*

Public Comments and Concerns

The Bromine Science and Environmental Forum stated that the introductory sentences are inconsistent with many definitions of PBTs:

WAC 173-333-100 Introduction. *Persistent, bioaccumulative and toxic substances (PBTs) are chemicals that may pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, and can build up in the food chain.[The definition of PBT – including the definition set forth by the U.S. Environmental Protection Agency – does not typically include the long range transport or ready movement between media and the criteria set for PBT substances in this document do not include that for long range transport or movement between media. The generally accepted definition of PBT only includes toxicity to and bioaccumulation in aquatic organisms. We suggest the Department of Ecology reconsider the proposed criteria.]* ***(Raymond Dawson and David Sanders, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that the EPA or Ecology definitions for PBTs do not explicitly include the concepts of long-range transport and cross-media transfer. However, the opening paragraph in WAC 173-333-100 represents a problem statement – not a definition. Ecology believes that part of the challenge posed by PBTs stems from their ability to travel long distance and move between different environmental media and, consequently, Ecology believes it is appropriate to refer to these properties in this section of the rule. As noted above, EPA has included similar statements on long range transport and cross-media transfer in the Executive Summary of the

document "EPA's Multi-media Strategy for Priority Persistent, Bioaccumulative and Toxic (PBT) Pollutants".

3.2. What is the purpose of this chapter (WAC 173-333-110)

Issue 3-5: Should Ecology use the term persistence, bioaccumulative toxins?

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following language (WAC 173-333-110(1)):

> *Establish criteria ecology will use to identify persistent bioaccumulative toxins that pose human health or environmental threats in Washington state;*

Public Comments and Concerns

The Bromine Science and Environmental Forum recommended that Ecology replace the word "toxins" with "toxicants" when referring to PBT chemicals in this section and other parts of the rule:

> *[NOTE: the term 'toxins' is defined as substances which cause adverse effects and which are produced by biological systems; e.g. venoms, algal secondary metabolites, bacterial or fungal toxins such as botulinum or aflatoxin, etc.]**(Raymond Dawson and David Sanders, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment. While the BSEF raises a valid concern on terminology, Ecology decided not to modify the rule language in order to avoid inconsistencies with the directive from the Washington Legislature and earlier Ecology documents. When reviewing other state, federal and international programs, Ecology found that agencies are using a wide range of terms to describe PBTs. With respect to this issue, several other organizations refer to toxins instead of "toxicants" or "persistent, bioaccumulative and toxic (PBT) chemicals"[6],[7],[8],[9].

3.3. Applicability (WAC 173-333-120)

Several organizations and individuals referred to this section when providing comments on Ecology's decision to adopt the PBT rule as a "procedural" rule (See Issue 2-1). However, Ecology did not receive comments on the proposed language in WAC 173-333-120.

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[6] Great Lakes Regional Pollution Prevention Roundtable. 2005 Available at: http://www.glrppr.org/contacts/gltopichub.cfm?sectorid=57#contacts. Viewed on December 27, 2005.

[7] ***California State PTA - Resolution on Persistent Bioaccumulative Toxins (PBTs), May 2002. Available at: http://www.mindfully.org/Pesticide/2002/CA-PTA-PBT-ResolutionMay02.htm. Viewed on December 27, 2005.***

[8] Utah Department of Environmental Quality, 2004. Persistent Bioaccumulative Toxins (PBTs) Fact Sheet. Available at: http://www.deq.utah.gov/issues/Mercury/PBTs.htm. Viewed on December 27, 2005.

[9] Wisconsin Department of Natural Resources, 2005. Available at: http://www.dnr.state.wi.us/org/water/greatlakes/priorities/toxins.html. Viewed on December, 27, 2005.

3.4. Exemptions to the PBT list (WAC 173-333-130)

Issue 3-6: Should Ecology include registered pesticides and regulated fertilizers on the PBT List?

Proposed Rule

Ecology proposed that the Department would not include registered pesticides and regulated fertilizers on the PBT list:

> ***WAC 173-333-130 Exemptions to the PBT list.*** *Any pesticide with a valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter.*

Public Comments and Concerns

Several organizations and individuals expressed support of Ecology's proposal to exempt registered pesticides and regulated fertilizers. For example:

> *AWB appreciates Ecology's exemption of EPA registered pesticides under the Federal Insecticide, Fungicide and Rodenticide Act and fertilizers regulated under the Washington Fertilizer Act from the PBT List.* ***(Grant Nelson, p. 2 of July 2005 written comments)***

However, many organizations and individuals recommended that Ecology remove this section from the rule. For example:

> *The PBT program was established because current regulatory approaches are not working. It is not scientifically defensible to exclude pesticides and fertilizers from a program that has a goal of eliminating PBT chemicals. Science, not politics, should determine what qualifies as a PBT. We urge Ecology to include pesticides and fertilizers on the list.*
>
> *If Ecology should decide to include the exemption, we ask that Ecology change the current language to reflect that pesticides that lose their registration after the pesticide that was registered on the date of the rule's adoption. This would mean that regardless of whether a pesticide's registration becomes invalid at a later date, the pesticide would remain exempt. The intent of the exemption, we believe, was to only exempt those pesticides with an ongoing valid registration, rather than to provide a never-ending exemption for all pesticides validly registered at the time of the rule adoption.* ***(Ivy Sager-Rosenthal, p. 3 of July 2005 written comments)***
>
> *Also, it is an outrage that pesticides and fertilizers have been exempted from the rule. I have lots of lead and mercury in my cells. These elements are both neurologically damaging. I vote, and the companies whose products have received these exemptions do not. Ecology should request immediately that the Legislature remove the exemption for these dangerous chemicals so that they can be addressed as part of the PBT Program.* ***(Allisa Berteig, p.1 of July written comments)***[10]
>
> *Comment 2, WAC 173-333-130. Delete this section. Any pesticide or fertilizer should be subject to the same scrutiny as other chemicals for consideration by Ecology as PBTs. PBT screening of pesticides and fertilizers is critical for Ecology's mission, given the potential of widespread pesticide use directly into the environment and in food crops. For example, Lindane meets the PBT criteria and is commonly used on seeds and in products for treatment of lice or scabies in humans.* ***(Dave Galvin, p. 2 of July 2005 written comments)***

[10] Ecology received 371 e-mails recommending that the Department incorporate the precautionary principle into the PBT rule.

Ecology's Review and Response to Public Comments

Ecology has reviewed these comments and decided not to remove this section from the PBT rule since the Washington Legislature directed Ecology to exempt registered pesticides and regulated fertilizers. However, Ecology did elect to insert the word "currently" into the first sentence in order to clarify that if EPA cancels or suspends the registration for a pesticide the exemption no longer applies. Under those circumstances, a formerly-registered pesticide could be included on the PBT list if it meets or exceeds the PBT criteria in WAC 173-333-320. The final rule includes the following language:

> *"Any pesticide with a **currently** valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter."*

Issue 3-7: Should Ecology include chemicals on the PBT list if they are regulated under the Toxics Substances Control Act?

Proposed Rule

Ecology proposed that the Department would not include registered pesticides and regulated fertilizers on the PBT list:

> ***WAC 173-333-130 Exemptions to the PBT list.*** *Any pesticide with a valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter.*

Public Comments and Concerns

The Bromine Science and Environmental Forum recommended that Ecology consider exempting chemicals regulated under the Toxic Substances Control Act.

> *If the Department intends to exempt substances that are currently regulated under other statutes, then consideration should be given to extending this exemption to industrial chemicals that are regulated under the U.S. Toxic Substances Control Act (TSCA). The Department of Ecology should explain its concerns with TSCA and why it believes additional measures must be taken at the state level.* ***(Raymond Dawson and David Sanders, November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and decided not to extend the exemption to chemicals regulated under the U.S. Toxics Substances Control Act (TSCA) because:

- EPA may establish a wide variety of regulations under TSCA ranging from information collection to bans on certain chemical uses. A blanket exemption fails to take into account the different purposes and scope of EPA's regulatory efforts under TSCA.
- Such an approach is inconsistent with EPA's PBT programs. For example, EPA has included PCBs on initial PBT list and has prepared a chemical action plan for this chemical group.
- Ecology believes that the proposed PBT rule provides the flexibility to address Washington-specific issues in coordination with federal actions under TSCA.

3.5. Administrative Principles (WAC 173-333-140)

Issue 3-8: Should the PBT rule include a statement on the precautionary principle and, if so, what should that statement say?

Proposed Rule

The Precautionary Principle is a decision-making approach that is applicable to situations where (1) we suspect actions may threaten human health and the environment and (2) scientific uncertainty may otherwise prevent people or organizations from taking cost-effective actions to prevent harm. For example, the Rio Treaty states "...[w]hen there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation..." The PBT Rule Advisory Committee discussed the application of this principle to the PBT issue and whether Ecology should include a statement in the PBT rule.

Based on those discussions, Ecology decided not to include an explicit reference to the precautionary principle in the PBT rule. However, the concept of "precaution" was incorporated into the second sentence of WAC 173-333-140(1). The proposed PBT rules published in June and October 2005 included the following statement:

> *(1)* ***Scientific information.*** *Ecology will base decisions on PBTs on sound public policy and credible scientific information. However, ecology believes that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.*

Public Comments and Concerns

Ecology received numerous comments on role of scientific information in identifying PBT chemicals and developing recommendations for reducing and phasing-out PBT uses, releases and exposures. Those comments are summarized under Issue 2-3 along with Ecology's review and response.

Many organizations and individuals expressed support for Ecology's statement "...that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment..." For example:

> *The Local Hazardous Waste Management Program in King County supports the concept expressed in this proposed rule "...that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment* ***(Dave Galvin, p. 3 of July written comments)***

> *We support WAC 173-333-140 (1) Scientific information. We believe that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment....* ***(John Dohrmann, p. 1 of July 2005 written comments)***

Many of the organizations and individuals expressing support for the second sentence in WAC 173-333-140(1) also urged Ecology to incorporate the precautionary principle into the PBT rule. For example:

> *...Further, we believe that whenever possible the precautionary principle should be invoked to protect Puget Sound's marine resources. Specifically, we ask you to consider incorporating the precautionary principle approach into WAC 173-333-420 (1)(f).* ***(John Dohrmann, p. 1 of July 2005 written comments)***

Incorporate the precautionary principle ***(Heather Trim, p. 2 of July 2005 written comments).***

Specifically incorporate the precautionary principle, which calls for taking action to prevent harm when the best scientific evidence available shows harm may occur. ***(Allisa Berteig, p.1 of July written comments)***[11]

However, several organizations expressed the opinion that the second sentence in subsection (1) was unnecessary and potentially in conflict with a science-based approach. For example:

WAC 173-333-140(1) Scientific Information *– The second sentence in this subsection announcing a decision-making bias based on a precautionary principle is unnecessary and should be removed.....This regulation will be useful, credible, accepted and actively supported primarily because it has a science-based foundation. Physical, chemical and biological criteria will be defined in rule to identify PBTs. The CAP development process will reveal the effective and reasonable measures that can be taken to reduce human health and environmental exposures. This logical and transparent approach would be undercut should Ecology reserve to itself an ability to impose a decision based on inconclusive science.* ***(Ken Johnson, p. 2 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that "precaution" is appropriate feature of environmental regulation (in general) and the PBT rule (in particular). Consequently, Ecology decided not to remove or modify the language in WAC 173-333-140(1). As discussed under Issue 2-3, Ecology's position on this issue is based on the following considerations:

- Precaution in the face of uncertain risks is a key feature in most state and federal laws: Precautionary concepts are embedded in many state and federal health, safety and environmental laws. The vast majority of state and federal environmental laws are based on the principle that in order to protect human health and environment it will often be necessary to take action before scientists have gained a complete understanding of how a chemical affects people and the environment. In some cases, the application of precaution in response to scientific uncertainty is explicit (e.g. use of safety factors, use of new scientific information under Model Toxics Control Act, evaluation of alternatives under the Growth Management Act, etc). In other cases, the application is more implicit (e.g. anti-degradation provisions in state water quality laws).

- Precaution is the face of uncertain risks is inherent in everyday life. In his review of the precautionary principle, Weiner (2002) made the following observations:

  In the face of uncertainty about a risk, we often take precautionary measures, such as posting warning labels, driving safely, cooking foods to kill microbes, and saving money for future needs. Yet we never know for sure if these precautionary measures are effective (since, if they are successful, they result in the absence of an adverse outcome that might not have occurred anyway), nor do we know whether they are directed at the most important risks. At the same time, we rarely forego beneficial activities entirely just because they might be risky; we do not forego eating for fear of choking (but we do chew more carefully), no do we forego crossing the street even though there is an uncertain probability of death (but we do use crosswalks and look both ways). We choose prudent precautions that are proportionate to the expected risk, the cost of sacrifice, and the availability of alternatives. ***(Weiner, 2002, p. 1513)***

[11] Ecology received 371 e-mails recommending that the Department incorporate the precautionary principle into the PBT rule.

- Precaution in the face of uncertain risks is particularly important when dealing with irreversible risks with long latency periods: Some environmental risks have long latency periods. This was discussed by Weiner (2002):

> *Moreover, some risks are especially latent: Their adverse impacts will only occur a long time (perhaps many years) after the event that set the risk in motion. For example, a highway accident typically causes fatality (if at all) within seconds or minutes after the accident; but if there are any brain tumors caused by cell phone use, it might take years after the exposure to the cell phone before the tumors become manifest. The longer the latency period between cause and effect, then the earlier (relative to the adverse outcome) measures must be taken if they are to be effective in preventing the outcome. If we wait to observe the latent outcome, it can become too late to take preventive measures.* ***(Weiner, 2002, p. 1512)***

Ecology's decision not to incorporate an explicit reference to the precautionary principle in the PBT rule is based on two main considerations:

- Multiple Versions of the Precautionary Principle: The precautionary principle is not a monolithic concept. There are at least nineteen versions of the precautionary principles that have been adopted by state, federal and international agencies. As shown in Table 2, different versions of the precautionary principle may include different combinations of features. This creates the potential for confusion and multiple interpretations as people point to different versions of the precautionary principle as the appropriate version for Washington. Indeed, it is unclear which version of the precautionary principle members of the public were urging Ecology to adopt.

- Practical Implementation Guidance: Most of the current versions of the precautionary principle do not provide guidance on the practical implementation of the principle (e.g. how do you deal with a chemical that has benefits as well as risks?, do we apply the same level of precaution to the risks of substitutes?, etc.).

- Overall Rule Framework: The Seattle Precautionary Principle Working Group prepared "A Policy Framework for Adopting the Precautionary Principle"[12] that identifies five key components of the precautionary principle. Ecology believes that four of those components have been incorporated into the processes for identifying PBT chemicals and preparing chemical action plans. These four components are: (1) Taking anticipatory action to prevent harm in the face of scientific uncertainty[13]; (2) Exploring alternatives, including the alternative of "no-action"[14]; (3) Considering the full cost of environmental and health impacts over time; and (4) Increasing public participation in decision-making. The fifth component (shifting responsibility for providing evidence to proponents of an activity) is not a specific element of the PBT rule in that full implementation of this concept would require statutory revisions.

[12] Seattle Precautionary Principle Working Group. 2004. A Policy Framework for Adopting the Precautionary Principle. Submitted by the Seattle Precautionary Principle Working Group to the City of Seattle and King County for consideration as an amendment to the 2004 City and County comprehensive plans. January 2004.

[13] Ecology's statement on precaution in the face of uncertainty is similar to the statements in the Rio Treaty etc. (Column 1 of Table 2). The Seattle PP Working Group recommendations appear to more closely mirror the PP articulated in the Wingspread Statement (Column 2 of Table 2).

[14] The chemical action plan process provides a mechanism for evaluating alternative approaches for achieving the overall goal of reducing and phasing-out PBT uses, releases and exposures. This allows for the consideration of multiple risks and the potential impacts of the precautionary actions themselves. It is also important to note that "no action" alternative in the Seattle PP Working Group paper is similar to the phase-out alternative in the PBT rule.

Table 2: Features of Alternate Versions of Precautionary Principle (Based on Weiner, 2002; Ticknor, 2003)

	(Uncertainty does not justify inaction)	(Uncertain risks justify action)	(Uncertain risks justify prohibition)
Degree of Precaution	Where there are threats of serious or irreversible harm, lack of full scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation.	When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established.	The applicant or proponent of an activity or process or chemical needs to demonstrate to the satisfaction of the public and regulatory community that the environment and public health will be safe.
Type of Action to be Taken	Does not address the question of what action to take in the face of uncertain risks.	Some type of action (Type of action not specified)	Forbid the activity unless certain standard of proof met by proponent
Burden of Proof	"Innocent until proven guilty" Burden is initially on regulatory community to justify action and then to define action.	Guilty until proven innocent"	"Guilty until proven innocent" Burden is shifted to the party or entity that will benefit from the activity and that is most likely to have the information.
Standard of Proof	Highly Variable. Examples include: • Any level of risk (Delaney Clause) • Unreasonable risk (TSCA/FIFRA) • Significant risk (OSHA Benzene Case)	Highly Variable. Examples include: • Any level of risk (Delaney Clause) • Unreasonable risk (TSCA/FIFRA) • Significant risk (OSHA Benzene Case)	Highly Variable. Examples include: • Any level of risk (Delaney Clause) • Unreasonable risk (TSCA/FIFRA) • Significant risk (OSHA Benzene Case)
Proportionality	May include concept that precautionary actions must be "commensurate" with risks	May include concept that precautionary actions must be "commensurate" with risks	May include concept that precautionary actions must be "commensurate" with risks
Net benefits/multiple risks	May include concept of net benefits or maximizing benefits through consideration of multiple risks including risks associated with alternatives and/or substitutes	May include concept of net benefits or maximizing benefits through consideration of multiple risks including risks associated with alternatives and/or substitutes	May include concept of net benefits or maximizing benefits through consideration of multiple risks including risks associated with alternatives and/or substitutes
Exemptions	May provide exemptions for essential uses (CFC phase-out), multiple risks, disproportionate costs or net benefits.	May provide exemptions for essential uses (CFC phase-out), multiple risks, disproportionate costs or net benefits.	May provide exemptions for essential uses (CFC phase-out), multiple risks, disproportionate costs or net benefits.
Examples	Ethyl Corp vs. EPA court decision on leaded gasoline; Rio Declaration; European Commission statement on implementing the PP (EC, 2000)	Wingspread Statement	Delaney Clause

Issue 3-9: Should the PBT rule include a statement on coordination with federal agencies?

Proposed Rule

The proposed PBT rule published in June 2005 included the following provision (WAC 173-333-140(5)):

> *(5)* ***Coordination.*** *Ecology will coordinate with other state agencies and local governments, tribes, and interested parties in the development and implementation of CAPs and when revising the PBT list.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following language:

> *(5)* ***Coordination.*** *Ecology will coordinate with federal and state agencies and local governments, tribes, and interested parties in the development and implementation of CAPs and when revising the PBT list.*

Public Comments and Concerns

Numerous organizations and individuals stressed the importance of coordination with other organizations. Several organizations note that "federal" agencies were not identified in this subsection and recommended that Ecology add "federal" agencies to the list of entities identified in this subsection. For example:

> *Ecology should add "federal" agencies to its list of entities to coordinate the development and implementation of CAPs and when revising the PBT list.* ***(Grant Nelson, p. 2 of July 2005 written comments)***

> ***WAC 173-333-140(5) Coordination*** *– Adjust the sentence to read "Ecology will coordinate with federal, other state…"....Ecology should also be willing to coordinate with federal regulatory agencies on matters relating to PBT identification, and CAP development and implementation.****(Ken Johnson, p. of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that it will be important to coordinate implementation of the PBT rule with federal agencies and has identified federal agencies in this subsection.

Chapter 4 Definitions (Part II)

Issue 4-1: *Application of the Definitions*

Proposed Rule

The proposed PBT rules published in June and October 2005 did not include an explicit statement on the application of the definitions included in the PBT rule.

Public Comments and Concerns

The Association of Washington Business recommended that Ecology include a phrase in WAC 173-333-200 that clearly states that the definitions are limited to the implementation of the PBT rule:

> ***WAC 173-333-200 Definitions.*** *The definitions section is intended to help define and clarify terms within the PBT rule and should be limited only to the rule to ensure the definitions do not conflict with other state laws and regulations.* ***(Grant Nelson, p. 1 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comment on this issue and decided to include a phrase at the beginning of WAC 173-333-200:

> *For the purposes of this chapter, the following definitions shall apply:*

Ecology believes this phrase addresses the concerns about the potential use of the definitions for other purposes. The revised language is similar to language included in the definition sections of other state and federal rules (e.g. Model Toxics Control Act Cleanup Regulation).

Issue 4-2: *Bioaccumulation*

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> *"**Bioaccumulation**" means the process by which substances increase in concentration in living organisms as they take in contaminated air, water, soil, sediment or food because the substances are very slowly metabolized or excreted.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology modify the proposed definition by inserting the phrase "with repeated exposure":

> *"Bioaccumulation" means the process by which substances, with repeated exposure, increase in concentration in living organisms as they take in contaminated air, water, soil, sediment or food because the substances are very slowly metabolized or excreted.* ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comment on this issue and decided not to make the suggested change because (1) the proposed definition was developed based on comments and suggestions from the PBT Rule Advisory Committee and appeared to have broad support among committee members;

(2) the proposed definition is consistent with definitions used by EPA programs; and (3) Ecology believes the concept of repeated exposure that is inherent in the methods used to develop bioaccumulation factors and bioconcentration factors which are based on assumptions of steady-state conditions and repeated exposure.

As background, Ecology reviewed the definitions used by several EPA programs during the PBT Rule Advisory Committee process. For example:

- **EPA's Glossary of Environmental Terms** defines "**bioaccumulants**" as "...[s]ubstances that increase in concentration in living organisms as they take in contaminated air, water, or food because the substances are very slowly metabolized or excreted."
- **EPA's Office of Pollution Prevention and Toxics Substances (OPPTS)** defines "**bioaccumulation**" as "...the process by which organisms may accumulate chemical substances in their bodies. The term refers to both uptake of chemicals from water (bioconcentration) and from ingested food and sediment residues.
- **EPA's Office of Water** defines "**bioaccumulation**" as "...[t]he net accumulation of a chemical by an aquatic organism as a result of uptake from all environmental sources.
- **McGeer et al. (2004)**[15] define "**bioaccumulation**" as the net accumulation of a metal in a tissue of interest or a whole organism that results from exposure. ...Bioaccumulation that occurs under steady-state conditions (i.e., where accumulation remains relatively constant because uptake is offset by elimination) is often of primary concern in risk assessments.

Ecology included a definition for bioaccumulation in the initial draft rule distributed to the PBT Rule Advisory Committee on November 10, 2004 that synthesized elements of the above definitions. The Association of Washington Business (AWB) recommended that Ecology base the rule definition for this term on the definition included in EPA's Glossary of Environmental Terms. Ecology agreed with this recommendation and subsequent versions of the rule have included the AWB suggested language. As noted above, the proposed definition appeared to have broad support among committee members.

Issue 4-3: ***Bioaccumulation Factor***

Proposed Rule

The proposed PBT rule published in June and October 2005 included the following definition:

> ***"Bioaccumulation factor"*** *or* ***"BAF"*** *means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF is a measure of the extent to which the organism accumulates the chemical as a result of uptake through ingestion as well as contact from contaminated media, such as water.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology modify the proposed definition to read as follows:

[15] EPA has reviewed and discussed the concepts and definitions of bioaccumulation as part of their effort to develop a metals assessment framework. As of December 2005, EPA has not completed work on the framework. However, as part of the review process, EPA commissioned a series of issue papers that were finalized in August 2004. McGeer et al. evaluated issues related to bioavailability and bioaccumulation of metals and most of the concepts and definitions in the issue paper have been incorporated into the draft EPA metals assessment framework document.

> **"Bioaccumulation factor"** or **"BAF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF represents exposures/uptake via all routes, e.g. in the case of fish - food as well as water. ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

The North American Metals Council also recommended that Ecology modify the BAF definition in order to provide a clearer distinction between BAFs and BCFs:

> *The definitions of "Bioaccumulation factor" and "Bioconcentration factor" include identical first sentences, but these concepts are not the same. The words "including intake attributable to ingestion," should be added at the end of the first sentence of the definition of "Bioaccumulation factor."(**William Adams, p. 1 of Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revised the proposed definition because (1) the proposed definition was developed based on comments and suggestions from the PBT Rule Advisory Committee and appeared to have broad support among committee members; (2) the proposed definition is consistent with definitions used by EPA programs; and (3) Ecology believes that the proposed definition correctly incorporates the concept of multiple routes or pathways.

As background, Ecology reviewed definitions used by various EPA programs when discussing potential rule language with the PBT Rule Advisory Committee. For example:

- **EPA's Office of Water** defines "***bioaccumulation factor (BAF)***" as "...[t]he ratio (in liters per kilogram of tissue) of the concentration of a chemical in the tissue of an aquatic organism to its concentration in water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time. (p 2-1)
- **EPA's Office of Pollution Prevention and Toxic Substances (OPPTS)** defines "***bioaccumulation factor (BAF)***" as "...the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time.[16]
- **McGeer et al. (2004)** defines "***bioaccumulation factor (BAF)"*** as "...the ratio of the metal concentration in an organism to that in the surrounding medium, at steady state..." (p. 7)

Ecology included a definition for bioaccumulation factor in the initial draft rule distributed to the PBT Rule Advisory Committee on November 10, 2004 that synthesized elements of the above definitions. As noted above, the proposed definition appeared to have broad support among committee members.

Issue 4-4: ***Bioconcentration Factor***

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"Bioconcentration factor"*** *or* ***"BCF"*** *means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BCF is a measure of the extent of chemical partitioning between an organism and the surrounding environment.*

[16] 64 FR 703

Public Comments and Concerns

The Bromine Science and Environmental Forum recommended that Ecology replace the word "organisms" with the word "fish" and revise the second sentence. The revised definition would include the following language:

> ***"Bioconcentration factor"*** *or* ***"BCF"*** *means the ratio of the concentration of a chemical in fish tissue to the concentration of the chemical in water The BCF represents exposures via water through the gills.* ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition. The revised definition includes the following language:

> ***"Bioconcentration factor"*** *or* ***"BCF"*** *means the ratio of the concentration of a chemical in an aquatic organism to the concentration of the chemical in water. The BCF is a measure of the extent of chemical partitioning between an aquatic organism and water.*

Ecology's decision to revise the proposed definition is based on several factors:

- Rule Clarity: Ecology believes the revisions to the proposed definition provide a clearer distinction between "bioconcentration factor" and "bioaccumulation factor". Ecology also believes the revised definition better reflects how this term is actually used in the PBT rule. [NOTE: Ecology decided not to replace the term "aquatic organism" with the narrower term "fish" to maintain consistency with other rules and allow consideration of BCF values from aquatic organisms other than fish when evaluating individual chemicals.]
- Consistency with Definitions Used by Other Ecology Programs: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other Ecology programs. Based on a review of Ecology regulations (see below), Ecology believes that the revised definition is more consistent with definitions used by other Ecology programs. For example:
  - **Ecology's Toxics Cleanup Program** defines "**bioconcentration factor**" as "the ratio of the concentration of a hazardous substance in the tissue of an aquatic organism divided by the hazardous substance concentration in the ambient water in which the organism resides.
  - **Ecology's Water Quality Program** has adopted surface water quality standards based on EPA water quality criteria that were developed using the BCF definition shown below.
- Consistency with Definitions Used by the Environmental Protection Agency: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other state, federal and international agencies. Based on a review of EPA Ecology regulations and guidance materials, Ecology believes that the revised definition is more consistent with definitions used by the Environmental Protection Agency. For example:
  - **EPA's Office of Water** defines "**bioconcentration[17] factor (BCF)"** as "....[t]he ratio (in liters per kilogram of tissue) of the concentration of a chemical in the tissue of an aquatic organism to its concentration in water, in situations where the organism is exposed through the water only and the ratio does not change substantially over time..." (p. 2-3)

[17] EPA's Office of Water defines "Bioconcentration" as "...[t]he net accumulation of a chemical by an aquatic organism as a result of uptake directly from the ambient water, through gill membranes or other external body surfaces.

- **EPA's Office of Pollution Prevention and Toxic Substances (OPPTS)** defines "**bioconcentration factor (BCF)**" as "...the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism is exposed through water only and the ratio does not change substantially over time.[18]
- **McGeer et al. (2004)** [19] defines **"bioconcentration factor (BCF)"** as **"**the ratio of metal concentration in an organism to metal concentration in water, at a steady state. Metal concentrations are usually expressed on a weight-adjusted whole organism basis and waterborne metals as total metals. BCFs have been developed primarily with hydrophobic organic chemicals in aquatic systems, but have been applied to organic chemicals and metals in various matrices. Strictly speaking, metal bioconcentration in sediment and soil systems is the net accumulation of a metal in or on an organism from pore water only. Hence in sediment and soil, the denominator for the ratio should comprise the pore water concentration of metal, not the total metal concentration in the sediment or soil." (p. 7)
- **EPA's Glossary of Environmental Terms** defines **"bioconcentration"** as "the accumulation of a chemical in tissues of a fish or other organism to levels greater than in the surrounding medium".

Issue 4-5: *Carcinogen*

Proposed Rule

The proposed PBT rule published in June 2005 identified general criteria that Ecology proposed to use to determine whether a chemical or chemical group was toxic. Several organizations stated that Ecology's proposal was too vague and did not provide clear criteria for evaluating toxicity. In response to those comments, Ecology modified the proposed rule by including more specific criteria for judging toxicity. The revised rule language published in October 2005 states that Ecology will consider whether a chemical or chemical group is a "carcinogen" when making decision on revising or amending the PBT list. The proposed PBT rule published in October 2005 also included the following definition:

> *"**Carcinogen**" means a chemical or chemical group that is known or suspected to increase the probability of developing cancer. For purposes of implementing this chapter, the term carcinogen applies to substances that have been identified as "carcinogenic to humans" or "likely to be carcinogenic to humans" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology modify the first sentence in the proposed definition by replacing the phrase "increases the probability of developing" with the word "causes".

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[18] 64 FR 703

[19] EPA has reviewed and discussed the concepts and definitions of bioaccumulation as part of their effort to develop a metals assessment framework. As of December 2005, EPA has not completed work on the framework. However, as part of the review process, EPA commissioned a series of issue papers that were finalized in August 2004. McGeer et al. evaluated issues related to bioavailability and bioaccumulation of metals and most of the concepts and definitions in the issue paper have been incorporated into the draft EPA metals assessment framework document.

*"**Carcinogen**" means a chemical or chemical group that is known or suspected to cause ~~increase the probability of developing~~ cancer..... **(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

However, several other organizations and individuals recommended that Ecology delete the first sentence. For example, one commenter recommended that Ecology delete the first sentence because it is inconsistent with a "science-based approach":

*All of the PBT Advisory Committee members agree that the rule should be based on credible scientific information. The definitions of "carcinogen", "developmental and reproductive toxicant" and "neurotoxicant" conflict with this science-based approach by using the term "suspected". The first sentence in each of these definitions should therefore be deleted. **(Grant Nelson, pp. 1-2 of November 2005 Written Comments)***

Other organizations recommended that Ecology delete the first sentence because it is too vague and allows for subjective judgment to be substituted for application of the more objective criteria in the second part of the definition. For example:

*WAC 173-333-200 Definition of Carcinogen – The initial phrase "means a chemical or chemical group that is known or suspected to increase the probability of developing cancer" is ambiguous and is usurped by the specificity of the remainder of the definition. This initial phrase should be deleted. **(Ken Johnson, p. 1 of November 2005 Written Comments)***

*You have qualified the language here with comments on implementation, but have left open that you will consider anything that anyone suspects might increase the probability of causing cancer, developmental or reproductive effects. I suspect that the list of things that I suspect might increase the probability of causing cancer and that of some of the other members of the advisory group would be quite different. I will be making written comments later, but feel that this change in language which we were not able to discuss at the meeting, is very unfortunate. **(Diana Graham, p. 1 of November 2005 Written Comments)***

*The language used to define carcinogen should be the same as that presented in the footnote at the September 14, 2005 Advisory Committee meeting: "Carcinogen" means a chemical or chemical group that has been identified as a "known human carcinogen" or "probable human carcinogen" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program. The language that appears in the current draft, "'Carcinogen' means a chemical or chemical group that is known or suspected to increase the probability of developing cancer…" was discussed when it appeared in an earlier draft and was removed after healthy discussion by the Advisory Committee because it was unacceptably vague. **(Michael Walls and Clifford Howlett, p. 2 of November 2005 Written Comments)***

Several organizations recommended that Ecology modify this definition so that it applies to chemicals – not chemical groups. For example:

Continued references in the rule to "chemical groups" are confusing and should be deleted.** The continued reference to "chemical groups" in the revised proposal is confusing considering that Ecology has otherwise acknowledged that only individual chemicals can be judged to meet the individual P, B, and T criteria. Although the definition of "chemical group" given in WAC 173-333-200 is reasonable it has no relevance under this rule, and so is essentially academic. However, the other multiple references to chemical groups or mixtures sprinkled throughout the rule could be construed as carrying meaning conflicting with the clear intent of Ecology to include only individual chemicals on the PBT list. Because of this, all references to groups of chemicals should be deleted from the text of the rule. **(Jeff Louch, p. 6 of November 2005 Written Comments)

Finally, several organizations and individuals expressed concerns about the process used by Ecology to develop the definition for this term. In particular, several PBT Rule Advisory

Committee members were concerned that Ecology had modified the definition between the September 14, 2005 PBT Rule Advisory Committee meeting and the publication of the proposed rule. For example:

> *I do have some concerns about the language that appeared in this draft relative to what was presented at the last advisory committee meeting and in the previous draft. This is particularly true for definitions of carcinogen, developmental and reproductive toxicant, and neurotoxicant. These were not in the definitions section of the draft that we discussed at that meeting. Definitions for carcinogen and developmental and reproductive toxicant were in the footnotes, but were worded substantially differently. The current wording in these definitions includes the phrases "known or suspected to increase the probability of" or "known or suspected to cause" which were not present in the wording presented at the advisory committee meeting. I find these phrases unacceptably vague and would ask that they be removed from the definitions.* ***(Diana Graham, p. 1 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition. The revised definition includes the following language:

> *"**Carcinogen**" means a chemical or chemical group that has been identified as "carcinogenic to humans" or "likely to be carcinogenic to humans" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program.*

Ecology considered several factors when evaluating how to address the comments on this issue. Ultimately, Ecology decided to remove the first sentence of the definition because (1) the second sentence contained the substantive features of the proposed definition and (2) uncertainty surrounding Ecology intent might unnecessarily complicate rule implementation. The factors considered by Ecology in reaching this decision are summarized below.

- Protectiveness: One of Ecology's overall rulemaking objectives is to promote decisions that protect human health and the environment. Ecology concluded that the suggested changes would not impact the overall protectiveness of the PBT criteria and process because the substantive portions of the definitions are not altered by the revisions.

- Scientific Defensibility: One of Ecology's overall rulemaking objectives is promote decisions that are consistent with current scientific knowledge. One organization expressed the opinion that including the term "suspected" in the first sentence created a conflict with a "science-based approach". Ecology disagrees. Although the revised language does not include the term "suspected", Ecology does not believe it's inclusion in the proposed definition conflicts with a science-based approach because (1) the substantive portions of the proposed definition were included in the second sentence and, consequently, the phrase "is known or suspected to increase the probability of developing cancer" did not determine whether a particular chemical is identified as a carcinogen and (2) the use of the term "known or suspected" may be more consistent with a science-based approach than using the term "known" in that the former term acknowledges the uncertainties and limitations associated with current testing strategies for identifying carcinogenic substances. Specifically, the majority of substances included on the EPA, IARC and NTP lists of carcinogens were identified based on results from animal bioassays – not human epidemiological studies. While results from animal bioassays are widely accepted as a sound predictor of human carcinogenicity, the need to extrapolate results from one species to another creates additional

uncertainty. The use of the term "known and suspected" implicitly factors this uncertainty into the definition.

- Balancing Predictability and Flexibility: One of Ecology's overall rulemaking objectives is to provide greater predictability on agency decision-making processes and criteria while at the same time retaining enough flexibility to consider new scientific information. Ecology believes that by identifying clear decision-making criteria and processes, the PBT rule will promote more timely and efficient decisions and enable Ecology to focus on the most important chemical-specific issues when deciding whether to add or remove a chemical from the PBT list (as opposed to draining limited resources to discuss and debate the application of more general criteria). After reviewing the public comments on this issue, Ecology concluded that the phrase "known or suspected to increase the probability of developing cancer" appeared to be undermining that goal by producing uncertainty and anxiety among some organizations on Ecology's plans for implementing the substantive portions of the definition included in the second sentence.

- Consistency with Definitions Used by Other Ecology Programs: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other Ecology programs. Based on a review of Ecology regulations (see below), Ecology believes that both the proposed definition and the revised definition are consistent with definitions used by other programs. For example:

  - **Ecology's Toxics Cleanup Program** defines **"Carcinogen"** as **"...**any substance or agent that produces or tends to produce cancer in humans. For implementation of this chapter, the term carcinogen applies to substances on the United States Environmental Protection Agency lists of A (known human) and B (probable human) carcinogens, and any substance that causes a significant increased incidence of benign or malignant tumors in a single, well conducted animal bioassay, consistent with the weight of evidence approach specified in the United States Environmental Protection Agency's Guidelines for Carcinogen Risk Assessment as set forth in 51 FR 33992 et seq."

  - **Ecology's Hazardous Waste and Toxic Reduction (HWTR) Program** defines "**Carcinogenic**" as "...a material known to contain a substance which has sufficient or limited evidence as a human or animal carcinogen as listed in both IARC and either IRIS or HEAST."

  - **Ecology's Water Quality Program** defines "**Carcinogen**" as "...any substance or agent that produces or tends to produce cancer in humans. For implementation of this chapter, the term carcinogen will apply to all substances on the United States Environmental Protection Agency Integrated Risk Information System, IRIS data base, of A (known human) and B1 and B2 (probable human) carcinogens for which IRIS listed an oral slope factor."

- Consistency with Definitions Used by Federal and International Programs: Ecology reviewed the definitions used by various federal and international programs during the PBT Rule Advisory Committee process. Specifically, Ecology has referenced determinations by EPA, IARC and the NTP.

- Opportunities for Public Review of Proposed Definition: Several members of the PBT Rule Advisory Committee stated that was inappropriate to include rule language that was different than the draft rule language discussed at the PBT Rule Advisory Committee meeting held on September 14, 2005. Ecology has reviewed the comments on this issue and believes they mischaracterize the process leading from the language in the draft rule shared with the PBT Rule Advisory Committee to the proposed rule language published in the State Register. At the September 14, 2005 advisory committee meeting, Ecology clearly stated that the Department was still considering whether to include more specific toxicity criteria and

definitions for terms used in the revised criteria (e.g. carcinogen, neurotoxicant, etc.). For example, the language included in several explanatory footnotes[20] highlighted that Ecology was still considering whether to make the draft revisions and that comments from the advisory committee would help to shape a final determination on language to be included in the proposed rule.

Ecology's review and response to comments on the use of the term "chemical group" in various parts of the rule (e.g. the PBT list and criteria) is included in Chapter 5.

Issue 4-6: *Chemical Action Plan*

Proposed Definition

The proposed PBT rule published in June 2005 included the following definition:

> ***"Chemical action plan"*** *or* ***"CAP"*** *means a plan that identifies, characterizes and addresses uses and releases of a specific PBT or a group of PBTs and facilitates implementation of measures to manage, reduce or eliminate such uses and releases.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following definition:

> ***"Chemical action plan"*** *or* ***"CAP"*** *means a plan that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and recommends actions to protect human health or the environment.*

Public Comments and Concerns

Several organizations and individuals provided comments on the proposed definitions in the two versions of the proposed rule. Those comments reflected a range of viewpoints and highlight several key issues.

For example, several organizations and individuals urged Ecology to incorporate the goal statement into the proposed definition. The range of recommendations reflected the range of recommendations on the environmental goal (see Issue 2-1). For example:

> *200 and 400—the definition of CAP must be changed to reflect that a CAP is a plan to reduce and eliminate PBTs and is not used to manage PBTs.* ***(Ivy Sager-Rosenthal, p. 2 of July 2005 written comments)***[21]

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[20] Footnote 22 included the following text: Several people recommended that Ecology develop quantitative toxicity criteria similar to those for persistence and bioaccumulation. Ecology agrees that more definitive criteria for assessing whether a chemical is "toxic" will provide greater predictability, promote more timely and efficient decisions and enable Ecology to focus on the most important chemical-specific issues when deciding whether to add or remove a chemical from the PBT list (as opposed to draining limited resources to discuss and debate general criteria). However, Ecology is still reviewing whether the more detailed criteria should be included in the rule or accompanying guidance materials. The alternative language provides an example of how more detailed toxicity criteria could be incorporated into the PBT rule.

[21] The Washington Toxics Coalition provided the following suggested language: **"Chemical Action Plan" or "CAP"** means a plan to reduce and eliminate PBTs from the environment that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and recommends actions Washington state should take to protect human health and the environment.

Establish that the goal of chemical action plans is to eliminate the toxic chemical. Because chemical action plans are only developed for those chemicals where a problem has been identified, it is crucial that the goal of the plans is to eliminate the chemical for the program to be effective ***(Pam Tazioli et al., p. 2 of July 2005 written comments)***

*Ecology has sensibly included the word "manage" in describing measures designed to control the uses and releases of PBTs. Consistent with earlier comments highlighting the need to implement a rule with realistic expectations and a strong consideration of costs and benefits of recommended actions, AWB requests that the word "feasible" proceed "reduce" and "phase-out" be inserted in place of "eliminate". (****Grant Nelson, p. 2 of July 2005 written comments****)*

Several organizations recommended that Ecology incorporate the concept of feasibility into the definition for chemical action plan. For example:

WAC 173-333-200 Chemical Action Plan - *The terms of a CAP should incorporate the concept of feasibility. Please consider adjusting the definition to read "…facilitates implementation of measures to manage, and where feasible, reduce or phase out such uses and releases."*
Discussion – The term "feasible" will be defined in the regulation. As a matter of "good public policy," the elements of any Chemical Action Plan must consider feasibility. ***(Ken Johnson, p. 2 of July 2005 written comments)***

The Association of Washington Business recommended that Ecology modify the definition to state that such plans include an evaluation of exposure pathways. They also expressed concerns that the use of the phrase "protect human health and the environment" is inconsistent with general agreements reached by the PBT Rule Advisory Committee and may facilitate a departure from a science-based approach:

*In addition to evaluating uses and releases of PBT chemicals, a chemical action plan should also determine and evaluate exposure pathways to help ensure that recommended actions in the CAP are best directed. A CAP should include specific recommendations to manage and where feasible, reduce or phase-out PBT uses and releases. This, along with the agreed upon goal of the rule to "reduce risk to human health and the environment" were common points of agreement during the stakeholder advisory process. Ecology's proposed language in the current draft is inconsistent with these agreements by using the word "protect", and may inappropriately facilitate a departure from a science-based rule****.(Grant Nelson, p. 2 of November 2005 Written Comments)***[22]

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the proposed language in response to the above comments[23]. Ecology believes that the proposed language describing the CAP as "a plan" that "identifies, characterizes and evaluates" the "uses and releases" of a specific PBT or group of PBTs and "recommends actions to protect human health or the environment" provides an accurate description of these documents. Equally important, Ecology believes the proposed language is neutral and balanced in that it does not selectively repeat goals and evaluation factors that are described elsewhere in the rule.

[22] The Association of Washington Business provided the following suggested language: **"Chemical action plan"** or **"CAP"** means a plan that identifies, characterizes and evaluates uses and releases and exposure pathways of a specific PBT or a group of PBTs and recommends actions to manage and where feasible, reduce or phase-out such uses and releases.

[23] Ecology did insert the phrase "or metals of concern" into this definition as part of the response to comments on lead and cadmium (See Issue 5-18).

Issue 4-7: ***Chemical Group***

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"Chemical group"*** *means a grouping of chemicals which share a common chemical structure.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology add the phrase "and common toxicological properties/modes of action" to the end of the proposed definition. They included the following note with the suggested revision:

> *NOTE: On what basis will the Department determine that certain chemicals can be classified as a group? This approach may be valid as a screening tool for chemicals with insufficient data (e.g. as used by EPA's New Chemicals Program), but chemicals with existing data should not be grouped. .....* ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

However, several organizations and individuals recommended that Ecology remove this definition from the rule because implementation of the rule is based on evaluating individual chemicals (not chemical groups) and, consequently, continued use of this term was no longer necessary. For example:

> *WAC 173-333-200 Definition of Chemical Group – With the decision in this proposed regulation to list and provide a technical rational for individual PBTs; i.e., a Chemical, the use of the term Chemical Group has lost relevance. Stated differently, there are no proposed elements of this regulation where a required action is differentiated for a Chemical and a Chemical Group. The Chemical Group term is redundant and, in the interests of clarity, could be removed from the rule.* ***(Ken Johnson, pp. 1-2 of November 2005 Written Comments)***

> ***Continued references in the rule to "chemical groups" are confusing and should be deleted.*** *The continued reference to "chemical groups" in the revised proposal is confusing considering that Ecology has otherwise acknowledged that only individual chemicals can be judged to meet the individual P, B, and T criteria. Although the definition of "chemical group" given in WAC 173-333-200 is reasonable it has no relevance under this rule, and so is essentially academic. However, the other multiple references to chemical groups or mixtures sprinkled throughout the rule could be construed as carrying meaning conflicting with the clear intent of Ecology to include only individual chemicals on the PBT list. Because of this, all references to groups of chemicals should be deleted from the text of the rule.* ***(Jeff Louch, p. 6 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition to incorporate the language suggested by the Bromine Science and Environmental Forum (BSEF). The revised definition includes the following language:

> ***"Chemical group"*** *means a grouping of chemicals which share a common chemical structure and common toxicological properties.*

Ecology believes the revised definition is consistent with current scientific knowledge and is consistent with how chemical groups are defined in practice under other Ecology programs and other state, federal and international agencies.

Ecology's review and response to comments on the use of the term "chemical group" in various parts of the rule (e.g. the PBT list and criteria) is included in Chapter 5.

Issue 4-8: ***Credible Scientific Information***

Proposed Rule

The proposed PBT rule published in October 2005 included the following definition:

> ***"Credible scientific information"*** *means information that is based on a theory or technique that is generally acceptable in the relevant scientific community or has been collected or derived using standard methods and protocols and appropriate quality assurance and control procedures.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following definition:

> ***"Credible scientific information"*** *means information that is based on a theory or technique that is generally acceptable in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures.*

Public Comments and Concerns

Several organizations and individuals emphasized the importance of using credible scientific information to support decision-making. Many of these organizations found that several terms in the definition were too vague and they recommended that Ecology modify the definition to clarify certain terms. For example:

> *The definition of "credible scientific information" is vague as to what are "standard" methods and protocols. We suggest replacing "standard" with "generally accepted". The definition also is not clear on whether peer-reviewed scientific journals are acceptable. We suggest clarifying this point by specifically adding peer-reviewed scientific articles to the definition.* ***(Ivy Sager-Rosenthal, p. 6 of July 2005 Written Comments)***[24]

> ***"Credible scientific information"*** *means information that is based on a theory or technique that is generally accept**ed**~~able~~ in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures.* ***(Grant Nelson, Attachment to November 2005 written comments)***

The American Chemistry Council/Chlorine Chemistry Council emphasized the need to consider the varying quality of data and studies and identified several principles to help differentiate data and studies to ensure the highest quality information is considered by Ecology:

> ***1. Consistently Use "Credible Scientific Information."*** *The draft Rule requires that a determination as to whether a chemical or group of chemicals meets the persistence, bioaccumulation, or toxicity criteria must be based on "credible scientific information." The requirement that scientific information be "credible" is to be commended. For consistency, however, all references to scientific information throughout the proposed Rule should be prefaced with "credible." (e.g., 173-333-410(2)(a)(iii) - information on the effects of exposure; 173-333-410(2)(a)(iv) - information on the susceptibility of sensitive populations, and; 173-333-420(1)(c) - information on "rates of diseases that have been associated with exposure to the particular PBT").*
>
> *Importantly, the Rule should contain a more clear definition of "credible scientific information" to recognize the varying quality of data and studies. Application of evaluative principles would help*

[24] The Washington Toxics Coalition provided the following suggested language: ***"Credible Scientific Information"*** *means information that is based on a theory or technique that is generally acceptable in the relevant scientific community, has been collected or derived using generally accepted methods and protocols and appropriate quality assurance and control procedures, or has been published in a peer-reviewed scientific journal.*

differentiate data and studies to ensure the highest quality information is considered by Ecology. The following principles could be employed by Ecology:

a. Studies should be critically evaluated with respect to their validity and acceptability. Wherever possible, existing internationally recognized approaches for assessing the validity of studies should be applied (e.g., approaches outlined in the EU Technical Guidance Document, the Klimish scoring approach, etc.)

b. Decisions should be based on studies conducted using VALIDATED experimental guidelines (EPA, OECD, ASTM, ISO, etc), and preferably under Good Laboratory Practices.

c. Decisions should consider the "data hierarchy" of available studies and information (e.g., valid experimental/field data should take precedence over QSAR/modeled predictions, etc.).

d. Emphasis should be place on a "weight of the evidence" approach. ***(Michael Walls and Clifford Howlett, pp. 1-2 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and has modified the definition of "credible scientific information" to read:

> ***"Credible scientific information"*** *means information that is based on a theory or technique that is generally accepted in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures.*

Ecology understands that this definition and its' application in different parts of the rule create a number of expectations and fears based on experiences with the federal Data Quality Act.

- Ecology does not intend to apply this definition in ways that create lengthy delays in decision-making. One of Ecology's rulemaking objectives is to establish processes for rationale and timely decision-making. One of the concerns identified with the implementation of the Data Quality Act and similar provisions is that such procedures create paralysis by analysis. Within this context, Ecology believes it is important to discuss the use of scientific reviews performed by other agencies or scientific panels. In particular, Ecology believes that it will not always be necessary or appropriate that Ecology devote the time and resources that would be needed to duplicate scientific reviews conducted by other environmental agencies or scientific panels. This approach is consistent with current Ecology procedures and promotes consistency and coordination among state and federal agencies. However, Ecology recognizes that there are limits on the extent to which the Department can rely upon scientific evaluations performed by other agencies or scientific panels. In particular, Ecology will need to consider whether the conclusions reached by past groups remain valid in light of more recent studies (if any) and evolving scientific knowledge and methods.

- Ecology does not intend to apply this definition in ways that narrowly restrict consideration of available scientific information. Ecology agrees that it is poor public policy to persist in efforts to reduce/phase-out uses and releases of chemicals that have inappropriately been classified as PBTs. However, Ecology agrees with organizations and individuals who recommended that Ecology consider all available scientific information when implementing this chapter. Ecology believes the constructing high barriers to the consideration of individual studies is inconsistent with that objective and loses sight of the value that individual studies (while not meeting all of today's current protocols) can contribute to the overall understanding of a particular chemical. Toward that end, Ecology decided to replace

the word "standard" with "generally accepted". Ecology made the suggested change because the term "standard methods and protocol" is often interpreted to mean methods and protocols formally approved by EPA, ASTM or other scientific organizations. Ecology believes this would be too narrow an interpretation given that some of the chemicals on the PBT list have not been routinely addressed by current regulatory programs. For example, the National Report on Human Exposure to Environmental Chemicals includes information on a wide range of chemicals. The methods used to collect that information have been extensively reviewed and are generally accepted methods and protocols. However, it is not clear whether such methods rise to the point of being considered "standard" in the sense they are approved by EPA or ASTM. Consequently, Ecology has inserted language to clarify that information collected using "generally accepted methods and protocols" will be considered credible scientific information.

One person recommended that scientific information "...published in a peer-reviewed scientific journal..." should be considered "credible scientific information". Ecology believes that information published in a peer-reviewed scientific journal will generally be considered "credible scientific information". However, Ecology also recognizes that there are a wide range of scientific journals published in the world and there are wide variations in the peer review practices of those journals. Ecology believes that the "generally accepted" language in the proposed definition (while more subjective than publication in a peer reviewed scientific journal) provides a more appropriate standard of review.

Ecology also considered the suggestion that the rule include a more detailed definition for this term that incorporates concepts or principles such as weight of evidence, data hierarchy, etc. While Ecology agrees with many of the specific suggestions, the Department believes that such issues are more appropriately addressed in guidance materials.

Issue 4-9: ***Cross-media transfer of chemicals***

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"Cross-media transfer of chemicals"*** *means the movement of a chemical from one medium, such as air, water, soil, or sediment, to another.*

Public Comments and Concerns

The Bromine Science and Environmental Forum expressed concerns that the proposed definition was too generally-worded and could be applied to all chemicals. They recommended that Ecology included a more specific definition in the PBT rule:

> *....Any chemical will do this to some extent. We would recommend a more specific definition....* ***(Raymond Dawson and David Sanders, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and decided not to modify the proposed definition. Ecology agrees that the proposed definition is broadly applicable to most chemicals. However, as discussed in the response to Issue 3-4, the term "cross-media transfer of chemicals" is used to describe the challenges associated with addressing PBT chemicals. Ecology has not proposed criteria for characterizing cross-media transfer that would be considered when identifying PBT

chemicals. Consequently, Ecology does not believe that further specificity is needed in the PBT rule.

Issue 4-10: ***Degradation***

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"Degradation"*** *means the processes by which organic chemicals are transformed into derivative chemicals and ultimately broken down.*

Public Comments and Concerns

The Bromine Science and Environmental Forum expressed concerns that the proposed definition was too generally-worded and needed additional criteria in order to provide a complete definition:

> ***"Degradation"*** *means the processes by which organic chemicals are transformed into derivative chemicals and ultimately broken down to ???? [additional criteria required to complete definition]* ***(Raymond Dawson and David Sanders, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and decided not to modify the proposed definition. As discussed in Chapter 5, Ecology agrees that additional guidance/criteria would be useful to define how Ecology will judge the potential for degradation of particular chemicals. However, Ecology also believes that such criteria/guidance are more appropriately placed in guidance materials and/or WAC 173-333-320.

Issue 4-11: ***Developmental and Reproductive Toxicant***

Proposed Rule

The proposed PBT rule published in June 2005 identified general criteria that Ecology proposed to use to determine whether a chemical or chemical group was toxic. Several organizations stated that Ecology's proposal was too vague and did not provide clear criteria for evaluating toxicity. In response to those comments, Ecology modified the proposed rule by including more specific criteria for judging toxicity. The revised rule language published in October 2005 states that Ecology will consider whether a chemical or chemical group is a "developmental or reproductive toxicant" when making decisions on revising or amending the PBT list. The proposed PBT rule published in October 2005 also included the following definition:

> ***"Developmental or reproductive toxicant"*** *means a chemical or chemical group that is known or suspected to cause adverse effects on development or reproduction. For purposes of implementing this chapter, the term developmental or reproductive toxicant applies to chemicals or chemical groups identified as posing developmental or reproductive hazards by the National Toxicology Program or chemicals or chemical groups with sufficient evidence of a developmental or reproductive hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Reproductive Toxicity Risk Assessment and Guidelines for Developmental Toxicity Risk Assessment as set forth in 61 FR 56274 et seq. and 56 FR 63798 et seq., respectively.*

Public Comments and Concerns

The comments on Ecology's proposed definition for this term were similar to the comments on the proposed definition for "carcinogen". For example, several organizations and individuals recommended that Ecology delete the first sentence because it is inconsistent with a "science-based approach" and/or it is too vague and allows for additional subjective judgment. For example:

> *All of the PBT Advisory Committee members agree that the rule should be based on credible scientific information. The definitions of "carcinogen", "developmental and reproductive toxicant" and "neurotoxicant" conflict with this science-based approach by using the term "suspected" The first sentence in each of these definitions should therefore be deleted.* ***(Grant Nelson, pp. 1-2 of November 2005 Written Comments)***

> *WAC 173-333-200 Definition of Developmental or reproductive toxicant – The initial phrase "means a chemical of chemical group that is known or suspected to cause adverse effects on development of reproduction" is unnecessary and should be deleted. The remainder of the definition is more specific and functional, and will suffice.* ***(Ken Johnson, p. 2 of November 2005 Written Comments)***

One organization recommended that Ecology replace the proposed definition with the definition provided in the footnote discussed at the September 14, 2005 Advisory Committee meeting.

> *The language used to define developmental or reproductive toxicant should be the same as that presented in the footnote at the September 14, 2005 Advisory Committee meeting: "Developmental or Reproductive Toxicant" means a chemical or chemical group identified as adversely affecting development or reproduction by the National Toxicology Program, the Environmental Protection Agency, the National Institute for Occupational Safety and Health or other authoritative scientific body. The language that appears in the current draft, "'Developmental or Reproductive Toxicant' means a chemical or chemical group that is known or suspected to cause adverse effects on development or reproduction…" was neither discussed nor agreed to by the Advisory Committee and is unacceptably vague.* ***(Michael Walls and Clifford Howlett,, pp. 2-3 of November 2005 Written Comments)***

Several organizations recommended that Ecology modify this definition so that it applies to chemicals – not chemical groups. For example:

> ***Continued references in the rule to "chemical groups" are confusing and should be deleted.*** *The continued reference to "chemical groups" in the revised proposal is confusing considering that Ecology has otherwise acknowledged that only individual chemicals can be judged to meet the individual P, B, and T criteria. Although the definition of "chemical group" given in WAC 173-333-200 is reasonable it has no relevance under this rule, and so is essentially academic. However, the other multiple references to chemical groups or mixtures sprinkled throughout the rule could be construed as carrying meaning conflicting with the clear intent of Ecology to include only individual chemicals on the PBT list. Because of this, all references to groups of chemicals should be deleted from the text of the rule.* ***(Jeff Louch, p. 6 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition. The revised definition includes the following language:

> ***"Developmental or reproductive toxicant"*** *means a chemical or chemical group that has been identified as posing developmental or reproductive hazards by the National Toxicology Program or chemicals or chemical groups with sufficient evidence of a developmental or reproductive hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's*

Guidelines for Reproductive Toxicity Risk Assessment and Guidelines for Developmental Toxicity Risk Assessment as set forth in 61 FR 56274 et seq. and 56 FR 63798 et seq., respectively.

Ecology considered several factors when evaluating how to address the comments on this issue. Ultimately, Ecology decided to remove the first sentence of the definition because (1) the second sentence contained the substantive features of the proposed definition and (2) uncertainty surrounding Ecology intent might unnecessarily complicate rule implementation. The factors considered by Ecology in reaching this decision are summarized below.

- Protectiveness: One of Ecology's overall rulemaking objectives is to promote decisions that protect human health and the environment. Ecology has concluded that the suggested changes would not impact the overall protectiveness of the PBT criteria and process because the substantive portions of the definitions are not altered by the revisions.

- Scientific Defensibility: One of Ecology's overall rulemaking objectives is promote decisions that are consistent with current scientific knowledge. One organization expressed the opinion that including the term "suspected" in the first sentence created a conflict with a "science-based approach". Ecology disagrees. As discussed under Issue 4-5 above, Ecology believes that use of the word "known" in place of the phrase "known or suspected" implies a degree of scientific certainty that is inconsistent with current scientific information on the relationships between exposure to hazardous chemicals and resulting health risks. Ecology also believes the revised definition is consistent with a science-based approach in that it enables Ecology to consider new scientific information on the health effects of individual chemicals using an assessment framework that has been peer-reviewed by EPA's Science Advisory Board.

- Balancing Predictability and Flexibility: One of Ecology's overall rulemaking objectives is to provide greater predictability on agency decision-making processes and criteria while at the same time retaining enough flexibility to consider new scientific information. Ecology hopes that by identifying clear decision-making criteria and processes, the PBT rule will promote more timely and efficient decisions and enable Ecology to focus on the most important chemical-specific issues when deciding whether to add or remove a chemical from the PBT list (as opposed to draining limited resources to discuss and debate the application of more general criteria). After reviewing the public comments on this issue, Ecology concluded that the phrase "known or suspected to cause adverse effects on development and reproduction" appeared to be undermining that goal by producing uncertainty and anxiety among some organizations on Ecology's plans for implementing the substantive portions of the definition included in the second sentence. Conversely, Ecology believes the recommendation to use the language presented in the footnote at the September 14, 2005 PBT Rule Advisory Committee meeting would unreasonably constrain Ecology's ability to consider new scientific information. Specifically, the language in the footnote would limit the definition to substances identified by the National Toxicology Program and the National Institute for Occupational Safety and Health. Unlike the federal and international programs for evaluating carcinogens, these programs have evaluated a relatively small number of chemicals. Based on comments and questions from the Advisory Committee, Ecology decided to modify the definition to enable Ecology to consider available scientific information within the context of the risk assessment guidelines established by EPA. The EPA guidelines are based on current scientific review and have undergone extensive peer review by EPA's Science Advisory Board.

- Consistency with Definitions Used by Other Ecology Programs: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other Ecology programs. Other Ecology programs have not established a definition of developmental and reproductive toxicants. However, the concepts reflected in the revised definition is consistent with the Ecology regulatory definitions for "carcinogen" in that it references determinations made by an authoritative scientific body (e.g. National Toxicology Program) and provides the flexibility to identify additional chemicals as developmental and reproductive toxicants using EPA risk assessment guidelines.
- Consistency with Definitions Used by Federal and International Programs: Ecology believes the revised definition is consistent with current federal policies and guidelines because references determinations made by an authoritative scientific body (e.g. National Toxicology Program) and provides the flexibility to identify additional chemicals as developmental and reproductive toxicants using EPA risk assessment guidelines.
- Opportunities for Public Review of Proposed Definition: Several members of the PBT Rule Advisory Committee stated that was inappropriate to include rule language that was different than the draft rule language discussed at the PBT Rule Advisory Committee meeting held on September 14, 2005. As discussed under Issue 4-5, Ecology has reviewed the comments on this issue and believes they mischaracterize the process leading from language in the draft rule shared with the PBT Rule Advisory Committee to the proposed rule language published in the State Register. Ecology clearly stated that it was still considering whether to include more specific toxicity criteria and definitions for terms used in the revised criteria (e.g. carcinogen, neurotoxicant, etc.). In addition, the language included in several explanatory footnotes also highlighted that Ecology was still considering whether to make these revisions and that comments from the advisory committee would help to shape a final determination on the language to be included in the proposed rule.

Ecology's review and response to comments on the use of the term "chemical group" in various parts of the rule (e.g. the PBT list and criteria) is included in Chapter 5.

Issue 4-12: ***Feasible***

Proposed Rule

The proposed PBT rule published in June 2005 included the following definition:

> ***"Feasible"*** *means capable of being accomplished or brought about or capable of being utilized or dealt with successfully.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following definition:

> ***"Feasible"*** *means reasonably capable of being accomplished or brought about or capable of being utilized or dealt with successfully.*

Public Comments and Concerns

Several organizations expressed concerns that the proposed definition did not adequately distinguish between the concepts of "possible" and "feasible" and recommended several revisions to the proposed definition:

The current definition more accurately describes the definition of what is "possible" rather than "feasible". A possible action may in fact not be feasible. Merriam-Webster provides a qualitative word to its definition of "feasible", which is "reasonable". "Reasonable" is defined as "not extreme or excessive; moderate; fair". AWB requests that this concept be included in the definition of "feasible" and offers the words "viable, workable and practicable" for Ecology's consideration in better defining what is "feasible". ***(Grant Nelson, p. 2 of July 2005 written comments)***[25]

AWB appreciates Ecology's improvement from the previous version of the proposed rule in defining the term "feasible". The added language in AWB's mark-up should be included to ensure feasible actions are "viable, workable and practicable". ***(Grant Nelson, p. 2 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment on the June 2005 proposed rule and modified the definition of "feasible" to read:

> ***"Feasible"*** *means reasonably capable of being accomplished or brought about or capable of being utilized or dealt with successfully.*

Ecology agrees that the proposed definition in the June 2005 proposed rule blurred the distinction between "feasible" and "possible". Ecology inserted the word "reasonable" in order to capture the concept that there are several factors that influence whether "possible" options can actually be implemented in the real world and/or the time frames for implementing such measures.

