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Response to Comments Document

Hazardous Waste Listing Determination for Inorganic Chemicals Industry Wastes (Final Rule)

**Volume II:
Responses to Comments ICMP-00013
through ICMP-00021**

**Public Comments on the
Inorganic Chemical Manufacturing Listing Determination
(Proposed September 14, 2000)**

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Comment ICMP-00013, The Ferroalloys Association

Cover letter: Request for hearing

In the enclosed comments, the Manganese Committee of The Ferroalloys Association (TFA) is asking the Environmental Protection Agency (EPA) to drop from further consideration the portion of the above-referenced proposal affecting manganese. TFA believes that EPA's scientific basis for regulating manganese is unreasonable in several respects, and that EPA is precluded from setting the proposed treatment levels for manganese because the Agency has not adequately established the existence of a corresponding level of hazard. *Hazardous Waste Treatment Council v. EPA*, 886 F.2d 355 (D.C. Cir. 1989), cert. denied, 498 U.S. 849 (1990).

Moreover, TFA continues to be disturbed by EPA's refusal to extend the deadline for comment on the proposed rule by 30 days. EPA was wrong to assume that the title of the proposed rule would immediately place industry on notice that a primary outcome would be the regulation of manganese in all characteristic hazardous waste.¹ The proposal does not begin to discuss the effect of regulating manganese on sectors other than titanium dioxide until page 87 of the 100 page rulemaking, and then provides only cursory treatment. TFA did not become aware of the proposal until after EPA's September 28, 2000, deadline for requesting a hearing.

TFA respectfully submits that the mantle of a court order to complete the rule by October 2001, is not a sufficient basis with which to gloss over the broad and unexpected effects on manganese stemming from this proposal. If EPA insists on moving forward with manganese, TFA formally requests a hearing on the specific issue of manganese prior to EPA finalizing this rule.

Response to request for hearing : EPA denied the request for a hearing in November, 2000, although, as explained below, EPA has decided to defer regulations for manganese in response to the comments submitted by TFA and other organizations.

Introduction The U.S. Environmental Protection Agency (EPA) is considering whether to list as hazardous waste three (3) inorganic waste streams under the Resource Conservation and Recovery Act (RCRA) at 40 CFR 261.32. 65 FR 55684 (Sept. 14, 2000). One chemical substance - manganese - is proposed for addition to the list of hazardous constituents in Appendix VIII of 40 CFR Part 261. EPA is required by consent decree to promulgate a final listing determination for certain inorganic chemical industry wastes before October 31,

¹ The complete title of the proposal as it appears in the Federal Register is, "Hazardous Waste Management System; Identification and Listing of Hazardous Waste: Inorganic Chemical Manufacturing Wastes; Land Disposal Restrictions for Newly Identified Wastes; and CERCLA Hazardous Substance Designation and Reportable Quantities; Proposed Rule".

2001. The Agency has examined 170 waste streams from 14 inorganic chemical manufacturing sectors, including titanium dioxide.

The Manganese Committee of the Ferroalloys Association (TFA) opposes the proposed addition of manganese (Chemical Abstract Services Registry Number (CASRN) 7439-97-6) to Appendix VII and the group of hazardous constituents in Appendix VIII to Part 261 and the associated proposed treatment standards for manganese. Manganese is being proposed for addition to Appendix VII and Appendix VIII in connection with the proposed 40 CFR 261.11(a)(3) listing of titanium dioxide non-wastewaters from the chloride-ilmenite process as a hazardous waste.² TFA submits, however, that this element of EPA's proposal must fail because:

- EPA did not consider the essential nutritional role that manganese performs in all forms of life. Even though the safe level of manganese is known in humans to a reasonable medical certainty, EPA's risk assessment includes a proposed "modifier" to the oral reference dose (RfD) for manganese that yields a corresponding daily dose that is right in the middle of the safe and necessary daily dose range.³ EPA has offered no evidence that levels of manganese in drinking water above 3.3 mg/day are toxic or hazardous to humans.
- C EPA offered no evidence that levels of manganese above the proposed hazardous waste treatment levels of 3.6 mg/L in nonwastewater sludge and 17.1 mg/L in wastewater are toxic or hazardous to humans or the environment, and has failed to consider that naturally occurring levels of manganese in soil and water can exceed these levels.
- C EPA did not adequately evaluate the toxicology data associated with oral exposure to

²The two other waste streams proposed for listing are K176, baghouse filters from the production of antimony oxide and K177, slag from the production of antimony oxide that is not disposed of or speculatively accumulated. For various reasons, EPA is proposing to not list as hazardous waste the other wastes streams under consideration. EPA has found these waste streams to be "Bevill exempt" mineral processing wastes under sections 3001(b)(3) and 8002(p) of RCRA, or involving the further processing of a saleable mineral product, or reused or recycled, or otherwise outside the scope of the consent decree. Because TFA intends to focus exclusively on the specific treatment of manganese in this proposal, we are not commenting on decisions by EPA under the Bevill exemption for mineral processing wastes or on EPA's other listing decisions at this time.

