SUMMARY REPORT OF THE MEETING ON DEVELOPMENT OF A METALS ASSESSMENT FRAMEWORK

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NOTICE

The statements in this report reflect the views and opinions of the workshop experts. They do not represent analyses or positions of the Risk Assessment Forum or the U.S. Environmental Protection Agency (EPA).

This report was prepared by Eastern Research Group, Inc., an EPA contractor, as a general record of discussion held during the Meeting on Development of a Metals Assessment Framework (February 20, 2002). As EPA requested, this report captures the main points and highlights of the meeting. It is not a complete record of all details discussed, nor does it embellish, interpret, or enlarge upon matters that were incomplete or unclear.

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EXECUTIVE SUMMARY

EPA convened a one-day meeting on February 20, 2002 to gather stakeholder input for an Action Plan for the development of a Metals Assessment Framework. The meeting was held at the Holiday Inn Washington Capitol Hotel in Washington, D.C. Approximately 40 stakeholders representing industry and regulatory agencies attended the meeting. Five stakeholders presented comments.

The stakeholders agreed that the Metals Assessment Framework should be based on sound science, and that it should provide a basis for appropriately identifying the risks of metals to human health and the environment. The Framework should support EPA's principles and should be structured to mesh with similar EPA and international programs.

The stakeholders believed that the method of determining the hazard of a metal should be modified from the Persistence, Bioaccumulation, and Toxicity (PBT) approach developed for evaluating organics. Suggested alternative methods for evaluating metals toxicity included redefining "persistence" in metals to consider bioavailability, consideration of the nonintrinsic bioaccumulation property of metals, and consideration of speciation and bioavailability.

The stakeholders agreed that EPA should continue to solicit input from stakeholders and other interested parties in the development of the Framework. Further, the stakeholders agreed that the Science Advisory Board should review the Action Plan and the Framework and that EPA should solicit public comment during this review.

1. INTRODUCTION

1.1 Meeting Purpose

Since the promulgation of the Toxics Release Inventory (TRI) lead rulemaking, there has been considerable interest in the scientific assessments that the U.S. Environmental Protection Agency (EPA) conducts on metals and metals compounds. Based on discussions with stakeholders and concerns expressed formally by Congress, EPA recognizes the importance of developing a more comprehensive approach to metals assessments that could serve as the basis for future Agency actions. To this end, EPA is developing an Action Plan in coordination with Science Advisory Board consultation and review. To gather stakeholder input for the Action Plan, EPA convened a one-day meeting on February 20, 2002 at the Holiday Inn Washington Capitol Hotel in Washington, D.C. This meeting was announced in a Federal Register notice (FRL-7138-3) on February 6, 2002.

The purpose of the meeting was to collect input from stakeholders to help EPA formulate an Action Plan for developing a Metals Assessment Framework. Specifically, EPA solicited input on the following questions, which were listed in the Federal Register notice:

- What organizing principles should the Framework follow?
- What scientific issues should the Framework address?
- What methods and models should be considered for inclusion in the Framework?
- What specific steps should be taken to further involve the public and the scientific community in the development of the Framework?

Approximately 40 stakeholders representing both industry and regulatory agencies attended the meeting (see Appendix A).

1.2 Meeting Agenda

Appendix B presents the meeting agenda. EPA began the meeting with opening remarks and a presentation of the background and scope of the development of a Metals Assessment Framework. Then, EPA accepted questions from the audience regarding the background and scope. Next, three preregistered commenters gave presentations on the hazard assessment of metals, bioaccumulation of metals and metal compounds, and the development of a Framework for assessing metals and metals compounds. The presenters responded to questions from the audience about their presentations.

Then, two additional preregistered commenters gave presentations addressing EPA's specific questions from the Federal Register notice, the state of the science for PBT chemical assessment, and the peer review procedures that EPA should implement in developing the Metals Assessment Framework. Two other preregistered commenters who were listed in the agenda did not speak. Finally, the audience was invited to ask further questions of the presenters; however, no questions were asked. The audience was invited to make comments; none were made. EPA concluded the meeting by thanking the participants.

1.3 Meeting Summary

This report summarizes the workshop presentations and discussions and is organized as follows:

- Section 2 summarizes EPA's opening presentation and remarks, including clarification questions and answers. Appendix C presents the slides used in the presentation.

- Section 3 summarizes the five presentations, including clarification questions and answers. Appendices D, E, F, and H present slides used in these presentations. Appendices G and I contain written comments submitted by two of the presenters.

- Section 4 summarizes EPA's concluding remarks.

2. SUMMARY OF OPENING PRESENTATION AND REMARKS

Vanessa Vu of EPA's Office of Research and Development opened the meeting and welcomed the commenters and observers. Dr. Vu began her presentation by providing an overview of the background for the development of the Framework. (See Appendix C for slides of Dr. Vu's presentation.)

After the 2001 TRI lead rule was promulgated, EPA deferred the rule's findings regarding the bioaccumulative properties of lead and lead compounds, and stated that it would solicit external review from the Science Advisory Board (SAB) before taking any further action. EPA tasked an ad hoc technical panel to develop a white paper to frame the issues and set the charge for the SAB regarding whether lead compounds are highly bioaccumulative. While this technical panel was underway, EPA determined that it was necessary to develop a comprehensive Metals Assessment Framework that could provide a basis for future actions for all metals and metals compounds. To develop this Framework, EPA is soliciting comment from other government agencies, stakeholders, and the scientific community at large. EPA believes that this and future scientific workshops will facilitate receiving comment from all interested parties, so that EPA can incorporate these comments and expert advice in the Action Plan and provide this input to the SAB.

Dr. Vu said EPA envisioned that the Action Plan will present the issues and elements of the Framework, and will outline the steps that are needed to address these issues. The Action Plan will require public participation and SAB input to properly address the stated issues.

The purpose of the February 20, 2002 Meeting on Development of a Metals Assessment Framework was to receive comments from stakeholders on the Framework, focusing on the following key issues: organizing principles to be used; scientific issues; methods, models, and approaches; and steps to include in the development of the Framework. EPA is proposing the following schedule for completing the Action Plan:

January 2002:	EPA began development of the Action Plan and formed the Science Policy Council Metals Action Plan Workgroup.
February 2002:	EPA held this first public meeting to solicit comment.
March 2002:	EPA will bring the draft Action Plan to the Science Policy Council for review.
May 2002:	EPA will publish the draft Action Plan.
June 2002:	SAB will review the draft Action Plan.

July 2002:	EPA will begin developing the Framework based on SAB review of the Action Plan.
March 2003:	SAB will review the Framework.
June 2003:	SAB will publish their review of the Framework.
December 2003:	EPA will publish the Framework.

Dr. Vu reiterated that EPA is committed to considering stakeholder comments and recommendations, and requested that commenters focus on the scientific issues and suggest approaches for the Framework. Dr. Vu then introduced Bill Wood, the Director of EPA's Risk Assessment Forum (RAF), co-chair of the Metals Action Plan Workgroup, and moderator for the meeting.

Dr. Wood explained the purpose of the Risk Assessment Forum. The Forum is a standing committee in EPA that is charged with developing risk assessment guidelines and fostering consistency within EPA in using these guidelines. The RAF was asked to put together an ad hoc technical panel to begin evaluating the issues associated with the TRI lead rule, persistence, and bioaccumulation. This effort will continue once the Framework is developed. The EPA Deputy Administrator feels that it is critical to develop a Framework for metals and metal compounds prior to continuing work on the TRI lead rule.

Questions and Answers

Audience participants questioned how long the public will be able to comment on the draft Action Plan. Dr. Vu explained that the draft Action Plan will not be available until May, and interested parties may submit input for up to 2 weeks before publication of the draft plan. Stakeholders may present comments on the draft Action Plan at the SAB meeting in June 2002.

An audience participant inquired if the Action Plan will encompass similar efforts underway in the national and international community, including the Organization for Economic Cooperation and Development (OECD) and the Harmonization of Classification of Substances. Dr. Vu responded that EPA will consider the ongoing efforts of other organizations in the development of the Action Plan.

An audience participant asked when the plenary discussion would occur during the meeting. Dr. Wood responded that stakeholders could comment after each presentation and during the "Public Comments" portion of the agenda.

3. COMMENTER PRESENTATIONS

Following EPA's opening remarks, Andrew Green, of the International Lead Zinc Research Organization presented the first of three linked presentations on metals assessment by the metals industry representatives. Dr. Green's presentation focused on metals hazard assessment and the issues present in the existing approaches. Kevin Brix of the Metals Ad Hoc Coalition followed with a presentation on the bioaccumulation properties of metals. William Adams from Kennecott Utah Copper completed the series with a presentation proposing principles and steps that should be considered for the Metals Assessment Framework. The audience then asked questions. Then, Neil King of Wilmer, Cutler, & Pickering provided comments on behalf of the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States. Finally, Kevin Bromberg of the U.S. Small Business Administration discussed review procedures. This section summarizes these presentations and the brief question-and-answer session.

3.1 Andrew Green, International Lead Zinc Research Organization

Dr. Green introduced his presentation as an overview of hazard assessment for persistent, bioaccumulative, and toxic (PBT) substances. Slides of Dr. Green's presentation are provided in Appendix D. Dr. Green used the context of the PBT approach to identify the scientific issues, methods, and models that should be considered in developing the Framework.

EPA developed the PBT approach for organic chemicals in the 1970s. Based on this approach, tools were developed to prioritize PBT chemicals. During hazard assessment, EPA currently defines a PBT chemical as one that exhibits varying degrees of persistence, bioaccumulative properties, and toxicity.

Dr. Green noted that EPA is using the Waste Minimization Prioritization Tool as the current Framework for a hazard screening tool. This tool uses a scoring system for each of the three criteria (persistence, bioaccumulative properties, and toxicity). There are two issues to note in using this tool for metals assessment:

- First, this tool ranks the bioaccumulative and persistence criteria equally for both ecological and human endpoints.

- Second, this tool is specifically a hazard assessment tool, and the Metals Assessment Framework should provide a more comprehensive assessment of metals.

Dr. Green presented the current approach to evaluating the **persistence** of a chemical. A chemical is considered persistent in the environment if the half-life of the compound in soil, water, or sediments is longer than 2 months. Because metals are naturally present in the environment, they are, by nature, persistent, although they do not necessarily present a hazard.

Dr. Green proposed an alternative definition of persistence for metals and metal compounds: the property of a chemical whereby it remains in a bioavailable form in the environmental compartment. Other properties can also be used to evaluate persistence of metals, including the presence of the free metal ion, the tendency of partitioning to suspended solids, residence time in the water column before the metal becomes associated with sediments, the tendency for partitioning to sulfide in sediments, and whether the metal is easily re-suspended and re-entrained within the water column from the sediments.

Dr. Green presented three alternative sources of information that could be considered in developing a Metals Assessment Framework. Data were collected in Perch Lake, Canada to characterize the persistence of cobalt, iron, and zinc in the water column. The study demonstrated that the persistence of each metal varied widely. The Windermere Humic Acid model (WHAM) allows prediction of the concentration of free metal ion in water based upon water quality. Finally, the variation of the suspended solids partition coefficient (Kd) for various metals should also be considered in developing a Metals Assessment Framework.

Bioaccumulation is used as an indicator of chronic toxicity and of the potential for trophic transfer and biomagnification. A chemical is considered bioaccumulative if the bioaccumulation factor (BAF) or the bioconcentration factor (BCF) is greater than 1,000, or if the log octanol-water partition coefficient (K_{ow}) is greater than 3.0. Existing data and models can address the scientific issues associated with this criterion (see Section 3.2).

The current approach for evaluating **toxicity** was developed for organic chemicals and does not specifically address metals. Under this approach, a chemical is considered highly toxic if its toxicity values are less than 1 milligram per liter. Therefore, nearly all metals receive a high toxicity score based on the score for soluble metal salts, even though acute and chronic toxicity vary widely between metals and metal compounds. To adequately characterize metals toxicity, the following scientific issues should be considered in developing the Framework:

- There should be a distinction between metals and metal compounds.
- Speciation and transformation should be considered; soluble metal compounds should not be treated equally to insoluble metals.
- The scale of the Waste Minimization Prioritization Tool is not adequate to describe the variability of metals and metals compounds.
- Bioavailability is not considered. EPA has current methodologies in place that would more adequately characterize bioavailability, including the Biotic Ligand Model (BLM) for water and the Acid Volatile Sulfide - Simultaneously Extracted Metal (AVS-SEM) approach.

Dr. Green concluded his remarks by reiterating that the current approach that was developed for organic chemicals is inappropriate for use in metals assessment. In developing a Metals Assessment Framework, EPA should consider criteria that are specific to metals and incorporate the physicochemical properties of metals, and should consider existing data, information, concepts, and models that adequately characterize metals and metal compounds.

3.2 Kevin Brix, Metals Ad Hoc Coalition

Mr. Brix began his presentation by stating that the current approach for assessing bioaccumulation for metals has significant limitations. (See Appendix E for slides of Mr. Brix's presentation.) There is an inverse relationship between accumulation factors and exposure concentrations for metals, which is not reflected in the existing approach. He proposed an alternative approach to using accumulation factors.

The theoretical basis of the existing approach is based on organics and passive diffusion. Accumulation of organic substances is not expected to be concentration-dependent. The accumulation in an organism will be constant over a range of water concentrations.

Most metals, however, require active transport to facilitate uptake into organisms. Active transport mechanisms are rate-limited and, therefore, concentration-dependent. There is a range of water concentrations for metals over which an organism will maintain normal body burden. That is, the organism intake and excretion of the metal is maintained within normal levels. As the metal levels increase, the organism increases the metal excretion rate and decreases the intake rate. At high levels, the organism cannot maintain this regulatory mechanism and begins to exhibit toxic levels of the metal. For essential metals, when concentrations are low enough that the organism cannot uptake the metal at a rate to maintain normal body burden, then the organism will experience a deficiency and strive for a higher intake rate. Therefore, the BCF is inversely related, because the organism's intake rate increases as the concentration decreases and decreases as the concentration increases.

Mr. Brix presented data supporting this inverse BCF relationship. McGreer et al.[1] calculated a zero-slope relationship of the aquatic concentration of an organic (hexachlorobenzene) to the observed bioconcentration in five aquatic species. Therefore, the BCF is constant regardless of the organic aquatic concentration. Conversely, the relationship of the BCF to cadmium in water was observed to be inversely proportional for a wide range of organisms. The same inverse relationship was found for zinc BCFs. Biota-sediment accumulation factors (BSAFs) demonstrated the same inverse relationship for studies on

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[1]*McGreer, J.C., K.V. Brix, J.M. Skeaff, D.K. DeForest, S.I. Brigham, W.J. Adams and A.S. Green (2002). "The inverse relationship between bioconcentration factor and exposure concentration for metals: implications for hazard assessment of metals in the aquatic environment."* *Environ. Toxicol. Chem.* *Submitted.*

cadmium, copper, and zinc. Efroymson et al.[2] observed this same trend in observed plant-soil accumulation factors for arsenic, copper, lead, mercury, nickel, cadmium, and zinc.

As a side note, Mr. Brix noted that a report published a few years ago demonstrated a flat relationship for lead for bivalves. Since then, these data were reanalyzed to consider only steady-state conditions, and the inverse relationship is present under these conditions.

Mr. Brix presented an alternative to the fixed accumulation factor approach that evaluates the hazard potential of metals via bioaccumulation, based on dietary toxicity to consumer organisms. First, the wildlife dietary toxicity threshold is determined for a metal; this is a set threshold for an organism. Then, the threshold is related to the tissue concentration of the metal in prey organisms. Next, the concentration of metal in an aquatic environment that would produce that tissue concentration is determined. This approach was presented by Skorupa and Ohlendorf in 1991[3] and Ohlendorf and Santalo in 1994[4].

This regression approach was used to estimate the water concentration that results in the dietary threshold of an organism for six metal compounds. The wildlife dietary threshold is used with the inverse-BCF relationship to determine the water concentration that could cause effects via bioaccumulation.

Mr. Brix concluded his presentation noting that accumulation factors are not an intrinsic property for metals, and are clearly inversely related to water, sediment, and soil concentration. The regression approach is one that could be used to estimate threshold water concentration. The interpretation of this approach needs to be further developed.

Questions and Answers

An audience member stated that it may be appropriate to consider a range of dietary thresholds to account for age and health variability among organisms. Mr. Brix agreed that using a range or a conservative threshold is appropriate.

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[2]*Efroymson, R.A., B.E. Sample, and G.W. Suter (2001). "Uptake of inorganic chemicals from soil by plant leaves: regressions of field data."* <u>*Environ. Toxicol. Chem.*</u> ***20****(11):2561-2571.*

[3]*Skorupa, J.P. and H.M Ohlendorf (1991). Contaminants in drainage water and avian risk thresholds.* <u>*The Economics and Management of Water and Drainage in Agriculture*</u>*. A. Dinar and D. Zilberman. Boston, Kluwer Academics Publishers: pp. 346-368.*

[4]*Ohlendorf, H.M. and G.M. Santolo (1994). Kesterson Reservoir past, present, and future: an ecological risk assessment.* <u>*Selenium in the Environment.*</u> *W.T. Frankenberger and S. Benson. New York, Marcel Dekker, Inc.: pp. 69-117.*

An audience member inquired if the BCF data were analyzed using any other nonlinear methods. Mr. Brix stated that these data have only been analyzed using the log-linear approach, and it may be appropriate to analyze these data using other nonlinear transformations.

An audience member inquired why one would need to calculate the slope of the BCF if the water concentration and dietary threshold were known. Mr. Brix stated that this approach is intended to estimate the relationship between tissue concentration and threshold water concentration based on the dietary threshold.

3.3 William Adams, Kennecott Utah Copper

Dr. Adams began his presentation by noting that his remarks expand upon those offered in the preceding presentations. (See Appendix F for slides of Dr. Adam's presentation.) He first presented the issues associated with hazard assessment of metals, then discussed bioaccumulation of metals, and then discussed the overarching questions directed for this meeting by proposing a conceptual Framework.

Dr. Adams presented some organizing principles that could be considered in developing a Metals Assessment Framework. The Framework should:

- Support agency wide strategic goals and complement existing programs.
- Be based on sound science and models.
- Focus initially on hazard assessment as a screening mechanism.
- Utilize more detailed assessments for metals and metal compounds identified in the screening process, which might include lifecycle and uses of metals as well as release and exposure.

The Waste Minimization Prioritization Tool is a hazard identification tool, and should identify compounds that warrant further evaluation. The tool was developed based on organics, and it is thought to have a strong practical and theoretical basis. However, it is not particularly helpful for screening different metals because, for the most part, all metals receive the same score. Further, Dr. Adams indicated that there are no metals that have been identified that biomagnify, other than methylmercury, an organo-metallic substance. Because metals are naturally present in the environment, persistence as it is currently defined is not a useful metric. Therefore, this tool is not useful to prioritize metals.

Dr. Adams proposed an alternative metals assessment approach, and suggested that this three-tiered approach is used in other programs. The first tier is the hazard screening, which does not consider exposure or risk, but rather simply presents the hazard of the substance. The Canadian approach and the OECD for the classification of substances have a hazard screening at the first tier. Dr. Adams suggested that perhaps in this first tier, the Metals Assessment Framework should also evaluate persistence and bioaccumulation of metals, in addition to multitoxicity scales. This would help to identify the metals that are of most concern in terms of hazard.

Whether these issues are resolved and included for a Tier 1 assessment or they are deferred to Tier 2, methodologies for determining the following items need to be developed for metals assessment:

- Persistence
- Bioavailability
- Bioaccumulation
- Toxicity
- Speciation

These items could be considered a tool box for making hazard determinations on metals.

Tier 2 of this proposed approach is the next step looking beyond the intrinsic properties of the metal using physicochemical property estimations. Tier 2 would incorporate product use patterns, products, lifecycle considerations, recycle rate, and production volume.

Tier 3 would occur when the preliminary assessments from Tiers 2 and 3 identify a potential problem with a product or a substance. It would be helpful if some criteria and guidelines were established that set protocols for when it is appropriate to move from one tier to another. Tier 3 would be a site-specific assessment that includes the detail of monitoring and modeling studies in addition to site-specific information. The Ecological Risk Assessment Framework is consistent with this proposed approach.

Dr. Adams believes that it would facilitate the Metals Assessment Framework to incorporate the existing EPA programs that involve metals. There are already designations for hazardous metals within the Agency. There are eleven metals listed as hazardous air pollutants, thirteen metals on the priority pollutant list, and there are eight metals listed on the RCRA hazardous metals list. However, these programs do not assess risk for the metals.

The second question posed in the Federal Register notice asks what scientific issues should the Framework address. Dr. Adams proposed that the following key issues are important to include in the development of the Framework:

- Valid approaches for assessing persistence.