Issue 4-13: ***High exposure populations***

Proposed Rule

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"High-exposure populations"*** *means groups of people that are at greater risk because they have a higher potential for exposure than the general population.*

Public Comments and Concerns

The Bromine Science and Environmental Forum recommended that Ecology delete the phrase "are at greater risk because they..." from the proposed definition:

> ***"High-exposure populations"*** *means groups of people that [previous phrase struck because equates exposure to risk without consideration of hazard. Generally accepted principal is Hazard X Exposure = Risk.] have a higher potential for exposure than the general population.* ***(Raymond Dawson and David Sanders, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and decided not to modify the proposed definition. Ecology agrees that the principle "risk = hazard times exposure" is an important concept. However, the definition of "high exposure populations" is intended to focus on the exposure term. In proposing this definition, Ecology considered how the term is being used in the context

[25] *The Association of Washington Business provided the following suggested language:* ***"Feasible"*** *means viable, workable and practicable; Capable of being accomplished or brought about or capable of being utilized or dealt with successfully.*

of the CAP selection process (WAC 173-333-410). Specifically, Ecology proposed to consider both the relative exposure of different population groups and the relative susceptibility of different population groups. The proposed definition refers to the first consideration.

Issue 4-14: ***Low Adverse Effect Concentration (LOEC)***

Proposed Rule

The proposed PBT rule published in October 2005 did not include a definition for the term "low adverse effect concentration".

Public Comments and Concerns

The Bromine Science and Environmental Forum recommended that Ecology include the following definition in WAC 173-333-200:

> *"Low adverse effect concentration" or "LOEC" is the lowest concentration at which an adverse effect is seen in an aquatic toxicity test****.(Raymond Dawson and David Sanders, p. 6 of Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comment on this issue and elected not to include a definition for this term because the term is not used elsewhere in the rule. (For further discussion on this issue, see Chapter 5)

Issue 4-15: ***Neurotoxicant***

Proposed Rule

The proposed PBT rule published in June 2005 identified general criteria that Ecology proposed to use to determine whether a chemical or chemical group was toxic. Several organizations stated that Ecology's proposal was too vague and did not provide clear criteria for evaluating toxicity. In response to those comments, Ecology modified the proposed rule by including more specific criteria for judging toxicity. The revised rule language published in October 2005 states that Ecology will consider whether a chemical or chemical group is a "neurotoxicant" when making decisions on revising or amending the PBT list. The proposed PBT rule published in October 2005 also included the following definition:

> ***"Neurotoxicant"*** *means a chemical or chemical group that is known or suspected to cause adverse changes in the structure or function of the central and/or peripheral nervous system. For purposes of implementing this chapter, the term neurotoxicant applies to chemicals or chemical groups with sufficient evidence of a neurotoxic hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Neurotoxicity Risk Assessment as set forth in 63 FR 26926 et seq.*

Public Comments and Concerns

The comments on Ecology's proposed definition for this term were similar to the comments on the proposed definition for "carcinogen". For example, several organizations and individuals recommended that Ecology delete the first sentence because it is inconsistent with a "science-based approach" and/or it is too vague and allows for additional subjective judgment. For example:

All of the PBT Advisory Committee members agree that the rule should be based on credible scientific information. The definitions of "carcinogen", "developmental and reproductive toxicant" and "neurotoxicant" conflict with this science-based approach by using the term "suspected" The first sentence in each of these definitions should therefore be deleted. ***(Grant Nelson, pp. 1-2 of November 2005 Written Comments)***

WAC 173-333-200 Definition of Neurotoxicant. The initial phrase "means a chemical or chemical group that is known or suspected to cause adverse changes in the structure or function of the central and/or peripheral nervous system" should be deleted. The remainder of the definition provides a more specific and meaningful definition of the term. ***(Ken Johnson, p. 2 of November 2005 Written Comments)*** [26]

Several organizations recommended that Ecology modify this definition so that it applies to chemicals – not chemical groups. For example:

Continued references in the rule to "chemical groups" are confusing and should be deleted. *The continued reference to "chemical groups" in the revised proposal is confusing considering that Ecology has otherwise acknowledged that only individual chemicals can be judged to meet the individual P, B, and T criteria. Although the definition of "chemical group" given in WAC 173-333-200 is reasonable it has no relevance under this rule, and so is essentially academic. However, the other multiple references to chemical groups or mixtures sprinkled throughout the rule could be construed as carrying meaning conflicting with the clear intent of Ecology to include only individual chemicals on the PBT list. Because of this, all references to groups of chemicals should be deleted from the text of the rule.* ***(Jeff Louch, p. 6 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition. The revised definition includes the following language:

*"**Neurotoxicant**" means a chemical or chemical group with sufficient evidence of a neurotoxic*[27] *hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Neurotoxicity Risk Assessment as set forth in 63 FR 26926 et seq.*

Ecology considered several factors when evaluating how to address the comments on this issue. Ultimately, Ecology decided to remove the first sentence of the definition because (1) the second sentence contained the substantive features of the proposed definition and (2) uncertainty

[26] Similar recommendations were made by Dr. Jeff Louch (NCASI), Dr, Diana Graham, Grant Nelson (AWB), Michael Walls and Clifford Howlett (ACC/CCC).

[27] EPA (1998) identified the range of health effects that might fit within the classification of neurotoxicity: The various health effects that fall within the broad classification of neurotoxicity are described and examples are provided. Adverse effects include alterations from baseline or normal conditions that diminish an organism's ability to survive, reproduce, or adapt to the environment. Neurotoxicity is an adverse change in the structure or function of the central and/or peripheral nervous system following exposure to a chemical, physical, or biological agent (Tilson, 1990). Functional neurotoxic effects include adverse changes in somatic/autonomic, sensory, motor, and/or cognitive function. Structural neurotoxic effects are defined as neuroanatomical changes occurring at any level of nervous system organization; functional changes are defined as neurochemical, neurophysiological, or behavioral effects. Chemicals can also be categorized into four classes: those that act on the central nervous system, the peripheral nerve fibers, the peripheral nerve endings, or muscles or other tissues (Albert, 1973). Changes in function can result from toxicity to other specific organ systems, and these indirect changes may be considered adverse. For example, exposure to a high dose of a chemical may cause damage to the liver, resulting in general sickness and a decrease in a functional endpoint such as motor activity. In this case, the change in motor activity could be considered as adverse, but not necessarily neurotoxic. A discussion concerning problems associated with risk assessment of high doses of chemicals in the context of drinking water and health was published by the National Research Council (1986). (EPA, 1998, p. 8)

surrounding Ecology intent might unnecessarily complicate rule implementation. The factors considered by Ecology in reaching this decision are summarized below.

- Protectiveness: One of Ecology's overall rulemaking objectives is to promote decisions that protect human health and the environment. Ecology has concluded that the suggested changes would not impact the overall protectiveness of the PBT criteria and process because the substantive portions of the definitions are not altered by the revisions.

- Scientific Defensibility: One of Ecology's overall rulemaking objectives is promote decisions that are consistent with current scientific knowledge. One organization expressed the opinion that including the term "suspected" in the first sentence created a conflict with a "science-based approach". Ecology disagrees. As discussed under Issue 4-5 above, Ecology believes that use of the word "known" in place of the phrase "known or suspected" implies a high degree of scientific certainty that is inconsistent with current scientific information on the relationships between exposure to hazardous chemicals and resulting health risks. Ecology also believes the revised definition is consistent with a science-based approach in that it enables Ecology to consider new scientific information on the health effects of individual chemicals using an assessment framework that has been peer-reviewed by EPA's Science Advisory Board.

- Balancing Predictability and Flexibility: One of Ecology's overall rulemaking objectives is to provide greater predictability on agency decision-making processes and criteria while at the same time retaining enough flexibility to consider new scientific information. Ecology hopes that by identifying clear decision-making criteria and processes, the PBT rule will promote more timely and efficient decisions and enable Ecology to focus on the most important chemical-specific issues when deciding whether to add or remove a chemical from the PBT list (as opposed to draining limited resources to discuss and debate the application of more general criteria). After reviewing the public comments on this issue, Ecology concluded that the phrase "known or suspected to cause adverse effects on development and reproduction" appeared to be undermining that goal by producing uncertainty and anxiety among some organizations on Ecology's plans for implementing the substantive portions of the definition included in the second sentence.

- Consistency with Definitions Used by Other Ecology Programs: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other Ecology programs. While other Ecology programs have not established a definition for neurotoxicant, the concepts reflected in the revised definition are consistent with the Ecology regulatory definitions for "carcinogen" in that it provides the flexibility to identify a chemical as a neurotoxicant using EPA's risk assessment guidelines.

- Consistency with Definitions Used by Federal and International Programs: Ecology believes the revised definition is consistent with current federal policies and guidelines because it references the EPA risk assessment guidelines.

- Opportunities for Public Review of Proposed Definition: Several members of the PBT Rule Advisory Committee stated that was inappropriate to include rule language that was different than the draft rule language discussed at the PBT Rule Advisory Committee meeting held on September 14, 2005. Ecology has reviewed the comments on this issue and believes they mischaracterize the process leading from language in the draft rule shared with the PBT Rule Advisory Committee to the proposed rule language published in the State Register. At the September 14th meeting, Ecology clearly stated that it was still considering whether to

include more specific toxicity criteria and definitions for terms used in the revised criteria (e.g. carcinogen, neurotoxicant, etc.). In addition, the language included in several explanatory footnotes highlighted that Ecology was still considering whether to make these revisions and that comments from the advisory committee would help to shape a final determination on the language to be included in the proposed rule.

Ecology's review and response to comments on the use of the term "chemical group" in various parts of the rule (e.g. the PBT list and criteria) is included in Chapter 5.

Issue 4-16: *No Observed Effect Concentration (NOEC)*

Proposed Definition

The proposed PBT rule published in June 2005 identified general criteria that Ecology proposed to use to determine whether a chemical or chemical group was toxic. Several organizations stated that Ecology's proposal was too vague and did not provide clear criteria for evaluating toxicity. In response to those comments, Ecology modified the proposed rule by including more specific criteria for judging toxicity. The revised rule language published in October 2005 states that Ecology will consider whether a chemical or chemical group has "...a chronic no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L" when making decisions on revising or amending the PBT list. The proposed PBT rule published in October 2005 also included the following definition:

> *"**No observed effect concentration**" or "**NOEC**" means the highest concentration of a chemical evaluated in an aquatic toxicity test that does not cause a statistically significant difference in effects compared with controls.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology should revise this definition to incorporate the concept of biological significance and toxicological relevance:

> *Definition must include that statistical differences are also biologically significant. For example, a study may include measurement of an irrelevant parameter, and find a statistical difference. That statistical difference does not mean that the so-called 'effect' is biologically significant or a relevant toxicological end point.* ***(Raymond Dawson and David Sanders, p. 6 of Attachment A to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to modify the proposed definition. The revised definition includes the following language:

> *"**No observed effect concentration**" or "**NOEC**" means the highest concentration of a chemical evaluated in an aquatic toxicity test that does not cause a statistically or biologically significant difference in effects compared with controls.*

Ecology's decision to revise the proposed definition is based on several factors:

- Scientific Defensibility: One of Ecology's overall rulemaking objectives is promote decisions that are consistent with current scientific knowledge. Ecology believes that the

"biological" significance of test results should be considered when making toxicity determinations.

- Consistency with Definitions Used by Other Ecology Programs: One of Ecology's rulemaking objectives is to develop decision-making criteria and processes that are consistent with other Ecology programs. Several Ecology programs have incorporated the concept of biological significance into definitions for "no observed effect concentration" or similar terms. For example:
  - ***Ecology's Toxics Cleanup Program*** *defines* ***"No observed adverse effect level"*** *or* ***"NOAEL"*** *as "...the exposure level at which there are no statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered to be adverse, nor precursors to specific adverse effects."*
  - ***Ecology's Toxics Cleanup Program*** *and* ***Water Quality Program*** *define* ***"No adverse effects"*** *as"... a level of effects that: (a) Has been determined by rule by the department, except in cases subject to WAC 173-204-110(6); and (b) Meets the following biological criteria: (i) No acute or chronic adverse effects to biological resources as measured by a statistically and biologically significant response relative to reference in any appropriate biological test as defined in WAC 173-204-200(3); and ...."*
- Consistency with Definitions Used by Federal and International Programs: Ecology believes that incorporating the concept of biological significance in the definition no observed effect concentration" is consistent with current federal policies and guidelines. For example:
  - **EPA's Glossary of Environmental Terms** defines "**No-Observed-Effect-Level (NOEL)**" as the "...[e]xposure level at which there are no statistically or biological significant differences in the frequency or severity of any effect in the exposed or control populations."

Issue 4-17: *Persistent bioaccumulative toxin (PBT)*

Proposed Rule

The proposed PBT rule published in June 2005 included the following definition:

> ***"Persistent bioaccumulative toxin"*** *or* ***"PBT"*** *means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in this chapter.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following definition:

> ***"Persistent bioaccumulative toxin"*** *or* ***"PBT"*** *means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in WAC 173-33-320.*

Public Comments and Concerns

The Washington Toxics Coalition expressed concerns that reference to criteria "established in this chapter" could be misinterpreted and recommended that Ecology include a citation to WAC 173-333-320 in this definition:

> *Because there are now two sets of criteria for determining whether a chemical is a PBT, the reference to "criteria established in this chapter" in the definition for "persistent bioaccumulative toxin" is unclear . Is a chemical a PBT because it meets the criteria outlined in section 320 or because it*

meets the second set of more stringent criteria in section 410? We believe the criteria in section 320 better define a PBT so the definition should specifically reference section 320. ***(Ivy Sager-Rosenthal, p. 6 of July 2005 written comments)***[28]

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and concurs. The modified definition now reads:

> ***"Persistent bioaccumulative toxin"*** *or* ***"PBT"*** *means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in WAC 173-33-320.*

Issue 4-18: ***Sensitive Population Group***

Proposed Rule

The proposed PBT rule published in June 2005 included the following definition:

> ***"Sensitive population group"*** *means groups of people that exhibit a different or enhanced response to a PBT than most people exposed to a similar level of the PBT because of genetic makeup, age, nutritional status or exposure to other toxic substances*

Ecology modified the June 2005 proposed rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following definition:

> ***"Sensitive population group"*** *means groups of people that exhibit a different or enhanced response to a chemical than most people exposed to a similar level of the chemical because of genetic makeup, age, nutritional status or exposure to other toxic substances.*

Public Comments and Concerns

The Washington Toxics Coalition expressed concerns with the proposed definition in the June 2005 proposed rule and recommended two revisions:

> *In the definition of "sensitive population group," the term "different" should be eliminated. Sensitive population groups experience the same response to a chemical that others experience but just at a lower level of exposure.*
>
> *Also the term "PBT" in the definition of "sensitive population group" should be changed to chemical because it is possible that a person's exposure comes from a chemical that contains a PBT but is not a PBT itself. The wood preservative pentachlorophenol is an example of this. It may not qualify as a PBT itself but it contains dioxin, which is a PBT.* ***(Ivy Sager-Rosenthal, p. 6 of July 2005 written comments)***[29]

Ecology's Review and Response to Public Comments

Ecology has reviewed this comment and agrees that the definition of sensitive population group should not be constrained to responses arising from exposure to PBT chemicals. Specifically, Ecology intended this definition to be focused on the characteristics of particular population

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[28] The Washington Toxics Coalition suggested the following rule language: ***"Persistent bioaccumulative toxin" or "PBT"*** *means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in WAC 173-333-320 ~~this chapter~~.*

[29] The Washington Toxics Coalition suggested the following rule language: *"**Sensitive Population Group**" means groups of people that exhibit an enhanced response to a chemical than most people exposed to a similar level of the chemical because of genetic makeup, age, nutritional status or exposure to other toxic substances.*

groups (e.g. children, pregnant women, etc.) and not the particular adverse effects and/or substances causing those effects. Consequently, Ecology has revised the proposed definition to incorporate the suggested language:

> ***"Sensitive population group"*** *means groups of people that exhibit a different or enhanced response to a chemical than most people exposed to a similar level of the chemical because of genetic makeup, age, nutritional status or exposure to other toxic substances.*

Ecology also considered the recommendation to delete the word "different" from the proposed definition. Ecology agrees there are many examples where the sensitive population group exhibits the same types of responses to a toxic chemical as the general population – with those effects occurring at lower exposure levels and/or displaying different dose-response relationships. However, there are also examples where the critical effects in the sensitive population are different than those observed in the general population (e.g. adverse impacts on neurological development associated with child lead exposure vs. adverse effects following adult exposure). Consequently, Ecology elected not to make the suggested change.

Issue 4-19: ***Toxicity***

Proposed Definition

The proposed PBT rules published in June and October 2005 included the following definition:

> ***"Toxicity"*** *means the degree to which a substance or mixture of substances can harm humans, plants or wildlife.*

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) recommended that Ecology limit this definition to aquatic toxicity.

> *As note previously, the definition of toxicity when referring to PBT chemicals is restricted to aquatic toxicity* ***(Raymond Dawson and David Sanders, p. 14 of Attachment A to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comment on this issue and decided not to revise the proposed definition. In making this decision, Ecology considered the following factors:

- Statutory Directives and PBT Executive Order: Ecology is responsible for implementing a wide range of environmental statutes that are designed to protect human health and the environment.
- Scientific Defensibility: Ecology believes that limiting the definition of toxicity to aquatic toxicity is inconsistent with available scientific information demonstrating that various PBT chemicals pose risks for humans and terrestrial plants and animals.
- Consistency with Definitions Used by Other Ecology Programs: Several Ecology programs have published definitions for toxicity or similar terms in rules and guidance materials. Restricting the definition to aquatic toxicity would be inconsistent with those definitions.
- Consistency with Definitions Used by Federal and International Programs: Other state, federal and international PBT programs consider the potential for toxic effects in humans and terrestrial organisms when evaluating toxicity.

Chapter 5: The PBT List and Criteria and Procedures for Revising the List (Part III)

5.1. What is the purpose of the PBT List? (WAC 173-333-300)

Issue 5-1: **What are the purposes of the PBT List?**

Proposed Rule

Ecology proposed that "....[t]he purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington." (WAC 173-333-300(1)).

Ecology also proposed that a "....decision to include a particular chemical on the PBT list does not represent a decision that all uses and releases of that chemical should be reduced and eliminated." (WAC 173-333-300(3)).

Public Comments and Concerns

Several organizations expressed concerns that the purpose of the list identified in the proposed rule was at odds with the purpose of the list articulated in the proposed Ecology PBT Strategy. For example:

> *One of the biggest problems that we see the rule right now is it's departure from the 1998 strategy document, or actually I guess it was the 1999 strategy document, that outlines the vision for the PBT program, and in that document, then director, Tom Fitzsimmons, established some really groundbreaking goals, goals that truly protective of children's health, my families health, the environment, and those goals were to reduce and eliminate PBTs in Washington State, and he even set forward a timeline of doing this by 2020. There's also some really strong language in that strategy document about the precautionary principle and how important it is to apply the precautionary principle when making decisions relating to toxic chemicals. Now that I look at this rule, none of those goals or ideas are really included. I can flag a number of instances in the rule which really depart from the original vision. For example, in the purpose statement of the rule, it talks about when or whether we would phase out these chemicals. The strategy is not about whether we phase out those chemicals. The strategy is pretty clear. Yes, we will phase out these chemicals. The question isn't whether, it's how quickly.* ***(Ivy Sager-Rosenthal, Testimony at November 9, 2005 Public Hearing)***

Several organizations expressed concerns about WAC 173-333-300(3)(a) and recommended that Ecology remove this subsection from the final rule because it sends a message to businesses and consumers that might be interpreted as being inconsistent with a goal of phasing-out uses and releases of chemicals on the PBT list. For example:

> *WAC 173-333-300 (3) (a) must be deleted, or at the very least amended (see below). This section states that listing a chemical on the PBT list does not represent a decision that its uses and releases should be reduced and phased-out.....Both sections completely undermine the purpose of the PBT program, which is to reduce and eliminate PBTs in Washington. They create a huge loophole in the program and remove an important incentive—the phase-out of the use and release of PBT chemicals—for business, government, and consumers to find and use less toxic alternatives. If the sections remain as currently drafted, each time a CAP is developed, the focus will be on whether a chemical should be reduced and phased-out and not how a chemical will be reduced and phased-*

out. The decision of whether a chemical should be phased out has already been made when the chemical was listed. To continue the debate will be counterproductive and make it more difficult for Ecology to take action on these chemicals and to protect human health and the environment. ***(Ivy Sager-Rosenthal, p. 2 of November 2005 written comments)***

.....in the section 300, 3A, it said, Ecology's decision to include a particular chemical on the PBT list does not represent a decision that all uses and releases of that chemical should be reduced or eliminated, and I think that language should be removed. I think that the intent of this is to ultimately eliminate these chemicals, and these are the worst of the worst chemicals, and I think this language was put in here to send a message that is not a clear message. I think the clear message should be to the business community and to consumers and to all of us, that these chemicals are bad and they need to be eliminated, and we need to do all we can to get there. So, I'd like that language to be removed. ***(Laurie Valeriano, Testimony at July 13th public hearing).***

The Washington Toxics Coalition proposed several revisions to WAC 173-333-300(3)(a) to address the above concerns:

We understand that WAC 173-333-300 (3) (a) may have been included because of concern that listing a chemical on the PBT list means that it must be eliminated immediately without consideration of such important factors as the availability of alternatives. This concern is unfounded. The rule contains several provisions that allow for the consideration of alternatives, cost, and technical feasibility. If the concern is about the timing of phase-outs, we would suggest amending the language to read the following:

(a) Ecology's decision to include a particular chemical on the PBT list does not ~~represent a decision that all uses and releases of that chemical should be reduced and phased out~~ necessarily mean the chemical must be phased out immediately. Rather it represents a decision by Ecology that the uses and releases of the chemical must be reduced and phased out on a reasonable timeline after careful consideration during the CAP process of the opportunities for reduction and phase out.

We believe this proposed language addresses any concern about the timing of phase-outs while at the same time committing to the reduction and elimination goals of the PBT program. ***(Ivy Sager-Rosenthal, p 2 of November 2005 Written Comments).***

Other organizations and individuals stated that the primary purpose of the PBT List was to identify candidates for further action. Under this approach, further actions would be identified after more detailed evaluations performed when selecting chemicals for CAP preparation and preparing CAP recommendations. For example:

WAC 173-333-300 What is the purpose of the PBT list? *Consistent with purpose of the rule and the possible actions to be considered in a CAP, the list identifies chemicals that may require further action. Chemicals are placed on the list if they meet defined P, B and T criteria without regard to their presence or risk in Washington. It is therefore premature to assume any PBT on the list requires further action. To presuppose otherwise dilutes the purpose of the screening and criteria identification process outlined in WAC 173-333-320 and 330. It is also an incorrect assumption to presume that a chemical is a potential threat to human health and the environment and in need of further regulatory action based solely on the fact that the chemical qualifies as a "PBT.* ***(Grant Nelson, p. 2 of November 2005 Written Comments)***

*Screening of PBT characteristics is a critical step for identifying candidate substances rapidly. However, screening of PBT characteristics is only the starting point for conducting appropriate risk assessments to determine if new or additional risk management efforts are necessary****. (Michael Walls and Clifford Howlett, p. 4 of July 2005 Written Comments)***

The Association of Washington Business recommended that Ecology modify WAC 173-333-300(1) to reflect this phased evaluation approach. They proposed the following change:

The purpose of the PBT list is to identify toxic chemicals that <u>may</u> require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington. ***(Grant Nelson, p. 7 of Attachment to November 2005 Written Comments)***

The Washington Toxics Coalition recommended that Ecology remove the phrase "in Washington" from the purpose statement ***(Ivy Sager-Rosenthal, p. 5 of Attachment to July 2005 Written Comments.)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the rule language[30] describing the purpose for the PBT list. However, Ecology decided to make the following change to WAC 173-333-300(3)(a) in order to clarify the relationship between the PBT list and decisions on actions to reduce and phase-out PBT uses and releases:

Ecology's decision to include a particular chemical on the PBT list does not represent a <u>final determination</u> ~~decision~~ that all uses and releases of that chemical should be reduced and eliminated.

Ecology's decisions to make some of the recommended changes and not others were based on three primary considerations:

- <u>Ecology believes that the purpose statement and the revised language in WAC 173-333-300(3)(a) are consistent with the phased decision-making process established by the PBT rule</u>: The PBT rule establishes a phased evaluation and decision-making process that begins with preparing (and periodically updating) the PBT List. Placing a chemical on the PBT List creates a presumption for action with the goal of reducing and phasing out uses and releases of the chemical. However, that presumption can be overcome at subsequent stages in the decision-making process as additional factors are considered. For example, evaluations at subsequent steps in the decision-making process may demonstrate that the chemical is not used or released in Washington. Consequently, the preparation of the PBT list is the entry point for the overall decision-making process.
- <u>Ecology believes that the purpose statement and the revised language in WAC 173-333-300(3)(a) are consistent with Ecology's proposed PBT strategy and the Department's early implementation of that strategy</u>: Several organizations expressed concerns that the proposed PBT rule was a departure from the proposed Ecology PBT Strategy. Specifically, they argued that there are critical differences between the proposed strategy and the proposed rule in terms of the overall goal, purpose of the list and application of the precautionary principle. Although there are differences on specific issues, Ecology believes that a critical review of the proposed PBT strategy and it's early implementation (e.g. preparation of the mercury action plan) indicates a high degree of consistency on several broad points:
    - <u>Environmental Goal</u>: The two proposed documents identify similar environmental goals. The proposed PBT rule states that "...[t]he goal of this chapter is to reduce and phase-out PBT uses, releases and exposures in Washington...". This goal is consistent with the proposed PBT strategy which includes an overall vision (...continually reducing risks to human health and the environment from exposures to PBTs, by the year 2020...) and

[30] WAC 173-333-300(1) states "....[t]he purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington."

several goals associated with achieving that vision including reducing and, where possible, phase-out existing sources of PBTs, clean up PBTs from historical sources and prevent new sources of PBTs.

- Phased Decision-Making Process: The two proposed documents both envision a phased decision-making process. The proposed PBT rule establishes a decision-making process for evaluating what actions should be taken to reduce and phaseout PBT uses, releases and exposures. Identification of PBTs is the first step in that process. This represents a preliminary determination that actions are needed with a preference being given to actions that achieve the overall goal. However, that presumption can be overcome at later stages in the decision-making as additional factors are considered as part of the processes for selecting and preparing chemical action plans. The proposed PBT strategy (in the discussion of the precautionary principle) describes a similar process:

  > *New and Existing Sources of PBTs: Once a substance has been identified as a PBT, a full range of response options (e.g. control, prevention, use reduction, phase-out) need to be identified and evaluated. Consistent with many current environmental laws, applying the precautionary principle creates a preference for using safer alternatives. However, that presumption can be overcome by considering the technical, economic, and social circumstances surrounding the specific activity.* ***(Ecology, 2000, p. 16)***

- Chemical Action Plans: Both proposed documents establish a central role for chemical action plans. The proposed PBT rule establishes a decision-making process where chemical action plans are the primary vehicle for decisions on actions to reduce and phase-out uses, releases and exposures. Although the proposed PBT strategy identified a number of potential implementation mechanisms, Ecology proposed that "...*Chemical action plans*, to be developed by Ecology in collaboration with others for specific high-priority chemicals, will be the primary means by which specific reduction actions and activities will be developed and implemented..." (Ecology 2000, p. 6).

Ecology acknowledges that "consistent" does not mean "identical". The proposed PBT Strategy and the proposed PBT rule have several important differences. For example, the proposed strategy envisions Ecology working with others to establish more generic requirements that extend beyond the chemical-by-chemical approach embodied in the preparation and implementation of chemical action plans.

- Ecology believes that the purpose statement and the revised language in WAC 173-333-300(3)(a) are consistent with Ecology's determination that this chapter is a "procedural rule": Ecology proposed the PBT rule as a "procedural rule" that defines the criteria and processes Ecology will use to identify PBT chemicals and develop recommendations on actions to reduce and phase-out uses, releases and exposures. Ecology believes that an interpretation that listing a chemical on the PBT list represents a final decision that all uses and releases of that chemical will be phased out is inconsistent with the procedural nature of the rule. Specifically, the listing of a chemical does not impose substantive requirements on companies or individuals that produce, use or release the chemical. Ecology believes that listing a chemical on the PBT List represents a preliminary determination that actions should be taken to reduce and phase-out uses and releases of the chemical. However, the chemical action plan process provides a decision-making process for making final determinations on particular uses and releases.

One person recommended that Ecology delete the phrase "in Washington". The purpose of the PBT list is to identify chemicals where further action is required. Such actions will be directed

at uses, releases and exposures occurring in Washington. Consequently, Ecology continues to believe that it is appropriate to include the phrase "in Washington" in the purpose statement. However, Ecology recognizes that inclusion of this phrase may be interpreted as creating an additional listing criterion (i.e. evidence that a chemical is used, released or present in Washington before adding it to the PBT list.). That is an incorrect interpretation. Decisions on whether to list a particular chemical will be based on persistence, bioaccumulation, toxicity and (in the case of metals) bioavailability.

Issue 5-2: What are the intended uses of the PBT List?

Proposed Rule

Ecology identified five intended uses of the PBT list in the proposed rule (WAC 173-333-300 (2)):

> *(2)* ***Intended uses of the PBT list.*** *Ecology will use the PBT list in the following ways:*
>
> *(a)* ***Chemical action plans.*** *To select chemicals for chemical action plan development.*
>
> *(b)* ***Ambient monitoring.*** *To help guide decisions on the design and implementation of ecology programs for characterizing chemical concentrations in the ambient environment.*
>
> *(c)* ***Biomonitoring.*** *To encourage and inform the department of health regarding their efforts to monitor chemicals in human tissue.*
>
> *(d)* ***Public awareness.*** *To promote greater public awareness on the problems associated with PBT chemicals, the uses and sources of individual PBTs and steps that individuals and organizations can take to reduce PBT uses, releases and exposure.*
>
> *(e)* ***Voluntary measures.*** *To help identify opportunities for government agencies, businesses and individuals to implement voluntary measures for reducing and phasing out PBT uses and releases.*

Public Comments and Concerns

Several organizations stated that the intended uses identified in the PBT rule were more limited than the uses identified in the Ecology PBT Strategy document[31] and recommended that Ecology expand the intended uses of the PBT list. For example:

> *Expand the Intended Uses Of the PBT List. The intended uses of the PBT list in WAC 173-333-300 (2) do not reflect the goals and purposes of the PBT Strategy. The section must be expanded to include all of the elements of the PBT Strategy. The specific language is included in the redlined version of the rule attached to these comments****. (Ivy Sager-Rosenthal, p. 4 of July 2005 written comments)***
>
> *Expand the Intended Uses Of the PBT List* ***(Heather Trim, p. 2 of July 2005 written comments).***

The Washington Toxics Coalition recommended the following additional intended uses be identified in the PBT rule:

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[31] The comparison table attached to the comments submitted by the Washington Toxics Coalition describes actions/uses identified in the PBT Strategy. Strategy sets out comprehensive list of actions Ecology will take to achieve reduction and elimination goal. These actions include: Develop chemical action plans; Revise environmental regulations to address cross-media effects of PBT releases; Lower emission limits; Demonstrate how PBT releases can be reduced within classes of permits; Develop economic incentives; Increase focus on PBT-contaminated sites; Enhance efforts to prevent the use and release of PBTs from new industrial and commercial sources; Increase public awareness.

(f) *Improve Regulatory and Non-Regulatory Approaches: Ecology and Health will use the list to inform efforts to maximize the effectiveness of regulatory and non-regulatory approaches for phasing out the use and production of PBTs, including improving collaboration among regulatory programs and improving regulatory and economic incentives for eliminating PBTs.*

(g) Clean up PBTs from historical sources: Ecology and Health will use the list to increase focus on PBTs found at contaminated sites and enhance efforts to clean up sediment contamination problems.

(h) Prevent new sources of PBTs. Ecology will use the list to enhance efforts to prevent the use and release of PBTs from new industrial and commercial sources and to encourage extended product responsibility for new sources and products.

(i) Build partnerships. Ecology and Health will use the list to promote efforts to eliminate PBTs and coordinate with other jurisdictional programs, ***(Ivy Sager-Rosenthal, p. of July 2005 Written Comments).***

Several organizations expressed concerns that Ecology would use the PBT list as the sole basis for establishing additional monitoring requirements and recommended revisions to the proposed rule language. For example:

AWB members remain concerned that the PBT rule could be used by Ecology staff as the sole basis for additional monitoring requirements and requests the modification in the mark-up to remedy this concern. ***(Grant Nelson, p. 2 of November 2005 Written Comments)***

(b) Ecology ~~does not intend to~~ will not use the PBT list as the sole basis for establishing discharge monitoring requirements that are not required under current permits. Ecology will evaluate and, if necessary ~~appropriate~~, prepare recommendations for additional monitoring requirements when preparing chemical action plans (WAC 173-333-420 and 173-333-430).

The Bromine Science and Environmental Forum recommended that Ecology take into account actions being taken by other agencies when deciding how to use the PBT list. For example:

NOTE: Many of the listed chemicals are currently regulated under U.S. law. Some are banned in the U.S. Some are available only for restricted uses. Others have been voluntarily withdrawn from production and require prior EPA notification and approval before resumption of production and/or use. Some are not intentionally produced. After quick review that is not intended to be inclusive, those which are banned, voluntarily withdrawn, not intentionally produced or available only for restricted use are marked with a X in the table below. ***(Raymond Dawson and David Sanders, Attachment A of November 2005 Written Comments)***

The Association of Washington Business recommended that Ecology take into account the inherent performance qualities of individual chemicals when using the PBT list:

The department would be wise to recognize the inherent performance qualities related to "persistence", including an increase in the stability of that chemical, which not only allows that chemical to be used in less quantity and toxicity, but also retains its effectiveness over the course of time. In the case of a fire retardant for example, persistence is a valuable quality. ***(Grant Nelson, p. 2 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on the proposed uses of the PBT list. Those comments fall into three main categories: (1) additional uses of the list; (2) use of the PBT list to establish discharge monitoring requirements; and (3) factors to consider when using the PBT list. Ecology has organized its response around those three categories.

- **Additional Uses of the PBT List**: Several organizations recommended that Ecology expand the list of intended uses of the PBT List. Ecology reviewed those comments and

decided not to expand the list of intended uses for the PBT list. The rationale for this decision includes the following:

- The Legislature directed Ecology to prepare a PBT List that would be used to identify chemicals that would be addressed in chemical action plans: The Legislative budget proviso identifies one use for the PBT list (identifying chemicals to be evaluated in chemical action plans). Ecology believes the proposed uses of the PBT list are consistent with that directive in that the five proposed uses include chemical action plans and several other activities that are closely related to preparing, implementing and evaluating the effectiveness of chemical action plans.

- The five intended uses of the PBT list identified in the proposed rule are consistent with the proposed Ecology PBT strategy in that the five uses include (directly or indirectly) many of the major implementation vehicles identified in the proposed strategy. The proposed PBT strategy established an overall vision (...continually reducing risks to human health and the environment from exposures to PBTs, by the year 2020...) and eight goals associated with achieving that vision. Although the proposed PBT strategy identified eight goals and a number of potential implementation mechanisms, Ecology proposed that "...*Chemical action plans*, to be developed by Ecology in collaboration with others for specific high-priority chemicals, will be the primary means by which specific reduction actions and activities will be developed and implemented..." (Ecology 2000, p. 6). Consequently, the proposed uses include the primary implementation tool identified in the proposed PBT strategy.

  With respect to cleaning-up historical releases of PBTs, Ecology's proposed PBT strategy identified several potential activities associated with enhancing current efforts under state and federal Superfund programs. In discussing the application of the precautionary principle, Ecology (2000) indicated that current programs would continue to be used to cleanup releases from historical sources when it stated that "...efforts to cleanup historical releases will continue to be guided by risk assessment/risk management concepts" (p. 16). Consequently, Ecology has not identified a practical difference (relative to implementing current programs) of including "clean-up PBTs from historical sources" on the list of intended uses.

  As noted above, Ecology acknowledges that "consistent" does not mean "identical". The proposed PBT Strategy and the proposed PBT rule have one primary difference in that the proposed strategy envisions Ecology working with others to establish more generic requirements that extend beyond the chemical-by-chemical approach embodied in the preparation and implementation of chemical action plans.

- Ecology is using it's legal authority under the state's air, water and waste laws to reduce PBT uses, releases and exposures. The proposed PBT rule is not the only mechanism for reducing and phasing-out PBT uses, releases and exposures. Ecology is currently implementing a wide range of measures to address PBT chemicals as part of efforts to cleanup contaminated sites, develop and implement air and water permits and implement measures to manage hazardous and solid waste.

- **Use of the PBT List to Establish Discharge Monitoring Requirements**: The PBT Advisory Committee discussed this issue at several of their meetings in late 2004 and the proposed rule language was developed during those discussions. Ecology's position on this issue is that the Department possesses the legal authority to require dischargers to conduct monitoring for PBTs under the state water quality laws and regulations. However, Ecology

agrees that listing a chemical on the PBT list does not eliminate the need for Ecology to meet the substantive requirements associated with imposing additional monitoring requirements that are specified in existing water quality laws and regulations. In other words, Ecology agrees that a decision to include a chemical on the PBT list does not create an independent basis for establishing additional monitoring requirements under other state laws and regulations. Ecology has reviewed the comments on this issue and decided to modify the proposed language in order to eliminate the ambiguity on Ecology's position. The revised language is shown below:

> *(b) Ecology ~~does not intend to~~ will not use the PBT list as the sole basis for establishing discharge monitoring requirements that are not required under current permits. Ecology will evaluate and, if appropriate, prepare recommendations for additional monitoring requirements when preparing chemical action plans (WAC 173-333-420 and 173-333-430).*

- **Factors to Consider When Using the PBT List**: Ecology agrees with suggestions that factors such as actions being taken by other agencies and performance qualities of particular PBT chemicals be considered when implementing this chapter. The processes for prioritizing PBT chemicals (WAC 173-333-410) and preparing chemical action plans (WAC 173-333-420) identify a wide range of factors (including the two factors identified in comments on this section) that Ecology will consider when implementing the rule. Consequently, Ecology does not believe that such factors need to be explicitly identified in WAC 173-333-300.

5.2. What chemicals or chemical groups are included on the PBT list? (WAC 173-333-310)

Issue 5-3: ***Should Ecology base listing decisions on an evaluation of health and environmental "hazards" or health and environmental "risks"?***

Proposed Rule

Ecology proposed to make decisions on whether to include a chemical on the PBT List based on an evaluation of the chemical's "hazard" as measured by the chemicals' persistence, bioaccumulation potential and toxicity. Under the proposed approach, Ecology will not evaluate the potential exposures and risks to Washington residents or environment when preparing the PBT List. However, Ecology will consider those and other factors when (1) prioritizing chemicals for CAP preparation (WAC 173-333-410) and (2) evaluating actions to reduce and phase-out uses and releases as part of preparing the CAP (WAC 173-333-420).

Public Comments and Concerns

Several organizations supported Ecology's decision to use a hazard-based approach to decide which chemicals to include on the PBT list. For example:

> *We should not wait until a chemical is found to specifically pose a problem in Washington before taking action. The PBT program is an opportunity to take preventive action before PBT chemicals contaminate our bodies and the environment. The PBT list should include all chemicals that qualify as a PBT regardless of if they "currently" pose human health or environmental impacts in Washington. Also, data on levels of PBTs in Washington is incomplete making it difficult to*

determine whether a PBT poses a problem in Washington. ***(Ivy Sager-Rosenthal, p. 3 of July 2005 Written Comments)***

However, several other organizations recommended that Ecology consider a risk-based approach that takes into account potential exposures and risks when making decisions on whether to include a chemical on the PBT list. For example:

The process for developing, amending, and removing chemicals from the PBT list should include an assessment of exposure levels to determine if further action is warranted or whether a chemical might be removed or shifted to another category. Relying solely on the PBT criteria does not give a complete picture of the risk presented by the chemical because a chemical's intrinsic characteristics will not change. Overall, the PBT criteria should be consistent with internationally recognized criteria that have already been negotiated. (See Section 5 below.) Screening of PBT characteristics is a critical step for identifying candidate substances rapidly. However, screening of PBT characteristics is only the starting point for conducting appropriate risk assessments to determine if new or additional risk management efforts are necessary. ***(Michael Walls and Clifford Howlett, pp. 2-3 of July 2005 written comments)***

*Ecology should continue to take a science-based approach to their assessment of chemicals. The proposed Rule is appropriately guided by sound science and risk assessment, rather than utilizing a purely precautionary approach based on hazard characteristic alone..... .****(Michael Walls and Clifford Howlett, pp. of July 2005 Written Comments)***

The business community has asked the department to be objective in their listing of PBTs based on credible scientific information. The PBT rule has sufficient provisions to achieve this goal, once the concerns in item 1, 2 and 3 above are addressed. Missing from the rule is an adjunct screening mechanism to ensure that agency and public resources are not expended on chemicals with minimal risk to the public or environment. Early discussions on this rule included a mechanism to conduct a preliminary risk screening of candidate PBT chemicals prior to in-depth study. This screening process had several valuable functions that should be reincorporated into the rule. First; the screening eliminated those chemicals not likely to be a problem in the State. Examples are:

- *Chemicals not being used in the State.*
- *Chemicals used in quantities insufficient to create risk,*
- *Chemicals used in a controlled industrial environment subject to other controls*
- *Chemicals already banned under Federal law which are properly focused on cleanup programs.*

The importance of this preliminary screening process goes to the heart of the original reason that the business community supported the PBT rulemaking- establishing certainty that PBTs would be selected on the merit of risk rather than politics du jour. Using a prescreening process establishes which chemicals need further risk analysis to support the activation of the process for adding a PBT to the list. This creates a de-facto prioritization process, based on risk, for which PBTs will be proposed and which chemical actions plans will be targeted first. The first plans being those for PBTs that present the greatest risk to the public and environment. The current list has many chemicals listed simply on a P-B & T number pulled from scientific literature. This list does not provide the agency with sufficient guidance as to which chemical action plan to address first. Worse, the agency will find itself whipsawed by competing political agendas to pick a particular PBT for action from this chemical laundry list- without a supporting Washington risk analysis. Recommend that in conjunction with the action to re-evaluate the listing based on scientific credibility that the agencies consider creating a listing of PBT candidates consisting of the chemicals that fall off the current listing. A risk assessment provision should be reinstated in the PBT rule to facilitate the initial risk screening for these chemicals. Chemicals show a substantial risk of affecting Washington's people and environment can then be forwarded to the appropriate independent science

panel for review and recommendation as to inclusion in the PBT listing and ultimately a chemical action plan. ***(Kirk Thomson, pp. 5-6 of November 2005 written comments)***

Also we're concerned, when you added phthalates to the PBT list, there was, and I sent Mike a letter on this that, all of a sudden it said it's contained in wild Chinook salmon in Puget Sound. Well maybe it's detectable, but does that mean that people should stop eating wild Chinook salmon? Well, it may not seem big to you guys, it's big to us because it's our product we sell. All of a sudden you're saying that this salmon can cause reproductive problems in young boys. Well, that's a big issue to us. We've also had studies starting to come out from medical groups that are stating all these scares on environmental issues and PBTs are moving people away from eating fish. It's impacting the market, and they're believing they're moving to a more unhealthy diet, which will lead to less brain development and IQ in children. So, you do not have – we're concerned with how Ecology's done this in the past. We're concerned how it's continuing to do this, and we need another method to go address these issues from a scientific point of view. You're not always going to agree with us. We understand it, but we need a better forum for it and I don't think it's the current, only committing inside of the chemical action plan. ***(Randy Ray, Testimony at November 9, 2005 Public Hearing)***

The National Council for Air and Stream Improvement (NCASI) stated that satisfying the PBT criteria (i.e. persistence, bioaccumulation potential and toxicity) did not demonstrate risk and urged Ecology to identify criteria for action/inaction:

*T**he proposed rule makes no mention of what level of risk is acceptable**. As discussed at the stakeholder meetings, science can provide an estimate of risk but cannot make the determination of what level of risk is acceptable. Although PBT chemicals have the potential to pose risks based purely on their PBT characteristics, this does not mean that there is an actual risk present in any specific set of circumstances. Thus simply satisfying the PBT criteria does not demonstrate risk. Because the ultimate goal of the proposed rule is to limit risk ("threat"), the rule should address this issue explicitly and criteria for action or inaction should be set.*

The issue of risk could be addressed as part of the process of selecting chemicals from the PBT list for development of CAPs. Thus, each chemical on the PBT list would be subject to a preliminary risk assessment, and chemicals would be ranked based on their relative risks. CAPs would be developed for chemicals in the order in which they appear on this list. Alternatively, a risk assessment could be a central component of a CAP. This approach would logically require some initial ranking or prioritization of the PBT list itself (see comment 2 below), but this might be accomplished using some scoring system; for example, a system based on presence and quantity in Washington State as previously proposed by Ecology [1,2].

Considering the complexity associated with performing rigorous risk assessments, NCASI suggests that they be performed as part of developing CAPs. Thus, Ecology should modify the proposed rule to state this explicitly. ***(Jeff Louch, p. 1 of July 2005 written comments)***

While the Washington Toxics Coalition strongly opposed including information on uses, releases or environmental presence as a necessary requirement for including a chemical on the PBT list, they suggested that Ecology consider using an "exposure-based" approach to supplement the hazard-based approach in the proposed rule. Specifically, they suggested that Ecology should provide itself the flexibility to include a chemical on the PBT list if there was data available showing that highly toxic chemicals were measured in people:

The third thing is that, I think to deal with some of these chemicals like phthalates, is to add some criteria to the PBT so that Ecology has the authority to add chemicals with similar characteristics, or chemicals that are going to pose similar problems for us, and that it doesn't necessarily have to meet the numeric criteria, but, for example, phthalates, we're measuring them in people, we're measuring them in the environment. We're experiencing similar problems that we're experiencing with PBTs, and they're showing it has very severe toxicity issues, and so, I think that there needs to be more

flexible criteria so that Ecology can add chemicals like that to the list. ***(Laurie Valeriano, Testimony at July 13th Public Hearing)***

The Bromine Science and Environmental Forum expressed concerns that Ecology's proposed approach did not allow consideration of the health and safety benefits of a chemical when deciding whether to include it on the PBT list. ***(Raymond Dawson and David Sanders, Attachment to November 2005 written comments).***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the proposed rule to incorporate the various concepts suggested by one or more organizations. However, Ecology believes the comments on the consideration of "risks" and "hazards" are extremely important in that they touch upon several fundamental issues related to the proposed decision-making process, the scientific basis for decision-making and the precautionary nature of actions to prevent health threats. Consequently, Ecology has prepared the following responses to several of the points reflected in the comments on this issue.

- How does a hazard-based approach for identifying PBT chemicals differ from a risk-based approach? The concepts of "risk" and "hazard" are confusing to many people and the two terms are often used interchangeably. For purposes of the PBT rulemaking, Ecology has used the term "risk" to mean "the probability that exposure to a hazard will lead to a negative consequence"[32]. This definition includes four main elements:
  - "Hazard" refers to the intrinsic characteristics of a chemical (it's ability to cause cancer, etc.);
  - "Exposure" refers to amount of a chemical that people or organisms come into contact with;
  - "Probability" refers to the likelihood or statistical chance that something will happen (e.g. a person's risk of dying is one in a million"); and
  - "Consequence" refers the severity of an event (risk generally involves a negative outcome)[33].

  With this terminology, the key difference is that a hazard-based approach for identifying PBT chemicals only considers the intrinsic properties of a chemical (e.g. persistence, bioaccumulation and toxicity) while a "risk-based" approach considers both the intrinsic properties of the chemical (hazard) and the potential for exposure/probability of a negative consequence. Both hazard-based and risk-based approaches can be further divided into qualitative, semi-quantitative and quantitative risk assessment approaches.
- How has Ecology proposed to consider information on hazard and risks? The proposed PBT rule establishes a phased decision-making process that systematically considers information on hazards, exposures, risks and other factors at different stages of the decision-making process:

[32] Ropiek, D. and G. Gray. 2002. Risk: A Practical Guide for Deciding What's Really Safe and What's Really Dangerous in the World Around You. Houghton Mifflin Company. New York. (page 4).

[33] Ropiek and Gray also observed that "...the facts about risk are only part of the matter. Ultimately we react to risk with more emotion than reason" (p. 15). They also identified a number of risk perception factors that help predict people's responses to risk information. These include: Most people are more afraid of risks that are new than those they've lived with for a while; Most people are less afraid of risks that are natural than those that are human-made; Most people are less afraid of a risk they choose to take than of a risk imposed on them; Most people are less afraid of risks if the risk also confers some benefits they want; Most people are less afraid of risks they feel they have some control over (e.g. driving); People are much more afraid of risks where uncertainty is high, etc. (pp. 16-17)

- Preparing the PBT List: The initial step in the decision-making process is identifying PBT chemicals and preparation of the PBT list. Under the proposed rule, Ecology's decision to include a chemical on the PBT list is based on an assessment of the chemical's hazard. Under the proposed rule, Ecology uses information on a chemical's persistence, bioaccumulation potential and toxicity to assess its hazard.

- Prioritizing Chemicals for Chemical Action Plan Preparation: The second step in the decision-making process is screening and setting priorities for preparing chemical action plans. At this stage of the process, Ecology plans to use information on potential exposure (e.g. is the chemical found in products used in Washington, is it being released by Washington sources, etc) to prepare a qualitative or semi-quantitative estimate of the relative risks posed by the chemicals on the PBT. Ecology's decisions on preparing chemical action plans are based on (1) the relative risk rankings, (2) information on opportunities for reducing uses and releases and (3) other factors such as sensitive population groups, existing regulations, etc.

- Preparing and Implementing Chemical Action Plans: The third step in the decision-making process is preparing and implementing chemical action plans. Phasing-out PBT chemical uses and releases is the preferred management alternative. However, the actual measures that Ecology recommends to reduce or prevent exposure, uses and releases of a particular chemical will be identified through the CAP process. Ecology recognizes that many factors will influence whether and when the goal (reduce and phase-out) can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. Ecology will identify the reasons for recommending alternatives other than phasing-out the chemical in the CAP. At this stage of the decision-making process, Ecology will assess the benefits and costs of the recommended alternative. This will include estimates of health and environmental risks. Based on the available data, risk estimates may be expressed in qualitative, semi-quantitative or quantitative terms.

- Why does Ecology believe that a hazard-based approach is an appropriate basis for preparing the PBT List? Ecology reviewed the comments on this issue and continues to believe that decisions on whether to include a chemical on the PBT List should be based on an evaluation of the hazards posed by that chemical. The hazard assessment takes into account a chemical's persistence, bioaccumulation potential and toxicity. The rationale for this approach is based on the following considerations:

  - Ecology believes that basing listing decisions on chemical hazard is consistent with the multiple uses of the PBT List. In the proposed rule, Ecology identified five intended uses for the PBT List. The majority of intended uses identified in the proposed rule relate to (1) information collection and (2) promoting greater awareness in order to facilitate voluntary choices by companies and individuals to reduce and phase-out PBT uses, releases and exposures. EPA evaluated this issue when lowering the reporting thresholds for PBT chemicals under the Toxics Release Inventory (TRI) program:

    > *...EPA does not believe that it would be good public policy to consider factors related to quantitative risk with respect to establishing thresholds for PBT chemicals. Given the degree of persistence and bioaccumulation that these toxic chemicals exhibit, EPA believes that the value of this information to the public outweighs the policy considerations presented in favor of considering risk factors in establishing revised thresholds. Any other decision would be inconsistent with the legislative intent underlying EPCRA section 313. (FR 58694)*

  - Ecology believes that proposed rule establishes a reasonable decision-making approach that systematically evaluates both hazard and risk at various stages in the process. Ecology agrees with organizations and individuals who stated that information on

exposure and risk should be considered when establishing priorities and evaluating options for reducing and phasing-out PBT uses, releases and exposures. Contrary to some of the comments on this issue, the proposed PBT rule already includes such a screening mechanism (WAC 173-333-410) for establishing priorities for CAP preparation. Specifically, Ecology proposed to consider information on uses, releases and environmental concentrations (as well as other factors) at this stage of the decision-making process. Ecology also proposed to consider information on exposure and risk when preparing CAP recommendations (WAC 173-333-420).

- Ecology does not believe that the decision to use a "hazard-based" approach for identifying PBT chemicals is inherently less scientific than a "risk-based" approach: Some organizations providing comments on the PBT rule appeared to equate a "risk-based" approach with a "science-based" approach and (by inference) that a "hazard-based" had less of a scientific foundation. Ecology disagrees. The preparation of the PBT list is the first step in a phased decision-making process that systematically considers hazard and exposure information. The fact that exposure information is not considered at this initial step does not make this approach any less "scientific", particularly since information on exposure is considered at later stages of the decision-making process.
- Ecology does not believe that the decision to use a "hazard-based" approach for identifying PBT chemicals is inherently more precautionary than a "risk-based" approach: Some organization providing comments on the PBT rule appeared to equate a "hazard-based" approach with a "precautionary" approach and (by inference) that a "risk-based" approach was not "precautionary". Ecology largely disagrees. In general, a regulation or program is considered "more precautionary" if it results in earlier or more stringent actions to prevent uncertain future adverse consequences. While creating additional information collection and analysis requirements for identifying PBT chemicals may delay listing particular chemicals on the PBT list, Ecology believes that the precautionary features of the PBT rule are more heavily influenced by the (1) choice of PBT criteria; (2) the amount of scientific information considered to be sufficient to justify including a chemical on the PBT list; and (3) the evaluation factors and decision-making processes associated with the chemical action plan process.

Issue 5-4: *Should Ecology divide the PBT List into multiple categories?*

Proposed Rule

In the October 2005 proposed PBT rule, Ecology proposed to establish a single PBT list and then use the procedures in WAC 173-333-410 to rank and prioritize the chemicals on the list for further evaluation and action.

This approach represented a change from the approach included in the June 2005 proposed rule where Ecology proposed to place the chemicals on the PBT list into one of the following three categories:

(a) ***Category 1.*** *Ecology will place chemicals in this category if the department determines that the chemical is used, released or present in Washington.*

(b) ***Category 2.*** *Ecology will place chemicals in this category if the department determines that there is insufficient information to reach a conclusion on whether the chemical is used, released or present in Washington.*

(c) ***Category 3.*** *Ecology will place chemicals in this category if the department determines that:*

(i) All uses and releases of the chemical are prohibited under other state or federal laws or regulations; or

(ii) There are no feasible measures for reducing or phasing out uses and releases of the chemical beyond levels required under other federal and state laws and regulations; or

(iii) Is not present in Washington's environment.

Public Comments and Concerns

Several individuals and organizations expressed support for the June 2005 proposal to place chemicals into three categories (e.g. Northwest Pulp and Paper Association (NWPPA); Weyerhaeuser; Association of Washington Business, National Council for Air and Stream Improvement (NCASI)). However, these individuals and organizations also identified several issues that they believed needed further clarification. For example, the NWPPA identified the following issues:

- *Clarification of the language describing the three categories would be helpful. For example, as written, Category 1 could include chemicals present and used, but not released to the environment and/or subject to other comprehensive regulation. In actuality, these would belong in Category 3. NWPPA suggests simple language revision or clarification in the record.*
- *WAC 173-33-410(3)(a)(i) appears to be a reference to the categories in WAC 173-333-310(3) as it repeats some of the concepts, but not in the same terms. As a matter of statutory interpretation, the fact that different wording is used could be construed to mean something different than -310(3).*
  - *Ecology should clarify that the two sections are referring to the same thing (categories 1, 2 and 3); or clarify that it is something different.*
  - *If Ecology means something different (for example, a first cut at ranking), it should be clarified that this is not a substitute for the assessment of relative risk, a more technical undertaking. (**Llewellyn Matthews, p. 2 of July 2005 written comments**)*

Several of the organizations and individuals supporting the June 2005 proposed rule expressed concerns about Ecology decision to remove the three categories from the October 2005 proposed rule. For example:

> ***The rules should reinstate a ranking system for chemicals that have been determined to meet the PBT criteria. This is needed as part of a clear and transparent process to determine if CAPs are needed. ...****NWPPA was very disappointed that Ecology has revised the process for selecting chemicals from the PBT List for development of chemical action plans by eliminating the three list categories originally in the June 1st version of WAC 173-333-410(2). The three categories were:*
>
> *Category 1: PBTs actually used, released or present in Washington;*
>
> *Category 2: PBTs for which there are insufficient information on use, release or presence; and*
>
> *Category 3: Those for which there are no other laws or are addressed by other laws**.(Llewellyn Matthews, p. 3 of November 2005 Written Comments)***
>
> *The business community has asked the department to be objective in their listing of PBTs based on credible scientific information. The PBT rule has sufficient provisions to achieve this goal, once the concerns in item 1, 2 and 3 above are addressed. Missing from the rule is a adjunct screening*

mechanism to ensure that agency and public resources are not expended on chemicals with minimal risk to the public or environment. Early discussions on this rule included a mechanism to conduct a preliminary risk screening of candidate PBT chemicals prior to in-depth study. This screening process had several valuable functions that should be reincorporated into the rule. First; the screening eliminated those chemicals not likely to be a problem in the State. Examples are:

- *Chemicals not being used in the State.*
- *Chemicals used in quantities insufficient to create risk,*
- *Chemicals used in a controlled industrial environment subject to other controls*
- *Chemicals already banned under Federal law which are properly focused on cleanup programs.*

The importance of this preliminary screening process goes to the heart of the original reason that the business community supported the PBT rulemaking- establishing certainty that PBTs would be selected on the merit of risk rather than politics du jour. Using a prescreening process establishes which chemicals need further risk analysis to support the activation of the process for adding a PBT to the list. This creates a de-facto prioritization process, based on risk, for which PBTs will be proposed and which chemical actions plans will be targeted first. The first plans being those for PBTs that present the greatest risk to the public and environment. The current list has many chemicals listed simply on a P-B & T number pulled from scientific literature. This list does not provide the agency with sufficient guidance as to which chemical action plan to address first. Worse, the agency will find itself whipsawed by competing political agendas to pick a particular PBT for action from this chemical laundry list- without a supporting Washington risk analysis.... ***(Kirk Thomson, pp. 5-6 of Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue that were received during both the July and November public comment periods. Based on that review, Ecology continues to agree with people who emphasized the importance of prioritizing chemicals for evaluation and action based on multiple factors (e.g. uses, opportunities for reductions, existing regulations, etc). However, Ecology also continues to believe that the three categories included in WAC 173-333-310 of the June 2005 proposed rule would complicate the screening and prioritization process and, consequently, are more logically integrated into WAC 173-333-410. Ecology's conclusion is based on consideration of the following factors:

- Ecology believes that the three categories in the June 2005 proposed rule were not well integrated with the prioritization process defined in WAC 173-333-410. Ecology believes the lack of integration would have created unnecessary confusion on the steps that Ecology would take to prioritize and select chemicals for chemical action plan preparation.
- Ecology believes that the combination of categories, additional criteria and selection factors in the June 2005 proposed rule contained a number of redundant features. Ecology believes this redundancy would have contributed to significant decision-making delays and administrative inefficiency with no discernible benefits in terms of improved decisions.
- Ecology believes that the consolidated language in the October 2005 proposed rule continues to reflect Ecology's position that chemical action plans will not be needed for all of the chemicals on the PBT list. Ecology believes that concept is more logically placed in WAC 173-333-410(2)(b).

Issue 5-5: How should Ecology handle chemicals that share common chemical characteristics?

Proposed Rule

In October 2005, Ecology proposed a PBT list that included several chemical groups[34] (e.g. polynuclear aromatic hydrocarbons). Ecology also identified the specific chemicals meeting the proposed PBT criteria where information was available for individual chemicals.

Public Comments and Concerns

Several organizations stated that the PBT list should be chemical-specific. For example:

> ***WAC 173-333-310(2) PBT List*** *– The PBT list should be chemical specific. References to a "Chemical Group" throughout the regulation should be removed.....* ***(Ken Johnson, p. 1 of July 2005 Written Comments)***
>
> *AWB supports comments submitted by NCASI and Weyerhaeuser Company regarding chemical groups. Ecology should base its decision whether or not to list chemicals on the mean or weighted value of credible scientific information and only if an individual chemical meets the criteria for "P", "B" and "T". There is no apparent reason to include "chemical groups" in the rule.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

These organizations appeared to support the approach used by Ecology for most chemical groups and urged Ecology to use the same approach for PCBs. For example:

> *As noted in discussions at the stakeholder meetings, every chemical exhibits its own unique properties with respect to persistence, bioaccumulation, and toxicity. Therefore, the rule should not list chemical groups. Instead, application of the PBT criteria should be made on a chemical-specific (molecule-specific) basis, and the PBT list should identify individual chemicals (not groups). Ecology has, for the most part, already addressed this issue by listing specific molecules in the footnotes to the table in 173-333-310 when the list itself cites a chemical group. For example, footnotes identify the specific PAHs that meet the proposed rule's PBT criteria. In addition, Ecology has provided data showing that these specific PAHs meet the PBT criteria [3]. Thus, the listing of PAHs in the table is functionally the listing of specific molecules. This is scientifically correct.*
>
> *....However, Ecology has also included PCBs as a group on the draft PBT list given in the proposed rule without citing the specific PCB congeners. Understanding that essentially all toxicity data for PCBs were derived based on Aroclor (or coplanar PCB) concentrations and that many of the mono- and di-chlorinated PCBs have pK_{ow}s <5, it is clear that not all of the 209 PCB congeners would meet the PBT criteria. In fact, this situation illustrates why all listings should be on a chemical-specific basis.*
>
> *Prior to full promulgation of this rule, Ecology must apply the PBT criteria adopted by the rule to PCBs on a congener-specific basis, and only those congeners meeting all the criteria should be included on the PBT list. Ecology has already done this for the other "chemical groups" included on the draft PBT list (PAH, PBDE, PCDD/DF, PCN, etc.), and PCBs should be treated likewise.* ***(Jeff Louch, pp. 3-4 of July 2005 written comments)***

[34] The Table in WAC 173-333-310 was divided into two parts: (1) chemicals and (2) chemical categories. The North American Metals Council (NMAC) noted that the use of the word "categories" instead of "groups" was inconsistent with other portions of the section and recommended that the word "categories" be changed to "groups" in the list headings. Ecology agrees and has made the suggested revision.

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe it is appropriate to consider information on chemical groups when making listing decisions. Ecology's preferred approach is to base listing decisions on information for individual chemicals with a chemical group (as opposed to listing all members of a chemical group) because of the variability in PBT characteristics and potential sources and uses of individual chemicals. However, Ecology believes that it may be appropriate to list chemical mixtures on the PBT list when (1) the primary information on persistence, bioaccumulation and toxicity is available for the chemical mixture, (2) the chemical group/mixture meets the definition of chemical group in WAC 173-333-200 (i.e. the chemicals in the group have a common chemical structure and common toxicological properties) and (3) individual chemicals that are considered part of the group do not have distinctly different uses[35]. Based on these considerations, Ecology included short chain chlorinated paraffins and decabromodiphenyl ether as a single entry on the PBT List.

In reaching this conclusion, Ecology considered the following information:

- Other State, Federal and International Approaches: Lists of hazardous substances prepared by other state, federal and international programs typically include individual chemicals and chemical groups/mixtures. For example:
  - Stockholm Convention on Persistent Organic Pollutants: The United Nations Environmental Program has identified two chemical groups (polychlorinated biphenyls (PCBs) and polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)) as persistent organic pollutants. In addition, the European Commission has nominated several chemical groups for inclusion on the POPs list (e.g. short-chain chlorinated paraffins, polychlorinated naphthalenes, perfluoro sulphonates, octabromodiphenyl ether mixtures and pentabromodiphenyl ether mixtures.[36]
  - Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR): OSPAR has identified 315[37] substances of possible concern. This list includes a wide range of individual chemicals and chemical groups and mixtures (e.g. short chain chlorinated paraffins (SSCP), coal tar mixtures, octabromodiphenyl ether (commercial mixture), etc.). OSPAR has also prepared a list of chemicals for priority action that includes several chemical groups (e.g. PCBs, PAHs, PCDD/PCDF and SSCPs).
- Other Ecology Programs: The lists of hazardous substances developed by other Ecology programs include individual chemicals and chemical groups/mixtures. For example:
  - Model Toxics Control Act: The MTCA Cleanup Regulation (Chapter 173-340 WAC) specifies Method A cleanup levels for hazardous substances frequently found at contaminated sites in Washington. Cleanup levels are provided for several individual chemicals and chemical groups (e.g. PCB mixtures, PAHs (carcinogenic), naphthalenes).

[35] The OSPAR Commission's 2003 Strategy includes a definition for "group of substances" that includes the following provision to guide the identification of groups of substances: "...are sufficiently related both in terms of their physio-chemical properties and their field of application to be jointly managed for purposes of this strategy".
[36] United Nations Economic Commission for Europe. 2005. Webpage for Convention on Long Range Transboundary Air Pollution. Task Force for Persistent Organic Pollutants. Viewed on January 4, 2006.
[37] Note: Not all of the 315 substances of possible concern are identified as PBT chemicals.

