

US EPA ARCHIVE DOCUMENT

Comments on Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals

US EPA ARCHIVE DOCUMENT

<u>Commenter</u>
Ad Hoc Metals Coalition
The Aluminum Association
Copper and Brass Fabricator's Council, Inc.
Department of Energy (Office of Fossil Energy, and the Office of Policy and International Affairs)
Specialty Steel Industry of North America, and the Chrome Coalition

KING & SPALDING

1730 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20006-4706
TELEPHONE: 202/737-0500
FACSIMILE: 202/626-3737

DIRECT DIAL:

202/626-2627

EMAIL:

jluxton@kslaw.com
www.kslaw.com

July 2, 2002

Via email: metals.assessment@epa.gov

Technical Information Staff (8623D)
NCEA-W
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Comments of the Ad Hoc Metals Coalition on EPA's
Draft Action Plan for the Development of a Framework
for Metals Assessment and Guidance for Characterizing
and Ranking Metals, EPA/630/P-02/EPA/630/P-02/003A

Dear Sir or Madam:

I am attaching the Comments of the Ad Hoc Metals Coalition on EPA's Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals, published at 67 Fed. Reg. 39982 (June 11, 2002).

Please call me if there are any questions.

Sincerely,

Jane C. Luxton

Enclosure

**Comments of the Ad Hoc Metals Coalition on
EPA's Draft Action Plan
for the Development of a Framework for Metals Assessment and
Guidance for Characterizing and Ranking Metals
(EPA/630/P-02/EPA/630/P-02/003A)**

The Ad Hoc Metals Coalition is pleased to submit these comments on EPA's Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals, published at 67 Fed. Reg. 39982, (June 11, 2002). The Ad Hoc Metals Coalition is a group of associations and companies with an interest in regulatory and scientific issues relating to metals.

The Agency should be complimented on putting together a Draft Action Plan that should allow for the development of a comprehensive Framework for Metals Assessment and associated Guidance. The draft Action Plan represents a significant step toward implementing state-of-the-science hazard and risk assessment techniques for metals and inorganic metal compounds. The Agency has done a good job of summarizing the available literature and current thinking on the issues involved in evaluating metals with respect to PBT, particularly in the case of bioaccumulation. We would like to take this opportunity to build on this foundation and to correct some outdated concepts that were retained in the Draft Action Plan.

GENERAL COMMENTS

1. Executive Summary: The Agency indicates that the Metals Assessment Framework and Guidance will cover organo-metallics in addition to inorganic metal substances. Developing a Framework and Guidance for metals and inorganic metal compounds is a major undertaking in itself. The concept of developing an all-encompassing Metals Framework (covering organo-metals as well) has merit, but may be too ambitious at this point. Since the number of organo-metallics that are likely to be of interest to EPA is relatively small, and since they cannot properly be lumped together with the elemental metal and its inorganic compounds for purposes of hazard evaluation and risk assessment, we believe EPA should review organo-metals on a case-by-case basis in light of their individual and unique physical, chemical and toxicological properties (e.g., organotins are not the same as, nor do they behave like, elemental tin).
2. On page 1, EPA says it has decided "to develop a more comprehensive approach to metals assessments that could be the basis for *future* Agency actions." (Emphasis added). We applaud that decision and we further urge the Agency not to foreclose the possibility of applying the new "more comprehensive approach" to reconsider some *past* actions that were based on a different methodology (e.g., evaluating the potential hazards of lead through application of PBT criteria that lack consideration of factors particularly applicable to metals.) At the very least, EPA should leave open the possibility of reconsidering past actions if the results

- of the Science Advisory Board review suggest that the approach followed in the past may have led to scientifically questionable conclusions. This is in keeping with the Agency's commitment to "good science" and would be consistent with the Information Quality Guidelines being developed by EPA and OMB.
3. The difference between bioaccumulation and bioconcentration is defined in the document; however, these terms are not used consistently or appropriately throughout. In many cases, bioaccumulation is used as a surrogate term when bioconcentration factors (BCFs) are really being discussed. This implies that assessments of bioaccumulation and BCFs are synonymous which they clearly are not given all the caveats and concerns raised about the use of BCFs for metals.
 4. The Draft Action Plan makes reference to a PBT Framework(s) in several places. In some cases the document refers to "PBT frameworks" used by "several Agency Programs" and "EPA's PBT framework" (e.g., pages 20 and 27), but in others it refers to the "TRI PBT Framework" (e.g., pages 25 and 38). EPA should include in the Action Plan a description of each of the PBT frameworks used by the different EPA programs (e.g., TRI, TSCA, RCRA) and explain how and why they differ and if or how they address metals. The description should include the criteria used by these differing PBT frameworks and whether they have received independent peer review.
 5. In several places in the Draft Action Plan, EPA refers to "national hazard/risk ranking and characterization" as a "priority setting" exercise and suggests that, as a result, such assessments are "very broad." However, EPA's efforts at "national hazard/risk ranking" often have direct or indirect regulatory consequences -- particularly when they purport to reflect a PBT characterization, which we think is inappropriate in the case of metals. Thus, as the Agency acknowledges on page 38 (paragraph 2), "[m]any PBT chemicals are included in international agreements directed at reduction or elimination of hazardous PBT pollutants." In addition, a number of states have been moving to take action to eliminate the discharge or use of metals that were preliminarily labeled as "PBT" substances by EPA. EPA should recognize that its broad-brush approach to national hazard assessments and rankings may have very significant real-world impacts. Accordingly, the Framework and Guidance ought to address how the limits of these national hazard/ risk ranking characterizations will be conveyed to potential audiences so they will not be misused.

SPECIFIC COMMENTS

1. Executive Summary, 4th paragraph, 4th sentence: While it is the case that essential metals are different in that they can bioaccumulate for beneficial purposes, this statement is misleading in suggesting that non-essential metals bioaccumulate to an extent indicative of hazard. In addition, while it is the case that essential metals are different in that they have a range of exposure below which deficiency

will occur, it is not the case, as suggested in the Draft Action Plan, that non-essential metals are toxic at any level of exposure.

2. Page 13, 3rd paragraph, 5th sentence: "While the availability of a metal in the environment is an important factor in determining its bioavailability in aquatic species, it appears to be considerably less important in controlling its bioavailability in humans or other terrestrial species." This statement appears to lack scientific support when all routes of exposure are considered. At face value the statement may mean that metal availability in the aquatic environment is very important because it controls uptake at the gill and, hence, direct toxicity. Metal toxicity for a given aquatic organism can, indeed, vary by one to two orders of magnitude as a function of changes in speciation and complexation. But speciation and other factors affecting the environmental availability of a metal are important for bioavailability in humans and other terrestrial organisms as well. For example, the absolute bioavailability of different lead compounds can vary by more than an order of magnitude (ATSDR, 1999). Gastrointestinal uptake will further be modulated by factors such as nutritional status and the composition and physical characteristics of the ingested material containing lead. The physico-chemical mechanisms that modulate the bioavailability of ingested metals in humans and terrestrial organisms may differ from those that occur in aquatic organisms, but their impact can be just as significant.