- Alternative approaches for assessing bioaccumulation.

- The inclusion of the bioavailability property of the substance.

- Determination of what is considered significant bioaccumulation of metals in human beings.

- Differentiation between substances and elements.

The third question posed in the Federal Register notice asks what methods and models should be included in the Framework. Dr. Adams proposes that the bioaccumulation model presented by Kevin Brix be considered. Also, there are a number of existing speciation models that could be used to predict species of metals present in water and soils, such as the Windermere Humic Acid model. The Biotic Ligand Model (BLM) has been well developed for copper, reasonably developed for silver and is under development for cadmium, zinc, and other metals. The BLM addresses bioavailability and predicts toxicity in an aquatic environment. Another model under development within industry is the Unit World Model. This model is similar in concept to the MacKay Fugacity model for organic chemicals, which predicts the distribution of a chemical to water, soil, and air upon release in the environment. The Unit World Model will perform the same function for metals in the environment.

The fourth question posed in the Federal Register asks what steps should be taken to further involve the public and the scientific community in developing the Metals Assessment Framework. Dr. Adams believes that the Framework can be effectively laid out if there is continued dialogue between EPA and stakeholders; perhaps stakeholder groups could be established specifically tasked to work with EPA in this effort. Finally, the Pellston workshop will be held this summer and will focus on the science of bioaccumulation and persistence. This workshop is organized under the Society of Toxicology and Chemistry and is being developed in coordination with EPA and other organizations.

Questions and Answers

An audience member noted that the inverse relationship of accumulation factors to metals concentration is contrary to what was presented during the TRI lead proceedings, and that this relationship is now based on steady-state conditions, whereas previously it included all data. The participant inquired if this inverse relationship holds true for other metals. Mr. Brix responded that this relationship has been observed for the accumulation of all metals in bivalves. The reanalysis of the lead data is what triggered the analysis for other metals. Dr. Adams noted further that not all organics have accumulation factors independent of concentration, even though the organic theory is that BCF is independent.

An audience member inquired if the BAF and BCF for aluminum, copper, zinc, and iron could all have values exceeding 1,000 and 5,000 for all species and any water concentrations. Dr.

Adams explained that the BAF for those metals in a clean environment is above 1,000. The BCF is the water concentration divided by the tissue level for the organism, and it is derived in a laboratory and does not take diet into consideration. The BAF is calculated the same way, but considers diet and is usually derived from data collected in the field. BAF is usually greater than BCF.

An audience member requested that Dr. Adams elaborate on how speciation is incorporated into his approach. Dr. Adams explained that elemental metal is zerovalent and not ionic; therefore, it is not very soluble. Rather, the metal has to be transformed to an ionic metal species that has greater solubility. Typically, the metal oxide is the first metal compound that is formed, followed by more complex metal compounds. These metal compounds dissociate in water to provide free metal ions. Metals and metal compounds need to be distinguished from each other, because it may be only certain forms of the metal that are toxic. Speciation models, such as the BLM, account for these different metal forms and their bioavailability.

Bill Wood (EPA Risk Assessment Forum) asked how Dr. Adams would apply these principles to the hazard assessment Tier 1 approach. Dr. Adams proposed that the rate of transformation and dissolution should be considered, as it is considered by OECD. OECD is developing a system of classification to distinguish between highly toxic, toxic, and less toxic compounds. This system will need to distinguish between different metal compounds. Relatively insoluble metals have slow rates of dissolution, so it is important to measure the rate and extent of transformation (i.e., to determine if the compound can go into solution at a sufficient rate and extent to express its toxicity). These principles could be incorporated into a Tier 1 assessment.

Vanessa Vu noted that Dr. Adams referenced a few models for use in the Metals Assessment Framework, and asked him to comment on how these models could be applied in a screening level assessment or a higher level risk assessment. Dr. Adams answered that this issue may be a good topic for a group to discuss, given that some models are more developed than others. The Unit World Model does not yet exist; however, it would apply to the screening level. The models that measure sorption to suspended solids, DOC binding, etc. would be appropriate for Tier 1, although that subject may be under debate. The proposed accumulation model could be applied across all three assessment tiers. The BLM for speciation may be most appropriate for Tier 2 or 3.

3.4 Neil King, Wilmer, Cutler, & Pickering

Neil King made comments representing the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States, Inc. Mr. King noted that the three previous presentations reflected much of the nickel industry's positions. Mr. King provided written comments to EPA, which are provided in Appendix G.

The Framework should provide a basis for identifying and prioritizing potentially unreasonable risks to human health and the environment that may be posed by some metals and metals species. To that end, the Framework should be able to discriminate between the various metals, metal alloys, and other metal compounds (including different species of a particular metal) with respect to hazard and risk.

Mr. King noted some organizing principles that should be incorporated into the Framework. The Framework should be developed using sound science, and it should be flexible enough to allow for the incorporation of new methods and models as our understanding of metals' fate, transport, bioavailability, and toxicity increases over time. The Framework should recognize that "inherent toxicity" is not meaningful with respect to metals and metal compounds, because there are other factors that determine if the compound will become bioavailable under specific circumstances. It would be useful to structure the Framework using a tiered approach. The most generalized level would be a hazard evaluation, and higher tiers would include screening-level risk assessments and site-specific risk assessments. Finally, the Framework should be designed to serve as a predicate for establishing voluntary and regulatory initiatives to achieve significant risk reduction benefits in a cost-effective manner. For many metals, this will involve increasing the rate at which wastes and other secondary materials containing the metal are recycled.

Mr. King identified three broad scientific issues that should be addressed in the Framework:

1) The Framework has to distinguish between the persistence of metals as fundamental elements and "bioavailable persistence." This latter concept requires consideration of speciation, transformation, and bioavailability.

2) The Framework should recognize that bioaccumulation as it is applied to organic compounds is highly problematic as a criterion to evaluate potential hazard or risk in the case of metals. Bioaccumulation is not an inherent property of metals, nor is it an indicator of toxicity for metals. Moreover, virtually all metals do not biomagnify in the food chain.

3) In evaluating the toxicity of metals, the Framework must consider speciation, transformation, and bioavailability.

Mr. King then commented that EPA might use both formal and informal mechanisms to involve the public and scientific community in developing the Framework. Informal mechanisms could include Federal Register notices and an e-mail network to keep interested parties apprized of developments. At the same time, EPA should establish a more formalized consultation mechanism utilizing a group of scientifically knowledgeable stakeholders, as well as expert workshops. Mr. King noted that the January 2000 workshop was very helpful, and hopes that EPA will schedule similar workshops on this topic in the future. Mr. King emphasized that EPA should allow enough time for meaningful public comments when the draft Action Plan and draft

Framework are submitted for SAB review, and enough time to present public comment during the SAB meetings themselves.

Mr. King stated that the Framework should be developed for application to all metals and inorganic metal compounds, including lead. With that in mind, when the Framework is completed, EPA should apply it to lead as a reality check on the PBT characterization that was assigned to lead for the purposes of the TRI program.

Finally, Mr. King asked that state agencies be kept up-to-date regarding the development of EPA's Metals Assessment Framework. In the regard, he noted that when the draft PBT chemical list was published a couple of years ago, some state agencies began—prematurely—to design programs to regulate the chemicals on that list as PBT substances, even though EPA was not even close to deciding what chemicals should appear on the PBT list as finalized. Keeping state agencies more closely "in the loop" as the Framework is developed should help prevent premature actions of this sort in the future.

The audience was invited to ask questions; no questions were asked.

3.5 Kevin Bromberg, U.S. Small Business Administration, Office of Advocacy

Mr. Bromberg introduced himself and the Office of Advocacy within the U.S. Small Business Administration (SBA), stating that the function of the Office of Advocacy is to be the advocate for small business within the Federal Government. Mr. Bromberg described his background in science and law, and then opened his presentation with two key questions:

- What is the state of the science of PBTs and metals at EPA?
- What peer review procedures should EPA now conduct for the TRI lead rule?

Mr. Bromberg disclosed his agency's position on the TRI lead rule to provide a context for his comments. The SBA Office of Advocacy sent a letter to the Administrator on the TRI Rule stating their belief that there was no scientific basis for the rule, and urged the EPA to get SAB review. There has been a 13-month delay between the publication of the TRI Rule and the initiation of the SAB review, which reflects the combination of science and politics involved in this issue.

The state of the science now at EPA includes equal treatment of metals and organics. The 1999 PBT rule treats metals like organics because "under certain conditions, all metals can be bioavailable under some conditions." Therefore, the EPA asserted that it was appropriate to consider all metals under this scheme. The Agency did not address, however, bioaccumulation in

1999, which also is different for metals and organics. A 1998 OECD report[5] states that research into this issue should be approached with care, because metals are different in several ways from PBT organic chemicals. However, despite the OECD precaution and other international organization recognition that metals should be treated differently than organics, EPA continued the lead rule under the assumption that all metals are bioavailable under certain circumstances.

When the TRI interagency review occurred, Mr. Bromberg solicited U.S. government scientists to review this issue of bioavailability and bioaccumulation. These two scientists were on the Canadian working group studying this same issue. Margaret Cavinaugh, a well-respected inorganic scientist stated, “The criteria for organics do not provide a sound basis for discriminating benign and harmful substances.” Jim Hickey from the U.S. Geological Survey stated, “The BAF approach should not be used for the assessment of metal compounds.” These comments were forwarded to EPA, and yet the rule went forward with the same approach used for metals as for organics. Mr. Bromberg requested literature support for this decision from EPA, but none was provided. The peer review procedures in the December 2000 SPC handbook[6] were not followed. EPA indicated that the SAB would conduct its review after the rule was published.

The recently published Inorganic Working Group’s report (December 2001)[7] noted that the approach to synthetic organics is not applicable to inorganics. Mr. Bromberg feels that these findings should be incorporated into the Framework.

EPA did not follow SAB peer review procedures for the TRI lead rule. Mr. Bromberg noted that the peer review process is well outlined in the SPC handbook, and EPA should simply follow these procedures. EPA has indicated that it will follow the handbook as a matter of procedure. There is a question as to when an independent peer review should occur versus an internal EPA review. Mr. Bromberg stated that, according to EPA procedures, an independent review should occur for significant rules.

The SAB enacted new procedures to supplement the handbook, and SBA commends that effort. EPA should be cognizant of these procedures, including the procedures for selecting the review panel, with full disclosure of the experts’ qualifications and any conflict of interest. EPA

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[5] *OECD (1998). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances. As endorsed by the 28th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals in November 1998. OECD, Paris, France.*

[6] *ORD (December 2000). Peer Review, EPA Science Policy Council Handbook, 2nd edition, EPA100-B-00-0001.*

[7] *IWG Report to Environment Canada (December 2001). Categorization of Inorganic Substances on the Domestic Substances List (DSL): Findings and Recommendations from the Inorganic Working Group (IWG). IWG Secretariat, Environment Canada, Hull, Quebec.*

is beginning the SAB consultation process for the Action Plan, and EPA should also include a full SAB review for both the Metals Assessment Framework and the TRI lead rule.

Mr. Bromberg does not believe that the PBT method is applicable to metals assessment. Therefore, the PBT method is not appropriate for lead assessment. Further, BCF and BAF factors cannot be used for metals assessment, given the state of the science today. An alternative scheme could be used; previous commenters presented some possibilities.

Mr. Bromberg then discussed next steps. After EPA develops the Action Plan, the Agency should solicit public comment. The selection of the SAB panel should consider background, balance, and diversity. As part of the SAB review of the new Metals Assessment Framework, the SAB will also review the former methodology that underlies the TRI lead rule.

EPA has stated in the Federal Register notice for this meeting, "EPA will not reconsider past actions." Mr. Bromberg stated that this does not mean that EPA is not looking at the TRI lead rule. EPA is looking at the TRI rule and possibly refining it. Perhaps EPA intended to state that it does not intend to reconsider past actions. Mr. Bromberg believes that EPA will do what is appropriate at the appropriate time to develop this Framework and the TRI lead rule, if it finds that its approach lacked a scientific foundation. Slides for Mr. Bromberg's presentation are included in Appendix H and a summary of his presentation is provided in Appendix I.

The audience was invited to ask questions; no questions were asked.

4. CLOSING REMARKS

Vanessa Vu clarified that the SAB has three levels of review: consultation, advisory, and full review. The SAB will provide an advisory review of the Action Plan, and a full review of the Metals Assessment Framework.

Dr. Vu thanked the speakers for their presentations and comments. Dr. Wood also thanked the presenters. He noted that the schedule for developing the Framework is aggressive, and will therefore need good dialogue between EPA, the stakeholders, and the scientific community. The Action Plan will outline what some of these interactions will be. The comments received during this meeting offered constructive ideas that EPA will consider and discuss. The meeting notes will be available online, and EPA will announce when the SAB meeting will occur. Dr. Wood asked participants to provide information on candidates for the peer review panel to Don Barnes, who will be assembling this panel.

APPENDIX A

Final Attendee List

United States
Environmental Protection Agency
National Center for Environmental Assessment

Meeting on the Development of a Metals Assessment Framework

Holiday Inn Washington Capitol Hotel
Washington, DC
February 20, 2002

Final Attendee List

Fern Abrams
Director of Environmental Policy
IPC - The Association Connecting Electronic Industries

William Adams
Director Environmental Affairs
Kennecott Utah Copper Corporation

Bill Allen
Research & Regulatory Manager
Color Pigments Manufacturers Association

John Arnett
Government Affairs Counsel
Copper & Brass Fabricators Council

Steven Barringer
McClure, Gerard & Neuenschwander

John Bell
Senior Consultant/Principal
SAFRISK, LC

Ed Bender
U.S. Environmental Protection Agency

William Berti
DuPont Central Research & Development

Andrew Bopp
Executive Director
Society of Glass and Ceramic Decorators

Christian Brittle
International Trade Specialist
Office of Materials, Metals & Chemicals
International Trade Administration
U.S. Department of Commerce

Kevin Brix
Ecotoxicologist
Metals Ad Hoc Coalition

Kevin Bromberg
Asst. Chief CounselEnvironmental Policy
Office of Advocacy
U.S. Small Business Administration

Marilyn Brower
Office of Research and Development
Risk Assessment Forum
U.S. Environmental Protection Agency

Joseph Bunnell
U.S. Geological Survey

Charles Delos
Environmental Scientist
Health and Ecological Criteria Division
U.S. Environmental Protection Agency

Sara Dennis
Environmental Scientist
Science Appl. International Corporation

Stephen Devito
U.S. Environmental Protection Agency

John Dombrowski
Chief
TRI Regulation Development Branch
U.S. Environmental Protection Agency

Robert Dwyer
Assistant Program Director - Ecotoxicology
International Copper Association, LTD.

Daniel Eddinger
Program Analyst
Small Business Division
Office of the Administrator
U.S. Environmental Protection Agency

Elizabeth Festa Watson
Managing Director, CHEMSTAR Panels
Metal Catalysts Panel
American Chemistry Council

Edward Feuguson
Battevy Council International
c/o Howvey & Simon

Joseph Green
Specialty Steel Industry of North America
Collier Shannon Scott, PLLC

Andrew Green
Manager, Environmental Toxicology
Intl. Lead Zinc Research Organization

Jeff Hannapel
Vice President of Regulatory Affairs
The Policy Group, LLC

Melow Keener
Executive Director
Coalition for Resp. Waste Incineration

Neil King
Wilmer, Cutler, & Pickering

Jane Luxton
Partner
King & Spalding

Alexander McBride
U.S. Environmental Protection Agency

Kevin Minoli
Office of General Counsel
U.S. Environmental Protection Agency

Hugh Morrow
President, North America
International Cadmium Association

Mark Nealley
Senior Scientist
Intl. Center for Toxicology & Medicine

Edward Ohanian
U.S. Environmental Protection Agency

Paul Orum
Working Group on Community RTK

Lindsay Ott
Legislative Associate
Ferroalloys Association

Sueanne Pfifferling
Pfifferling & Associates, LLC

Meredith Preston
Reporter
Bureau of Environmental News
The Bureau of National Affairs, Inc.

Anthony Renzulli
Metals Division
U.S. Department of Commerce

Keith Sappington
Ecologist
Office of Research & Development
U.S. Environmental Protection Agency

Neil Shah
Associate Editor
Risk Policy Report
Inside Washington Publishers

Suhair Shallal Al-Mudallal
U.S. Environmental Protection Agency

Scott Slesinger
Vice President for Governmental Affairs
Environmental Technology Council

Ann Smith-Reiser
Program Manager/Engineer
Analytical Services Incorporated

Marc Stifelman
Environmental Toxicologist
Office of Environmental Assessment
Risk Evaluation Unit
U.S. Environmental Protection Agency

Bob Stricter
Vice President
Environment, Health & Safety
Aluminum Association

Vanessa Vu
U.S. Environmental Protection Agency

John Whalan
U.S. Environmental Protection Agency

Ronald Willson
Environmental Director
of Environmental Activities
Photo Marketing Association International

Bill Wood
Office of Research and Development
Risk Assessment Forum
U.S. Environmental Protection Agency

APPENDIX B

Agenda

United States
Environmental Protection Agency
National Center for Environmental Assessment

Meeting on the Development of a Metals Assessment Framework

Holiday Inn Washington Capitol Hotel
Washington, DC
February 20, 2002

Preliminary Agenda

WEDNESDAY, FEBRUARY 20, 2002

8:15AM	**Registration**
9:00AM	**Welcome, Background and Scope** *Vanessa Vu, Ph.D., U.S. Environmental Protection Agency*
9:15AM	**Questions and Answers on Background and Scope** *Audience*
9:35AM	**Public Comments** *Pre-registered Commenters* 9:35AM - *William Adams, Kennecott Utah Copper* 9:55AM - *Kevin Brix, Metals Ad Hoc Coalition* 10:15AM - *Andrew Green, International Lead Zinc Research Organization*
10:35AM	B R E A K
11:00AM	**Public Comments** *Pre-registered Commenters* 11:00AM - *Jane Luxton, King & Spaulding* 11:20AM - *Lynn Bergeson, American Chemical Council* 11:40AM - *Neil King, Wilmer, Cutler, & Pickering* 12:00N - *Kevin Bromberg, US Small Business Administration*
12:20PM	**Public Comments*** *Onsite Commenters*
12:50PM	**Closing Remarks** *Vanessa Vu*
1:00PM	ADJOURN

*If numerous people sign up onsite to make comments the workshop will break for lunch at 12:20PM and return at 1:20PM for additional comments.

APPENDIX C

Slides from Opening Presentation: "Metals Assessment Framework: Development of an Action Plan" (Vanessa Vu, EPA)

Metals Assessment Framework

Development of an Action Plan

Vanessa T. Vu, Ph.D.

Director

Office of Science Coordination and Policy

Co-Chair

Science Policy Council Metals Action Plan Workgroup

February 20, 2002

OUTLINE

- Background
  - *EPA Initiative for Development of a Cross-Agency Metals Assessment Framework*
- Process for Development of Metals Assessment Framework
  - *Development of an Action Plan*
- Objectives of Meeting
- Schedule and Next Steps

Development of Metals Assessment Framework

- EPA's Science Policy Council (SPC) Initiative
  - Multi-year science-based process to develop a comprehensive framework that could be the basis for future Agency actions
- EPA will submit to the Science Advisory Board (SAB) for review of whether lead and lead compounds should be classified as *highly bioaccumulative* at the same time as the SAB review of the metals assessment framework

Metals Assessment Framework- What is it?

- Cross- Agency guidance for consistent approach(es) to assessing potential hazard and risk of metals and metal compounds
  - Human health and ecological risks
  - Applicable to EPA programs *(e.g., priority setting, information collection, site specific assessments, national assessments, standards setting, etc.)*
- Basis for additional program specific guidance on metals and metal compounds

Process for Development of Metals Assessment Framework

- Cross-Agency participation
- Multiple opportunities for public participation
- Peer involvement via scientific workshop(s)
- Guidance from EPA's SPC
- Expert advice and peer review by EPA's SAB

Action Plan
Metals Assessment Framework

- Identify primary elements and critical issues that should be addressed in the metals framework
- Describe the necessary steps towards the development of the framework
- EPA to obtain early input from stakeholders
- Draft Action Plan to be reviewed by EPA's SPC
- EPA to submit the Action Plan to EPA's SAB for their expert advice

Public Participation

Public participation is an integral part of the development of a *Metals Assessment Framework*

- Early input in the development of the Action Plan
- The SAB advisory meeting on the Action Plan
- During the development process of the *Metals Assessment Framework*
- The SAB peer review of the Framework

Purpose of Meeting

- This meeting is the first opportunity for EPA's stakeholders to make recommendations, suggestions, and comments about the Action Plan and the nature of the Metals Assessment Framework
- Public input will be considered in the development of the Action Plan and presented to SAB advisory meeting

Major Topics for Public Input

- What organizing principles should the framework follow?
- What scientific issues should the framework address?
- What methods and models should be considered for inclusion in the framework?
- What specific steps should be taken to further involve the public and the scientific community in the development of the framework?