- Water Quality Standards: Ecology has established several types of water quality standards: Water Quality Standards for Surface Waters of the State of Washington (Chapter 173-201A WAC); Sediment Management Standards (Chapter 173-204 WAC); and Water Quality Standards for Ground Waters in the State of Washington (Chapter 173-200 WAC). Each of these regulations includes water quality standards for individual chemicals and chemical groups (e.g. PCBs, high molecular weight PAHs, etc.)

- Washington Clean Air Act: The New Sources Review for Toxic Air Pollutants Regulation (Chapter 173-460 WAC) establishes acceptable source impact levels (ASILs) for a wide range of toxic air pollutants. ASILs are established for several chemical groups including PCB, PAHs, lead and lead compounds, chlorophenols, etc.).

- Scientific Defensibility: Ecology agrees that basing listing decisions on individual chemicals reduces some of the scientific uncertainty and variability associated with making such determinations for a group of substances. For example, polychlorinated biphenyl mixtures can contain up to 209 congeners that differ in terms of the persistence, bioaccumulation and toxicity. Using congener-specific data and quantitative structure activity relationships, it is possible to estimate the persistence, bioaccumulation and toxicity of individual congeners. However, Ecology also believes that information on mixtures can provide a solid scientific basis for decision-making where (1) the individual chemicals share similar chemical structures and toxicological properties; and (2) reliable scientific information on persistence, bioaccumulation and toxicity are available for the chemical group.

- Available Data on Toxicity, Bioaccumulation and Persistence: Ecology believes the PBT rule needs to provide the flexibility to evaluate and list chemical mixtures because there are situations where chemical-specific information is not available for individual chemicals within a group or mixture of individual chemicals with common chemical structures and "common toxicological properties"[38]. For example, most of the available information on the short chain chlorinated paraffins is presented for the group or mixture – not individual components of the mixture.

- Practical Considerations: The Department believes it makes sense to list certain chemical groups because measures to reduce and phase-out uses and releases will generally address all of the chemicals in a group (rather than selectively focusing on one chemical on the group). Ecology recognizes that this will not always be the case and believes the chemical action plan process provides sufficient flexibility to address these exceptions.

Issue 5-6: ***Should Ecology include cadmium on the PBT List?***

[38] Ecology modified the definition for "chemical group" in the proposed PBT rule to incorporate a recommendation from the Bromine Science and Environmental Forum that chemical groups include chemicals that share a common chemical structure and "common toxicological properties".

Proposed Rule

Lead and cadmium were two of the substances or groups of substances that Ecology included on the proposed PBT list. However, Ecology included the following provision regarding the preparation of chemical action plans:

> ***Lead and cadmium.*** *Ecology will not develop a chemical action plan for lead and cadmium until the Environmental Protection Agency concludes the development of a metals assessment framework and ecology completes its review of the bioavailability of these two substances.*

Public Comments and Concerns

Several organizations and individuals providing comments on the June 2005 and October 2005 proposed PBT rules supported Ecology's proposal to include cadmium and lead on the PBT list. For example:

> *Thank you for including lead, cadmium, PFOS and short-chain chlorinated paraffins on the PBT list. The whole list is a good first start for this program. However, the extensively footnoted table format is difficult to read and understand. Please consider a new presentation format for the list and the detailed and important technical information that accompanies it* ***(Dave Galvin, p. 3 of July 2005 written comments)***

However, many of these organizations were concerned with Ecology's proposal to delay the preparation of chemical action plans and recommended that this provision be removed from the rule. For example:

> ***Do Not Delay CAPs on Lead and Cadmium*** *We strongly oppose the decision to delay CAPs on lead and cadmium until after the U.S. Environmental Protection Agency (EPA) completes its Metals Assessment Framework. There is no scientifically based reason for waiting to take action on these metals. Scientific evidence makes clear that these metals persist in the environment, are bioavailable and build up in people's bodies, and are toxic in small amounts. Studies have shown lead is absorbed in the blood and bones and easily crosses the placenta to affect the developing fetus. The affect of lead on children is of particular concern because children absorb more lead, often as much as five to ten times more, than adults. Lead also is extremely toxic at low levels, causing learning disabilities, drops in IQ, and neurological problems.*
>
> *Ecology's scientists appear to agree that both lead and cadmium are bioavailable. The footnote accompanying WAC 173-333-310 (3) states that "Ecology has prepared a preliminary review and believes that these compounds [lead and cadmium] are bioavailable under some environmental conditions based on monitoring data showing elevated levels in human and fish tissues." Despite these findings, Ecology has decided to wait for the completion of an EPA process that has been underway for at least four years and does not have a scheduled date for completion. This means that state action on lead and cadmium has been delayed indefinitely. This is inexcusable given the severe health problems that lead causes for children. Thus, we urge you to delete WAC 173-333-310 (3).* ***(Ivy Sager Rosenthal, pp. of November 2005 Written Comments)***

However, there were also several other organizations and individuals stated who that Ecology should not apply the PBT criteria to metals and recommended that the Department remove lead and cadmium from the proposed PBT list. For example:

> ***WAC 173-333-310(2) PBT List –*** *Cadmium and Lead should be removed from the proposed PBT list at this time....The notation added for these two elements indicates the evaluation of bioavailability is still underway. Until that work is complete and specific compounds can be identified, these elements are not ready for placement on the list.* ***(Ken Johnson, p. 2 of July 2005 written comments)***
>
> *.....In addition, Ecology has determined that it will follow EPA's lead in determining whether metals should be listed as PBTs through its Metals Risk Assessment Framework, which is still underway.*

AWB supports comments made by the North American Metals Council on this subject and requests that all metals be removed from the PBT list ***(Grant Nelson, p. 3 of July 2005 written comments)***.

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to classify lead and cadmium as "metals of concern" pending completion of EPA's Inorganic Metals Assessment Framework. Under this approach, Ecology would consider lead and cadmium during the process for selecting chemicals for chemical action plan preparation under WAC 173-333-410 and, if appropriate, prepare chemical action plans for one of both of these metals. (see Issue 5-18 for further discussion)

Issue 5-7: Should Ecology include decabromodiphenyl ether (Deca-BDE) on the PBT List?

Proposed Rule

Decabromodiphenyl ether was one of the three polybrominated diphenyl ethers that Ecology included on the proposed PBT list. After reviewing the information on the persistence, bioaccumulation and toxicity of this substance, Ecology concluded:

Ecology has determined that the following PBDEs meet the proposed PBT criteria in WAC 173-333-320(2) and/or degrade to PBDEs that meet the proposed PBT criteria in WAC 173-333-320(2): pentabromodiphenyl ether (CAS 32534-81-9); octabromodiphenyl ether (CAS 32536-52-0); and decabromodiphenyl ether (CAS 1163-19-5).

- ***Persistence****: PBDEs are very persistent in the environment. Estimated half-live values for PBDEs in surface water, soils and sediments exceed 60 days*[39].
- ***Bioaccumulation****: PBDEs have a high potential to bioaccumulate. Various tetraBDE, pentaBDE and hexaBDE congeners have been found to have BCF or BAF values that exceed the bioaccumulation critierion (BCF or BAF = 1000) in the proposed rule. Although available BCF values for octaPBDE and decaBDE are below 1000, several studies indicate that these higher brominated PBDEs can be degraded to lower brominated PBDEs*[40].
- ***Toxicity****: PBDEs have the potential to be toxic to human or plants and wildlife. PentaBDE, octaBDE and DecaBDE have been shown to cause endocrine effects (thyroid), liver toxicity and developmental neurotoxicity in laboratory animals. DecaBDE has been identified as a possible human carcinogen. TetraBDE, PentaBDE and HexaBDE have been shown to be toxic to aquatic*

[39] Environment Canada (2004b) reviewed available information on the environmental fate of the two main PBDE homologue groups found in the decabromodiphenyl ether commercial mixture (nona- and deca-BDEs) and concluded that both homologue groups are highly persistent with media-specific half lives greater than 180 days. The ECB (2003d) assumed an overall degradation of zero when characterizing health risks. However, both Environment Canada and the ECB also concluded that deca-BDE may degrade to less brominated PBDEs in the environment. OSPAR (2004s) concluded that deca-BDE is not readily biodegradable. The PBT Profiler (EPA, 2004c) predicts media-specific half-life values for deca-BDE in surface water (180 days), soil (360 days) and sediments (1,600 days).

[40] The ECB (2003d) reviewed available information on the bioaccumulation of decabromodiphenyl ether in aquatic organisms and used a BCF value of 3.2 to their assessment of health risks associated with secondary poisoning. Environment Canada (2004b) appears to have concluded that BCFs for decaBDE are below 5000 (e.g. not highly bioaccumulative). However, they concluded that there is a weight of evidence showing that highly brominated PBDEs (such as decaBDE) are precursors of bioaccumulative and persistent PBDEs and recommended that deca-BDE be considered a Track 1 substance. The PBT Profiler calculates a BCF value of 3.2 using the BCFWin computer program.

organisms with toxicity measures (LC50's, NOEC, etc) that are below the 0.1 mg/L (chronic toxicity) and 1 mg/L (acute toxicity) toxicity criteria in the proposed PBT rule (WAC 173-333-320). Although available aquatic toxicity values for octaPBDE and decaBDE are above the proposed PBT aquatic toxicity values, several studies indicate that these higher brominated PBDEs can be degraded to lower brominated PBDEs[41], [42].

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) stated that Deca-BDE should not be included on the PBT list.

BSEF's concern with the proposed rule is relatively simple: Decabromodiphenyl ether (Deca-BDE) does not meet the Department of Ecology's criteria for classification as a persistent, bioaccumulative toxin and therefore should not be included in this proposed rule.

Specifically, Deca-BDE does not have a "high potential to bioaccumulate based on evidence that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1,000." In fact, under the European Union's Risk Assessment, concluded in May 2004 after 10 years of study, Deca-BDE was assigned a measured bioconcentration factor of 41 for fish.[43] *Additionally, Deca-BDE was not classified as "toxic" under the EU Risk Assessment.*

These facts, as well as numerous other studies, demonstrate that while Deca-BDE is persistent, it is not bioaccumulative or toxic. Additional studies supporting this position include:

- *Decabromodiphenyl Ether (DBDPE): "None of the available data give any indication of toxic risk from the levels of exposure envisaged from the use of DBDPE in consumer products. It is very poorly absorbed from the gastrointestinal tract and its low vapour pressure indicates that inhalation exposure is unlikely to be significant. Its tendency to bioaccumulate is low."*[44]
- *"The results of this bioaccumulation study are consistent with previous work showing insignificant bioconcentration of DBDPO in fish, [and] do not provide evidence that DBDPO is debrominated metabolically."*[45]

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[41] DecaBDE has been shown to be neurotoxic (Viberg, et al. 2003) and cause thyroid hyperplasia in animal studies (NTP, 1996a). EPA (2004a) has published a chronic reference dose (0.01 mg/kg/day) for decaBDE in the IRIS database. ATSDR (2004b) has established a Minimal Risk Level for decabrominated PBDE (oral intermediate exposure (10 mg/kg/day based on developmental effects). DecaBDE has been shown to cause liver tumors in rats and mice and EPA has classified this substance as possibly carcinogenic to humans (NTP, 1986a).

[42] ECB (2003d) presented aquatic toxicity predictions based on quantitative structure activity relationships ranging from 3.5 ug/L (16 day NOEC for Daphnia) to 183 ug/L (96 hour LC50 for fish). However, the ECB noted that (1) the high Log Kow of this compound means that it is not ideally suited for QSAR predictions and (2) all of the predicted values exceeded the water solubility of Deca-BDE. ECB (2003d) and OSPAR (2004s) also identified two aquatic toxicity values: acute toxicity algae IC50 (> 1 mg/L) and acute toxicity fish NOEC (>500 mg/L). Environment Canada (2004b) concluded that PBDEs (including nonBDE and decaBDE) may have an immediate or long-term harmful effect on the environment or its biological diversity and should be considered toxic as defined in section 64 of the Canadian Environmental Protection Act.

[43] European Union Risk Assessment Report: Bis(pentabromodiphenyl ether). 1st Priority List, Volume 17. European Commission Joint Research Centre, EUR 20402 EN, 2004: "The available data indicated that little or no uptake of decabromodiphenyl ether occurs in aquatic organisms exposed via the water phase. Some limited uptake had been seen in experiments with fish exposed via food, but the tissue concentrations reached were much lower than those present in the food. Overall it was concluded that the substance can be considered to have a low bioaccumulation potential. A low fish BCF of 4 l/kg was assumed in the assessment."

[44] G.C. Stevens, A.H. Mann, Risks and Benefits in the Use of Flame Retardants in Consumer Products, a report for the Department of Trade and Industry. Polymer Centre, University of Surrey, January 1999, 29.

[45] Voluntary Children's Chemical Evaluation Program (VCCEP) Data Summary Decabromodiphenyl Ether, CAS # 1163-19-5, American Chemistry Council's Brominated Flame Retardant Industry Panel (BFRIP), Arlington,VA, December 2002, 52.

- *"No human toxicity data were located from oral exposure to DBDPO. In animals, DBDPO has low acute toxicity following oral exposure in part because of its poor gastrointestinal absorption."*[46]
- *"In the study juvenile fish (~10 cm) were exposed to 940-950 ng/day of decabromodiphenyl ether via their food for a period of 60 days. This exposure period was followed by a 40 day depuration period. The results showed that little or no accumulation of decabromodiphenyl ether occurred (less than 1% of the total decabromodiphenyl ether administered was accumulated during the study)… The available data also indicate that decabromodiphenyl ether has a relatively short elimination half-life from organisms. This should limit the potential for bioaccumulation of decabromodiphenyl ether."*[47]

Additionally, the proposed rule appears to include Deca-BDE on the basis that it degrades into lower congeners that may meet the PBT profile. In fact, there is no evidence that, in the real world, Deca-BDE degrades or debrominates in any significant manner into lower-brominated PBDE congeners of concern. The pattern of congeners found in the real world environment is characteristic of the congeners present in the commercial Penta-BDE product, which is no longer manufactured or used. Laboratory studies of the degradation of Deca-BDE need to be carefully evaluated as to their relevance in the real world.

Photolytic studies in organic solvents do not result in the pattern of congeners found in the environment. Recent reports of catalytic degradation in sludge also do not result in the pattern of congeners found in the environment. Put more simply, if Deca-BDE was a significant source of the lower-brominated congeners of concern, then we would expect much higher concentrations of particular congeners than are, in fact, found.

Given these facts, we respectfully suggest that including Deca-BDE in this proposed rule is inappropriate and unjustified, and we ask that it be removed. ***(Raymond Dawson and David Sanders, pp. 1-3 of July 2005 written comments)***

Issue 1: Decabromodiphenyl ether (Deca-BDE) does not meet the Department of Ecology's criteria for classification as a persistent, bioaccumulative toxin. The Department of Ecology proposes that a substance would be considered persistent, bioaccumulative and toxic if:

- It's half-life in water, soil or sediment is > 60 days;
- It's bioconcentration/bioaccumulation factor is > 1000; and
- It is a known carcinogen, reproductive or neurologic toxicant, has a reference dose (RfD) of < 0.003 mg/kg/d, or is toxic to fish on chronic exposure.

(Detailed comments on the proposed criteria themselves are enclosed in Attachment A.)

Specifically, while Deca-BDE meets the Department's proposed criteria for persistence, it does not meet the proposed criteria for a bioaccumulative and toxic substance, and cannot therefore be properly classified as a PBT.

Persistence. Deca-BDE would be considered persistent under the Department's proposed criteria. Its estimated (EPIwin, v3.04) half-lives in water, soil and sediment are all > 60 days.

Bioconcentration/Bioaccumulation. Deca-BDE does not meet the Department's proposed criteria for this end point. Deca-BDE's measured fish BCF is <50.

[46] National Research Council, Toxicological Risks of Selected Flame-Retardant Chemicals, National Academy Press, ISBN 0-309-07047-3, 2000, 77.

[47] European Union Risk Assessment Report: Bis(pentabromodiphenyl ether), European Commission Joint Research Centre, Draft TM IV 2003.

Toxic. Deca-BDE does not meet the proposed criteria for this end point. Deca-BDE is not a known carcinogen, reproductive, developmental or neurological toxicant. Deca-BDE's oral RfD, established by the U.S. National Academy of Sciences (2000) is 4 mg/kg/d. Deca-BDE is not toxic to fish, daphnia or algae, either acutely or chronically, at its limit of saturation in water. Deca-BDE is not toxic to sediment organisms, bacteria, or terrestrial plants. ***(Raymond Dawson and David Sanders, p. 1 of November 2005 written comments)***

Several organizations stated that Ecology's conclusion that Deca-BDE degrades to less brominated congeners was not supported by current scientific information and was inconsistent with conclusions reached by European scientists. For example:

The proposed rule appears to include Deca-BDE as a PBT on the basis that it degrades into lower congeners that may themselves meet the PBT profile. In fact, there is no evidence that, in the environment, Deca-BDE degrades or debrominates in any significant manner into lower-brominated PBDE congeners of concern. The pattern of congeners detected in the environment is characteristic of the congeners present in the commercial Penta-BDE product, which is no longer manufactured or used. Further, the Department of Ecology has not identified which lower brominated congeners in believes Deca-BDE degrades to and why those congeners meet the proposed PBT criteria. ***(Raymond Dawson and David Sanders, p. 1 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and agrees that decabromodiphenyl does not meet the PBT criteria in WAC 173-333-320(2). However, Ecology believes there is sufficient evidence that decabromodiphenyl ether degrades in the environment to less-brominated congeners that meet the PBT listing criteria. This issue was discussed in the recently-released PBDE Chemical Action Plan (January 2006). Specifically:

IN BRIEF: Considerable scientific research on the degradation of deca-BDE has been conducted in recent years. (Refer to the scientific literature documented in Appendixes D and E.[48]) Existing studies focus on both how deca-BDE breaks down (by exposure to light, through biological degradation, and others), as well as what the composition of degradation products is. Studies have used a wide range of media (sediments, sewage sludge, and water) and conditions (aerobic, anaerobic, sunlight, UV light, etc.). The degradation of deca-BDE has been evaluated in detail in both laboratory studies and in environmental samples.

In laboratory tests, deca-BDE was found to degrade to lower PBDE species, that is, PBDEs with fewer bromines. The relevancy of these results to conditions deca-BDE may experience in the environment has been questioned. Many of these concerns are legitimate and can only be addressed with additional research. As with many laboratory tests, conditions were often exaggerated in order to determine chemical degradation and dynamics within a useful time period. However, the main difference between laboratory studies and the fate of deca-BDE in the environment is thought to be the rate at which these reactions occur. Therefore, the laboratory results provide valuable information to support the concern that deca-BDE breaks down in the environment.

Ecology and DOH also reviewed many, if not all, of the same technical articles included in the European Union Risk Assessment and its two updates, and have monitored scientific progress since the Interim CAP was published. While further research is needed, Ecology and DOH believe the following conclusions are appropriate:

1. *Deca-BDE undergoes degradation. The most common path in laboratory studies is the debromination of deca-BDE to lower PBDE species. Other degradation products have been found in some studies, including brominated dioxins, phenols and dibenzofurans. The negative impact these degradation products have upon human health and the environment is*

[48] This reference is to appendices included in the PBDE Chemical Action Plan.

unquantified, but the abundance of studies that document negative impacts makes this a matter of considerable concern.

2. *Debromination of deca-BDE occurs through light exposure (both UV radiation and direct sunlight) and biological activity. These pathways lead to a variety of degradation products.*
3. *The rate of debromination has been determined in laboratory studies. Further work is needed to determine the debromination rate under environmental conditions. Degradation in the environment occurs more slowly. This phenomenon is consistent with what occurs to halogenated compounds with similar chemical structure, and is supported by knowledge of standard chemical processes.*
4. *Deca-BDE will continue to be a source of lower brominated diphenyl ethers and other degradation products for some time.*

Note: The terms "degradation" and "debromination" have similar meanings in the context of this chapter. "Debromination" is the most common degradation process Deca-BDE undergoes: when it degrades, it loses bromine atoms.

Issue 5-8: Should Ecology include di-(2-ethylhexyl) phthalate (DEHP) on the PBT List?

Proposed Rule

The proposed PBT list included chemicals that Ecology determined meet the listing criteria in the proposed rule. When preparing the proposed PBT list, Ecology reviewed available scientific information on the persistence, bioaccumulation potential and toxicity of di-(2-ethylhexyl) phthalate (DEHP) and concluded it did not meet the criteria for inclusion on the PBT List. Specifically:

- *Persistence: Mackey et al. (1995), Howard et al. (1990), EPA (1998b) and EPA (2004c) have published estimates for surface water and soil that are all below the proposed criterion in the PBT rule. With respect to persistence in sediments, EPA (1998b) used a sediment half live value of 60 days to characterize the persistence of DEHP for purposes of the WMPT model. The EPA value was based the information published by Mackay et al. 1995) (1,000 – 3,000 hours (42 – 126 days) with a mean value of 1,700 hours (@ 71 days)). The value calculated by the EPA PBT Profiler (140 days) exceeds the persistence criterion in the proposed PBT rule. In addition, the PBT Profiler predicts that 66% of DEHP released to the environment will partition to sediments. OSPAR (2004ii) identified DEHP as "not inherently biodegradable" based on the results from a European Commission report on existing chemicals. However, OSPAR also summarized several results indicating DEHP is "readily degradable" (based on Quantitative Structure Activity Relationships (QSAR) and modified Sturm test (301B).*
- *Bioaccumulation: ECB (2001), EPA (1998b), OSPAR (2004ii) and WHO (1997) used BCF values of 840, 851, 851 and 890, respectively, to characterize the bioaccumulation potential for DEHP. The PBT Profiler calculates a BCF value of 310 using the BCFWin computer program.*
- *Human Toxicity: ATSDR (2002) has established a MRL for DEHP for intermediate (0.1 mg/kg/day) and chronic (0.06 mg/kg/day) exposures based on the potential for reproductive effects. EPA (2004a) has established an oral RfD value (0.02 mg/kg/day) that is published in the IRIS database. DEHP has been found to increase the incidence of liver tumors in mice and rats and the National Toxicology Program has concluded that DEHP is reasonably anticipated to be a human carcinogen" (NTP, 2004). EPA (2004a) classifies DEHP as a probable human carcinogen (Group B2) and calculate an oral slope factor of 0.014 (mg/kg/day)$^{-1}$ that is published in the IRIS database. However, IARC (2004) lists DEHP as not classifiable as to carcinogenicity in humans (Group 3) based on their conclusion that DEHP's mechanism of action in rats and mice is not relevant to evaluating the carcinogenic*

risks for human. The Expert Panel completed a review of the scientific literature relating to the seventh phthalate compound (di-(2-ethylhexyl) phthalate). However, the NTP-CERHR did not complete a monograph for DEHP. The NTP-CERHR has convened a second expert panel which is presently reviewing the scientific literature and updating the earlier panel report. The earlier expert panel convened by the NTP-CERHR (2000) concluded that the available scientific information is adequate for purposes of identifying DEHP as a developmental and reproductive toxicant.

- *Ecological Toxicity: EPA (1998b) reported the following aquatic toxicity values for DEHP: GLWQI SCV Tier II (0.032 mg/L); 21 day chronic MATC for daphnia (0.11 mg/L); acute EC50 daphnia (0.13 mg/L); chronic fish ECOSAR value (0.0001 mg/L); and acute ECOSAR value (algae) (0.0005 mg/L). Although these values indicated high toxicity based on the EPA scoring framework, EPA assigned an ecological score of one (low toxicity) to this compound based on expert judgment. OSPAR (2004ii) identified no valid aquatic toxicity studies at concentrations up to 2 orders of magnitude above the water solubility limit. However, OSPAR classified DEHP as very toxic based on an Aquatox QSAR of 0.0007 mg/L. The PBT Profiler (2004c) does not list a ChV for DEHP.*

Public Comments and Concerns

During the July public comment period, several organizations and individuals recommended that Ecology add phthalate esters to the PBT list. For example:

Consistent with the precautionary approach, we recommend including at least two phthalate compounds, which we believe meet the selection criteria, into the PBT list (WAC 173-333-310) (2)): di(2-ethylhexyl) phthalate (DEHP) (CAS no. 117-81-7) and di-isodecyl phthalate (DIDP) (CAS no. 26761-40-0). Other phthalate compounds should be considered for inclusion in the PBT list as appropriate. ***(John Dohrmann, p. 1 of July 2005 written comments)***

Revise Criteria to Include Phthalates On the List. The PBT Rule must address phthalates and other reproductive toxins. Phthalates are found in our sanitary wastes, household dust, stormwater, air, and aquatic species and sediment. In humans, recent research has shown that as reproductive toxins they may be mostly causing impacts on male fertility.

Washington needs to develop a comprehensive plan for controlling and eliminating phthalates and it makes sense to do it through the PBT program. Statewide coordination is needed because we have found that local agencies are on one hand working to identify sources of and remove phthalates from the system and on the other hand doing actions that contribute phthalates.

Phthalates have been found in the tissue of Chinook salmon in the Duwamish River. In addition, phthalates are associated with 13 of the 18 Puget Sound sediment Superfund Sites. Phthalates are an environmental problem that have been ignored for too long and must be addressed by Ecology in order to protect both human and wildlife health. ***(Heather Trim, p. 3 of July 2005 written comments)***

After reviewing those comments and available scientific information, Ecology identified two phthalate ester compounds that the Department believed met the PBT criteria. These two compounds (di-n-hexyl phthalate (DnHP) and di-isodecyl phthalate (DIDP)) were included on the proposed PBT list published in October 2005. The Washington Physicians for Social Responsibility recommended that Ecology add di-ethyhexyl phthalate (DEHP) to the PBT list.

We would like to reiterate from our previous comments that a strong rule should encompass a goal to phase out persistent toxic chemicals, and be based upon a framework of prevention. It is vital that phthalates remain on the list of chemicals to phase out. In addition, we advocate that additional phthalates be included, particularly di-ethylhexyl phthalate (DEHP). This phthalate is linked to reproductive damage, particularly in male infants, as well as other serious health concerns. It is important to take action on this phthalate now, to avert continued exposures to a chemical linked to harm. In addition, the Washington State Public Health Association and the Washington State Medical

Association both passed resolutions in Fall, 2005 urging adoption of safer, alternative products to those containing DEHP. ***(Nancy Dickeman, p. 1 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to include DEHP on the PBT List. As summarized above, Ecology reviewed information on the persistence, bioaccumulation potential and toxicity of DEHP and concluded it did not meet the bioaccumulation criterion in WAC 173-333-320(2)(b).

Issue 5-9: Should Ecology include di-isodecyl phthalate (DIDP) on the PBT List?

Proposed Rule

Ecology proposed to include DIDP on the PBT list. After reviewing the information on the persistence, bioaccumulation and toxicity of this substance, Ecology concluded:

Ecology has determined that Di-isodecyl phthalate (DIDP) (CAS 68515-49-1 and 26761-40-0) and Di-n-hexyl phthalate (DnHP) (CAS 84-75-3) meet the proposed PBT criteria specified in WAC 173-333-320.

- ***Persistence****: DIDP and DnHP are persistent in the environment. Estimated half-live values for these two compounds in sediments exceed 60 days*[49].
- ***Bioaccumulation****: DIDP and DnHP have a high potential to bioaccumulate. Estimated BCF values exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000).*[50]
- ***Toxicity****: DIDP and DnHP have the potential to be toxic to humans, plants and wildlife. The NTP-CERHR (2003b,f) judged that the scientific evidence was sufficient to conclude that DIDP and DnHP are developmental toxicants and could adversely affect human development if exposure levels were sufficiently high*[51, 52].

Public Comments and Concerns

During the July public comment period, several organizations and individuals recommended that Ecology add phthalate esters to the PBT list. After reviewing those comments and available

[49] EPA (1998b) estimated half life values for DIDP in surface water (38 days), soils (38 days) and sediments (150 days) using the Ultimate Source Model and HYDROWIN computer program. The EPA PBT Profiler calculates the following media-specific half-life values: water (38 days); soil (75 days); and sediments (340 days). In addition, the PBT Profiler predicts that the vast majority of DIDP released to the environment will partition to soils (32%) and sediments (66%). ECB (2003a) estimated biodegradation rate constants and half-live values in surface water, soil and sediments of 50, 300 and 3,000 days, respectively.

[50] The ECB (2003a) used a BCF value of 4000 to their assessment of health risks associated with secondary poisoning. This value was based on study in which mussels were exposed to DIDP in a flow-through system for 28 days. The concentrations in the water and mussels were determined by measuring total radioactivity[50]. This value is also considerably higher than the BCF value (3.2) predicted by the EPA PBT Profiler.

[51] The NTP-CERHR concluded that the scientific evidence for 5 DIDP is sufficient to conclude that the compound is a developmental and/or reproductive toxicant that could possibly adversely affect human development and/or reproduction if exposures were high enough.

[52] ECB (2003a) and OSPAR (2004ll) reported several aquatic toxicity values for 1,2-benzendicarboxylic acid di-C8-C10 alkyl esters, branched: acute toxicity algae IC50 (> 2.8 mg/L); acute toxicity daphnia EC50 (> 0.086 mg/L); acute toxicity fish LC50 (> 0.14 mg/L); chronic toxicity daphnia NOEC (> 1 mg/L); chronic toxicity fish NOEC (> water solubility). OSPAR classified this compound as very toxic on the basis of the acute toxicity daphnia EC50 value.

scientific information, Ecology identified two phthalate ester compounds that the Department believed met the PBT criteria. These two compounds (di-n-hexyl phthalate (DnHP) and di-isodecyl phthalate (DIDP)) were included on the proposed PBT list published in October 2005. Several organizations supported Ecology's proposal to include these two phthalates on the PBT list. For example:

> ***Keep Phthalates and Nonylphenol on the PBT List*** *We support the addition of the two phthalates and nonylphenol to the list. The chemicals satisfy the PBT criteria and should be on the list because of their dangerous effects on people and wildlife. Recent studies have linked phthalates to effects on human development, most recently reproductive problems in male infants. The European Union already is taking steps to ban the chemical in children's toys. Nonylphenol has been shown to adversely affect the endocrine system, causing hormonal problems that can lead to numerous health effects, including reproductive problems.* ***(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)***
>
> *On behalf of Washington Physicians for Social Responsibility's physicians, nurses, and children's health advocates, we urge you to finalize a strong PBT rule which maintains the inclusion of phthalates and includes lead and other metals as chemicals to be addressed. It is crucial that the PBT rule embody a solid framework from which to address phasing out persistent toxic chemicals. This is essential for protecting the health and potential of children, our most vulnerable population, as well as the public health of communities throughout Washington State.* ***(Nancy Dickeman, p. 1 of November 2005 Written Comments)***

However, there were also several organizations and individuals who disagreed with Ecology's conclusion that DIDP meets the proposed PBT criteria and recommended that the substance be deleted from the PBT list. For example:

> *Under Chapter 173-333 WAC, chemicals may be included on the PBT list only if they satisfy each of the criteria for persistence, bioaccumulation and toxicity. DIDP and DnHP do not satisfy these three criteria, and therefore cannot be included on the PBT list.* ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***
>
> *NWPPA strongly urges the deletion of Di-isodecyl phthalate (DIPP), Di-n-hexyl phthalate (DnHP) and nonylphenol as per NCASI comments. NWPPA also endorses AWB comments with respect to metals and other chemicals that should be removed from the list.* ***(Llewellyn Matthews, p. 2 of November 2005 Written Comments)***

Several lines of reasoning were used to support the position that DIDP should not be included on the PBT List:

- <u>DIDP is not persistent</u>. The American Chemistry Council/Phthalate Esters Council (ACC/PEC) stated that the data used by Ecology to characterize DIDP as persistent are incorrect and DIDP is readily degraded in the environment.

  > *DIDP and DnHP are not persistent. The data relied upon by Ecology to characterize DIDP as persistent are incorrect and these phthalates are readily biodegraded, and so do not persist in the environment.* ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

- <u>DIDP does not meet bioaccumulative criteria</u>. Several commenters stated that DIDP is readily metabolized and excreted by fish and mammals and does not accumulate in tissues.

  > *The data demonstrate that DIDP and DnHP are not of bioaccumulative concern. Because they are readily metabolized and excreted by fish and mammals, they do not accumulate in tissues. Traveling up the food chain, higher molecular weight phthalates, including DIDP and DnHP, decrease in tissue concentration with increasing trophic position (i.e., biodilute) rather than biomagnify.* ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

Categorization of di-isodecyl phthalate as bioaccumulative is not supported by the data. *Ecology (WDOE 2005) cites a single experimentally determined BCF (BCF = 4000) and pKows in the range of 8.9 to 10.5 as the basis for identifying di-isodecyl phthalate (DIDP) as bioaccumulative. This is tenuous for a number of reasons.*

First, the range of pKows cited by Ecology is consistent with a chemical that should not bioaccumulate to any significant degree (see comment 2). According to Meylan et al. (1999, equation 4), a chemical with a pKow >8.5 is predicted to have a BCF/BAF no greater than ≈ 600 without accounting for any metabolism. Because phthalates are expected to be metabolized by higher level organisms (Mackay et al. 2000), a BCF of 4000 is inconsistent with the order of magnitude BCF that would be expected, suggesting that this value is an experimental artifact. In fact, Ecology acknowledges problems with the specific experimental approach used to obtain this measured BCF (WDOE 2005).

Overall, the data cited by Ecology are insufficient to justify characterizing DIDP as a bioaccumulative chemical; thus this chemical should not be listed as a PBT as part of the proposed rule. ***(Jeff Louch, p. 5 of November 2005 Written Comments)***

- DIDP does not pose ecological toxicity concerns. The ACC/PEC stated that high molecular weight phthalates are not toxic to aquatic organisms at levels up to and including their solubility limits.

  DIDP and DnHP do not pose ecological toxicity concerns. The higher molecular weight phthalates, including DIDP and DnHP, are not toxic to aquatic organisms at levels up to and including their solubility limits. ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

- DIDP poses low concern for human toxicity. The ACC/PEC stated that DIDP poses a low level of concern with respect to human developmental or reproductive toxicity and other health effects:

  DIDP and DnHP pose low concern for human toxicity. The extent of Ecology's support for concluding that these phthalates meet the criteria for toxicity is "The NTP-CERHR . . . judged that the scientific evidence was sufficient to conclude that DIDP and DnHP are developmental toxicants that could adversely affect human development, if exposure levels were sufficiently high." .... For DIDP, NTP-CERHR reached only a qualified conclusion stating that DIDP could adversely affect human development only "if the levels of exposure were sufficiently high." NTP-CERHR exposure estimates show that conservative estimates of exposure levels are more than 1000-fold lower than the no effect levels for these phthalates, and are therefore not "sufficiently high" to pose a significant risk to human health. Indeed, NTP-CERHR itself found minimal to negligible concern for human developmental or reproductive toxicity from DIDP. ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to include DIDP on the PBT list at this time because of questions on the underlying data used to characterize the bioaccumulation potential and persistence of DIDP. Specifically, comments from ExxonMobil Biomedical Sciences[53], American Chemistry Council's Phthalate Esters Council and the National Council for Air and Stream Improvement raised several valid questions regarding the use of the bioconcentration factor and media-specific half life values developed by the European Chemicals Bureau (2003) to characterize DIDP's bioaccumulation potential and persistence, respectively.

[53] September 19, 2005 e-mail from Douglas Winkelmann to Mike Gallagher (with 3 attachments).

- Bioaccumulation: Ecology's determination that DIDP meets the bioaccumulation criterion in WAC 173-333-320(2)(b) was based on a BCF value calculated by the European Chemicals Bureau (2003) using the results from a study where mussels were exposed to DIDP in a flow-through system for 28 days. The concentrations in the water and mussels were determined by measuring total radioactivity. Ecology has decided to re-evaluate this determination because of questions on the study design[54], results from studies completed subsequent to the ECB report[55], categorical reviews of high molecular weight phthalate esters[56] and the results of more recent environmental reviews[57].
- Persistence: Ecology's determination that DIDP meets the persistence criterion in WAC 173-333-320(2)(a) was based on environmental half-live values calculated by the European Chemicals Bureau (2003). Ecology has decided to re-evaluate this determination based on the results from other available studies, categorical reviews of high molecular weight phthalate esters[58] and the results of more recent environmental reviews[59].

Issue 5-10: Should Ecology include di-n-hexyl phthalate (DnHP) on the PBT List?

Proposed Rule

Ecology proposed to include DnHP on the PBT list. After reviewing the information on the persistence, bioaccumulation and toxicity of this substance, Ecology concluded:

> *Ecology has determined that Di-isodecyl phthalate (DIDP) (CAS 68515-49-1 and 26761-40-0) and Di-n-hexyl phthalate (DnHP) (CAS 84-75-3) meet the proposed PBT criteria specified in WAC 173-333-320.*

[54] The ECB value is based on study in which mussels were exposed to DIDP in a flow-through system for 28 days. The concentrations in the water and mussels were determined by measuring total radioactivity. The organizations commenting on this issue noted that studies using radiolabelled test material are no longer favored for regulatory decision-making because they do not distinguish between the test compound and derivatives.

[55] MacKintosh et al. (2004) in which the researchers studied the distribution of 8 individual phthalate esters, 5 commercial mixtures (including di-isodecyl phthalate (C10)) and several PCB congeners in a marine aquatic food web. The researchers did not measure the concentrations of various phthalate esters or PCB congeners in water which precluded estimating bioconcentration factors or bioaccumulation factors. However, the researchers reported that the phthalate esters measured in the study did not biomagnify – while PCBs were found to biomagnify with increasing trophic level.

[56] The OECD has completed an initial assessment of high molecular weight phthalate esters (HMWPE). This category includes phthalate ester compounds that range from C7-9 to C13. The OECD member states concluded that HMWPEs have a low potential to bioaccumulate in aquatic species with metabolic transformation being identified as the most likely explanation for decreasing concentrations with higher trophic levels. [Note: DIDP falls within this category, but was not one of the specific compounds reviewed by the OECD because it had already been considered in the European Union risk assessment report.]

[57] Environment Canada (2005) concluded that DIDP is not bioaccumulative based on an empirical BAF of 2.2.

[58] Environment Canada (2005) performed a categorical review for phthalates and concluded that few compounds in the class are persistent. In their review of substances on the Domestic Substances List, Environment Canada (2005) identified DIDP as not persistent.

[59] Environment Canada (2005) concluded that DIDP is not persistent. OSPAR Commission (2005) concluded that DIDP is readily biodegradable and does not exceed the persistence criterion in the OSPAR or EU guidelines.

- ***Persistence***: *DIDP and DnHP are persistent in the environment. Estimated half-live values for these two compounds in sediments exceed 60 days.*[60]
- ***Bioaccumulation***: *DIDP and DnHP have a high potential to bioaccumulate. Estimated BCF values exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000).*[61]
- ***Toxicity***: *DIDP and DnHP have the potential to be toxic to humans, plants and wildlife. The NTP-CERHR (2003b,f) judged that the scientific evidence was sufficient to conclude that DIDP and DnHP are developmental toxicants and could adversely affect human development if exposure levels were sufficiently high.*[62]

Public Comments and Concerns

General comments supporting or opposing Ecology's proposal to include DIDP and DnHP on the PBT List are summarized under Issues 5-8 and 5-9. Several lines of reasoning were used to support arguments that DnHP should not be included on the PBT list:

- DnHP is not persistent. The American Chemistry Council/Phthalate Esters Panel (Panel) stated that the data used by Ecology to characterize DnHP as persistent are incorrect and DnHP is readily degraded in the environment.

  DIDP and DnHP are not persistent. The data relied upon by Ecology to characterize DIDP as persistent are incorrect and these phthalates are readily biodegraded, and so do not persist in the environment. ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

- DnHP does not meet bioaccumulative criteria. Several commenters stated that DnHP is readily metabolized and excreted by fish and mammals and do not accumulate in tissues.

  The data demonstrate that DIDP and DnHP are not of bioaccumulative concern. Because they are readily metabolized and excreted by fish and mammals, they do not accumulate in tissues. Traveling up the food chain, higher molecular weight phthalates, including DIDP and DnHP, decrease in tissue concentration with increasing trophic position (i.e., biodilute) rather than biomagnify. ***(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

  Categorization of n-hexyl phthalate as persistent and bioaccumulative is not supported by the data. *Ecology (WDOE 2005) cites a predicted half-life of 78 days in sediment, a value which exceeds the criterion (60 days) by only 30%, as the basis for identifying n-hexyl phthalate (DnHP) as persistent. Because there are apparently no experimentally derived half-life data available for this chemical, NCASI suggests (consistent with comments 1 and 3) that chemical-specific half-lives be obtained from all relevant models and that the mean of these be used to assess persistence. At the very least, media-specific half-lives from HYDROWIN should be generated and averaged with the value from EPA's PBT profiler prior to comparison to the persistence criteria.*

  As noted earlier, phthalate esters are known to be metabolized by higher level organisms, so phthalates are not anticipated to bioaccumulate to any significant extent. Thus, even though the range of pKows cited by Ecology (6.2 to 6.8) suggest a potentially bioaccumulative chemical, a measured BCF/BAF is actually necessary to demonstrate this potential. Because of metabolism,

[60] The EPA PBT Profiler calculates the following media-specific half-life values: water (8.7 days); soil (17 days); and sediments (78 days). The PBT Profiler predicts that the majority of DnHP released to the environment will partition to sediments (60%).
[61] The PBT Profiler calculates a BCF value of 1,100 using the BCFWin computer program.
[62] The EPA (1998b) reported the following aquatic toxicity values for DnHP: 21 day chronic MATC for daphnia (0.11 mg/L); acute LC50 trout (2.2 mg/L); chronic fish ECOSAR value (0.003 mg/L); and acute ECOSAR value (algae) (0.017 mg/L). EPA assigned an ecological score of two (moderate toxicity) to DnHP. The PBT Profiler (EPA 2004a) calculates a ChV of 0.003 mg/L.

any BCF/BAF obtained as an estimate from a model not incorporating metabolism should not be used as the basis for characterizing DnHP as bioaccumulative.

*Overall, the data cited by Ecology are insufficient to justify characterizing DnHP as a persistent and bioaccumulative chemical; thus this chemical should not be listed as a PBT as part of the proposed rule. (**Jeff Louch, p. 5 of November 2005 Written Comments)***

- DnHP does not pose ecological toxicity concerns. The ACC/PEC stated that high molecular weight phthalates are not toxic to aquatic organisms at levels up to and including their solubility limits.

  *DIDP and DnHP do not pose ecological toxicity concerns. The higher molecular weight phthalates, including DIDP and DnHP, are not toxic to aquatic organisms at levels up to and including their solubility limits. **(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

- DnHP poses low concern for human toxicity. The ACC/PEC noted that the NTP-CERHR did not reach a conclusion on regarding the potential for DnHP to adversely affect human development or reproduction.

  *DIDP and DnHP pose low concern for human toxicity. The extent of Ecology's support for concluding that these phthalates meet the criteria for toxicity is "The NTP-CERHR . . . judged that the scientific evidence was sufficient to conclude that DIDP and DnHP are developmental toxicants that could adversely affect human development, if exposure levels were sufficiently high." For DnHP this statement is not correct; NTP-CERHR, in fact, did not reach a conclusion regarding the potential for DnHP to adversely affect human development or reproduction..... **(Courtney Price, p. i of Attachment to November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to include di-n-hexyl phthalate on the PBT list at this time. Ecology's decision is based on consideration of two main factors:

- Persistence: Ecology's determination that DnHP meets the persistence criterion in WAC 173-333-320(2)(a) was based on a sediment half-life (78 days) predicted by the PBT Profiler. Ecology has decided to re-evaluate this determination because of questions on the reliability of basing conclusions on a single model (particularly when the predicted half-life is not significantly above the 60 day criterion)[63], results from biodegradation test for di-hexyl phthalate (DHP), categorical reviews of phthalate esters[64] and the results of more recent environmental reviews[65].

- Bioaccumulation: Ecology's determination that DnHP met the bioaccumulation criterion in WAC 173-333-320((2)(b) was based on a BCF value of 1,100 predicted by the BCFWin computer model. Ecology has decided to re-evaluate this determination because of questions on the reliability of basing conclusions on a single model (particularly when the predicted

[63] Ecology determination was based on the results of a single computer model that predicted sediment half life value that marginally exceeded the 60 day persistence. McKay et al. (2005) have observed that most commonly used environmental models are based on similar principles and information and, consequently, produce similar results. However, given the relatively small exceedance predicted by the PBT Profiler, Ecology believes it is inappropriate to consider the results of a single model.

[64] Environment Canada (2005) performed a categorical review for phthalates and concluded that few compounds in the class are persistent. In their review of substances on the Domestic Substances List, Environment Canada (2005) identified DnHP as not persistent.

[65] Environment Canada (2005) concluded that DnHP is not persistent.

BCF value is not substantially above the 1000 bioaccumulation criterion)[66], information on the metabolism of phthalate esters and categorical reviews of phthalate esters[67].

Issue 5-11: Should Ecology include hexabromocyclododecane on the PBT List?

Proposed Rule

Ecology proposed to include hexabromocyclododecane (HBCD) on the PBT list. After reviewing the information on the persistence, bioaccumulation and toxicity of this substance, Ecology concluded:

> Ecology has determined that hexabromocyclododecane meets the proposed PBT criteria specified in WAC 173-333-320.

- **Persistence**: HBCD is persistent in the environment. Estimated half-live values for HBCD in surface water, soils and sediments are equal to or greater than 60 days.[68]
- **Bioaccumulation**: HBCD has a high potential to bioaccumulate. BCF values ranging up to 11,220 have been measured and/or estimated using computer models. Many of these values exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000).[69]
- **Toxicity**: HBCD has the potential to be toxic to human or plants and wildlife. Exposure to HBCD has been shown to cause effects on the liver (and possibly the skin and immune system). HBCD has also been shown to be toxic to aquatic organisms with toxicity measures (EC50's, NOEC, etc) that are below the 0.1 mg/L (chronic toxicity) and 1 mg/L (acute toxicity) toxicity criteria in the proposed PBT rule (WAC 173-333-320).[70]

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[66] Ecology determination was based on the results of a single computer model that predicted a BCF value that marginally exceeded the bioaccumulation criterion (BCF > 1000). McKay et al. (2005) have observed that most commonly used environmental models are based on similar principles and information and, consequently, produce similar results. However, given the relatively small exceedance predicted by the PBT Profiler, Ecology believes it is inappropriate to consider the results of a single model. [Note: Environment Canada (2005) report a log BCF maximum value of 4.8 (maximum BCF = @63,000) that was calculated using the OASIS model.]

[67] Environment Canada (2005) performed a categorical review for phthalates. Based on that categorical review, Environment Canada identified DnHP as not bioaccumulative.

[68] EPA (1998b) estimated half life values for HBCD in surface water (38 days), soils (38 days) and sediments (150 days) using the Ultimate Source Model and HYDROWIN computer program. The EPA PBT Profiler calculates the following media-specific half-life values: water (60 days); soil (120 days); and sediments (540 days). In addition, the PBT Profiler predicts that the vast majority of HBCD released to the environment will partition to soils (36%) and sediments (62%). OSPAR (2004k) concluded that HBCD was not inherently biodegradable based on their interpretation of computer modeling results (BIOWIN1 and BIOWIN3). KemI/EPA (2002) also reviewed available information and concluded that HBCD is not readily biodegradable

[69] Log K_{ow} values for HBCD indicate there is a potential for bioaccumulation. EPA (1998b) evaluated the range of available BAF/BCF values and used a BCF value of 11,220 to characterize the bioaccumulation potential of this substance. This is consistent with the information identified by the KemI/EPA (2002) who concluded that this substance meets the United Nation's bioaccumulation criteria (BCF > 5000) based on the results of two fish studies where BCF values of 9,000-18,000 were reported. The EPA PBT Profiler (2004c) predicts a BCF of 6,200.

[70] HBCD is predicted to be toxic to aquatic organisms. EPA (1998b) includes a geometric mean maximum acceptable toxicant concentration (GMATC) of 0.009 mg/L based on structure-activity relationships. This is consistent with findings and conclusions reached by the KemI/EPA (2002) who reported that HBCD affects the growth of algae (*Skeletonema costatum*, EC_{50} (72 h) = 0.011 mg/L) and growth, reproduction, and survival of *Daphnia magna* (NOEC (0.003 mg/L)). The PBT Profiler calculates a fish chronic toxicity value (ChV) of 0.00062 mg/L.

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) stated that HBCD does not meet the Department's proposed PBT criteria and recommended that HBCD be removed from the proposed rule. Key points raised in their written comments include the following:

- ***Persistence**: HBCD was determined not to be 'readily biodegradable' in the MITI test; e.g. it was not degradable by sewage microbes within a 28 day period when tested under stringent conditions. However, HBCD was degradable under more environmentally realistic conditions, and therefore should not be considered persistent.* ***(Raymond Dawson and David Sanders, p. 2 of November 2005 Written Comments)***
- ***Toxicity, Mammalian:** HBCD is not acutely toxic, irritating or sensitizing. It is not mutagenic. Its no-adverse-effect-level in repeated dose studies is 1000 mg/kg/d. It is not a developmental or reproductive toxicant, with a no affect level of 1000 mg/kg/d.* ***(p. 18)***
- ***Toxicity, Fish Chronic:** HBCD was not chronically toxic to fish or daphnia at the limits of its aqueous concentration, based on the gamma isomer.* ***(p. 27)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that HBCD meets the PBT criteria in WAC 173-333-320(2). The following paragraphs summarize Ecology's review and response to the above comments:

Ecology has reviewed the comments on this issue and continues to believe that TBBPA meets the PBT criteria in WAC 173-333-320(2).

- Persistence: The BSEF commented that HBCD should not be considered persistent because it has been shown to be degradable under more environmentally realistic conditions. Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Ecology agrees that the data provided by BSEF indicates that HBCD can degrade in anaerobic sediments. However, the available studies included in the IUCLID data summary describe several results that support Ecology's earlier conclusions on the persistence of HBCD: (1) Zero degradation was observed in a 28 closed bottle test[71]; (2) an estimated half-life of @63 days in an aerobic soil microcosm[72]; and (3) no degradation in soil microcosms incubated under aerobic conditions[73]. This conclusion is consistent with (1) computer modeling results and (2) conclusions reached by Environment Canada (2005)[74].
- Mammalian Toxicity: The BSEF commented that HBCD has not been shown to be toxic at doses up to 1000 mg/kg bw. Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Ecology considered this information when deciding whether to identify HBCD as a PBT chemical and, in general, agrees with BSEF's conclusions.

[71] Schaefer, E. and Haberlein, D. 1996. Hexabromocyclododecane (HBCD): Closed Bottle Test. Project No. 43E-102. Wildlife International, Easton MD.
[72] Davis, J., Gonsior, S. and G. Marty. 2003. Evaluation of Aerobic and Anaerobic Transformation of Hexabromocyclododecane in Soil. Study Number 021082. Environmental Chemistry Research Laboratory. Toxicology and Environmental Research and Consulting. The Dow Chemical Company. Midland, MI.
[73] Davis, J.W, Gonsior, S.J. and G.T. Marty. 2004. Investigation of the biodegradation o f[14C] hexabromocyclododecane in sludge, sediment and soil. Laboratory Project Study ID 031178. Toxicology and Environmental Research and Consulting. The Dow Chemical Company. Midland, MI.
[74] Environment Canada (2005) has concluded that HBCD meets the criteria for PBiT (persistent, bioaccumulative and inherent toxicity to non-human organisms).

However, as summarized in the Technical Background Document, Ecology conclusions on the toxicity of HBCD were based on ecological toxicity.

- Chronic Fish Toxicity: The BSEF commented that HBCD is not chronically toxic to fish or daphnia at the limits of its aqueous concentration (based on the gamma isomer). Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Ecology recognizes that available toxicity values are similar or slightly above reported water solubility limits for the gamma isomer. However, Ecology continues to believe these values are biologically significant. This conclusion is consistent with (1) QSAR results and (2) conclusions reached by Environment Canada (2005)[75].

Issue 5-12: Should Ecology include lead on the PBT List?

Proposed Rule

Lead and cadmium were two of the substances or groups of substances that Ecology included on the proposed PBT list. However, Ecology included the following provision regarding the preparation of chemical action plans:

> ***Lead and cadmium.*** *Ecology will not develop a chemical action plan for lead and cadmium until the Environmental Protection Agency concludes the development of a metals assessment framework and ecology completes its review of the bioavailability of these two substances.*

Public Comments and Concerns

Several organizations and individuals supported Ecology's proposal to include cadmium and lead on the PBT list. For example:

> *Thank you for including lead, cadmium, PFOS and short-chain chlorinated paraffins on the PBT list. The whole list is a good first start for this program. However, the extensively footnoted table format is difficult to read and understand. Please consider a new presentation format for the list and the detailed and important technical information that accompanies it* ***(Dave Galvin, p. 3 of July 2005 written comments)***

However, there were also several other organizations and individuals who stated that Ecology should not apply the PBT criteria to metals and recommended that Ecology not include lead and cadmium on the PBT list. For example:

> ***WAC 173-333-310(2) PBT List –*** *Cadmium and Lead should be removed from the proposed PBT list at this time....The notation added for these two elements indicates the evaluation of bioavailability is still underway. Until that work is complete and specific compounds can be identified, these elements are not ready for placement on the list****. (Ken Johnson, p. 2 of November 2005 written comments)***
>
> *.....In addition, Ecology has determined that it will follow EPA's lead in determining whether metals should be listed as PBTs through its Metals Risk Assessment Framework, which is still underway. AWB supports comments made by the North American Metals Council on this subject and requests that all metals be removed from the PBT list* ***(Grant Nelson, p. 3 of November 2005 written comments)***.
>
> *....NAMC urges Ecology to remove any reference to metals from its Draft PBT Rule.* ***(William Adams, p. 1 of November 2005 written comments)***

[75] Environment Canada (2005) has concluded that HBCD meets the criteria for PBiT (persistent, bioaccumulative and inherent toxicity to non-human organisms).

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to classify lead and cadmium as "metals of concern" pending completion of EPA's Inorganic Metals Assessment Framework. Under this approach, Ecology would consider lead and cadmium during the process for selecting chemicals for chemical action plan preparation under WAC 173-333-410 and, if appropriate, prepare chemical action plans for one of both of these metals. (see Issue 5-18 for further discussion)

Issue 5-13: Should Ecology include mercury on the PBT List?

Proposed Rule

Mercury was one of the 26 substances or groups of substances that Ecology included on the proposed PBT list. In evaluating whether to include mercury on the PBT list, Ecology considered information on persistence, bioaccumulation and toxicity and reached the following conclusion:

> *Ecology has reviewed readily available information on the persistence, bioaccumulation potential and toxicity for mercury.*
>
> - ***Persistence**: Mercury is transformed into methylmercury in the environment. Methylmercury is highly persistent and EPA used a range of soil half-life values (1.5 – 20 years) to characterize the persistence of mercury when deciding whether to identify as PBT chemicals for the TRI program (EPA, 1999a).*
> - ***Bioaccumulation**: EPA (1998b) evaluated the range of BAF/BCF values available for mercury and used a BAF value of 6,800,000 to characterize the bioaccumulation potential of this substance. This value is based on a measured bioaccumulation factor included in the Mercury Study Report to Congress (EPA, 1997a). EPA used a range of BCF values (7,000 – 36,000)[76] to characterize bioaccumulation potential when deciding whether to include mercury and mercury compounds among the substances identified as PBT chemicals for purposes of reporting under the TRI program (EPA, 1999a).*
> - ***Toxicity (Non-cancer)**: Several developmental and neurological effects are associated with exposure to mercury and methylmercury. EPA has established an inhalation RfC value (0.0003 mg/m3)[77] for elemental mercury and an oral RfD value (0.0001 mg/kg/day)[78] for methylmercury that are published in the IRIS database. ATSDR (1999b) has established Minimal Risk Levels for mercury for chronic inhalation exposure (0.0002 mg/m3) and chronic oral exposure to methylmercury (0.0003 mg/kg/day) based on reproductive and developmental effects, respectively.*
> - ***Ecological Toxicity**: Mercury is highly toxic to aquatic organisms. EPA has established a Tier I Final Chronic Value (FCV) (0.0009081 mg/L) developed through the Great Lakes Water Quality*

[76] EPA (1999a) listed a range of BCF values (29,600 – 66,000) and a bioaccumulation factor for piscivorous fish (> 2,500,000). Environmental modeling performed as part of the Mercury Study Report to Congress was based on BAF values for trophic level 3 (1,600,000) and trophic level 4 (6,800,000).

[77] The RfC value was based on the results of several occupational studies where workers were observed to have a variety of neurological effects (e.g. hand tremors, memory disturbance, etc.) EPA calculated an adjusted LOAEL of 0.009 mg/m3 and applied an uncertainty factor of 30. EPA assigned a medium level of confidence to the study, database and the RfD (EPA, 2004a).

[78] The RfD for methylmercury of 0.0001 mg/kg/day is based on epidemiology studies where neurological development was evaluated in young children (See NRC 2000a). EPA assigned a high level of confidence to the study, database and RfD value.

Initiative [79], a Tier II Secondary Chronic Value (FCV) (0.0013 mg/L) developed through the Great Lakes Water Quality Initiative [80] and an AWQC FCV (0.0011 mg/L) developed by EPA's Office of Water.[81]

- ***Metal Bioavailability**: Numerous studies have demonstrated that mercury/methylmercury is bioavailable under many environmental conditions. EPA (1997a) reviewed the environmental fate and transport of mercury. Mercury can exist in several different forms in the environment which are influenced by pH, temperature, organic matter, etc.). Soil conditions generally favor the formation of inorganic Hg(II) compounds such as $HgCl_2$, $Hg(OH)_2$ and inorganic Hg(II) compounds complexed with organic anions. Hg(II) compounds can be transformed into methylmercury by various microbial processes in soils, sediments and marine and freshwater environments. Hg(II) and methylmercury can enter marine and freshwater environments via atmospheric runoff, surface water runoff and/or leaching of contaminated ground water. The same transformation and complexation processes that occur in soils also occur in aqueous environments. Methylmercury is very bioavailable and accumulates in fish tissue through the aquatic food web with nearly 100% of the mercury found in fish muscle tissue being present in methylated forms.*

Public Comments and Concerns

Several individuals and organizations recommended that Ecology not apply the PBT criteria to metals. For example:

> *Metals should not be listed as PBTs. Ecology should follow the lead of EPA and wait until EPA's metal assessment is finalized.* ***(Grant Nelson, p of July 2005 Written Comments)***
>
> *Preferably, metals should be removed from the PBT list all together until after the EPA concludes its metals assessment framework. AWB supports comments made by NAMC on this subject. If Ecology determines it is necessary to mention metals in the PBT rule, then AWB has suggested "footnote" language in our mark-up that could be used to explain the current status of metals, and why they are not being listed as PBTs at this time. We believe this footnote is consistent with the agencies 2002 letter to the NAMC, stating that the department will be consistent with EPA.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***
>
> *....NAMC urges Ecology to reject the current draft's attempt to extend the use of PBT criteria to the hazard assessment of metals. The Draft PBT Rule would identify a metal as a PBT chemical if it is found to meet general PBT criteria and if "ecology determines that [the metal] is likely to be present in forms that are bioavailable." ..... In any event, the mere fact that a metal is likely to be present to some extent in a "bioavailable" form does not mean that the application of Ecology's general PBT criteria to assess its hazard is appropriate as a matter of science or policy.* ***(William Adams, p. of November 2005 Written Comments)***

The rationale used by these organizations and individuals generally fell into one of three categories: (1) it is inappropriate (from a scientific and policy standpoint) to apply the PBT criteria to metals; (2) it is premature for Ecology to apply the PBT criteria to metals because of

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[79] The GLWQI values were derived using the same methods that EPA uses to derive ambient water quality criteria in cases where final residues values are not used. The source document for the Tier I FCV for cadmium is the Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water (EPA, 1995b).

[80] The GLWQI values were derived using the same methods that EPA uses to derive ambient water quality criteria in cases where final residues values are not used. The source document for the Tier I FCV for cadmium is the Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water (EPA, 1995b).

[81] The Ambient Water Quality Criteria FCV values were developed in the mid-1980's and distributed for public review. The values are compiled in the Ecotox Thresholds ECO Update (Volume 3 No. 2) (EPA, 1996)

the ongoing EPA review; and (3) application of the PBT criteria to metals and listing cadmium, lead and mercury is at odds with past Ecology statements. (See Issue #6 for discussion).

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to continue to include mercury on the PBT list. However, Ecology decided to revise WAC 173-333-310(2) to specify that "methylmercury" is the listed compound (instead of broader listing of "mercury" which would include a wide range of inorganic and organic mercury compounds). The rationale for this decision includes:

- Methylmercury is acknowledged to be a significant threat to infants and developing fetuses with large percentage of exposure occurring as a result of the bioaccumulation of this compound in fish and other aquatic organisms (NRC, 2000; EPA 2005; Ecology and Health, 2003).
- Methylmercury meets the PBT criteria in WAC 173-333-320(2) and Ecology believes those criteria are appropriate for evaluating organometallic compounds such as methylmercury. The application of the PBT criteria to organo-metallic compounds is consistent with the approach recently developed by Environment Canada (2005) for the evaluation of organometallic substances that "...generally follows the existing approach for organic substances but with certain modifications..."
- EPA's Inorganic Metals Assessment Framework is designed to address inorganic metals. The authors of that report clearly stated that other EPA guidance documents are relevant to evaluating organometallic compounds such as methylmercury.
- Methylmercury and/or mercury are included on a number of PBT lists developed by EPA and other state, federal and international PBT programs. Mercury and/or methylmercury have been identified as a Level I substance under the Bi-National Toxics Strategy (GLNPO, 1997), one of the initial PBT chemicals identified by EPA (EPA, 1998b), a PBT chemical for purposes of reporting under EPA's TRI program (EPA, 1999a), a PBT by the State of Wisconsin (WDNR, 2005) and a PBT chemical on the OSPAR Commission's List of Substances of Possible Concern (OSPAR, 2004b).
- Ecology and Health have already prepared a chemical action plan for mercury. Ecology efforts to develop that plan were underway when then-Director Fitzsimmons stated that the agency would consider the results of the EPA Inorganic Metals Assessment Framework before making final decisions on identifying individual metals as PBT chemicals. Ecology is currently working with other agencies and organizations to implement the CAP recommendations. Ecology believes that completely removing mercury/methylmercury from the PBT list would unnecessarily complicate ongoing implementation of those recommendations.

Issue 5-14: ***Should Ecology include nonylphenol on the PBT List?***

Proposed Rule

Nonylphenol was one of the substances or groups of substances that Ecology included on the proposed PBT list. In evaluating whether to include nonylphenol on the PBT list, Ecology considered information on persistence, bioaccumulation and toxicity and concluded:

Ecology has determined that nonylphenol/4-nonylphenol (branched) (CAS 25154-52-3/84852-15-3) meets the PBT criteria in WAC 173-333-320:

- ***Persistence**: NP/4-NP (branched) is persistent in the environment. Estimated half-live values for NP/4-NP (branched) in soils and sediments exceed 60 days*[82].
- ***Bioaccumulation**: NP/4-NP (branched) has a high potential to bioaccumulate. BCF values ranging from 79 to 7,200 have been measured and/or estimated using computer models. EPA, ECB and OSPAR have characterized the bioaccumulation potential of NP/4-NP (branched) using BCF values that exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000)*[83].
- ***Toxicity**: NP/4-NP (branched) has the potential to be toxic to human or plants and wildlife. NP/4-NP (branched) has been shown to be toxic to aquatic organisms with toxicity measures (LC50's, NOEC, etc) that are below the 0.1 mg/L (chronic toxicity) and 1 mg/L (acute toxicity) toxicity criteria in the proposed PBT rule (WAC 173-333-320)*[84].

Public Comments and Concerns

During the July public comment period, several organizations and individuals recommended that Ecology add nonylphenol to the PBT list. After reviewing those comments and available scientific information, Ecology decided to include nonylphenol on the proposed PBT list published in October 2005. Several organizations supported Ecology's proposal to include nonylphenol on the PBT list. For example:

> ***Keep Phthalates and Nonylphenol on the PBT List** We support the addition of the two phthalates and nonylphenol to the list. The chemicals satisfy the PBT criteria and should be on the list because of their dangerous effects on people and wildlife. Recent studies have linked phthalates to effects on human development, most recently reproductive problems in male infants. The European Union already is taking steps to ban the chemical in children's toys. Nonylphenol has been shown to*

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[82] UNEP (2002) concluded that "...NPs and t-OP are persistent in the environment with half-lives of 30-60 years in marine sediments, 1-3 weeks in estuarine waters and 10-48 hours in the atmosphere..." ECB (2002) reviewed the results of several biodegradation tests and estimated biodegradation half lives of 150 days and 300 days in surface water and soils, respectively. The media-specific half-life values predicted by the EPA PBT Profiler (EPA 2004c) are surface water (15 days), soil (30 days) and sediments (140 days).