The bioavailability of inhaled metals within the lung can also be an important issue for terrestrial organisms that is not applicable to aquatic biota. The pulmonary deposition patterns of metal-containing aerosols vary as a function of particle size. Fine particles that deposit in the deep lung tend to be retained and absorbed with relatively high efficiency. Larger particles deposit in the upper airways, to be cleared to the gastrointestinal tract by mucociliary clearance mechanisms. Following this translocation, compound specific differences in gastrointestinal bioavailability are observed (ICRP, 1994). Consequently, it is misleading to assume that bioavailability is a relatively unimportant issue for humans compared to aquatic life without accounting for all exposure pathways. In addition, the importance of considering bioavailability of metals in terrestrial organisms is well documented (SETAC, 2001; Crommentuijn et al., 1997). Key physico-chemical parameters affecting metal bioavailability in water such as pH and organic carbon play a similar role for metals in soils.

The Draft Action Plan (page 13) goes on to say that "the bioavailability of lead in humans, for example, from seemingly non-bioavailable forms is well documented." The Agency provides no support for this statement and it does not reflect the state-of-the-science. It is known that lead is more or less available for uptake across the gut depending upon the form of the lead present. For example, lead oxide and lead carbonate are much more available in the gut than lead sulfide. This is especially true when exposures occur via environmentally relevant pathways such as soil ingestion. (ATSDR, 1999).

3. Page 14 to the top of page 15: "While some organisms may have an ability to store metals in a form that is not toxic to the organism in which the metal is stored, it is possible that the detoxified form may be bioavailable in a consumer organism (e.g., humans) and toxic to the consumer organism." While available literature is limited, the studies performed to date with manganese, nickel, copper, zinc and silver indicate that inorganic granules fed to higher trophic level organisms are not readily available (Nott and Nicolaidou 1990, 1994). Chromium appears to be the only metal for which dietary transfer of metal in a granular form has been demonstrated (Nott and Nicolaidou 1994).
4. Page 15, Current Agency Practice-Bioavailability: The Agency indicates that it relies to a large extent upon default values, and some site-specific values, but to a great extent does not incorporate bioavailability measures more broadly due to complexity and lack of data. The Agency is encouraged to use the Metals Action Plan and subsequent Framework to explore ways to more broadly incorporate bioavailability into its metal assessments.
5. Page 16, 1st full paragraph: A description is provided of the IEUBK model developed by EPA; however, several statements made characterizing the model are inaccurate and/or incomplete. While it is true that the model can be used to predict blood lead levels as a result of environmental lead exposure, it is also true that the model can overestimate the potential impact of environmental lead upon the blood lead levels of children (Bowers and Mattuck, 2001). The default bioavailability factors utilized by the model are generally recognized to represent worst-case assumptions. Downward adjustment (calibration) of model assumptions is frequently undertaken based upon either blood lead surveys or the results of bioavailability determinations made in experimental animals. In addition, the default bioavailability values cited for soil are only applicable when considered in conjunction with the default assumptions of the model for soil ingestion rates. The values chosen optimize model performance at the assumed levels of soil ingestion, but are not necessarily indicative of actual bioavailability. Furthermore, while it may be true that protection of children's health also affords protection to adults, this is in part related to bioavailability issues. Uptake rates of lead from the gastrointestinal tract of adults are approximately an order of magnitude lower than in children (ATSDR, 1999). The default values listed for water and soil are thus not appropriate for adults. In the specific case of the default value provided for air, this is not actually a bioavailability estimate. Rather, it is an estimate of uptake that will occur after exposure to a given level of lead in air. The value of 32% represents a composite estimate of the efficiency of pulmonary deposition following inhalation and the subsequent uptake of lead into the body. The validity of this composite estimate will vary as a function of parameters such as particle-size distribution and chemical speciation.
6. Page 16 (just before Issue Summary No. 2.2.1): The document suggests that if environmental conditions that would cause a metal to become or remain available in the environment (or favor formation of bioavailable forms of the metal) exist

anywhere within the U.S., such conditions could drive a decision about national hazard/risk ranking and characterization. We question whether it is appropriate to allow the exceptional situation to drive national hazard/risk ranking determinations.

7. Pages 17-19, Bioaccumulation: The information presented on bioaccumulation on these pages is well written and accurately reflects the state-of-the-science. We commend the Agency for this concise summary.
8. Pages 19 (last paragraph)- 21: The information presented here places heavy reliance upon the use of BCFs and BAFs for regulatory programs -- the TRI program in particular. This is done without discussion of the importance of exposure concentration or how one interprets a BCF or BAF (as acknowledged on page 22 of the document). The critical assumption regarding the use of BCF/BAFs is that larger values should reflect greater potential exposure and associated hazard. For metals, however, this is not the case. While the Agency presents a nice discussion on the relevance and importance of the inverse relationship that exists between exposure concentration and BCF/BAFs for metals, it is not taken to its logical conclusion, i.e., that these values cannot be used to indicate potential hazard. Using actual BCF data for zinc, the following provides an example of how the inverse BCF-exposure concentration relationship confounds the use of BCFs for hazard classification.

Zinc BCFs for amphipods show a strong inverse relationship with zinc water concentrations (data from Brix and DeForest 2000). This results in the highest water and tissue concentrations being associated with the lowest BCFs. Conversely, the lowest water and tissue concentrations are associated with the highest BCFs. The lowest tissue concentrations, and highest BCFs, are observed at zinc concentrations in the water that are at background zinc concentrations in the environment. Clearly, therefore, the magnitude of the BCF cannot be used as an indication of hazard potential for zinc. This same scenario applies to every metal and organism that has been evaluated to date, including lead.

9. Page 20, 2nd paragraph, 2nd sentence: We note that in the Lead TRI rule, EPA did not use these criteria in screening data. For example, the study conducted by Shulz-Baldes (1974) on *Mytilus edulis* clearly did not reach steady-state and yet was used to support the contention that lead is bioaccumulative.
10. Page 20, 2nd paragraph, 4th sentence: "Some limited guidance is provided for evaluating BAFs and BCFs for essential metals." What is the citation for this guidance?
11. Page 21, 1st (carryover) paragraph, last sentence: It is unclear how lead is identified as bioaccumulative in humans because, as far as we are aware, neither EPA nor any other group has identified criteria against which to evaluate bioaccumulation in humans.