Schedule

January 2002	Develop Action Plan
February 2002	First Public Meting
March 2002	SPC Review of Draft Action Plan
May 2002	Publication of Action Plan
June 2002	SAB Meeting on Action Plan
July 2002	Develop Framework
March 2003	SAB Review of Framework
June 2003	SAB Report
December 2003	Publication of Framework

Next Steps

- SPC Metals Action Plan Workgroup to incorporate public comments into the Action Plan as deemed appropriate
- Workgroup to present draft Action Plan along with summary of public comments to SPC (March 2002)
- Publish Action Plan on RAF's website http://www.epa.gov/ncea/raf/ (May 2002)
- Hold SAB Advisory meeting (June 2002)

APPENDIX D

Slides from "Hazard Assessment of Metals: An Overview" (Andrew Green, International Lead Zinc Research Organization)

Hazard Assessment of Metals: An Overview

Andrew Green
ILZRO
RTP, NC
(919) 361-4647
agreen@ilzro.org

February 20, 2002

Metals Assessment Questions

- What organizing principles should the framework follow?
- What scientific issues should the framework address?
- What methods and models should be considered for inclusion in the framework?
- What specific steps should be taken to further involve the public & the scientific community in the development of the framework?

Presentations Outline

- Hazard Assessment Overview – Andrew Green
- Bioaccumulation Hazard of Metals – Kevin Brix
- Framework for Assessing Metals – Bill Adams

Hazard Assessment of Metals

- PBT hazard assessment approach has become basis of regulatory initiatives & stakeholder discussions
  - US EPA/States
  - Canada
  - EU/OECD

- PBT not focus of presentation but will use to:
  - Identify current hazard approach
  - Identify related scientific issues
  - Identify additional approaches/concepts for consideration

Hazard Assessment of Metals: PBT

- “Persistent, Bioaccumulative, and Toxic” (PBT) approach developed for organic chemicals in the 1970s

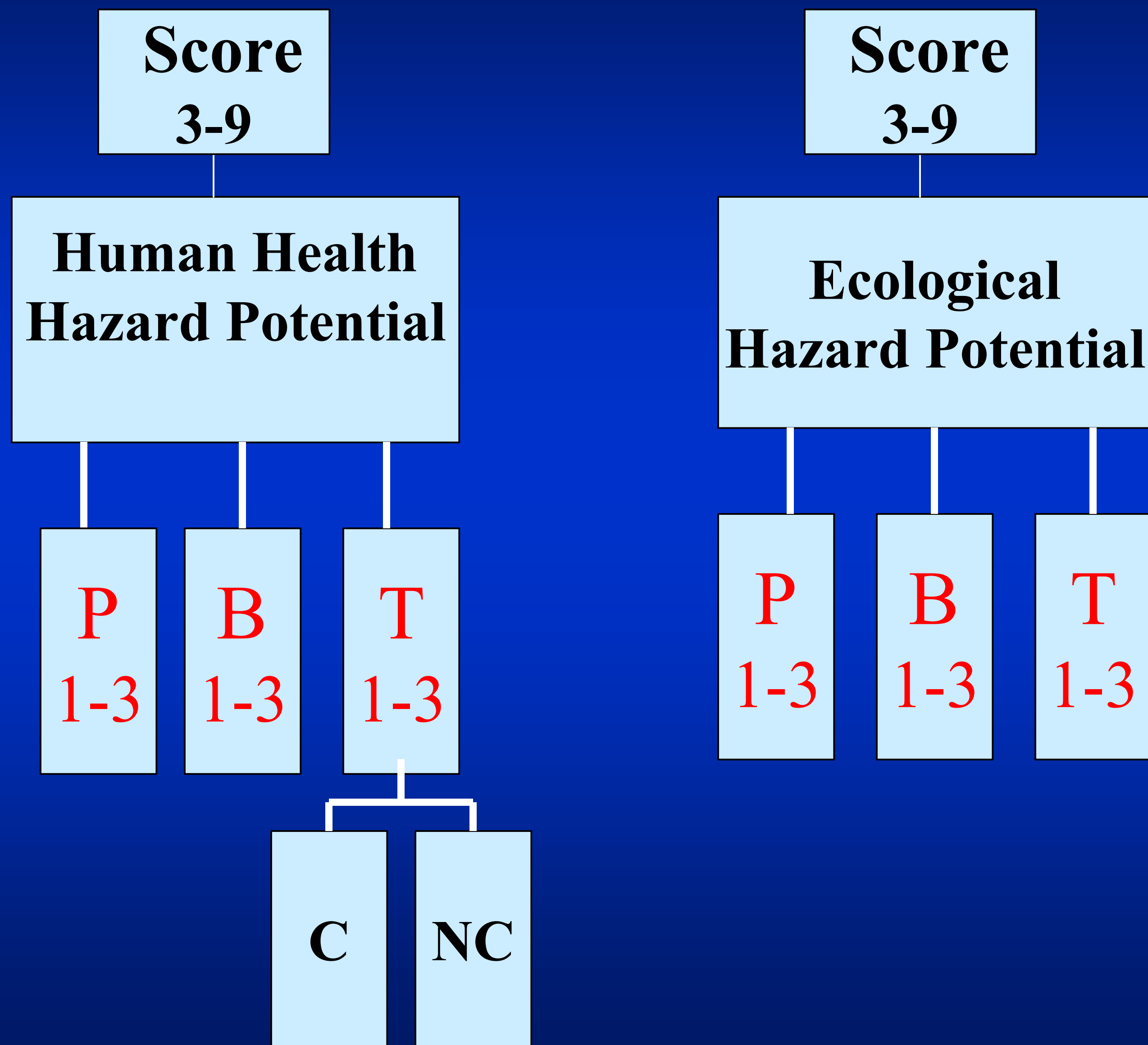
- Current EPA definition of a PBT chemical is one that exhibits varying degrees of the 3 criteria:

  - **Persistent**: chemicals that do not readily breakdown in the environment

  - **Bioaccumulative**: chemicals that accumulate in humans or ecological food chains

  - **Toxic**: chemicals that are hazardous to humans or the environment

Hazard Assessment of Metals: PBT



Hazard Assessment of Metals: Persistence

Current Approach-

- "The ability of a chemical to remain in a particular environment in an unchanged form"
- Chemical is **P** if half-life in water/sediment/soils is > 2 months
- All metals get default **P** score of 3

element and does not provide a discrimination of hazard between metals

Hazard Assessment of Metals: Persistence

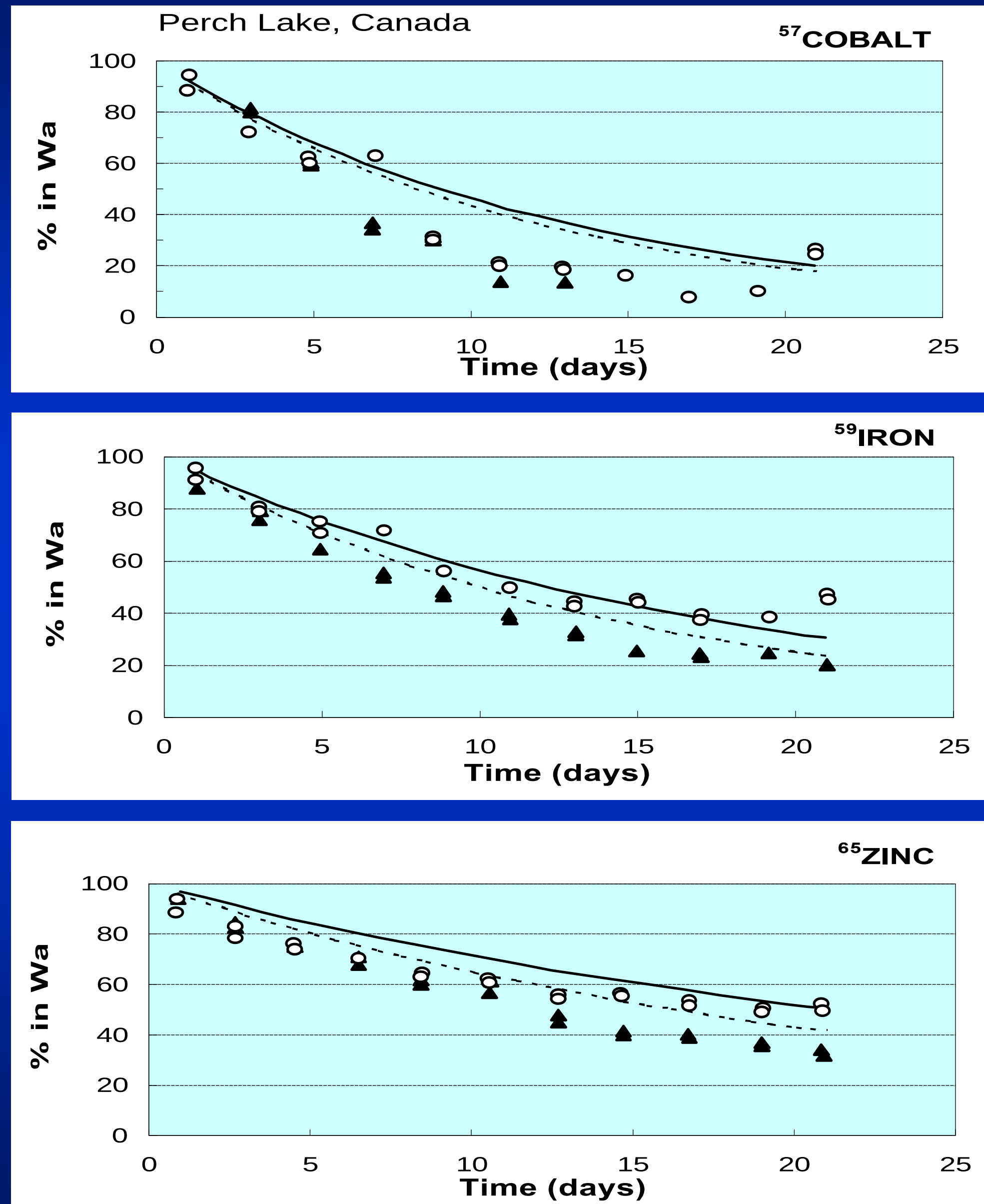
Scientific Issues-

- Alternative definition for metals: "**P** is a property of a chemical whereby it remains in a bioavailable form in an environmental compartment"

- What properties can be used to assess **P** of metals?
  - presence/absence of free metal ion – Me^{2+}
  - partitioning to suspended solids
  - residence time in water column
  - partitioning to sulfide in sediments
  - resuspension and flux to water column

Hazard Assessment of Metals: Persistence

Scientific Issues-



Mesocosm	Data	Model	TSS (mg/L)
Control 1	•	_____	3.0 $\pm$1.1
Control 2	o		1.5 $\pm$ 0.8

Hazard Assessment of Metals: Persistence

Scientific Issues-

predicted free metal ion fraction using WHAM and DOC = 2 mg/L

Metal	Free Metal Ion (Fraction) – pH 6.0
Manganese	0.94
Cadmium	0.91
Cobalt	0.77
Nickel	0.68
Z inc	0.71
Iron (II)	0.70
Lead	0.06
Copper	0.01
Beryllium	3.4×10^{-4}
Aluminum	7.9×10^{-5}
Chromium (III)	9.0×10^{-8}
Mercury	1.6×10^{-9}
Iron (III)	2.7×10^{-11}

Hazard Assessment of Metals: Persistence

Metal	Suspended Solids Partition Coefficient (Kd)	$(1/Kd) \times 10^5$
Iron (II)	10,000	10
Manganese	10,000	10
Cadmium	20,000	5
Cobalt	20,000	5
Nickel	20,000	5
Z inc	25,000	4
Tin	30,000	3.3
Copper	40,000	2.5
Chromium	40,000	2.5
Lead	50,000	2.0
Silver	80,000	1.3
Mercury	90,000	1.1
Iron (III)	>100,000	1.0
Aluminum	>100,000	1.0

Draft Kds

Hazard Assessment of Metals: Bioaccumulation

Current Approach-

- **B** used as an indicator of long-term (chronic) toxicity &
- Chemical is **B** if BAF/BCF > 1000 or log $K_{ow} > 3.0$

Problem: stay tuned for Kevin Brix presentation

Hazard Assessment of Metals: Toxicity

Current Approach-

- Chemical is highly **T (3)** if toxicity values < 1.0 mg/L
- Nearly all metals get **T** score of 3

Problem: No discriminatory power for the hazard assessment of metals

Soluble Metal Salt	Aquatic **Acute** (ug/L)	Aquatic **Chronic** (ug/L)
Iron		1000
Arsenic	340	150
Zinc	120	120
Aluminum	750	87??
Chromium III	570	74
Nickel	470	52
Chromium VI	16	11
Selenium	20	5
Copper	13	9
Lead	65	2.5
Mercury	1.4	0.77*
Silver	3.4	----
Cadmium	1.0	0.15

Hazard Assessment of Metals: Toxicity

Scientific Issues-

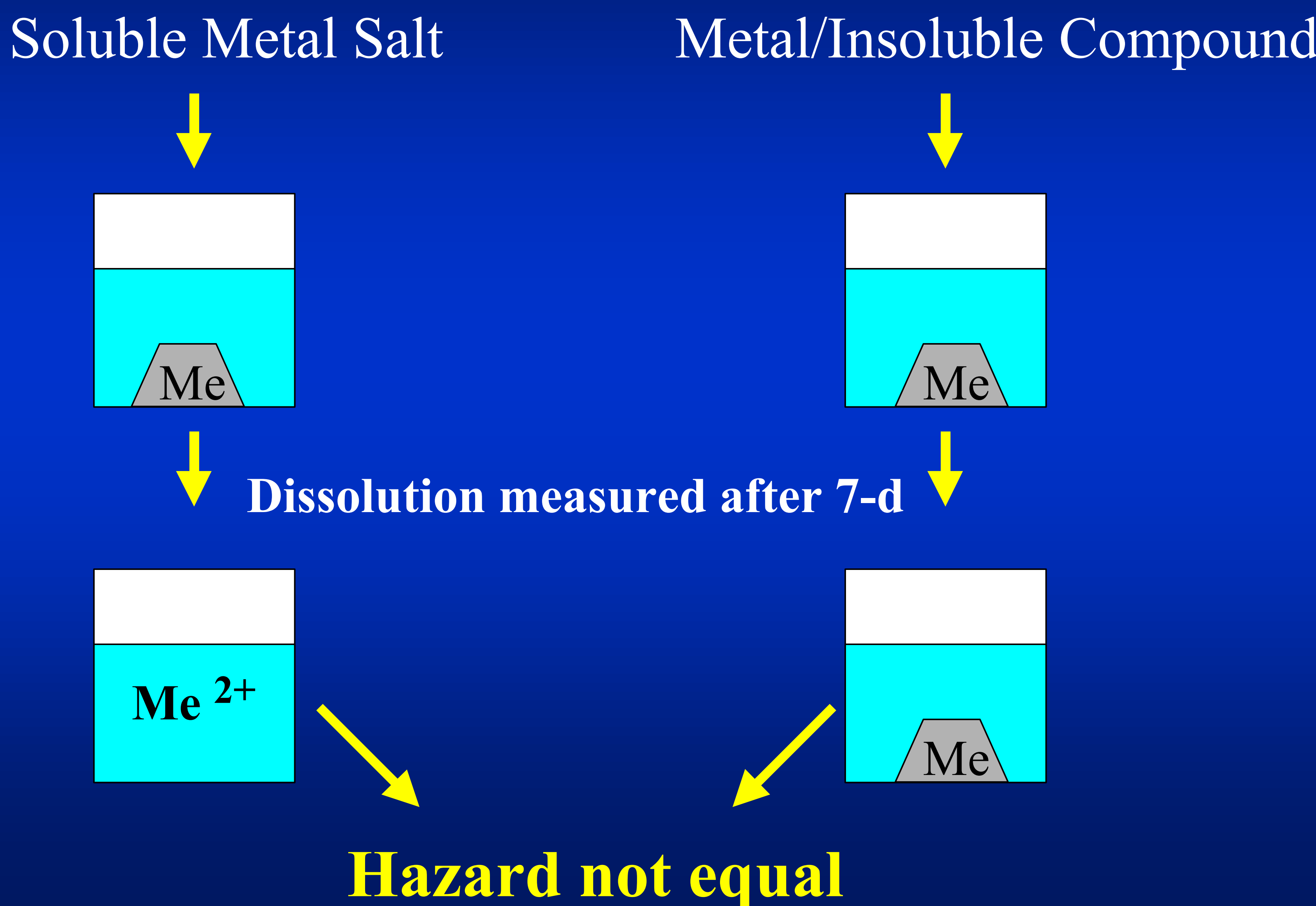
- no distinction between metal elements & metal compounds
- speciation and transformation/dissolution not considered
- scale does not allow discrimination
- bioavailability not considered

- Comparison of Acute EPA WQC with 5th % tile Acute Species Sensitivity Values

Soluble Metal Salt	**Acute WQC** (ug/L)	**5th % tile** (ug/L)
Chromium III	570	3330
Aluminum	750	3053
Iron	----	1621
Selenium (VI)	20	1011
Selenium (IV)	20	568
Nickel	470	790
Arsenic	340	680
Zinc	120	165
Lead	65	105
Chromium VI	16	55.8
Copper	13	10.8
Cadmium	4.3	9.4
Mercury	1.4	8.2
Silver	3.4	0.93

Hazard Assessment of Metals: Toxicity

Scientific Issues -Transformation



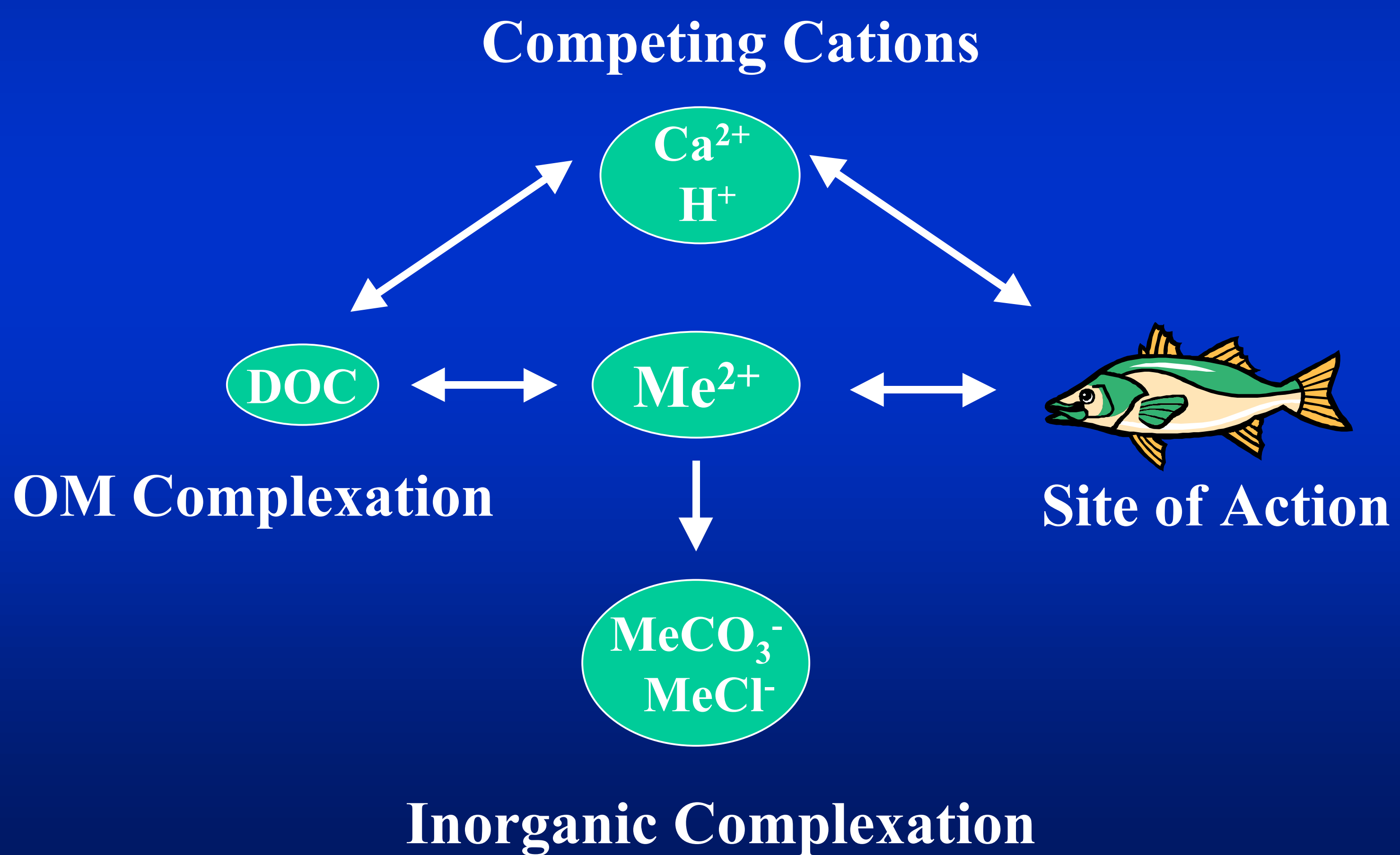
Hazard Assessment of Metals: Bioavailability