[83] Published K_{ow} values for nonylphenol (K_{ow} values range from 4.2 - 6) indicate there is a potential for bioaccumulation in aquatic organisms and humans. ECB (2002) reviewed information on bioaccumulation of NP and concluded "...[i]t is clear from the available data that NP bioconcentrates to a significant extent in aquatic species..." and used a BCF of 1,280 to characterize the bioaccumulation potential of this substance. Other recent evaluations have used a range of BCF values to characterize the bioaccumulation potential of NP compounds. For example, EPA (1998b) used a BCF of 1,288 for 4-NP, 550 for NP and 7,079 for 4-NP (branched)); the OSPAR Commission (2002) reported BCF values ranging from 280-4,120 for 4-NP and used a BCF of 1,280 (from ECB (2002)) for NP and 4-NP(branched); EPA (2003) reported lipid normalized BCF values ranging from 39-209 (freshwater fish) and 78.75 to 2,168 (salt water organisms). Environment Canada (2000) reported the same range of BCF values and concluded that "...the available literature suggests that the ability of NP and NPEs to bioaccumulate in aquatic biota in the environment is low to moderate...". The PBT Profiler (EPA, 2004c) calculates the following BCF value using the BCFWin computer program: 540 (4-NP); 540 (NP) and 7,200 (4-NP (branched)).

[84] Available data indicate that NP is toxic to aquatic species. NP is considered an endocrine disruptor chemical and has been shown to feminize male fish interfering with the reproductive process. EPA (2003) has published a draft water quality criterion for nonylphenol. Under the draft criteria, four day average water concentrations should not exceed 5.9 ug/L (freshwater) or 1.4 ug/L (marine waters) more than once every three years on the average. Staples et. al. (2004) used a Species Sensitivities Distribution (SSD) approach to evaluate the potential impacts of chronic exposure to NP and NPEs. They concluded that "...[u]sing the SSD analysis for NP with higher quality study results, the 10th percentile chronic effect value is 5.7 ug/L, which supports the USEPA criteria on NP of 5.9 ug/L. The EPA water quality criterion is similar to the chronic toxicity value for fish (0.005 mg/L) calculated for 4-nonylphenol (branched) by the PBT Profiler (EPA, 2004c)

adversely affect the endocrine system, causing hormonal problems that can lead to numerous health effects, including reproductive problems. ***(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)***

However, there were several other organizations and individuals who disagreed with Ecology's conclusion that nonylphenol meets the proposed PBT criteria and recommended that the substance not be included on the PBT list. For example:

NWPPA strongly urges the deletion of Di-isodecyl phthalate (DIPP), Di-n-hexyl phthalate (DnHP) and nonylphenol as per NCASI comments. NWPPA also endorses AWB comments with respect to metals and other chemicals that should be removed from the list. ***(Llewellyn Matthews, p. 2 of November 2005 Written Comments)***

Perhaps the most disturbing aspect related to the listing of NP on the proposed Washington State PBT list in the Revised Draft Rule (September 29, 2005) was the fact that Ecology acknowledges the extensive comments and scientific references provided by APERC in 2001 while apparently choosing to ignore the data - already in hand - that support with well-founded science the conclusion that NP does not meet the proposed Washington State criteria for persistence and bioaccumulation. Ecology should use the extensive body of high quality data, which are summarized in the attached comments, to conduct its assessment on NP. These data support a weight-of-evidence based conclusion that NP should not be classified as PBT. ***(Barbara Losey, p. 2 of November 2005 Written Comments)***

Several lines of reasoning were used to support recommendations to remove nonylphenol from the proposed PBT list. These include:

- Nonylphenol is not persistent: Several commenters stated that nonylphenol does not persist in the environment for periods of time that exceed the persistence criteria in the proposed PBT rule. For example:

  In summary, none of the half-life values cited in Ecology's short discussion of persistence of NP should be used as a basis for categorizing NP as persistent. Following is a discussion of the more relevant and extensive biodegradation data available in the published literature, which should be used in this evaluation. ***(Barbara Losey, p. 28 of Attachment to November 2005 written comments)***

- Nonylphenol is not bioaccumulative: Several commenters stated that nonylphenol does not meet the bioaccumulation criteria in the proposed PBT rule. For example:

  In summary, an examination of fish uptake and elimination constants indicate that all NP isomers demonstrate uptake into fish that is significantly attenuated by rapid elimination/metabolism processes in fish, resulting in generally low to moderate laboratory BCF values and no significant bioaccumulation in field studies. Overall, the weight of evidence supports the conclusion that NP does not meet the Washington State proposed criteria to be categorized as bioaccumulative. ***(Barbara Losey, p. 28 of Attachment to November 2005 written comments)***

  Categorization of 4-nonylphenol as bioaccumulative is not supported by the data. *As summarized by EPA (USEPA 2003), the pKow of 4-nonylphenol ranges from 3.8 to 4.8, and the range of experimentally determined BCFs/BAFs is from 37 to 984 for freshwater organisms and from 110 to 4120 for saltwater organisms. The mean value (n=28) of all these BCFs/BAFs is 685.*

  As summarized by Environment Canada (EC 2001), the pKow of 4-nonylphenol ranges from 4.2 to 4.5, the range of experimentally determined BAFs is from 6 to 487, and the range of experimentally determined BCFs is from 0.9 to 4120. From these data, the mean (n=8) BAF is 128 and the mean (n=18) BCF is 575.

  In both the EPA and EC data sets the only experimental BCFs >1000 were determined using 14Clabelled- 4-nonylphenol (radiolabeled nonylphenol) and measurements of total 14C in the organism. Thus, the measurements did not discriminate against metabolites of 4-nonylphenol in

the organism, so these experimental BCFs should be considered suspect; i.e., they are potentially high biased. If these specific BCFs are dropped from consideration there are no measured BCF/BAFs >1000 listed in either data set.

Overall, the body of data as summarized by both EPA and EC does not support categorizing 4-nonylphenol as a bioaccumulative chemical according to Ecology's criteria; thus this chemical should not be listed as a PBT as part of the proposed rule. ***(Jeff Louch, pp. 4-5 of November 2005 Written Comments)***

- Failure to Account for Differences in Data Quality: Several organizations criticized the Department for focusing on a limited amount of data and recommended that the Department use a weight of evidence approach that is consistent with those generally accepted in the scientific community. For example:

  The values selected by Ecology to justify listing NP as either persistent or bioaccumulative are from inadequate quality data sources, especially in light of the fact that there are numerous other high quality data available from which to conduct a weight-of-evidence assessment. Ecology should conduct assessments that are consistent with those generally accepted in the scientific community; utilizing a preferred hierarchy of data sources where the weight of evidence is preferred over single measured values, which are in turn preferred over estimated, calculated or modeled values. ***(Barbara Losey, p. 3 of Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to include nonylphenol on the PBT list at this time because of questions on the underlying data used to characterize the bioaccumulation potential and persistence of nonylphenol. Specifically, comments from Alkylphenols and Ethoxylates Research Council (APERC) and the National Council for Air and Stream Improvement raised several questions regarding the use of the bioconcentration factor and media-specific half life values used by Ecology to characterize the bioaccumulation potential and persistence of nonylphenol, respectively.

- Bioaccumulation: Ecology's determination that nonylphenol meets the bioaccumulation criterion in WAC 173-333-320(2)(b) was based on a BCF value of 1280 used by the European Chemicals Bureau (2002). Ecology has decided to re-evaluate this determination because of questions on the study design, results from studies completed subsequent to the ECB report and the results of more recent environmental reviews.
- Persistence: Ecology's determination that nonylphenol meets the persistence criterion in WAC 173-333-320(2)(a) was based on environmental half-live values calculated by the European Chemicals Bureau (2002). Ecology has decided to re-evaluate this determination because of questions on the assumptions underlying the environmental modeling results, results from biodegradation tests and the results of more recent environmental reviews.

Issue 5-15: ***Should Ecology revise the PBT list to provide additional detail on PCB congeners?***

Proposed Rule

The PBT List in the October 2005 proposed rule included eight (8) polychlorinated biphenyls (PCBs) congeners that Ecology concluded meet the proposed persistence, bioaccumulation and toxicity criteria in WAC 173-333-320(2).

Public Comments and Concerns

PCBs was one of the 26 chemicals and chemical groups that Ecology included on the proposed PBT list published in June 2005. In evaluating whether to include PCBs on the PBT list, Ecology considered information on the persistence, bioaccumulation and toxicity of specific congeners or Arochlor mixtures.

Several individuals and organizations recommended that Ecology specify which congeners or Arochlor mixtures meet the PBT criteria. For example:

> *However, Ecology has also included PCBs as a group on the draft PBT list given in the proposed rule without citing the specific PCB congeners. Understanding that essentially all toxicity data for PCBs were derived based on Aroclor (or coplanar PCB) concentrations and that many of the mono- and di-chlorinated PCBs have pK_{ow}s <5, it is clear that not all of the 209 PCB congeners would meet the PBT criteria. In fact, this situation illustrates why all listings should be on a chemical-specific basis.*
>
> *Prior to full promulgation of this rule, Ecology must apply the PBT criteria adopted by the rule to PCBs on a congener-specific basis, and only those congeners meeting all the criteria should be included on the PBT list. Ecology has already done this for the other "chemical groups" included on the draft PBT list (PAH, PBDE, PCDD/DF, PCN, etc.), and PCBs should be treated likewise.* ***(Jeff Louch, p. 3 of July 2005 written comments)***

Similar comments were provided by other organizations including Mr. Grant Nelson (AWB), Ms. Llewellyn Matthews (NWPPA) and Mr. Ken Johnson (Weyerhaeuser).

Ecology reviewed the comments on the June 2005 proposed rule and decided to revise the format of the PBT List. As part of the formatting changes, Ecology decided to identify the specific PCB congeners that meet the persistence, bioaccumulation and toxicity criteria. Organizations providing earlier comments on this issue agreed with the revised approach. For example:

> *...modification of the proposed PBT rule to include individual chemicals only (as opposed to listing chemical groups) are clear improvements....* ***(Jeff Louch, p. 1 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

As described above, Ecology reviewed the July 2005 public comments and decided to identify individual PCB congeners rather than listing PCBs as a single group or mixture. Ecology's decision to modify the list was based on several considerations:

- This approach allows Ecology to take into account the differences in persistence, bioaccumulation and toxicity of various PCB congeners;
- This approach is consistent with the approach used by EPA when identifying PBT chemicals for purposes of reporting for the Toxics Release Inventory.
- This approach is consistent with the approach used by Ecology for other chemical groups (e.g. polynuclear aromatic hydrocarbons, polychlorinated dibenzo-p-dioxins (PCDDs), etc.)

In making this change, Ecology recognizes that it is not possible to be completely consistent with all of the different approaches used to identify PCB mixtures and that such inconsistencies will need to be more fully addressed if Ecology elects to prepare a chemical action plan for this group of chemicals.

Issue 5-16: Should Ecology include short-chain chlorinated paraffins (SSCPs) on the PBT List?

Proposed Rule

Short-chain chlorinated paraffins were one of the substances or groups of substances that Ecology included on the proposed PBT list. In evaluating whether to include SSCPs on the PBT list, Ecology considered information on persistence, bioaccumulation and toxicity and concluded:

> *Ecology has determined that SSCPs meet the draft PBT criteria in WAC 173-333-320.*
>
> - ***Persistence**: SSCPs are very persistent in the environment. Estimated half-live values for SSCPs in surface water, soils and sediments exceed 60 days.*[85]
> - ***Bioaccumulation**: SSCPs have a high potential to bioaccumulate. BCF values ranging up to 140,000 have been measured and/or estimated using computer models. BCF values used by other agencies to characterize the bioaccumulation potential of SSCPs exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000).*[86]
> - ***Toxicity**: SSCPs has the potential to be toxic to human or plants and wildlife. IARC and the NTP have classified SSCPs as "possibly carcinogenic to humans" and "reasonably anticipated to be a human carcinogen", respectively. SSCPs have also been shown to be toxic to aquatic organisms with toxicity measures (LC50's, NOEC, etc) that are below the 0.1 mg/L (chronic toxicity) and 1 mg/L (acute toxicity) toxicity criteria in the proposed PBT rule (WAC 173-333-320).*[87, 88]

Public Comments and Concerns

Several organizations and individuals providing comments on the June 2005 and October 2005 proposed PBT rules supported Ecology's proposal to include SSCP on the PBT list. For example:

> *Thank you for including lead, cadmium, PFOS and short-chain chlorinated paraffins on the PBT list. The whole list is a good first start for this program. However, the extensively footnoted table format is difficult to read and understand. Please consider a new presentation format for the list and the detailed and important technical information that accompanies it* ***(Dave Galvin, p. 3 of July 2005 written comments)***

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[85] SCCPs are considered very persistent. They do not readily hydrolyze in water and are not considered readily biodegradable nor inherently biodegradable (OSPAR, 2001b; ECB, 2000a). KemI/EPA (2002) and Environment Canada (2003b) have both concluded that SCCPs meet the United Nations persistence criterion.

[86] Log K_{ow} values for SSCP indicate there is a potential for bioaccumulation[86]. BCF and BAF values between 1000 and 140,000 are summarized in the Substance Dossier prepared by Environment Canada (2003) and the EU Risk Assessment (ECB, 2000a).[86] KemI/EPA (2002) and Environment Canada (2003b) both concluded that SCCPs meet the United Nations bioaccumulation criterion

[87] The International Agency for Research on Cancer (IARC 2004a) and the National Toxicology Program (2004a) have concluded that chlorinated paraffins (C_{12} and @ 60% chlorine) are "possibly carcinogenic to humans" and "reasonably anticipated to be human carcinogens", respectively. These conclusions are based on the results of a NTP bioassay in which an increased incidence of liver tumors was observed in male and female mice and rats exposed to chlorinated paraffins administered via gavage (NTP 1986b)

[88] KemI/EPA (2002) and Environment Canada (2003b) have both concluded that SCCP exhibits high toxicity towards aquatic organisms. Environment Canada (1993, 2003b) summarized several studies that provide evidence that SSCPs are toxic to aquatic invertebrates and fish at the ug/L level[88]. Environment Canada (2003b) calculated NOEC values for benthic organisms using two equilibrium-partitioning approaches. The first approach is typically used by Environment Canada (based on Di Toro et al., 1991) and yielded a $NOEC_{benthic}$ of 19.95 ug/g DW. The second approach is from the European Technical Guidance Document for risk assessments and yielded a $NOEC_{benthic}$ of 2.17 ug/g DW. The ECB (2000a) and the OSPAR Commission (2004cc) list an acute toxicity algae IC50 (0.043 mg/L), an acute toxicity daphnia EC50 (0.3 mg/L), acute toxicity fish LC50 (100 mg/L), chronic toxicity daphnia NOEC (0.005 mg/L) and chronic toxicity fish NOEC (0.28 mg/L).

The Chlorinated Paraffins Industry Association recommended that Ecology remove SCCPs from the PBT List. Several organizations expressed support for this recommendation. For example:

> *.... AWB supports comments made by the Bromine Science and Environmental Forum and the Chlorinated Paraffins Industry regarding these two chemicals and requests that they be removed from the PBT list....* ***(Grant Nelson, p. 3 of July 2005 written comments)****.*

The Chlorinated Paraffins Industry Association provided several arguments to support their recommendation that Ecology should not identify SSCP as a PBT chemical. These include:

> *...Ecology has not provided any scientific evidence to justify classifying SCCPs as meeting the persistence criteria.* ***(Robert Fensterheim, p. 2 of July 2005 written comments);***
>
> *...the various reports cited do suggest that SCCPs have persistent properties, these reports have not concluded that the properties of SCCPs meet the Washington State criteria****....(p. 2)****;*
>
> *....SCCPs have not been nominated for consideration by the UNECE...* ***(p. 3)****;*
>
> *To address the uncertainties surrounding its persistence properties, the CP industry initiated a program to conduct a simulation test for biodegradability using a water-sediment test system (based on OECD Guideline 308). A draft protocol (attached) has been provided to the UK authorities for their review and comment and is being provided to Ecology for its input as well. The CP industry maintains that the results from this test should be considered by Ecology prior to concluding that SCCPs meet the states persistence criteria.* ***(p. 4)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that short-chain chlorinated paraffins meet the PBT criteria in WAC 173-333-320(2). The following paragraphs summarize Ecology's review and response to the above comments:

- Scientific Evidence on Persistence: The Chlorinated Paraffins Industry Association stated that Ecology has not provided scientific evidence demonstrating that SSCPs meet the persistence criteria in WAC 173-333-320(2). This is technically true in that Ecology chose to summarize the conclusions reached by other agencies – not the scientific studies underlying those conclusions – as the basis for the conclusion that SSCPs are persistent[89]. Those reports summarize the scientific studies and information considered by these organizations when reaching conclusions on the persistence of SSCPs.
- Swedish Chemical's Inspectorate and Environment Canada Reports: The Chlorinated Paraffins Industry Association stated that the Swedish Chemical's Inspectorate and Environment Canada have not concluded that SSCP meets the Washington State persistence criteria. The CPIA is technically correct in that neither agency was charged with evaluating the persistence of SSCPs relative to criteria developed for use in Washington State. However, both agencies reached conclusions on the persistence of SSCPs using criteria that include longer media-specific environmental half life values that the values in the Washington PBT rule. For example, the persistence criteria used by Environment Canada to identify PBiT (persistent, bioaccumulative and inherent toxicity to non-human organisms) chemicals include the following media-specific environmental half-life values: air (2 days); water (6 months); soil (6 months); and sediment (1 year).

[89] ***Persistence***: SCCPs are considered very persistent. They do not readily hydrolyze in water and are not considered readily biodegradable nor inherently biodegradable (OSPAR, 2001b; ECB, 2000a). KemI/EPA (2002) and Environment Canada (2003b) have both concluded that SCCPs meet the United Nations persistence criterion. **(Ecology, 2005, p. 76)**

- Lack of UNECE Nomination: Ecology does not agree that a nomination of SSCPs or any other chemical for inclusion on the POPs list is a prerequisite for addition to the Washington PBT List. However, subsequent to the submission of CPIA's comments on July 29, 2005, the European Commission completed the "*Risk Profile and Summary Report for Short-chained Chlorinated Paraffins (SSCPs)*" in August 2005. On September 9, 2005, the European Commission submitted a proposal to the Executive Body for the Convention on Long Range Transboundary Air Pollution to include SSCPs as a Persistent Organic Pollutant under the Convention.
- Future Studies: Ecology understands that the Chlorinated Paraffins Industry Association is currently working with the United Kingdom to conduct further testing to evaluate the persistence of SSCPs. Ecology decided not to wait the results this testing before making a final determination on whether SCCPs meet the persistence criterion. However, Ecology will consider the results of such studies when they become available.

Issue 5-17: Should Ecology include tetrabromobisphenol (TBBPA) on the PBT List?

Proposed Rule

Tetrabromobisphenol (TBBPA) one of the substances or groups of substances that Ecology included on the proposed PBT list. In evaluating whether to include TBBPA on the PBT list, Ecology considered information on persistence, bioaccumulation and toxicity and concluded:

> *Ecology has determined that tetrabromobisphenol A meets the proposed PBT criteria specified in WAC 173-333-320.*
>
> - ***Persistence**: TBBPA is very persistent in the environment. Estimated half-live values for TBBPA in surface water, soils and sediments are equal to or greater than 60 days.*[90]
> - ***Bioaccumulation**: TBBPA has a high potential to bioaccumulate. BCF or BAF values ranging up to 14,000 have been measured and/or estimated using computer models. The values used by EPA and OSPAR to characterize the bioaccumulation potential of TBBPA exceed the bioaccumulation criterion in the proposed PBT rule (BCF = 1000)*[91].

[90] EPA (1998b) used half-lives in surface water (64 days) and soils (89 days) to characterize the persistence of this substance. EPA states these values were based on expert review. EPA (1999a) identified a range half-life values for TBBPA in surface water (48-84 days) and soil (44 – 179 days) when evaluating whether TBBPA should be identified as a PBT chemical under the TRI program. WHO (1995) reported that TBBPA is partially degraded in soils and sediments under both aerobic and anaerobic conditions. They reported that 40-90% of TBPPA remained in soils after 56-64 days with degradation rates varying with soil type and composition, temperature and humidity. The EPA PBT Profiler calculates the following media-specific half-life values: water (180 days); soil (320 days); and sediments (1,600 days). In addition, the PBT Profiler predicts that the vast majority of TBBPA released to the environment will partition to soils (53%) and sediments (46%).

[91] Log K_{ow} values for TBBPA indicate there is a potential for bioaccumulation[91]. EPA (1998b) evaluated the range of BAF/BCF values available for TBBPA and used a BCF value of 3,200 to characterize the bioaccumulation potential of this substance. EPA stated this value was based on expert review. The EPA PBT Profiler includes a BCF (14,000) that was calculated using the BCFWin computer model. EPA (1999a) listed three BCF values (780, 1,200 and 3,200) in the Federal Register notice establishing lower reporting thresholds for PBT chemicals under the TRI Program. WHO (1995) states that accumulation studies on aquatic organisms indicate bioconcentration factors ranging from 20 to 3,200. However, the authors of the WHO report noted that the relatively high bioconcentration factor seems to be balanced by rapid excretion and the compound has not normally been found in environmental samples. The OSPAR Commission (OSPAR, 2004dd) fact sheet for TBBPA used a BCF of 1235 (which is identified as a representative value for fish) to characterize the bioaccumulation potential for this substance.

- ***Toxicity***: *TBBPA has the potential to be toxic to human or plants and wildlife. TBBPA is toxic to aquatic organisms with toxicity measures (LC50's, NOEC, ChV, etc) that are below the 0.1 mg/L (chronic toxicity) and 1 mg/L (acute toxicity) toxicity criteria in the proposed PBT rule (WAC 173-333-320)*[92].

Public Comments and Concerns

The Bromine Science and Environmental Forum (BSEF) concluded that TBBPA does not meet the Department's proposed criteria for a persistent, bioaccumulative and toxic substance recommended that TBBPA be removed from the proposed rule. Key points raised in their written comments include the following:

- ***Persistence***: *TBBPA was determined not to be 'readily biodegradable' in the MITI test; e.g. it was not degradable by sewage microbes within a 28 day period when tested under stringent conditions. However, TBBPA was degradable under more environmentally realistic conditions, and therefore should not be considered persistent. Aerobic and anaerobic studies indicate a soil half-life of approximately 50 days. An aerobic sediment/water degradation study produced a half-life of approximately 67 days, and half-lives of 28 and 40 days were estimated from an anaerobic sediment study. TBBPA also appears rapidly photodegradable in water, with half-lives ranging from 16-360 minutes depending on pH.* ***(Raymond Dawson and David Sanders, p. 2 of November 2005 written comments)***
- ***Bioaccumulation***: *TBBPA's measured BCF in fish is < 500. With two hydroxyl groups, TBBPA is readily metabolized to more water soluble conjugates and rapidly eliminated. Studies confirm that TBBPA is not bioaccumulative and is rapidly eliminated.* ***(Raymond Dawson and David Sanders, p. 5 of November 2005 written comments)***
- ***Toxicity, Mammalian***: *TBBPA is not acutely toxic or irritating to the skin and eye. It does not elicit delayed skin hypersensitivity. It is not mutagenic. It is not a developmental toxicant and does not affect reproduction at doses up to 1000 mg/kg bw. It produces essentially no effects when administered repeatedly at doses up to 1000 mg/kg/d, and has been tested in several different species. It is rapidly metabolized and eliminated as glucuronide and sulfate conjugates, and is not expected to bioaccumulate.* ***(Raymond Dawson and David Sanders, p. 8 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that TBBPA meets the PBT criteria in WAC 173-333-320(2).

- Persistence: The BSEF commented that TBBPA should not be considered persistent because it has been shown to be degradable under more environmentally realistic conditions. Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Ecology agrees that the data provided by BSEF indicates that TBBPA can degrade to a certain extent under certain environmentally realistic conditions. However, the available studies included in the IUCLID data summary also indicate that persistence half-life values

[92] TBBPA is toxic to aquatic organisms. EPA (1998b) used an acute toxicity value (0.4 mg/L) to characterize the toxicity of TBBPA. This value was based on expert review. The OSPAR Commission fact sheet for TBBPA (OSPAR, 2004dd) reports an acute toxicity daphnia EC50 (0.96 mg/L), acute toxicity fish LC50 (0.54 mg/L), chronic toxicity daphnia NOEC (0.3 mg/L) and chronic toxicity fish NOEC (0.16 mg/L). The PBT Profiler calculates a chronic fish toxicity value of 0.003 mg/L. The printout includes a note stating that the predicted water solubility (0.001 mg/L) is less than the estimated ChV (0.003 mg/L) and, consequently, there may be no effect at saturation. However, the water solubility limit estimated by the PBT Profiler is significantly lower than the water solubility listed in the OSPAR fact sheet for TBBPA (4.16 mg/L = measured value at 25 degrees Celsius).

in soil range from 44 to 179 days and sediment half life values ranging from 20 to 84 days based on results from sediment/water microbial test systems and a study which examined the anaerobic biotransformation of TBBPA in estuarine sediments. While the reported ranges bracket the 60 day persistence criteria in the PBT rule, Ecology continues to believe that TBBPA meets the persistence criteria in WAC 173-333-320(2)(a). This conclusion is consistent with conclusions reached by EPA (1999)[93], Environment Canada (2005)[94] and the OSPAR Commission (2005)[95].

- Bioaccumulation: The BSEF commented that TBBPA is not bioaccumulative and is rapidly eliminated. Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Those materials summarize a range of BCF values in fish that generally fall below 500. The highest measured BCF value for fish is 1,234 is based to total 14C activity and should be considered to be a maximum value for that study since it may include accumulation of metabolites. However, Ecology continues to believe that TBBPA meets the bioaccumulation criteria in WAC 173-333-320(2)(b) given the chironomid BCF value and the supporting information provided by the predicted BCF values calculated using the BIOWIN and OASIS computer models.
- Mammalian Toxicity: The BSEF commented that TBBPA has not been shown to be toxic at doses up to 1000 mg/kg w. Ecology has reviewed the BSEF comments and the attached IUCLID data summary. Ecology considered this information when deciding whether to identify TBBPA as a PBT chemical and, in general, agrees with BSEF's conclusions. However, as summarized in the Technical Background Document, Ecology conclusions on the toxicity of TBBPA were based on ecological toxicity.

5.3. Metals of concern (WAC 173-333-315)

Issue 5-18: *Should Ecology include metals on the PBT List?*

Proposed Rule

When preparing the proposed rule, Ecology decided that it was appropriate to include metals on the PBT list if (1) the metal meets the PBT criteria and (2) Ecology determines that the metal is likely to be present in the environment in forms that are bioavailable and environmentally accessible. Ecology included three metals (cadmium, lead, and mercury) on the proposed PBT lists published in June 2005 and October 2005.

In the October 2005 proposed rule, Ecology also included the following provision which was designed to address concerns raised by the public during the initial public comment period:

> *(3)* ***Lead and cadmium****. Ecology will not develop a chemical action plan for lead and cadmium until the environmental protection agency concludes the process for preparing a metals assessment framework and ecology completes it's review of the bioavailability of these two substances.*

[93] EPA (1999) determined that TBBPA has persistence half-life values in soil of 44 to 179 days and persistence half-lives in water of 48-84 days.
[94] Environment Canada (2005) identified TBBPA as persistent based on a soil half life of 182 days (Ultimate degradation half life estimated using the BIOWIN model v. 4.01)
[95] OSPAR (2005) concluded that "....TBPPA is not considered to be readily biodegradable in the risk assessment, hence it meets the screening criteria for P or vP..." [a half-life >60 days in marine water (or >40 days in fresh water) or >180 days in marine sediment (or >120 days in freshwater sediment)].

Public Comments and Concerns

Several individuals and organizations provided comments on this issue. The range of viewpoints reflected in those comments is similar to the range of viewpoints expressed by members of the PBT Advisory Committee. In general, people providing comments on this issue fell into two main categories: (1) people supporting Ecology's proposal to include metals on the PBT list; and (2) people opposed to Ecology's proposal to include metals on the PBT list.

A number of individuals and organizations provided comments supporting Ecology's decision to include metals on the PBT list, but recommended that the Department not impose restrictions on developing chemical actions plans for lead and cadmium. For example:

> ***Do Not Delay CAPs on Lead and Cadmium.*** *We strongly oppose the decision to delay CAPs on lead and cadmium until after the U.S. Environmental Protection Agency (EPA) completes its Metals Assessment Framework. There is no scientifically based reason for waiting to take action on these metals. Scientific evidence makes clear that these metals persist in the environment, are bioavailable and build up in people's bodies, and are toxic in small amounts. Studies have shown lead is absorbed in the blood and bones and easily crosses the placenta to affect the developing fetus. The affect of lead on children is of particular concern because children absorb more lead, often as much as five to ten times more, than adults. Lead also is extremely toxic at low levels, causing learning disabilities, drops in IQ, and neurological problems.*
>
> *Ecology's scientists appear to agree that both lead and cadmium are bioavailable. The footnote accompanying WAC 173-333-310 (3) states that "Ecology has prepared a preliminary review and believes that these compounds [lead and cadmium] are bioavailable under some environmental conditions based on monitoring data showing elevated levels in human and fish tissues." Despite these findings, Ecology has decided to wait for the completion of an EPA process that has been underway for at least four years and does not have a scheduled date for completion. This means that state action on lead and cadmium has been delayed indefinitely. This is inexcusable given the severe health problems that lead causes for children. Thus, we urge you to delete WAC 173-333-310 (3)***.(Ivy Sager-Rosenthal, p. 3 of November 2005 Written Comments)***
>
> *This rule is a step in the right direction and I encourage the Department of Ecology to implement it expeditiously. However, I have one reservation, at least, about the current version of the rule, and it relates to the statement in the rule that Ecology will not develop a chemical action plan for lead and cadmium until the EPA concludes its process for preparing the metals assessment framework, and completes its review of the bioavailability of these two substances, and this proviso has already been mentioned. By the Department of Ecology's own admission, lead meets the criteria for persistent bioaccumulation, toxicity, and bioavailability. Moreover, recent economic studies indicate that childhood exposure to lead is an important economic issue in this state and elsewhere. In Washington State alone, the costs of lead exposure amount to over $1.5 billion a year in lost income and lost productivity. This estimate is supported by similar figures of the costs nationally, and now in four other states, including Massachusetts, New York, Ohio and most recently last week, Montana. Quite simply, childhood exposure to lead is costing our economy billions of dollars. Childhood exposure to lead is the single largest health cost resulting from environmental contaminants by at least or in order of magnitude – that's at least a factor of 10 – more then any other disease and disability attributed to environmental contaminants. Reducing or eliminating exposure to lead in this state would thus increase productivity and be good for our economy, aside from its public health benefits. Moreover, lead exposure affects some of the most vulnerable members of our society, children, ethnic minorities, and people living in poverty. Surely, these people deserve a healthy environment just as much as the rest of us. Reducing or eliminating exposure to lead is, therefore, not simply an economic issue or even a health issue. It's a question of social justice and social equity. Therefore, I strongly urge the Department to prepare a chemical action plan for lead absolutely as soon as possible, and not to delay waiting for a metals assessment framework that may*

take years to complete. In closing, I'd like to reiterate my support for the rule and urge Ecology to develop a chemical action plan for lead in the very near future. Thank you. And I have with me a table of the costs of lead poisoning, childhood poisoning, nationally, that I can leave as well. ***(Kate Davies, Testimony at November 9, 2005 Public Hearing)***

However, several individuals and organizations recommended that Ecology not apply the PBT criteria to metals. For example:

Metals should not be listed as PBTs. Ecology should follow the lead of EPA and wait until EPA's metal assessment is finalized. ***(Grant Nelson, p of July 2005 Written Comments)***

Preferably, metals should be removed from the PBT list all together until after the EPA concludes its metals assessment framework. AWB supports comments made by NAMC on this subject. If Ecology determines it is necessary to mention metals in the PBT rule, then AWB has suggested "footnote" language in our mark-up that could be used to explain the current status of metals, and why they are not being listed as PBTs at this time. We believe this footnote is consistent with the agencies 2002 letter to the NAMC, stating that the department will be consistent with EPA. ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

....NAMC urges Ecology to reject the current draft's attempt to extend the use of PBT criteria to the hazard assessment of metals. The Draft PBT Rule would identify a metal as a PBT chemical if it is found to meet general PBT criteria and if "ecology determines that [the metal] is likely to be present in forms that are bioavailable." ..... In any event, the mere fact that a metal is likely to be present to some extent in a "bioavailable" form does not mean that the application of Ecology's general PBT criteria to assess its hazard is appropriate as a matter of science or policy. ***(William Adams, p. of November 2005 Written Comments)***

The rationale used by these organizations to support their recommendations included three main arguments: (1) it is inappropriate (from a scientific and policy standpoint) to apply the PBT criteria to metals; (2) it is premature for Ecology to apply the PBT criteria to metals because of the ongoing EPA review; and (3) application of the PBT criteria to metals and listing cadmium, lead and mercury is at odds with past Ecology statements. The North American Metals Council discussed each of these points in their comments:

EPA's Science Advisory Board ("SAB") review of the agency's draft Metals Risk Assessment Framework is still ongoing. See http://www.epa.gov/sab/panels/mraf_rev_panel.htm. However, all indications are that the outcome will not support the use of PBT criteria to evaluate the hazard and risk of metals. For example, in its October 23, 2002 Review of the EPA Metals Action Plan, a key step in the process under which the draft Metals Risk Assessment Framework is being developed, the SAB Panel stated its conclusion "that persistence is a problematic scientific issue for assessing metals hazards and risks." Similarly, the SAB concluded that "[w]hile bioaccumulation data can be useful for site-specific assessment of risk, bioaccumulation metrics such as BCF/BAF measures can be problematic for assessing generic metals hazard ranking." Id. Ecology's Draft PBT Rule relies on the use of both persistence and BCF/BAF metrics -- and the SAB has specifically called each of these approaches into question as a matter of science when used for metals. Expert issue papers that EPA commissioned in 2004 to examine the scientific considerations relating to hazard assessment of metals echoed the scientific concerns identified by the SAB's 2002 report regarding attempts to apply PBT criteria to metals.5 Most recently, the SAB's draft report in its Review of EPA's Draft Framework for Inorganic Metals Risk Assessment (September 2005), available at http://www.epa.gov/sab/panels/mraf_rev_panel.htm, raised similar points, noting that "[t]he SAB agrees with the statement that BCF/BAFs do not apply for metals." Draft Report at 69 (paragraph 6.3.12.1).

Similar concerns have been expressed in other leading scientific reviews of this issue. For example, the recently published summary of the Society of Environmental Toxicology and Chemistry, Assessing the Hazard of Metals and Inorganic Metal Substances in Aquatic and Terrestrial Systems (2005),6

pointed out scientific issues with the use of both persistence and bioaccumulation for evaluating hazard for metals. With regard to persistence, the SETAC report notes that "[t]raditional degradation mechanisms used for organic substances to evaluate persistence (or the converse, biodegradation) of metals have been criticized as inappropriate." Id. at 6. As for bioaccumulation, the report goes even further:

Unlike organic substances, bioaccumulation potential of metals cannot be estimated using log octanol-water partition coefficients (Kow). Bioconcentration and bioaccumulation factors (BCFs and BAFs) are inversely related to exposure concentration and are not reliable predictors of chronic toxicity or food chain accumulation for most aquatic organisms and most metals. The inverse relationship between exposure concentration and BCF results in organisms from the cleanest environments (i.e., background) having the largest BCF or BAF values. This result is counterintuitive to the use of BCF and log Kow as originally derived for organic substances. [Id., citations omitted.] For the foregoing reasons, NAMC urges Ecology not to include metals on the Proposed PBT List. Instead, NAMC recommends that Ecology insert the following language as a footnote to its PBT list:

Application of the Bioaccumulation criterion (a BCF >1,000) to metals has been called into question on the ground that BAF/BCF values are not meaningful for metals; instead, the BAF/BCF varies inversely with the concentration of the metal in water. Accordingly, Ecology will not make a decision whether to include mercury, cadmium and lead or other metals on the PBT list until after the U.S. Environmental Protection Agency ("U.S. EPA") concludes the process of preparing a Metals Risk Assessment Framework. This Framework will address the utility of using PBT criteria for evaluating the potential hazards of metals. The decision not to list metals does not mean, however, that Ecology or other state agencies will refrain from taking actions necessary to reduce risks to human health and the environment posed by the release or presence of mercury, cadmium and lead....

However, we have an even more pressing concern -- viz., that the treatment of metals in the Draft PBT Rule is contrary to a commitment Ecology made in 2002, after being advised that U.S. EPA was conducting a comprehensive scientific review of the question whether PBT criteria can appropriately be applied to metals.

As Ecology stated in a letter dated March 5, 2002:

> *Ecology has learned that EPA will be working with its Science Advisory Board to develop comprehensive cross-agency guidance for assessing the hazards and risks of metals. Until this issue posed to EPA's Science Advisory Board is addressed, Ecology will include a footnote on any PBT Working List identifying that any metals on the working list are currently undergoing this review and that Ecology will revise any PBT working list so as to be consistent with EPA waste minimization treatment of metals.*[96]

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided to classify lead and cadmium as "metals of concern" pending completion of EPA's Inorganic Metals Assessment Framework. Under this approach, Ecology would consider lead and cadmium during the process for selecting chemicals for chemical action plan preparation under WAC 173-333-410 and, if appropriate, prepare chemical action plans for one of both of these metals. Under this revised approach, methylmercury is included on the PBT list.

The final PBT rule includes a new section (WAC 173-333-315 Metals of Concern) with the following rule language:

(1) ***Purpose****. The purpose of this section is to identify metals of concern to be addressed under this chapter. This category was established as an interim category pending completion of EPA's inorganic metals assessment framework process.*

[96] Letter from Tom Fitzsimmons, Director, Department of Ecology, to Greg Hanon, March 5, 2002 (copy attached).

(2) ***Metals of concern****. Ecology has identified the following metals of concern based on a determination that these metals pose threats to human health and the environment in Washington.*

Metals of Concern	***CAS Number***
Cadmium	7440-43-9
Lead	7439-92-1

(3) ***Actions****. Ecology may prepare chemical action plans for one or more metals of concern using the process defined in WAC 173-333-420.*

(4) ***Revising the metals of concern list.*** *Ecology will evaluate the relationship between the metals of concern list and PBT list in WAC 173-333-310 following the completion of the EPA's inorganic metals assessment framework process.*

Ecology's decision to identify lead and cadmium as "metals of concern" is based on several factors:

- Health Threats: Based on available scientific information, Ecology believes that lead and cadmium present threats to human health and the environment. For example, the Agency for Toxic Substances and Disease Registry (ATSDR) recently distributed an update to the *Toxicological Profile for Lead* for public review and comment. In that document, ATSDR stated:

  > *An enormous amount of information is available on the health effects of lead on human health. In fact, the toxic effects of lead have been known for centuries, but the discovery in the past few decades that levels of exposure resulting in relatively low levels of lead in blood (e.g., < 20 ug/dL) are associated with adverse effects in the developing organism is a matter of grave concern.....* ***(ATSDR, 2005, p. 21 of public review draft)***

- Status of EPA Inorganic Metals Assessment Framework: One of Ecology's overall rulemaking objectives is to promote decisions that are consistent with current scientific knowledge. As noted above, EPA is still working on an approach for assessing inorganic metals. As part of that approach, EPA is addressing several key questions surrounding the methods for characterizing the persistence and bioaccumulation potential for inorganic metals including (1) whether the methods used for organic compounds are appropriate methods for inorganic metals and (2) if not, what methods are available for characterizing persistence and bioaccumulation potential of inorganic metals. As of December 2005, EPA had not finalized that document. However, based on the draft report and reviews by EPA's Science Advisory Board, it appears that EPA and the Science Advisory Board have serious reservations about using methods that are based on the partitioning behavior of organic chemicals to evaluate the persistence and bioaccumulation potential of inorganic metals. Ecology believes that the final report will (at a minimum) identify additional factors that should be considered when characterizing the persistence and bioaccumulation of inorganic metals. Consequently, Ecology decided it was important to review the final EPA report prior to making a final decision on whether to include lead and cadmium on the PBT List.

- Approaches Currently Being Used by Other State, Federal and International Programs: One of Ecology's rulemaking goals is to develop a process that is consistent with other state, federal and international organizations. However, this goal is complicated by the fact that there are a wide range of programs with different goals, requirements, methods, etc. Consequently, Ecology believes it is impossible to be consistent with all state, federal and international programs if consistency is defined as being "identical". This is particularly true with respect to the metals issue where state, federal and international PBT programs

have taken varying approaches with respect to identifying or not identifying inorganic metals as PBT chemicals. Some programs have identified lead and/or cadmium as PBT chemicals (e.g. EPA Toxic Release Inventory[97], EPA Great Lakes Program, OSPAR, State of Wisconsin, etc.). Other PBT programs have elected to focus on organic chemicals (e.g. Stockholm Convention, UN-ECE POPs Protocol). Ecology's decision to identify lead and cadmium as "metals of concern" is modeled upon the approach used by EPA's Waste Minimization Program. Similar to Ecology, the EPA initially proposed to identify lead, cadmium and mercury as PBT chemicals for purposes of establishing priorities for actions to minimize the generation of hazardous waste. Like Ecology, EPA received numerous public comments urging them to refrain from identifying these three metals as PBT chemicals until EPA had completed the Inorganic Metals Assessment Framework. In response to those comments, EPA developed a final list of priority chemicals that included organic chemicals and chemical compounds (identified based on a review of information on persistence, bioaccumulation and toxicity) and metals and metal compounds (identified based on presence in RCRA waste streams and toxicity characteristics).

- Predictability: Ecology believes that removing these two chemicals from the PBT List (and potentially adding them to the PBT list in the future) would be inconsistent with our current knowledge and send mixed signals to the public about those threats.

After reviewing the comments on this issue, Ecology decided to include methylmercury on the PBT list [See Issue 5-13].

5.4. What criteria will Ecology use to identify and add chemicals or chemical groups to the PBT list? (WAC 173-333-320)

Issue 5-19: *What chemical characteristics should Ecology consider when evaluating health and environmental hazards?*

Proposed Rule

Ecology proposed to make decisions on whether to list individual chemicals or chemical groups based on an evaluation of persistence, bioaccumulation, toxicity and (for metals) bioavailability.

Public Comments and Concerns

Several organizations and individuals expressed general support for Ecology's June 2005 proposed approach for preparing the PBT list. For example:

> *Overall, the proposed Rule represents a sound approach to PBT chemicals management, and we would recommend that Ecology apply the processes proposed in the Rule, with the few key changes discussed here, for a minimum term of three to five years before making significant changes. ACC and CCC's recommendations will help strengthen the proposed approach.* ***(Michael Walls and Clifford Howlett, p. 1 of July 2005 written comments)***
>
> *... AWB supports Ecology's decision that a chemical must be persistent, bioaccumulative and toxic (P&B&T) in order to be listed. The department has also set specific criteria defining a certain level*

[97] Note: EPA's decision to list lead compounds as PBT chemicals for purposes of reporting for the Toxics Release Inventory prompted EPA to begin developing the inorganic metals assessment framework.

of persistence, bioaccumulation and toxicity that a chemical must exhibit in order to be listed in WAC 173-333-320... ***(Grant Nelson, p. 3 of July 2005 written comments)***.

However, several other organizations and individuals recommended that Ecology base decisions on whether to include a particular chemical on the PBT list on an evaluation of either bioaccumulation and toxicity (BT) or persistence and toxicity (PT). For example:

The first one is that the chemical list is much too narrow. It needs to be much broader. We think that the criteria should be PB or T, not PB and T. .... We also think that the criteria should be applied to a broader list of chemicals, not just those chemicals that have appeared on PBT lists elsewhere. ***(Ivy Sager-Rosenthal, Testimony at July 13 Public Hearing)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and continues to believe that it is appropriate to base decisions on an evaluation of a chemical's persistence, bioaccumulation and toxicity. The rationale for this approach includes the following:

- Legislative Direction: The Legislature directed Ecology to develop specific criteria for identifying persistent, bioaccumulative toxins. Ecology has interpreted this directive to mean that the Department needs to consider all three characteristics (P, B, and T) – not just two of the three (e.g. P and T or B and T).
- Previous Ecology Efforts: Previous Ecology efforts to identify PBT chemicals have been based on an evaluation of persistence, bioaccumulation and toxicity. These efforts include the *Proposed Strategy to Continually Reduce Persistent, Bioaccumulative Toxins (PBTs) in Washington State* (Ecology, 2000) and the PBT Working List (Ecology, 2002).
- Other State, Federal and International Approaches: The general framework being used by Ecology to identify PBT chemicals (consideration of persistence, bioaccumulation and toxicity) is similar to those being used by other programs and agencies. **(See Issue 2-5)**

Issue 5-20: ***What criteria should Ecology use to evaluate environmental persistence?***

Proposed Rule

Ecology proposed that a chemical or group of chemicals would be considered persistent enough to warrant adding to the PBT list if Ecology determines it meets the following criteria:

Persistence. *The chemical or chemical group can persist in the environment based on evidence that:*

i. The half-life of the chemical in water is greater than or equal to sixty (60) days;

ii. The half-life of the chemical in soil is greater than or equal to 60 days; or

iii. The half-life of the chemical in sediments is greater than or equal to 60 days.

Public Comments and Concerns

Several organizations supported Ecology's proposal to use a 60 day half-life for surface water, soil and sediments to evaluate a chemical's persistence. For example:

We fully support the persistence and bioaccumulation criteria. ***(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)***

Other organizations expressed the opinion that Ecology's proposed persistence criteria were overly conservative and inconsistent with internationally-recognized criteria. For example:

> *AWB believes that Ecology has proposed PBT criteria that are overly conservative and inconsistent with established internationally recognized criteria for PBTs.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

Several organizations and individuals urged Ecology to adopt the criteria used by international organizations (e.g. the Stockholm Convention on Persistent Organic Pollutants, the North American Commission for Environmental Cooperation's Sound Management of Chemicals (SMOC) Initiative) or recommended by the International Council of Chemical Associations. For example:

> *Note: The criteria proposed for persistence as those used by the U.S. EPA as screening criteria for use in the evaluation of new chemicals. These half-lives are highly conservative because they are used as screening tools in assessing new chemicals. These screening criteria are not appropriate for the identification of persistent organic pollutants. Criteria values recommended by ICCA which are indicative of environmental persistence are the half-life of the substance in water (180 days), sediment (360 days) and soil (360 days). (ICCA Briefing Note on Persistent Organic Pollutants, 9/17/98, www.chem.upen.ch/pops/iccappops.htm). Half-lives greater than 60 days, typically 120-180 days for soil and/or sediment, have also been recommended by various international protocols (UNECE 1966, UNEP 2001, EU Guidelines on the Performance of Risk Assessments).* ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

> *A.* ***The persistence criteria for soil and sediment should be consistent with other PBT programs****. Ecology has established a half-life of 60 days in water, soil and sediment as the single criteria by which persistence is established. The North American Commission for Environmental Cooperation's Sound Management of Chemicals (SMOC) Initiative,1 under which the U.S., Canadian and Mexican governments have agreed to address priority PBT issues and develop Regional Action Plans (RAPs) on select chemicals, adopts persistence criteria of six months (180 days) in soil or water, and 1 year in sediment. The Stockholm Convention on Persistent Organic Pollutants (POPs)2, a global legally-binding instrument to control emissions of the PBT-subset that are transported in air or water, adopts persistence criteria of 60 days in water, and 180 days in soil or sediment. ACC and CCC recommend that Ecology adopt persistence criteria for soil and sediment that are consistent with the North American regional program and internationally agreed programs. In the case of the Stockholm Convention, for example, the criteria were adopted after lengthy negotiations on the criteria that would assure the identification of potential chemicals of concern, and have a well-accepted scientific basis.* ***(Michael Walls and Clifford Howlett, p. 3-4 of November 2005 Written Comments)***

During the PBT Advisory Committee process, one committee member stated it was important to consider the program objectives of different programs when comparing the criteria used by those programs. She expressed the opinion that the criteria used by several international agencies were more appropriate than the Toxics Release Inventory criteria because Ecology's program objectives were more closely aligned with the international programs than the TRI objectives:

> ***Persistence:*** *My biggest concern is the apparent continuing disconnect between the objectives and the criteria. According to the goals and objectives section, this rule is not going to be used to collect information or to manage chemicals but to reduce and where feasible phase out or ban chemicals. The WMPT does indeed use 60 days for water, soil or sediment half-lives. The reference is to the TRI reporting revision in 64 FR 688. According to that citation "However, EPCRA section 313 is an information collection and dissemination program. EPA believes that persistence criteria consistent with the criteria applied to chemicals that are of global or regional (e.g., Europe and the Great Lakes) concern and that are targeted for ban, restriction, or phase-out are inappropriate for such a program. Chemicals that meet the persistence criteria used in the international agreements are the extremely persistent chemicals. Applying these strict criteria to EPCRA section 313 would result in a*

very narrow list of chemicals that would focus on only extremely persistent chemicals. This is inconsistent with one of the fundamental tenets of right-to know which is to provide the public with information on toxic chemicals that have the potential to cause adverse effects in their community. Further, persistence criteria of half-lifes of 6 months and 5 days have not been used to establish whether a chemical is a PBT chemical but rather whether a chemical should have restrictions on its uses. The Agency stated in the proposal its belief that half-life criteria of 2 months for water, sediment, and soil and 2 days for air will include a better representative sample of chemicals that persist in the environment. Therefore, EPA used a half-life criterion of 2 months for water, sediment, and soil and a half-life of 2 days for air for the purposes of determining under EPCRA section 313 whether a toxic chemical is persistent in the environment. Under these criteria, if a toxic chemical meets any one of the media-specific criteria, it is considered to be persistent." Since this rule is targeting chemicals for "ban, restriction, or phase-out" it would seem that the persistence criteria should be similar to those programs with similar regulatory goals referenced above rather than the TRI criteria. ***(Diana Graham, p. 1 of written comments on November 10, 2004 draft rule distributed for review by the PBT Advisory Committee)***

Ecology's Review and Response to Public Comments

The Legislature directed Ecology to consider a chemical's persistence when developing criteria for identifying chemicals to include on a PBT list. Executive Order 04-01 specifies that Ecology shall develop criteria for identifying persistent toxic chemicals. However, neither the budget proviso nor the Executive Order identified specific criteria for identifying "persistent" chemicals. Ecology has reviewed the comments on this issue and continues to believe that the proposed persistence criteria (surface water, soil and sediment half-lives greater than 60 days) are appropriate criteria for implementing these two directives. The rationale for Ecology's choice includes the following:

- Federal and International Criteria and Uses: Criteria used by other state, federal and international provide a way to judge the reasonableness of Ecology's proposed criteria. As shown in Table 3, a wide range of persistence criteria are being used by other state, federal and international organizations to identify PBT chemicals. As shown in Table 3, Ecology's criteria fall within the range of PBT criteria being used by other programs to evaluate the persistence of individual chemicals or chemical groups.

Table 3: Comparison of Persistence Criteria

Agreement/Organization	Persistence	Protection Goals & Risk Management
Washington Proposed PBT Rule	Half life in water, sediment, soil > 60 days	Reduce and phase-out uses, releases and exposures
United States/Canada		
EPA – Water Quality Criteria (1995)	Half life in water, sediment or biota > 56 days	Phase-out mixing zones for Bio-accumulative chemicals of concern
EPA – Toxics Release Inventory (EPA, 1999a)	Half life in water, sediment, soil > 2 months; air > 5 days	Reporting required for releases. (lower reporting thresholds for PBT chemicals)
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – New Chemicals Policy	Half life in water, sediment, soil > 2 months; air > 5 days	Testing and release control required.
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – Presumption of Ban	Half life in water, sediment, soil > 6 months	Commercialization denied unless testing justifies removing from "high risk concern" category.
Canada Toxics Substances	Half life in air (> 2 days); water or	Risk assessment; if toxic and P &B

Management Programme	soil (> 6 months); sediments (> 1 year)	and primarily anthropogenic – then virtual elimination
International		
Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)	Half life > 50 days	Continuously reducing discharges, emissions and losses with ultimate goal of achieving concentrations in marine environment close to zero for man-made synthetic substances
Stockholm Convention	Half life in water (> 2 months); soil (> 6 months); sediments (> 6 months).	Objective is to protect human health and the environment by reducing or eliminating releases.
European Union PBT Criteria	Half life in marine water (> 60 days); freshwater (> 40 days); marine sediments (> 180 days); freshwater sediments (> 120 days)	Source inventory and emission reduction w/o risk assessment.
European Union vPBT Criteria	Half life in marine or fresh water (> 60 days); or marine or freshwater sediments (> 180 days)	Phase out or ban (may authorize production as intermediate in closed system)

- Purpose and Intended Uses of Washington's PBT List: Ecology also compared the persistence criteria relative to the purposes and uses of different lists. In general, Ecology believes that the purposes and uses of the OSPAR criteria and list most closely resemble the purposes and uses in Washington's proposed rule in that OSPAR strategy includes a similar goal and phased-decision-making process. The OSPAR persistence criteria are similar to the persistence criteria developed by EPA for implementation of the Toxics Release Inventory (TRI) program and, consequently, Ecology proposed to use the somewhat higher TRI persistence criteria in order to promote consistency with the EPA regulations. Ecology acknowledges that the Washington PBT criteria are generally more health-protective (in that they will identify more chemicals as PBTs) that many of the criteria established by international organizations (e.g. Stockholm Convention on Persistent Organic Pollutants (UNEP, 2001)). For example, the UNEP has established more restrictive criteria (e.g., half life in water (> 2 months), soil (> 6 months) and sediments (> 6 months)) to identify chemicals whose uses will be eliminated or severely restricted than those used by Ecology to develop the PBT List. Ecology believes that the shorter half-live values are a more relevant measure for Washington because, the closer the source is to the receptor, the more likely it is that the released chemical will reach the receptor. Ecology also believes that these differences are appropriate given the multiple purposes of the PBT list and the phased decision-making process in the Washington rule.
- Scientific Foundation: The decision on the degree of persistence that is high enough to justify identifying a chemical as a PBT is primarily a policy choice. However, it is important that the measures used to characterize persistence have a firm scientific grounding. Media-specific half-life values are commonly-used measures of persistence that have a sound scientific foundation. Information on media-specific half life values is available for a wide range of chemicals in agency databases and the peer-reviewed scientific literature.

Issue 5-21: ***What criteria should Ecology use to evaluate bioaccumulation potential?***

Proposed Rule

Ecology proposed that a chemical or chemical group would be considered to have a bioaccumulation potential that is high enough to warrant including on the PBT list if Ecology determined:

> ***Bioaccumulation***. *The chemical or chemical group has a high potential to bioaccumulate based on evidence that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1000 or, in the absence of such data, that the log Kow is greater than five (5);*

Public Comments and Concerns

Several organizations supported Ecology's proposal to use a BAF/BCF greater than 1000 or a log Kow greater than 5 to evaluate a chemical's bioaccumulation potential. For example:

> *We fully support the persistence and bioaccumulation criteria.* ***(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)***

However, other organizations expressed the opinion that Ecology's proposed bioaccumulation criteria were overly conservative and inconsistent with internationally-recognized criteria. For example:

> *AWB believes that Ecology has proposed PBT criteria that are overly conservative and inconsistent with established internationally recognized criteria for PBTs.* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

Several organizations and individuals urged Ecology to adopt the bioaccumulation criteria used by several international agencies (BAF or BCF > 5000). For example:

> *B.* ***Ecology should adopt a bioaccumulation or bioconcentration factor of 5,000****. The rule establishes that a bioaccumulation (BAF) or bioconcentration factor (BCF) of 1,000 identifies a chemical as bioaccumulative. In the absence of such data, an octanol-water partition coefficient (LogKow) of 5 establishes the bioaccumulative characteristic under the rule. ACC and CCC believe the BAF and BCF criteria should more properly be 5,000.... Further, in both the North American SMOC initiative and the Stockholm Convention BCF and BAF values of 5,000 are used to identify chemicals as bioaccumulative. Again, there is a strong scientific basis for setting bioaccumulation values at 5,000. Setting BCF and BAF factors at the low level of 1,000 risks identifying substantially more chemicals as potential candidates for Washington's PBT program – particularly chemicals that do not pose a risk to human health or the environment. .)...****(Michael Walls and Clifford Howlett, p. 4 of November 2005 Written Comments)***
>
> *...Note: A 'HIGH' potential to bioconcentrate is typically defined as a BCF>5000. The primary criterium recommended by ICCA as an indicator of bioaccumulation potential is a fish bioconcentration factor (BCF)>5000. Secondary criteria for non-polar, hydrophobic organic chemicals only is 5<log Kow<7.5, molecular weight<700 and the substance is not metabolized. We recommend reconsideration of the value indicating bioaccumulation in the proposed rule in order to be consistent with criteria developed by other agencies****.)...(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

During the PBT Advisory Committee process, one committee member stated it was important to consider the program objectives of different programs when comparing the criteria used by those programs. She expressed the opinion that the criteria used by several international agencies were

more appropriate than the Toxics Release Inventory criteria because Ecology's program objectives were more closely aligned with the international programs than the TRI objectives:

> *My biggest concern is the apparent continuing disconnect between the objectives and the criteria. According to the goals and objectives section, this rule is not going to be used to collect information or to manage chemicals but to reduce and where feasible phase out or ban chemicals.* ***(Diana Graham, p. 1 of written comments on November 10, 2004 draft rule distributed for review by the PBT Advisory Committee)***

The Bromine Science and Environmental Forum (BSEF) also recommended that Ecology base its evaluations of bioaccumulation potential on BAF or BCF values in "fish" instead of "aquatic species". (Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments).

Several organizations and individuals provided comments on Ecology's proposal to use pKow values to evaluate bioaccumulation potential. The American Chemistry Council/Chlorine Chemistry Council (ACC/CCC) noted that the proposed criterion contains an internal inconsistency because a pKow of 5 corresponds to a BCF/BAF of 5000 (not 1000):

> *Ecology should be aware that a LogKow of 5 is very closely associated with BAFs and BCFs of 5,000, not 1,000. In the context of the negotiations on the Stockholm Convention, the International Council of Chemical Associations (ICCA), of which ACC is a member, reviewed the technical basis for concluding that LogKow of 5 is equivalent to a BCF of 5,000. A copy of that paper, developed for the Criteria Expert Group (CEG) that met during the Stockholm Convention negotiations, is contained in Appendix 2.).****(Michael Walls and Clifford Howlett, p. 4 November 2005 Written Comments)***

Several organizations and individuals stated that pKow values are not always appropriate for evaluating the potential for bioaccumulation and recommended that Ecology modify the rule to provide more guidance on this issue. For example:

> ***The use of pKow as a criterion for assessing bioaccumulative potential is not always appropriate.*** *The current version of the rule gives multiple metrics for judging a chemical to be bioaccumulative. Specifically, a chemical can be judged bioaccumulative based on a pKow >5, a BCF >1000, or a BAF >1000. Exceedence of any one of these criteria qualifies a chemical as bioaccumulative, meaning that the three metrics are given equal weight. There are a number of circumstances under which the use of a pKow alone to assess bioaccumulative potential is contrary to sound science. The reasons for this are:*
>
> – *Chemicals subject to metabolism (e.g., PAH) do not bioaccumulate to significant levels in higher trophic level organisms regardless of their pKows (e.g., Thomann and Komlos 1999).*
>
> – *For chemicals with pKows greater than approximately 7, bioaccumulative potential decreases with increasing pKow (e.g., Meylan et al. 1999).*
>
> *Thus the rule should give priority to BCFs and BAFs when determining if a chemical qualifies as bioaccumulative. This means that if the only two pieces of data available are an experimental BAF <1000 and a pKow >5, the experimental BAF should be considered definitive and the chemical should not be categorized as bioaccumulative. Further, chemicals with pKows greater than 8 (Meylan et al. 1999) simply should not be categorized as bioaccumulative unless there are experimental BCFs or BAFs exceeding the criterion.* ***(Jeff Louch, pp. 3-4 of November 2005 Written Comments)***

The Bromine Science and Environmental Forum (BSEF) provided similar comments on this issue and recommended that Ecology modify the provisions related to the use of pKow values by incorporating the concepts from screening methods developed by European scientists:

*....or, in the absence of such data, that the log-octanol water partition coefficient (log K_{ow}) is greater than five provided however, that a chemical may be considered as not bioaccumulative if it has a maximum molecular length of 43 Å, a maximum cross-sectional diameter of 17.4 Å plus a molecular weight of 700-1100, or a measured octanol solubility (mg/L) of < 0.002*MW [NOTE: This definition of 'not bioaccumulative' was developed as a screening tool by UK and Dutch ecotoxicologists.].*
(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on the proposed bioaccumulation criteria. Those comments fall into three main categories: (1) Use of a BAF/BCF value of 1000; (2) use and interpretation of log Kow values; (3) consideration of bioaccumulation in aquatic species other than fish. Ecology has organized its response around those three categories.

- **Use of a BAF/BCF value of 1000**: The Legislature directed Ecology to consider a chemical's bioaccumulation potential when developing criteria for identifying chemicals to include on a PBT list. Executive Order 04-01 specifies that Ecology shall develop criteria for identifying persistent toxic chemicals. However, neither the budget proviso nor the Executive Order identified specific criteria for identifying "bioaccumulative" chemicals. Ecology has reviewed the comments on this issue and continues to believe that the proposed bioaccumulation criterion (BAF/BCF > 1000) is an appropriate value for implementing these two directives. The rationale for Ecology's choice includes the following:
  - Federal and International Criteria and Uses: Criteria used by other state, federal and international provide a way to judge the reasonableness of Ecology's proposed criteria. As shown in Table 4, a wide range of bioaccumulation criteria are being used by other state, federal and international organizations to identify PBT chemicals. As shown in Table 4, Ecology's criteria fall within the range of PBT criteria being used by other programs to evaluate the bioaccumulation potential of individual chemicals or chemical groups.