12. Page 22, 1st full paragraph: This paragraph does a good job of accurately reflecting the difficulties in applying individual BCF/BAFs, without reference to exposure concentration, to regulate metals. However, this contradicts statements on page 20 that imply BCFs can be used.
13. Page 22, 2nd full paragraph, 4th sentence: “Although BCF/concentration dependency has commonly been described for essential trace elements, it has also been documented for nonessential metals in some organisms (Brix and DeForest 2000).” As noted at the PBT Workshop in Washington, D.C. and in McGeer et al. (In Review), it should be clarified that the concentration dependency of BCFs for non-essential metals has been demonstrated for *all* organisms that have been evaluated (not just some organisms). Subsequent analyses to Brix and DeForest (2000) have demonstrated the importance of steady state being reached for the concentration dependency of the BCF to be observed. Brix and DeForest (2000) used the default duration of 28 days (Stephan et al. 1985; ASTM 1996); however, this has been shown to be an insufficient exposure duration for some organisms, and bivalves in particular.
14. Page 22, 2rd full paragraph, last sentence: Although it is true that the concentration dependency of BCFs may be an artifact of the study or reflect factors such as growth dilution, the possibility of regulation by the organism should not be dismissed for non-essential metals. For example, Schulz-Baldes (1974) showed that lead depuration rates in the blue mussel (*Mytilus edulis*) were more rapid as the tissue concentration increased, possibly suggesting active regulation of this non-essential metal.
15. Page 22, last paragraph (and continuation on page 23): “...early guidance recommends using the BCF from the lowest exposure concentration above the control treatment (U.S. EPA 1985, 1995).” These references are not relevant to a hazard classification ranking, but rather apply to the development of water quality criteria, and they are not specific to metals. Furthermore, the logic in these documents is presumably to use a BCF based on an exposure concentration at which the test organisms were minimally affected. However, this has little relevance to the hazard ranking of metals because BCFs are concentration-dependent over a range of “no effect” concentrations. Use of BCFs based on exposure to the lowest water concentration above the control would result in elevated BCFs that are more than likely reflective of background metal concentrations in the environment (see Comment #8). Therefore, such guidance is not applicable to the hazard classification of metals.
16. Page 25, 1st paragraph, 1st sentence: This sentence is misleading because it implies that EPA has a framework or criteria for classifying chemicals according to their bioaccumulative properties based on human bioaccumulation data. In fact, as EPA acknowledges on page 26 (1st paragraph), there are no such criteria

(“...there currently are no universally accepted indices of these [bioaccumulation] data”).

17. Page 27, 3rd full paragraph, 4th sentence: Although it is true that some humans use algae for food, this pertains to macroalgae (e.g., seaweed), not microalgae (e.g., phytoplankton). We note this because data on microalgae were inappropriately included in the lead TRI rule.
18. Page 27, 3rd full paragraph: In performing a hazard ranking or characterization, it is appropriate to consider potential pathways linking organisms having high BCFs for a metal like lead with higher trophic organisms (notably humans) that are sensitive to that metal. However, the mere existence of a potential pathway should not be the end of the analysis. The evaluation should be taken a step further by considering the potential dose that a human may receive from ingesting lead bioaccumulated in the aquatic food chain. The significance of declining lead concentration as one moves up the food chain warrants more discussion before concluding that “exposure comparable to that associated with high BCF values” may result from trophic transfer.
19. Page 28, 2nd full paragraph, 1st sentence: “Bioaccumulation data” should technically be “bioaccumulation/bioconcentration data” and “bioaccumulation potential” should be “bioaccumulation/bioconcentration potential, respectively.”
20. Page 29, 1st full paragraph: Lead is identified as a substance that bioaccumulates in humans but, as noted earlier in these comments, no criteria have been specified through which this determination is made. This section then goes on to note that lead deposition occurs in bone and equates this with bioaccumulation without any further explanation. The pharmacokinetics of lead are similar to that characteristic of many metals -- partitioning to different body compartments occurs and compartment-specific retention half-times will be evident. In the specific case of lead, bone deposition and remobilization occur largely as a function of bone remodeling during processes such as growth and aging -- lead binds to and is released from the mineral matrix of bone tissue as part of a dynamic equilibrium whereby cation exchange occurs between bone and blood plasma. This dynamic and freely reversible binding process has kinetics most conveniently measured in years. (O’Flaherty, 1993). The process really is one of pharmacokinetics, not bioaccumulation. On a more generic level, if the mere existence of body pools with different turnover kinetics is construed as the criterion that defines “bioaccumulation,” almost every organic and inorganic substance would be classified as “bioaccumulative.”

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The Aluminum Association

Incorporated

900 19th Street, N.W., Washington, D.C. 20006



July 2, 2002

Technical Information Staff (8623D)
NCEA-W,
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Re: Metal Assessment Action Plan

Dear Sir or Madam:

The Aluminum Association submits these comments in response to the Environmental Protection Agency's (EPA) recently published draft Metal Assessment Action Plan (67 Federal Register 39982, June 11, 2002). The Aluminum Association is a trade association founded in 1933 and comprised of 62 members and associate members of the U.S. aluminum industry, many of whom are impacted by requirements for release reporting of metal and metal compounds through the Toxic Release Inventory (TRI) persistent bioaccumulative toxic (PBT) release reporting requirements. Our members are engaged in a variety of operations in the U.S., including alumina refining, primary aluminum reduction, secondary reclamation, fabrication, and the manufacturing of consumer packaging.

The Aluminum Association supports the comments submitted by the Ad Hoc Metals Coalition group. In addition to the comments submitted by the coalition, we offer the following for consideration in revising the action plan and in developing the metal assessment framework.

While the Association supports the metal assessment framework development and recognizes many valuable contributions and considerations in the draft metal assessment action plan, we believe that the plan overlooks a critical issue in addressing the bioavailability of metals. The critical issue overlooked is the physical form and physical conditions of the release for metal and metal compounds that can dramatically influence availability of metals to the biota. The Association recommends that the action plan be revised to more fully address physical factors affecting metal and metal compounds in addressing bioavailability determinations and reporting requirements.

The action plan, as currently drafted, emphasizes bioavailability determinations in terms of chemical factors affecting the entry, exposure and environmental matrix

of the metal contaminant. Although important factors influencing bioavailability, chemical factors alone do not adequately address bioavailability for metals and metal compounds. Physical conditions and other factors are also important in determining bioavailability. As outlined in the report by Dr. Herbert E. Allen, Ph.D.¹ prepared on behalf of the Counsel for Lead Industries Association, metals are infinitely persistent, but numerous processes in the environment can transform their availability. Toxicity is affected by physical form through processes such as sorption, complexation and speciation. Bioavailability is also dependent on physiological need of an organism, metal availability and speciation. Because the characteristics of metals are different from organic compounds, a toxicity assessment of metal compounds must be performed with a different methodology than for organic compounds, and must take into account other factors such as physical conditions.

Other scientific organizations have drawn similar conclusions. The Organization for Economic Co-operation and Development (OECD) has developed procedures for classifying and labeling chemicals.² OECD concluded:

For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally the use of bioaccumulation data should be treated with care.

Of particular concern to the Aluminum Association and its members is the mandated and nonsensical requirement that lead and lead compounds in aluminum alloys be reported as a toxic 'release'.³ This requirement promulgated under the PBT regulations dramatically ignores the physical factors affecting bioavailability for lead. As a minute contaminant entrained in aluminum alloys, lead physically is not bioavailable to the biota, and is therefore not a toxic release in such form.

¹ "Persistent, Bioaccumulative, and Toxic (PBT) Chemicals: Considerations for RCRA Waste Minimization of Metal" Herbert E. Allen, Ph.D., Professor of Environmental Engineering, University of Delaware, May 22, 1999, as included in the Counsel for Lead Industries Association, Inc. submission by Jane Luxton, King & Spalding, to Arthur G. Fraas, OMB on June 22, 1999 on the EPA proposed TRI reporting thresholds for lead and lead compounds.