³The National Research Council's (NRC's) Food and Nutrition Board has established an estimated safe and adequate daily dietary intake (ESADDI) for manganese of 2 - 5 mg/day. Risk Assessment Background Document at p. 6-31. By comparison, the dose corresponding to EPA's proposed RfD of 0.047 mg/kg/day is 3.3 mg/day. An ESADDI is normally recommended when the scientific literature is not sufficient to establish a recommended dietary allowance, but where adequate information exists to indicate a range of intakes that are sufficient to meet nutritional needs without representing a threat of toxicity. Known upper limits of daily dietary intake actually are 2 - 3 times the ESADDI. Some nutritionists feel that the ESADDI level may be too low. (Freeland-Graves et al. 1987).

manganese. Key data completed since 1994 receives no mention in the record, and EPA's concern about uncertainty with regard to children is misplaced.

Based on these and other deficiencies, EPA's science does not support the addition of manganese to Appendix VII or Appendix VIII under 261.11(a)(3). The proposed K178 wastestream does not meet the criteria of 261.11(a)(3) based on the presence of manganese. Manganese itself does not meet the Appendix VIII criteria of 261.11(a)(3). EPA is not permitted under 42 U.S.C. 3004(m) to require treatment for manganese beyond a level at which there is no threat to human health or the environment. If EPA's proposal is to go forward, it must proceed without the inclusion of manganese. If EPA proceeds with this rule, inclusive of manganese, TFA hereby requests a hearing. The reasons for these conclusions are set forth more fully below.

The TFA Manganese Committee and Ferro Alloys Industry.

TFA is an industry advocacy group whose members are producers and users of manganese, chromium, silicon, vanadium ferroalloys and related basic alloys/metals in the United States. Founded in 1971, TFA represents over 20 companies with facilities in 25 different states.

Approximately 100 years ago, the U.S. ferroalloy industry emerged with the introduction of the electric arc furnace and rapidly expanded to meet the United States' domestic needs for projectiles and armor plates during the Spanish American War. Today, the U.S. ferroalloy industry continues to make products vital to U.S. national security and economic interests, such as steel, iron, and aluminum, available to the American economy due to ferroalloys such as: ferrochrome, manganese metal, and silicon metal, as well as specialty inoculants and graphitizers.

However, in recent years, the domestic ferroalloy industry has sharply declined, largely due to foreign import penetration and rising environmental standards. From 1970 to 1990, the annual domestic production of alloys decreased from 2,340,000 to 645,000 net tons per year, while imports increased from 350,000 to 1,490,000 net tons per year. Foreign competitors flooded the U.S. market at significantly lower costs, resulting from foreign government subsidization of electricity costs, capital investments, transportation, and taxes. As a result, U.S. producers faced high operating costs and declining prices, which forced them to reluctantly lay off workers and shut down plants at an alarming rate. These closings resulted in plants abandoning vital research and development programs, in order to remain in business. Simultaneously, the U.S. government imposed strict environmental standards on metals producers, forcing companies to direct large amounts of capital to environmental control equipment.

Despite such gloomy statistics, the American ferroalloy industry is emerging from previous years smaller and leaner, and, through cooperation with the government, can become more prepared to compete in the global economy.

In 1991, TFA formed a committee designed to engage the industry, in a proactive manner, in the ongoing study of the health effects of manganese and to participate in regulatory activities concerned with protecting the environment. This group, the TFA Manganese Committee, has been hard at work since that time funding studies, sponsoring conferences, and working with federal agencies and international organizations in an effort to help develop sensible and scientifically based guidelines. TFA has always stated and has demonstrated that it will let the science lead the way. The TFA Manganese Committee is composed of a wide cross-section of the Manganese Industry. In addition, the TFA Manganese Coalition includes several allied organizations including the International Manganese Institute, the American Feed Industry Association, and the National Electric Manufacturers Association.

Comment ICMP-00013-1: Effect of the Proposed Rule on Manganese.

EPA is proposing that non-wastewaters from the chloride-ilmenite process meet the hazardous waste criteria set out in 40 CFR 261.11(a)(3). The K178 listing would appear at 40 CFR 261.32, and would make this specific waste stream subject to hazardous waste management and land disposal restrictions as a listed hazardous waste under RCRA. Currently, TFA understands that this waste stream is managed as solid waste or used as structural fill material in landfills and related applications.