Table 4: Comparison of Bioaccumulation Criteria

Agreement/Organization	Bioaccumulation	Protection Goals & Risk Management
Washington Proposed PBT Rule	BAF/BCF > 1000 or pKow > 5	Reduce and phase-out uses, releases and exposures
United States/Canada		
EPA – Water Quality Criteria (1995)	BAF > 1000	Phase-out mixing zones for Bio-accumulative chemicals of concern
EPA – Toxics Release Inventory (EPA, 1999a)	BAF/BCF > 1000	Reporting required for releases. (lower reporting thresholds for PBT chemicals)
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – New Chemicals Policy	BAF/BCF > 1000	Testing and release control required.
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – Presumption of Ban	BAF/BCF > 5000	Commercialization denied unless testing justifies removing from "high risk concern" category.
Canada Toxics Substances Management Programme	BAF/BCF > 5000	Risk assessment; if toxic and P &B and primarily anthropogenic – then virtual elimination
International		
Convention for the Protection of the Marine Environment of the	BCF > 500 or pKow > 4	Continuously reducing discharges, emissions and losses with ultimate

North-East Atlantic (OSPAR)		goal of achieving concentrations in marine environment close to zero for man-made synthetic substances
Stockholm Convention	BAF/BCF > 5000 or Log Kow > 4 or 5; evidence that substance with lower BCF /BAF is of concern or monitoring indicates concern.	Objective is to protect human health and the environment by reducing or eliminating releases.
European Union PBT Criteria	BCF > 2000	Source inventory and emission reduction w/o risk assessment.
European Union vPBT Criteria	BCF > 5000	Phase out or ban (may authorize production as intermediate in closed system)

- Purpose and Intended Uses of Washington's PBT List: Ecology also compared the bioaccumulation criteria relative to the purposes and uses of different lists. As noted above, Ecology believes that the purposes and uses of the OSPAR criteria and list most closely resemble the purposes and uses in Washington's proposed rule in that OSPAR strategy includes a similar goal and phased-decision-making process. The OSPAR bioaccumulation criteria are similar to the bioaccumulation criteria developed by EPA for implementation of the Toxics Release Inventory (TRI) program. Ecology proposed to use the somewhat higher TRI bioaccumulation criteria in order to promote consistency with EPA regulations. Ecology acknowledges that the Washington PBT criteria are generally more health-protective (in that they will identify more chemicals as PBTs) that many of the criteria established by international organizations (e.g. Stockholm Convention on Persistent Organic Pollutants (UNEP, 2001)). However, Ecology believes that these differences are appropriate given the multiple purposes of the PBT list and the phased decision-making process in the Washington rule.
- Scientific Foundation: BAF/BCF and log Kow values are commonly-used measures of bioaccumulation potential that have a sound scientific foundation. Information on media-specific half life values is available for a wide range of chemicals in agency databases and the peer-reviewed scientific literature. One commenter expressed the opinion that a BAF/BCF criterion of 5,000 has a "strong scientific basis". However, the commenter did not explain why they believe a BAF/BCF has a strong scientific basis or why (by inference) a lower value lacks a strong scientific basis. Ecology agrees with the Environmental Protection Agency that it is incorrect to frame the selection of the bioaccumulation criteria as a "scientific" decision:

  > *The degree of bioaccumulation that should be used as a criterion is not an absolute scientific determination. Rather it is a combination of science and policy. ... From a scientific perspective there is no one bioaccumulation criterion....As discussed above, there is no scientifically ``best'' bioaccumulation criterion. The degree of bioaccumulation is a continuum. A chemical does not bioaccumulate only if it has a BCF that is 5,000 or greater. A chemical that has a BCF of 1,000 will bioaccumulate, specifically the chemical will be present in an organism at a concentration that is 1,000 times greater than its concentration in the surrounding aqueous environment. Rather the choice of a value along the bioaccumulation spectrum is based to a large degree on how the criterion is to be used, e.g., to track chemicals entering a particular environment, or to restrict the use of chemicals, etc. As such the choice of a bioaccumulation criterion is a combination of science and policy. (EPA, 1999, p. 58682)*

- **Use and Interpretation of Log K_{ow} Values**: Ecology has reviewed the comments on this issue and agrees that log K_{ow} values are not a valid indicator of bioaccumulation for certain types of chemicals. Ecology will develop guidance on this issue as part of the process to update the PBT List. Ecology also decided not to include DIDP on the final PBT List because (1) Log K_{ow} values were used to justify including these chemicals on the PBT List and (2) the log K_{ow} values for DIDP fall outside the range of log K_{ow} values where such values provide an appropriate basis for predicting bioaccumulation.
- **Restricting Consideration of Bioaccumulation to Fish**: Ecology has reviewed the comment on this issue and continues to believe that it is appropriate to consider information on bioaccumulation in all aquatic species. Ecology is responsible for implementing a wide range of environmental statutes that are designed to reduce/prevent threats to aquatic species. However, Ecology agrees that if the toxicity determination is based on human health it is important to base the bioaccumulation determination on BAF/BCF values from fish and shellfish.

Issue 5-22: *Should Ecology consider information on bioaccumulation of chemicals associated with exposure to household dust?*

Proposed Rule

The proposed definition for bioaccumulation states that bioaccumulation may result from exposure to chemicals in air, water, soil, sediments and food. However, the proposed bioaccumulation criteria provide specific measures (BAF, BCF and Log K_{ow}) that are applicable to evaluating food chain exposure.

Public Comments and Concerns

Several organizations and individuals stated that dust exposure can be a significant source of exposure and urged Ecology to consider this pathway when evaluating the potential for bioaccumulation. For example:

> *Pioneers always get roughed up, and I know it. One of the things that concerns me is, this is a pioneering effort to reduce the total exposure of people by all routes, and infants are discriminated against in our society. We all know that house dust is one of the ways in which infants get exposed to many PBTs, and their exposure with the PBTs in house dust would not be tolerated on the job, at a Superfund site, or in the ambient air. These are very high risks. The average infant gets the equivalent of three cigarettes a day of benzo-a-pyrene), a very strong carcinogen, a PAH, and I was co-author of an article in 1998, the Scientific American, in which this information was published, and we think that we – we think that it's wonderful that you're doing this. We think that babies get a double whammy from PBTs in house dust and breast milk. At the same time, breast feeding is recommending, but we can reduce their exposure to house dusts by 90-99 percent in one week, just by getting the dust out of carpets, and I think that's the responsibility of the Department of Health, and we hope that you can work with them, and we think that two efforts should go side by side. I've been monitoring lead in house dust for 30 years, and after they took the lead out of gasoline, I observed a drop-off of about 50 percent in the concentration and lead in house dust over 12 years, and as has taken off since then, but half of the houses that are over – were built before 1940, have concentrations of lead in their house dust above 400 parts per million, and that's the cleanup level for a Superfund site. So, I encourage you to move forward with courage and conviction, and I thank you very much for the opportunity to testify.* ***(John Roberts, testimony at July 13th public hearing)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and agrees that household dust represents a significant exposure pathway. This is one of the pathways considered by Ecology and the Department of Health when developing the chemical action plan for polybrominated diphenyl ethers (PBDEs). Ecology also believes that log Kow values represent an indicator of a chemical's bioaccumulation potential via this pathway.

Issue 5-23: ***What criteria should Ecology use to evaluate human toxicity?***

Proposed Rule

The proposed PBT rule distributed for public review in June 2005 included the following toxicity criterion:

> ***Toxicity***. *The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:*
>
> *(i) The chemical or a chemical group is known to cause or can reasonably be anticipated to cause cancer or teratogenic effects, reproductive effects, neurological disorders or other acute or chronic health effects; or*
>
> *(ii) The chemical or chemical group is known to cause or can reasonably be anticipated to cause adverse effects in aquatic and terrestrial plants and animals.*

Ecology reviewed the comments on the June 2005 proposed rule and made several revisions prior to republishing the proposed rule. In the October 2005 proposed rule, Ecology proposed that a chemical or group of chemicals would be considered to be toxic to if Ecology determines it meets the following criteria:

> *(c)* ***Toxicity.*** *The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:*
>
> *i. The chemical or (chemical group) is a carcinogen, a developmental or reproductive toxicant or neurotoxicant;*
>
> *ii. The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day; or*
>
> *iii. The chemical (or chemical group) has a chronic no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L.*

Public Comments and Concerns

Several organizations and individuals expressed concerns about the lack of objective criteria for judging toxicity and recommended that Ecology incorporate quantitative criteria for evaluating toxicity similar to those provided for persistence and bioaccumulation. For example:

> *The proposed rule provides hard, quantitative criteria defining persistence and bioaccumulative potential, but nothing similar for defining a chemical as toxic. Thus, in essence, the determination of whether or not a chemical is "toxic" is left to Ecology's best professional judgment. ….The proposed rule should incorporate a system for scoring or ranking chemicals based on what is known about their toxicity so that these decisions will be made in a systematic and transparent manner [1,2].* ***(Jeff Louch, p. 4 of July 2005 written comments)***

As drafted, the decision basis for toxicity appears to be a "best professional judgment" determination by Ecology. There are objective science-based measures or indices defining these properties. Ecology should consider incorporating a system for scoring or ranking chemical based on what is known about their toxicity so that these decisions will be made in a systematic and transparent manner. ***(Ken Johnson, p. 2 of July 2005 written comments)***

Many of the organizations and individuals providing comments at the July 13th public hearing on urged Ecology to consider a broad range of health impacts when evaluating the toxicity of individual chemicals and chemical groups (e.g. Steve Gilbert, Ivy Sager-Rosenthal, Heather Trim)

Based on a review of the public comments on June 2005 proposed rule, Ecology modified the criteria for evaluating toxicity. The following paragraphs summarize (1) comments on the October 2005 proposed rule and (2) comments on the June 2005 proposed rule on provisions that were included in both proposals.

Several organizations expressed general support for the proposed toxicity criteria included in the October 2005 proposed PBT rule. For example:

In general, the October 19, 2005, revision is an improvement relative to the preceding (June 1, 2005) proposal. Specifically, the addition of language providing some guidelines for determining if a chemical is "toxic" and modification of the proposed PBT list to include individual chemicals only (as opposed to listing "chemical groups") are clear improvements. ... ***(Jeff Louch, p. 1 of November 2005 Written Comments)***

...We are also generally supportive of the toxicity criteria. *However, we are concerned that other toxic endpoints, such as endocrine disruption, will not be considered. ....* **(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)**

However, these and other organizations identified several issues and concerns with the proposed toxicity criteria. For example, several organizations expressed concerns that the phrase "...known to cause or can reasonably be anticipated to cause..." creates too high a burden for concluding that a chemical is "toxic". They recommended that Ecology provide additional guidance on how the Department would interpret and implement this phrase. For example:

The criteria "known to cause" or "anticipated to cause" is a very high standard. We suggest identifying the lists under other regulatory authorities or other sources which will be used to establish these effects.(***Steve Nicholas, p. 2 of July 2005 written comments)***

....From a practical standpoint, the pediatricians were interested in the PBT of the polychlorinated biphenyls in trying to work on a phase-out plan that the Legislature was considering in this past session, and one of the interesting things that I think could be helped in the chemical action plan, would be under the form of toxicity where it talks about the chemical group that's known to cause or can reasonably be anticipated to cause a variety of effects.....so the words can reasonably be anticipated, you almost wish it could be tightened up. Instead of saying, reasonably anticipated, would it need double blinded, randomized control trials? Would it need retrospective control data over a certain number of years? Would it need animal data? Would it need physical data? I think that would be helpful, because in practicality, we basically lost our argument over our inability to play the burden of proof issue. ***(Barry Loston, Testimony at July 13th Public Hearing)***

The Washington Toxics Coalition expressed concerns that the proposed language did not encompass the full range of potential health impacts and recommended that Ecology modify the proposed rule:

Include Other Chronic Health Effects in Toxicity Criteria. *We fully support the persistence and bioaccumulation criteria. We are also generally supportive of the toxicity criteria. However, we are*

concerned that other toxic endpoints, such as endocrine disruption, will not be considered. We suggest amending the language in WAC 173-333-320 (2) (c) (i) to read:

> ***(c) Toxicity.*** *The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on credible scientific information that:*
>
> > *(i) The chemical (or chemical group) is a carcinogen, a developmental or reproductive toxicant, or a neurotoxicant, or there is credible scientific evidence that the chemical has other chronic health effects, such as endocrine disruption;* ***(Ivy Sager-Rosenthal, p. of November 2005 Written Comments)***

The North American Metals Council (NMAC) recommended that Ecology revise the toxicity criterion by adding the phrase "at concentrations or exposure levels that may reasonably be anticipated to occur in the State of Washington" to the end of subparagraphs (i) and (ii).

> *The criterion for toxicity should be revised to add the following phrase to the end of subparagraphs (i) and (ii): "at concentrations or exposure levels that may reasonably be anticipated to occur in the State of Washington." (Explanation: The recommended language provides a nexus to a basis for concern by the state.)* ***(William Adams, p. 2 of Attachment of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

The proposed toxicity criteria include a combination of qualitative and quantitative criteria for evaluating human toxicity. Ecology believes the proposed criteria provide a reasonable basis for considering a chemical's toxicity when preparing the PBT List. This is based on the following factors:

- Consistency with Other State, Federal and International PBT Programs: The proposed toxicity criteria include a combination of qualitative and quantitative criteria for evaluating human toxicity. Ecology believes these criteria are consistent with approaches being used by other state, federal and international PBT programs (See Table 5). The use of these criteria produces a list of chemicals that have toxicity characteristics similar to those appearing on other federal and international PBT lists.

Table 5: Comparison of Toxicity Criteria

Agreement/Organization	Toxicity	Protection Goals & Risk Management
Washington Proposed PBT Rule	Carcinogen, developmental or reproductive toxicant or neurotoxicant; reference dose < 0.003 mg/kg/day; chronic NOEC < 0.1 mg/L; acute NOEC < 1.0 mg/L	Reduce and phase-out uses, releases and exposures
United States/Canada		
EPA – Water Quality Criteria (1995)	Potential to cause adverse effects.	Phase-out mixing zones for Bio-accumulative chemicals of concern
EPA – Toxics Release Inventory (EPA, 1999a)	Potential to cause cancer, non-cancer and ecological effects.	Reporting required for releases. (lower reporting thresholds for PBT chemicals)
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – New Chemicals Policy	Potential to cause adverse effects	Testing and release control required.
EPA – Office of Pollution Prevention and Toxics (EPA, 1999b) – Presumption of Ban	Potential to cause adverse effects.	Commercialization denied unless testing justifies removing from "high risk concern" category.
Canada Toxics Substances	Acute L(E)C50=< 1mg/L; chronic	Risk assessment; if toxic and P &B

Management Programme	NOEC =< 0.1 mg/L; or determined by Health Canada.	and primarily anthropogenic – then virtual elimination
International		
Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)	Carcinogen, mutagen or reproductive toxicant (CMR) or chronic toxicity (mammalian T) or acute L(E)C50=< 1mg/L or long-term NOEC =< 0.1 mg/L.	Continuously reducing discharges, emissions and losses with ultimate goal of achieving concentrations in marine environment close to zero for man-made synthetic substances
Stockholm Convention	Chronic toxicity or ecotoxicity data indicate a potential for damage human health or the environment due to long-range transport.	Objective is to protect human health and the environment by reducing or eliminating releases.
European Union PBT Criteria	Chronic NOEC < 0.01 mg/L or carcinogen, mutagen or repro-ductive toxicant (CMR) category 1 or 2 or endocrine disrupting effects.	Source inventory and emission reduction w/o risk assessment.

- Consistency with Current Ecology Programs: Several Ecology programs currently base their evaluations of toxicity on determinations by EPA, the National Toxicology Program and the International Agency for Research on Cancer (IARC) when establishing cleanup standards, water quality standards, dangerous waste requirements and air pollution requirements for new and existing sources.
- Scientific Basis: The toxicity criteria and relevant definitions are consistent with current scientific knowledge and rely upon scientific reviews and evaluations performed by toxicological experts within the Environmental Protection Agency, the National Toxicology Program, the International Agency for Research on Cancer, etc.
- Managing Variability and Uncertainty: Ecology believes that combination of qualitative and quantitative criteria take into account the variability in susceptibilities to chemical exposure and the uncertainties associated with extrapolating from high-to-low levels of exposure. The hazard determinations, toxicity values and guidelines used by the EPA, NTP and IARC to address variability and uncertainty are consistent with recommendations from expert committees (e.g., NRC, 1994, NAS, 2000a, b, NAS 2001).
- Predictability: The proposed toxicity criteria provide clear criteria for evaluating human toxicity which is in marked contrast to some of the other approaches for identifying PBT chemicals (see Table 5) that are based on more general criteria (e.g., potential to increase the risk of cancer).
- Flexibility: The proposed toxicity criteria provide the flexibility to consider new scientific information on individual chemicals as it becomes available.

Ecology has reviewed the comments on this issue and decided not to revise the proposed rule language. However, Ecology believes that those comments raised several important issues which are discussed in the following paragraphs.

- Phrase "...known to cause or can reasonably be anticipated to cause...": Ecology reviewed the concerns regarding the phrase "...known to cause or can reasonably be anticipated to cause...". In general, Ecology disagrees with the interpretation that this phrase establishes a standard of proof that is too high and at odds with a precautionary approach. As background, the phrase is based on similar language that appears in Section 313 (d)(2)(B) of the

Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA)[98]. EPA guidance materials and the relevant legislative history recognize that conclusive scientific or medical evidence does not exist for many toxic chemicals and that action to prevent threats to human health and the environment will be based on information that scientists would universally consider to be conclusive. For example, EPA (and other agencies) have concluded that many types of chemicals "can reasonably be anticipated to cause [cancer] in humans" based on the results from animal bioassays.

- Consideration of Other Health Endpoints: Ecology reviewed the recommendation that the Department revise the toxicity criterion to allow consideration of other toxicity endpoints. Ecology believes the proposed rule provides the flexibility to consider other toxicity and decided not to modify the proposed rule language. Specifically, subparagraph (ii) provides the flexibility to consider a wide range of health endpoints ("The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day")

- Consideration of Concentrations and Exposures in Washington: Ecology reviewed the recommendation that the Department revise the toxicity criterion by adding the phrase "at concentrations or exposure levels that may reasonably be anticipated to occur in the State of Washington" to the end of subparagraphs (i) and (ii). Based on that review, Ecology decided not to make the recommended changes. As discussed under Issue 5-3, the PBT rule establishes a decision-making process where (1) decisions to include a chemical on the PBT List are based on an evaluation of the chemicals hazard (e.g. persistence, bioaccumulation and toxicity) and (2) information on environmental concentrations are considered when establishing priorities and preparing chemical action plans. This approach is similar to the approach used by EPA when identifying PBT chemicals for purposes of reporting under the Toxics Release Inventory.[99]

- Rationale for Reference Dose Criterion: The Bromine Science and Environmental Forum (BSEF) requested that Ecology describe the rationale/basis for using a reference dose value of less than 0.003 mg/kg/day or less to evaluate toxicity. As background, EPA used a reference dose value of 0.0006 mg/kg/day to identify "highly" toxic chemicals under the Waste Minimization Prioritization Tool (WMPT). EPA calculated this benchmark value by arraying the EPA reference dose values available in 1994 from the highest value (least toxic)

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[98] EPCRA section 313 provides toxicity criteria at section 313(d)(2) to be used in adding a chemical to or deleting a chemical from the EPCRA section 313 list of toxic chemicals. These criteria are:

(A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

(B) The chemical is known to cause or can reasonably be anticipated to cause in humans- (i) cancer or teratogenic effects, or(ii) serious or irreversible-(I) reproductive dysfunctions,(II) neurological disorders,(III) heritable genetic mutations, or(IV) other chronic health effects.

(C) The chemical is known to cause or can reasonably be anticipated to cause, because of- (i) its toxicity,(ii) its toxicity and persistence in the environment, or(iii) its toxicity and tendency to bioaccumulate in the environment, a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

[99] The Agency believes that exposure considerations are not appropriate in making determinations (1) under section 313(d)(2)(B)for chemicals that exhibit moderately high to high human toxicity. (These terms, which do not directly correlate to the numerical screening values reflected in the Draft Hazard Assessment Guidelines, are defined in unit II.) based on a hazard assessment, and (2) under section 313(d)(2)(C) for chemicals that are highly ecotoxic or induce well-established adverse environmental effects (at 59 FR 61441).

to the lowest value (most toxic). EPA selected a value corresponding to the 75th percentile of this range to define "high" toxicity. Ecology repeated that calculation using the chronic reference dose values included in EPA's Integrated Risk Information System database in early 2004. A reference dose value of 0.003 mg/kg/day falls near the 75th percentile of the 2004 values. Ecology used this value in the proposed PBT rule because:

- Consistency With WMPT Methodology: Ecology used the same methodology employed by EPA to identify the benchmark value used to identify "highly" toxic chemicals (toxicity score = 3). Based on review of written comments submitted on the WMPT methodology, there appeared to be general support for this methodology and the resulting benchmark values.
- Scientific Foundation: The updated values are based on more current scientific information since it was calculated using the reference doses in the IRIS database in 2004 (as opposed to 1994 values that formed the basis for the WMPT value).
- Consistency with Regional Dredge Management Programs: The Dredged Material Management Program currently uses a reference dose of 0.003 mg/kg/day as part of their approach for evaluating bioaccumulation hazards associated with contaminated sediments.

Issue 5-24: What criteria should Ecology use to evaluate ecological toxicity?

Proposed Rule

The proposed PBT rule distributed for public review in June 2005 included the following toxicity criterion:

> ***Toxicity***. *The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:*
>
> *(i) The chemical or a chemical group is known to cause or can reasonably be anticipated to cause cancer or teratogenic effects, reproductive effects, neurological disorders or other acute or chronic health effects; or*
>
> *(ii) The chemical or chemical group is known to cause or can reasonably be anticipated to cause adverse effects in aquatic and terrestrial plants and animals.*

Ecology reviewed the comments on the June 2005 proposed rule and made several revisions prior to republishing the proposed rule. In the October 2005 proposed rule, Ecology proposed that a chemical or group of chemicals would be considered to be toxic to if Ecology determines it meets the following criteria:

Ecology proposed that a chemical or group of chemicals would be considered to be toxic if Ecology determines it meets the following criteria:

> *(c)* ***Toxicity.*** *The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:*
>
> *i. The chemical or a chemical group is a carcinogen, a developmental or reproductive toxicant or neurotoxicant;*
>
> *ii. The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day; or*

iii. The chemical (or chemical group) has a chronic no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L.

Public Comments and Concerns

Several organizations provided comments on the toxicity that are equally applicable to evaluating human and ecological toxicity. Those comments are addressed under Issue 5-23.

Ecology also received several comments on the criteria and procedures for evaluating ecological toxicity. The Bromine Science and Environmental Forum recommended that definition of toxicity be restricted to aquatic toxicity:

> *(c)* ***Toxicity.*** *[As noted previously, the definition of toxicity when referring to PBT chemicals is restricted to aquatic toxicity.] The chemical has the potential to be toxic to humans or wildlife based on credible scientific information that:...(****Raymond Dawson and David Sanders, Attachment A of November 2005 Written Comments)***

The Bromine Science and Environmental Forum also recommended that Ecology use (1) a chronic fish lowest observable effect concentration (LOEC) that is less than 0.1 mg/L as a measure of toxicity only in situations where the LOEC is below the limits of saturation for the particular chemical and this concentration is expected to be achieved in the environment for greater than or equal to 20 days/year and (2) an acute lethal/effect concentration (LC50 or EC50) less than 1.0 mg/L only in situations where the environmental occurrence is expected to be less than 20 days/year:

> *(iii) The chemical (or chemical group) has a chronic fish low observed effect concentration (LOEC) or equivalent toxicity measure that is less than 0.1 mg/L (unless the water solubility is below this value in which case there is only concern for substances which are toxic below the limits of their saturation) and this concentration is expected to be achieved in the environment for >= 20 days/yr or in the event of environmental occurrence less than 20 days/yr - an acute lethal /effect concentration (LC50 or EC50) or equivalent toxicity measure that is less than 1.0 mg/L. [NOTE: these definitions of toxic are consistent with EPA's New Chemicals policy.]* ***(Raymond Dawson and David Sanders, Attachment A of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the proposed rule language. Ecology's response to individual comments is summarized in the following paragraphs.

- Restricting Toxicity Criterion to Aquatic Toxicity: Ecology reviewed the issues surrounding the recommendation to limit the definition of toxicity of PBT chemicals to aquatic toxicity. Based on that review, Ecology decided not to make the suggested changes. Ecology's decision on this issue is based on the following considerations:
  - Statutory Directives and PBT Executive Order: Ecology is responsible for implementing a wide range of environmental statutes that are designed to protect human health and the environment.
  - Scientific Defensibility: Ecology believes that limiting the evaluation of toxicity to aquatic toxicity is inconsistent with available scientific information demonstrating that various PBT chemicals pose risks for humans and terrestrial plants and animals.

- Consistency with Definitions Used by Other Ecology Programs: Several Ecology programs have developed procedures for evaluating toxicity that include consideration of aquatic and terrestrial plants and wildlife.
- Consistency with Other Federal and International Programs: Other state, federal and international PBT programs consider the potential for toxic effects in humans and aquatic and terrestrial plants and wildlife when evaluating toxicity.

- Use of Lowest Observable Effect Concentration: Ecology reviewed the issues surrounding the recommendation that (1) Ecology use a chronic fish lowest observable effect concentration (LOEC) that is less than 0.1 mg/L as a measure of toxicity and (2) constrain the use of this toxicity measure to situations where the LOEC is below the limits of saturation for the particular chemical and this concentration is expected to be achieved in the environment for greater than or equal to 20 days/year. Based on that review, Ecology decided not to make the suggested changes because Ecology's proposed criterion is consistent with criteria being used by other federal and international agencies (See Table 5) and takes into account the uncertainties in characterizing the relationships between exposure to toxic chemical and potential ecological impacts and inter-species and individual variability in susceptibility.
- Use of Acute Lethal/Effect Concentrations: Ecology reviewed the issues surrounding the recommendation that Ecology use an acute lethal/effect concentration (LC50 or EC50) less than 1.0 mg/L as a measure of toxicity only in situations where the environmental occurrence is expected to be less than 20 days/year. Based on that review, Ecology decided not to make the suggested changes. .....

Issue 5-25: ***How will Ecology determine whether a metal is likely to be present in bioavailable forms?***

Proposed Rule

In addition to persistence, bioaccumulation and toxicity, Ecology proposed to consider the bioavailability of metals when evaluating whether to include metals on the PBT list. The proposed rule included the following criterion that would be applicable to metals:

> *(d)* ***Additional criteria applicable to metals:*** *The chemical or chemical group is a metal and Ecology determines that it is likely to be present in forms that are bioavailable.*

Public Comments and Concerns

As discussed under Issue 5-18, several organizations urged Ecology not to apply the PBT criteria to the hazard assessment of metals. Many of these organizations also raised questions on how Ecology intends to evaluate whether a metal is likely to be present in a bioavailable form. For example:

> *The Draft PBT Rule would identify a metal as a PBT chemical if it is found to meet general PBT criteria and if "ecology determines that [the metal] is likely to be present in forms that are bioavailable." Draft PBT Rule, Section 173-333-320 (2)(d). Indeed, two metals, cadmium and lead, are included in the PBT list in Section 173-333-310 (2) of the Draft Rule, with a parenthetical notation indicating that the metal has been listed "pending review of bioavailability." While it is not entirely clear, we presume this means that the two metals will remain on the list if Ecology determines they are "likely to be present in forms that are bioavailable." Exactly how Ecology would make that determination is not explained, and the term "bioavailability" is not defined, so one*

can only guess at how the Draft Rule would actually be applied to metals. That is a serious concern. In any event, the mere fact that a metal is likely to be present to some extent in a "bioavailable" form does not mean that the application of Ecology's general PBT criteria to assess its hazard is appropriate as a matter of science or policy. ***(William Adams, pp. 1-3 of July 2005 Written Comments)***

One individual expressed concerns that the proposed rule provided no place for expert judgment on the question of bioavailability when considering persistence:

The issue is particularly important with soil and sediment because of actual bioavailability. The methods used to determine half-lives in these media are those required to extract all of the residue from the soil or sediment. The procedures necessary are determined using radioactive material and may include such things as boiling with nitric acid. This rule has no place for expert judgment as to whether chemicals are actually available to target organisms. ***(Diana Graham, p. 1 of written comments on November 10, 2004 draft rule distributed for review by the PBT Advisory Committee)***

The Washington Toxics Coalition recommended that Ecology delete the proposed language and replace it with the following provision:

If no criteria are available on bioaccumulation, then there is evidence that the chemical accumulates in animals or humans. ***(Ivy Sager-Rosenthal, p. of July 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that this subsection does not provide a clear process and/or criteria for evaluating bioavailability. Ecology will consider this issue when the Department considers the broader issue of identifying metals as PBT chemicals and the characteristics, methods and information needed to support such determinations. That review will occur after EPA completes the Inorganic Metals Assessment Framework and be integrated with Ecology's initial consideration of revisions to the PBT List.

Ecology does not have immediate plans to review the metals issue. In the interim (between finalizing the PBT rule and any future process to revise the PBT List), Ecology will consider this issue when (1) developing the relative ranking framework for prioritizing chemicals for CAP preparation and (2) developing CAPs for lead or cadmium (if one or both of these metals of concern are selected for CAP preparation).

With respect to the recommendation provided by the Washington Toxics Coalition, Ecology's proposed language reflects a decision that the Department would review the environmental behavior of candidate metals (including the influence of such factors as pH, redox conditions, dissolved solids, soil types, etc.) and whether the particular metal is likely to exist in bioavailable forms under conditions present in Washington environments. Ecology agrees that the issues of bioaccumulation and bioavailability are interconnected (some level of bioavailability is a prerequisite for bioaccumulation). However, Ecology believes that the suggested language essentially duplicates the bioaccumulation criteria without factoring in considerations of environmental behavior and Washington environmental conditions.

Issue 5-26: How should Ecology take into account information on degradation products?

Proposed Rule

Ecology proposed to consider chemical degradation products when making decisions on whether to include a chemical or chemical on the PBT List. The proposed rule included the following language:

> *(3)* ***Degradation products.*** *Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will be considered in the development of a CAP for those derivative chemicals.(WAC 173-333-320(3))*

Public Comments and Concerns

Several organizations urged Ecology to consider potential degradation products when developing the PBT List and preparing chemical action plans. For example:

> *Both the chemical and its degradation products shall be considered when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If the chemical or chemical group results from the degradation or transformation of a parent substance in the environment, the parent substance is also considered a PBT.* ***(Laurie Valeriano, Testimony at July 13th Public Hearing)***

Several organizations expressed concerns that the proposed rule does not provide objective criteria for determining what constitutes a level of degradation that should be considered cause for concern. They recommended that the Department establish clear criteria for identifying and evaluating degradation, including the level of scientific evidence required to show degradation. For example:

> *Note: Section 173-333-110 states that the purpose of the chapter is to establish the criteria that the Department of Ecology will use to identify persistent bioaccumulative toxicants that pose human health or environmental threats in the State of Washington. The rule creates very objective, measurable values in Section 173-333-320 for persistence, bioaccumulation and toxicity, consistent with what BSEF believes is the intent of the rule: To create a clear standard for designating chemicals as PBTs so that the state can focus its resources on areas of true scientific concern.*
>
> *Subsection 3 of 173-333-320 (degradation) is inconsistent with this purpose because there is no criteria established for objectively determining what constitutes a level of degradation that should be considered cause for concern. Just as all substances can have toxic effects at a high enough concentration, all substances (save elements) will degrade – to some extent and under some circumstances and in some time periods – into other chemical configurations. If degradation is to be considered, the Department of Ecology should establish clear criteria for identifying and evaluating degradation, including the level of scientific evidence required to show degradation. The Department of Ecology should not be using a proposed rule to arbitrarily add chemicals to the PBT list and thereby circumvent the criteria set forth in Subsection (2), paragraphs a, b, and c of the same section.* ***(Raymond Dawson and David Sanders, Attachment to November 2005 Written Comments)***

Several organizations expressed concerns that subsection (3) did not clearly state whether parent chemicals will be included on the PBT list and/or addressed in specific chemical action plans. They recommended that Ecology not list parent chemicals on the PBT list if they do not meet PBT criteria and address sources/releases/uses of the parent chemicals when preparing chemical action plans for degradation products that do meet the PBT criteria. For example:

Another section that has become less clear in the current version is 320(3). This section deals with degradates that are PBTs and how the parent compound should be treated. I believe that it was agreed by all that if a chemical was not a PBT, but degraded into something that was a PBT, the degradate would be listed, but the parent would not – because it is not a PBT. The parent would however be considered for regulation in the Chemical Action Plan. The current language in this section is unclear and I would like to suggest the following alternative language:

> *320(3) Degradation products. Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will not be listed as a PBT but will be considered in the development of a CAPs for those ~~derivative chemicals~~ degradation products that do meet the criteria in this section for a PBT and are on the PBT list.* ***(Diana Graham, pp. 1-2 of November 2005 Written Comments)***

The degradation concept included in this rule {173-3330320 (3) }establishes a process by which non-PBT chemicals may be evaluated in context of a chemical action plan if a direct degredation association can be shown between the chemicals. Ecology's implementation of this provision violates the basic principle underlying this section that a substance be designated as a PBT based on its own chemical P-B & T characteristics; not that of its degradation products. We suggest that the application of this rule section be re-evaluated where it was applied to selecting chemicals for the PBT listing. Only those materials that are themselves PBTs should be listed. During the PBT action plan process would issues relating to the parent material be addressed. The designation of deca-bde as a PBT due to its alleged degradation into possibly more toxic octa-bde and penta-bde formulations is a case in point. The Deca-bde has no toxic properties that would justify its listing as a PBT. This is borne out by extensive research conducted world wide. Special note is made of the decision by the European Union to not designate Deca-bde as a PBT under its RoHs directive. This was subsequent to ten years of studies on the toxicity of Deca-bde and a supplemental study of the possible concerns over degradation products. The result of these ten years of studies was that risk to public health and the environment were negligible. This EU result illustrates the fallacy of attempting to "reverse engineer" a PBT designation to a parent chemical. The failure of the EU's scientific review of degradation products to identify Deca-bde as a PBT cast doubt on any proposed Ecology listing of any product due to degradation. Deca-bde and all other materials listed due to use of the degradation concept in the draft PBT rule should be removed subject to substantial, verifiable and impartial research. ***(Kirk Thomson, p. of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to modify the language in WAC 173-333-320(3) to address the issue of whether Ecology will include parent chemicals on the PBT list in situations where (1) the parent chemical does not meet the PBT criteria and (2) the chemicals formed during the degradation and breakdown of the parent chemical (derivative chemicals) meet the PBT criteria. Specifically, members of the public appeared to read the proposed language in one of two ways - Ecology will always list parent chemicals or Ecology will never list parent chemicals. However, Ecology was trying to craft rule language that acknowledged this is not "a one size fits all issue" and that determinations would be made on a chemical-by-chemical basis during each rulemaking process. The revised language is designed to capture that approach:

> *Ecology will consider both the parent chemical and its degradation products when making decisions on whether a chemical meets the PBT criteria in subsection (2) . If a parent chemical does not meet the PBT criteria, but degrades into chemicals that do meet the PBT criteria, Ecology decide to include both the parent chemical and the derivative chemicals on the PBT list. Alternately, Ecology*

may decide not to include the parent chemical on the PBT list, but consider it during the development of a chemical action plan for the derivative chemicals.

Ecology believes the revised language is consistent with approaches used by other agencies and programs. For example, the Guidance Manual for Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List *published by Environment Canada (2003) establishes a similar approach for consideration of degradation products:*

> *The degradation products or the potential for degradation products will not be assessed systematically for organic substances. However, where information is available, it will be considered on a case-by-case basis. When a substance or class of substances (e.g. peroxides) is well known to undergo abiotic or biotic degradation leading to more persistent or bioaccumulative and inherently toxic products, the products may be categorized on the same basis as the parent compound. The results of the categorization for a product or products of degradation may be used to categorize the parent compound.* ***(Environment Canada, 2003, p. 35)***

Ecology agrees with the comment that including objective criteria for judging degradation (similar to persistence, bioaccumulation and toxicity) would result in a more transparent and predictable process. However, Ecology has decided not to develop such criteria as part of this rulemaking process because:

- Degradation products is a significant issue (with respect to including a chemical on the PBT List) for only one chemical (decabromodiphenyl ether);
- Issues associated with the degradation of decabromodiphenyl ether are being addressed in a an ongoing Ecology process involving the evaluation of options for reducing and phasing out uses of penta-, octa- and decabromodiphenyl ether. As discussed under Issue 5-7, Ecology has concluded that available scientific information indicates that DecaBDE undergoes degradation when released into the environment and will continue to be a source of lower-brominated congeners for some time into the future;
- The PBT rule is a "procedural rule" that establishes a process for revising the PBT rule in the future. Consequently, if Ecology proposes to list a particular chemical on the PBT list because of the chemicals' degradation products, that proposal will be distributed for public review and comment.

Issue 5-27: ***Should Ecology use a weight of evidence approach when making decisions on whether to include a chemical on the PBT List?***

Proposed Rule

The proposed PBT rules published in June and October 2005 did not include language that explicitly addressed this issue.

Public Comments and Concerns

Several organizations also recommended that Ecology use a "weight of evidence" approach when evaluating whether a chemical does or does not meet the PBT criteria. For example:

> *The values selected by Ecology to justify listing NP as either persistent or bioaccumulative are from inadequate quality data sources, especially in light of the fact that there are numerous other high quality data available from which to conduct a weight-of-evidence assessment. Ecology should conduct assessments that are consistent with those generally accepted in the scientific community; utilizing a preferred hierarchy of data sources where the weight of evidence is preferred over single*

measured values, which are in turn preferred over estimated, calculated or modeled values. ***(Barbara Losey, p. 3 of Attachment to November 2005 written comments)***

Application of the PBT criteria should have two distinct levels of analysis: (a) whether the numeric criteria are satisfied; and (b) whether the weight of the scientific evidence is adequate. *As currently written, the proposed rules specify numeric criteria for P, B, or T, but do not contain any provision for dealing with the weight of the scientific evidence. Under the rules as proposed, a chemical could be listed as a PBT based solely on one scientific study, even if that study produced findings that differed from the majority of findings regarding that chemical. Also, rules could lead to a result whereby a chemical could be listed solely based on modeling.*

As a consequence, Ecology rules would result in a bias against predominant scientific findings and towards listing chemicals that, in fact, might not truly be PBTs. This will lead to an overly broad list and negative public perception that may be misdirected.

NWPPA recognizes that it may be difficult for Ecology to exclude scientific studies that depart from the predominant science for a particular chemical. However, Ecology should evaluate the reasons that a particular study departs. There could be many reasons. The scientist may have been investigating another issue and offered speculation regarding a particular chemical. The scientist might have extrapolated from existing valid data sets, but extrapolated into a range outside of the data set. These and other scenarios are surprisingly common, but are in effect, opinions.

As a strongly recommended solution, NCASI comments support an approach whereby the rules would specify that Ecology consider <u>all</u> available credible science, but will evaluate a chemical against the numeric criteria base on a mean or median; if that is not practicable, then Ecology will look at the weight of scientific information. Actual experimental data would be given greater weight than data derived from modeling efforts. Furthermore, if possible, in its technical memorandum supporting listing decisions, Ecology should include an analysis of the reasons a particular study departs from the predominant findings.

NWPPA believes this would be the least burdensome approach to Ecology, and helps avert debate over whether a particular study should be excluded. ***(Llewellyn Matthews, pp. 2-3 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that all meaningful scientific information should be considered when making determinations on whether to include a chemical on the PBT list and that some type of "weight of evidence approach" is useful for making decisions on whether to include a particular chemical on the PBT List. Environmental agencies typically use "weight of evidence" approaches when evaluating hazardous substances. For example:

- EPA's 2005 Guidelines for Carcinogen Risk Assessment "...emphasize the importance of weighing all of the evidence in reaching conclusions about the human carcinogenic potential of agents. This is accomplished in a single integrative step after assessing all of the individual lines of evidence, which is in contrast to the step-wise approach in the 1986 cancer guidelines..." (EPA, 2005, p. 1-11).
- Environment Canada's Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List also includes a weight of evidence approach that is used to select pivotal values for persistence, bioaccumulation and inherent toxicity which is then compared to the applicable P, B and T criteria. (Environment Canada, 2003).

However, Ecology decided not to make revisions to the rule language in order to incorporate general guidelines for integrating and synthesizing the results from multiple studies and multiple lines of evidence because:

- Ecology believes this type of information is more appropriately placed in guidance materials such as the Environment Canada guidance materials;
- Amending the rule at this point in the rulemaking process would not allow for a full public review and discussion on this issue.
- Ecology believes that the process to consider adding or removing chemicals from the PBT list provides a more logical mechanism for developing guidance on this issue.
- The actual implementation of a "weight of evidence" approach is complicated by the fact that the term "weight of evidence" has been used to characterize a wide range of approaches that differ in terms of level of detail and methodology.

With respect to the latter point, Ecology sees some similarity between comments on the use of a "weight of evidence" approach and comments on the use of the "precautionary principle" in that both terms have multiple definitions that include different combinations of features. With respect to the "weight of evidence" approach, Dr. Douglas Weed (2005) has reviewed the concept and its use in the published scientific and policy-making literature. Based on a review of 92 papers published between 1994 and 2004, Dr. Weed observed:

> *...WOE has three characteristic uses in this literature (1) metaphorical, where WOE refers to a collection of studies to an unspecified methodological approach; (2) methodological, where WOE points to established interpretative methodologies (e.g. systematic narrative review, meta analysis, causal criteria, and/or quality criteria for toxicological studies) or where WOE means that "all" rather than some subset of the evidence is examined, or rarely where WOE points to methods using quantitative weights for evidence; and (3) theoretical, where WOE serves as a label for a conceptual framework. Several problems are identified: frequent lack of definition of the term "weight of evidence", multiple uses of the term and a lack of consensus about its meaning, and the many different kinds of weights, both qualitative and quantitative, which can be used in RA....* ***(Weed, 2005, p. 1545)***

As with comments on the precautionary principle, it was generally unclear which "weight of evidence" approach members of the public were urging Ecology to implement. Because there are multiple "weight of evidence" approaches being employed by various organizations, Ecology believes this creates the potential for confusion and multiple interpretations as people point to different "weight of evidence" approaches as the appropriate version for implementing the Washington PBT rule.

Issue 5-28: ***How should Ecology take into account the quality of different types of scientific information when making decisions on whether to include a chemical on the PBT List?***

Proposed Rule

The proposed PBT rules published in June and October 2005 did not include language that explicitly addressed this issue.

Public Comments and Concerns

Several organizations recommended that Ecology take into account the varying quality of data and studies. For example:

> ***Ecology should conduct assessments that are consistent with those generally accepted in the scientific community; utilizing a preferred hierarchy of data sources where the weight-of-evidence is preferred over single measured values, which are in turn preferred over estimated, calculated or modeled values.*** *The Revised Draft PBT Rule states that listings will be based on "credible scientific information," which is defined as "information that is based on a theory or technique that is generally acceptable in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures." Ecology should adopt a policy on hierarchy of data sources that is consistent with other regulatory authorities and the scientific community in general.* ***(Barbara Losey, p. 2 of November 2005 Written Comments)***
>
> ***All available scientific information must be incorporated when evaluating a chemical versus the P, B, or T criteria.*** *The proper use of science in identifying and listing of chemicals for inclusion on the PBT listing is critical to the success of this process. A strong adherence to use of scientifically valid data is essential in selecting the relevant numbers for each aspect of persistence (P), bioaccumulation (B) and toxicity (C). The PBT rule properly emphasizes these concepts; however, in application problems occur in failing to clearly describe what is valid scientific data for use in the selection process. Through-out the PBT process and its allied PBDE stakeholder process the agency staff has placed high reliance on a few scientific studies that provided P, B or T numbers that supported PBT designation This reliance on a very limited data set is in direct conflict with the most basic principles of scientific investigation. These criteria are clearly stated in the comments from the ALKYLPHENOLS & ETHOXYLATES RESEARCH COUNCIL....* ***(Kirk Thomson, p. of Attachment to November 2005 Written Comments)***

Several organizations and individuals recommended that experimental data should take precedent over modeled predictions if a discrepancy exists between the two sources of information. They also recommended that chemicals should not be judged to meet PBT criteria solely on the basis of predictions from one model.

> *Another factor is how Ecology weights experimental data relative to modeled values, and the apparent willingness to list a chemical as a PBT based on modeling alone. Although NCASI recognizes that relevant experimental data may not always be available and that models can often be trusted to provide reliable estimates, excessive reliance on modeling alone seems somewhat speculative. Comparing the information cited in support of the listing of n-hexyl phthalate, for which there are essentially no "hard" (i.e., experimentally measured) data supporting the PBT determination, to that cited in support of listing DDT, for which there is a plethora of experimental data supporting the PBT listing, suggests this kind of speculation. Overall, review of the data cited by Ecology to support expansion of the PBT list to include n-hexyl phthalate, di-isodecyl phthalate, and nonylphenol reveals a lack of scientific rigor, and NCASI strongly recommends that these chemicals be deleted from the proposed rule.* ***(Jeff Louch, p. 1 of November 2005 Written Comments)***
>
> ***Experimental data should have precedent over model predictions, and chemicals should not be judged to meet the P, B, or T criteria based solely on predictions from a single model.*** *In general, experimental data should be given greater weight than model predictions. Thus, in cases were model output would qualify a chemical as a PBT but experimental data do not, the experimental data should be considered definitive and the chemical should not be classified as PBT.*
>
> *Although modeling often provides accurate information, NCASI is concerned at the potential for basing a PBT listing solely on predicted properties. This level of discomfort increases as the margin between the predicted value and a numerical criterion decreases. As an example of this, the decision*

to classify n-hexyl phthalate as persistent based solely on an estimated 78 day half-life in sediment is tenuous.

The rule should clearly state that when valid experimental data and modeled data conflict, the experimental data are definitive and will drive the decision of whether or not a chemical meets the PBT criteria. NCASI also suggests that Ecology should not conclude that a chemical meets a specific criterion based exclusively on the output of a single model, especially in instances where the difference between the estimated value and the criterion is small (e.g., less than a factor of 2). Instead, in cases where valid experimental data are not available, the rule should specify that all relevant models will be run and the resulting mean of the multiple estimated values will be used to evaluate exceedence of the appropriate PBT criteria. ***(Jeff Louch, p. 4 of November 2005 Written Comments)***

Ecology's Review and Response to Public Comments

Ecology agrees that some types of data should be weighted as more reliable than other types of data and that some type of data hierarchy can be useful in helping to guide efforts to integrate, synthesize and weight results from multiple studies. Several agencies have established "data hierarchies" for use in evaluating the persistence, bioaccumulation potential and toxicity of particular chemicals. For example:

- EPA's Waste Minimization Prioritization Tool (EPA 1998) includes data preference hierarchies for persistence, bioaccumulation, human toxicity and ecological toxicity data that reflect the level of peer review, consensus in use, etc.
- Environment Canada's Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List also includes several data hierarchies that are used to guide that agency's evaluation of data on the persistence, bioaccumulation and inherent toxicity of chemicals and chemical groups. (Environment Canada, 2003).

However, Ecology decided not to make revisions to the rule language in order to incorporate general guidelines for weighting different types of evidence because:

- Ecology believes this type of information is more appropriately placed in guidance materials such as the Environment Canada guidance materials;
- Amending the rule at this point in the rulemaking process would not allow for a full public review and discussion on this issue.
- Ecology believes that the process to consider adding or removing chemicals from the PBT list provides a more logical mechanism for developing guidance on this issue.

Issue 5-29: ***How should Ecology taken into account scientific uncertainty and variability when making decisions on whether to include a chemical on the PBT List?***

Proposed Rule

In developing the PBT rule, Ecology recognized there are numerous sources of scientific uncertainty that complicate decisions on whether to include a particular chemical on the PBT list. The complications arising from scientific uncertainty are compounded by studies showing there are wide variations in levels of exposure and sensitivity to chemicals within (and between) species and population groups. In the proposed PBT rules published in June and October 2005, Ecology acknowledged this complexity when it stated "...lack of full scientific consensus should

not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment." However, Ecology did not propose rule language to define how the Department will take into account sources of variability when making decisions on whether to include a chemical on the PBT List.

Public Comments and Concerns

Several organizations recommended that Ecology take into account scientific uncertainty and information on variations in exposure and sensitivity in population groups when evaluating available scientific information and making decisions on whether to include a chemical on the PBT list. For example:

> *We support WAC 173-333-140 (1) Scientific information. We believe that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment. Further, we believe that whenever possible the precautionary principle should be invoked to protect Puget Sound's marine resources. Specifically, we ask you to consider incorporating the precautionary principle approach into WAC 173-333-420 (1)(f).* ***(John Dohrmann, p. 1 of July 2005 Written Comments)***

> *In making PBT chemical management decisions, sensible precaution should include a full assessment of the level of uncertainty and the benefits that might be sacrificed if the products and technologies in question are restricted or otherwise called into question. The assessment process should also factor the uncertainties and risks that accompany potential alternatives into any decisions. The proposed Rule rightly incorporates necessary elements of science and risk prioritization.****(Michael Walls and Clifford Howlett, p. of July 2005 written comments)***

Several organizations provided recommendations on how Ecology should address the variability in persistence, bioaccumulation and toxicity data when making decisions on whether to list a chemical on the PBT List. Specifically, they recommended that Ecology average the results from multiple studies and use the mean or median value as a basis for deciding whether a chemical does or does not meet the PBT criteria. For example:

> *.... Ecology should base its decision whether or not to list chemicals on the mean or weighted value of credible scientific information... .* ***(Grant Nelson, p. 3 of November 2005 Written Comments)***

> *The current version of the PBT rule gives hard numeric criteria for judging a chemical to be persistent (P), bioaccumulative (B), or toxic (T). However, the rule is mute with respect to how evaluations against these criteria will be made when there are multiple valid data points for any specific numeric metric (e.g., pKow). Review of the Technical Background document provided by Ecology (WDOE 2005) suggests that a chemical will be judged to be P, B, or T if there is a single number meeting the associated (P, B, or T) criterion even in cases where there are additional numbers indicating that a chemical does not meet the same criterion. In these instances, relevant scientific information is effectively excluded from the decision making process. This is inconsistent with the practice of sound science.*

> *Without a detailed evaluation of the validity of all data points used in evaluating a chemical's P, B, or T characteristics, there is no basis for selectively excluding data when determining if a chemical meets a specific criterion. On the other hand, it is common practice to utilize some statistical measure of the central tendency, such as a mean or median, when summarizing a range of numeric data. Use of a mean or median value accounts for variability and ensures that all relevant data are incorporated as part of the decision making process, and systems for scoring PBT characteristics have specified the use of means when ranges of numeric data are available (e.g., Snyder et al. 2000a, b, c, d).*

To ensure that a chemical is not categorized as a PBT based on anomalous data and to provide confidence in the final PBT list, Ecology should modify the rule to clearly state that evaluation of a chemical against a numeric criterion will be based on a mean or median of all available data. As a corollary to this, in cases where no relevant experimental data are available, Ecology should obtain output from all relevant models and use the resulting mean to assess a chemical's PBT properties. [Note that there are multiple subtleties not mentioned here that should be addressed when considering how to incorporate (or weight) all available data as part of the decision making process (e.g., how to weight BAFs from different species, or how to weight a NOAEL for one species vs. an EC50 for another). These are issues that should be addressed, if not in the rule then as part of a CAP.] ***(Jeff Louch, p. 3 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the proposed rule to specify that Ecology will use a measure of central tendency (mean or median) when summarizing a range of numeric data because:

- Ecology believes this type of information is more appropriately place in guidance materials – particularly since it is unclear how frequently there will be an enough data for a particular chemical to enable someone to calculate a median, mean or other statistical measure;
- Ecology agrees with Dr. Louch that a general decision rule (e.g. use of a mean value to characterize a range of measured values from different studies) fails to take into account the subtleties of dealing with data of varying reliability, etc.
- Ecology believes that the choice of a mean or median value as the statistical measure to characterize a chemical's persistence, bioaccumulation or toxicity may be at odds with Ecology policies and approaches that are based on protecting highly exposed and/or sensitive population groups.

With respect to the latter point, environmental agencies are often faced with the need to select a particular value to characterize persistence, bioaccumulation potential or toxicity from a range of values. The selected value will have a certain amount of inaccuracy because of scientific uncertainty and variability. Agencies often lump these two terms together. This is unfortunate because the nature of the errors that arise due to uncertainty are different than those that arise as a result of variability. Similarly, environmental agencies responses to uncertainty are inherently different than responses to variability.

Uncertainty arises in situations where agencies lack knowledge of the true value (e.g. BAF, half-life, reference dose, etc). In these situations, the choice of any value leads to the potential for overestimating or underestimating the true (but unknown) value of that parameter. A conservative response reflects a choice between errors: it is better to overestimate risk than to underestimate risk. In other words, conservatism is a specific response to uncertainty that favors one type of error (overestimation) over its converse (underestimation).

With variability, agencies know that there is a range of actual values for the parameter in question. In these situations, the agency's response does not require a choice between overestimating or underestimating - agencies must simply decide which value to use to characterize the range of values. The National Research Council (1994) identified four approaches for resolving this issue:

- Ignore the variability and hope for the best;
- Explicitly disaggregate the variability;

- Use the average value of a quantity that varies;
- Use a maximum or minimum of a quantity that varies.

A number of environmental laws and regulations require Ecology and EPA to consider exposure and health effects for population groups at the high end of exposure and/or susceptibility. For example, cleanup levels established under the Model Toxics Control Act are based on reasonable maximum exposure (RME) which is intended to correspond to roughly the 95th percentile of the range of potential exposure levels. Consequently, the RME is a summary measure selected to represent the range of potential exposures. In this case, choosing to characterize a variable quantity (exposure) by an estimate of the 95th percentile reflects the explicit (or implicit) choice that an error of underestimation (the five percent chance the actual value exceeds the summary estimator) is nineteen times as bad as an error of overestimation. Similarly, EPA has typically focused on the 95th percentile in the distribution of species sensitivity when establishing water quality criteria.

Finkel (1989) noted that "...all summary estimators of an uncertain quantity are value laden. Summary measures are little more than ways to interpret facts in light of a subjective calculus of the costs of error..." (pp. 436-437). He described several other common statistical measures which he observed would strike a different balance between overestimating and underestimating a particular value:

- **Statistical mode** (most frequently measured value) which embodies the value judgment that one should minimize the probability of error, without regard to it's type (over- or under-estimation) or it's magnitude;
- **Statistical median** (the 50th percentile value) which embodies the value judgment that the costs of the two types of errors are exactly equivalent (as the probability of each error is fifty percent when the median is chosen).
- **Statistical mean** (the average of measured values) which embodies the value judgment that that larger errors are more important than smaller errors independent of the direction of the error. When dealing with highly skewed distributions, the mean of the distribution will often (but not always) fall at the upper-end of the distribution and (in some cases) may approach the 95th percentile value or higher.

As noted by Dr. Louch, the choice of statistical measure can have a substantial impact on the determination of whether or not a chemical is classified as a PBT. To illustrate the practical distinctions between the various measures, Ecology expanded upon Dr. Louch's calculations with respect to nonylphenol. Specifically, Ecology calculated the median, arithmetic mean, the 95th percent upper confidence limit on the mean and the 95th percentile value that might serve as a summary parameter for characterizing the bioaccumulation potential of nonylphenol. Those calculations (which do not take into account differences in the quality of the various studies) show that the choice of summary statistic will have a substantial impact on the decision to list or not list a particular chemical. This comparison indicates that (1) the use of the median values is not consistent with approaches used by other Ecology programs to address variability; and (2) the use of the arithmetic mean may (in some cases) be consistent with approaches used by other Ecology programs. However, the location of the mean value (percentile) will vary depending on the underlying data and distribution.

Comparison of Statistical Measures to Characterize Bioaccumulation Potential of Nonylphenol

Data Set	Number of Study Results	Range	Median	Mean	UCL 95 on the Mean[100]	95th Percentile of Fitted Distribution
All studies	28	37-4,120	275	685	1,222 (lognormal)	2,130 (lognormal)
Freshwater – Fathead Minnow	12	203	640	579	890 (lognormal)	1137 (lognormal)
Saltwater	6	110-4,120	1,250	1,728	41,191 (lognormal) 2,921 (normal)	4,400 (lognormal) 4,113 (normal)

5.6. What criteria will Ecology use to remove a PBT from the PBT list? (WAC 173-333-330)

Ecology did not receive comments on the proposed language in WAC 173-333-330.

5.7. What process would Ecology follow to revise the PBT list? (WAC 173-333-340)

Issue 5-31: Does the proposed rule establish a reasonable process for revising the PBT list?

Proposed Rule

The proposed rule identified the process and procedures Ecology will use to revise the PBT list (removing or adding chemicals). The proposed process included provisions for periodic review of the list, public notification on preliminary determinations to revise the list and procedures for amending the rule in order to revise the list (WAC 173-333-340).

Public Comments and Concerns

The Weyerhaeuser Company recommended that Ecology explicitly state that the Department will prepare a discussion paper supporting the addition or removal of a chemical from the list and make that available for public review:

> ***WAC 173-333-340(3) Public Notification*** *– A technical and regulatory discussion paper supporting the addition or removal of a chemical should be developed and be part of the public notification....The need for a written presentation is implied, but not specifically mentioned, as part of the public notification process.* ***(Ken Johnson, p. 2 of July 2005 written comments)***

[100] The subscripts refer to whether the Upper 95 percent confidence limit and the 95th percentile value were estimated based on the assumption that the distribution of study results is either lognormal or normal.

Several organizations and individuals expressed support for Ecology's proposal that addition or removal of chemicals from the list be implemented as rule amendments in accordance with the Administrative Procedures Act. However, the Washington Toxics Coalition expressed concerns that the process for adding chemicals to the PBT list was unnecessarily cumbersome and would delay efforts to protect human health and the environment.

Several organizations and individuals urged Ecology to provide greater detail on how often the PBT list will be reviewed and revised. For example:

> *Review and Update the PBT List Every Three Years. Because new scientific information on chemicals is continually emerging Ecology should review, and if necessary update, the PBT list at least every three years.* ***(Ivy Sager-Rosenthal, p. 4 of July 2005 written comments)***

> *WAC 173-333-310 (4): We recommend that section 173-333-310 include a specific expectation for how often the PBT list will be reviewed. On average, over 700 new chemicals are introduced into commerce each year and subsequently into the environment. In addition, our scientific understanding of how certain chemicals interact with the marine environment is changing at a rapid pace. Due to these rapidly changing variables, we suggest adopting an annual review of the PBT list. We suggest modeling this review approach after the Sediment Management Annual Review Meeting (SMARM) used by the Dredged Material Management Program.* ***(John Dohrmann, p. 2 of July 2005 written comments)***

The King County Hazardous Waste Management Program suggested that, as part of the process for amending the PBT List, Ecology publish a list of chemicals that did not meet the PBT criteria:

> *As Ecology reviews chemicals proposed for the PBT list, it would be helpful to create a list of those that did not meet the criteria at the time of the review. This list would not need to be included in the rule itself, but could be a publication updated annually or every couple of years. It could ensure that knowledge gained from past reviews is readily accessible and not repeated needlessly.* ***(David Galvin, p. 3 of July 2005 written comments)***

Several organizations recommended that Ecology take additional steps to involve scientific experts when revising the PBT list or other rulemaking provisions (e.g. chemical action plans). For example:

> ***The Advisory Committee Process Should Incorporate More Scientific Expertise.*** *An advisory committee provides valuable external stakeholder input to the PBT management process. While we generally agree with the suggested representatives for the committee, including more science-based expertise and less advocacy input may be more valuable to Ecology. Specifically, the inclusion of qualified scientific experts in areas such as medical toxicology, risk assessment, epidemiology, and/or analytical chemistry could provide important science-based input to the process.* ***(Michael Walls and Clifford Howlett, p. 6 of November 2005 written comments)***

The Boeing Company recommended that Ecology staff be removed from the science review process and that such reviews be conducted by an independent science panel:

> ***3) Use of independent science panels to evaluate and designate PBTs*** *Recommend that designation of any chemical, other than USEPA listings, to the PBT list be conducted by an independent scientific panel with participant equally selected by stakeholders. Employing an independent science panel will ensure all science is reviewed and incorporated into a PBT designation determination. This approach will address the insufficient quality and quantity of scientific information; is not a recurring significant problem with the PBT rule and PBT listing in particular. Employing an impartial science panel will remove the perception that designation under this rule lacks checks and balances crafted to preclude agency staff from selecting the science that best fits the desired outcome. Removing agency staff from the science review process will assure the public and business community that a full, fair and impartial analysis of the data has been conducted. This may garner support for developing and*

implementing a chemical action plan from all stakeholders; rather than resistance and challenge. ***(Kirk Thomson, p. of November 2005 Written Comments)***

Mr. Randy Ray also discussed the need for a better forum to discuss scientific issues in his testimony at the November 9th public hearing:

Also we're concerned, when you added phthalates to the PBT list, there was, and I sent Mike a letter on this that, all of a sudden it said it's contained in wild Chinook salmon in Puget Sound. Well maybe it's detectable, but does that mean that people should stop eating wild Chinook salmon? Well, it may not seem big to you guys, it's big to us because it's our product we sell. All of a sudden you're saying that this salmon can cause reproductive problems in young boys. Well, that's a big issue to us. We've also had studies starting to come out from medical groups that are stating all these scares on environmental issues and PBTs are moving people away from eating fish. It's impacting the market, and they're believing they're moving to a more unhealthy diet, which will lead to less brain development and IQ in children. So, you do not have – we're concerned with how Ecology's done this in the past. We're concerned how it's continuing to do this, and we need another method to go address these issues from a scientific point of view. You're not always going to agree with us. We understand it, but we need a better forum for it and I don't think it's the current, only committing inside of the chemical action plan. ***(Randy Ray, Testimony at November 9, 2005 Public Hearing)***

The American Chemistry Council/Chlorine Chemistry Council recommended that Ecology evaluate available monitoring data when revising the PBT list:

Include Ambient Monitoring as Consideration When Updating PBT List. *Section 173-333-340 (2) calls for Ecology to periodically review and update the list of PBT chemicals. In addition to the considerations listed in this section, Ecology should also consider the results of ongoing 'ambient monitoring' when reviewing and updating the PBT list. The results of ambient monitoring will help inform Ecology as to the levels a chemical is present in Washington State and help determine the relative risk represented by that PBT. This consideration should also include an evaluation of environmental monitoring trend data to determine whether levels in the environment are increasing, decreasing, or relatively constant. Monitoring trends can also help inform Ecology as to the appropriate level of priority for action on a chemical.* ***(Michael Walls and Clifford Howlett, p. 6 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on the process for preparing and revising the PBT List. Ecology's responses are provided in the following paragraphs.

- **Technical Discussion Paper**: Ecology agrees that in order to provide meaningful comments on a proposal to add or remove a chemical from the PBT list, the public needs to understand the technical bases and rationale supporting Ecology's determination. Based on comments on the June 2005 proposed rule, Ecology modified the rule language to specify that the Department will prepare and distribute a technical discussion paper that summarizes the scientific information that was considered by Ecology when preparing a proposal to revise the PBT List (WAC 173-333-340(3)). Ecology prepared and distributed a technical discussion paper summarizing the scientific information for the chemicals included on the October 2005 proposed rule. As discussed in several sections of this document, several organizations found the document contained an insufficient amount of detail on the information used by Ecology to make determinations on the persistence, bioaccumulation and toxicity of individuals. Ecology will consider those comments when structuring and preparing future summary documents.

- **Administrative Process for Revising the PBT List**: The Washington Legislature directed Ecology to adopt a PBT rule that included both the PBT criteria and the PBT list. Consequently, Ecology will continue to comply with rulemaking requirements in the Administrative Procedures Act when proposing to revise the PBT list.
- **Frequency for Reviewing the PBT List**: Ecology reviewed the recommendation that the Department update the PBT List at least once every three years and decided not to specify a minimum review period in the PBT rule. Ecology believes that the review frequency should be determined by the availability of information on the persistence, bioaccumulation and toxicity of individual chemicals and that identifying a specific time period may result in limited resources being diverted from preparing and implementing chemical action plans.
- **Publishing A List of Chemicals Not Meeting the PBT Criteria**: Ecology reviewed the suggestion that the Department identify chemicals that do not meet the PBT criteria and believes this suggestion has merit in terms of promoting the use of safer alternatives. However, Ecology believes that such a list would only be useful if people had a high degree of confidence that such determinations would not be revised based on future reviews. Although Ecology currently does not have the resources that would be needed to systematically perform such evaluations on a comprehensive basis, Environment Canada is scheduled to complete a screening level review of over 23,000 chemicals that appear on Canada's Domestic Substances List in 2006. That project will provide an enormous amount of information and evaluation of the available data on persistence, bioaccumulation and toxicity.
- **Scientific Review**: Ecology reviewed the suggestion that Ecology incorporate more scientific expertise into the advisory committee process. Ecology agrees that advisory committees play an important role in Ecology's rule development processes and that it is important to have range of interests and expertise represented on committees that provide a blend of scientific expertise and advocacy. During this rulemaking process, Ecology worked with business and environmental groups to establish an advisory committee that provided valuable advice on the overall decision-making process, criteria for identifying PBTs and the initial PBT list. Given the combination of programmatic, policy and scientific issues addressed during this rulemaking, Ecology believes the composition of the PBT Advisory Committee provided an appropriate blend of scientific expertise and advocacy. However, future rulemakings will be focused on whether to add or remove chemicals from the PBT list. Given this focus, Ecology agrees that the composition of future advisory committee should be more heavily weighted toward scientific expertise with the members providing a blend of scientific expertise in the areas of toxicology, environmental fate and transport, chemistry, statistics, etc. However, the composition of the committee will also need to take into account the range of scientific policy determinations inherent reaching conclusions on the persistence, bioaccumulation and toxicity of individual chemicals.
- **Independent Science Panel**: Ecology reviewed the suggestion that determinations on the persistence, bioaccumulation potential and toxicity of individual chemicals be made by an independent science panel. Ecology agrees on the need for the best scientific evaluation of all meaningful scientific data that considers the "weight of evidence", data preferences/data hierarchy, scientific uncertainty and variability. However, Ecology believes that the proposal to create an independent science panel would be resource intensive, inefficient in its division of responsibilities, would be subject to unreasonable delays and would not provide significant benefits relative to the use of a rule advisory committee as discussed above.

Chapter 6 – Chemical Action Plans (Part IV)

6.1. What is a chemical action plan (CAP)? (WAC 173-333-400)

Issue 6-1: What is a chemical action plan?