² OECD, 1998. Environment Directorate Chemicals Group and Management Committee, Advisory Group on Harmonization of Classification and Labeling. Draft Proposal for a Harmonized Classification System for Substances to the Aquatic Environment. ENV/MC/CHEM/HCL(98)11 (July 20, 1998).

³ "Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting; Final Rule" 40 CFR Part 372 (66 Federal Register 4500, January 17, 2001).

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The Agency has recognized that lead entrained in alloys has the potential for very limited toxicity by granting, subject to further review, exemption to stainless steel, brass and bronze alloys from lead threshold reporting requirements.⁴ However, no such exemption is applied to other alloys including aluminum alloys. We believe that the metal assessment framework must more fully address the metals bioavailability issue, and provide the means for establishing alloy exemptions from release reporting of lead and other listed metal compounds.

For further information or questions, please contact my office (202/862-5132, bstriete@aluminum.org) at your convenience.

Sincerely,

Robert P. Strieter
V.P., Environment Health & Safety

cc:
Mark Mazanec, Baker & Hostetler

⁴ IBID at page 4547 of the Federal Register notice.

COPPER & BRASS FABRICATORS COUNCIL, INC.

1050 SEVENTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
SUITE 440
TELEPHONE (202) 833-8575
FACSIMILE (202) 331-8267
E-MAIL: COPBRASS@AOL.COM

July 2, 2002

Technical Information Staff (8623D)
NCEA-W
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals (External Review Draft): 67 Fed. Re2. 39982, June 11, 2002

Dear Staff Members:

On behalf of the Copper and Brass Fabricator's Council, Inc. ("Council"), set forth below are comments in response to the United States Environmental Protection Agency's ("Agency") notice of a draft for public review and comment, "Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals (External Review Draft)," published in the June 11, 2002 Federal Register at 67 Fed. Reg. 39982. (Hereafter "Draft Action Plan"). The Council welcomes the opportunity to comment on the Agency's Draft Action Plan.

The Copper and Brass Fabricators Council is a trade association that represents the principal copper and brass mills in the United States. The 20 member companies (see attached appendix A for a list of member companies) together account for the fabrication of more than 80% of all copper and brass mill products produced in the United States, including sheet, strip, plate, foil, bar, rod, and both plumbing and commercial tube. These products are used in a wide variety of applications, chiefly in the automotive, construction, and electrical/electronic industries.

The Council commends the Agency for its willingness to undertake the development of a separate framework for the assessment of the relative hazards of metals in the environment, and for recognizing that much of the scientific basis for such a framework has been developed over

the last few years by various researchers in the scientific community. We endorse the Agency's conclusion that any useful framework for assessing metals must consider the following:

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- essentiality
- speciation
- bioavailability
- limitations in usefulness of bioaccumulation as a factor in evaluating metals (e.g, due to essentiality, homeostasis, inverse relationship of BCF/BAF with environmental concentrations of metals, etc.)
- transformation is a natural phenomenon, consideration of which is critical for evaluating persistence (also explicitly acknowledging the limited usefulness of persistence as applied to metal assessment, especially hazard ranking)

We believe that the Draft Action Plan represents a major step forward in the development of a scientific means for hazard classification and risk assessment of metals and metal compounds. Below we list some concerns and suggestions for improving and refining the overall approach.

I. Historical Context.

A. Recognition of the Need for a Separate Assessment Framework for Metals.

In the Draft Action Plan (hereafter "DAP"), the Agency acknowledges that there is a lack of consensus as to how to evaluate the persistence, bioaccumulation, and toxicity of metals. DAP at 38. Further, the document states that there appears to be consensus among a number of organizations as to how to evaluate the persistence, bioaccumulation, and toxicity of organic chemicals. DAP at 39. The simplifying assumptions that made this a workable and valid screening tool for organic chemicals were made principally from data generated for synthetic organic chemicals. The tests and criteria that were developed to assess persistence, bioaccumulation and toxicity were designed for organic chemicals." 2 Not surprisingly, when this tool designed specifically for organic chemicals was applied to metals and metal compounds, "unique challenges" arose.

As the Agency begins the task of devising a similar tool for the hazard classification of metals, we agree that "...the assessment of metals and metal compounds presents unique challenges not generally encountered with organics in the development of an assessment framework." (DAP at page 7). The assessment of metal and metal compounds will require

Mien, H.E. (1999), "Persistence, Bioaccumulation, and Toxic (PBT) Chemicals: Considerations for RCRA Waste

Minimization of Metals," submission to EPA Docket Number F-98-MMILP-FFFFF.

² We note that this PBT classification approach may be appropriate for organic compounds of mercury, precisely

because these behave in the environment and in the body like organic compounds, not metals. The DAP appropriately recognizes such fundamental differences between the behavior of organic compounds and most other metals and metal compounds (DAP at 18, 13).

**Copper & Brass
Fabricators Council,
Inc.**

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achievement of the four goals of the DAP: to establish a process for developing guidance that will assure 1) a consistent application of scientific principles for assessing hazard and risk for metals, 2) state-of-the-science application of methods and data, 3) a transparent process (i.e. articulating assumptions and uncertainties), and 4) the flexibility to address program-specific issues.

- B. The 2001 TRI/Lead Rule is Not the Central Controversy Surrounding the Current Application of PBT to Metals; the Central Issue is Listing Metals Such as Copper and Zinc on the 1998 Draft RCRA PBT List.

In several locations, the DAP references the TRI/Lead Rule (see e.g. pages 7 and 38) as the central controversy surrounding the application of PBT to metals. The DAP also notes that the interlocking issues that need to be addressed in developing a new framework for metals were based on comments received during the development of the TRI/Lead Rule. DAP at page 7. In fact, reading the DAP one could get the impression that the TRI/Lead Rule was the only issue confronting stakeholders as a result of the Agency's application of PBT analysis to metals. This is completely erroneous and ignores extensive Agency interaction with stakeholders preceding the emergence of the TRI/Lead Rule. The dialogue over the misapplication of PBT to metals arose much earlier, during the 1997-1999 time period, with the development of the Agency's Waste Minimization Prioritization Tool (WMPT) and its use to develop a RCRA Draft PBT list of 53 PBT chemicals that included 11 metals. A better perspective on the current work to develop a separate Metals Assessment Framework can only be achieved if the earlier interactions are considered. Numerous comments filed in the earlier proceedings provide abundant scientific authority and analysis relevant to the issues being considered by the DAP:

1. Waste Minimization Prioritization Tool (WMPT). On August 7, 1997, the

Agency, under Docket No. F-97-MPCA-FFFF, published a Draft Prioritized Chemical List and a Waste Minimization Prioritization Tool. The purpose of the tool was to develop a manageable list of priority chemicals to track progress toward the goals of the 1994 Waste Minimization National Plan. The essence of the tool was to rank each chemical according to its score on persistence, toxicity and bioaccumulation (PBT) scales. The Federal Register notice soliciting comments resulted in over 50 formal responses from industry. Many of these submissions, including those of the Council³, contain thoughtful analyses of the issues presently being addressed by the Agency, such as bioavailability, speciation, essentiality, and the problems related to bioaccumulation as a ranking tool for metals, with useful references. Generally, the information provided clearly demonstrates the inability of PBT to accurately rank the hazards of metals and metal compounds.