Scientific Issues -

- Bioavailability needs to be considered for proper hazard assessment of metals
- Bioavailability integral component in assessing PB & T
- Models developed by/with USEPA considering bioavailability for use in a hazard assessment exist:
  - Biotic Ligand Model – for water
  - AVS-SEM – for sediment

Hazard Assessment of Metals: Bioavailability

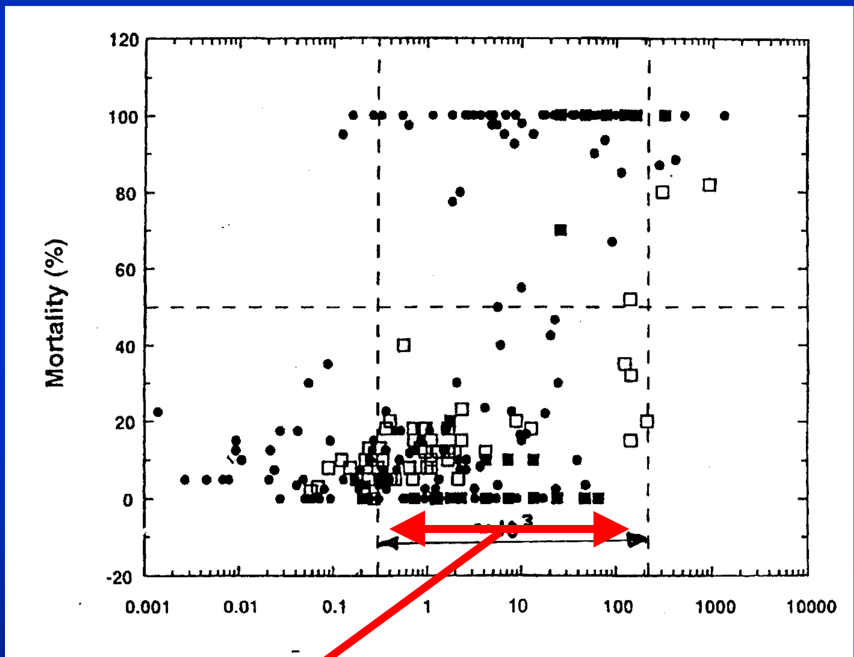
Biotic Ligand Model



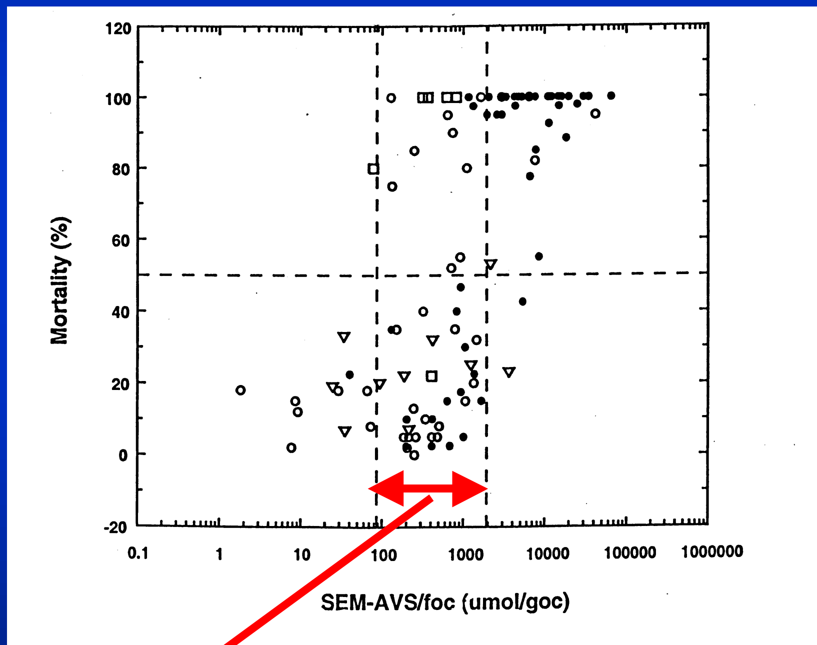
Hazard Assessment of Metals: Bioavailability

AVS-SEM Model

Total [Me]



$\frac{\text{AVS – SEM}}{foc}$



Uncertainty = 10^3

Uncertainty = 10^1

Hazard Assessment of Metals: Conclusions

- Approach developed for organic chemicals won't work with metals, new approach needs to be developed for metals
- Criteria used should be metal specific; based upon metal properties
- New approach should provide discriminatory power for the the proper hazard assessment of metals and inorganic metal substances
- Existing data/information can be used in this effort

APPENDIX E

Slides from "Assessing Bioaccumulation Hazard of Metals and Metal Compounds" (Kevin Brix, EcoTox)

Assessing Bioaccumulation Hazard of Metals and Metal Compounds

Kevin Brix
EcoTox
Newport, Oregon
(541) 574-9623
kevinbrix@actionnet.net

February 20, 2002

Presentation Overview

- Current approach to assessing bioaccumulation hazard for metals and metal substances has limitations
- Inverse relationship between accumulation factors (e.g., BCF) and exposure concentration for metals
  - Theoretical basis
  - Data supporting theoretical basis
- Alternative Approach to BCF
  - Conceptual framework
  - Preliminary evaluation

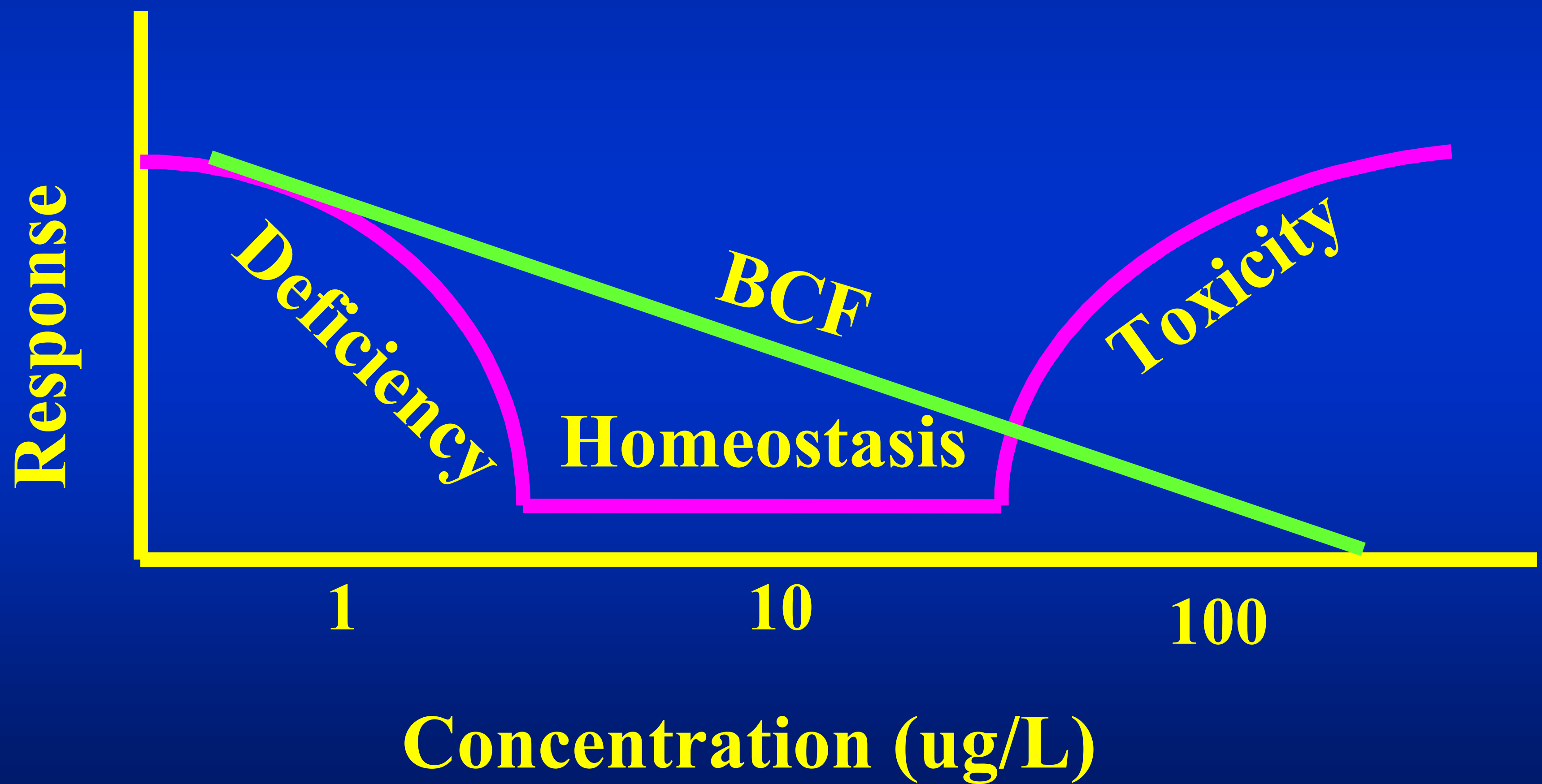
Theoretical Basis - Organics

- Neutral lipophilic organics
  - Uptake via passive diffusion across lipid bilayer
- Accumulation of neutral lipophilic organics not expected to be concentration dependent
- Satisfies intrinsic property criteria

Theoretical Basis - Metals

- Most metals occur as charged ions in aqueous solutions and require active transport to facilitate uptake
- Active transport mechanisms exhibit saturable kinetics (i.e., rate limited)
- Many metals are essential for biological function
  - Organisms actively regulate internal body burdens to satisfy essentiality requirements

Metal Regulation

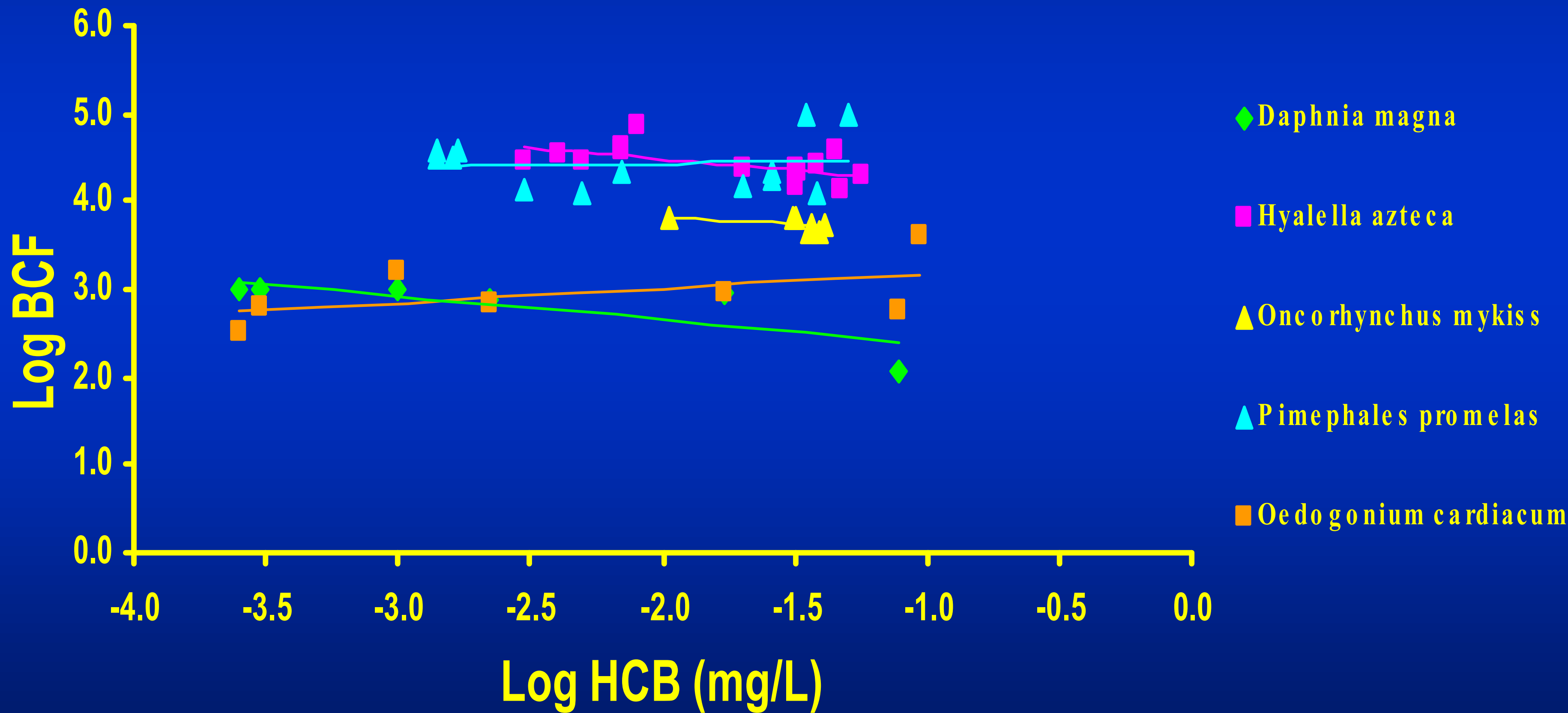


Theoretical Basis - Metals

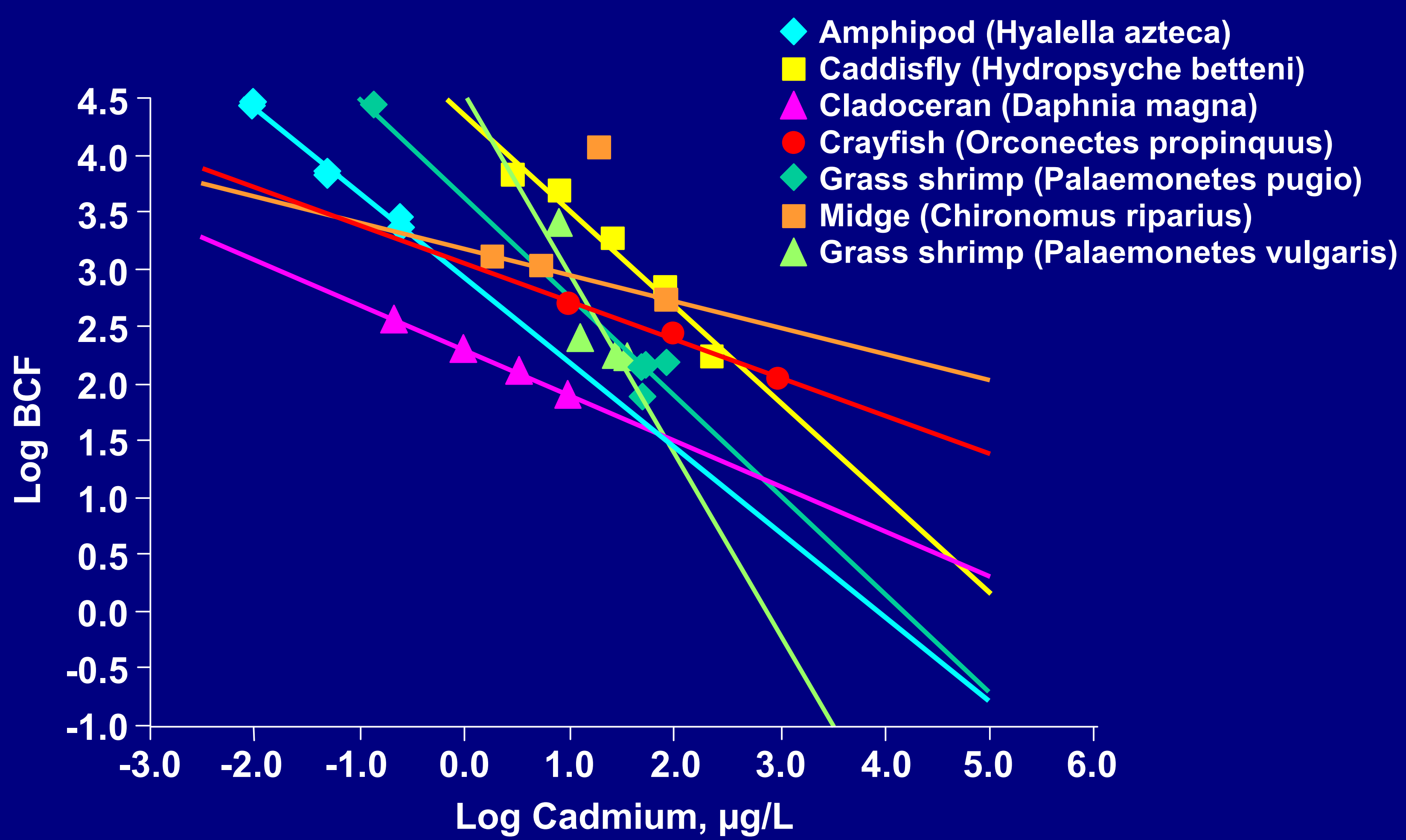
- The characteristics of active transport and essentiality do not satisfy intrinsic property criteria
- Metal accumulation expected to be concentration dependent and inversely related to exposure concentration

Data Supporting Theoretical Predictions

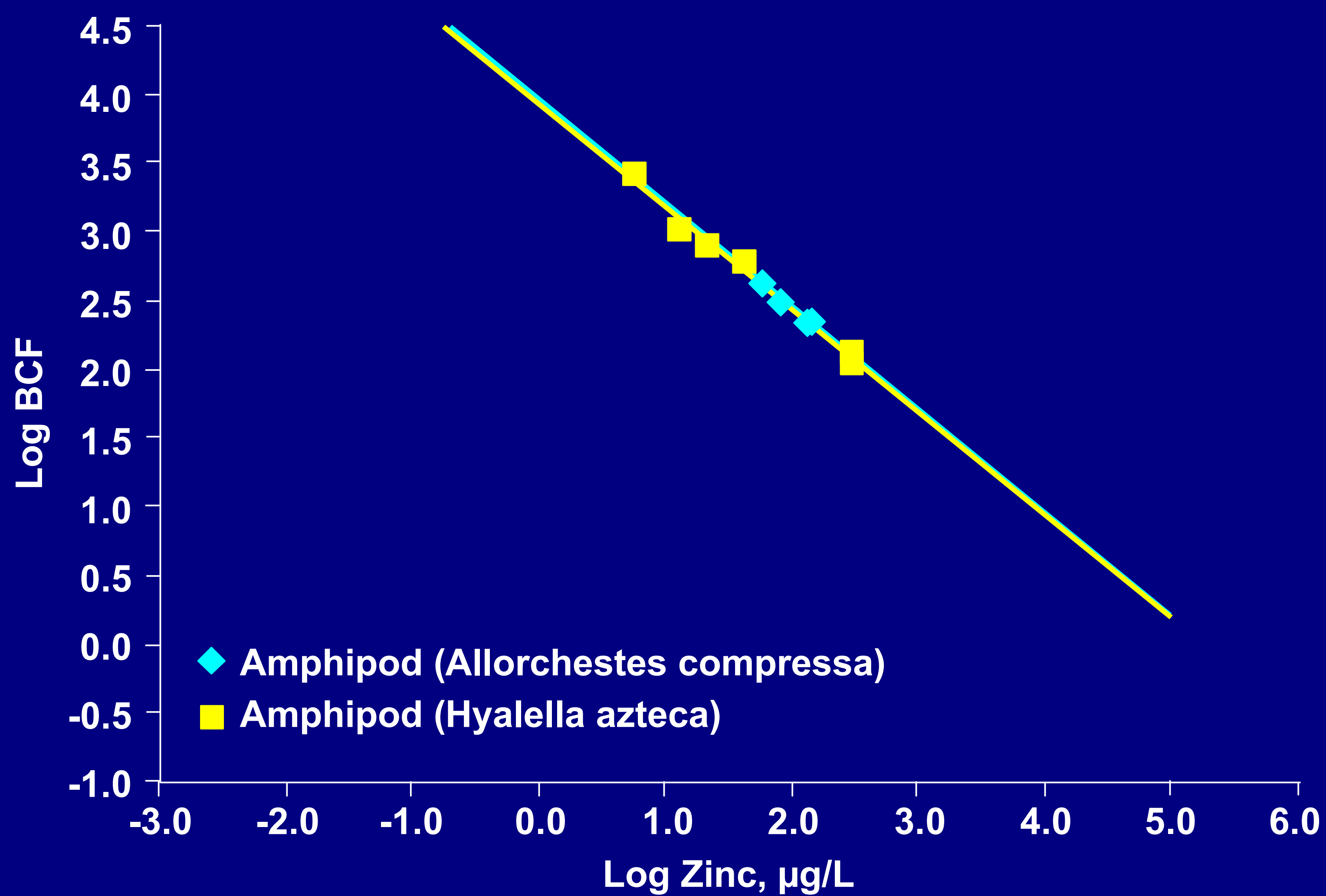
Hexachlorobenzene BCFs
(McGeer et al. In Prep)