Proposed Rule

The proposed PBT rules published in June 2005 and October 2005 included the following language:

> ***WAC 173-333-400 What is a chemical action plan (CAP)?*** *(1) A chemical action plan (CAP) is a plan that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and includes recommendations on actions to protect human health or the environment.*

Public Comments and Concerns

Several organizations and individuals provided comments on the proposed language. These comments were similar to the comments on the definition for chemical action plan. Those comments are summarized in Issue 4-6.

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to revise the proposed language. As discussed in Ecology's response to comments on the proposed definition, Ecology believes that the proposed language describing the CAP as "a plan" that "identifies, characterizes and evaluates" the "uses and releases" of a specific PBT or group of PBTS and "recommends actions to protect human health or the environment" provides an accurate description of these documents. Equally important, Ecology believes the proposed language is neutral and balanced in that it does not selectively repeat goals and evaluation factors that are described elsewhere in the rule.

Issue 6-2: What types of recommendations should Ecology include in a chemical action plan?

Proposed Rule

The proposed PBT rule published in June 2005 included the following language:

> *(2) CAPs will include recommendations for:*
>
> *a. Reducing and eliminating uses and releases of the specific PBT or group of PBTs addressed in the CAP;*
> *b. Managing products or waste that contain the specific PBT or group of PBTs addressed in the CAP;*
> *c. Minimizing exposure to the specific PBT or group of PBTs;*
> *d. Collecting additional information needed to evaluate the feasibility of potential actions; and*
> *e. Measuring or monitoring the effectiveness of actions being implemented in Washington.*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. In the October 2005 proposed rule, Ecology deleted subsection (2) and integrated the language with similar language in WAC 173-333-420. [See Issue 6-15]

Public Comments and Concerns

Several organizations recommended changes to the list of recommendations included in the June 2005 proposed rule:

- The Association of Washington Business recommended that the word "eliminating" be replaced by the word "phasing-out" in paragraph (a);
- The Washington Toxics Coalition recommended that Ecology revise paragraph (b) to read as "Properly disposing of products or waste that contain the specific PBT or group of PBTs addressed in the CAP";
- The Association of Washington Business recommended that the word "minimize" be replaced with the word "reduce in paragraph (c). The Washington Toxics Coalition recommended that this paragraph be revised to read as "Actions individuals can take to minimize their exposure to the specific PBT or group of PBTs.

Several organizations emphasized the importance of finding safer alternatives for current processes and products. The Washington Toxics Coalition recommended that CAPs include recommendations for developing markets for less toxic alternatives:

> *We also suggest that CAPs include recommendations for developing markets for less toxic alternatives. This approach can be a strong driver for getting large sectors (business, government) to move away from toxic chemicals to safer substitutes.* ***(Ivy Sager-Rosenthal, p. 5 of July 2005 written comments)***[101]

Ecology's Review and Response to Public Comments

Ecology reviewed the comments received on the June 2005 proposed rule and concluded that the proposed language largely duplicated similar language in WAC 173-333-420. In reviewing how to address the comments on this subsection, Ecology decided that it made more sense to consolidate the list of recommendations in one place (WAC 173-333-420). Ecology's review and response to the above comments are provided under Issue 6-15.

6.2. What evaluation factors and processes will Ecology use to select PBTs for chemical action plan preparation (WAC 173-333-410)

Issue 6-3: ***Does the proposed rule provide a clear and logical process for ranking and prioritizing chemicals for preparation of chemical action plans?***

Proposed Rule

The proposed rule published in June 2005 included a multi-step process for selecting chemicals for CAP development. This process included the following steps:

- Ecology would place the chemicals on the PBT list into categories 1, 2 or 3 (WAC 173-333-320(3));

[101] The Washington Toxics Coalition provided the following suggested language: (f) Developing markets for less toxic alternatives.

- Ecology would screen the chemicals in Category 1 based on the selection criteria in WAC 173-333-410(2);
- Ecology would develop a relative ranking for the chemicals that passed the screening step using information on PBT characteristics, uses, releases and environmental concentrations (WAC 173-333-410(3)(a)(i);
- Ecology would evaluate opportunities for reductions, multiple chemicals releases and exposures, sensitive population groups and high-exposure populations, existing plans or regulatory requirements and available information (WAC 173-333-410(3)(a) (ii) through (vi).
- Ecology would select chemicals or groups of chemicals for CAP preparation and provide opportunities for public review and comment (WAC 173-333-410(3)(b) through (d).

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. The proposed PBT rule published in October 2005 included the following changes:

- Ecology deleted the three chemical categories in WAC 173-333-320(3)) [Issue 5-4);
- Ecology proposed to develop a multi-year schedule for CAP development [Issue 6-4];
- Ecology deleted the screening criteria identified in WAC 173-333-410(2) [Issue 6- 5];
- Ecology identified situations where CAPs would not be prepared [See Issue 6-10]

Public Comments and Concerns

Several organizations and individuals found the CAP selection process in the June 2005 proposed rule to be unclear and confusing. For example:

> ***There is no clear process for selecting chemicals from the PBT list for development of CAPs.*** *Based on the language in the proposed rule, it appears that Ecology is proposing the following:*
>
> - *Chemicals on the PBT list will be placed in one of three categories based on available information/data, and only Category 1 chemicals will be targeted for CAPs.*
> - *Chemicals in Category 1 will be ranked according to the criteria given in 173-333-410(2), and those with soil/sediment half-lives >180 days and BAFs or BCFs >2000 in combination with some toxicity score (see comment 3) will be given priority for CAP development.*
>
> *As described, this is a logical approach to ranking/prioritizing chemicals for CAPs. Is this what Ecology intends? If so, the language in the proposed rule should be modified to clearly express this. If not, Ecology needs to modify the rule by incorporating some clearly defined scheme for ranking chemicals on the PBT list for use in prioritizing CAPs [1,2]****.(Jeff Louch, p.3 of July 2005 written comments)***

Several organizations submitting comments on the October 2005 proposed rule concluded that the revised approach lacks clarity and transparency and recommended that Ecology incorporate a "high-medium-low" categorization system into the PBT rule. For example:

> ***The rules should reinstate a ranking system for chemicals that have been determined to meet the PBT criteria. This is needed as part of a clear and transparent process to determine if CAPs are needed.*** *NWPPA was very disappointed that Ecology has revised the process for selecting chemicals from the PBT List for development of chemical action plans by eliminating the three list categories originally in the June 1st version of WAC 173-333-410(2). The three categories were:*
>
> *Category 1: PBTs actually used, released or present in Washington;*
> *Category 2: PBTs for which there are insufficient information on use, release or presence; and*
> *Category 3: Those for which there are no other laws or are addressed by other laws.*

NWPPA's first preference remains that Ecology rules have a strong clear articulation of how it plans to conduct relative ranking. For the purposes of this rule, NWPPA can support the multi-year schedule concept, provided Ecology include in the proposed rules language that reflect "high, medium and low" priorities, as per the AWB language. The "high, medium and low" categories should incorporate the concepts of the original three-category system. ***(Llewellyn Matthews, p. of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on the June 2005 and October 2005 proposed rules. Ecology believes that the final rule (which largely tracks the October 2005 proposed rule) provides a logical and workable approach for ranking and prioritizing chemicals for preparation of chemical action plans. Ecology considered the following factors when revising the approach in the June 2005 proposed rule:

- Ecology believes that the tiered evaluation process in the June 2005 proposed process was too complicated and (in some places) confusing.
- Ecology believes that the combination of categories, additional criteria and selection factors included in the June 2005 proposed rule were redundant and might actually lead to decisions that contradict a "worst first" priority-setting approach. Ecology also believes that the October 2005 proposal retains the "high-medium-low" concept reflected in the three category system in the June 2005 proposal in that much of that language that appeared in WAC 173-333-320 was moved to WAC 173-333-410(2)(b) of the final rule.
- Ecology believes that the integrated evaluation in the October 2005 proposal is consistent with approaches used by other programs such as the RCRA Waste Minimization Program.
- Ecology believes that developing a multi-year schedule will promote increased public dialogue on the CAP priorities, greater predictability for individuals and organizations and greater administrative efficiencies.

Ecology also received numerous comments suggesting changes to individual components of the selection process. Comments on specific features of the priority-setting process are discussed in the following sections:

- Three Year Schedule for CAP Preparation (Issue 6-4)
- Screening Criteria (Issue 6-5)
- Selection Factors (Issue 6-6)
- Relative Rankings (Issue 6-7)
- Opportunities for Reduction (Issue 6-8)
- Existing Plans and Requirements (Issue 6-9)
- Situations where Ecology will not prepare CAPs (Issue 6-10)
- Public Review Process for CAP Selection (Issue 6-11)

Issue 6-4: Should Ecology establish a three year schedule for CAP preparation that provides for the completion of 2 CAPs/year?

Proposed Rule

The proposed PBT rule published in June 2005 specified that Ecology would consult with the Department of Health when selecting PBTs for CAP preparation. Ecology modified the June 2005 rule language to address issues identified during the initial public comment period. In the proposed PBT rule published in October 2005, Ecology proposed to establish a multi-year schedule for preparing chemical action plans.

> *Ecology will consult with the department of health to develop a multiyear schedule for the preparation of chemical action plans.*

Public Comments and Concerns

Several organizations and individuals providing comments on the June 2005 proposed rule recommended that Ecology develop a three-year schedule for preparing chemical action plans and that the schedule should provide for completing a minimum of two (2) chemical action plans/year. For example:

> *Establish Three-year Schedule For the Preparation of CAPs and Prepare Two CAPs Per Year. The current process for determining what chemicals will be selected for CAPs (proposed WAC (3) b.-d.) is extremely time consuming and expensive and will slow down the CAP process significantly. Instead of putting each proposed chemical selection out for public comment, we suggest that Ecology develop and submit for public comment a three-year schedule for proposed CAPs. The schedule would outline the chemicals for which phase-out plans will be prepared, include a timeline for completing the plans, and provide the rationale for selecting each chemical. We believe such a schedule will provide stakeholders, the public, and policymakers with a clearer understanding of what chemicals Ecology will be addressing and the what resources will be necessary to do the work.*
>
> *The pace for CAP development is too slow. Ecology has only completed two action plans in five years. This is much too slow when you considered how quickly these chemicals are increasing in the environment and our bodies. Ecology should be completing at least 2 CAPs per year.* ***(Ivy Sager-Rosenthal, p. 5 of June 2005 written comments****)*
>
> *Establish Three-year Schedule For the Preparation of CAPs and Prepare Two CAPs Per Year* ***(Heather Trim, p. 2 of June 2005 written comments).***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to incorporate the multi-year schedule concept into the PBT rule because (1) a multi-year planning period will facilitate agency resource planning and management, (2) developing a multi-year schedule will provide greater predictability for organizations and individuals that produce or use various PBTs, and (3) it is more efficient from a program administration standpoint.

However, Ecology decided not to identify a minimum number of CAPs that Ecology will prepare on a yearly basis. Given Ecology's experience preparing CAPs for mercury and PBDEs, Ecology believes this recommendation is unrealistic. Ecology believes that the number of CAPs prepared per year will be a function of the (1) CAP complexity and the number of sources, uses and options considered in the CAP process, (2) the types and amount of information that will need to be collected to support the evaluation of various policy options, (3) the level of public interest and (4) the level of agency funding and staffing allocated to this activity. Given the

variability in these parameters, Ecology believes it would be counterproductive to establish such a requirement in the PBT rule.

Issue 6-5: Should Ecology use a second set of PBT criteria for selecting candidates for chemical action plan development?

Proposed Rule

The proposed PBT rule published in June 2005 included the following language:

> *(2)* ***Candidates for CAP development.*** *Ecology will consider developing chemical action plans for chemicals on the PBT list that meet the following criteria:*
>
> *(a) Ecology determines that the chemical or chemical group has a half-life in water that is greater than or equal to sixty days, soil or sediment that is greater than or equal to one hundred eighty days;*
>
> *(b) Ecology determines that the chemical or chemical group has a bioconcentration factor or bioaccumulation factor in aquatic species that is greater than 2,000; and*
>
> *(c) Ecology determines that the chemical or chemical group is "toxic" as defined in WAC 173-333-302 (2)(c).*

Ecology modified the June 2005 rule language to address issues identified during the initial public comment period and decided to delete this subsection. Consequently, this subsection was not included in the October 2005 proposed rule.

Public Comments and Concerns

Many organizations and individuals providing comments on the June 2005 proposed rule recommended that Ecology not establish a second set of PBT criteria for use in identifying candidates for chemical action plans. For example:

> *We recommend omitting WAC 173-333-410 (2) (a), (b), and (c). We believe a chemical action plan should eventually be developed for all category 1 chemicals on the PBT list, as identified under WAC 173-333-310 (2). We recommend using the decision-making process in WAC 173-333-410 (3) to rank order the chemical action plans that will be developed for each chemical.* ***(John Dohrmann, p. 2 of July 2005 written comments)***
>
> *Eliminate the second set of P, B, and T criteria* ***(Heather Trim, p. 2 of July 2005 written comments)****.*
>
> *We oppose using two sets of P,B, and T criteria—one for identifying chemicals on the list and one for choosing the chemicals for CAPs. There is no scientific reason to include a second set of criteria. All chemicals on the PBT list should be eligible for CAPs, not just those Ecology has determined are the "worst of the worst". The purpose of the list is to identify "chemicals that require further action because they remain in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment . . . . " (WAC 173-333-300 (1)) If chemicals on the list have the potential to cause harm, then Ecology should be taking action on those chemicals on the list. There is no need to have a second set of criteria that make it more difficult to select a chemical for a chemical action plan.* ***(Ivy Sager-Rosenthal, p. 4 of July 2005 written comments)***

Other organizations supported Ecology decision to include a second set of criteria. However, these organizations also recommended that Ecology provide a clear description of how the various steps in the prioritization and selection process fit together (See Issue 5-4). For example:

> ***173-333-410(2)(a)*** *– This section implies that DOE will prioritize chemicals with half-lives in soil or sediment >180 days above those with half-lives <180 days. This is scientifically rational, but exactly*

how this prioritization might mesh with, for example, the categories suggested in 173-333-310(3) is unclear. Would a Category 2 chemical with a half-life >180 days be prioritized over a Category 1 chemical with a half-life <180 days?

173-333-410(2)(b)** – This section implies that DOE will prioritize chemicals with BCFs or BAFs >2000 above those with BCFs or BAFs <1000. Prioritizing chemicals with higher BCFs or BAFs makes scientific sense, but exactly how this prioritization fits in the overall scheme is unclear.* ***(Jeff Louch, p. of July 2005 written comments)

Several organizations expressed concerns about Ecology's decision to remove this step from the CAP selection process. For example:

> *The rules should reinstate a ranking system for chemicals that have been determined to meet the PBT criteria. This is needed as part of a clear and transparent process to determine if CAPs are needed.* ***(Llewellyn Matthews, p. 3 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on the June 2005 proposed rule and decided to delete the screening criteria identified in that proposed rule. This revision was part of a larger set of changes designed improve the workability of the approach for ranking and prioritizing chemicals for preparation of chemical action plans. Ecology decision to delete the screening factors considered the following factors:

- Ecology believes that the tiered evaluation process in the June 2005 proposed process was too complicated and (in some places) confusing.
- Ecology believes that the combination of categories, additional criteria and selection factors included in the June 2005 proposed rule were redundant and might actually lead to decisions that contradict a "worst first" priority-setting approach.
- Ecology believes that the October 2005 proposal retains the "high-medium-low" concept reflected in the three category system in the June 2005 proposal in that much of the June 2005 proposed rule language that appeared in WAC 173-333-320 was included in WAC 173-333-410(2)(b) of the final rule.

Issue 6-6: What factors should Ecology consider with selecting chemicals for CAP preparation?

Proposed Rule

The proposed PBT rules published in June and October 2005 identified five factors that Ecology will consider when selecting chemicals for CAP preparation: (1) relative ranking; (2) opportunities for reduction; (3) multiple chemical releases and exposures; (4) sensitive population groups and high-exposure populations; and (5) existing plans or regulatory requirements.

Public Comments and Concerns

Most organizations and individuals providing comments on the proposed PBT rule appeared to agree that Ecology should consider the five evaluation factors identified in the proposed rule. However, this support was more implicit than explicit. For example, Ecology received edited versions of the proposed PBT rule showing rule changes recommended by the Association of Washington Business, the Washington Toxics Coalition and the Bromine Science and

Environmental Forum. Although these groups suggested changes to specific evaluation factors, none of the three groups recommended that Ecology delete or add one or more evaluation factors. These suggested changes are discussed under Issues 6-7 through 6-9.

Several organizations and individuals emphasized the importance of considering the relative ranking and opportunities for reductions at this stage of the decision-making process. For example:

> ***WAC 173-333-410 What evaluation factors and processes will ecology use to select PBTs for chemical action plan preparation?*** *The relative ranking of each PBT should be based on risk to Washington residents. Opportunities for reductions must be feasible and have, or likely to have a measurable net benefit to human health and the environment. CAPs should not be developed if the likely net benefit to human health and the environment does not justify necessary further actions, or there are no feasible opportunities for reduction.* ***(Grant Nelson, p. 3 of November 2005 written comments)***
>
> *NWPPA continues to express the view that Ecology's decisions as to whether CAPs are needed should be based on credible science and relative ranking of risk. These determinations should be clear, prior to undertaking the CAP itself. The CAP process should not become the mechanism for determining if a CAP is needed.* ***(Llewellyn Matthews, p. 3 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on the proposed rule and continues to believe that the five evaluation factors should all be considered when prioritizing chemicals for CAP preparation and preparing the multi-year schedule.

Ecology has listed the five evaluation factors in a rough order of relative importance or weight. Ecology believes that assigning higher weights to relative rankings and opportunities for reduction is consistent with (1) the EPA Waste Minimization Program system and (2) discussions with the PBT Rule Advisory Committee held in late 2004. Ecology considered (but decided against) identifying primary and secondary criteria using an approach that is conceptually similar to the CERCLA remedy selection process which identifies threshold and balancing criteria. However, Ecology decided that this would be too prescriptive. Ecology plans to consider several options for weighting the various evaluations factors when developing the initial multi-year schedule.

Issue 6-7: Does the proposed PBT rule identify an appropriate range of factors to be evaluated when preparing a relative ranking of PBT chemicals?

Proposed Rule

The proposed PBT rules published in June and October 2005 specify that Ecology would prepare a relative ranking that would serve as one of the evaluation factors used to select PBTs for CAP preparation. The October 2005 proposed rule (WAC 173-333-410(2)(a)(i)) included the following language:

> *(i)* ***Relative ranking.*** *The relative ranking assigned to each PBT based on ecology's evaluation of information on PBT characteristics, uses of the chemical in Washington, releases of the chemical in Washington, the levels of the chemical present in the Washington environment, and levels of the chemical present in Washington residents.*

Public Comments and Concerns

Several organizations and individuals expressed general support for considering the relative ranking of PBT chemicals during this stage of the decision-making process. For example:

> *Throughout the advisory committee process and in comment to the June 1st proposal, both NCASI and NWPPA strongly advocated for the need for a relative ranking system for listed chemicals. With respect to PBTs, relative ranking is perhaps the most important policy decision Ecology can make. In the PBT advisory committee process, NWPPA recognized practical issues and supported the briefer categorization system in lieu of an articulation in the rules regarding relative ranking would be performed.* ***(Llewellyn Matthews, p. __ of November 2005 written comments)***

However, most organizations and individuals providing comments on the proposed rule found the rule language to be too vague and recommended that Ecology provide additional detail on the process used to assign relative rankings to individual PBT chemicals. For example:

> *The rule mentions a ranking process for prioritizing chemicals on the PBT list for development of CAPs. However, no information on this ranking scheme is provided. Informed comment is not possible without knowledge of how DOE will develop this ranking. As described, this ranking will guide implementation, so the ranking process should be incorporated as part of the rule.....* ***173-333-410 (3)(a)(i)*** *– This section explicitly states that DOE will select chemicals for CAP development based on a relative ranking "based on Ecology's evaluation of information on PBT characteristics, uses of the chemical in Washington, releases of the chemical in Washington, and the levels of the chemical present in the Washington environment." While these factors are all relevant in determining the risk posed by a specific chemical, in order to be fully transparent and allow informed comment this ranking scheme must be fully described and should be incorporated into the rule. Does this language simply refer to the sections addressed above (Section 173-333-310(3) specifically)?* ***(Jeff Louch, pp. 2-3 of July 2005 written comments)***
>
> *The rule also must clarify what data will be used to determine environmental presence, uses, and releases for the purposes of selecting chemicals for chemical action plans. We propose including all of the following:*
> - *Body burden data*
> - *Data from permits (NPDES, waste, and others)*
> - *Data from the MTCA site list*
> - *If Washington state data is not available (e.g. body burden), then information from other geographical areas such as the data in the national reports on human exposure to environmental contaminants and other state and local studies* ***(Ivy Sager-Rosenthal, p. 4 of July 2005 written comments)***
>
> *Some reviewers of the June 1st proposal found even this simple categorization system too complex. In response, Ecology has substituted vague language regarding relative ranking and a multi-year schedule, perhaps to be supplemented with additional guidance on selection factors.* ***(Llewellyn Matthews, p. 3 of November 2005 written comments)***
>
> ***7. The rule should provide a process for selecting chemicals for development of CAPs.*** *The rule proposed on June 1, 2005, provided a simple ranking scheme for prioritizing chemicals already on the PBT list for development of chemical action plans (CAPs). This language is not present in the revised proposal. The rule should include a systematic approach for ranking chemicals already on the PBT and use this ranking to prioritize chemicals for CAP development. As part of this ranking system, NCASI encourages Ecology to incorporate metrics for quantity and prevalence in Washington.* ***(Jeff Louch, p. 6 of November 2005 written comments)***

The Association of Washington Business recommended that Ecology modify the rule to clearly state that the relative ranking would be based on Ecology's evaluation of relative risk to Washington residents.[102]

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on this issue and decided not to modify the proposed language. Ecology's rationale for not making the suggested changes is briefly described below:

- Level of Detail: Ecology acknowledges that a simple listing of evaluation factors does not provide a clear indication of how those factors will be considered in a particular ranking framework because the development of such a framework will require choices on metrics, data sources, evaluation scales and weighting of different factors. Those design choices can have a considerable impact on the relative ranking of individual PBT chemicals. However, Ecology decided not to expand this section to provide additional detail because (1) adding more detailed language at this stage of the rulemaking process would preclude meaningful public comment on those details, (2) Ecology has determined this is a "procedural rule"; and (3) members of the public will have an opportunity to review and provide comments on the relative ranking and the multi-year schedule prior to Ecology finalizing the initial multi-year schedule. Ecology encourages interested organizations and individuals to participate in the development of the multi-year schedule.
- Phrase "Risk to Washington Citizens": Ecology reviewed the Association of Washington Business's recommendation that Ecology insert the phrase "risk to Washington residents" into this subsection and decided not to make the suggested change. While Ecology agrees with the underlying concept, the Department believes that the suggested language may create expectations for highly quantitative risk estimates that are inconsistent with ranking an prioritization approaches used by other Ecology programs (e.g. Washington Ranking Method used to rank sites under the Model Toxics Control Act) and approaches discussed with the PBT Rule Advisory Committee in October 2004.

Issue 6-8: Should Ecology evaluate opportunities for reductions during the priority-setting process?

Proposed Rule

The proposed PBT rules published in June and October 2005 specify that Ecology would consider opportunities for reduction when selecting PBTs for CAP preparation. The October 2005 proposed rule included the following language:

> *(ii) Opportunities for reductions. Whether there are opportunities for reducing or phasing out uses, production or releases of the PBT in Washington. In reviewing available information, the agencies shall consider whether more than one PBT is present in particular products, generated in particular processes or released from particular sources (co-occurring chemicals).*

[102] The Association of Washington Business provided the following suggested language: (i) **Relative ranking.** The relative ranking assigned to each PBT based on ecology's evaluation of risk to Washington residents, information on PBT characteristics, uses of the chemical in Washington, releases of the chemical in Washington, the levels of the chemical present in the Washington environment, and levels of the chemical present in Washington residents.

Public Comments and Concerns

Several organizations and individuals supported Ecology's proposal to consider "opportunities for reduction" when selecting chemicals for CAP preparation. However, Ecology received several suggestions for revising the proposed rule language in order to incorporate concepts of "feasibility", "effectiveness", "reasonable probability of success" and "measurable net benefit to human health and the environment". For example:

> *Opportunities for reducing or phasing-out uses and releases should be "feasible" and need to "have a measurable net benefit to human health and the environment". The concept of ensuring alternative chemicals and/or recommending actions that have a net benefit to human health and the environment was a widely shared viewpoint by stakeholders who participated on Ecology's advisory committee* ***(Grant Nelson, p. 3 of July 2005 written comments)***[103]
>
> *Fundamental to this rule is the decision whether a CAP is needed. Preparation of a CAP is a resource-intensive activity and every possible consideration should be explored before determining that a CAP is needed and will be effective. There was much debate in the stakeholder group regarding the concern that CAPs be addressed to actual environmental problems in Washington State and the measures selected are effective in reducing the identified problem.*
>
> *The proposed rule contains two important sections in this regard. WAC 173-333-310(3) allows Ecology to place chemicals in Category 3 if already prohibited or if there are no feasible measures beyond those already required under other laws and regulations. In a companion section, WAC 173-33-410(3)(a)(ii), Ecology is charged with examining whether there are opportunities for reduction as part of the criteria for selection of chemicals for CAPs.*
>
> *NWPPA appreciates these steps but upon further reflection on the relationship between the two sections, it appears that an important concept was not captured in the proposed rule. The proposed rule sections, when viewed together, fall short of assessing whether measures could be effective for abating an identified problem.*
> *Comment:*
> - *Assessment of "probability of success" should be a specific consideration in the rule.*
> - *A logical place would be to insert an additional section following WAC 173-333-410(3)(a)(ii)* ***.(Llewellyn Matthews, p. 3 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments received on this issue and decided not to revise the proposed language. Ecology's rationale for not making the suggested changes is briefly described below.

- Consideration of "Feasibility": Ecology agrees that "feasibility" is an appropriate consideration when preparing chemical action plans. However, Ecology believes that inserting the word "feasible" into this sub-paragraph could create the expectation that Ecology will need to determine that an alternative is feasible before deciding whether to evaluate the feasibility of the alternative. In other words, Ecology does not believe it is appropriate to require the Department to prepare the evaluations that are part of the CAP in

[103] The Association of Washington Business provided suggested rule language with their comments on the June and October proposals. They included the following suggested language with the comments submitted in November 2005: *(ii)* ***Opportunities for reductions.*** *Whether there are feasible opportunities for reducing or phasing out uses, production or releases of the PBT in Washington that will have a measurable net benefit to human health or the environment. In reviewing available information, the agencies shall consider whether more than one PBT is present in particular products, generated in particular processes or released from particular sources (co-occurring chemicals).*

order to decide whether to prepare a CAP for a particular chemical. However, the PBT rule creates a phased decision-making process with increasing levels of evaluations needed to support decisions at various stages of the process. Ecology does not believe that the process creates a "bright line" that restricts consideration of relevant information at various stages of the decision-making process. Consequently, Ecology believes that consideration of "feasibility" or "potential feasibility" is a relevant consideration in determining whether there are "available" opportunities for reducing or phasing-out uses, releases and exposures during the CAP selection process. However, Ecology is concerned that inserting the word "feasible" into this subsection could create an expectation that such evaluations would extend beyond a screening level consideration of feasibility.

- Consideration of "Net Benefits to Human Health and the Environment": Ecology believes that "net benefits to human health and the environment" is an appropriate consideration when preparing chemical actions plans. However, Ecology believes that characterization of such benefits at the CAP selection stage would require Ecology to first prepare the CAP in order to justify a decision on whether to prepare a CAP for a particular PBT in the first place.
- Consideration of "Probability of Success": Ecology believes that the underlying concept reflected in this comment is a good one in that Ecology should consider the likelihood that its efforts will make a difference in terms of reducing PBT uses, releases and exposures. However, Ecology believes this concept is already incorporated into the existing evaluation factors (particularly WAC 173-333-410(1)(a)(ii), WAC 173-333-410(1)(a)(iv) and WAC 173-333-410(1)(b)). Ecology is also concerned that this term implies a level of analysis that is at odds with the phased decision-making process included in the rule. Similar to the rule revisions discussed above, Ecology believes that an evaluation of the "probability of success" at the CAP selection stage of the process would require Ecology to complete significant portions of the CAP in order to justify a decision on whether to prepare the CAP in the first place.

Issue 6-9: Should Ecology consider existing plans and requirements when setting priorities for chemical action plans?

Proposed Rule

The proposed PBT rules published in June and October 2005 specify that Ecology would consider opportunities for reduction when selecting PBTs for CAP preparation. The October 2005 proposed rule included the following language:

> *(v) Existing plans or regulatory requirements. Whether there are existing plans or regulatory requirements that reduce and phase out uses and releases of a particular PBT or group of PBTs.*

Public Comments and Concerns

Several organizations supported Ecology's proposal to consider existing plans and regulatory requirements when selecting chemicals for CAP preparation. For example:

> *....A determination of whether measures already in place are appropriate to protect human health and the environment is also critical to guiding Ecology's priorities and determining whether or not there is a need for Ecology to take additional actions to address a particular chemical.* ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

However, several organizations also recommended that Ecology limit consideration of existing plans and requirements to those that have been effective in reducing and phasing out uses and releases of a particular PBT or group of PBTs. The Washington Toxics Coalition recommended the following revisions:

> *Existing plans or regulatory requirements. Whether there are existing plans or regulatory requirements that have been effective in reducing and phasing-out uses and releases of a particular PBT or group of PBTs.*

The Association of Washington Business recommended that Ecology modify this paragraph by referring to "requirements that reduce or phase-out" instead of "requirements that reduce and phase-out".

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on this issue and decided not to revise the proposed rule language. Ecology's rationale for not making the suggested changes is briefly described below.

- Consideration of "Effectiveness": Ecology agrees that "effectiveness" of existing plans or requirements is an appropriate consideration when preparing chemical action plans. Ecology also believes that consideration of "effectiveness" is implicit in reviewing whether there are "existing plans or regulatory requirements that reduce or phase-out uses and releases" during the CAP selection process. However, Ecology is concerned that inserting the word "effectiveness" into this paragraph would blur the distinction between a screening level consideration of effectiveness during the CAP selection process and a more detailed assessment performed as part of the CAP.
- Choice of "and" vs. "or": With respect to the choice of "and" versus "or", Ecology believes that the choice of one or the other term does not translate into a substantive difference in how this particular paragraph is implemented. In either case, Ecology will consider plans/requirements that (1) reduce uses and releases, (2) phase-out uses and releases and (3) reduce and phase-out uses and releases. When setting priorities, Ecology would consider existing plans and requirements within the context of whether there are additional opportunities for reductions.

Issue 6-10: Are there situations where Ecology should not prepare chemical action plans for chemicals on the PBT List?

Proposed Rule

The proposed rule published in October 2005 identified several situations where Ecology would not prepare chemical action plans for particular PBT chemicals:

> *(b) Ecology will not prepare CAPs if the department determines:*
> *(i) All uses and releases of the PBT are prohibited under other state and federal laws or regulations;*
> *(ii) There is credible scientific information to support a conclusion that the PBT is not used, released or present in Washington; or*
> *(iii) There are no available opportunities for reducing or phasing out the uses, releases or exposures of the PBT beyond levels required under other federal or state laws or regulations.*

Public Comments and Concerns

Several organizations and individuals expressed support for Ecology's proposed approach.

> *....A determination of whether measures already in place are appropriate to protect human health and the environment is also critical to guiding Ecology's priorities and determining whether or not there is a need for Ecology to take additional actions to address a particular chemical.* ***(Michael Wall and Clifford Howlett, p. 4 of July 2005 written comments)***

However, organizations providing comments on this issue suggested several modifications to the proposed language. For example:

> *WAC 173-333-410(2)(b) Ecology will not prepare CAPs – Subsection (2)(b) is a very practical acknowledgement that there could be valid reasons why the effort and expense of CAP development is not warranted. Still, the wording of subsections (2)(b)(i) and (ii) and (iii) is so narrow that it might literally preclude a smart decision not to proceed to a CAP. Weyerhaeuser believes (2)(b)(iii) should be adjusted to read*
>
> *(iii) There are no ~~available~~ feasible opportunities for reducing or phasing out the uses, releases or exposures of the PBT beyond levels required under other federal or state laws or regulations.* ***(Ken Johnson, p. 3 of November 2005 written comments)***

The Association of Washington Business provided similar suggestions for revision subparagraph (iii) and recommended that Ecology include a fourth situation where a CAP is not warranted:

> *(iii) There are no available feasible opportunities for reducing or phasing out the uses, releases or exposures of the PBT beyond levels required under other federal or state laws or regulations.*
>
> *(iv) The likely net benefit or risks to human and health or the environment does not justify the development of a CAP****. (Grant Nelson, Attachment to November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments and decided not to modify the rule language included in the October 2005 proposed rule. Ecology agrees that there will be situations where it does not make sense to prepare a chemical action plan and that the proposed rule language provides sufficient direction and flexibility to consider factors relevant to this issue. Ecology's rationale for not making the suggested changes is similar to the rationale discussed under Issue 6-8. Specifically, Ecology believes the suggested language would result in the Department having to prepare evaluations that are normally prepared as part of the CAP process in order to justify a decision to prepare a CAP in the first place. Ecology believes this is at odds with (1) the phased-decision-making process established in the rule and (2) comments from several organizations who stated that Ecology should not be preparing chemical action plans to justify the preparation of those plans.

Issue 6-11: Does the proposed rule provide reasonable opportunities for public review during the CAP selection process?

Proposed Rule

The proposed rule published in October 2005 established a process for public review of the multi-year schedule that included (1) preparing a preliminary schedule; (2) publishing an announcement of the preliminary selection in the State Register with a 60 day public comment period; and (3) publishing an announcement of the final schedule in the State Register after review and evaluation of public comments.

Public Comments and Concerns

Organizations providing comments on the proposed rule appeared to support the proposed process for public review of Ecology's decisions on the multi-year schedule. For example, both the Association of Washington Business and the Washington Toxics Coalition provided the redlined versions of the proposed rule that included the main features of the public review process.

The Puget Sound Action Team recommended that Ecology use the public review process to collect information and suggestions from the public that could be used to prepare individual chemical action plans:

> *We see the public notice and comment section outlined in WAC 173-333-410 (3)(c) as an excellent opportunity to collect information from the public to help develop a Chemical Action Plan. Specifically, we recommend directing the public to comment on the rank order of the chemical under review for the chemical action plan, the PBT's presence in the environment, and suggestions for corrective actions to include in the chemical action plan.* ***(John Dohrmann, p. 2 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comment on this issue and agrees with the comment and plans to use the public comment period on the preliminary schedule as a mechanism for obtaining information on uses, releases, environmental concentrations, etc.

6.3. What are the contents of a CAP? (WAC 173-333-420)

Issue 6-12: ***Does the proposed rule identify a reasonable range of factors to consider on the production, uses and releases of PBT chemicals?***

Proposed Rule

WAC 173-333-420(1)(b) of the proposed PBT rule published in October 2005 specified that chemical action plans will include information on production, uses and releases:

> *(b)* ***Production, uses and releases.*** *An analysis of information on the production, unintentional production, uses and disposal of the chemical. This will include estimates on the amount of each PBT used and released from all sources or activities in Washington and other man-made and naturally occurring sources that may contribute to exposures in Washington. Sources may include other chemicals or products that are known or suspected to degrade to the chemical included on the PBT list.*

Public Comments and Concerns

In their comments on the June 2005 proposed rule, the Association of Washington Business recommended that Ecology insert the phrase "man-made and naturally-occurring" into this paragraph.

> *PBTs include man-made and naturally occurring sources and need to be part of any analysis estimating the amount of PBTs used and released* ***(Grant Nelson, p. 3 of July 2005 written comments)***

...CAPs should be based on a proper characterization of the actual risk presented by the chemical, including an accounting of sources within the state – both natural and manmade.... ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

In their comments on the October 2005 proposed rule, the Association of Washington Business recommended that Ecology remove the word "suspected" from last sentence in this subsection because they believe it undermined the integrity of the PBT rule and was inconsistent with using the weight of credible scientific information to support Ecology decision-making:

WAC 173-333-420 What are the contents of a CAP? *Consistent with earlier comments regarding the integrity of the PBT rule and the weight of credible scientific information being used, the term "suspected" should be deleted from the rule identifying sources.* ***(Grant Nelson, p. 3 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on this section. In response to the comment on the June 2005 proposed rule, Ecology modified this paragraph to clearly recognize that sources of PBT chemicals may be naturally-occurring or man-made. However, Ecology believes that it is appropriate to use the term "suspected" in this paragraph because it incorporates concepts such as scientific uncertainty, differences in the quality of available data, etc. Ecology believes it is important to consider such factors when compiling information on production, uses and releases.

Issue 6-13: Does the proposed rule identify a reasonable range of factors to consider on human health and environmental impacts?

Proposed Rule

WAC 173-333-420(1)(c) of the proposed PBT rule published in June 2005 specified that chemical action plans will include an evaluation of human health and environmental impacts:

(c) ***Human health and environmental impacts.*** *Information on the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.*

The proposed PBT rule published in October 2005 specified that chemical action plans will include information on human health and environmental impacts:

(c) ***Human health and environmental impacts.*** *Information on the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.*

Public Comments and Concerns

Several organizations expressed support for Ecology's proposal to include an evaluation of human health and environmental impacts in chemical action plans. For example:

Screening of PBT characteristics is a critical step for identifying candidate substances rapidly. However, screening of PBT characteristics is only the starting point for conducting appropriate risk assessments to determine if new or additional risk management efforts are necessary. ....CAPs should

be based on a proper characterization of the actual risk presented by the chemical, including an accounting of sources within the state – both natural and manmade....In developing CAPs, Ecology should also consider utilizing existing risk assessment documents developed by EPA and other reputable governmental agencies (for example, risk assessments developed by EPA's National Center for Environmental Assessment). Using existing assessments avoids duplicative work for Ecology as they examine the human health and environmental impacts a PBT chemical may pose in Washington.... As called for in Section 420 (1)(c), a CAP should be based on an assessment of existing levels in the environment and evidence of adverse effects to human health or the environment. ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

However, several other organizations stated that additional evaluation was unnecessary once a chemical was on the PBT list. For example:

COMMENTS: An evaluation of the health and environmental impacts is not necessary as part of the CAP. If a chemical is on the list and eligible for a CAP, then the chemical has already been determined to be harmful to human health and the environment. Further analysis is not warranted and will only waste time on a debate about whether a chemical is a problem. We recommend requiring information on the health and environmental impacts instead of requiring an evaluation. (Ivy Sager-Rosenthal, p. 11-12 of July 2005 written comments)

The Association of Washington Business recommended that Ecology the potential for exposure when evaluating human health and environmental impacts:

WAC 173-333-420 What are the contents of a CAP? .....*When assessing impacts on human health and the environment, the "potential for exposure" should be included.* ***(Grant Nelson, p. 3 of November 2005 written comments)***

The American Chemistry Council/Chlorine Chemistry Council recommended that Ecology replace the term "body burden" with "biomonitoring":

Replace the Term "Body-Burden" with "Biomonitoring." *Section 173-333-420(1)(d) states "This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available* ***body-burden data****, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT." Rather than refer to "body-burden" data, the Rule should refer to "biomonitoring" data. Biomonitoring is the more commonly used and accepted term for data on levels of chemicals in the body. Also, "biomonitoring" is the term used by the U.S. Centers for Disease Control and Prevention.* ***(Michael Walls and Clifford Howlett, p. 6 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to make the following revisions to the language in the October 2005 proposed rule:

(c) ***Human health and environmental impacts.*** *Information on the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, potential for exposure, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.*

The final rule language reflects several changes relative to the rule language in the June 2005 proposed rule. Ecology's rationale for those changes is briefly summarized below:

- Information vs. Evaluation: Ecology reviewed the suggestion that the Department clarify that chemical action plans will include information on human health and environmental impacts, but would not re-evaluate information used to prepare the PBT list. Ecology has made the suggested change because the Department does not plan to re-evaluate earlier information. However, Ecology also believes that CAPs will include further evaluations of health and environmental impacts to support conclusions on (1) the environmental and human health benefits associated with recommended actions, (2) economic and social impacts of the recommended alternatives, (3) determinations on whether various substitutes are "safer" or "less harmful" and (4) consideration of new scientific information that is developed subsequent to the preparation of the PBT list and multi-year schedule.
- Potential for Exposure: Ecology has reviewed and evaluated the comments on this issue and decided to include "potential for exposure" on the list of information considered in the chemical action plan. Ecology believes this includes consideration of exposure pathways, potential for exposure via those pathways and the relative importance of those pathways in terms of overall exposure. This information will inform other steps in the evaluation process. For example, information on the relative importance of different pathways will help Ecology to develop recommendations for minimizing exposure to specific PBTs or group of PBTs (WAC 173-333-420(1)(f)(iii)).

Ecology also agrees with the recommendation to replace the term "body-burden" with "biomonitoring". However, that change was not included in the final revisions submitted to the Office of the Code Reviser's Typing Service and the final rule contains the term "body burden". Ecology intends to make this revision as part of a future rule update.

Issue 6-14: Does the proposed rule identify a reasonable range of policy options to be considered when preparing the chemical action plans?

Proposed Rule

WAC 173-333-420(1)(e) in proposed PBT rules published in June and October 2005 specified that chemical action plans will include a list of options for managing, reducing and eliminating the different uses and releases of PBTs addressed in the CAP:

> *(e)* ***Identification of policy options.*** *A list of options for managing, reducing and eliminating the different uses and releases of the PBTs addressed in the CAP. The range of options for particular uses and releases will include:*
>
> *(i) A no-action option;*
> *(ii) An option that results in the elimination of PBT uses and releases;*
> *(iii) An option to manage chemicals to reduce exposure; and*
> *(iv) Other options, including the use of available substitutes, which will enable full consideration of the opportunities and constraints for reducing particular uses, releases and exposures.*

Public Comments and Concerns

Several organizations expressed support for Ecology's proposal to consider a range of policy options when preparing chemical action plans. For example:

> *We applaud Ecology for proposing a focused and workable list of recommended policy options for Chemical Action Plan (CAP) development. Successful CAPs will give full consideration to the possible risk reduction actions, including reduction or elimination of uses and releases, waste and*

product management, and exposure minimization, coupled with a feasibility analysis and measures of effectiveness.... ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

However, the Washington Toxics Coalition recommended that Ecology delete this subsection and replace it with a subsection that focuses on the analysis of options. They also recommended that the analysis of policy options be designed to place greater emphasis on analyzing options that involve replacing chemicals or processes with safer alternatives. They provided the following suggested language to illustrate how this concept could be included in the rule:

i. ***Analysis of policy options****. An analysis of policy options for addressing each PBT. In conducting the analysis, the department reduction and elimination options, including any material, process or function substitutions that could be implemented to replace the chemical.*

1. *Availability of alternatives. Whenever safer alternatives for a particular use are identified, the recommendation shall be to eliminate the chemical for that particular use. If a safer alternative is not available, then the recommendation shall be to conduct additional research on potential alternatives and provide incentives for those businesses actively involved in researching potential alternatives. The department shall re-evaluate the availability of alternatives at least every two years after the issuance of the CAP* ***(Ivy Sager-Rosenthal, Attachment to July 2005 written comments)***

Several organizations stated it was particularly important that the list of options include a "management" option. For example:

....Actions recommended as part of chemical action plans to accomplish the goal of reducing threats to human health and the environment must consider and include a "management" option. An example might include a process or handling change in operation to address a particular exposure pathway, rather than a reduction in use of that particular chemical. ***(Grant Nelson, p. 2 of July 2005 written comments)***

There were also several organizations who urged Ecology to consider" available alternatives" or "safer substitutes" that pose less harm to human health and the environment. For example:

Focus on preventing pollution through process/product changes and finding safer substitutes ***(Heather Trim, p. 2 of July 2005 written comments).***

The Association of Washington Business recommended that Ecology modify the rule language in to be more consistent with other parts of the rule:

In order for policy options to remain consistent with other sections of the rule, actions should be "feasible" and the term "elimination" should be replaced with "phasing-out". ***(Grant Nelson, p. 4 of November 2004 written comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to make the following revisions to the language contained in the October 2005 proposed rule:

(e) ***Identification of policy options.*** *A list of options for managing, reducing and ~~eliminating~~ phasing-out the different uses and releases of the PBTs addressed in the CAP. The range of options for particular uses and releases will include:*

(i) A no-action option;
(ii) An option that results in the ~~elimination~~ phase-out of PBT uses and releases;
(iii) An option to manage chemicals to reduce exposure; and
(iv) Other options, including the use of available substitutes, which will enable full consideration of the opportunities and constraints for reducing particular uses, releases and exposures.

These changes are part of Ecology's efforts to use consistent terminology throughout the rule. In this case, Ecology has decided to use the term "phase-out" instead of "elimination" since the former reflects the concept that getting rid of particular uses and releases will occur over a period of time [See Issue 3-1].

In preparing the final PBT rule, Ecology also considered the other comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

- Recommendation to Delete Subsection: The three-step process of identifying policy options, evaluating those options and preparing recommendations is at the center of the CAP process. Ecology believes that identification of policy options is a necessary first step in this three-step process. This step includes identification of a wide range of options followed by an initial screening to select the options that will be evaluated in greater detail. The concept of identifying available alternatives and performing a screening level analysis is inherent in several other environmental review processes (e.g. environmental impact statements prepared pursuant to the State Environmental Policy Act; remedial investigation/feasibility study prepared pursuant to the Model Toxics Control Act, etc.).
- Use of the Term "Feasibility": Ecology agrees that the "feasibility" of various policy options/alternatives needs to be evaluated when preparing CAP recommendations. However, that evaluation occurs after identifying the range of policy options/alternatives. Consequently, Ecology believes that inserting the word "feasible" into this paragraph would create a situation where Ecology has to determine that an alternative is feasible before deciding whether to evaluate the feasibility of the alternative. Although Ecology decided not to insert the word "feasible" into this paragraph, Ecology views the CAP evaluation process as a phased process with increasing levels of detail at each stage of the evaluation process. Consequently, Ecology believes that an initial consideration of "feasibility" is implicit in reviewing whether there are "available" substitutes. However, Ecology does not want to create an expectation that such screening level analyses will be equivalent to the assessment of technical feasibility performed to support the final CAP recommendations.
- Use of the Term "Less Harmful": Similar to the concerns about inserting the word "feasibility" into this paragraph, Ecology believes that replacing the word "available" with "less harmful" would create a situation where Ecology has to determine that an alternative is "less harmful" before deciding whether to evaluate the safety of the alternative. Ecology envisions that the actual preparation of a CAP will involve identification of available substitutes followed by an evaluation of whether those substitutes are "less harmful". This evaluation approach was used in the chemical action plan for PBDEs. Under this approach, the range of policy options/alternatives may include alternatives that are screened out later in the process because they are not "less harmful" than the PBT being evaluated in the CAP.

Issue 6-15: Does the proposed rule identify a reasonable range of recommendations to be included in chemical action plans?

Proposed Rule

The proposed PBT rule published in June 2005 included the following language in WAC 173-333-400(2):

(2) CAPs will include recommendations for:

a. Reducing and eliminating uses and releases of the specific PBT or group of PBTs addressed in the CAP;

b. Managing products or waste that contain the specific PBT or group of PBTs addressed in the CAP;
c. Minimizing exposure to the specific PBT or group of PBTs;
d. Collecting additional information needed to evaluate the feasibility of potential actions; and
e. Measuring or monitoring the effectiveness of actions being implemented in Washington.

Ecology reviewed the comments on the June 2005 proposed rule and decided to consolidate similar provisions that appear in more than one section of the rule. The proposed PBT rule published in October 2005 specified that chemical action plans will include several types of recommendations:

(f) ***Recommendations.*** *Recommendations for:*
(i) Reducing and phasing-out uses and releases of the specific PBT or group of PBTs addressed in the CAP;
(ii) Managing products or wastes that contain the specific PBT or group of PBTs addressed in the CAP; and
(iii) Minimizing exposure to the specific PBT or group of PBTs.

Public Comments and Concerns

The June 2005 proposed rule listed the types of recommendations to be included in a chemical action plan in two different sections. In their comments on the June 2005 proposed rule, several organizations recommended changes to the language on particular recommendations identified in WAC 173-333-400(2). For example:

- The Association of Washington Business recommended that the word "eliminating" be replaced by the word "phasing-out" in paragraph (a);
- The Washington Toxics Coalition recommended that Ecology revise paragraph (b) to read as "Properly disposing of products or waste that contain the specific PBT or group of PBTs addressed in the CAP";
- The Association of Washington Business recommended that the word "minimize" be replaced with the word "reduce in paragraph (c). The Washington Toxics Coalition recommended that this paragraph be revised to read as "Actions individuals can take to minimize their exposure to the specific PBT or group of PBTs.

In their comments on the June 2005 proposed rule, the Washington Toxics Coalition recommended that WAC 173-333-420(f) be re-titled ("recommendations for reducing and eliminating the chemical") and that CAPs include recommendations for developing markets for less toxic alternatives:

> *We also suggest that CAPs include recommendations for developing markets for less toxic alternatives. This approach can be a strong driver for getting large sectors (business, government) to move away from toxic chemicals to safer substitutes.* ***(Ivy Sager-Rosenthal, p. 5 of July 2005 written comments)***[104]

The Association of Washington Business recommended that Ecology modify WAC 173-333-420(1)(f)(i) by replacing the word "and" with the word "or". ***(Grant Nelson, p. 4 of November 2004 written comments)***

The Washington Toxics Coalition recommended that Ecology clarify the role of safer alternatives:

[104] The Washington Toxics Coalition provided the following suggested language: (f) Developing markets for less toxic alternatives.

Clarify Role of Safer Alternatives *We appreciate Ecology's willingness to incorporate the idea of safer substitutes into CAPs. However, the new language does not capture what we believe to be the role of safer substitutes in phasing out PBTs. The rule as currently drafted appears to use the availability of safer alternatives to determine whether to take action on a PBT rather than as stand alone recommendations. One of the most important purposes of the PBT program is to encourage businesses and others to develop safer alternatives so they can switch out of PBT chemicals. CAPs must include recommendations for switching businesses to safer alternatives if the safer alternatives exist. If safer alternatives do not currently exist, CAPs should include recommendations on how to encourage the development of safer alternatives and how Ecology will check back to determine whether a safer alternative has been developed.* ***(Ivy Sager-Rosenthal, p. 4 of November 2005 written comments)***[105]

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to make the following revisions to the language contained in the October 2005 proposed rule:

(f) ***Recommendations.*** *Recommendations for:*

(i) *Reducing and phasing-out uses and releases of the specific PBT or group of PBTs addressed in the CAP;*

(ii) *Managing products or wastes that contain the specific PBT or group of PBTs addressed in the CAP; and*

(iii) *Minimizing exposure to the specific PBT or group of PBTs.*

(iv) *Switching to safer substitutes; and*

(v) *Encouraging the development of safer alternatives.*

This revision was made as part of a package of revisions on the issue of safer substitutes. The rationale for these revisions is discussed under Issue 6-21. In preparing the October 2005 proposed rule, Ecology also decided to use the term "phase-out" instead of "elimination" since the former reflects the concept that getting rid of particular uses and releases will occur over a period of time [See Issue 3-1]. These changes were part of Ecology's efforts to use consistent terminology throughout the rule.

In preparing the final PBT rule, Ecology considered the range of other comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

Use the Term "Managing" vs. "Properly Disposing": Ecology reviewed the suggestion that Ecology replace the word "managing" with "properly disposing" and decided to retain the proposed language. Ecology believes that the term "managing" encompasses "properly disposing" but does not limit recommendations to disposal. The recommendations for managing products or wastes may include recycling or reuse which are options that are often preferable to disposal.

[105] The Washington Toxics Coalition recommended that Ecology add the following measures to list of recommendations: (iv) Switching to safer substitutes; and (v) Encouraging the development of safer alternatives.

- Use of the Term "Minimizing" vs. "Reducing": Ecology reviewed the suggestion that Ecology replace the word "minimizing" with "reducing" and decided to retain the proposed language because a primary focus of this type of recommendation will be steps that individuals can take to reduce exposure. Ecology believes that the choice of the word "minimizing" is consistent with the fact that implementation of these types of recommendations will require continuing efforts to reduce uses, releases and exposures.
- Developing Markets for Less Toxic Alternatives: CAPs for individual PBTs may include an evaluation of available markets for less toxic alternatives (safer substitutes) and/or the feasibility that such markets could be developed in the future. If the CAP includes recommendations on the use of safer substitutes, Ecology might also identify steps the Department will take to implement such a recommendation (e.g. agency purchases, research, etc.) However, Ecology does not envision the CAPs addressing the mechanics of "how" to develop such markets. In general, Ecology does not think the Department is well suited to address the myriad of issues associated with how to develop markets for safer alternatives; these issues are best addressed by the business community.
- Subsection Title: Ecology considered the recommendation to revise the title of this subsection and decided not to make the suggested change. Based on Ecology's experience preparing chemical action plans for mercury and PBDEs, chemical action plans will include a wide range of actions that extend beyond reducing and eliminating the chemical (e.g. information collection, additional evaluations, etc.).
- Choice of "and" vs. "or": With respect to the choice of "and" versus "or", Ecology believes that the choice of one or the other term does not translate into a substantive difference in how this particular paragraph is implemented.

Issue 6-16: Are recommendations included in chemical action plans considered mandatory requirements or voluntary actions?

Proposed Rule

The proposed PBT rules published in June 2005 and October 2005 specified that chemical action plans will include several types of recommendations. Based on past experience, Ecology believes those recommendations will be implemented through a combination of regulatory and voluntary approaches. The October 2005 proposed rule specified that Ecology should describe the steps it intends to take to implement both regulatory and voluntary approaches.

- *How ecology will promote and assist voluntary actions (WAC 173-333-420(1)(g)(iv));*
- *Any recommended regulatory actions and how ecology will pursue them (WAC 173-333-420(1)(g)(vi)).*

Public Comments and Concerns

The Independent Business Association recommended that Ecology provide a clear statement in the rule that the CAP recommendations are voluntary actions:

> *IBA is willing to accept the conclusion of the Department that the proposed new rule will not have an economic impact on small businesses and thus no Small Business Economic Impact Statement is required for this proposed rule if one clarification is made...We believe one additional clarification is needed to clearly notify all parties that a CAP's recommendations are truly voluntary actions and*

someone or some entity who does not follow a CAP's recommendations will not be subject to any citation or sanction...

> *WAC 173-333-420(f) Recommendations. Recommendations in a CAP are voluntary actions that are recommended and failure to take voluntary action shall not subject a person to any sanction or penalty, nor shall any recommendation be the basis of a directive or interpretation for the application of any existing agency law or rule****....(Gary Smith, p. 1 of July 2005 written comments)***

However, other organizations recommended that Ecology clearly state that chemical action plans may include recommendations for regulatory actions. For example, the Washington Toxics Coalition recommended that Ecology revise WAC 173-333-420(1)(f)(ii) in the June 2005 proposed rule to state that chemical actions plans will include descriptions of "...how Ecology will pursue further regulatory actions identified in the plan..."

Ecology's Review and Response to Public Comments

Ecology has reviewed the comments on this issue and decided not to make revisions to the language in the October 2005 proposed rule. Ecology believes the current rule language reflects the following concepts:

- Chemical action plans may include recommendations to establish regulatory requirements that would be implemented through existing regulatory programs and processes. Ecology and other applicable agencies will comply with applicable rulemaking, permitting or other administrative requirements when establishing regulatory requirements to implement particular recommendations. For example, if a chemical action plan includes a recommendation for Ecology to establish a rule to limit certain PBT uses or releases, Ecology will comply with the applicable APA rulemaking requirements when preparing such rules.
- Chemical action plans may include recommendations that require new statutory authority for Ecology or other implementing agencies. Implementation of these recommendations will require action by the Washington Legislature.
- Chemical action plans may include recommendations to reduce/phase-out PBT uses and releases through voluntary actions. Ecology will implement these recommendations in a manner that is similar to other Ecology voluntary programs. Since these are voluntary programs, persons who elect not to implement the recommended measures will not be subject to penalties and sanctions.
- Chemical action plans will include performance measures to evaluate progress in implementing actions using regulatory and voluntary approaches. Ecology may decide to modify the initial approaches if they prove to be ineffective in reducing and phasing-out PBT uses and releases. For example, Ecology may decide to establish regulatory requirements for certain uses and releases if voluntary programs are found to be ineffective. As stated above, Ecology would comply with applicable rulemaking, permitting or other administrative requirements when establishing such regulatory requirements.

Issue 6-17: Does the proposed rule identify a reasonable range of evaluation factors that will be considered when preparing the recommendations included in chemical action plans?

Proposed Rule

The proposed PBT rule published in June 2005 specified that recommendations in the chemical action plans will be based on several factors:

> *The recommendations will be based on an evaluation of the following factors:*
> *(A) Feasibility of implementing the action;*
> *(B) Environmental and human health benefits associated with implementing the action;*
> *(C) Economic and social impacts associated with implementing the action; and*
> *(D) Consistency with existing federal and state regulatory requirements.*

Ecology reviewed the public comments and made several modifications to this subsection prior to republishing the proposed PBT rule in October 2005. The October 2005 proposed rule specified that recommendations in the chemical action plans will be based on several factors:

> *The recommendations will be based on an evaluation of the following factors:*
> *(A) Environmental and human health benefits associated with implementing the action;*
> *(B) Economic and social impacts associated with implementing the action;*
> *(C) Feasibility of implementing the action;*
> *(D) Availability, cost and effectiveness of safer substitutes for uses of the PBT being addressed in the plan; and*
> *(E) Consistency with existing federal and state regulatory requirements.*

Public Comments and Concerns

Several organizations expressed general support for the evaluation factors in the proposed rule. For example:

> *The success of a CAP will also be enhanced by consideration of the factors Ecology lists for evaluation in the development of recommended actions in the CAPs.*[106] *Feasibility, human health and environmental benefits, economic and social impacts, and consistency with existing federal and state regulatory requirements are critical factors in a CAP's ability to effectively manage, reduce, or phase-out PBT uses and releases.* ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

In their July 2005 comments, the Washington Toxics Coalition recommended that Ecology replace "feasibility of implementing the action" with "availability of alternatives" and that Ecology revise the language to incorporate a "decision rule" on the use of available alternatives[107].

Several organizations recommended that the list of evaluation factors include an assessment of "available alternatives" or "safer substitutes". The Association of Washington Business recommended that Ecology include an additional evaluation factor relevant to the consideration of safer substitutes:

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[106] WAC 173-333-420 Section 1(f(i)).

[107] The Washington Toxics Coalition provided the following suggested rule language to replace the phrase "Feasibility of implementing the action": Availability of alternatives. Whenever safer alternatives for a particular use are identified, the recommendation shall be to eliminate the chemical for that particular use. If a safer alternative is not available, then the recommendation shall be to conduct additional research on potential alternatives and provide incentives for those businesses actively involved in researching potential alternatives. The department shall re-evaluate the availability of alternatives at least every two years after the issuance of the CAP.

Consistent with the comment above and with comments made by members of the Advisory Committee, AWB requests that Ecology include in its recommendations "an assessment of available alternatives that pose less harm to human health and the environment than the PBT being addressed". ***(Grant Nelson, p. 4 of July 2005 written comments)***

The American Chemistry Council/Chlorine Chemistry Council urged Ecology to create a level playing field when evaluating particular chemicals and available substitutes:

As was discussed during the development of the proposed Rule, Ecology should recognize in the Rule that available substitutes must be evaluated for feasibility and potential risks just as the chemical for which the CAP is being developed. Substituting the risks presented by one chemical for known and unknown risks presented by another may lead to little or no benefit to human health or the environment. ***(Michael Walls and Clifford Howlett, p. 4 of written comments)***

Section 420 – It is not clear if the CAPs will include statements on what the recommended actions can reasonably expect to accomplish in terms of reduced exposure to residents. If specific actions are proposed to reduce or eliminate exposure, it is logical to identify the extent to which each action will impact exposure. This will provide a context for the Department's recommendations, allowing Ecology to demonstrate that the proposed actions are targeting priority sources. ***(Michael Walls and Clifford Howlett, p. 4 of written comments)***

In response to the comments on the June 2005 proposed rule, Ecology identified a fifth evaluation factor ("Availability, cost and effectiveness of safer substitutes for uses of the PBT being addressed in the plan") in the October 2005 proposed rule. The Washington Toxics Coalition recommended that Ecology delete the word "cost" from this phrase.

The Puget Sound Action Team recommended that Ecology clarify in the rule whether all factors would receive equal weight when preparing recommendations:

If the recommendations outlined in WAC 173-333-420 (1)(f)(i) (A-D) are in a rank order, we recommend that (B) Environmental and human health benefits associated with implementing the action is considered first. If they are not listed in rank order, include language that makes it clear that each of the criteria will be considered equally. ***(John Dohrmann, p. 2 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on this issue and decided to make the following revisions to the language contained in the October 2005 proposed rule:

The recommendations will be based on an evaluation of the following factors:

(A) Environmental and human health benefits associated with implementing the action;
(B) Economic and social impacts associated with implementing the action;
(C) Feasibility of implementing the action;
(D) Availability~~, cost~~ and effectiveness of safer substitutes for uses of the PBT being addressed in the plan; and
(E) Consistency with existing federal and state regulatory requirements.

The final rule language reflects several changes relative to the rule language in the June 2005 proposed rule. Ecology rationale for those changes is briefly summarized below:

- Evaluation of Safer Substitutes: Ecology added the phrase "availability, cost and effectiveness of safer substitutes for uses of the PBT being addressed in the plan" in response to comments on the June 2005 proposal rule. Ecology believes this is an important factor that should be evaluated when preparing chemical action plans. Ecology believes that explicitly identifying this as an evaluation factor will facilitate identification and full

evaluation of measures that are clearly linked to the goal of the chapter ("reduce and phase-out PBT uses and releases"). Ecology also believes that evaluation of safer substitutes will promote consistency with local, state, federal and international agencies that have established programs to encourage greater use of safer alternatives.

Ecology agrees that addressing "cost" as part of the assessment of safer substitutes is somewhat duplicative in that the costs of safer substitutes are considered when evaluating the economic and social impacts associated with implementing the action (subparagraph (B)).

- Relative Importance of Evaluation Factors: Ecology re-ordered the list of evaluation factors to provide a qualitative sense of the relative importance of each factor. The order in which the factors are listed reflects Ecology's view that "environmental and human health benefits associated with implementing the action" is the most important consideration when evaluating different policy options/alternatives. Ecology believes this is consistent with Ecology's mission and the statutory responsibilities assigned to the Department by the Washington Legislature.

In preparing the final PBT rule, Ecology considered the other comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

- "Feasibility of Implementing the Action" as an Evaluation Factor: Ecology disagreed with the suggestion that "feasibility of implementing the action" not be included on the list of evaluation factors. Ecology continues to believe that the "feasibility" of implementing various alternatives is an important factor in determining whether and when a particular option can be implemented in the real world. Ecology believes that the practical value and/or utility associated with preparing chemical action plans (in terms of changing real-world conditions) will be reduced if the feasibility of various alternatives is not considered when preparing the CAP recommendations.

Issue 6-18: Does the proposed rule identify a reasonable range of implementation steps to be included in chemical action plans?

Proposed Rule

The proposed PBT rule published in June 2005 specified that chemical action plans will include:

(ii) A description of the steps ecology will take to implement the CAP, including a description of:
(A) The existing resources and necessary additional budget ecology intends to use;
(B) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;
(C) How ecology intends to inform and educate affected persons about the CAP;
(D) How ecology will promote and assist voluntary actions;

The proposed PBT rule published in October 2005 specified chemical action plans will include:

(g) **Implementation steps.** A description of the steps ecology will take to implement the CAP, including a description of:
(i) The existing resources and necessary additional budget ecology intends to use;
(ii) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;
(iii) How ecology intends to inform and educate affected persons about the CAP;
(iv) How ecology will promote and assist voluntary actions;
(v) How ecology will collect additional information needed to evaluate the feasibility of potential actions; and

(vi) Any recommended regulatory actions and how ecology will pursue them.

Public Comments and Concerns

In their comments on the June 2005 proposed rule, the Washington Toxics Coalition recommended that Ecology identify "any recommended regulatory actions and how Ecology will pursue them" in the chemical action plan (Ivy Sager-Rosenthal, Attachment to July 2005 written comments).