~ Collier, Shannon, Rill and Scott, counsel to the Copper and Brass Fabricators Council, to RCRA Docket Number F-97-MPCA-FFFF, comments on the EPA's Waste Minimization Prioritization Tool ("WMPT") and Draft Prioritized Chemical List ("DPCL"), August 7, 1997

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Fabricators Council,
Inc.**

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2. RCRA Draft PBT List. On November 9, 1998, the Agency published a RCRA Draft PBT List containing 53 chemicals, including 11 metals. 63 Fed. Reg. 60,332 (Nov.9, 1998), and solicited comments under Docket No. F-98-MMLP-FFFF. Comments were filed by industry, including those by the Council⁴, containing extensive scientific and policy considerations supporting opposition to the inclusion of these metals under a PBT list umbrella dominated by organic chemicals. During calendar year 1999, there followed numerous meetings between metals industry representatives and the Agency. The scientific and policy issues raised during these meetings, and in the comments filed, led to an agreement between the Agency and industry to more fully explore the issues during a scientific workshop to review PBT and its applicability to metals.
3. Experts Workshop: Review of the State-of-the-Science Regarding PBT Concepts and Metals and Metal Compounds, January 19, 2000, Crystal City, VA. This workshop was co-sponsored by the Agency and the International Copper Association, the International Lead Zinc Research Association, the Nickel Producers Environmental Research Association, the Electric Power Research Institute, and the International Council on Metals and the Environment.

Throughout the meeting, various presenters from the Agency, the metals industry, the chemical industry, and academia presented detailed scientific reviews of the origins and applicability of the PBT model to metals. More importantly, alternative criteria for ranking metals were reviewed. It was agreed that the information required to provide a hazard classification for metals different from PBT was available, and a joint program to complete the ranking system was discussed. An official transcript⁵ of the workshop was developed and copies distributed to the Agency and other participants. The transcript represents a virtual compendium of the state-of-the-science regarding PBT concepts and their inapplicability to metals, as well as the currently available criteria for ranking metals. As such, the transcript represents a foundation upon which the Metals Action Plan Workgroup can build. If needed, additional copies of the transcript can be provided by the Council (simply contact us at the address or phone number listed on the letterhead).

~ Copper and Brass Fabricators Council, to RCRA Docket Number F-98-MivILP-FFFF, comments on the EPA's draft list of persistent, bioaccumulative and toxic (PBT) chemicals, February 16, 1999.

~ Transcript, "Experts Workshop: Review of the State-of-the-Science Regarding PBT Concepts and Metal and Metal Compounds," sponsored by U.S. EPA, EPRI, ICA, ILZRO, NIIPERA in Collaboration with ICME, January 19, 2000.

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Perhaps the most significant development during the workshop was the acknowledgment by an EPA representative that metals such as copper and zinc should not have been included in the RCRA Draft PBT List. This conclusion was confirmed by EPA in correspondence with the Council following the workshop. Despite recognition by the Agency of the extremely damaging consequences of erroneously listing copper and zinc as priority PBT chemicals, as of the date of this submission, EPA has failed to revise the RCRA Draft PBT list.

It is absolutely essential that the first step in the DAP should be the revision of the RCRA

Draft PBT list to eliminate inclusion of metals such as copper and zinc which the Agency has agreed should be removed from the list. In view of the extended time frame of the DAP, immediate revision of the Draft RCRA PBT list is essential to any future metals assessment framework.

II. **Additional** Considerations not Presently Included in **the Draft Action Plan.**

As noted in the introduction to these comments, the Council agrees with the Agency decision that speciation, bioavailability, essentiality, transformation, and the inapplicability of bioaccumulation, are critical to the development of a workable hazard classification system for metals and metal compounds. In addition, the Agency should consider the following factors:

- A. There should be a distinction between metals and metal compounds, i.e. differentiate between elements and compounds. As cited earlier, the Agency states in the DAP that metals and metal compounds present unique challenges not encountered with organic chemicals using the PBT framework. As we noted, this is primarily due to the PBT framework being a tool specifically developed for organics. However, it should be noted that in assessing organics, the Agency does not evaluate the element carbon separate from all its myriad compounds to arrive at a single classification. Because there are far fewer metal compounds than there are carbon compounds, one approach has been to include a metal and its compounds under a single ranking. Because there are a limited number of compounds commercially associated with each metal, an attempt should be made to develop a useful framework that ranks metals and their compounds individually. For classes of inorganic compounds of each metal, it is likely that common classification approaches will emerge from the science, allowing simplification of this process. For instance, most inorganic compounds of a metal will dissociate in aqueous solution (i.e., in the aquatic environment), so classification schemes need only consider the behavior and fate of toxic moieties like the free metal ion.

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- B. Separate ranking systems should be developed for ecological versus human risk assessments, since the risk to humans and to ecological receptors varies widely for a given metal.
- C. The Agency should consider the effect of metal alloys in the assessment framework. Metals and metal compounds contained in alloys behave differently than pure metals. These differences should be factored into an assessment framework.

III. The Agency Should Make Full Use of Its Funded Center for the Study of Metals in the Environment.

During the development of the Metals Assessment Framework, we encourage the Agency to continue to rely on the advice of the academic scientists of the Agency-funded Center for the Study of Metals in the Environment (CSME). See page 42, DAP. The CSME is a multi-university consortium of scientists and engineers, which was established to assist the Agency in furthering the understanding of processes affecting the fate of metals in aquatic and terrestrial ecosystems and the biological effects of metals in these systems. As such, the work of the CSME is directly translatable into the development of a workable Metals Assessment Framework, and can be invaluable in filling information gaps.

IV. Conclusion.

The Council appreciates the opportunity to comment on the DAP for the development of a Metals Assessment Framework. We look forward to the Agency's continued outreach to stakeholders during the development process. We fully share the Agency's goal of achieving an effective classification system for metals and metal compounds.

Sincerely,

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Attachment

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July 2, 2002

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(610) 926-4131X2100

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**Copper & Brass
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July 2, 2002

Technical Information Staff (8623D)
NCEA-W
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Sirs:

Department of Energy (DOE) staff commend the Environmental Protection Agency on developing a Draft Action Plan for the development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals (External Review Draft) June 11, 2002 (67 FR 39982). The Draft Action Plan represents a significant step toward implementing state-of-the-science hazard and risk assessment techniques for metals. The Agency has done a good job of summarizing the current thinking on the scientific issues involved in evaluating metals through a persistent, bioaccumulative, and toxic (PBT) framework, and summarizing the available literature.

The development of a Metals Assessment Framework and associated Guidance is of interest to several Offices within the Department. As such, we are interested in closely participating in their development, including interagency reviews of white papers, drafts of the Framework and Guidance and Science Advisory Board (SAB) Charges, and participation in workshops and interagency groups.