Cadmium BCFs

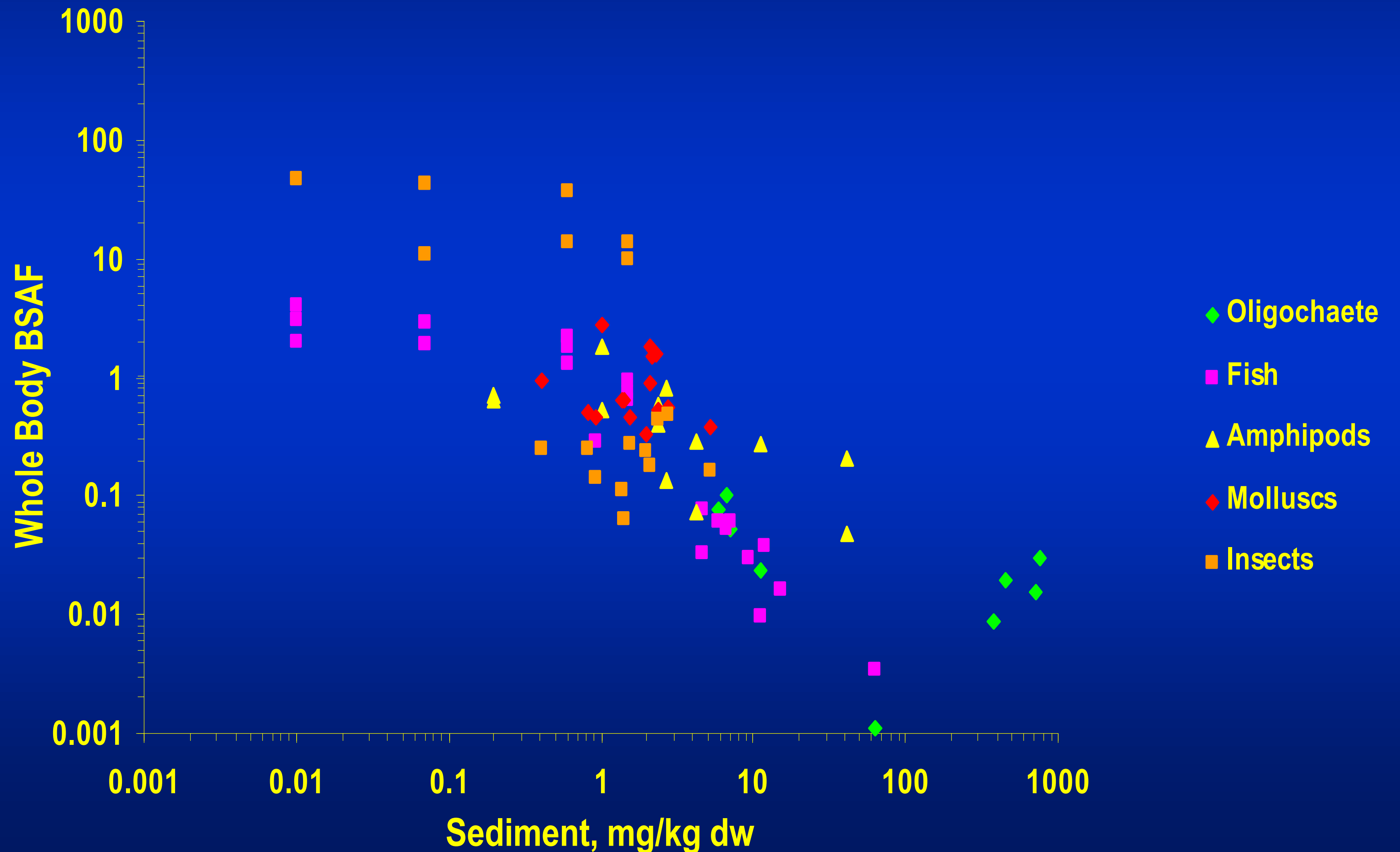


Zinc BCFs

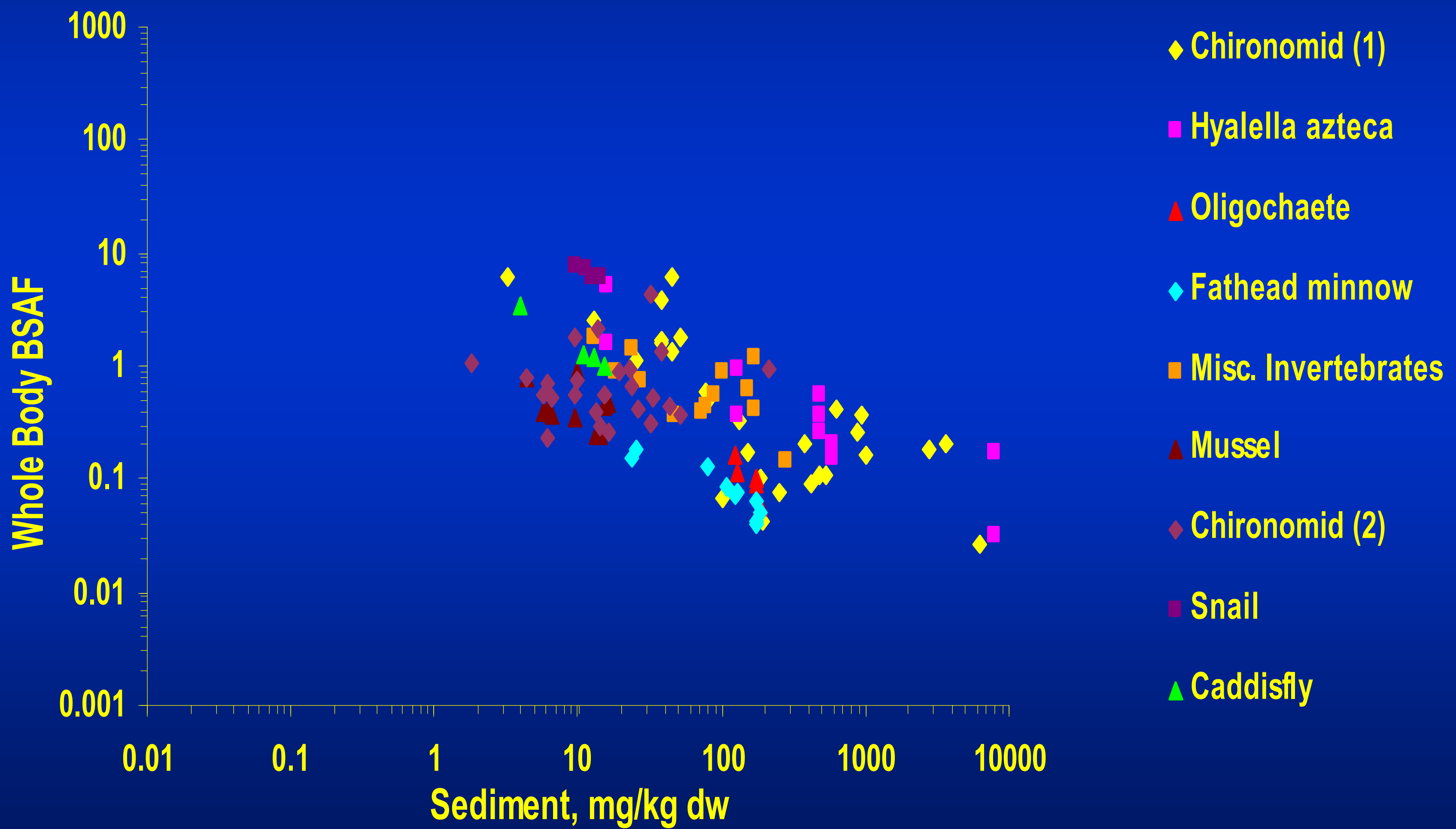


4.5
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
-0.5
-1.0
Log BCF
-3.0
-2.0
-1.0
0.0
1.0
2.0
3.0
4.0
5.0
6.0
Log Zinc, µg/L
Amphipod (Allorchestes compressa)
Amphipod (Hyalella azteca)

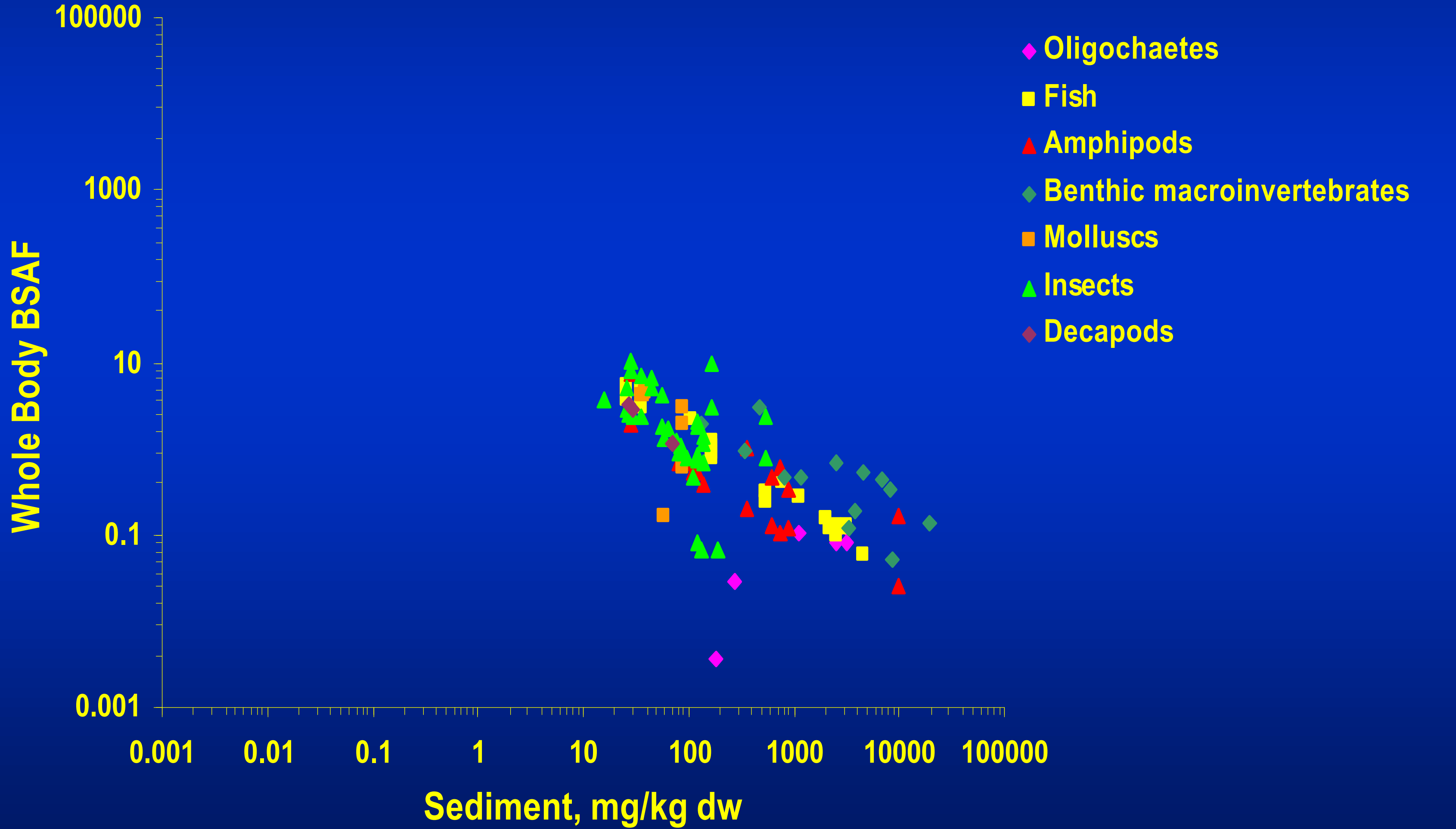
Cadmium BSAFs



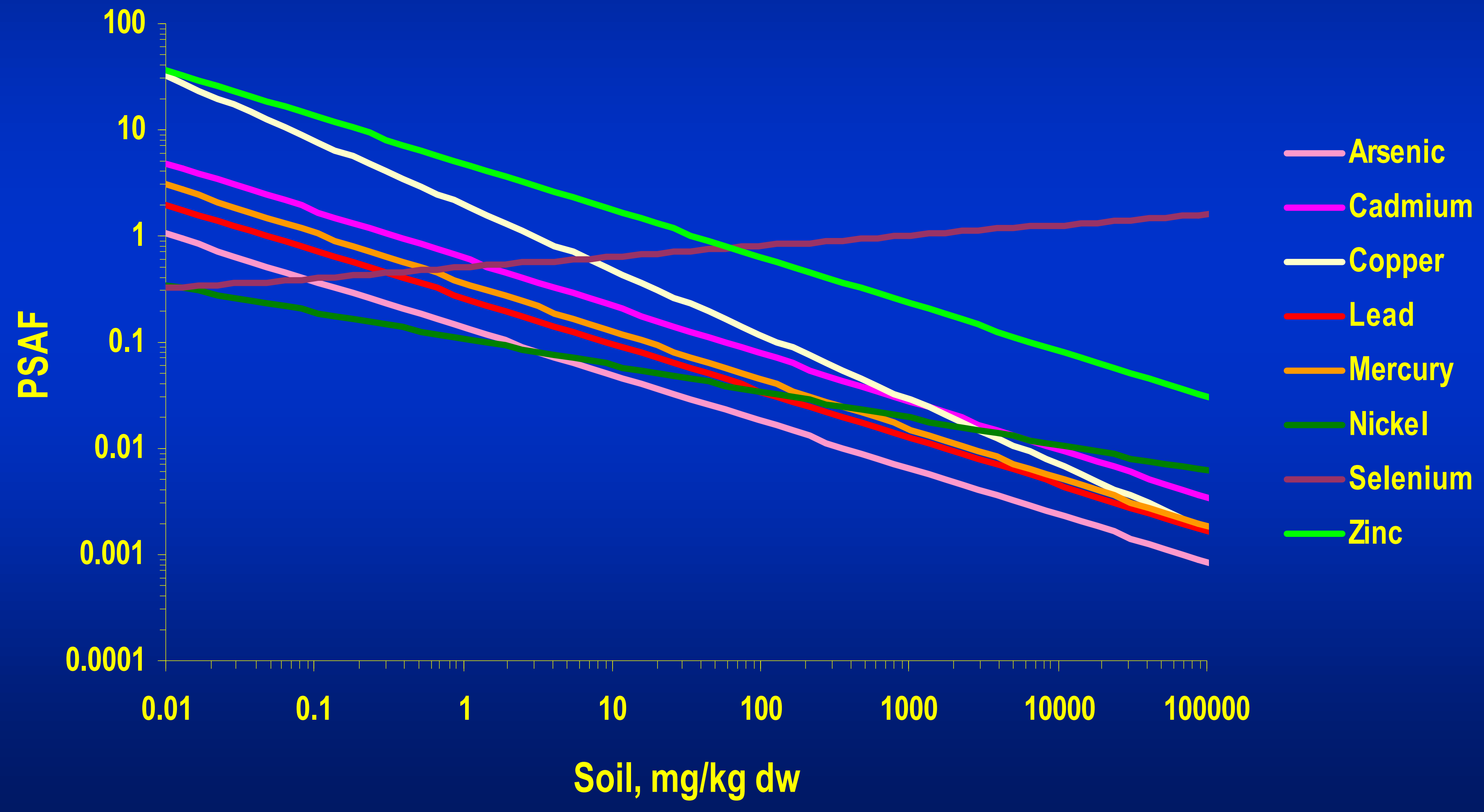
Copper BSAFs



Zinc BSAFs

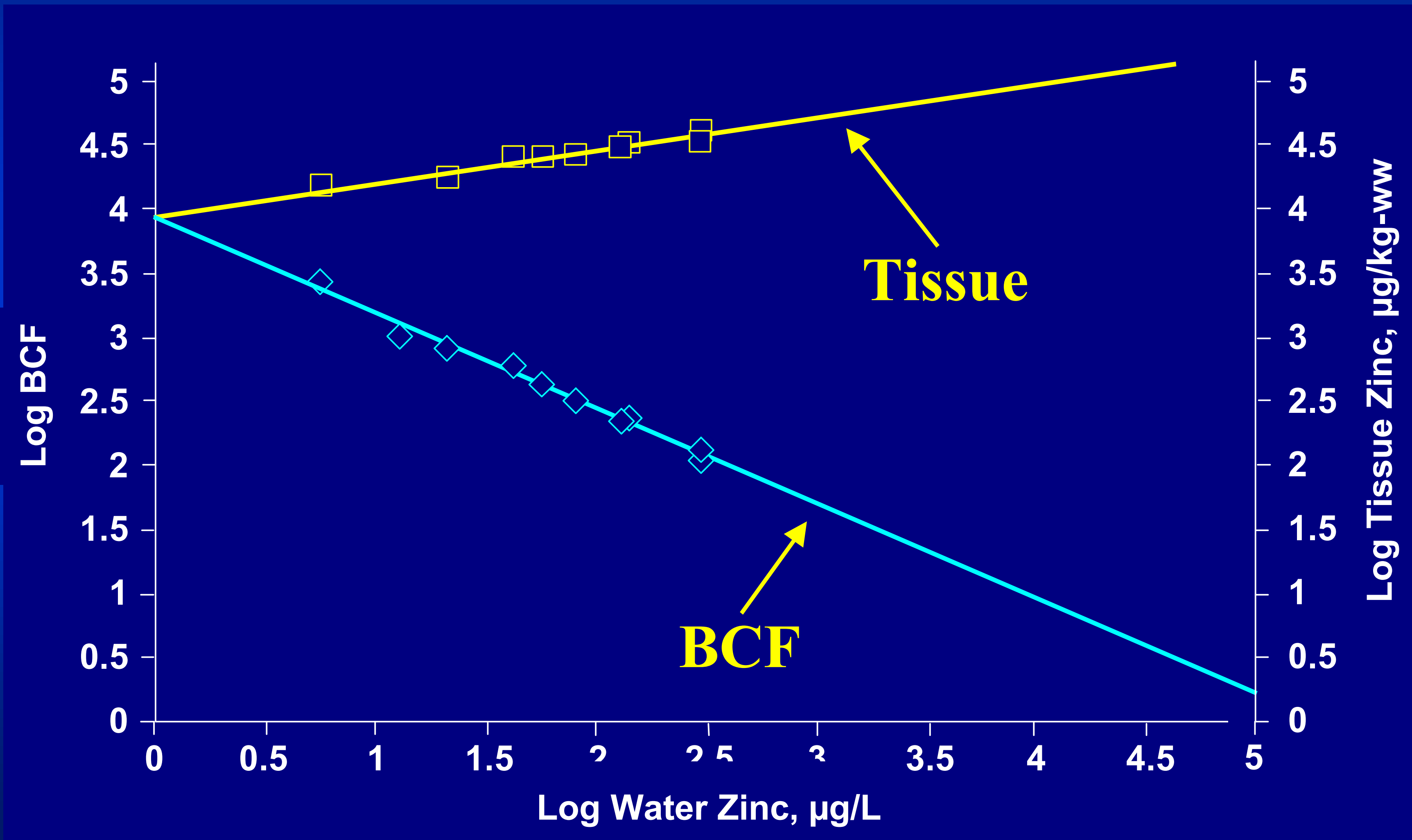

Whole Body BSAF
100000
1000
10
0.1
0.001
0.001
0.01
0.1
1
10
100
1000
10000
100000
Sediment, mg/kg dw
Oligochaetes
Fish
Amphipods
Benthic macroinvertebrates
Molluscs
Insects
Decapods

(from Efroymson et al. 2001)