In their comments on the October 2005 proposed rule, the Washington Toxics Coalition recommended that Ecology include timelines and performance measures for voluntary actions in each chemical action plan and identify regulatory alternatives that would be implemented if voluntary actions proved to be ineffective:

> *Ensure Success of Voluntary Programs The failure of the voluntary dental mercury MOU is evidence that unless backed with clear deadlines and mandatory actions, purely voluntary programs are not effective in achieving reductions and phase-outs. WAC 173-333-420 (1) (g) (iv) should be amended to include a description of how the effectiveness of voluntary measures will be evaluated, the timeline for implementation, and what will happen if the voluntary programs do not work. It is critical that voluntary programs be backed up with timelines and performance measures and plans for mandatory actions in case the voluntary measures do not work.* ***(Ivy Sager-Rosenthal, pp. 3-4 of November 2005 written comments)***[108]

The Weyerhaeuser Company recommended that Ecology consider the need for additional legislative authority and resources (for both Ecology and other implementing agencies) when preparing chemical action plans:

> *WAC 173-333-420(1)(g) Implementation Steps – It should be recognized that other state and/or local agencies might be better positioned to implement the CAP plan. It should also be acknowledged that additional statutory authority and regulation development may be required to equitably implement a CAP. Consequently, subsection (g) should be amended and supplemented:*
>
> *(g) Implementation steps. A description of the steps ecology and other state or local agencies will take to implement the CAP, including a description of:*
>
> *(vi) Any required legislative authority and recommended regulatory actions and how ecology will pursue them,*
>
> *(v) A projection of the resources and necessary budget required of other state agencies and local governments.* ***(Ken Johnson, p. 3 of November 2005 written comments)***

However, the American Chemistry Council/Chlorine Chemistry Council recommended that Ecology not consider potential funding sources during the CAP process.

> ***Identification of Funding Sources Should Not Be Included in the CAP.*** *Section 173-333-420 (1)(g)(ii) of the draft Rule, identifying potential funding sources ("PBT sources and products") for implementing CAPs, should be modified. Specifically, the reference to "including those that tie implementation costs to PBT sources and products" should be removed or modified. A more holistic approach would be "including an analysis of the impact and appropriateness of potential funding mechanisms." While certain economic instruments and market-based mechanisms may be appropriate, the state must carefully evaluate the impact and appropriateness of such mechanisms. In evaluating potential economic instruments it is important to emphasize the following:*

[108] The Washington Toxics Coalition provided the following suggested language with their July 2005 written comments: (D) How Ecology will promote and assist voluntary actions, including timelines for implementation of the voluntary action, performance measures, and alternate reduction ad mandatory actions if the voluntary action is not successful.

a. *Potential costs on a subset of products or processes may result in violation of the interstate commerce clause.*
b. *Potential costs on particular products or processes within a state are unlikely to be the most effective mechanism and can have unintended market distorting impacts. Any such policies need to first consider how this would impact in-state versus out-of state or out of country sources and products.*
c. *Potential costs on products or processes, assumes that the product or process is the resulting source impacting human health or the environment, when in fact such impacts may be the result of misuse by consumers or a consuming industry.*
d. *Potential costs on products or processes disregard the benefits of products and processes, which can provide critical benefits that are essential to society.* ***(Michael Walls and Clifford Howlett, pp. 5-6 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on this issue and decided to make the following revisions to the language contained in the October 2005 proposed rule:

(g) **Implementation steps.** A description of the steps ecology will take to implement the CAP, including a description of:
(i) The existing resources and necessary additional budget ecology intends to use;
(ii) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;
(iii) How ecology intends to inform and educate affected persons about the CAP;
(iv) How ecology will promote, ~~and~~ assist and evaluate the effectiveness of voluntary actions;
(v) How ecology will collect additional information needed to evaluate the feasibility of potential actions; and
(vi) Any recommended regulatory actions and how ecology will pursue them.

The final rule language reflects several changes relative to the rule language in the June 2005 proposed rule. Ecology rationale for those changes is briefly summarized below:

- Recommended regulatory actions: Ecology reviewed the suggestion that chemical actions plans describe "how Ecology will pursue further regulatory actions in the plan" and decided to include this provision in the final rule. EPA and Ecology have prepared chemical action plans that include recommendations for regulatory actions and steps for implementing those actions. Ecology believes this requirement will promote better agency planning, facilitate early public input on implementation steps and help to clarify that CAPs may include recommendations for both voluntary and regulatory actions.

- Effectiveness of voluntary actions: Ecology reviewed the suggestion that chemical action plans identify steps that Ecology will take to evaluate the effectiveness of voluntary actions and decided to include this provision in the final rule. Ecology believes this is consistent with government-wide effects to track progress and promote accountability[109]. Ecology also believes this requirement will promote better agency planning, improve long-term success and facilitate early public input on implementation steps. However, Ecology believes it will usually be premature for the chemical action plans to specify the steps that the Department will take if voluntary actions prove to be ineffective. Ecology believes it will be important to tailor any future agency actions so that such actions address the underlying reasons why the voluntary measures are not being implemented.

[109] State agencies in Washington are currently implementing a wide range of activities to measure and track performance through the Government Management, Accountability and Performance (GMAP) project.

In preparing the final PBT rule, Ecology also considered the other comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

- Other State and Local Agencies: Ecology agrees that other state and local agencies may be the most logical organizations to implement particular recommendations. The chemical actions plans for mercury and PBDE include several such recommendations[110]. However, Ecology has generally discussed the implementation of those recommendations in terms of the steps that Ecology can take to facilitate actions by other state and local agencies. Including a description of the steps and/or budget and resources for steps to be taken by other state and local agencies will require greater involvement by those entities in the CAP development process. Since Ecology is publishing this rule as a "procedural" rule, the Department decided not to revise the proposed language at this time. Ecology will re-evaluate the rule language if Ecology is able to obtain enough participation by other state and local agencies to include such implementation steps in future chemical action plans.
- Legislative Authority: Ecology agrees that the implementation of various CAP recommendations may require actions by the Legislature. Such actions may include creating laws prohibiting particular uses of PBTs, establishing additional legal authority for specific agency actions, funding recommended actions and/or directing agencies to conduct additional studies. The chemical action plans for mercury and PBDE include several such recommendations. Ecology believes the proposed rule language provides enough flexibility to include such recommendations in future chemicals action plans.
- Funding Sources: Ecology agrees that a holistic approach should be used to evaluate potential funding sources. Ecology believes that the first portion of subparagraph (g)(ii) reflects such an approach. The second portion of this subparagraph ("including those that tie implementation costs to PBT sources and products" was added to ensure that chemical action plans consider market-based mechanisms. Numerous agencies[111] have considered such approaches when implementing environmental programs. Ecology continues to believe such mechanisms should be considered when preparing chemical action plans, but agrees that Ecology must carefully evaluate the impact and appropriateness of such mechanisms. Ecology also agrees that such evaluation should consider, among other factors, the (1) interstate commerce clause issues, (2) potential for unintended market distortions, (3) relationship between product or process and human health and environmental impacts, and (4) benefits of products and processes.

Issue 6-19: Does the proposed rule identify a reasonable range of performance measures to be included in chemical action plans?

Proposed Rule

The proposed PBT rule published in October 2005 specified that recommendations in the chemical action plans will include performance measures:

[110] The PBDE chemical action plan includes recommendations for several state agencies other than Ecology. For example: "To ensure that workers in certain industries are not exposed to unacceptable levels of PBDEs, DOH and the state Department of Labor and Industries should continue to investigate the feasibility of implementing a workplace exposure study in collaboration with the federal Center for Disease Control and Prevention" (page xi)

[111] Environmental Protection Agency. 2001. The United States Experience with Economic Incentives for Pollution Control.: Environmental Protection Agency. 2004. International Experience with Economic Incentives for Protecting the Environment.

(h) ***Performance measures.*** *A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time.*

Public Comments and Concerns

Several organizations supported Ecology's proposal to identify performance for judging the effectiveness of actions taken to implement a chemical action plan. For example:

> *By including measuring and monitoring requirements for the steps proposed in the CAPs,* [112] *Ecology will better be able to determine the effectiveness of those actions. If it is determined that the actions are not protecting human health and the environment as desired, the appropriate revisions can then guide the CAP toward a more successful outcome. Overall, Ecology needs to approach the preparation of any CAP with realistic expectations about what can be accomplished and the benefits that will actually accrue to the people and environment of the State of Washington. Applying this approach will permit Ecology to assure that CAPs adopt the "least burdensome alternative"*[4]*.* ***(Michael Walls and Clifford Howlett, pp. 4-5 of written comments)***

The Association of Washington Business recommended that Ecology establish performance measures that include consideration of implementation costs and whether the goals and purposes of the CAP are being achieved:

> *....Performance measures need to include an assessment of costs to implement the CAP over time and a determination made as to whether the goals and purpose of CAPs are being met.* ***(Grant Nelson, p. 4 of November 2004 written comments)***[113]

As noted above, several organizations recommended that Ecology include timelines and performance measures for voluntary actions. For example:

> Voluntary Actions Must Include Timelines and Performance Measures. The rule should be amended to clarify that Ecology will require timelines for implementation and performance measures for any voluntary action adopted under a CAP. A voluntary action recommendation must also be accompanied by alternative reduction and mandatory actions if the voluntary action does not work. **(Ivy Sager-Rosenthal, p. 5 of July 2005 written comments)**[114]
>
> *Voluntary Actions Must Include Timelines and Performance Measures* ***(Trim, p. 2 of written comments)***

The Washington Toxics Coalition also discussed the importance of tracking progress in terms of promoting the use of safer substitutes:

> *CAPs must include recommendations for switching businesses to safer alternatives if safer alternatives exist. If safer alternatives do not currently exist, CAPs should include recommendations on how to encourage the development of safer alternatives and how Ecology will check back to determine whether a safer alternative has been developed.* ***(Ivy Sager-Rosenthal, p. 4 of November 2005 written comments)***

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[112] WAC 173-333-400 Section (1)(f)(iii) and WAC 173-333-420 (2)(e).

4 RWC 34.05.328 (1)(e)

[113] The Association of Washington Business provided the following suggested language: 420 (h) **Performance measures.** A description of interim milestones to assess progress and costs and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time and whether the goals and purpose of the CAPs are being achieved.

[114] The Washington Toxics Coalition provided the following suggested language: How Ecology will promote and assist voluntary actions, including timelines for implementation of the voluntary action, performance measures, and alternative reduction and mandatory actions if the voluntary action is not successful.

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments on performance measures and decided to make the following revision:

> *(h)* ***Performance measures.*** *A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time and whether the goals and purposes of the CAP are being achieved.*

The final rule language reflects several changes relative to the rule language in the June 2005 proposed rule. Ecology rationale for those changes is briefly summarized below:

- Achieving CAP Goals and Purposes: Ecology reviewed the suggestion that performance measures include indicators or measures to gauge whether the goals and purposes of the CAP are being achieved and decided to include that concept in the final rule. While this is a general statement, Ecology believes it provides additional guidance for identifying meaningful ways to gauge the impact of actions to implement chemical action plans.

In preparing the final PBT rule, Ecology also considered the other comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

- Implementation Costs: Ecology decided not to revise the rule language to create an expectation that Ecology will monitor implementation costs. While Ecology agrees this would be a useful indicator, Ecology believes that the suggested rule language would create unrealistic expectations given the difficulties the Department has encountered in obtaining reliable costs information for the purposes of evaluating the costs and benefits of agency rules and chemical action plans.
- Performance Measures for Voluntary Actions: Ecology decided not to revise this paragraph to single out performance measures for voluntary actions. Ecology believes the proposed rule language encompasses performance measures for voluntary actions. Ecology believes that the underlying concerns raised on this issue have also been addressed by the final language in WAC 173-333-420(1)(g)(iv) which was revised to incorporate language stating that CAPs will include a description of how Ecology will evaluate the effectiveness of voluntary actions.
- Performance Measures for Safer Alternative Development: Ecology decided not to revise this paragraph to single out performance measures for safer substitute development. Ecology believes the proposed rule language encompasses performance measures for the development of safer substitutes which can be included in chemical actions when the plans address this issue.

Issue 6-20: Does the proposed rule identify a reasonable range of factors to be considered when evaluating regulatory consistency?

Proposed Rule

The proposed PBT rule published in June and October 2005 specified several factors that Ecology would consider when evaluating regulatory consistency. The October 2005 rule included the following language:

> *(2)* ***Regulatory consistency.*** *When evaluating the consistency with existing federal and state regulatory requirements under subsection (1)(f)(iii)(E) of this section, ecology will:*

(a) Ensure that the recommendations do not violate existing federal or state laws;
(b) Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so; and
(c) Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal, state, and local laws applicable to the same activity or subject matter.

Public Comments and Concerns

Several organizations expressed support for Ecology's proposal for evaluating regulatory consistency. For example:

> *Finally, emphasizing coordination with existing federal, regional, and international initiatives will also further underscore the importance of regulatory consistency called for in WAC 173-333-420 Section (2).* ***(Michael Walls and Clifford Howlett, p. 4 of July 2005 written comments)***

> ***Ecology Should Ensure Integration of National and Regional Action Plans into CAPs.*** *In developing the Chemical Action Plans (CAPs), Ecology should ensure integration of existing Action Plans. Under the U.S. EPA PBT Chemical Program, the Agency is developing PBT Action Plans for priority PBT chemicals. In addition, North American Regional Action Plans (NARAPs) have been developed under the North American Commission for Environmental Cooperation (NACEC). These NARAPs were developed with input from Canada, U.S., Mexico, and interested stakeholders and reflect a regional perspective on existing international agreements, policies, and laws. Several EPA PBT Action Plans and NARAPs are in the implementation or development phase. Ecology should take advantage of these significant efforts and integrate any overlapping CAPs with these existing Action Plans.* ***(Michael Walls and Clifford Howlett, p. 5 of November 2005 written comments)***

> *...RCW 34.05.328 provides a set of safeguards pertaining to "significant legislative rules" (SLRs). AWB acknowledges that Ecology has determined that the PBT rule is a "procedural rule", however, because of the value they provide, we believe that these important SLR safeguards should be included in the development of CAPs and recommended actions....* ***(Grant Nelson, p. 4 of July 2005 written comments)***

However, other organizations recommended that Ecology remove portions of this section. The Puget Sound Action Team recommended that Ecology omit the requirement to identify and explain differences between CAP recommendations and existing federal regulations and statutes:

> *Since the purpose of the PBT rule is to address shortcomings in existing federal and state regulations dealing with these chemicals, limiting the plan to existing regulations would be counter to its purpose. We do, however, support the need for the chemical action plan to consist of recommendations that do not violate existing federal or state laws or regulations. We suggest omitting WAC 173-333-420 (2)(c). We do not believe an explanation is needed to elaborate on why the recommendations differ from existing regulations since a chemical action plan would only be developed if the chemical under consideration was not adequately addressed under existing regulations.* ***(John Dohrmann, p. 2 of July 2005 written comments)***

The Washington Toxics Coalition recommended that Ecology remove subparagraphs (a) and (b). They also recommended that subparagraph (c) be reworded to include a determination on "whether" not "how" Ecology will coordinate with other federal, state and local laws.

The Weyerhaeuser Company recommended that Ecology consider the impacts of subsection (2) (a) on the implementation of CAP recommendations:

> *WAC 173-333-420(2) Regulatory consistency – Subsection (2)(a) prohibits consideration of CAP recommendations not authorized by federal or state law. Many federal and state environmental laws*

exempt public or household activities from compliance with regulations implementing those laws. Yet, individual decisions and activities by citizens; i.e., collectively, "the public," could represent significant sources of PBT releases. (Good examples would be the emission of chlorinated dioxins and furans, and a variety of PAHs, arising from individual choices to burn garbage containing plastic and wood, in burn barrels and fireplaces.) If Ecology is serious with the effort to reduce the production, uses, and exposures to PBTs there could well be CAP recommendations which address the public contribution. To the extent state and local governments lack statutory authority to implement those recommendations, it should be noted by Ecology. ***(Ken Johnson, p. 3 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology believes that coordination with other local, state and federal agencies will be important to the overall success of individual chemical action plans. One of the underlying objectives of such coordination efforts is to promote consistency with other local, state and federal regulatory requirements.

"Consistency with existing state and federal regulatory requirements" is one of the evaluation factors identified in WAC 173-333-420(f). The language in subsection (2) is designed to provide guidance on the factors to be considered when evaluating regulatory consistency and is based on the "significant legislative rule" criteria in the Administrative Procedures Act.

Ecology has reviewed and evaluated the comments on this issue and decided not to modify the language in subsection (2). In preparing the final PBT rule, Ecology considered the various comments on this issue. Ecology's rationale for not making the suggested changes is briefly described below.

- Ensure that the recommendations do not violate existing federal or state laws: Ecology believes it is important that the CAP recommendations not create situations where compliance with those recommendations would cause people or organizations to violate existing federal and state laws. Ecology believes this is good public policy. However, this provision does not preclude recommendations to revise other state laws to prevent such violations. Ecology also believes that it is a misreading of subsection (a) to equate the term "violate" with the terms "not authorized" or "establishing more stringent requirements". Although a comparison of CAP recommendations and state and federal laws would depend upon the specific language in the CAP and the laws and regulations at issue, the hypothetical situation described above appears to be one in which the hypothetical CAP recommendations are more stringent than existing requirements that exempt household activities. Consequently, this situation does not appear to be one where someone would be forced to violate an existing requirement in order to comply with the hypothetical CAP recommendations.
- Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so: Ecology believes it is appropriate to consider the relative stringency of performance requirements for public and private entities and, if there are differences in the stringency of those requirements, to justify the need for such differences.
- Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal, state, and local laws applicable to the same activity or subject matter: Ecology agrees that

one of the reasons for the PBT initiative is that federal laws and regulations have failed to adequately address this problem. However, Ecology believes it is appropriate to consider the differences between CAP recommendations and federal regulations and statutes, describe why such differences are necessary and how Ecology will coordinate with other agencies. Although, Ecology believes that the relevant question is "how" to coordinate with other agencies if differences exist, the nature and extent of coordination will depend upon the nature of the differences and the impact of such differences on implementing agencies and persons attempting to comply with both the CAP recommendation and the existing laws and regulations.

Issue 6-21: Does the proposed rule identify a reasonable range of factors to be considered when assessing economic impacts?

Proposed Rule

The proposed PBT rule published in June and October 2005 specified several factors that Ecology would consider when assessing economic impacts. The October 2005 rule included the following language:

> *(3) **Economic analyses.** In assessing economic impacts under subsection (1)(f)(iii)(B) of this section, ecology will identify costs of implementing the recommendations. This may include a qualitative and/or quantitative analysis of the probable benefits and costs of the CAP.*

Public Comments and Concerns

The Washington Toxics Coalition recommended that Ecology provide greater detail on the types of economic and social impacts it intends to evaluate and how that analysis will be performed. For example:

> Clarify The Evaluation of Economic and Social Impacts. The rule is unclear about what economic and social impacts will be evaluated in CAPs (section 420 (1) (f)). How does Ecology plan to conduct this analysis? What economic and social impacts will be analyzed? **(Sager-Rosenthal, p. 5 of written comments)**

However, the WTC also recommended that Ecology remove subsection 430(3) because they believe it is redundant:

> *Remove the Economic Analysis of the CAP. The economic analysis of the CAP is redundant. Ecology will already be conducting a cost analysis for each recommendation.* ***(Sager-Rosenthal, p. 5 of written comments)***

Several other organizations provided comments expressing support for subsection (3) and recommended that Ecology include additional language that incorporates the concepts of cost-benefit analysis and least burdensome alternative. For example:

> *Economic Analysis. AWB appreciates Ecology's inclusion of concepts such as cost-benefit, economic impacts and feasibility as part of the contents of CAPs. AWB maintains that the PBT rule and CAPs could have a significant impact on Washington businesses. RCW 34.05.328 provides a set of safeguards pertaining to "significant legislative rules (SLRs). AWB acknowledges that Ecology has determined that the PBT rule is a "procedural rule", however, because of the value they provide, we believe that these important SLR safeguards should be included in the development of CAPs and recommended actions. Specifically, Ecology should:*
>
> *1. Determine that the CAP is needed and consider alternatives;*

2. *Complete a cost-benefit analysis and determine that the probable benefits of the CAP and recommendations are greater than their probable costs;*
3. *Recommend the least burdensome alternative between alternatives of the CAP;*
4. *Determine that the CAP does not recommend more stringent performance requirements on private entities than on public entities;*
5. *If recommended CAP actions exceed federal regulations, justify why;*
6. *Measure whether the CAP is achieving its stated purpose.* ***(Nelson, p. 4 of written comments)***

The Association of Washington Business also submitted suggested language illustrating how these concepts could be incorporated into subsection (3):

(3) ***Economic analyses.*** *In assessing economic impacts under subsection (1)(f)(i)(C) of this section, ecology will identify costs of implementing the recommendations on government entities, large and small businesses, and the public. This ~~will~~ may include a qualitative and/or quantitative analysis of the probable benefits and costs of the CAP and whether the probable benefits of the CAP will be greater than its costs. After the department determines that the CAP is needed to meet the goals and purpose in WAC 173-333-100, develops a cost-benefit analysis on the recommendations in the CAP and determines that the probable benefits of the CAP are greater that its probable costs, the department will ensure that recommendations contained in the CAP are the least burdensome alternative to achieve the goals and purpose in WAC 173-333-100.*

Ecology's Review and Response to Public Comments

"Economic and social impacts associated with implementing the action" is one of the evaluation factors identified in WAC 173-333-420(f). The language in subsection (3) is designed to provide guidance on the factors to be considered when evaluating such impacts. In particular, it is designed to emphasize that the evaluation will consider both "economic and social costs" (i.e. probable benefits and costs") and that such costs and benefits may be characterized in either qualitative or quantitative terms.

Issue 6-22: Does the proposed rule identify a reasonable range of factors to be considered when considering safer substitutes?

Proposed Rule

The proposed PBT rule published in October 2005 specified several factors that Ecology would consider when considering the availability of safer substitutes:

(4) ***Safer substitutes.*** *When evaluating the availability of safer substitutes for PBT uses, ecology will:*

(a) Determine if the recommendations include the use of safer substitutes, and if not, explain why ecology has not recommended this option.
(b) Determine if the recommendations call for additional research for uses with no safer substitutes, and if not, explain why ecology has not recommended this option.
(c) Provide for periodic reevaluation of whether substitutes are available.

Public Comments and Concerns

The Washington Toxics Coalition emphasized the importance of promoting greater use of substitutes in their July 2005 comments:

CAPs Should Focus On Preventing Pollution Through Process/Product Changes and Finding Safer Substitutes *CAPs should call for finding solutions through process and product changes, not*

purely through end-of-pipe measures. Following this approach, we believe that one of the major factors used to evaluate potential CAP recommendations should be the availability of alternatives. We suggest changing section 420 (1) (f) to require that CAPs include recommendations for eliminating a chemical for any use where safer alternatives are identified. If a safer alternative is not available, then the CAP should set a timeline for phase-out and provide for research on potential alternatives and incentives for businesses actively involved in researching safer substitutes. Please see our suggested language changes in proposed section 420.
We also suggest that CAPs include recommendations for developing markets for less toxic alternatives. This approach can be a strong driver for getting large sectors (business, government) to move away from toxic chemicals to safer substitutes. ***(Ivy Sager-Rosenthal, p. 5 of July 2005 written comments)***

After reviewing these and other comments on this issue, Ecology decided to modify the language in WAC 173-333-420. The October 2005 proposed rule included several changes related to the evaluation of alternatives and identifying recommended actions: (1) a fifth evaluation factor (availability of safer substitutes) to the list of evaluation factors in the proposed rule; and (2) a new subsection was added to provide further details on "how" Ecology will evaluate the availability of safer substitutes.

The Washington Toxics Coalition reiterated their support for Ecology's emphasis on promoting greater use of safer alternatives, but expressed some reservations about the language in the October proposed rule. Among other suggestions on this issue, they recommended that Ecology delete WAC 173-333-420(4):

Clarify Role of Safer Alternatives *We appreciate Ecology's willingness to incorporate the idea of safer substitutes into CAPs. However, the new language does not capture what we believe to be the role of safer substitutes in phasing out PBTs. The rule as currently drafted appears to use the availability of safer alternatives to determine whether to take action on a PBT rather than as stand alone recommendations. One of the most important purposes of the PBT program is to encourage businesses and others to develop safer alternatives so they can switch out of PBT chemicals. CAPs must include recommendations for switching businesses to safer alternatives if the safer alternatives exist. If safer alternatives do not currently exist, CAPs should include recommendations on how to encourage the development of safer alternatives and how Ecology will check back to determine whether a safer alternative has been developed.* ***(Ivy Sager-Rosenthal, p. 4 of November 2005 written comments)***

The American Chemistry Council/Chlorine Chemistry Council recommended that Ecology fully evaluate potential substitutes before making recommendations on their use:

Substitutes Must Be Fully Considered and Assessed Before Being Recommended in the Creation of CAPs. *The draft Rule makes several references to "available substitutes" and "safer substitutes." It is unclear as to the evaluation process Ecology will undertake to determine the safety of a potential substitute. While use of a substitute may be one viable risk management option, <u>any</u> substitute should be subjected to a rigorous and defined set of criteria before a decision to use the substitute is considered. For example, the Stockholm POPs Convention sets out criteria for alternatives in Annex F (See Appendix 1), which includes a consideration of technical feasibility, costs, efficacy, risk, availability, and accessibility.*

While the draft Rule requires that Chemical Action Plans include recommendations regarding the "[a]vailability, cost, and effectiveness of safer substitutes," technical feasibility, efficacy, and any risks of a proposed substitute should also be considered. Any consideration of a substitute should be on a life-cycle basis, evaluating performance and impact over the entire life-cycle of the potential substitute – including manufacture, distribution, use, maintenance and disposal. Overall, any proposed substitute must be thoroughly tested and evaluated in order to avoid inadvertently

increasing risks to human health and the environment. ***(Michael Walls and Clifford Howlett, p. 2 of November 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology reviewed the comments on this issue and decided to delete subsection (4) and revise WAC 173-333-420 (1)(f) by stating that chemicals shall include recommendations for

(iv) Switching to safer substitutes; and
(v) Encouraging the development of safer substitutes.

Ecology's decision to revise the language on safer substitutes included in the October 2005 proposed rule was based on the following factors:

- Importance of Using Safer Alternatives: Ecology agrees that use of safer alternatives is an essential component of efforts to reduce and phase-out PBT uses and releases. Ecology believes that the rule promotes the evaluation and use of safe alternatives by requiring CAPs to include recommendations on "switching to safer alternatives" and "encouraging the development of safer alternatives" and identifying consideration of the availability and effectiveness of safer alternatives as an evaluation factor.
- Consistency with Other Programs: Many local, state, federal and international programs have been established to promote greater use of safer alternatives.
- Minimizing Confusion: Subsection (4) was designed to promote a common understanding on how Ecology will evaluate safer substitutes and avoid the need to re-invent the evaluation process with each chemical action plan. However, based on the public comments on this subsection, Ecology believes the proposed language created additional confusion that may be counterproductive to effectively considering this issue when preparing individual CAPs. Consequently, Ecology decided not to include this subsection in the final rule.

In preparing the final PBT rule, Ecology considered the range of other changes suggested by one or more organizations or individuals. Ecology's rationale for not making the suggested changes is briefly described below.

- Decision Rule on Safer Substitutes: One person recommended that Ecology insert the following language into this section: "Availability of alternatives. Whenever safer alternatives for a particular use are identified, the recommendation shall be to eliminate the chemical for that particular use. If a safer alternative is not available, then the recommendation shall be to conduct additional research on potential alternatives and provide incentives for those businesses actively involved in researching potential alternatives. The department shall re-evaluate the availability of alternatives at least every two years after the issuance of the CAP." Ecology reviewed the suggested language and concluded that it was overly prescriptive and at odds with the fact that this chapter is a procedural rule. However, Ecology agrees with the underlying concepts in the proposal and included language in the October 2005 proposed rule that reflected this hierarchy and required Ecology to explain recommendations that differed from the preferences reflected in the hierarchy. This remains Ecology's intent. However, as noted above, Ecology deleted subsection (4) because it appeared to create unnecessary confusion and uncertainty on this issue.

6.4. What process will ecology use to develop CAPs (WAC 173-333-430)

Issue 6-23: Does the proposed rule establish a reasonable process for preparing chemical action plans?

Proposed Rule

Ecology proposed a process for developing chemical action plans that included the following seven main elements: workplan/scoping; formation of an advisory committee; information collection phase; preparation of draft recommendations; public review and comment; final recommendations; and coordination with other agencies (WAC 173-333-430).

Public Comments and Concerns

Most organizations supported Ecology efforts to provide an open public process for preparing chemical actions plans. Two organizations (the Association of Washington Business and the Washington Toxics Coalition) submitted redlined versions of the proposed rule with suggested changes. Neither organization recommended revisions to the overall process and rule language in Section 430. However, each of these organizations recommended changes or additions to specific provisions. The AWB recommended that Ecology add language to clarify that the Department would prepare a written response to public comments on the draft chemical action plan:

> *WAC 173-333-430(7) What process will ecology use to develop CAPs? Final Recommendations. Consistent with good rulemaking, agencies include a responsiveness summary to comments received during the rulemaking process. Ecology should not only review all public comments on its recommendations in a draft CAP, but also respond to those comments to assist stakeholders and interested parties in understanding agency decisions.* ***(Grant Nelson, p. 4 of July 2005 written comments)***

The Washington Toxics Coalition recommended that Ecology add a provision to this section that states Ecology will prepare two chemical action plans per year:

> *The pace for CAP development is too slow. Ecology has only completed two action plans in five years. This is much too slow when you considered how quickly these chemicals are increasing in the environment and our bodies. Ecology should be completing at least two CAPs per year.* ***(Ivy Sager Rosenthal, p. 6 of July 2005 written comments)***

Ecology's Review and Response to Public Comments

Ecology has reviewed and evaluated the comments received regarding the issue of should Ecology modify the administrative and public review process for CAP preparation. Ecology has modified Section 430 (7) to include the phrase that Ecology will "…provide responses…" to all public comments on the draft CAP prior to issuing final recommendations. Ecology believes the suggested modification represents good public policy, will promote better public understanding of the rationale for final CAP recommendations and is consistent with current practice (i.e. Ecology has prepared/is preparing responses to public comments on the mercury and PBDE CAPs).

As noted above (Issue 6-4), Ecology decided not to specify a specific number of CAPs that will be prepared on a yearly basis. Given Ecology's experience preparing CAPs for mercury and PBDE, Ecology believes this recommendation is unrealistic. Ecology believes that the number of CAPs prepared per year will be a function of the (1) CAP complexity and the number of sources, uses and options considered in the CAP process, (2) the types and amount of information that will need to be collected to support the evaluation of various policy options, (3) the level of public interest and (4) the level of agency funding and staffing allocated to this activity. Given the variability in these parameters, Ecology believes it would be counterproductive to establish such a requirement in the PBT rule.

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Appendix A -Initial PBT Rule Language filed on May 18, 2005

Chapter 173-333 WAC

PERSISTENT BIOACCUMULATIVE TOXINS

PART I
GENERAL PROVISIONS

NEW SECTION

WAC 173-333-100 Introduction. Persistent, bioaccumulative toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, can build up in the food chain, and can be transported long distances and readily move between air, land and water media.

Because of the unique threat that these PBTs pose, special attention is necessary to identify actions that will minimize or eliminate threats to human health and the environment. While ecology addresses PBTs through existing regulatory and nonregulatory programs, there remains a need for multimedia, cross-program measures that will reduce and eliminate releases and uses of PBTs over time.

The goal of this chapter is to reduce and eliminate the uses and releases of PBTs in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.

NEW SECTION

WAC 173-333-110 What is the purpose of this chapter? The purpose of this chapter is to:

(1) Establish criteria ecology will use to identify persistent bioaccumulative toxins that pose human health or environmental impacts in Washington state;

(2) Establish a list of persistent bioaccumulative toxins;

(3) Establish procedures ecology will use to review and periodically update the list;

(4) Establish criteria for selecting persistent bioaccumulative toxins for which ecology will prepare chemical action plans;

(5) Define the scope and content of chemical action plans and establish the process ecology will use to prepare those plans; and

(6) Define the processes ecology will use to coordinate the implementation of this chapter with the department of health and other state agencies.

NEW SECTION

WAC 173-333-120 Applicability. (1) This chapter applies to the department of ecology (ecology). This chapter does not impose new requirements on persons using or releasing PBTs, and it does not create new authorities nor does it constrain existing authorities for ecology.

(2) This chapter provides for public involvement opportunities to participate in the ecology processes for identifying PBTs and developing recommendations on measures to address uses and releases of PBTs.

NEW SECTION

WAC 173-333-130 Exemptions to the PBT list. Any pesticide with a valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter.

NEW SECTION

WAC 173-333-140 Administrative principles. (1) **Scientific information.** Ecology will base decisions on PBTs on sound public policy and credible scientific information. However, ecology believes that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.

(2) **Public involvement.** Ecology will provide opportunities for public involvement during the decision-making processes for identifying PBTs and preparing a CAP.

(3) **Clear documentation.** Ecology will provide clear and understandable descriptions and rationale for decisions implementing this chapter.

(4) **Predictability.** Ecology will implement this chapter in ways that allow stakeholders, interest groups, and the public to plan their participation in decision-making processes and future responses to recommendations that result from those processes.

(5) **Coordination.** Ecology will coordinate with other state agencies and local governments, tribes, and interested parties in the development and implementation of CAPs and when revising the PBT list.

(6) **Rule amendments.** When amending any portion of this rule, Ecology will follow the requirements of the Administrative Procedure Act (APA), chapter 34.05 RCW.

PART II
DEFINITIONS

NEW SECTION

WAC 173-333-200 Definitions. "Administrative Procedure Act" or **"APA"** means the Washington Administrative Procedure Act, chapter 34.05 RCW.

"Bioaccumulation" means the process by which substances increase in concentration in living organisms as they take in contaminated air, water, soil, sediment or food because the substances are very slowly metabolized or excreted.

"Bioaccumulation factor" or **"BAF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF is a measure of the extent to which the organism accumulates the chemical as a result of uptake through ingestion as well as contact from contaminated media, such as water.

"Bioconcentration factor" or **"BCF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BCF is a measure of the extent of chemical partitioning between an organism and the surrounding environment.

"Chemicals" means a naturally occurring element, mixture, or group of organic and inorganic compounds that is produced by or used in a chemical process.

"Chemical group" means a grouping of chemicals which share a common chemical structure.

"Chemical action plan" or **"CAP"** means a plan that identifies, characterizes and addresses uses and releases of a specific PBT or a group of PBTs and facilitates implementation

of measures to manage, reduce or eliminate such uses and releases.

"Credible scientific information" means information that is based on a theory or technique that is generally acceptable in the relevant scientific community or has been collected or derived using standard methods and protocols and appropriate quality assurance and control procedures.

"Cross-media transfer of chemicals" means the movement of a chemical from one medium, such as air, water, soil, or sediment, to another.

"Degradation" means the processes by which organic chemicals are transformed into derivative chemicals and ultimately broken down.

"Ecology" means the department of ecology.

"Environment" means any plant, animal, natural resource, surface water (including underlying sediments), ground water, drinking water supply, land surface (including tidelands and shorelands) or subsurface strata, or ambient air.

"Environmental half-life" means the time required for the concentration of a chemical to diminish to half its original value. The environmental half-life of a chemical is a measure of a chemical's persistence in the environment.

"Feasible" means capable of being accomplished or brought about or capable of being utilized or dealt with successfully.

"High-exposure populations" means groups of people that are at greater risk because they have a higher potential for exposure than the general population.

"Log-octanol water partition coefficient" or **"Log K_{ow}"** means the ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol/water system as expressed in a logarithmic format.

"Media" or **"medium"** means a component of the environment (air, water, soil or sediment) in which a contaminant is measured and an organism lives its life, and from which an organism can accumulate contaminants.

"Persistent bioaccumulative toxin" or **"PBT"** means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in this chapter.

"Persistence" means the tendency of a chemical to remain in the environment without transformation or breakdown into another chemical form. It refers to the length of time a chemical is expected to reside in the environment and be available for exposure.

"Sensitive population group" means groups of people that exhibit a different or enhanced response to a PBT than most people exposed to a similar level of the PBT because of genetic makeup, age, nutritional status or exposure to other toxic substances.

"Toxicity" means the degree to which a substance or mixture of substances can harm humans, plants or wildlife.

PART III
THE PBT LIST AND CRITERIA AND PROCEDURES FOR REVISING THE LIST

NEW SECTION

WAC 173-333-300 What is the purpose of the PBT list? (1) **Purpose.** The purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington.

(2) **Intended uses of the PBT list.** Ecology will use the PBT list in the following ways:

(a) **Chemical action plans.** To select chemicals for chemical action plan development.

(b) **Ambient monitoring.** To help guide decisions on the design and implementation of ecology programs for characterizing chemical concentrations in the ambient environment.

(c) **Biomonitoring.** To encourage and inform the department of health regarding their efforts to monitor chemicals in human tissue.

(d) **Public awareness.** To promote greater public awareness on the problems associated with PBT chemicals, the uses and sources of individual PBTs and steps that individuals and organizations can take to reduce PBT uses, releases and exposure.

(e) **Voluntary measures.** To help identify opportunities for government agencies, businesses and individuals to implement voluntary measures for reducing and phasing out PBT uses and releases.

(3) **Relationship to actions addressing chemical uses and releases.** Ecology has determined that the chemicals on the PBT list pose a potential threat to human health and the environment in Washington.

(a) Ecology's decision to include a particular chemical on the PBT list does not represent a decision that all uses and releases of that chemical should be reduced and eliminated.

(b) Ecology does not intend to use the PBT list as the sole basis for establishing discharge monitoring requirements that are not required under current permits. Ecology will evaluate and, if appropriate, prepare recommendations for additional monitoring requirements when preparing chemical action plans (WAC 173-333-420 and 173-333-430).

NEW SECTION

WAC 173-333-310 What chemicals or chemical groups are included on the PBT list? (1) **Purpose.** This section identifies the chemicals and chemical groups that ecology has determined meet the criteria specified in WAC 173-333-320.

(2) **PBT list.** Ecology has determined that the following chemicals or chemical groups meet the criteria specified in WAC 173-333-320.

Chemical or Chemical Group	CAS Number
Aldrin/Dieldrin	309-00-2/60-57-1
Cadmium (pending review of bioavailability)	7440-43-9
Chlordane	57-74-9
Chlordecone (Kepone)	3734-48-3
DDT, p,p'-	50-29-3
Endrin	72-20-8
Heptachlor/Heptachlor epoxide	76-44-8/1024-57-3
Hexabromobiphenyl	36355-01-8
Hexabromocyclododecane	25637-99-4
Hexachlorobenzene	118-74-1
Hexachlorobutadiene	87-68-3
Lead (pending review of bioavailability)	7439-92-1
Mercury	7439-97-6
Mirex	2385-85-5
Perfluorooctane sulfonates (PFOS)	(a)
Pentachlorobenzene	608-93-5
Polycyclic aromatic hydrocarbons (PAHs)	(b)
Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDF)	(c)
Polybrominated diphenyl ethers (PBDEs)	(d)
Polychlorinated biphenyls (PCBs)	1336-36-3
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)	(e)
Polychlorinated naphthalenes (PCN)	70776-03-3 (f)
Short-chain chlorinated paraffins (SSCP)	85535-84-8 (g)
Tetrabromobisphenol A	79-94-7
Tetrachlorobenzene, 1,2,4,5-	95-94-3
Toxaphene	8001-35-2

Explanatory Notes Regarding Specific Chemicals on the PBT List (WAC 173-333-310)

(a) **Perfluorooctane sulfonates (PFOS):** PFOS (Molecular formula $C_8F_{17}SO_3$) is a member of a group of organic compounds that consists of an eight-carbon chain where the hydrogen atoms have been substituted with fluorine atoms and a reactive sulfonate group at one end of the chain. PFOS derivatives and salts include: Acid (CAS 1763-32-1); ammonium salt (CAS 29081-56-9); diethanolamine salt (CAS 70225-14-8); lithium salt (CAS 29457-72-5); and potassium salt (CAS 2795-39-3).

(b) **Polycyclic aromatic hydrocarbons (PAHs):** PAHs are a group of compounds composed of two or more fused aromatic rings. Ecology has determined that the following PAH compounds meet the proposed PBT criteria in WAC 173-333-320(2): Dibenzo(a,h)anthracene (CAS 53-70-3); 3-methylchlolanthrene (CAS 56-49-5); benzo(r,s,t)pentaphene (CAS 189-55-9); dibenzo(a,h)pyrene (CAS 189-64-4); benzo(g,h,i)perylene (CAS 191-24-2); dibenzo(a,e)pyrene (CAS 192-65-4); indeno(1,2,3-cd)pyrene (CAS 193-39-5); 7H-dibenzo(c,g)carbazole (CAS 194-59-2); perylene (CAS 198-55-0); benzo(j)fluoranthene (CAS 205-82-3); benzo(b)fluoranthene (CAS 205-99-2); fluoranthene (CAS 206-44-0); benzo(k)fluoranthene (CAS 207-08-9); benzo(a)phenanthrene (CAS 218-01-9); dibenzo(a,j)acridine (CAS 224-42-0); and dibenzo(a,h)acridine (CAS 226-36-8).

(c) **Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDDs/PBDFs):** PBDDs/PBDFs consist of two groups of tricyclic aromatic compounds with similar chemical and physical properties. Ecology has determined that the following PBDD/PBDF congeners meet the proposed PBT criteria in WAC 173-333-320(2): 2,3,7,8-tetrabromodibenzo-p-dioxin (CAS 50585-41-6); and 2,3,7,8-tetrabromodibenzofuran (CAS 67733-57-7).

(d) **Polybrominated diphenyl ethers (PBDEs):** PBDEs are a class of chemicals with the general chemical formula of $C_{12}H_{(9-0)}Br_{(1-10)}O$ with the sum of H and Br atoms always equal to 10. There are theoretically 209 congeners which can be divided into 10 congener groups (mono- through decabromodiphenyl ethers). Ecology has determined that the following congener groups meet the proposed PBT criteria in WAC 173-333-320(2) and/or degrade to congeners that meet the draft PBT criteria in WAC 173-333-320(2): Pentabromodiphenyl ether (CAS 32534-81-9); octabromodiphenyl ether (CAS 32536-52-0); decabromodiphenyl ether (CAS 13654-09-6).

(e) **Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDDs/PCDFs):** PCDDs/PCDFs consist of two groups of tricyclic aromatic compounds with similar chemical and

physical properties. Ecology has determined that the following PCDD/PCDF congeners meet the proposed PBT criteria in WAC 173-333-320(2): 2,3,7,8-tetrachlorodibenzo-p-dioxin (CAS 1746-01-6); 1,2,3,7,8-pentachlorodibenzo-p-dioxin (CAS 40321-76-4); 1,2,3,4,7,8-hexachlorodibenzo-p-dioxin (CAS 39227-28-6); 1,2,3,6,7,8-hexachlorodibenzo-p-dioxin (CAS 576-53-8); 1,2,3,7,8,9-hexachlorodibenzo-p-dioxin (CAS 19408-74-3); 1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin (CAS 35822-46-9); 1,2,3,4,6,7,8,9-octachlorodibenzo-p-dioxin (CAS 3268-87-9); 2,3,7,8-tetrachlorodibenzofuran (CAS 51207-31-9); 1,2,3,7,8-pentachlorodibenzofuran (CAS 57117-41-6); 2,3,4,7,8-pentachlorodibenzofuran (CAS 57117-41-4); 1,2,3,4,7,8-hexachlorodibenzofuran (CAS 70648-26-9); 1,2,3,6,7,8-hexachlorodibenzofuran (CAS 57117-44-9); 1,2,3,7,8,9-hexachlorodibenzofuran (CAS 72918-21-9); 2,3,4,7,8,9-hexachlorodibenzofuran (CAS 60851-34-5); 1,2,3,4,6,7,8-heptachlorodibenzofuran (CAS 67562-39-4); 1,2,3,4,7,8,9-heptachlorodibenzofuran (CAS 55673-89-7); 1,2,3,4,6,7,8,9-octachlorodibenzofuran (CAS 39001-02-0).

(f) **Polychlorinated naphthalenes (PCN):** PCNs are a group of chlorinated naphthalenes that contain 1 to 8 chlorine atoms and are structurally similar to PCBs. Ecology has determined that the following compounds meet the proposed PBT criteria in WAC 173-333-320(2): Heptachloronaphthalene (CAS 32241-08-0); hexachloronaphthalene (CAS 1335-87-1); pentachloronaphthalene (CAS 1321-64-8); tetrachloronaphthalene (CAS 1335-88-2); and trichloronaphthalene (CAS 1321-65-9).

(g) **Short-chain chlorinated paraffins (SSCP):** SSCPs are chlorinated derivatives of n-alkanes that have carbon chains ranging from 10 to 13 carbon atoms and a chlorine content ranging from 50-70% by weight.

(3) **Categories.** Ecology will assign each chemical on the PBT list to one of the following three categories:

(a) **Category 1.** Ecology will place chemicals in this category if the department determines that the chemical is used, released or present in Washington.

(b) **Category 2.** Ecology will place chemicals in this category if the department determines that there is insufficient information to reach a conclusion on whether the chemical is used, released or present in Washington.

(c) **Category 3.** Ecology will place chemicals in this category if the department determines that:

(i) All uses and releases of the chemical are prohibited under other state or federal laws or regulations; or

(ii) There are no feasible measures for reducing or phasing out uses and releases of the chemical beyond levels required under other federal and state laws and regulations; or

(iii) Is not present in Washington's environment.

(4) **Revising the PBT list.** Ecology will periodically review and, as appropriate, revise the PBT list in subsection (2) of this section using the criteria and procedures in WAC 173-333-320 through 173-333-340.

NEW SECTION

WAC 173-333-320 What criteria will ecology use to identify and add chemicals or chemical groups to the PBT list? (1) **Purpose.** This section describes the criteria that ecology will use to determine whether a chemical or group of chemicals should be included on the PBT list.

(2) **Criteria for identifying PBTs.** A chemical or group of chemicals will be included on the PBT list if ecology determines it meets each of the following criteria:

(a) **Persistence.** The chemical or chemical group can persist in the environment based on evidence that:

(i) The half-life of the chemical in water is greater than or equal to sixty days; or

(ii) The half-life of the chemical in soil is greater than or equal to sixty days; or

(iii) The half-life of the chemical in sediments is greater than or equal to sixty days; and

(b) **Bioaccumulation.** The chemical or chemical group has a high potential to bioaccumulate based on evidence that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1,000 or, in the absence of such data, that the log-octanol water partition coefficient (log K_{ow}) is greater than five; and

(c) **Toxicity.** The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:

(i) The chemical or a chemical group is known to cause or can reasonably be anticipated to cause cancer or teratogenic effects, reproductive effects, neurological disorders or other acute or chronic health effects; or

(ii) The chemical or chemical group is known to cause or can reasonably be anticipated to cause adverse effects in aquatic and terrestrial plants and animals.

(d) **Additional criteria applicable to metals.** The chemical or chemical group is a metal and ecology determines that it is likely to be present in forms that are bioavailable.

(3) **Degradation products.** Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will be

considered in the development of a CAP for those derivative chemicals.

NEW SECTION

WAC 173-333-330 What criteria will ecology use to remove a PBT from the PBT list? (1) **Purpose.** This section describes the criteria and factors ecology will use to determine whether a chemical or group of chemicals should be removed from the PBT list.

(2) **Criteria for removing a chemical from the PBT list.** Ecology will remove a chemical or chemical group from the PBT list if the department determines that credible scientific information developed subsequent to the listing decision provides evidence that the chemical or chemical group does not meet the PBT criteria in WAC 173-333-320(2).

NEW SECTION

WAC 173-333-340 What process would ecology follow to revise the PBT list? (1) **Purpose.** This section describes the processes ecology will use to notify the public and amend the PBT list after making a determination that chemicals or groups of chemicals should be added or removed from the PBT list.

(2) **Reviewing and updating the PBT list.** Ecology will periodically review and update WAC 173-333-310. The frequency of review will be determined by credible scientific information available on individual chemicals or chemical groups, rule-making petitions submitted to ecology, and available agency resources. Ecology will comply with the requirements for reviewing and responding to rule-making petitions in the Administrative Procedure Act, chapter 34.05 RCW.

(3) **Public notification.** If ecology makes a preliminary determination that a chemical should be added or removed from the PBT list, it will notify the public through an announcement posted on the ecology web site and published in the *Washington State Register*.

(4) **Amending the PBT list.** If ecology makes a final determination that a chemical or chemical group should be added or removed from the PBT list, the department will initiate actions to amend WAC 173-333-310 through formal rulemaking.

PART IV
CHEMICAL ACTION PLANS (CAPs)

NEW SECTION

WAC 173-333-400 What is a chemical action plan (CAP)? (1) A chemical action plan (CAP) is a plan that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and includes recommendations on actions to protect human health or the environment.

(2) CAPs will include recommendations for:

(a) Reducing and eliminating uses and releases of the specific PBT or group of PBTs addressed in the CAP;

(b) Managing products or waste that contain the specific PBT or group of PBTs addressed in the CAP;

(c) Minimizing exposure to the specific PBT or group of PBTs;

(d) Collecting additional information needed to evaluate the feasibility of potential actions; and

(e) Measuring or monitoring the effectiveness of actions being implemented in Washington.

NEW SECTION

WAC 173-333-410 What evaluation factors and processes will ecology use to select PBTs for chemical action plan preparation? (1) **Purpose.** The purpose of this section is to describe the evaluation factors and processes ecology will use to decide when to develop a chemical action plan for a particular chemical or group of chemicals included on the PBT list.

(2) **Candidates for CAP development.** Ecology will consider developing chemical action plans for chemicals on the PBT list that meet the following criteria:

(a) Ecology determines that the chemical or chemical group has a half-life in water that is greater than or equal to sixty days, soil or sediment that is greater than or equal to one hundred eighty days;

(b) Ecology determines that the chemical or chemical group has a bioconcentration factor or bioaccumulation factor in aquatic species that is greater than 2,000; and

(c) Ecology determines that the chemical or chemical group is "toxic" as defined in WAC 173-333-302 (2)(c).

(3) **Decision-making process.** Ecology will consult with the department of health to select the chemicals for chemical action plan preparation. The process for deciding when to prepare a

chemical action plan for a particular chemical or group of chemicals includes the following:

(a) **Selection factors.** Ecology will consider the following factors when deciding whether to prepare a chemical action plan for a particular chemical or group of chemicals identified in WAC 173-333-310(2):

(i) Relative ranking. The relative ranking assigned to each PBT based on ecology's evaluation of information on PBT characteristics, uses of the chemical in Washington, releases of the chemical in Washington, and the levels of the chemical present in the Washington environment.

(ii) Opportunities for reductions. Whether there are opportunities for reducing or phasing out uses, production or releases of the PBT in Washington. In reviewing available information, the agencies shall consider whether more than one PBT is present in particular products, generated in particular processes or released from particular sources (co-occurring chemicals).

(iii) Multiple chemical releases and exposures. Scientific evidence on the combined effects of exposure to one or more PBTs and other substances commonly present in the Washington environment.

(iv) Sensitive population groups and high-exposure populations. Scientific evidence on the susceptibility of various population groups including the timing of the exposure and the cumulative effects of multiple exposures.

(v) Existing plans or regulatory requirements. Whether there are existing plans or regulatory requirements that reduce and phase out uses and releases of a particular PBT or group of PBTs.

(b) **Preliminary selection.** Ecology will prepare a written summary of the preliminary decision to prepare a chemical action plan for one or more PBTs and the rationale for selecting that particular PBT or group of PBTs.

(c) **Public notice and comment.** Ecology will notify the public when it makes a preliminary selection and provide an opportunity for public review and comment. Ecology will notify the public through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also send a written announcement to interested persons and organizations. Ecology will provide sixty days, from the date the notice is published in the *Washington State Register* for the public to review and submit comments on the preliminary selection.

(d) **Final decision.** Ecology will review all public comments on the preliminary selection prior to making a final decision to prepare a chemical action plan for a particular PBT

or groups of PBTs. Ecology will notify the public of the final decision through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the preliminary selection.

NEW SECTION

WAC 173-333-420 What are the contents of a CAP? (1) **Contents of the chemical action plans.** Chemical action plans will include, as appropriate, the following types of information, evaluations and recommendations:

(a) **General chemical information.** General information includes, but is not limited to, chemical name, properties, uses and manufacturers.

(b) **Production, uses and releases.** An analysis of information on the production, unintentional production, uses and disposal of the chemical. This will include estimates on the amount of each PBT used and released from all sources or activities in Washington and other sources that may contribute to exposures in Washington. Sources may include other chemicals or products that are known or suspected to degrade to the chemical included on the PBT list.

(c) **Human health and environmental impacts.** An evaluation of the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.

(d) **Current management approaches.** An evaluation of the regulatory and nonregulatory approaches that influence production, uses, releases and management of each PBT.

(e) **Identification of policy options.** A list of options for managing, reducing and eliminating the different uses and releases of the PBTs addressed in the CAP. The range of options for particular uses and releases will include:

(i) A no-action option;

(ii) An option that results in the elimination of PBT uses and releases;

(iii) An option to manage chemicals to reduce exposure; and

(iv) Other options, including the use of available substitutes, which will enable full consideration of the opportunities and constraints for reducing particular uses, releases and exposures.

(f) **Recommendations.** The recommendations will include:

(i) Recommendations on actions to manage, reduce or phase-out uses and releases of the PBT addressed in the CAP. The recommendations will be based on an evaluation of the following factors:

(A) Feasibility of implementing the action;

(B) Environmental and human health benefits associated with implementing the action;

(C) Economic and social impacts associated with implementing the action; and

(D) Consistency with existing federal and state regulatory requirements.

(ii) A description of the steps ecology will take to implement the CAP, including a description of:

(A) The existing resources and necessary additional budget ecology intends to use;

(B) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;

(C) How ecology intends to inform and educate affected persons about the CAP; and

(D) How ecology will promote and assist voluntary actions.

(iii) Performance measures. A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time.

(g) Other. Other information that ecology determines is necessary to support the decision-making process.

(2) **Regulatory consistency.** When evaluating the consistency with existing federal and state regulatory requirements under subsection (1)(f)(i)(D) of this section, ecology will:

(a) Ensure that the recommendations do not violate existing federal or state laws;

(b) Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so; and

(c) Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal, state, and local laws applicable to the same activity or subject matter.

(3) **Economic analyses.** In assessing economic impacts under subsection (1)(f)(i)(C) of this section, ecology will identify

costs of implementing the recommendations. This may include a qualitative and/or quantitative analysis of the probable benefits and costs of the CAP.

NEW SECTION

WAC 173-333-430 What process will ecology use to develop CAPs? (1) **Purpose.** The purpose of this section is to identify the process ecology will use to develop CAPs.

(2) **Workplan/scoping.** Once a chemical is selected for CAP development, ecology will initially plan and scope the CAP of the selected chemical based upon available information regarding the chemical's products, uses and releases; human health exposure and ecological hazards; environmental releases, fate, and transport; environmental concentrations and available substitutes; available options for managing uses and releases; estimated costs, benefits and effectiveness of alternate management options; and any other information ecology determines is necessary to support the CAP development process. Ecology will consult with the department of health regarding all portions of the CAP related to human health exposures.

(3) **Advisory committee.** Ecology will create an external advisory committee for each CAP that ecology develops. The purpose of the advisory committee is to provide stakeholder input and expertise.

(a) The advisory committee membership will include, but not be limited to, representatives from: Large and small business sectors, community, environmental and public health advocacy groups, local governments, and public health agencies. When appropriate, representatives from the following groups will also be invited to participate: Agricultural groups, worker safety advocacy groups, and other interested parties. Federally recognized tribal governments will also be encouraged to participate. In addition, representation from other state executive agencies may be requested to provide input and to represent agency interests in the CAP development process. Outside experts (if needed) may be requested to provide technical expertise.

(b) A neutral third-party facilitator may be hired to facilitate advisory committee meetings.

(c) The advisory committee will follow a consultative process, where ecology will draft the CAP in consideration of input from advisory committee members.

(d) All advisory committee meetings will be open to the public. Ecology will notify the public of advisory committee meetings through an announcement posted on the ecology web site

and written notification to interested individuals and organizations.

(4) **Information collection phase.** Ecology will collect all necessary and up-to-date information regarding the selected chemical. CAP advisory committee members will be asked to contribute, and as appropriate, review information from ecology during this phase of CAP development. The department of health will be asked to review any information related to human health.

(5) **Draft recommendations.** Ecology will develop a draft CAP for advisory committee review and comment. Ecology will review all advisory committee comments and, as appropriate, revise the draft CAP prior to distributing it for public review and comment.

(6) **Public review and comment.** Ecology will notify the public when it has developed a draft CAP and provide an opportunity for public review and comment. The public comment period for each draft CAP will be a minimum of sixty days. Ecology will notify the public through an announcement posted concurrently on the ecology web site, a notice in the *Washington State Register*, and sent to interested persons and organizations. The comment period shall start from the date the notice is published in the *Washington State Register*. During the comment period, ecology will hold a minimum of two public meetings on the draft CAP. One meeting shall be held on the western side of the state, and one meeting shall be held on the eastern side of the state. Ecology may hold additional public meetings during the public comment period if determined necessary. Ecology will provide a response to all public comments.

(7) **Final recommendations.** Ecology will review all public comments on the draft CAP prior to issuing the final recommendations. Ecology will notify the public of the final recommendations through an announcement that will be published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the draft CAP.

(8) **Coordination with other agencies.** Ecology will coordinate with other government agencies and interested parties as appropriate on the implementation of the final CAP. Ecology will consult with the department of health on public information materials addressing food safety issues.

Appendix B PBT Rule Language highlighting differences between the initial draft PBT Rule language and the re-filed draft PBT Rule language – filed on September 29, 2005

Persistent Bioaccumulative Toxins Regulation

Chapter 173-333 WAC

PART I
GENERAL PROVISIONS

NEW SECTION

WAC 173-333-100 Introduction. Persistent, bioaccumulative toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, can build up in the food chain, and can be transported long distances and readily move between air, land and water media.

Because of the unique threat that these PBTs pose, special attention is necessary to identify actions that will reduce and ~~minimize or~~ eliminate threats to human health and the environment. While ecology addresses PBTs through existing regulatory and nonregulatory programs, there remains a need for multimedia, cross-program measures that will reduce and phase-out ~~eliminate~~ releases and uses of PBTs over time.

The goal of this chapter is to reduce and ~~eliminate~~ phase-out PBT ~~the~~ uses, ~~and~~ releases and exposures ~~of PBTs~~ in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. These factors include environmental and human health benefits, economic and social costs, technical feasibility, availability of safer substitutes, and consistency with other regulatory requirements. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.

NEW SECTION

WAC 173-333-110 What is the purpose of this chapter? The purpose of this chapter is to:

(1) Establish criteria ecology will use to identify persistent bioaccumulative toxins that pose human health or environmental threats ~~impacts~~ in Washington state;

(2) Establish a list of persistent bioaccumulative toxins;

(3) Establish procedures ecology will use to review and periodically update the list;

(4) Establish criteria for selecting persistent bioaccumulative toxins for which ecology will prepare chemical action plans;

(5) Define the scope and content of chemical action plans and establish the process ecology will use to prepare those plans; and

(6) Define the processes ecology will use to coordinate the implementation of this chapter with the department of health and other ~~state~~ agencies.

NEW SECTION

WAC 173-333-120 Applicability. (1) This chapter applies to the department of ecology (ecology). This chapter does not impose new requirements on persons using or releasing PBTs, and it does not create new authorities nor does it constrain existing authorities for ecology.

(2) This chapter provides for public involvement opportunities to allow interested persons to participate in the ecology processes for identifying PBTs and developing recommendations on measures to address uses and releases of PBTs.

NEW SECTION

WAC 173-333-130 Exemptions to the PBT list. Any pesticide with a currently valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter.

NEW SECTION

WAC 173-333-140 Administrative principles. (1) **Scientific information.** Ecology will base decisions on PBTs on sound public policy and credible scientific information. However, ecology believes that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.

(2) **Public involvement.** Ecology will provide opportunities for public involvement during the decision-making processes for identifying PBTs and preparing a CAP.

(3) **Clear documentation.** Ecology will provide clear and understandable descriptions and rationale for decisions implementing this chapter.

(4) **Predictability.** Ecology will implement this chapter in ways that allow stakeholders, interest groups, and the public to plan their participation in decision-making processes and future responses to recommendations that result from those processes.

(5) **Coordination.** Ecology will coordinate with federal and ~~other~~ state agencies, ~~and~~ local governments, tribes, and other interested parties in the development and implementation of CAPs and when revising the PBT list.

(6) **Rule amendments.** When amending any portion of this rule, Ecology will follow the requirements of the Administrative Procedure Act (APA), chapter 34.05 RCW.

PART II
DEFINITIONS

NEW SECTION

WAC 173-333-200 Definitions. "Administrative Procedure Act" or **"APA"** means the Washington Administrative Procedure Act, chapter 34.05 RCW.

"Bioaccumulation" means the process by which substances increase in concentration in living organisms as they take in contaminated air, water, soil, sediment or food because the substances are very slowly metabolized or excreted.

"Bioaccumulation factor" or **"BAF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF is a measure of the extent to which the organism accumulates the chemical as a result of uptake through ingestion as well as contact from contaminated media, such as water.

"Bioconcentration factor" or **"BCF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BCF is a

measure of the extent of chemical partitioning between an organism and the surrounding environment.

“Carcinogen” means a chemical or chemical group that is known or suspected to increase the probability of developing cancer. For purposes of implementing this chapter, the term carcinogen applies to substances that have been identified as “carcinogenic to humans” or “likely to be carcinogenic to humans” by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a “known to be human carcinogen” or “reasonably anticipated to be a human carcinogen” by the National Toxicology Program.

"Chemicals" means a naturally occurring element, mixture, or group of organic and inorganic compounds that is produced by or used in a chemical process.

"Chemical action plan" or **"CAP"** means a plan that identifies, characterizes and evaluates addresses uses and releases of a specific PBT or a group of PBTs and recommends actions to protect human health or the environment. facilitates implementation of measures to manage, reduce or eliminate such uses and releases.

"Chemical group" means a grouping of chemicals which share a common chemical structure.

"Credible scientific information" means information that is based on a theory or technique that is generally acceptable in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures.

"Cross-media transfer of chemicals" means the movement of a chemical from one medium, such as air, water, soil, or sediment, to another.

"Degradation" means the processes by which organic chemicals are transformed into derivative chemicals and ultimately broken down.

“Developmental or Reproductive Toxicant” means a chemical or chemical group that is known or suspected to cause adverse effects on development or reproduction. For purposes of implementing this chapter, the term developmental or reproductive toxicant applies to chemicals or chemical groups identified as posing developmental or reproductive hazards by the National Toxicology Program or chemicals or chemical groups with sufficient evidence of a developmental or reproductive hazard in humans or experimental animals consistent with the United States Environmental Protection Agency’s Guidelines for Reproductive Toxicity Risk Assessment and Guidelines for

Developmental Toxicity Risk Assessment as set forth in 61 FR 56274 et seq. and 56 FR 63798 et seq., respectively.

"Ecology" means the department of ecology.

"Environment" means any plant, animal, natural resource, surface water (including underlying sediments), ground water, drinking water supply, land surface (including tidelands and shorelands) or subsurface strata, or ambient air.

"Environmental half-life" means the time required for the concentration of a chemical to diminish to half its original value. The environmental half-life of a chemical is a measure of a chemical's persistence in the environment.

"Feasible" means reasonably capable of being accomplished or brought about or capable of being utilized or dealt with successfully.

"High-exposure populations" means groups of people that are at greater risk because they have a higher potential for exposure than the general population.

"Log-octanol water partition coefficient" or **"Log K_{ow}"** means the ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol/water system as expressed in a logarithmic format.

"Media" or **"medium"** means a component of the environment (air, water, soil or sediment) in which a contaminant is measured and an organism lives its life, and from which an organism can accumulate contaminants.

"**Neurotoxicant**" means a chemical or chemical group that is known or suspected to cause adverse changes in the structure or function of the central and/or peripheral nervous system. For purposes of implementing this chapter, the term neurotoxicant applies to chemicals or chemical groups with sufficient evidence of a neurotoxic hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Neurotoxicity Risk Assessment as set forth in 63 FR 26926 et seq.

"No Observed Effect Concentration" or "NOEC" means the highest concentration of a chemical evaluated in an aquatic toxicity test that does not cause a statistically significant difference in effects compared with controls.

"Persistent bioaccumulative toxin" or **"PBT"** means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in WAC 173-333-320 ~~this chapter~~.