Our primary concern with the Draft Action Plan is the apparent intention of EPA to ask the SAB to evaluate lead and lead compounds under the current Toxic Release Inventory PBT criteria, prior to the completion of the Framework and Guidance. We believe EPA should charge the SAB to review lead and lead compounds applying the more comprehensive approach that is to be developed in the Framework rather than evaluating the potential hazards of lead through application of PBT criteria that lack a metals refinement. DOE staff further believe that EPA needs to reconsider the TRI Lead Rule and the PBT Framework, if the results of the SAB review suggest that the approach followed in the past may have led to scientifically questionable conclusions.

Our detailed comments are attached. If you have any questions, please feel free to contact either of us. Debra can be reached at 202 586-3033, and David at 202 586-2069.

Sincerely,

Debra Littleton
Office of Fossil Energy

David O. Moses
Office of Policy and International
Affairs

Attachment

**Department of Energy (DOE) Staff Comments on the EPA Draft Action Plan:
Development of a Framework for Metals Assessment and Guidance For
Characterizing and ranking Metals**

The development of a framework for metals assessment and guidance has cross-cutting interest within the Department of Energy (DOE). DOE facilities use various metals and metal compounds in the conduct of their missions, and the Department is charged with implementing the Nation's energy policy to develop reliable, affordable, and environmentally sound energy for America's future. Much of our Nation's current energy needs are being met through the use of fossil fuels, all of which contain metals and metal compounds.

DOE has been active in researching and submitting comments to EPA on metals issues in the Toxic Release Inventory (TRI) Persistent Bioaccumulative Toxic (PBT) Rule and Lead Rule processes. We also have been developing an Energy-Industry Metals Database that is an electronic, web-based applications that estimates the amounts of TRI metals and metal compounds that are manufactured, processed, or otherwise used and released by the energy sectors.

Below are our comments on the Draft Action Plan.

General Comments

DOE staff support EPA's effort to develop a framework and guidance for characterizing and ranking metals, and appreciates the opportunity to provide comments on the Draft Action Plan.

The discussion of EPA's Action Plan, particularly the overview of major science issues, is very thorough and brings out many of the major points we made during the TRI Lead Rule comment process. We have been consistently asserting, since our comments on the draft proposed PBT rule in 1998, that EPA's PBT methodology was developed for synthetic organic chemicals and should not be applied to metals and metal compounds. DOE has recognized the unique assessment issues that apply to metals that are outlined in the Draft Action Plan and has previously provided a multitude of references that have addressed these issues in our written comments, and in interagency meetings on both the TRI PBT and the TRI Lead Rules.

DOE staff support Science Advisory Board (SAB) Review of each step of development of the Framework and Guidance.

We have been a strong supporter of SAB involvement in the review of the PBT methodology, its applicability to metals, and their review of the Lead Rule. We are therefore supportive of EPA's commitment to have an SAB Advisory of the Action Plan, and full SAB reviews of the draft Framework and Guidance.

DOE staff believe that the current PBT Framework should be defined and undergo and SAB Review. EPA has not described exactly what the "PBT Framework" is, despite being referenced repeatedly in the Draft Action Plan. We recommend that the EPA provide a clear description of the PBT framework (and criteria applied under various Rules). EPA should also include a discussion of what review it has received to date.

DOE staff is concerned with the scope of the SAB review of TRI Lead Rule.

The Draft Action Plan states that EPA will request that the SAB “comment on whether lead is highly bioaccumulative” at the same time the SAB is reviewing the Draft Characterization Guidance. We request that EPA expand this section of the Draft Action Plan to fully identify what EPA’s current thinking is on what the charge to the SAB will be concerning lead. We would be concerned if EPA’s charge to the SAB is not a full review of the TRI Lead Rule, and simply to comment on whether or not lead and lead compounds can be considered to be highly bioaccumulative based on TRI’s current PBT criteria. We have commented during the TRI Lead Rule process that EPA needs to clarify the criteria for determining a chemical to be PBT. DOE also commented that the application of EPA’s bioconcentration factor (BCF) criteria is confusing and unclear.

Specifically, in our September 17, 1999 we commented (on the August 3, 1999 proposed Lead rule):

“DOE believes that EPA must clearly state whether the 1,000/5,000 BCF values (criteria) for determining whether a chemical is PBT or highly PBT are for the whole organism or part of an organism (for example, the whole fish, or just the liver of the fish.) Also, how many different kinds of organisms must exceed the 1,000/5,000 BCF values in order to classify a chemical as PBT or highly PBT? Is one organism sufficient, or is more than one required? Are different species considered as different organisms? For example, would two species of algae be considered two different organisms?”

We believe that the SAB should review the TRI Lead Rule after the final, peer reviewed Framework and Guidance documents are issued.

DOE staff support EPA’s Outreach Activities Plan.

EPA’s plan of involvement of the scientific and risk assessment communities, coordination with other Federal Agencies, and communication with stakeholders, is necessary in order to foster consensus building.

DOE staff want to continue to be closely involved in the development of the Metals Assessment Framework and Guidance.

We have been working with the EPA on the metals assessment issue since the draft PBT rule and the interagency review process in 1998. We also worked side-by-side on this issue with EPA during the Organization for Economic Cooperation and Development (OECD) meetings on the development of guidance for classifying metals that are hazardous to aquatic environments. The OECD guidance advises that in situations, as with metals and metal compounds, in which there is an inverse relationship between BCF and external water concentration, the bioconcentration data should be used with care.¹ As such, we recommend that EPA conduct an interagency review of the white papers that are developed, prior to the November 2002 workshop. We also request the opportunity to be involved in any interagency efforts or workgroups related to the metals assessment issue.

Specific Comments

Background, (page 1). EPA states that it has decided, "to develop a more comprehensive approach to metals assessments that could be the basis for *future* Agency actions." (Emphasis added.) While we agree with the need to develop a new approach to metals assessment, we believe EPA should apply the new "more comprehensive approach" to reconsider some *past* actions that were based on

a different methodology (e.g., evaluating the potential hazards of lead through application of PBT criteria that lack a “metals refinement”). If the SAB review suggests that the approach followed in the past may have led to scientifically questionable conclusions, then we believe past actions involving metals should be reevaluated using the newly developed approach.

Section 2.1, National Hazard/Risk Ranking and Characterization. (page 11). This section has a very narrow focus on the TRI Program and is not reflective of other programs that rank substances (e.g., Office of Solid Waste/Waste Minimization program). The criteria discussed reflect traditional TRI policy but do not reflect the broader criteria used by the scientific community and international organizations for ranking and classifying substances. We recommend that the focus of this section be broadened to include other national programs.

Section 2.2, National Hazard/Risk Ranking and characterization. (page 16). The document indicates that decisions about national hazard/risk ranking and characterization are usually driven by available toxicity data and whether environmental conditions within the U.S. would cause a metal to become or remain available in the environment (or favor formation of bioavailable forms of the metal). We are concerned that a strict interpretation of this will allow the exceptional situation to drive national hazard/risk ranking determinations, and could have the result of every metal and metal compound being ranked as a high hazard/risk chemical. We believe EPA needs to look carefully at this approach during the development of this Framework and Guidance.