Implication of the Inverse Accumulation Factor

Relationship Between Zn Water/Tissue Concentrations and BCFs in Amphipods



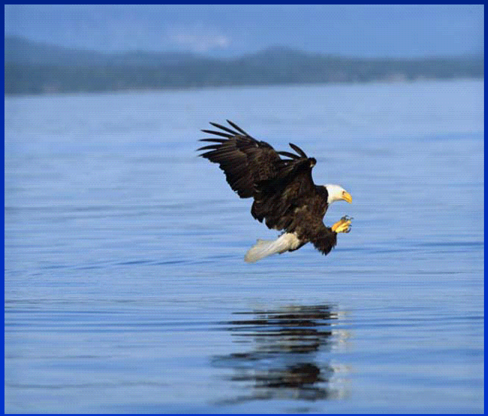
Alternative to the Fixed Accumulation Factor Approach

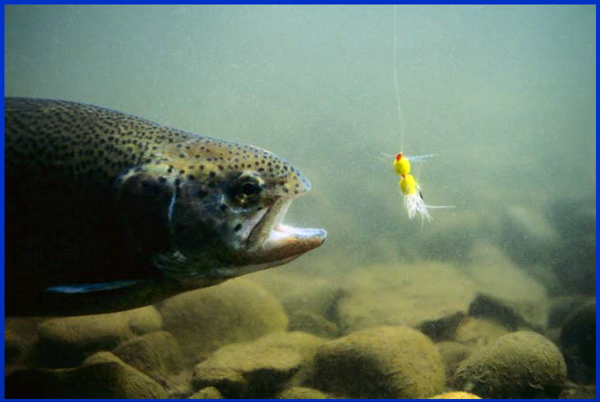
Approach Objectives

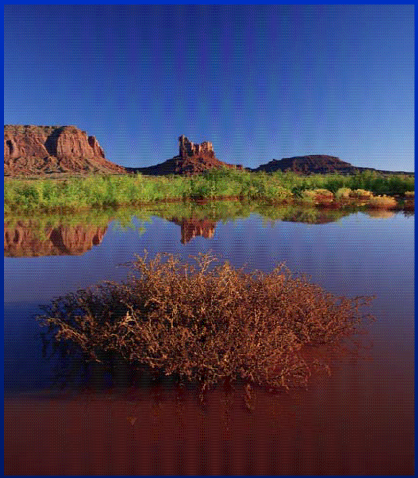
- Evaluate hazard potential of metals via bioaccumulation
- Chronic toxicity
- Dietary toxicity to consumer organisms

Dietarv Toxicitv

Dietary Toxicity







Given a wildlife dietary toxicity threshold

↓

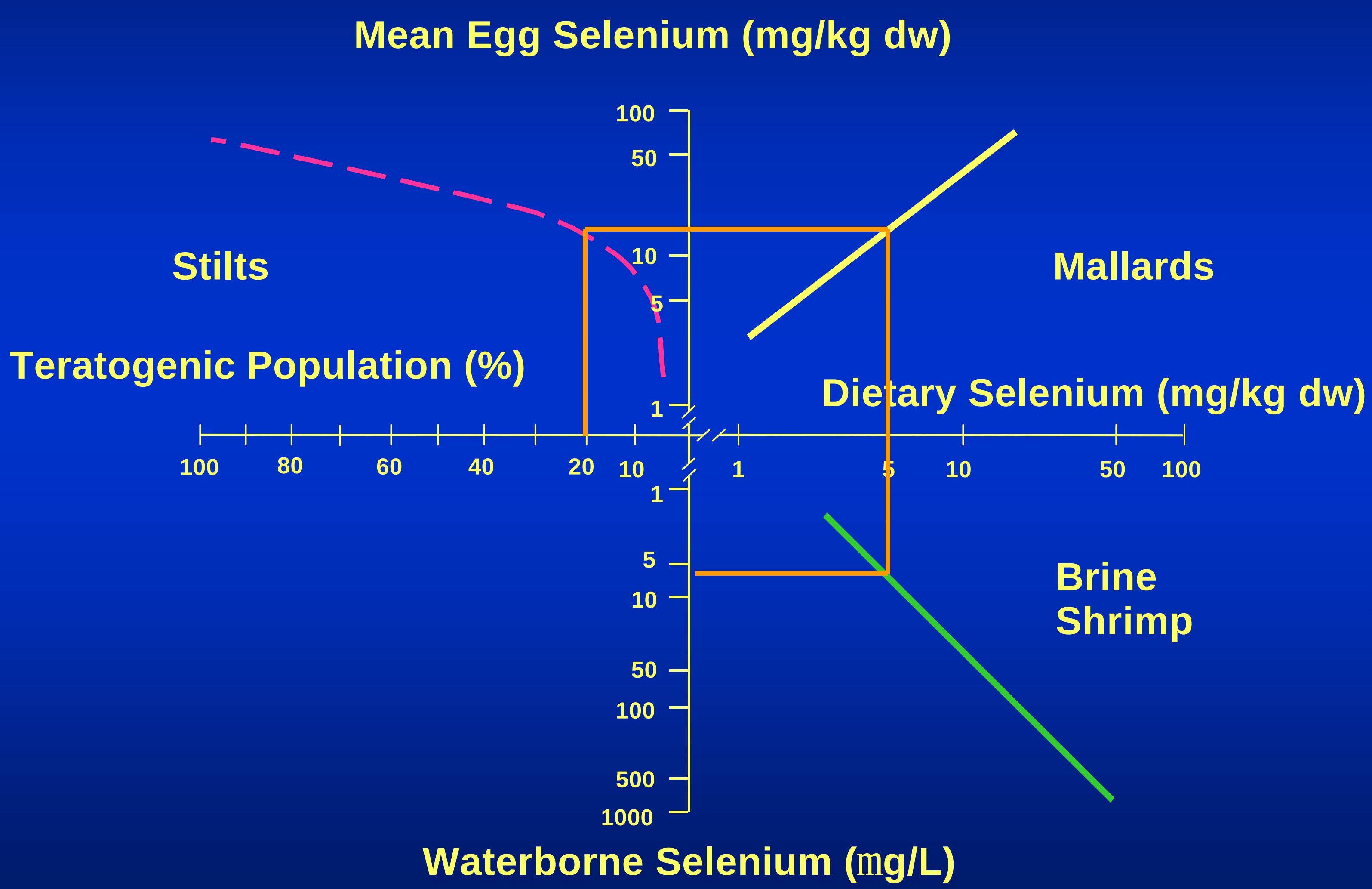
Tissue concentration in prey

↓

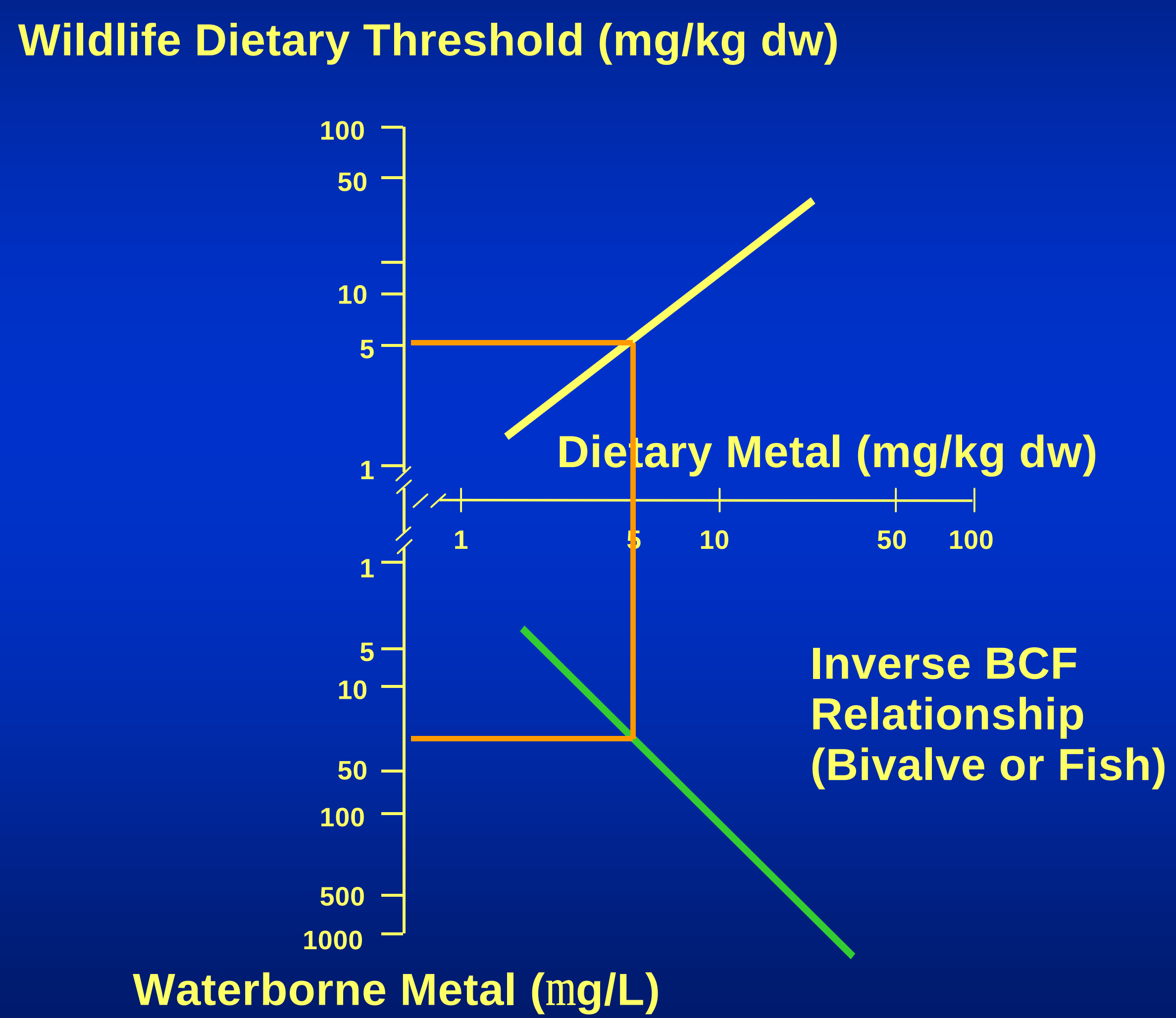
What concentration in water will lead to accumulation that equals the tissue concentration in prey?

Ohlendorf and Santalo (1994)

Based on Skorupa & Ohlendorf (1991)



Regression Approach



Regression Approach

Metal	Wildlife Dietary Threshold (mg/kg dw)	BCF Slope (Bivalves)	BCF Intercept (Bivalves)	Water Conc.* (mg/L)
Me-Hg	0.399	0.99	3.38	0.153
Cu	97	1.11	3.16	87
Pb	71	1.20	2.90	134
Cd	45	0.52	1.79	537
Ag	173	0.59	1.43	22,876
Zn	177	0.17	1.70	1.4×10^6

Water Concentration That Results in Dietary Threshold *

Regression Approach: Interpretation?

- Regression approach estimates water concentration that could cause effects via bioaccumulation
- Provides relative scale for comparing between metals
  - i.e., is 1 mg/L a greater concern for mercury or iron

Conclusions

- Accumulation factors are not an intrinsic property for metals
- BCF and other Accumulation Factors for metals are clearly inversely related to water/sediment/soil concentration
- Bioaccumulation of metals could be assessed using regression approach to estimate water concentration leading to exceedance of wildlife/human health dietary threshold

Conclusions

- Regression Approach appears to provide a reasonable method for ranking relative potential bioaccumulation hazard for metals
- Interpretation of the Regression Approach outputs requires further development
  - Pellston Workshop

APPENDIX F

Slides from “Developing a Framework for Assessing Hazard of Metals and Metal Compounds” (William Adams, Kennecott Utah Copper)

Developing A Framework For Assessing Hazard of Metals and Metal Compounds

William J. Adams, Ph.D.
Kennecott Utah Copper
Salt Lake City, UT
801-569-7553
Adamsw@kennecott.com

February 20, 2002

1. What Organizing Principles Should The Framework Follow?

- Framework should support agency-wide strategic goals for the protection of human health and environment

B. Complement current Agency programs

C. Be based on sound science and incorporate developing science and models as assessment tools

D. Focus initially on hazard assessment as a screening mechanism

E. Develop and utilize more in-depths assessments for metals / metal substances identified in the screening process

F. Incorporate life cycle/use as well as release and exposure data as part of in-depth assessments

EPA Programs

Air ↔ Water ↔ Solid Waste ↔ OPPTS ↔ Information

Protection of human health & environment

- **Clean air**
- **Clean and safe water**
- **Safe food**
- **Preventing pollution & reducing risk**
- **Better waste management**
- **Reducing global risks**
- **Expansion of American's right to know**
- **Sound science**
- **Greater compliance with the law**
- **Effective management**

PBT
Waste Minimization Prioritization

Current Use As A Prioritization Tool (RCRA):

- A hazard identification tool
- Historically based on organic substances
- Used to identify substances of highest concern
- Strong theoretical and practical basis

PBT

Significant Limitations For Metals

- Metals are naturally occurring substances
- Standard persistency measurements are not useful
- BCFs and BAFs are not intrinsic properties and do not provide a measure of concern
- Metals other than methylmercury do not biomagnify - trophic transfer factors frequently less than 1.0

PBT

Significant Limitations For Metals - continued:

5. Mercury is a special case due to the environmental transformation to the organo-form (methyl-mercury)

Conclusion

PBT approach not useful for metal hazard screening: an alternative approach is needed

_ _

Can Be Used To Assess Potential Hazards Of Metals And Metal Substances?

Metal Assessment Approach

- Level 1: Hazard screening
- Level 2: Screening level risk assessment
- Level 3: In-depth risk assessment

Metal Assessment Approach

Level 1
Hazard screening

- Toxicity
- P/C properties
- Persistency of bioavailable form
- Potential for food chain accumulation

Level 2
Screening level
Risk assessment

- Level 1 +
- Product use
- Volume production
- Emission / release info
- Regional / national level

Level 3
In-depth risk assessment

- Level 2+
- Detailed release info
- Exposure monitoring
- Detailed effects assessment
- Site specific detail focus

Tier I: Hazard Screening

Multi-Program Assessment Tools For Metals

Persistence
- Half –life
- Precipitation
- Mineral formation

Bioavailability
- Sorption to:
- Suspended solids, DOC, ligands

Bioaccumulation
- Tissue increase
- Biomagnification
- Trophic transfer
- Sediment BSAFs

Toxicity
- Acute/chronic
- Speciation
- Solubility

Speciation
- Speciation models
- pH effects
- Ion conc.

Tools

Tier II

Screening Level Risk Assessment

- Exposure considerations
  (Emission / release info)
- Product use
  (i.e., metal substances & use)
- Life cycle considerations
  (i.e., recycle rate)
- Volume production
- Regional / national level
  focus

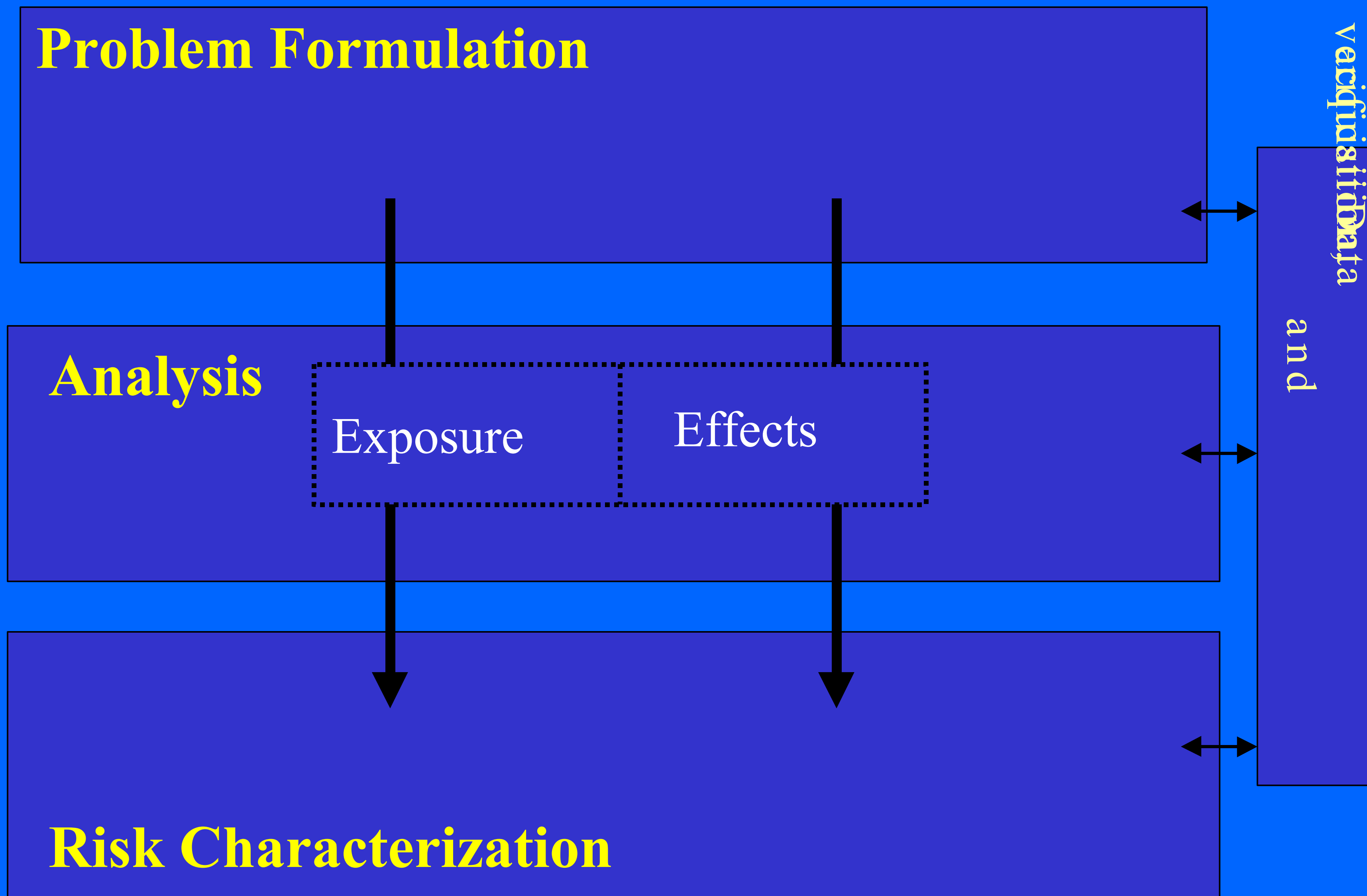
Tier III

Screening Level Risk Assessment

Tier II +

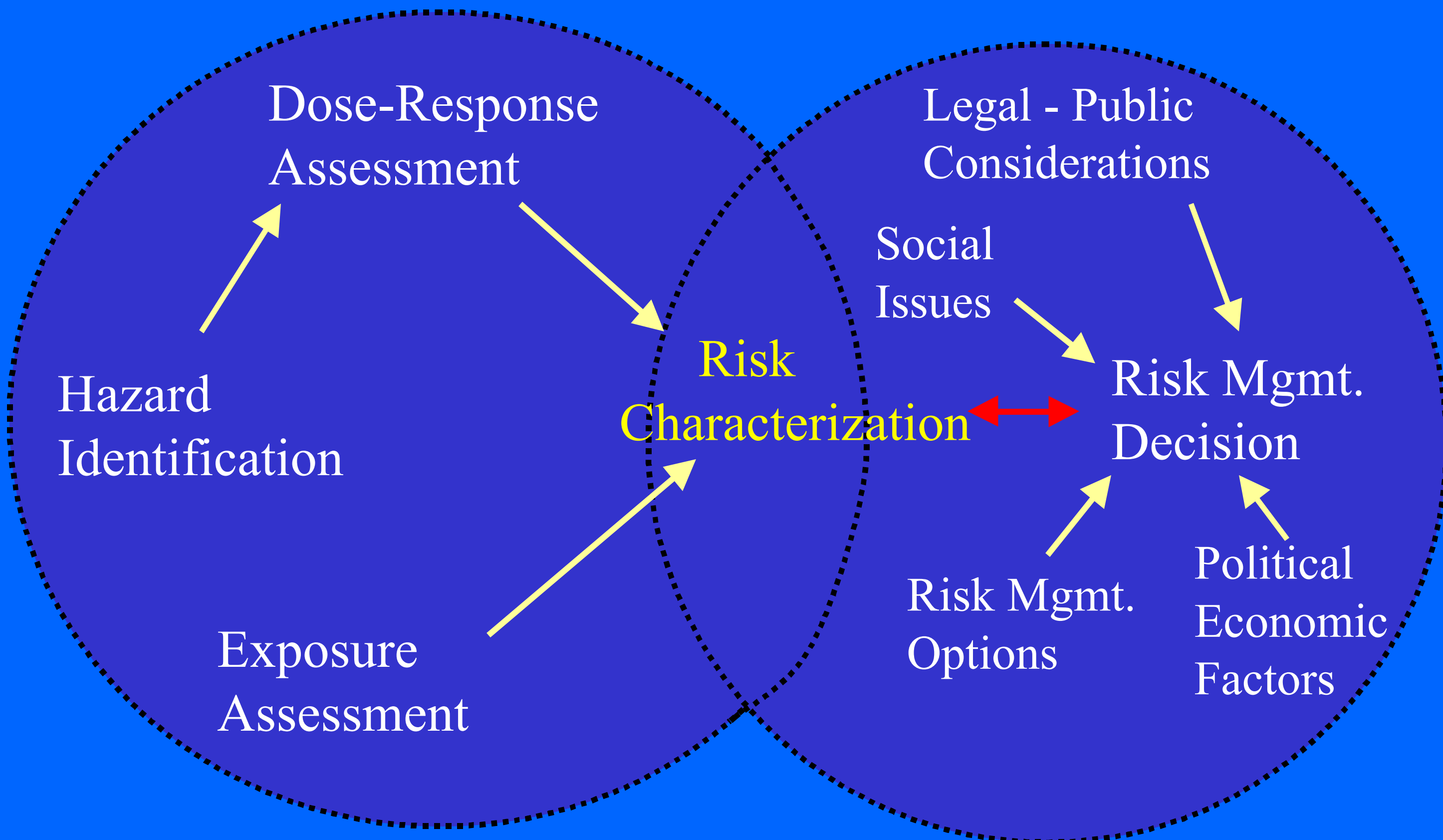
- **Detailed release info**
- **Exposure monitoring**
- **Detailed effects assessment**
- **Site-specific focus**
- **Use of site-specific models**

Ecological Risk Assessment Framework*



* USEPA Ecological Risk Assessment Framework (EPA, 1992)

Human Health Paradigm*



* Adapted from Risk Assessment in the Federal Government: Managing the Process. National Academy of Sciences, 1983.