"Persistence" means the tendency of a chemical to remain in the environment without transformation or breakdown into another chemical form. It refers to the length of time a chemical is

expected to reside in the environment and be available for exposure.

"**Reference Dose**" means a numerical estimate of a daily exposure to the human population, including sensitive subgroups such as children, that is likely to be without harmful effects during a lifetime.

"Sensitive population group" means groups of people that exhibit a different or enhanced response to a chemical ~~PBT~~ than most people exposed to a similar level of the chemical ~~PBT~~ because of genetic makeup, age, nutritional status or exposure to other toxic substances.

"Toxicity" means the degree to which a substance or mixture of substances can harm humans, plants or wildlife.

PART III
THE PBT LIST AND CRITERIA AND PROCEDURES FOR REVISING THE LIST

NEW SECTION

WAC 173-333-300 What is the purpose of the PBT list? (1) **Purpose.** The purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington.

(2) **Intended uses of the PBT list.** Ecology will use the PBT list in the following ways:

(a) **Chemical action plans.** To select chemicals for chemical action plan development.

(b) **Ambient monitoring.** To help guide decisions on the design and implementation of ecology programs for characterizing chemical concentrations in the ambient environment.

(c) **Biomonitoring.** To encourage and inform the department of health regarding their efforts to monitor chemicals in human tissue.

(d) **Public awareness.** To promote greater public awareness on the problems associated with PBT chemicals, the uses and sources of individual PBTs and steps that individuals and organizations can take to reduce PBT uses, releases and exposure.

(e) **Voluntary measures.** To help identify opportunities for government agencies, businesses and individuals to implement voluntary measures for reducing and phasing out PBT uses and releases.

(3) **Relationship to actions addressing chemical uses and releases.** Ecology has determined that the chemicals on the PBT

list pose a potential threat to human health and the environment in Washington.

(a) Ecology's decision to include a particular chemical on the PBT list does not represent a decision that all uses and releases of that chemical should be reduced and phased-out ~~eliminated~~.

(b) Ecology does not intend to use the PBT list as the sole basis for establishing discharge monitoring requirements that are not required under current permits. Ecology will evaluate and, if appropriate, prepare recommendations for additional monitoring requirements when preparing chemical action plans (WAC 173-333-420 and 173-333-430).

NEW SECTION

WAC 173-333-310 What chemicals or chemical groups are included on the PBT list? (1) **Purpose.** This section identifies the chemicals and chemical groups that ecology has determined meet the criteria specified in WAC 173-333-320.

(2) **PBT list.** Ecology has determined that the following chemicals or chemical groups meet the criteria specified in WAC 173-333-320.

Chemicals listed in alphabetical order	**CAS Number**
Aldrin	309-00-2
Cadmium	7440-43-9
Chlordane	57-74-9
Chlordecone (Kepone)	3734-48-3
Dichlorodiphenyltrichloroethane (DDT)	50-29-3
Dieldrin	60-57-1
Endrin	72-20-8
Heptachlor/Heptachlor epoxide	76-44-8/1024-57-3
Hexabromobiphenyl	36355-01-8
Hexabromocyclododecane	25637-99-4
Hexachlorobenzene	118-74-1
Hexachlorobutadiene	87-68-3
Lead	7439-92-1
Mercury	7439-97-6
Mirex	2385-85-5
Nonylphenol/4-nonylphenol (branched)	25154-52-3/84852-15-3
Pentachlorobenzene	608-93-5
Short-chain chlorinated paraffins	85535-84-8
Tetrabromobisphenol A	79-94-7
Tetrachlorobenzene, 1,2,4,5-	95-94-3
Toxaphene	8001-35-2

Chemical Categories listed in alphabetical order

Perfluorooctane sulfonates (PFOS)

Acid	1763-32-1
ammonium salt	29081-56-9
diethanolamine salt	70225-14-8
lithium salt	29457-72-5
potassium salt	2795-39-3

Phthalate esters

Di-isodecyl phthalate (DIDP)	68515-49-1 and 26761-40-0
Di-n-hexyl phthalate (DnHP)	84-75-3

Polycyclic aromatic hydrocarbons (PAHs)

3-Methyl chlolanthrene	56-49-5
7H-Dibenzo(c,g)carazole	194-59-2
Benzo(a)phenanthrene (Chrysene)	218-01-9
~~Benzo(a)pyrene~~	~~50-32-8~~
Benzo(b)fluoranthene	205-99-2
Benzo(g,h,i)perylene	191-24-2
Benzo(j)fluoranthene	205-82-3
Benzo(k)fluoranthene	207-08-9
Benzo(r,s,t)pentaphene	189-55-9
Dibenzo (a,e)pyrene	192-65-4
Dibenzo (a,h)pyrene	189-64-4
Dibenzo(a,h)acridine	226-36-8
Dibenzo(a,h)anthracene	53-70-3
Dibenzo(a,j)acridine	224-42-0
Fluoranthene	206-44-0
Indeno(1,2,3-cd)pyrene	193-39-5
Perylene	198-55-0

Polybrominated dibenzodioxins and furans

2,3,7,8-tetrabromodibenzo-p-dioxin	50585-41-6
2,3,7,8-tetrabromodibenzofuran	67733-57-7

Polybrominated diphenyl ethers

Pentabromodiphenyl ether	32534-81-9
Octabromodiphenyl ether	32536-52-0
Decabromodiphenyl ether	13654-09-6

Polychlorinated Biphenyls (PCBs)

2,3',4,4',5 Pentachlorobiphenyl	31508-00-6
2,3,4,4',5 Pentachlorobiphenyl	74472-37-0
2,3,3',4,4' Pentachlorobiphenyl	32598-14-4
3,3',4,4',5,5' Hexachlorobiphenyl	32774-16-6
2,3',4,4',5,5' Hexachlorobiphenyl	52663-72-6
2,3,3',4,4',5' Hexachlorobiphenyl	69782-90-7
2,3,3',4,4',5 Hexachlorobiphenyl	38380-08-4
2,3,3',4,4',5,5' Heptachlorobiphenyl	39365-31-9

Polychlorinated Dibenzo-p-dioxins

2,3,7,8 Tetrachlorodibenzo-p-dioxin	1746-01-6
1,2,3,7,8 Pentachlorodibenzo-p-dioxin	40321-76-4
1,2,3,4,7,8 Hexachlorodibenzo-p-dioxin	39227-28-6
1,2,3,6,7,8 Hexachlorodibenzo-p-dioxin	576-53-8
1,2,3,7,8,9 Hexachlorodibenzo-p-dioxin	19408-74-3
1,2,3,4,6,7,8 Heptachlorodibenzo-p-dioxin	35822-46-9
1,2,3,4,6,7,8,9 Octachlorodibenzo-p-dioxin	3268-87-9

Polychlorinated Dibenzofurans

2,3,7,8 Tetrachlorodibenzofuran	51207-31-9
1,2,3,7,8 Pentachlorodibenzofuran	57117-41-6
2,3,4,7,8 Pentaachlorodibenzofuran	57117-31-4
1,2,3,4,7,8 Hexachlorodibenzofuran	70648-26-9
1,2,3,6,7,8 Hexachlorodibenzofuran	57117-44-9
1,2,3,7,8,9 Hexachlorodibenzofuran	72918-21-9
2,3,4,7,8,9 Hexachlorodibenzofuran	60851-34-5
1,2,3,4,6,7,8 Heptachlorodibenzofuran	67562-39-4
1,2,3,4,7,8,9 Heptachlorodibenzofuran	55673-89-7
1,2,3,4,6,7,8,9 Octachlorodibenzofuran	39001-02-0

Polychlorinated Naphthalenes

Trichloronaphthalene	1321-65-9
Tetrachloronaphthalene	1335-88-2
Pentachloronaphthalene	1321-64-8
Hexachloronaphthalene	1335-87-1
Heptachloronaphthalene	32241-08-0

Aldrin/Dieldrin	309-00-2/60-57-1
.*Cadmium (pending review of bioavailability)	7440-43-9
Chlordane	57-74-9
Chlordecone (Kepone)	3734-48-3
DDT, p,p'-	50-29-3
Endrin	72-20-8
Heptachlor/Heptachlor epoxide	76-44-8/1024-57-3
Hexabromobiphenyl	36355-01-8
Hexabromocyclododecane	25637-99-4
Hexachlorobenzene	118-74-1
Hexachlorobutadiene	87-68-3
.*Lead (pending review of bioavailability)	7439-92-1
Mercury	7439-97-6
Mirex	2385-85-5
Perfluorooctane sulfonates (PFOS)	(a)
Pentachlorobenzene	608-93-5
Polycyclic aromatic hydrocarbons (PAHs)	(b)
Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDF)	(c)
Polybrominated diphenyl ethers (PBDEs)	(d)
Polychlorinated biphenyls (PCBs)	1336-36-3
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)	(e)
Polychlorinated naphthalenes (PCN)	70776-03-3 (f)
Short-chain chlorinated paraffins (SSCP)	85535-84-8 (g)
Tetrabromobisphenol A	79-94-7
Tetrachlorobenzene, 1,2,4,5-	95-94-3
Toxaphene	8001-35-2

Explanatory Notes Regarding Specific Chemicals on the PBT List (WAC 173-333-310)

(a) **Perfluorooctane sulfonates (PFOS):** PFOS (Molecular formula $C_8F_{17}SO_3$) is a member of a group of organic compounds that consists of an eight-carbon chain where the hydrogen atoms have been substituted with fluorine atoms and a reactive sulfonate group at one end of the chain. PFOS derivatives and salts include: Acid (CAS 1763-32-1); ammonium salt (CAS 29081-56-9); diethanolamine salt (CAS 70225-14-8); lithium salt (CAS 29457-72-5); and potassium salt (CAS 2795-39-3).

(b) **Polycyclic aromatic hydrocarbons (PAHs):** PAHs are a group of compounds composed of two or more fused aromatic rings. Ecology has determined that the following PAH compounds meet the proposed PBT criteria in WAC 173-333-320(2): Dibenzo(a,h)anthracene (CAS 53-70-3); 3-methylchlolanthrene (CAS 56-49-5); benzo(r,s,t)pentaphene (CAS 189-55-9); dibenzo(a,h)pyrene (CAS 189-64-4); benzo(g,h,i)perylene (CAS 191-24-2); dibenzo(a,e)pyrene (CAS 192-65-4); indeno(1,2,3-cd)pyrene (CAS 193-39-5); 7H-dibenzo(c,g)carbazole (CAS 194-59-2); perylene (CAS 198-55-0); benzo(j)fluoranthene (CAS 205-82-3); benzo(b)fluoranthene (CAS 205-99-2); fluoranthene (CAS 206-44-0); benzo(k)fluoranthene (CAS 207-08-9); benzo(a)phenanthrene (CAS 218-01-9); dibenzo(a,j)acridine (CAS 224-42-0); and dibenzo(a,h)acridine (CAS 226-36-8).

(c) **Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDDs/PBDFs):** PBDDs/PBDFs consist of two groups of tricyclic aromatic compounds with similar chemical and physical properties. Ecology has determined that the following PBDD/PBDF congeners meet the proposed PBT criteria in WAC 173-333-320(2): 2,3,7,8-tetrabromodibenzo-p-dioxin (CAS 50585-41-6); and 2,3,7,8-tetrabromodibenzofuran (CAS 67733-57-7).

(d) **Polybrominated diphenyl ethers (PBDEs):** PBDEs are a class of chemicals with the general chemical formula of $C_{12}H_{(9-0)}Br_{(1-10)}O$ with the sum of H and Br atoms always equal to 10. There are theoretically 209 congeners which can be divided into 10 congener groups (mono- through decabromodiphenyl ethers). Ecology has determined that the following congener groups meet the proposed PBT criteria in WAC 173-333-320(2) and/or degrade to congeners that meet the draft PBT criteria in WAC 173-333-320(2): Pentabromodiphenyl ether (CAS 32534-81-9); octabromodiphenyl ether (CAS 32536-52-0); decabromodiphenyl ether (CAS 13654-09-6).

(e) **Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDDs/PCDFs):** PCDDs/PCDFs consist of two groups of

~~tricyclic aromatic compounds with similar chemical and physical properties. Ecology has determined that the following PCDD/PCDF congeners meet the proposed PBT criteria in WAC 173-333-320(2): 2,3,7,8-tetrachlorodibenzo-p-dioxin (CAS 1746-01-6); 1,2,3,7,8-pentachlorodibenzo-p-dioxin (CAS 40321-76-4); 1,2,3,4,7,8-hexachlorodibenzo-p-dioxin (CAS 39227-28-6); 1,2,3,6,7,8-hexachlorodibenzo-p-dioxin (CAS 576-53-8); 1,2,3,7,8,9-hexachlorodibenzo-p-dioxin (CAS 19408-74-3); 1,2,3,4,6,7,8-heptachlorodibenzo-p-dioxin (CAS 35822-46-9); 1,2,3,4,6,7,8,9-octachlorodibenzo-p-dioxin (CAS 3268-87-9); 2,3,7,8-tetrachlorodibenzofuran (CAS 51207-31-9); 1,2,3,7,8-pentachlorodibenzofuran (CAS 57117-41-6); 2,3,4,7,8-pentachlorodibenzofuran (CAS 57117-41-4); 1,2,3,4,7,8-hexachlorodibenzofuran (CAS 70648-26-9); 1,2,3,6,7,8-hexachlorodibenzofuran (CAS 57117-44-9); 1,2,3,7,8,9-hexachlorodibenzofuran (CAS 72918-21-9); 2,3,4,7,8,9-hexachlorodibenzofuran (CAS 60851-34-5); 1,2,3,4,6,7,8-heptachlorodibenzofuran (CAS 67562-39-4); 1,2,3,4,7,8,9-heptachlorodibenzofuran (CAS 55673-89-7); 1,2,3,4,6,7,8,9-octachlorodibenzofuran (CAS 39001-02-0).~~

~~(f) **Polychlorinated naphthalenes (PCN):** PCNs are a group of chlorinated naphthalenes that contain 1 to 8 chlorine atoms and are structurally similar to PCBs. Ecology has determined that the following compounds meet the proposed PBT criteria in WAC 173-333-320(2): Heptachloronaphthalene (CAS 32241-08-0); hexachloronaphthalene (CAS 1335-87-1); pentachloronaphthalene (CAS 1321-64-8); tetrachloronaphthalene (CAS 1335-88-2); and trichloronaphthalene (CAS 1321-65-9).~~

~~(g) **Short-chain chlorinated paraffins (SSCP):** SSCPs are chlorinated derivatives of n-alkanes that have carbon chains ranging from 10 to 13 carbon atoms and a chlorine content ranging from 50-70% by weight.~~

(3) **Lead and cadmium**. Ecology will not develop a chemical action plan for lead and cadmium until the environmental protection agency concludes the development of a metals assessment framework and ecology completes its review of the bioavailability of these two substances.

~~(3) **Categories.** Ecology will assign each chemical on the PBT list to one of the following three categories:~~

~~(a) **Category 1.** Ecology will place chemicals in this category if the department determines that the chemical is used, released or present in Washington.~~

~~(b) **Category 2.** Ecology will place chemicals in this category if the department determines that there is insufficient~~

~~information to reach a conclusion on whether the chemical is used, released or present in Washington.~~

~~(c) **Category 3.** Ecology will place chemicals in this category if the department determines that:~~

~~(i) All uses and releases of the chemical are prohibited under other state or federal laws or regulations; or~~

~~(ii) There are no feasible measures for reducing or phasing out uses and releases of the chemical beyond levels required under other federal and state laws and regulations; or~~

~~(iii) Is not present in Washington's environment.~~

(4) **Revising the PBT list.** Ecology will periodically review and, as appropriate, revise the PBT list in subsection (2) of this section using the criteria and procedures in WAC 173-333-320 through 173-333-340.

NEW SECTION

WAC 173-333-320 What criteria will ecology use to identify and add chemicals or chemical groups to the PBT list? (1) **Purpose.** This section describes the criteria that ecology will use to determine whether a chemical or group of chemicals should be included on the PBT list.

(2) **Criteria for identifying PBTs.** A chemical or group of chemicals will be included on the PBT list if ecology determines it meets each of the following criteria:

(a) **Persistence.** The chemical or chemical group can persist in the environment based on credible scientific information ~~evidence~~ that:

(i) The half-life of the chemical in water is greater than or equal to sixty days; or

(ii) The half-life of the chemical in soil is greater than or equal to sixty days; or

(iii) The half-life of the chemical in sediments is greater than or equal to sixty days; and

(b) **Bioaccumulation.** The chemical or chemical group has a high potential to bioaccumulate based on credible scientific information ~~evidence~~ that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1000 or, in the absence of such data, that the log-octanol water partition coefficient (log K_{ow})is greater than five, and;

~~(c) **Toxicity.** The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on evidence that:~~

~~(i) The chemical or a chemical group is known to cause or can reasonably be anticipated to cause cancer or teratogenic~~

~~effects, reproductive effects, neurological disorders or other acute or chronic health effects; or~~

~~(ii) The chemical or chemical group is known to cause or can reasonably be anticipated to cause adverse effects in aquatic and terrestrial plants and animals.~~

(c) Toxicity. The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on credible scientific information that:

i. The chemical (or chemical group) is a carcinogen, a developmental or reproductive toxicant or a neurotoxicant;

ii. The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day; or

iii. The chemical (or chemical group) has a chronic no-observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no-observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L.

(d) **Additional criteria applicable to metals.** The chemical or chemical group is a metal and ecology determines that it is likely to be present in forms that are bioavailable.

(3) **Degradation products.** Ecology will consider both the chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a chemical does not meet the criteria in this section for a PBT but degrades into chemicals that do meet the criteria in this section for a PBT, the parent chemical will be considered in the development of a CAP for those derivative chemicals.

NEW SECTION

WAC 173-333-330 What criteria will ecology use to remove a PBT from the PBT list? (1) **Purpose.** This section describes the criteria and factors ecology will use to determine whether a chemical or group of chemicals should be removed from the PBT list.

(2) **Criteria for removing a chemical from the PBT list.** Ecology will remove a chemical or chemical group from the PBT list if the department determines that credible scientific information developed subsequent to the listing decision provides evidence that the chemical or chemical group does not meet the PBT criteria in WAC 173-333-320(2).

NEW SECTION

WAC 173-333-340 What process would ecology follow to revise the PBT list? (1) **Purpose.** This section describes the processes ecology will use to notify the public and amend the PBT list after making a determination that chemicals or groups of chemicals should be added or removed from the PBT list.

(2) **Reviewing and updating the PBT list.** Ecology will periodically review and update WAC 173-333-310. The frequency of review will be determined by credible scientific information available on individual chemicals or chemical groups, rule-making petitions submitted to ecology, and available agency resources. Ecology will comply with the requirements for reviewing and responding to rule-making petitions in the Administrative Procedure Act, chapter 34.05 RCW.

(3) **Public notification.** If ecology makes a preliminary determination that a chemical should be added or removed from the PBT list, the department will prepare a technical discussion paper that summarizes the scientific information supporting the addition or removal of a chemical and ~~it will~~ notify the public through an announcement posted on the ecology web site and published in the *Washington State Register*.

(4) **Amending the PBT list.** If ecology makes a final determination that a chemical or chemical group should be added or removed from the PBT list, the department will initiate actions to amend WAC 173-333-310 through formal rulemaking.

PART IV
CHEMICAL ACTION PLANS (CAPs)

NEW SECTION

WAC 173-333-400 What is a chemical action plan (CAP)? A chemical action plan (CAP) is a plan that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and recommends actions to protect human health or the environment.

~~(1) A chemical action plan (CAP) is a plan that identifies, characterizes and evaluates uses and releases of a specific PBT or a group of PBTs and includes recommendations on actions to protect human health or the environment.~~

~~(2) CAPs will include recommendations for:~~

~~(a) Reducing and eliminating uses and releases of the specific PBT or group of PBTs addressed in the CAP;~~

~~(b) Managing products or waste that contain the specific PBT or group of PBTs addressed in the CAP;~~

~~(c) Minimizing exposure to the specific PBT or group of PBTs;~~

~~(d) Collecting additional information needed to evaluate the feasibility of potential actions; and~~

~~(e) Measuring or monitoring the effectiveness of actions being implemented in Washington.~~

NEW SECTION

WAC 173-333-410 What evaluation factors and processes will ecology use to select PBTs for chemical action plan preparation? (1) **Purpose.** Ecology will consult with the department of health to develop a multi-year schedule for the preparation of chemical action plans. The purpose of this section is to describe the evaluation factors and processes ecology will use to prepare and update the multi-year schedule. ~~decide when to develop a chemical action plan for a particular chemical or group of chemicals included on the PBT list.~~

~~(2) **Decision-making process.** Ecology will consult with the department of health to develop a multi-year schedule for the preparation of chemical action plans. The schedule shall outline the chemicals for which chemical action plans will be prepared, the timeline for completing the plans and the rationale for selecting each chemical. The process for deciding when to prepare a chemical action plan for a particular chemical or group of chemicals includes the following:~~

~~(2) **Candidates for CAP development.** Ecology will consider developing chemical action plans for chemicals on the PBT list that meet the following criteria:~~

~~(a) Ecology determines that the chemical or chemical group has a half-life in water that is greater than or equal to sixty days, soil or sediment that is greater than or equal to one hundred eighty days;~~

~~(b) Ecology determines that the chemical or chemical group has a bioconcentration factor or bioaccumulation factor in aquatic species that is greater than 2,000; and~~

~~(c) Ecology determines that the chemical or chemical group is "toxic" as defined in WAC 173-333-302 (2)(c).~~

~~(3) **Decision-making process.** Ecology will consult with the department of health to select the chemicals for chemical action plan preparation. The process for deciding when to prepare a chemical action plan for a particular chemical or group of chemicals includes the following:~~

(2) **Evaluation ~~Selection~~ factors.**

(a) Ecology will consider the following factors when preparing the multi-year schedule ~~deciding whether to prepare a chemical action plan for a particular chemical or group of chemicals identified in WAC 173-333-310(2)~~:

(i) **Relative ranking.** The relative ranking assigned to each PBT based on ecology's evaluation of information on PBT

characteristics, uses of the chemical in Washington, releases of the chemical in Washington, ~~and~~ the levels of the chemical present in the Washington environment, and levels of the chemical present in Washington residents. ~~Ecology will not prepare a chemical action plan for a PBT if the department determines that the chemical is not used, released or present in Washington state.~~

(ii) **Opportunities for reductions.** Whether there are opportunities for reducing or phasing out uses, production or releases of the PBT in Washington. In reviewing available information, the agencies shall consider whether more than one PBT is present in particular products, generated in particular processes or released from particular sources (co-occurring chemicals).

(iii) **Multiple chemical releases and exposures.** Scientific evidence on the combined effects of exposure to one or more PBTs and other substances commonly present in the Washington environment.

(iv) **Sensitive population groups and high-exposure populations.** Scientific evidence on the susceptibility of various population groups including the timing of the exposure and the cumulative effects of multiple exposures.

(v) **Existing plans or regulatory requirements.** Whether there are existing plans or regulatory requirements that reduce and phase out uses and releases of a particular PBT or group of PBTs. ~~Ecology will not prepare a chemical action plan for a PBT if the department determines that all uses and releases of the chemical are prohibited under other state or federal laws and regulations.~~

~~(vi) Available information. Whether information is available on uses, releases and concentrations in the Washington environment or Washington residents. Ecology will prioritize PBTs for information collection if the department determines there is insufficient information to reach a conclusion on whether the PBT is used, released or present in Washington.~~

~~(b) **Preliminary selection.** Ecology will prepare a written summary of the preliminary decision to prepare a chemical action plan for one or more PBTs and the rationale for selecting that particular PBT or group of PBTs.~~

(b) Ecology will not prepare CAPs if the department determines:

(i) All uses and releases of the PBT are prohibited under other state and federal laws or regulations;

(ii) There is credible scientific information to support a conclusion that the PBT is not used, released or present in Washington; or

(iii) There are no available opportunities for reducing or phasing out the uses, releases or exposures of the PBT beyond levels required under other federal or state laws or regulations.

(3) **Preliminary schedule.** Ecology will prepare a preliminary schedule that will identify the PBTs for which CAPs will be developed for the multi-year schedule, the rationale for selecting these PBTs and a timeline for completing CAPs for these PBTs.

(4)~~(c)~~ **Public notice and comment.** Ecology will notify the public when it has prepared a ~~makes a~~ preliminary schedule ~~selection~~ and provide an opportunity for public review and comment. Ecology will notify the public through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also send a written announcement to interested persons and organizations. Ecology will provide sixty days, from the date the notice is published in the *Washington State Register* for the public to review and submit comments on the preliminary selection.

(5)~~(d)~~ **Final schedule ~~decision.~~** Ecology will review all public comments on the preliminary schedule ~~selection~~ prior to preparing a final schedule. ~~making a final decisions on which PBTs to include on the schedule and the timelines for completing plans for those PBTs. to prepare a chemical action plan for a particular PBT or groups of PBTs.~~ Ecology will notify the public of the final decision through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the preliminary schedule ~~selection~~.

(6) Schedule updates. Ecology will review and, as appropriate, update the schedule for chemical action plans at least once every three years. In making such revisions, Ecology will follow the process for preparing the schedule (including an opportunity for public review and comment) specified in this section.

NEW SECTION

WAC 173-333-420 What are the contents of a CAP? (1) **Contents of the chemical action plans.** Chemical action plans will include, as appropriate, the following types of information, evaluations and recommendations:

(a) **General chemical information.** General information includes, but is not limited to, chemical name, properties, uses and manufacturers.

(b) **Production, uses and releases.** An analysis of information on the production, unintentional production, uses and disposal of the chemical. This will include estimates on the amount of each PBT used and released from all sources or activities in Washington and other man-made and naturally occurring sources that may contribute to exposures in Washington. Sources may include other chemicals or products

that are known or suspected to degrade to the chemical included on the PBT list.

(c) **Human health and environmental impacts.** Information on ~~An evaluation of~~ the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.

(d) **Current management approaches.** An evaluation of the regulatory and nonregulatory approaches that influence production, uses, releases and management of each PBT.

(e) **Identification of policy options.** A list of options for managing, reducing and eliminating the different uses and releases of the PBTs addressed in the CAP. The range of options for particular uses and releases will include:

(i) A no-action option;

(ii) An option that results in the elimination of PBT uses and releases;

(iii) An option to manage chemicals to reduce exposure; and

(iv) Other options, including the use of available substitutes, which will enable full consideration of the opportunities and constraints for reducing particular uses, releases and exposures.

f) **Recommendations.** (i) Recommendations for:

(A) Reducing and phasing-out uses and releases of the specific PBT or group of PBTs addressed in the CAP;

B) Managing products or wastes that contain the specific PBT or group of PBTs addressed in the CAP;

C) Minimizing exposure to the specific PBT or group of PBTs.

(i) Recommendations on actions to manage, reduce or phase-out uses and releases of the PBT addressed in the CAP.

(ii) The recommendations will be based on an evaluation of the following factors:

(A) Environmental and human health benefits associated with implementing the action;

(B) Economic and social impacts associated with implementing the action;

(C) Feasibility of implementing the action;

(D) Availability, cost and effectiveness of safer substitutes for uses of the PBT being addressed in the plan; and

(E) Consistency with existing federal and state regulatory requirements;

(g) **Implementation Steps**. A description of the steps ecology will take to implement the CAP, including a description of:

(A) The existing resources and necessary additional budget ecology intends to use;

(B) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;

(C) How ecology intends to inform and educate affected persons about the CAP;

(D) How ecology will promote and assist voluntary actions;

(E) How ecology will collect additional information needed to evaluate the feasibility of potential actions; and

(F) Any recommended regulatory actions and how ecology will pursue them.

(h) **Performance measures**. A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time.

(i) Other. Other information that ecology determines is necessary to support the decision-making process.

(2) **Regulatory consistency.** When evaluating the consistency with existing federal and state regulatory requirements under subsection (1)(f)(i)(D) of this section, ecology will:

(a) Ensure that the recommendations do not violate existing federal or state laws;

(b) Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so; and

(c) Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal, state, and local laws applicable to the same activity or subject matter.

~~(f) **Recommendations.** The recommendations will include:~~

~~(i) Recommendations on actions to manage, reduce or phase-out uses and releases of the PBT addressed in the CAP. The recommendations will be based on an evaluation of the following factors:~~

~~(A) Feasibility of implementing the action;~~

~~(B) Environmental and human health benefits associated with implementing the action;~~

~~(C) Economic and social impacts associated with implementing the action; and~~

~~(D) Consistency with existing federal and state regulatory requirements.~~

~~(ii) A description of the steps ecology will take to implement the CAP, including a description of:~~

~~(A) The existing resources and necessary additional budget ecology intends to use;~~

~~(B) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;~~

~~(C) How ecology intends to inform and educate affected persons about the CAP; and~~

~~(D) How ecology will promote and assist voluntary actions.~~

~~(iii) Performance measures. A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time.~~

~~(g) Other. Other information that ecology determines is necessary to support the decision-making process.~~

~~(2) **Regulatory consistency.** When evaluating the consistency with existing federal and state regulatory requirements under subsection (1)(f)(i)(D) of this section, ecology will:~~

~~(a) Ensure that the recommendations do not violate existing federal or state laws;~~

~~(b) Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so; and~~

~~(c) Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal, state, and local laws applicable to the same activity or subject matter.~~

(3) **Economic analyses.** In assessing economic impacts under subsection (1)(f)(i)(C) of this section, ecology will identify costs of implementing the recommendations. This may include a qualitative and/or quantitative analysis of the probable benefits and costs of the CAP.

(4) **Safer Substitutes**: When evaluating the availability of safer substitutes for PBT uses, Ecology will:

(a) Determine if the recommendations include the use of safer substitutes, and if not, explain why Ecology has not recommended this option.

(b) Determine if the recommendations call for additional research for uses with no safer substitutes, and if not, explain why Ecology has not recommended this option.

(c) Provide for periodic re-evaluation of whether substitutes are available.

NEW SECTION

WAC 173-333-430 What process will ecology use to develop CAPs? (1) **Purpose.** The purpose of this section is to identify the process ecology will use to develop CAPs.

(2) **Workplan/scoping.** Once a chemical is selected for CAP development, ecology will initially plan and scope the CAP of the selected chemical based upon available information regarding the chemical's products, uses and releases; human health exposure and ecological hazards; environmental releases, fate, and transport; environmental concentrations and available

substitutes; available options for managing uses and releases; estimated costs, benefits and effectiveness of alternate management options; and any other information ecology determines is necessary to support the CAP development process. Ecology will consult with the department of health regarding all portions of the CAP related to human health exposures.

(3) **Advisory committee.** Ecology will create an external advisory committee for each CAP that ecology develops. The purpose of the advisory committee is to provide stakeholder input and expertise.

(a) The advisory committee membership will include, but not be limited to, representatives from: Large and small business sectors, community, environmental and public health advocacy groups, local governments, and public health agencies. When appropriate, representatives from the following groups will also be invited to participate: Agricultural groups, worker safety advocacy groups, and other interested parties. Federally recognized tribal governments will also be encouraged to participate. In addition, representation from other state executive agencies may be requested to provide input and to represent agency interests in the CAP development process. Outside experts (if needed) may be requested to provide technical expertise.

(b) A neutral third-party facilitator may be hired to facilitate advisory committee meetings.

(c) The advisory committee will follow a consultative process, where ecology will draft the CAP in consideration of input from advisory committee members.

(d) All advisory committee meetings will be open to the public. Ecology will notify the public of advisory committee meetings through an announcement posted on the ecology web site and written notification to interested individuals and organizations.

(4) **Information collection phase.** Ecology will collect all necessary and up-to-date information regarding the selected chemical. CAP advisory committee members will be asked to contribute, and as appropriate, review information from ecology during this phase of CAP development. The department of health will be asked to review any information related to human health.

(5) **Draft recommendations.** Ecology will develop a draft CAP for advisory committee review and comment. Ecology will review all advisory committee comments and, as appropriate, revise the draft CAP prior to distributing it for public review and comment.

(6) **Public review and comment.** Ecology will notify the public when it has developed a draft CAP and provide an opportunity for public review and comment. The public comment period for each draft CAP will be a minimum of sixty days. Ecology will notify the public through an announcement posted concurrently on the ecology web site, a notice in the *Washington*

State Register, and sent to interested persons and organizations. The comment period shall start from the date the notice is published in the *Washington State Register*. During the comment period, ecology will hold a minimum of two public meetings on the draft CAP. One meeting shall be held on the western side of the state, and one meeting shall be held on the eastern side of the state. Ecology may hold additional public meetings during the public comment period if determined necessary. Ecology will provide a response to all public comments.

(7) **Final recommendations.** Ecology will review and provide responses to all public comments on the draft CAP prior to issuing the final recommendations. Ecology will notify the public of the final recommendations through an announcement that will be published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the draft CAP.

(8) **Coordination with other agencies.** Ecology will coordinate with other government agencies and interested parties as appropriate on the implementation of the final CAP. Ecology will consult with the department of health on public information materials addressing food safety issues.

Appendix C PBT Rule Language highlighting differences between the re-filed draft PBT Rule language and the final adopted PBT Rule (January 13, 2006)

Chapter 173-333 WAC

PERSISTENT BIOACCUMULATIVE TOXINS

PART I
GENERAL PROVISIONS

NEW SECTION

WAC 173-333-100 Introduction. Persistent, bioaccumulative toxins (PBTs) are chemicals that pose a unique threat to human health and the environment in Washington state. They remain in the environment for long periods of time, are hazardous to the health of humans and wildlife, can build up in the food chain, and can be transported long distances and readily move between air, land and water media.

Because of the unique threat that these PBTs pose, special attention is necessary to identify actions that will reduce and eliminate threats to human health and the environment. While ecology addresses PBTs through existing regulatory and nonregulatory programs, there remains a need for multimedia, cross-program measures that will reduce and phase-out releases and uses of PBTs over time.

The goal of this chapter is to reduce and phase-out PBT uses, releases and exposures in Washington. Ecology recognizes that many factors will influence whether and when this goal can be attained and that those factors will often vary depending on the PBT and the uses of the PBT. These factors include environmental and human health benefits, economic and social costs, technical feasibility, availability of safer substitutes, and consistency with other regulatory requirements. This chapter establishes a process that ecology will use to evaluate and identify actions that should be taken for particular PBTs. This process is designed to enhance actions being taken under other environmental laws and regulations.

NEW SECTION

WAC 173-333-110 What is the purpose of this chapter? The purpose of this chapter is to:

(1) Establish criteria ecology will use to identify persistent bioaccumulative toxins that pose human health or environmental threats in Washington state;

(2) Establish a list of persistent bioaccumulative toxins;

(3) Establish procedures ecology will use to review and periodically update the list;

(4) Establish criteria for selecting persistent bioaccumulative toxins and metals of concern for which ecology will prepare chemical action plans;

(5) Define the scope and content of chemical action plans and establish the process ecology will use to prepare those plans; and

(6) Define the processes ecology will use to coordinate the implementation of this chapter with the department of health and other agencies.

NEW SECTION

WAC 173-333-120 Applicability. (1) This chapter applies to the department of ecology (ecology). This chapter does not impose new requirements on persons using or releasing PBTs, and it does not create new authorities nor does it constrain existing authorities for ecology.

(2) This chapter provides for public involvement opportunities to allow interested persons to participate in the ecology processes for identifying PBTs and developing recommendations on measures to address uses and releases of PBTs.

NEW SECTION

WAC 173-333-130 Exemptions to the PBT list. Any pesticide with a currently valid registration that has been issued by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136 et seq., or any fertilizer regulated under the Washington Fertilizer Act, chapter 15.54 RCW, will not be included on the persistent bioaccumulative toxin list established under this chapter.

NEW SECTION

WAC 173-333-140 Administrative principles. (1) **Scientific information.** Ecology will base decisions on PBTs on sound public policy and credible scientific information. However, ecology believes that lack of full scientific consensus should not be used as a justification for delaying reasonable measures to prevent harm to human health or the environment.

(2) **Public involvement.** Ecology will provide opportunities for public involvement during the decision-making processes for identifying PBTs and preparing a CAP.

(3) **Clear documentation.** Ecology will provide clear and understandable descriptions and rationale for decisions implementing this chapter.

(4) **Predictability.** Ecology will implement this chapter in ways that allow stakeholders, interest groups, and the public to plan their participation in decision-making processes and future responses to recommendations that result from those processes.

(5) **Coordination.** Ecology will coordinate with federal and state agencies, local governments, tribes, and other interested parties in the development and implementation of CAPs and when revising the PBT list.

(6) **Rule amendments.** When amending any portion of this rule, Ecology will follow the requirements of the Administrative Procedure Act (APA), chapter 34.05 RCW.

PART II
DEFINITIONS

NEW SECTION

WAC 173-333-200 Definitions. For the purposes of this chapter, the following definitions shall apply:

"Administrative Procedure Act" or **"APA"** means the Washington Administrative Procedure Act, chapter 34.05 RCW.

"Bioaccumulation" means the process by which substances increase in concentration in living organisms as they take in contaminated air, water, soil, sediment or food because the substances are very slowly metabolized or excreted.

"Bioaccumulation factor" or **"BAF"** means the ratio of the concentration of a chemical in an organism to the concentration of the chemical in the surrounding environment. The BAF is a measure of the extent to which the organism accumulates the chemical as a result of uptake through ingestion as well as contact from contaminated media, such as water.

"Bioconcentration factor" or **"BCF"** means the ratio of the concentration of a chemical in an aquatic organism to the

concentration of the chemical in water ~~the surrounding environment~~. The BCF is a measure of the extent of chemical partitioning between an aquatic organism and water ~~the surrounding environment~~.

"Carcinogen" means a chemical or chemical group ~~that is known or suspected to increase the probability of developing cancer. For purposes of implementing this chapter, the term carcinogen applies to substances~~ that have been identified as "carcinogenic to humans" or "likely to be carcinogenic to humans" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program.

"Chemical" means a naturally occurring element, mixture, or group of organic and inorganic compounds that is produced by or used in a chemical process.

"Chemical action plan" or **"CAP"** means a plan that identifies, characterizes and evaluates uses and releases of a specific PBT, ~~or~~ a group of PBTs or metals of concern and recommends actions to protect human health or the environment.

"Chemical group" means a grouping of chemicals which share a common chemical structure and common toxicological properties.

"Credible scientific information" means information that is based on a theory or technique that is generally accepted~~able~~ in the relevant scientific community or has been collected or derived using standard or generally accepted methods and protocols and appropriate quality assurance and control procedures.

"Cross-media transfer of chemicals" means the movement of a chemical from one medium, such as air, water, soil, or sediment, to another.

"Degradation" means the processes by which organic chemicals are transformed into derivative chemicals and ultimately broken down.

"Developmental or reproductive toxicant" means a chemical or chemical group ~~that is known or suspected to cause adverse effects on development or reproduction. For purposes of implementing this chapter, the term developmental or reproductive toxicant applies to chemicals or chemical groups~~ identified as posing developmental or reproductive hazards by the National Toxicology Program or chemicals or chemical groups with sufficient evidence of a developmental or reproductive hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Reproductive Toxicity Risk Assessment and Guidelines for Developmental Toxicity Risk Assessment as set forth in 61 FR 56274 et seq. and 56 FR 63798 et seq., respectively.

"Ecology" means the department of ecology.

"Environment" means any plant, animal, natural resource, surface water (including underlying sediments), ground water, drinking water supply, land surface (including tidelands and shorelands) or subsurface strata, or ambient air.

"Environmental half-life" means the time required for the concentration of a chemical to diminish to half its original value. The environmental half-life of a chemical is a measure of a chemical's persistence in the environment.

"Feasible" means reasonably capable of being accomplished or brought about or capable of being utilized or dealt with successfully.

"High-exposure populations" means groups of people that ~~are at greater risk because they~~ have a higher potential for exposure than the general population.

"Log-octanol water partition coefficient" or **"Log K_{ow}"** means the ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol/water system as expressed in a logarithmic format.

"Media" or **"medium"** means a component of the environment (air, water, soil or sediment) in which a contaminant is measured and an organism lives its life, and from which an organism can accumulate contaminants.

"Neurotoxicant" means a ~~chemical or chemical group that is known or suspected to cause adverse changes in the structure or function of the central and/or peripheral nervous system. For purposes of implementing this chapter, the term neurotoxicant applies to~~ chemical~~s~~ or chemical group~~s~~ with sufficient evidence of a neurotoxic hazard in humans or experimental animals consistent with the United States Environmental Protection Agency's Guidelines for Neurotoxicity Risk Assessment as set forth in 63 FR 26926 et seq.

"No observed effect concentration" or **"NOEC"** means the highest concentration of a chemical evaluated in an aquatic toxicity test that does not cause a statistically and biologically significant difference in effects compared with controls.

"Persistent bioaccumulative toxin" or **"PBT"** means a chemical or chemical group that meets or exceeds the criteria for persistence, bioaccumulation and toxicity criteria established in WAC 173-33-320.

"Persistence" means the tendency of a chemical to remain in the environment without transformation or breakdown into another chemical form. It refers to the length of time a chemical is expected to reside in the environment and be available for exposure.

"Reference dose" means a numerical estimate of a daily exposure to the human population, including sensitive subgroups such as children, that is likely to be without harmful effects during a lifetime.

"Sensitive population group" means groups of people that exhibit a different or enhanced response to a chemical than most people exposed to a similar level of the chemical because of genetic makeup, age, nutritional status or exposure to other toxic substances.

"Toxicity" means the degree to which a substance or mixture of substances can harm humans, plants or wildlife.

PART III
THE PBT LIST AND CRITERIA AND PROCEDURES FOR REVISING THE LIST

NEW SECTION

WAC 173-333-300 What is the purpose of the PBT list? (1) **Purpose.** The purpose of the PBT list is to identify toxic chemicals that require further action because they remain ("persist") in the environment for long periods of time where they can bioaccumulate to levels that pose threats to human health and environment in Washington.

(2) **Intended uses of the PBT list.** Ecology will use the PBT list in the following ways:

(a) **Chemical action plans.** To select chemicals for chemical action plan development.

(b) **Ambient monitoring.** To help guide decisions on the design and implementation of ecology programs for characterizing chemical concentrations in the ambient environment.

(c) **Biomonitoring.** To encourage and inform the department of health regarding their efforts to monitor chemicals in human tissue.

(d) **Public awareness.** To promote greater public awareness on the problems associated with PBT chemicals, the uses and sources of individual PBTs and steps that individuals and organizations can take to reduce PBT uses, releases and exposure.

(e) **Voluntary measures.** To help identify opportunities for government agencies, businesses and individuals to implement voluntary measures for reducing and phasing out PBT uses and releases.

(3) **Relationship to actions addressing chemical uses and releases.** Ecology has determined that the chemicals on the PBT list pose a potential threat to human health and the environment in Washington.

(a) Ecology's decision to include a particular chemical on the PBT list does not represent a ~~decision~~ final determination that all uses and releases of that chemical should be reduced and phased-out. Any recommendations on uses and releases of a particular chemical will be made in the CAP process.

(b) Ecology ~~does~~ will not ~~intend to~~ use the PBT list as the sole basis for establishing discharge monitoring requirements

that are not required under current permits. Ecology will evaluate and, if ~~appropriate~~ necessary, prepare recommendations for additional monitoring requirements when preparing chemical action plans (WAC 173-333-420 and 173-333-430).

NEW SECTION

WAC 173-333-310 What chemicals or chemical groups are included on the PBT list? (1) **Purpose.** This section identifies the chemicals and chemical groups that ecology has determined meet the criteria specified in WAC 173-333-320.

(2) **PBT list.** Ecology has determined that the following chemicals or chemical groups meet the criteria specified in WAC 173-333-320.

Chemicals listed in alphabetical order	**CAS Number**
Aldrin	309-00-2
~~Cadmium~~	~~7440-43-9~~
Chlordane	57-74-9
Chlordecone (Kepone)	~~3734-48-3~~ 143-50-0
Dichlorodiphenyltrichloroethane (DDT)	50-29-3
Dieldrin	60-57-1
Endrin	72-20-8
Heptachlor/Heptachlor epoxide	76-44-8/1024-57-3
Hexabromobiphenyl	~~36355-01-8~~ 59536-65-1
Hexabromocyclododecane	25637-99-4
Hexachlorobenzene	118-74-1
Hexachlorobutadiene	87-68-3
~~Lead~~	~~7439-92-1~~
Methyl m~~M~~ercury	~~7439-97-6~~ 22967-92-6
Mirex	2385-85-5
~~Nonylphenol/4-nonylphenol (branched)~~	~~25154-52-3/84852-15-3~~
Pentachlorobenzene	608-93-5
Short-chain chlorinated paraffins	85535-84-8
Tetrabromobisphenol A	79-94-7
Tetrachlorobenzene, 1,2,4,5-	95-94-3
Toxaphene	8001-35-2
Chemical groups ~~categories~~ listed in alphabetical order	
Perfluorooctane sulfonates (PFOS)	
Acid	1763-~~32~~23-1
Ammonium salt	29081-56-9
Diethanolamine salt	70225-14-8

Lithium salt	29457-72-5
Potassium salt	2795-39-3
~~**Phthalate esters**~~	
~~Di-isodecyl phthalate (DIDP)~~	~~68515-49-1 and 26761-40-0~~
~~Di-n-hexyl phthalate (DnHP)~~	~~84-75-3~~
Polycyclic aromatic hydrocarbons (PAHs)	
3-Methyl chlolanthrene	56-49-5
7H-Dibenzo(c,g)carazole	194-59-2
Benzo(a)phenanthrene (Chrysene)	218-01-9
Benzo(b)fluoranthene	205-99-2
Benzo(g,h,i)perylene	191-24-2
Benzo(j)fluoranthene	205-82-3
Benzo(k)fluoranthene	207-08-9
Benzo(r,s,t)pentaphene	189-55-9
Dibenzo(a,e)pyrene	192-65-4
Dibenzo(a,h)pyrene	189-64-40
Dibenzo(a,h)acridine	226-36-8
Dibenzo(a,h)anthracene	53-70-3
Dibenzo(a,j)acridine	224-42-0
Fluoranthene	206-44-0
Indeno(1,2,3-cd)pyrene	193-39-5
Perylene	198-55-0
Polybrominated dibenzodioxins and furans	
2,3,7,8-tetrabromodibenzo-p-dioxin	50585-41-6
2,3,7,8-tetrabromodibenzofuran	67733-57-7
Polybrominated diphenyl ethers	
Pentabromodiphenyl ether	32534-81-9
Octabromodiphenyl ether	32536-52-0

Decabromodiphenyl ether	~~13654-09-6~~ 1163-19-5
Polychlorinated biphenyls (PCBs)	
2,3',4,4',5 Pentachlorobiphenyl	31508-00-6
2,3,4,4',5 Pentachlorobiphenyl	74472-37-0
2,3,3',4,4' Pentachlorobiphenyl	32598-14-4
3,3',4,4',5,5' Hexachlorobiphenyl	32774-16-6
2,3',4,4',5,5' Hexachlorobiphenyl	52663-72-6
2,3,3',4,4',5' Hexachlorobiphenyl	69782-90-7
2,3,3',4,4',5 Hexachlorobiphenyl	38380-08-4
2,3,3',4,4',5,5' Heptachlorobiphenyl	39365-31-9
Polychlorinated dibenzo-p-dioxins	
2,3,7,8 Tetrachlorodibenzo-p-dioxin	1746-01-6
1,2,3,7,8 Pentachlorodibenzo-p-dioxin	40321-76-4
1,2,3,4,7,8 Hexachlorodibenzo-p-dioxin	39227-28-6
1,2,3,6,7,8 Hexachlorodibenzo-p-dioxin	576-53-8
1,2,3,7,8,9 Hexachlorodibenzo-p-dioxin	19408-74-3
1,2,3,4,6,7,8 Heptachlorodibenzo-p-dioxin	35822-46-9
1,2,3,4,6,7,8,9 Octachlorodibenzo-p-dioxin	3268-87-9
Polychlorinated dibenzofurans	
2,3,7,8 Tetrachlorodibenzofuran	51207-31-9
1,2,3,7,8 Pentachlorodibenzofuran	57117-41-6

2,3,4,7,8 Pentachlorodibenzofuran	57117-31-4
1,2,3,4,7,8 Hexachlorodibenzofuran	70648-26-9
1,2,3,6,7,8 Hexachlorodibenzofuran	57117-44-9
1,2,3,7,8,9 Hexachlorodibenzofuran	72918-21-9
2,3,4,6,7,8,~~9~~ Hexachlorodibenzofuran	60851-34-5
1,2,3,4,6,7,8 Heptachlorodibenzofuran	67562-39-4
1,2,3,4,7,8,9 Heptachlorodibenzofuran	55673-89-7
1,2,3,4,6,7,8,9 Octachlorodibenzofuran	39001-02-0
Polychlorinated naphthalenes	
Trichloronaphthalene	1321-65-9
Tetrachloronaphthalene	1335-88-2
Pentachloronaphthalene	1321-64-8
Hexachloronaphthalene	1335-87-1
Heptachloronaphthalene	32241-08-0

~~(3) **Lead and cadmium.** Ecology will not develop a chemical action plan for lead and cadmium until the Environmental Protection Agency concludes the development of a metals assessment framework and ecology completes its review of the bioavailability of these two substances.~~

(3) ~~(4)~~ **Revising the PBT list.** Ecology will periodically review and, as appropriate, revise the PBT list in subsection (2) of this section using the criteria and procedures in WAC 173-333-320 through 173-333-340.

NEW SECTION

WAC 173-333-315 Metals of Concern.

(4) **Purpose**. The purpose of this section is to identify metals of concern to be addressed under this chapter. The metals of concern category was established as an interim category pending completion of EPA's inorganic metals assessment framework process.

(5) **Metals of concern**. Ecology has identified the following metals of concern based on a determination that these metals pose threats to human health and the environment in Washington.

Metals of Concern	CAS Number
Cadmium	7440-43-9
Lead	7439-92-1

(6) **Actions**. Ecology may prepare chemical action plans for one or more metals of concern using the process defined in WAC 173-333-420.

(4) **Revising the metals of concern list.** Ecology will evaluate the relationship between the metals of concern list and PBT list in WAC 173-333-310 following the completion of the EPA's inorganic metals assessment framework process.

NEW SECTION

WAC 173-333-320 What criteria will ecology use to identify and add chemicals or chemical groups to the PBT list? (1) **Purpose.** This section describes the criteria that ecology will use to determine whether a chemical or group of chemicals should be included on the PBT list.

(2) **Criteria for identifying PBTs.** A chemical or group of chemicals will be included on the PBT list if ecology determines it meets each of the following criteria:

(a) **Persistence.** The chemical or chemical group can persist in the environment based on credible scientific information that:

(i) The half-life of the chemical in water is greater than or equal to sixty days; or

(ii) The half-life of the chemical in soil is greater than or equal to sixty days; or

(iii) The half-life of the chemical in sediments is greater than or equal to sixty days; and

(b) **Bioaccumulation.** The chemical or chemical group has a high potential to bioaccumulate based on credible scientific information that the bioconcentration factor or bioaccumulation factor in aquatic species for the chemical is greater than 1,000 or, in the absence of such data, that the log-octanol water partition coefficient (log K_{ow}) is greater than five; and

(c) **Toxicity.** The chemical or chemical group has the potential to be toxic to humans or plants and wildlife based on credible scientific information that:

(i) The chemical (or chemical group) is a carcinogen, a developmental or reproductive toxicant or a neurotoxicant;

(ii) The chemical (or chemical group) has a reference dose or equivalent toxicity measure that is less than 0.003 mg/kg/day; or

(iii) The chemical (or chemical group) has a chronic no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 0.1 mg/L or an acute no observed effect concentration (NOEC) or equivalent toxicity measure that is less than 1.0 mg/L.

(d) **Additional criteria applicable to metals.** The chemical or chemical group is a metal and ecology determines that it is likely to be present in forms that are bioavailable.

(3) **Degradation products.** Ecology will consider both the parent chemical and its degradation products when making decisions on whether a chemical meets the criteria in subsection (2) of this section. If a parent chemical does not meet the criteria in this section ~~for a PBT~~ but degrades into chemicals that do meet the criteria in subsection (2) ~~in this section for a PBT~~, the parent chemical may be considered for inclusion on the PBT list and in the development of a CAP ~~will be considered in the development of a CAP for those derivative chemicals~~. Alternately, Ecology may decide not to include the parent chemical on the PBT list, but consider it during the development of a CAP for derivative chemicals.

NEW SECTION

WAC 173-333-330 What criteria will ecology use to remove a PBT from the PBT list? (1) **Purpose.** This section describes the criteria and factors ecology will use to determine whether a chemical or group of chemicals should be removed from the PBT list.

(2) **Criteria for removing a chemical from the PBT list.** Ecology will remove a chemical or chemical group from the PBT list if the department determines that credible scientific information developed subsequent to the listing decision provides evidence that the chemical or chemical group does not meet the PBT criteria in WAC 173-333-320(2).

NEW SECTION

WAC 173-333-340 What process will ~~would~~ ecology follow to revise the PBT list? (1) **Purpose.** This section describes the processes ecology will use to notify the public and amend the PBT list after making a determination that chemicals or groups of chemicals should be added or removed from the PBT list.

(2) **Reviewing and updating the PBT list.** Ecology will periodically review and update WAC 173-333-310. The frequency of review will be determined by credible scientific information available on individual chemicals or chemical groups, rule-making petitions submitted to ecology, and available agency resources. Ecology will comply with the requirements for reviewing and responding to rule-making petitions in the Administrative Procedure Act, chapter 34.05 RCW.

(3) **Public notification.** If ecology makes a preliminary determination that a chemical should be added or removed from the PBT list, the department will prepare a technical discussion paper that summarizes the scientific information supporting the addition or removal of a chemical and notify the public through an announcement posted on the ecology web site and published in the *Washington State Register*.

(4) **Amending the PBT list.** If ecology makes a final determination that a chemical or chemical group should be added or removed from the PBT list, the department will initiate actions to amend WAC 173-333-310 through formal rule making.

PART IV
CHEMICAL ACTION PLANS (CAPs)

NEW SECTION

WAC 173-333-400 (1) **What is a chemical action plan (CAP)?** A chemical action plan (CAP) is a plan that identifies, characterizes and evaluates uses and releases of a specific PBT, ~~or~~ a group of PBTs or metals of concern and recommends actions to protect human health or the environment.

(2) For the purposes of this section, the term PBT refers to both the chemicals on the PBT List (section 310) and the chemicals on the metals of concern list (section 315).

NEW SECTION

WAC 173-333-410 What evaluation factors and processes will ecology use to select PBTs or metals of concern for chemical action plan preparation? (1) **Purpose.** Ecology will consult with the department of health to develop a multiyear schedule for the preparation of chemical action plans. The purpose of this section is to describe the evaluation factors and processes ecology will use to prepare and update the multiyear schedule.

(2) **Evaluation factors.**

(a) Ecology will consider the following factors when preparing the multiyear schedule:

(i) **Relative ranking.** The relative ranking assigned to each PBT based on ecology's evaluation of information on PBT characteristics, uses of the chemical in Washington, releases of the chemical in Washington, the levels of the chemical present in the Washington environment, and levels of the chemical present in Washington residents.

(ii) **Opportunities for reductions.** Whether there are opportunities for reducing or phasing out uses, production or releases of the PBT in Washington. In reviewing available information, the agencies shall consider whether more than one PBT is present in particular products, generated in particular processes or released from particular sources (co-occurring chemicals).

(iii) **Multiple chemical releases and exposures.** Scientific evidence on the combined effects of exposure to one or more PBTs and other substances commonly present in the Washington environment.

(iv) **Sensitive population groups and high-exposure populations.** Scientific evidence on the susceptibility of various population groups including the timing of the exposure and the cumulative effects of multiple exposures.

(v) **Existing plans or regulatory requirements.** Whether there are existing plans or regulatory requirements that reduce and phase out uses and releases of a particular PBT or group of PBTs.

(b) Ecology will not prepare CAPs if the department determines:

(i) All uses and releases of the PBT are prohibited under other state and federal laws or regulations;

(ii) There is credible scientific information to support a conclusion that the PBT is not used, released or present in Washington; or

(iii) There are no available opportunities for reducing or phasing out the uses, releases or exposures of the PBT beyond levels required under other federal or state laws or regulations.

(3) **Preliminary schedule.** Ecology will prepare a preliminary schedule that will identify the PBTs for which CAPs will be developed for the multiyear schedule, the rationale for selecting these PBTs and a timeline for completing CAPs for these PBTs.

(4) **Public notice and comment.** Ecology will notify the public when it has prepared a preliminary schedule and provide an opportunity for public review and comment. Ecology will notify the public through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also send a written announcement to interested persons and organizations. Ecology will provide sixty days, from the date the notice is published in the *Washington State Register* for the public to review and submit comments on the preliminary selection.

(5) **Final schedule.** Ecology will review all public comments on the preliminary schedule prior to preparing a final schedule. Ecology will notify the public of the final decision through an announcement published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the preliminary schedule.

(6) **Schedule updates.** Ecology will review and, as appropriate, update the schedule for chemical action plans at least once every three years. In making such revisions, ecology will follow the process for preparing the schedule (including an opportunity for public review and comment) specified in this section.

NEW SECTION

WAC 173-333-420 What are the contents of a CAP? (1) **Contents of the chemical action plans.** Chemical action plans will include, as appropriate, the following types of information, evaluations and recommendations:

(a) **General chemical information.** General information includes, but is not limited to, chemical name, properties, uses and manufacturers.

(b) **Production, uses and releases.** An analysis of information on the production, unintentional production, uses and disposal of the chemical. This will include estimates on the amount of each PBT used and released from all sources or activities in Washington and other man-made and naturally occurring sources that may contribute to exposures in Washington. Sources may include other chemicals or products that are known or suspected to degrade to the chemical included on the PBT list.

(c) **Human health and environmental impacts.** Information on the potential impacts on human health and the environment associated with the use and release of the PBT chemical. This will include consideration of available information on the levels of the PBT present in Washington's environment, potential for exposure, the likely fate and transport mechanisms, available body-burden data, toxicity effects, and the rates of diseases that have been associated with exposure to the particular PBT.

(d) **Current management approaches.** An evaluation of the regulatory and nonregulatory approaches that influence production, uses, releases and management of each PBT.

(e) **Identification of policy options.** A list of options for managing, reducing and ~~eliminating~~ phasing out the different uses and releases of the PBTs addressed in the CAP. The range of options for particular uses and releases will include:

(i) A no-action option;

(ii) An option that results in the ~~elimination~~ phase out of PBT uses and releases;

(iii) An option to manage chemicals to reduce exposure; and

(iv) Other options, including the use of available substitutes, which will enable full consideration of the opportunities and constraints for reducing particular uses, releases and exposures.

(f) **Recommendations.** Recommendations for:

(i) Reducing and phasing-out uses and releases of the specific PBT or group of PBTs addressed in the CAP;

(ii) Managing products or wastes that contain the specific PBT or group of PBTs addressed in the CAP; ~~and~~

(iii) Minimizing exposure to the specific PBT or group of PBTs.

(iv) Switching to safer substitutes; and

(v) Encouraging the development of safer alternatives.

The recommendations will be based on an evaluation of the following factors:

(A) Environmental and human health benefits associated with implementing the action;

(B) Economic and social impacts associated with implementing the action;

(C) Feasibility of implementing the action;

(D) Availability, ~~cost~~ and effectiveness of safer substitutes for uses of the PBT being addressed in the plan; and

(E) Consistency with existing federal and state regulatory requirements.

(g) **Implementation steps.** A description of the steps ecology will take to implement the CAP, including a description of:

(i) The existing resources and necessary additional budget ecology intends to use;

(ii) Potential funding sources for CAP implementation, including those that tie implementation costs to PBT sources and products;

(iii) How ecology intends to inform and educate affected persons about the CAP;

(iv) How ecology will promote, ~~and~~ assist, and evaluate the effectiveness of voluntary actions;

(v) How ecology will collect additional information needed to evaluate the feasibility of potential actions; and

(vi) Any recommended regulatory actions and how ecology will pursue them.

(h) **Performance measures.** A description of interim milestones to assess progress and the use of objectively measurable outcomes, including recommendations for environmental and human health monitoring to measure levels of the chemical(s) (in the CAP) over time and whether the goals and purposes of the CAP are being achieved.

(i) **Other.** Other information that ecology determines is necessary to support the decision-making process.

(2) **Regulatory consistency.** When evaluating the consistency with existing federal and state regulatory requirements under subsection (1)(f)(iii)(E) of this section, ecology will:

(a) Ensure that the recommendations do not violate existing federal or state laws;

(b) Determine if the recommendations would impose more stringent performance requirements on private entities than on public entities, unless already required to do so by federal or state law, and if so, describe the justification for doing so; and

(c) Determine if the recommendations differ from federal regulations and statutes, and if so, explain why the difference is necessary and how ecology will coordinate with other federal,

state, and local laws applicable to the same activity or subject matter.

(3) **Economic analyses.** In assessing economic impacts under subsection (1)(f)(iii)(B) of this section, ecology will identify costs of implementing the recommendations. This may include a qualitative and/or quantitative analysis of the probable benefits and costs of the CAP.

~~(4) **Safer substitutes.** When evaluating the availability of safer substitutes for PBT uses, ecology will:~~

~~(a) Determine if the recommendations include the use of safer substitutes, and if not, explain why ecology has not recommended this option.~~

~~(b) Determine if the recommendations call for additional research for uses with no safer substitutes, and if not, explain why ecology has not recommended this option.~~

~~(c) Provide for periodic reevaluation of whether substitutes are available.~~

NEW SECTION

WAC 173-333-430 What process will ecology use to develop CAPs? (1) **Purpose.** The purpose of this section is to identify the process ecology will use to develop CAPs.

(2) **Workplan/scoping.** Once a chemical is selected for CAP development, ecology will initially plan and scope the CAP of the selected chemical based upon available information regarding the chemical's products, uses and releases; human health exposure and ecological hazards; environmental releases, fate, and transport; environmental concentrations and available substitutes; available options for managing uses and releases; estimated costs, benefits and effectiveness of alternate management options; and any other information ecology determines is necessary to support the CAP development process. Ecology will consult with the department of health regarding all portions of the CAP related to human health exposures.

(3) **Advisory committee.** Ecology will create an external advisory committee for each CAP that ecology develops. The purpose of the advisory committee is to provide stakeholder input and expertise.

(a) The advisory committee membership will include, but not be limited to, representatives from: Large and small business sectors, community, environmental and public health advocacy groups, local governments, and public health agencies. When appropriate, representatives from the following groups will also be invited to participate: Agricultural groups, worker safety advocacy groups, and other interested parties. Federally recognized tribal governments will also be encouraged to participate. In addition, representation from other state executive agencies may be requested to provide input and to

represent agency interests in the CAP development process. Outside experts (if needed) may be requested to provide technical expertise.

(b) A neutral third-party facilitator may be hired to facilitate advisory committee meetings.

(c) The advisory committee will follow a consultative process, where ecology will draft the CAP in consideration of input from advisory committee members.

(d) All advisory committee meetings will be open to the public. Ecology will notify the public of advisory committee meetings through an announcement posted on the ecology web site and written notification to interested individuals and organizations.

(4) **Information collection phase.** Ecology will collect all necessary and up-to-date information regarding the selected chemical. CAP advisory committee members will be asked to contribute, and as appropriate, review information from ecology during this phase of CAP development. The department of health will be asked to review any information related to human health.

(5) **Draft recommendations.** Ecology will develop a draft CAP for advisory committee review and comment. Ecology will review all advisory committee comments and, as appropriate, revise the draft CAP prior to distributing it for public review and comment.

(6) **Public review and comment.** Ecology will notify the public when it has developed a draft CAP and provide an opportunity for public review and comment. The public comment period for each draft CAP will be a minimum of sixty days. Ecology will notify the public through an announcement posted concurrently on the ecology web site, a notice in the *Washington State Register*, and sent to interested persons and organizations. The comment period shall start from the date the notice is published in the *Washington State Register*. During the comment period, ecology will hold a minimum of two public meetings on the draft CAP. One meeting shall be held on the western side of the state, and one meeting shall be held on the eastern side of the state. Ecology may hold additional public meetings during the public comment period if determined necessary. Ecology will provide a response to all public comments.

(7) **Final recommendations.** Ecology will review and provide responses to all public comments on the draft CAP prior to issuing the final recommendations. Ecology will notify the public of the final recommendations through an announcement that will be published in the *Washington State Register* and posted on the ecology web site. Ecology will also provide written notification to individuals or organizations who submitted comments on the draft CAP.

(8) **Coordination with other agencies.** Ecology will coordinate with other government agencies and interested parties

as appropriate on the implementation of the final CAP. Ecology will consult with the department of health on public information materials addressing food safety issues.