Section 5, Overall Approach and Schedule for Development of the Framework and Guidance, and White Paper development (page 39). The development of white papers on the major scientific issues and sub-issues will serve as the major information source for the Framework and the Guidance. As such, it is important that the outside experts that EPA chooses to be on the white paper development team represent all stakeholder interests. The Draft Action Plan does not describe the process for the formation of the white paper issues and sub-issues teams. We believe this process should be transparent. We also believe that the white papers should undergo an interagency review upon their completion, and prior to the first workshop that will be based partly on the white papers.

Section 5, Overall Approach and Schedule or Development of the Framework and Guidance, Peer Consultation Workshops (page 39). We request an active role in each of the three planned workshops.

Section 6, Outreach Activities, The Scientific and Risk Assessment Communities (page 42). The Draft Action Plan states that EPA is trying to work with scientists, industry, and Environment Canada to organize a technical workshop titled, *Hazard Identification Approach for Metals and Inorganic Metal Substances*. We would like to participate in the development and conduct of this workshop.

Section 6, Outreach Activities, Coordination with Other Federal Agencies (page 42). The Draft Action Plan states that there is currently an interagency group that is characterizing and distilling the data needs for assessing the risks from exposure to metals in various settings. We request the charter and membership list for this interagency group, as DOE facilities use metals of various types in conducting their mission, and may have a useful role to play. EPA also states that another interagency group is forming that will work towards developing an overall strategy for metals risk assessment. We would like to participate in this interagency group, and request that EPA notify us during its formulation.

¹. Organization for Economic Cooperation and Development (OECD). “Classification of Metals and Metal Compounds. Guidance document on the use of the harmonized system for the classification of chemicals which are hazardous for the aquatic environment –chapter 7.” OECD Series on testing and assessment (Number 27), pages 97-115. Document ENV/JM/MONO(2001); July, 2001.

July 2, 2002

Via Electronic Mail

Technical Information Staff (8623D)
NCEA-W
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
metals.assessment@epa.gov

Re: Comments on Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals

Dear EPA:

On behalf of the Specialty Steel Industry of North America (“SSINA”) and the Chrome Coalition (“the Coalition”), we are pleased to submit the following comments regarding the Draft Action Plan for the Development of a Framework for Metals Assessment and Guidance for Characterizing and Ranking Metals (“the Draft Action Plan”). 67 Fed. Reg. 39,982 (June 11, 2002). In general, SSINA and the Coalition are pleased that the Draft Action Plan recognizes the importance of speciation to the proper assessment of the potential hazards and risks posed by metals, particularly chromium and nickel. The following comments urge that the Metals Assessment Framework recognize that alloys are unique substances with properties different than their constituent metals, and also identify some points raised in the Draft Action Plan that warrant correction or clarification. We look forward to working with the U.S. Environmental Protection Agency (“EPA”) as the development of the Metals Assessment Framework proceeds.

I. BACKGROUND

SSINA is a national trade association comprised of 17 producers of specialty steel products, including stainless, electric, tool, magnetic, and other alloy steels. SSINA members account for over 90 percent of the specialty steel manufactured in the United States. As the major producers of stainless steel and other alloys that contain chromium and nickel, SSINA members are interested in the proper characterization of these substances for regulatory purposes. SSINA has expressed substantial concern about the methodology used to identify PBT substances as it has been applied to chromium, nickel, and other naturally occurring metals by various EPA offices, including to develop the “Draft PBT” list issued by the Office of Solid Waste (“OSW”) in 1998. On March 7, 2002, SSINA submitted comments focused on the need to consider speciation as part of the Action Plan.

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The Chrome Coalition represents more than 20 companies and trade associations of chromium chemical manufacturers, users, distributors, and their customers, including SSINA. It has been in existence since 1986 and has worked with EPA and other federal and state regulatory agencies to develop scientific information relevant to a number of issues involving chromium. The Coalition also acts as an information clearinghouse to gather and disseminate chromium-related information, research, and studies to the chromium industry. The Coalition promotes chromium product stewardship by developing and distributing chromium product information and technical data. Accordingly, Coalition members are interested in the scientifically sound characterization of chromium.

Metals such as chromium and nickel are vital to the U.S. economy and essential raw materials in the production of many industrial and consumer items, including stainless steel. The most prevalent forms of these metals pose little, if any, risk to human health. By arbitrarily and capriciously, without any scientific basis, branding a number of metals, including chromium and nickel, as PBT substances and among the "worst" chemicals in the world, OSW's draft PBT list¹ and other past EPA actions relating to PBTs have sparked public concern and exposed metals industries to unwarranted regulatory efforts, particularly in states that adopted EPA's draft PBT list.

The Draft Action Plan appropriately recognizes that the existing PBT framework does not properly portray the potential hazards or risks posed by metals to human health and the environment for a number of reasons:

- Fundamental chemical differences between organic substances and metals militate against applying the PBT criteria to metals;
- Persistence is not a relevant consideration for assessing the potential hazard of most metals, including chromium and nickel, and is in fact a desirable trait;
- Bioaccumulation is not an appropriate measure of hazard for naturally occurring inorganic substances, especially essential metals like chromium and nickel; and
- The toxicity of metals is dependent on speciation and bioavailability.

SSINA and the Coalition therefore support the development of an alternative framework for assessing metals.

¹ While pleased that OSW's draft PBT list is expected to be replaced shortly by a "priority chemicals list" that appropriately does not include chromium and nickel, the proper characterization of the potential hazards and risks posed by these metals remains an important issue with widespread applicability under a number of EPA and state regulatory programs.

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II. THE METALS ASSESSMENT FRAMEWORK SHOULD CONSIDER ALLOYS

One important element that fails to receive any mention in the Draft Action Plan is the treatment of alloys in the Metals Assessment Framework. Alloys are solid “solutions” in which two or more metals are combined to form a substance with unique chemical properties. Because alloys are homogeneous, they are not properly considered to be simple chemical mixtures from which their constituents are easily separated. The Environment Directorate of the Organization for Economic Cooperation and Development (“OECD”), during its work on the harmonization of classification and labeling schemes, used the following definition of an alloy: “An alloy is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.”²

Metal constituents of an alloy are not readily available, and may only become available when subjected to particular aggressive environmental conditions. EPA’s recent “Report on the Corrosion of Certain Alloys” supports this conclusion. *See* 66 Fed. Reg. 44,107 (Aug. 22, 2001). Because alloys have different physical and chemical properties than their constituent metals, EPA should recognize that they also differ with respect to potential hazards and risk.

Thus, we urge EPA to recognize in the Metals Assessment Framework that alloys are not classifiable on the basis of their constituents. Rather, alloys should be evaluated on the basis of their own properties.