Multi-Program Assessment

EPA Programs
Air
Water
Waste
Pesticides & Toxics
TRI
Information

2. What Scientific Issues Should The Framework Address?

Key Scientific Issues Include:

A. Valid approaches for assessing persistence
B. Alternative methods for assessing bioaccumulation and food chain transfer for aquatic species
C. Need to evaluate bioavailability
D. What constitutes significant bioaccumulation of metals in human beings
E. Assessment of substances versus elements

3. What Methods And Models Should Be Considered For Inclusion In The Framework?

Key Methods/Models Include:

- New Bioaccumulation model for aquatic-linked food chains
- Incorporation of speciation models
- Use of complexation/binding models (WHAM)
- Use of biotic ligand type models
- Unit World Model for predicting environmental fate and bioavailability

EPA Questions 2 and 3:
to be addressed in
more detail by
Kevin Brix and Andrew Green

Multi-Program Assessment Tools For Metals

Bioavailability Bioaccumulation Speciation

- Half –life
- Precipitation
- Mineral formation
- Unit World Model

- Sorption to:
- Suspended solids, DOC, ligands
- WHAM Model

- Tissue increase
- Biomagnification
- Trophic transfer
- Sediment BSAFs

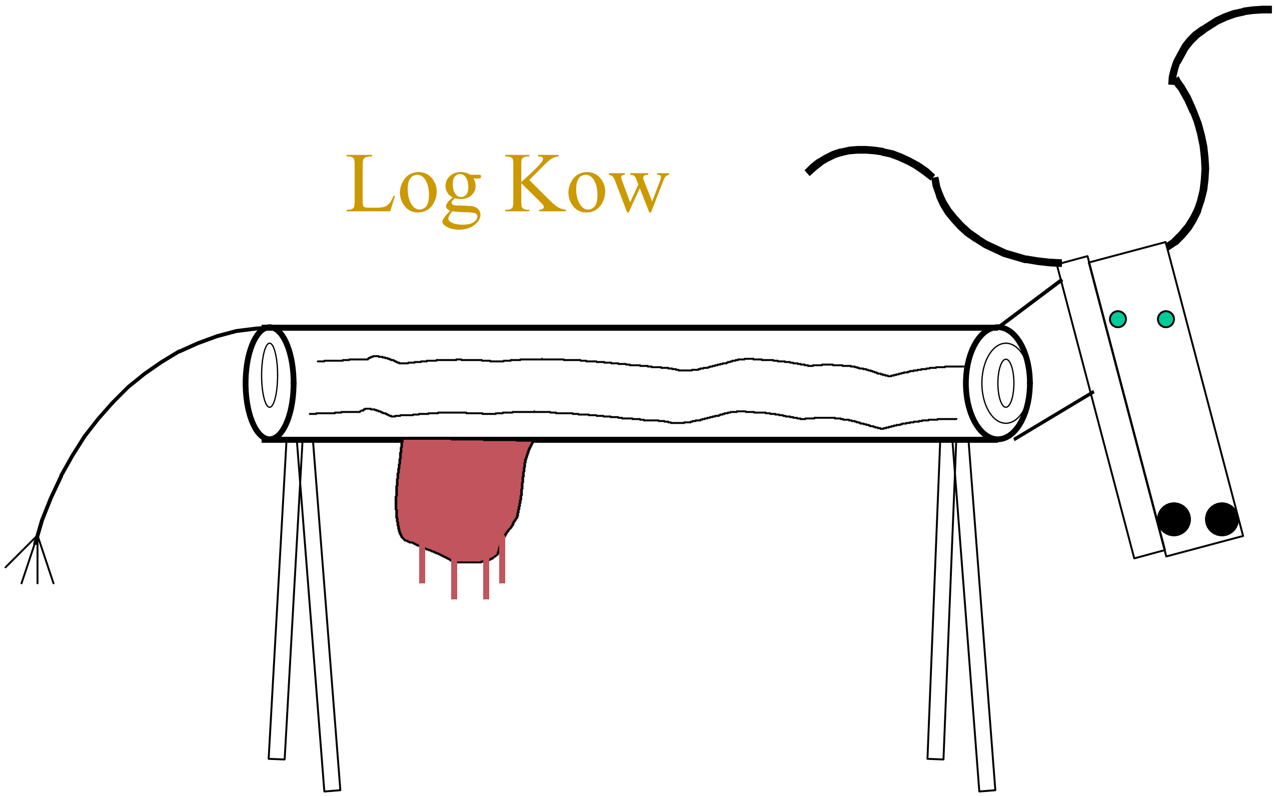
- Speciation models
- Solubility
- Biotic Ligand Model

Tools

Further Involve The Public And The Scientific Community?

- Continued dialog as the framework is developed
- Establishment of stakeholder group to work with Agency
- Scientific workshop developed under the auspices of the Society of Environmental Toxicology and Chemistry (SETAC)
  - regulators, academia, public, industry
  - to summarize state of science
  - to assist in exploring / developing assessment tools

END



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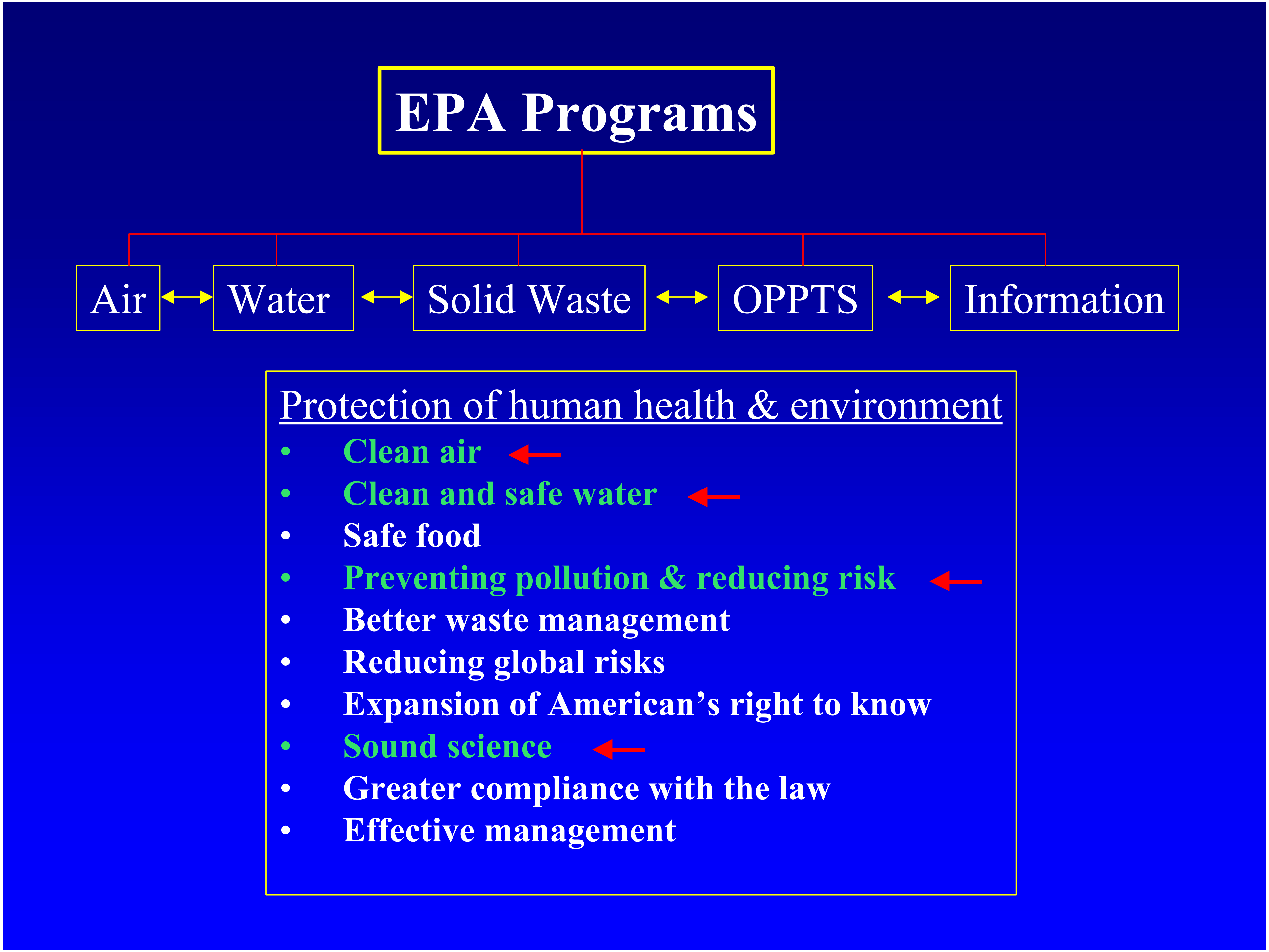

EPA Programs
Air
Water
Solid Waste
OPPTS
Information
Protection of human health & environment
• Clean air
• Clean and safe water
• Safe food
• Preventing pollution & reducing risk
• Better waste management
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Persistence	Bioavailability	Bioaccumulation	Toxicity	Speciation
Half –life Precipitation Mineral formation	Sorption to: Suspended solids, DOC, ligands	Tissue increase Biomagnification Trophic transfer Sediment BSAFs	Acute/chronic Speciation Solubility	Speciation models pH effects Ion conc.

Tools

Tier II

Screening Level Risk Assessment

- Exposure considerations
  (Emission / release info)
- Product use
  (i.e., metal substances & use)
- Life cycle considerations
  (i.e., recycle rate)
- Volume production
- Regional / national level
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Tier III

Screening Level Risk Assessment

Tier II +
- Detailed release info
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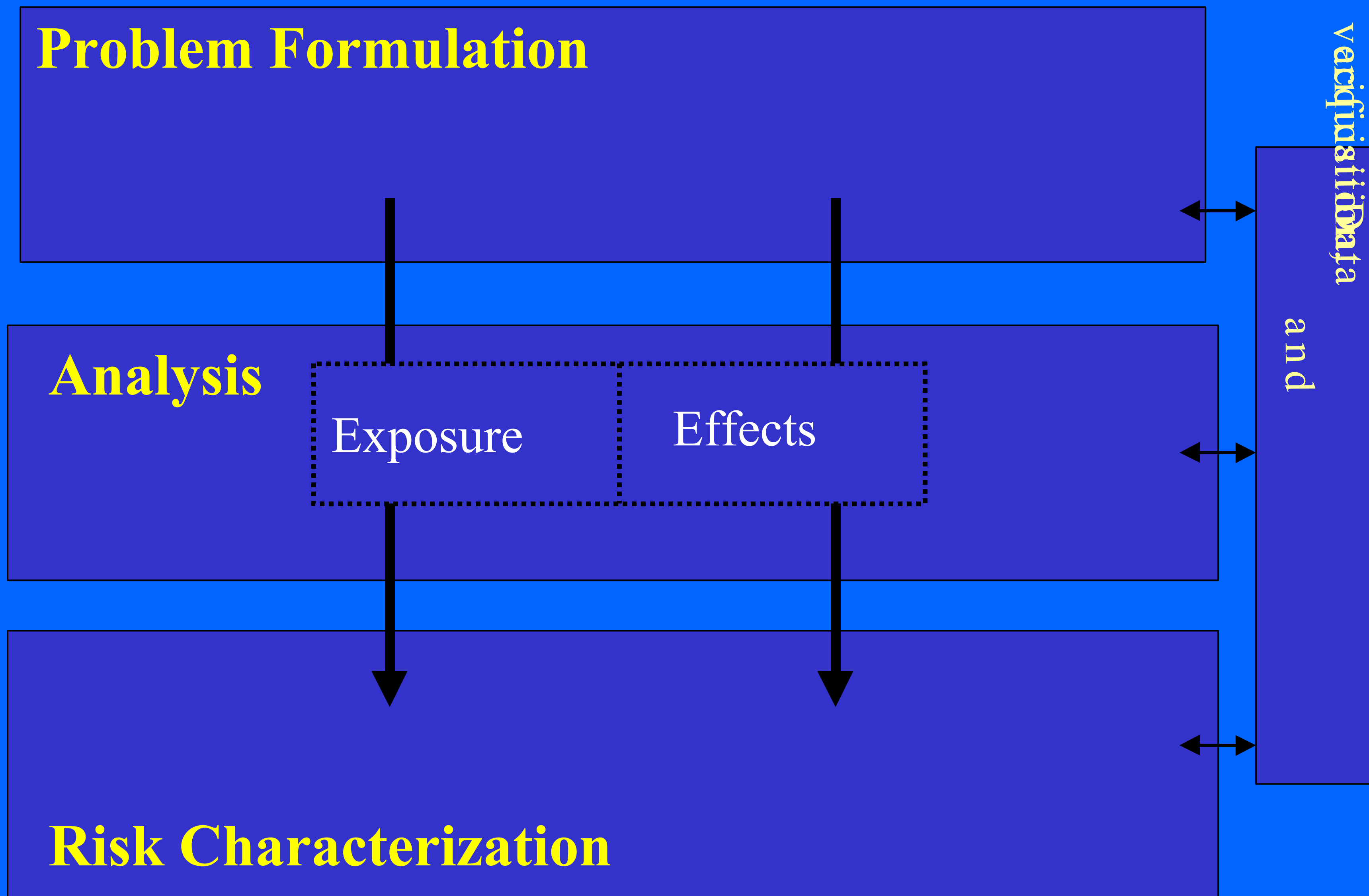

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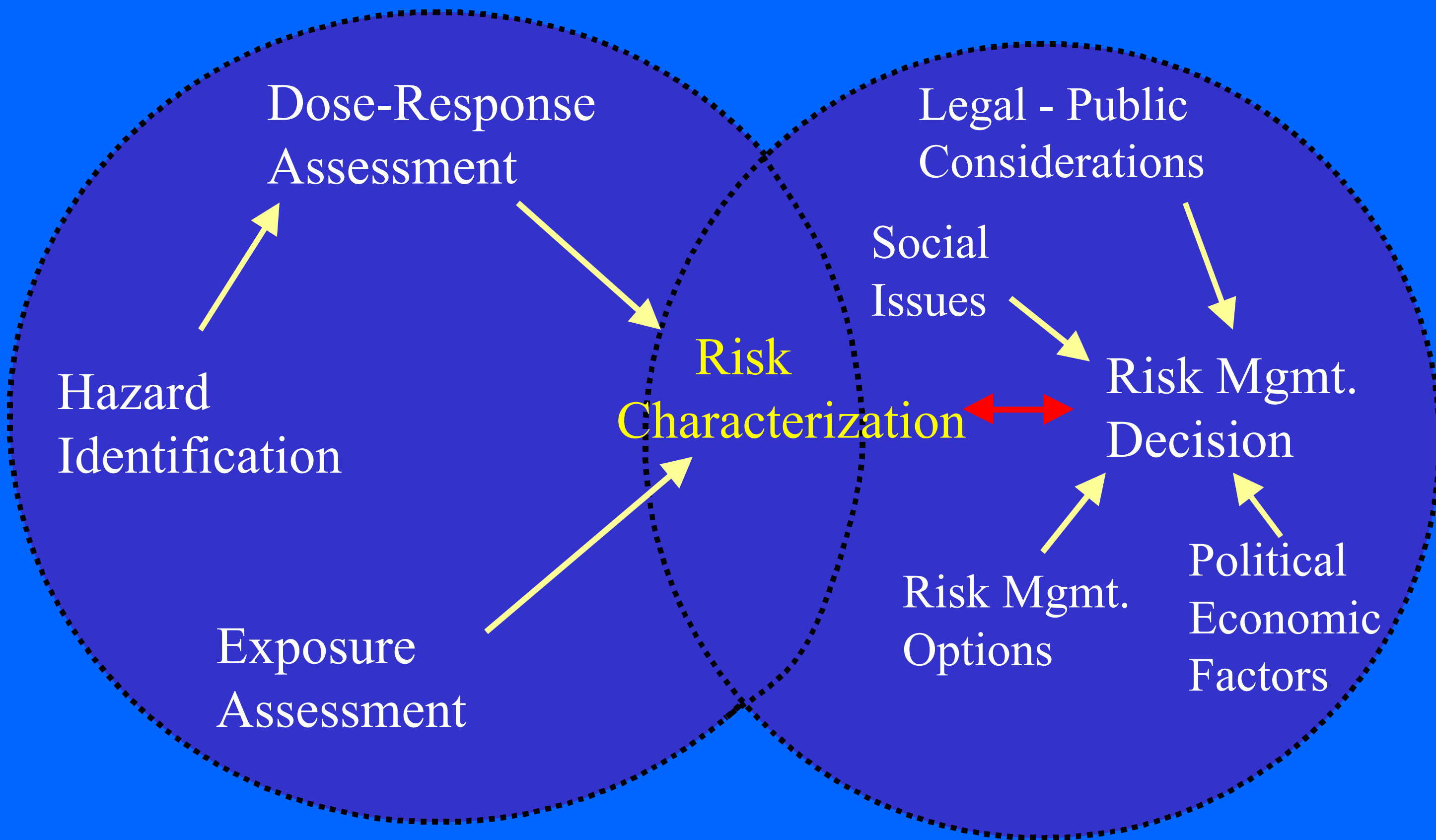