III. THE DRAFT ACTION PLAN MISCHARACTERIZES CHROMIUM SPECIATION ISSUES

While pleased that EPA apparently recognizes that speciation must be an important element of the metals assessment framework, we are concerned by some overbroad generalizations made in the Draft Action Plan with respect to chromium speciation. The Draft Action Plan correctly recognizes that “speciation affects the toxicity of metals” and that hexavalent chromium has a significantly different toxicity profile than trivalent or elemental chromium. Draft Action Plan at 7-8. However, EPA overstates the potential for transformation between various species of chromium in asserting that “Cr⁺⁶ emissions can transform into Cr⁺³ in the atmosphere and in soils Cr⁺³ can transform to Cr⁺⁶.” *Id.* at 8.

While theoretically true, the statement inaccurately suggests that there is a rough equivalence in the potential for transformation. In reality, the conversion from trivalent to hexavalent

² E.g., OECD Environment Directorate, Task Force on Harmonisation of Classification and Labelling, *Revised Step 2 Proposal For Harmonised Classification Criteria For Mixtures* 6 (Sept. 15, 2000). While the OECD working group includes alloys under the general “mixtures” category, for classification purposes, alloys are recognized as a special case. For example, alloys have a separate definition from mixtures.

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chromium may happen to only a very small extent under certain soil conditions.³ On the other hand, observed half-life values of hexavalent chromium in air range from a few seconds to approximately 13 hours under various atmospheric conditions.⁴ Hence, while almost all hexavalent chromium will convert to the relatively non-toxic trivalent form in the atmosphere, very little trivalent chromium will convert to hexavalent chromium in any media.

A proper metals assessment framework must recognize these differences in the potential for transformation among various metal species. Regrettably, current EPA efforts on this issue, most notably the National Air Toxics Assessment ("NATA"), include grossly erroneous estimates of the quantity of chromium emissions that are in hexavalent form. The metals assessment framework must not repeat these errors.

SSINA and the Coalition look forward to working with EPA on the proper characterization of chromium as the metals assessment framework is developed. Further analysis of this issue will be provided during opportunities to comment on the metals framework as it develops.

IV. CLARIFICATION OF CERTAIN STATEMENTS IN THE DRAFT ACTION PLAN

The Draft Action Plan generally is a cogent summary of the need for and process to develop an alternative metals assessment framework. That being said, there are several statements that warrant clarification or correction.

A. Metals Do Not Pose "Unique" Toxicity Concerns

EPA makes the perplexing statement that "the assessment of metals and metal compounds presents unique challenges not generally encountered with organics in the development of an assessment framework." Draft Action Plan at 7. This statement exaggerates the toxicity issue related to metals, suggesting that toxicity is a heightened concern for metals as opposed to organics. In fact, the problem is that the framework developed to assess the unique problems posed by organic compounds, especially synthetic organics, (*i.e.*, PBT) is not appropriate for metals.

³ See, e.g., James B.R., Petura J.C., Vitale R.J., Mussoline G.R., *Oxidation-reduction chemistry of chromium: Relevance to the regulation and remediation of chromate-contaminated soils*, 6 J. SOIL CONTAMINATION 569-580 (1997) (copy to be provided).

⁴ See, e.g., Seigneur C. and Constantinou E., *Chemical Kinetic Mechanism for Atmospheric Chromium*, 29 ENVTL. SCI. & TECH. 222-231 (1995) (identifying half lives ranging from a few seconds to several minutes depending on atmospheric conditions); see also Research Triangle Institute, "The Fate of Hexavalent Chromium in the Atmosphere" (RTI/3798/00-01F) (Oct. 1988) (commissioned by the California Air Resources Board) (laboratory studies found an average half life for hexavalent chromium in the atmosphere of 12.9 hours (+/- 5.8 hours), and field studies found an average half-life of 16.4 hours (+/- 6.9 hours) or excluding one possible outlier 14.4 hours (+/- 4.4 hours)). Copies of these studies will be provided.

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Metals are ubiquitous, fundamental building blocks of the earth's crust and living organisms. Society has a long history of working and living with metals. In contrast, synthetic organics are often new substances that are not naturally occurring and have properties that may be unfamiliar. While metals no doubt present issues of toxicity, it is misleading for EPA to state in the Draft Action Plan that these issues are more significant for metals than organics. SSINA and the Coalition urge EPA to correct such ill-informed and unfounded statements when revising the Draft Action Plan.

Similarly, EPA states that "[t]he ability of a metal to interconvert to different forms and the corresponding influence that the interconversion has on exposure potential and toxicity poses significant problems in ranking and characterizing metals." Draft Action Plan at 4. Again, this statement exaggerates concerns with metals. Organic and other non-metallic compounds also can change chemical forms in the environment with potential significance for toxicity. For example, the Toxic Release Inventory program recently has focused on the potential for nitric acid and other nitrogen-based compounds to convert to nitrates. Interconversion is not simply a "problem" for metals. It is an issue that relates to the proper assessment of all substances, inorganics, including metals, and organics. EPA should be careful that the discussion of interconversion in the Draft Action Plan is not unnecessarily biased against metals.

B. The Draft Action Plan Distorts The History Of The Need For An Alternative Assessment Framework For Metals

In recounting the history of the need for an alternative assessment framework for metals, the Draft Action Plan cites only to the TRI Lead rule and discussions during the February 2002 stakeholder meeting. *See* Draft Action Plan at 7. Although significant, these events occurred well after the need for an alternative framework had been voiced repeatedly by metals industries representatives, including SSINA and the Coalition. As noted above, this issue first came to the fore in 1998 with the misleading inclusion of numerous metals, including chromium and nickel, on OSW's draft PBT list. Subsequently, there were numerous meetings with OSW and other EPA staff, culminating in an important January 2001 work shop that was attended by numerous EPA and other agency representatives.

By focusing only on the TRI Lead rule and subsequent events, EPA implies that the issues concerning the assessment of metals are focused primarily on lead. This approach risks unnecessarily narrowing and politicizing a debate that is of great importance to all metals industries. We therefore urge EPA to reexamine the discussion in the Draft Action Plan regarding the need for an alternative framework for metals assessment, keeping in mind the broad array of metals and industries that will be affected during this process.

V. CONCLUSION

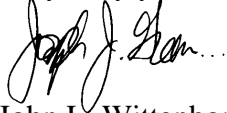
SSINA and the Chrome Coalition welcome EPA's development of an alternative assessment framework for metals. As noted above, the existing framework that was developed for organics

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simply does not work for metals. We are pleased that the Draft Action Plan recognizes that issues such as speciation are of critical importance. In moving forward, we urge EPA to be cognizant of the fact that the need for a metals assessment framework is broadly applicable to all metals. Further, EPA should recognize that the need for an alternative assessment framework does not mean that metals pose heightened hazards or risks. The Metals Assessment Framework also should recognize that alloys have different physical and chemical properties than their constituent metals, and, accordingly, differ with respect to potential hazards and risk.

Thank you for the opportunity to submit comments on the Draft Action Plan. We look forward to working with the Agency as the process for developing the Metals Assessment Framework moves forward.

Very truly yours,



John L. Wittenborn
Joseph J. Green
Counsel to the Specialty Steel Industry of North America
and the Chrome Coalition