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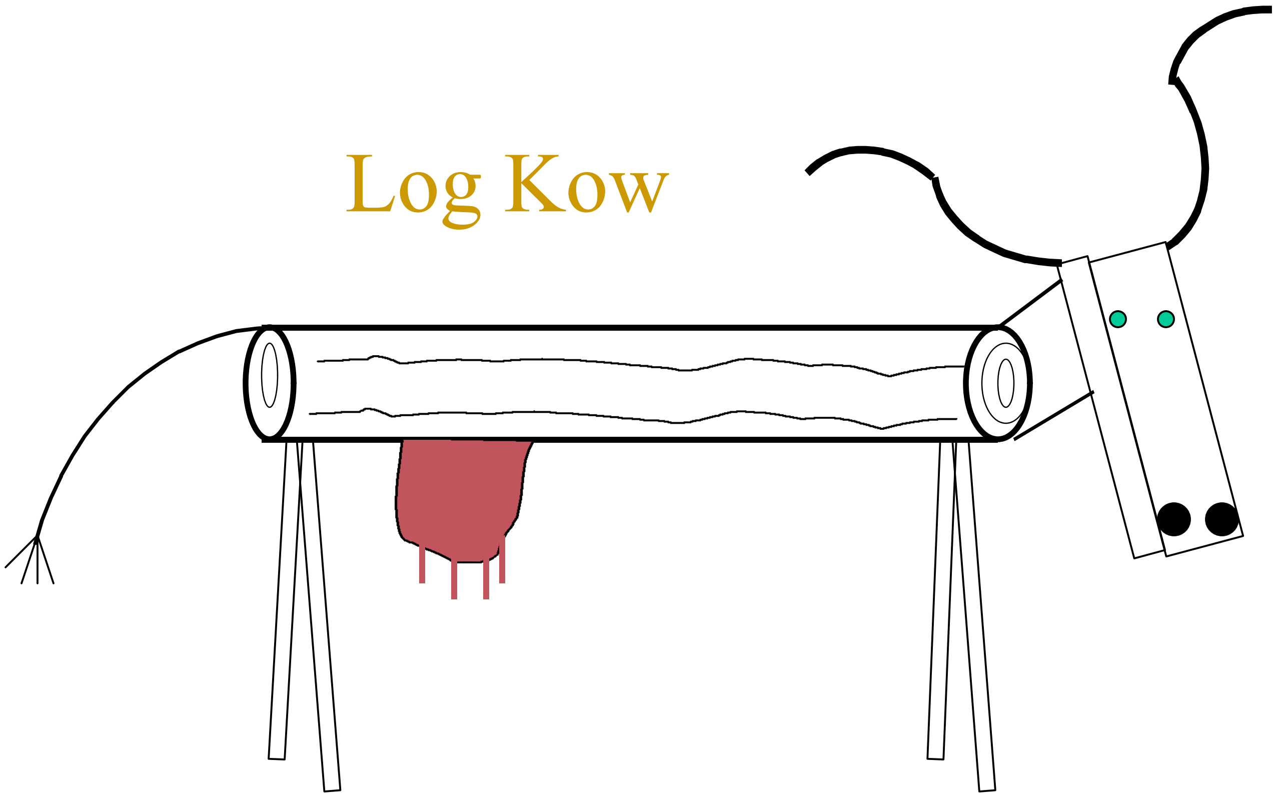

APPENDIX G

Summary Statement on Behalf of the Nickels Development Institute, The Nickel Producers Environmental Research Association, and Inco United States (Neil King, Wilmer, Cutler & Pickering)

DEVELOPMENT OF A METALS ASSESSMENT FRAMEWORK

Summary Statement on behalf of the Nickel Development Institute, the Nickel Producers Environmental Research Association, and Inco United States, Inc

1. **Organizing Principles: The Framework should:**
   a. **Provide a basis for identifying and prioritizing potentially unreasonable risks to human health and the environment;**
   b. **Be capable of discriminating among different metal species in terms of potential hazard and risk;**
   c. **Be based on sound science and allow for the incorporation of new scientific developments and models;**
   d. **Recognize that in the case of metals, the existence of an actual hazard to biological organisms depends on a host of factors other than "inherent toxicity" that determine whether the toxic moiety of the metal will actually become available to the organism at a level that cannot be safely managed through homeostatic processes;**
   e. **Allow for a tiered approach to assessing potential hazard and, thereafter, evaluating risk as necessary.**
2. **Scientific Issues that Must Be Addressed in the Framework:**
   a. **Need to distinguish between (1) the "persistence" that all metals exhibit as fundamental elements, and (2) "bioavailable persistence." The former concept has no discriminatory power for metals and is of questionable relevance for hazard and risk assessment. To address "bioavailable persistence," the Framework needs to incorporate concepts of speciation, transformation, and bioavailability.**
   b. **Framework should recognize that bioaccumulation is highly problematic as a measure of hazard for metals and inorganic metal compounds, because:**
      i. **BCF/BAF values are not an intrinsic property of a metal or inorganic metal compound;**
      ii. **BCF/BAF values are not an indication of toxicity in the case of metals;**
      iii. **Metals are not lipophilic, so Log K_{ow} cannot be used as a measure of bioaccumulation; and**
      iv. **With very rare exceptions, metals and inorganic metal compounds do not biomagnify up the food chain.**
   c. **With respect to toxicity, the Framework must take account of speciation and transformation, which help determine the metal ion's bioavailability and hence the potential toxicity of the metal substance.**
      i. **Metal ion bioavailability depends not only on the particular metal species, but also on the route of exposure—since deposition, clearance, and absorption of metal-containing substances and metal ions will vary for the different routes of exposure.**
      ii. **In addition, different species have different susceptibilities to the toxic effects of any particular metal substance. Some plants, *Alyssum* for example, can accumulate nickel to high concentrations without suffering toxic injury.**
3. **Encouraging Involvement by the Public and Scientific Communities**
   a. **Informal mechanisms like Federal Register notices and a "list-server" e-mail network.**

b. Regular consultation with a group of scientifically knowledgeable stakeholders organized for this purpose.
c. Scientific workshops like the Experts Workshop conducted in January 2000.

BEFORE THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

COMMENTS OF

THE NICKEL DEVELOPMENT INSTITUTE

THE NICKEL PRODUCERS ENVIRONMENTAL RESEARCH ASSOCIATION

and

INCO UNITED STATES, INC.

on

DEVELOPMENT OF A METALS ASSESSMENT FRAMEWORK

Communications Regarding These
Comments Should Be Directed to:
Neil J. King Wilmer, Cutler &
Pickering 2445 M Street, N.W.
Washington, D.C. 20037
(202) 663-6061
e-mail: nking@wilmer.com

February 20, 2002

Introduction

These Comments on EPA's initiative to develop comprehensive cross-agency guidance for assessing the hazards and risks of metals and metal compounds, 67 Fed. Reg. 5596 (February 6, 2002), are submitted by the Nickel Development Institute ("NiDI"); the Nickel Producers Environmental Research Association ("NiPERA"); and Inco United States, Inc. ("Inco"). NiDI and NiPERA are organizations of the world's primary nickel producers. Inco's Canadian parent company, Inco Limited, is a member of NiDI and NiPERA.

At the outset, we want to commend EPA for initiating this important project. In the past few years, the Agency has applied (or considered applying) to metals the Persistent, Bioaccumulative, Toxic ("PBT") hazard assessment framework that was originally developed to identify and prioritize the potential hazards posed by organic compounds. Metals industries (including nickel producers and users) have consistently taken the position that applying these PBT criteria to metals and inorganic metal compounds is scientifically inappropriate. Accordingly, we are greatly encouraged that EPA is "embarking on the development of, [a hazard and risk] assessment framework" specifically designed for application to metals and metal compounds. 67 Fed. Reg. 5596. In response to the four specific questions posed in the notice of meeting, we would like to make the following points.

What Organizing Principles Should the Metals Assessment Framework Follow?

1. The Framework should provide a basis for identifying and prioritizing potentially unreasonable risks to human health and the environment posed by specific metal and metal compound species.
2. The Framework should be capable of discriminating among different metals, metal compounds, and alloys-and among the various chemical species of any particular

metal-in terms of potential hazard and risk. If all metals are deemed to be infinitely persistent because they cannot be destroyed, the criterion of "persistence" does not provide a basis for discriminating among them.

3. The Framework should be based on sound science and should be flexible enough to allow new scientific developments and models to be incorporated into the Framework as our understanding of the factors that affect the fate and transport, bioavailability, and toxicity of metal substances increases.
4. The Framework should recognize that, for the most part, pronouncements about the "inherent hazard" of particular metals, metal compounds, or alloys will be overly simplistic-because the existence of an actual hazard to biological organisms depends on a host of other factors that determine, among other things, whether the toxic moiety of the metal will actually become available to the organism at a level that cannot be safely managed through homeostatic processes.
5. Given its goal of cross-agency application, the Framework should allow for a tiered approach to assessing potential hazard and, thereafter, evaluating risk as necessary. The depth of the evaluation might depend, for example, on its purpose *(e.g.,* national priority setting vs. site-specific risk management) and on the nature and extent of the available data *(e.g.,* monitored or modeled exposure information, physical/chemical characteristics of the relevant environmental media, etc.). To accommodate differences in purpose and availability of data, the Framework should provide not only for broad hazard assessments at high levels of generality, but also for screening level risk assessments and, in appropriate cases, for more in-depth risk assessments.

6. The Framework should be focused on metals, inorganic metal compounds, and metal alloys. Because of their special characteristics, organo-metallic compounds (like methylmercury) should be treated separately.
7. The Framework should produce assessments that can be the predicate for designing voluntary, as well as regulatory, initiatives that will achieve significant risk reduction benefits in the most cost-effective manner-for, example, through pollution prevention and waste minimization activities that increase recycling rates for metals, which are highly recyclable.

<u>What Scientific Issues Must Be Addressed in the Framework?</u>

1. Whether the criteria and models incorporated into the Framework can discriminate effectively among metals in terms of potential hazard. In this connection, we would note that the persistence and bioaccumulation criteria that EPA applies to organic compounds have low discriminatory power for the hazard categorization of metals and inorganic metal compounds.
2. Whether the criteria and models incorporated into the Framework properly reflect the critical importance of **speciation, transformation, and bioavailability** in categorizing metals, inorganic metal compounds, and metal alloys in terms of hazard and in assessing their potential risks.

3. <u>Issues Relating to Persistence.</u> The Framework should distinguish between:

   The "Persistence" that all metals exhibit as fundamental elements that cannot be destroyed; and

"Bioavailable persistence," a concept that connotes potential environmental hazard.

The scientific issues that will have to be considered in evaluating "bioavailable persistence" include transformation, bioavailability, and the extent to which bioavailable soluble cations will result from transformations of metals, metal compounds, and metal alloys in particular types of environments. This, in turn, requires consideration of issues such as complexation, particulate adsorption, sedimentation, secondary mineralization, and the chemical propensity of metals to react with elements and ligands such as carbon, oxygen, sulfur, oxyanions, and organic complexes.

4. Issues Relating to Bioaccumulation. The Framework should recognize that, for a variety of reasons, bioaccumulation is not a useful measure of hazard in the case of metals and inorganic metal compounds. In particular:

BCF/BAF values are not an intrinsic property of a metal or inorganic metal compound because

> In contrast to organic compounds (which are taken into biota primarily by simple passive diffusion across biological membranes), uptake of metals by organisms generally occurs via specific transport proteins that exhibit saturable transport kinetics.

> Organisms have homeostatic mechanisms that allow metals, as naturally occurring substances, to be stored in non-available forms (sometimes for later essential use) and that otherwise regulate the uptake and excretion of metals so as to prevent toxicity.

> The BCF/BAF for a metal is dependent, on level of exposure, so that for the same species, it can vary greatly from one study to another, depending on the environmental concentrations of the metal in the different studies.

- BCF/BAF values are not an indication of toxicity in the case of metals because

  > The metal may be an essential element for the organism;

  > Homeostatic mechanisms regulate available metal levels to prevent toxicity; and

  > BCF/BAF values tend to vary inversely with environmental concentrations of the metal, so that a high BCF/BAF value most likely would imply a lower risk of toxicity.

- Since metals are not lipophilic (but primarily use ionic transport to enter cells), Log K_{ow} cannot be used as a measure of bioaccumulation.
- In addition, with very rare exceptions, metals and inorganic metal compounds do not biomagnify up the food chain, so a high BCF/BAF value for a metal would not have significance in terms of potential biomagnification.

5. Issues Relating to Toxicity. With respect to toxicity, the Framework must take account of **speciation and transformation.**

   These concepts are crucial determinants of a metal's bioavailability. Several global regulatory initiatives have recognized the importance of these concepts (e.g., the European Union's Water Framework Directive and risk assessments performed under the European Union's Existing Substances regulations). EPA itself has drawn this conclusion with respect to water quality criteria for metals-by expressing the criteria in terms of dissolved concentrations with adjustments for water hardness, and by considering use of the biotic ligand model (BLM) to set water quality criteria for copper and silver.

The concepts of chemical speciation and metal ion bioavailability also are important in the context of human health.

> Metal-containing substances may differ substantially in their physicochemical and biological properties. These differences translate into different toxicological properties-because:

  - The physico-chemical properties of a metal substance determine the extent of metal ion bioavailability at target sites; and

  - Toxicity is dependent on bioavailability of the metal ions.

> Because toxicity is dependent on bioavailability, it is only the metal ion bioavailable fraction that is relevant in assessing toxicity.

> Metal ion bioavailability depends not only on the particular metal species, but also on the route of exposure-since deposition, clearance, and absorption of metal-containing substances and metal ions will vary for the different routes of exposure

> Therefore, metal speciation must be taken into account in all aspects of risk assessment. In particular, it is important to determine what metalcontaining substances are present, to what extent humans are exposed, what is the route of exposure, and what, amount of the metal ion in the

productive Experts Workshop in January 2000 and the convening of the present Stakeholders Meeting in February 2002. There must not be a similar hiatus following today's meeting. Instead, EPA should ensure that a meaningful and productive scientific dialogue continues throughout the process of developing the Framework.

EPA can employ a variety of formal and informal mechanisms to accomplish this. Examples of informal mechanisms are appropriate Federal Register notices and a "list-server" e-mail network to keep interested members of the public informed of developments. At the same time, we think it would be useful to establish a more formalized group of scientifically knowledgeable stakeholders to consult directly with EPA scientists as the work proceeds. Finally, based on our experience with the Experts Workshop in January 2000 and with a number of other scientific workshops on metals hazard assessment that have been held over the past decade, we believe it would be very productive to schedule a scientific workshop on these issues in the near future.

APPENDIX H

Slides from “Metals Workshop” (Kevin Bromberg, U.S. Small Business Administration, Office of Advocacy)

Metals Workshop

Presentation by

Kevin Bromberg

Assistant Chief Counsel for Environmental Policy

Washington, D.C.

February 20, 2002

SBA

Office of Advocacy

U.S. Small Business Administration
Championing America's Entrepreneurs

Key Questions

- What is the State of the Science of PBTs and Metals at EPA?

- What Peer Review Procedures for the Should EPA Now Conduct for the Lead/TRI Rule?

SBA Office of Advocacy Letter

- April 2001 Letter to Administrator Whitman
- No Scientific Basis for TRI Lead Rule
- Urge EPA to Seek SAB Review of Scientific Controversy

If You Liked

The Bush Administration's Reversal on

Arsenic

in America's Drinking Water,

You'll Love

What They're Considering for

Lead.

More **arsenic** in drinking water. More global warming **pollution**. More **toxic dumping** from mines. What's next on the Bush administration's chopping block? The public's right to know about **lead contamination** in air and water.

Even trace **exposure to lead** is extremely dangerous, especially for children. Lead can cause brain damage, learning disabilities, behavior disorders, even lower IQs. Incredibly, industrial users of lead **used to be exempt** from reporting toxic releases to EPA, so long as they used less than *five tons* of lead per year.

In January, EPA finally **closed this loophole**. By February, lead and chemical industry lobbyists were asking the new President to **reverse course**.

President Bush's decision is due soon. Will it be a re-run of the arsenic about-face? **Tell Congress and the White House that keeping the public in the dark about lead pollution is unacceptable public policy.**

A message from the Alliance To End Childhood Lead Poisoning, National Environmental Trust, Natural Resources Defense Council, Physicians for Social Responsibility, Sierra Club, U.S. Public Interest Research Group Education Fund, and Working Group on Community Right-to-Know.

U.S. PIRG EDUCATION FUND • 202-546-9707 • www.pirg.org/toxics

PBT Science at EPA

- Metals and Organics Can Be Treated Alike
- PBT Rule - 1999 - Metals Can Be Treated Like Organics - Because All Metals Can Be Bioavailable Under Some Conditions
- Did Not Address Bioaccumulation

1998 OECD Report

- Use "Care" in Addressing Metals and PBT Characterization Because Metals Are Different in Several Ways
- Bioavailability
- Bioaccumulation

1999 PBT Rule

- Did Not Address Issue with "Care"
- Failed to Address Individual Metals with respect to Bioavailability
- Failed to Address Bioaccumulation

Views of Leading US Gov't Scientists

- NSF - "The criteria for organics … do not provide a sound basis for discriminating benign and harmful [inorganic] substances"
- USGS - "The [BCF] approach … should not be used for the risk assessment of metal compounds."

TRI/Lead PBT Rule

- 2001 Lead Rule Also Claims Same PBT Methodology Can be Applied to Metals and Organics
- No Literature Support for Proposition
- No Peer Review as Required by EPA Procedures

Lead Rule Preamble

- EPA will seek SAB review after promulgation. "The external peer review will address how lead and other, as yet unclassified metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations."

SAB Charge Timeline

- TRI Final Rule - January 2001 Announcing Review
- SAB Charge Under Review - Spring/Summer/Fall
- Fisher Letter - December - Announces Two Part SAB Review Addressing Metals/PBT
- February 20th Stakeholder Meeting

2001 IWG Report

- Report of Inorganics Working Group to Environment Canada
- Approach for Synthetic Organics Not Applicable to Inorganics
- BCF/BAF Factors Should Generally Not Be Used for Inorganics

IWG on Bioaccumulation

- "Agreement was not achieved on the scientific relevance of B within Environment Canada's regulatory framework, however, the IWG agreed that most published BCF (bioconcentration factor) and BAF (bioaccumulation factor) data for inorganics are, in practice, not useful for categorization."

Peer Review at EPA

- TRI Lead Issue Never Received Peer Review - SAB Peer Review Report - September 2001

Peer Review Requirements

- December 2000 SAB Handbook
- Review of Supporting Materials for all "Major Scientific and Technical Products" Including TRI/Lead Rule
- Independent Review of Agency Science

Documents Underlying Lead Rule

- Final Rule Preamble
- Response to Comments
- Bioaccumulation Analysis Document
- Other Documents

- EPA Does Not Need to Create New Documentation for this Rule

Peer Review Procedures

- New SAB Procedures
- Diversity of Viewpoints and Expertise
- Public Comment on Expert List
- Full Disclosure of Background/ COI

Peer Review Procedures

- Full Review - Not Consultation
- SAB Handbook - Independent Review for All Major Rules

SAB Charge

- Is the PBT Methodology A Sound Method for Characterizing Inorganic Hazards?
- Can BCF and BAF Factors Be Used Appropriately for Metals?
- What Alternative Scheme Can Be Used?

SAB Charge - Continued

- For Lead/TRI - Is it Appropriate to Apply the PBT Methodology to Lead?
- If Appropriate, Did EPA Properly Adopt a PBT Methodology for Distinguishing High and Low PBT Properties of Inorganic Substances (proper data selection etc.?)

Next Steps

- Develop SAB Charge - Obtain Public Input
- Assemble SAB Panel
- Develop New Methodology
- Review Old Methodology and Materials

Conclusion

- “EPA Will Not Reconsider Past Actions”
- But EPA Science is Not Infallible; Nor is Science Static
- If EPA Science Is Incorrect - Review of Past Actions Will Be Required

APPENDIX I

Summary of February 20, 2002 Presentation Regarding EPA Metals Assessment Framework (Kevin Bromberg, U.S. Small Business Administration, Office of Advocacy)

U.S. SMALL BUSINESS ADMINISTRATION

WASHINGTON, DC 20416

OFFICE OF THE CHIEF COUNSEL FOR ADVOCACY

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The Office of Advocacy presents its views with respect to how EPA should proceed with the agency assessment of the hazards and risks of metals and metal compounds. The Office became involved in this subject through the EPA rulemaking that established a lower threshold for the reporting of lead, which culminated with the January 2001, final rule.

The Acting Chief Counsel for Advocacy advised Governor Whitman in April 2001 that the Toxic Release Inventory (TRI) rule was not based on sound science, and that the required internal peer review procedures had not been followed. The final rule preamble includes a determination to seek review of the final TRI rule by the Science Advisory Board (SAB), although the scope of that review remains unclear at this time. The December 2001 letter from Deputy Administrator Fisher announced this stakeholder meeting today to address the new metals framework, which includes consideration of the TRI rule.

In this presentation, we submit information about the state of the science of persistent bioaccumulative and toxic substances (PBTs) and metals as currently known to EPA, and new information from the-December 2001 report by the Inorganics Working Group QWG) to Environment Canada on metals hazard categorization. In this report, a group of 10 inorganics experts from government, industry and academia was tasked by the Canadian government to provide the latest views about this issue. They concluded that bioaccumulation and bioconcentration factors are generally not useful for hazard categorization, in agreement with the other published literature on this subject.

The December 2000 SAB handbook provides that all major technical scientific works, including major rules, such as the TRI lead rule, should be peer reviewed. Major rules, such as the TRI lead rule, should be subject to review by an independent body, such as the SAB. The required peer review did not occur prior to the final rule promulgation. The handbook also specifies the applicable procedures. Such procedures include panelist selection, conflict of interest procedures, materials to be reviewed, and public participation in the peer review process. The public should also be permitted to comment on the draft SAB charges before they are sent to the SAB.

The presentation includes suggested SAB charge questions. It seems most appropriate to determine first the appropriate framework for all metals generally, before the SAB addresses the specific application of any framework to the lead rule. To the extent that the SAB determines the TRI/lead rule science foundation may be inadequate, in agreement with our position, the TRI/lead rule should naturally be revisited by the agency.

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