The inclusion of manganese as a basis for the proposed K178 listing has the following effects:⁴

- C Manganese would be added to RCRA Appendix VII and Appendix VIII of 40 CFR Part 261;
- C A land disposal restriction would be established for the specific K178 waste stream based on levels of manganese of 17.1 mg/L in wastewater and 3.6 mg/L TCLP in leachate from treated non-wastewater.⁵
- C RCRA requires generators to ensure that characteristic hazardous waste is treated for underlying Appendix VIII hazardous constituents. Thus, all characteristic hazardous wastes containing manganese - and not just the proposed K178 waste stream - would have to meet the treatment standards for manganese prior to land disposal.⁶

⁴The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) statutory reportable quantity (RQ) of 1 pound is already applied to manganese based on its inclusion in section 112(b) of the Clean Air Act. 40 CFR Part 302, Table 302.4. In this proposal, EPA states that it is "has not developed a waste constituent RQ" for manganese, implying that the agency is either unaware of the current RQ or intends to reevaluate it. 65 FR 55773. EPA is proposing the statutory RQ of 1 pound for the proposed K178 waste stream. 42 U.S.C. 9601(14)(C).

⁵65 FR 55769.

⁶65 FR 55769, col. 2; 40 CFR 268.48.

Treatment would be required for characteristic metal hazardous waste, as well as hazardous waste exhibiting the characteristics of ignitability, reactivity, corrosivity, or toxicity due to an organic contaminant. The treatment levels for manganese would be added to the Universal Treatment Standards at 40 CFR 268.48 and leachate derived from the treatment, storage, and disposal of characteristic hazardous waste would need to meet these levels.⁷ Manganese also would be added to the list of regulated constituents for treating undifferentiated F039 multi-source leachate at 40 CFR 268.40.

C Groundwater monitoring programs at landfills would have to monitor for the presence of manganese. Permittees must monitor ground water for Appendix VIII constituents under the detection, compliance, and corrective action programs of 40 CFR 264.91(a)(2) and (3).

C Incinerator facilities would have to treat for manganese. The Principal Organic Hazardous Constituents specified in incineration permits are drawn from Appendix VIII as provided in 40 CFR 264.342.

C Debris containing proposed K178 waste would be subject to treatment for manganese pursuant to 40 CFR 268.45 prior to land disposal.⁸

C Soil containing proposed K178 wastes would be subject to treatment for manganese pursuant to 40 CFR 268.49 prior to land disposal, and non-soil residuals generated from the treatment of soil would be subject to the proposed treatment standard for manganese in this rule.⁹

C Proposed K178 waste would be largely prohibited from underground injection unless treated for manganese according to the proposed standards of this rule.¹⁰

C Surface impoundments currently used to manage the proposed K178 waste will need to be retrofitted in accordance with 42 U.S.C. 3004(o) and 3005(j)(11), closed, or replaced with tank systems. These impoundments will need to be managed as Subtitle C treatment, storage, and disposal facilities and waste in these impoundments will be subject to land disposal prohibitions.¹¹

C Owner/operators growing food-chain crops in or on any treatment zone under 40 CFR 264.276 will have to demonstrate to EPA that manganese will not occur in greater concentrations than in or on identical portions of the same crops grown on untreated soils under similar conditions in the same region. This is irrational in light of the fact that manganese may be added to fertilizer and soil amendments to replenish manganese-depleted soils.

⁷40 CFR 261.3(c)(2).

⁸65 FR 55768.

⁹65 FR 55769.

¹⁰Id.

¹¹65 FR 55771.

This is a far-reaching rule for the manganese industry with implications that go well beyond the chloride-ilmenite process.¹² TFA understands that the mere presence of manganese on Appendix VIII does not make manganese a listed hazardous waste, per se. A separate rulemaking by the Agency would be required to transform a non-hazardous solid waste stream containing manganese into a hazardous waste. Non-hazardous waste streams containing manganese remain unaffected, for the moment. However, EPA looks to the Appendix VIII hazardous constituents list in making new hazardous waste stream listing decisions as provided in 40 CFR 261.11(a)(3), and the treatment standard proposed for manganese also sets a precedent for the adoption of land disposal restrictions in any future listing decisions. Thus, an inappropriate decision to include manganese in Appendix VIII would create obligations and possible future regulations affecting TFA's members.

Response 13-1: EPA acknowledges that the inclusion of manganese as a basis of listing K178 as hazardous would affect various sections of the RCRA regulations. In the proposed rule, EPA explicitly identified several sections of the RCRA regulations that would be impacted (which the commenter cited). However, EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2: EPA's Case for Regulating Manganese Via Ingestion Is Flawed.

It appears that EPA analyzed the commingled non-wastewaters from the production of titanium dioxide from the chloride-ilmenite process, assessing the potential groundwater releases to both surface water and drinking water wells as well as air releases from an off-site industrial landfill and municipal landfill scenarios. The agency's risk assessment results indicate that levels of manganese in the drinking water scenario exceed EPA's Hazard Quotient (HQ) of 1 for adults at the 95th percentile, and for children at the 90th percentile.¹³ TFA respectfully disagrees with EPA's results and conclusions. We conclude that they are unreasonable, based on the following issues. First, the use of an inappropriate

¹²One could imagine that EPA specifically chose this route to avoid significant controversy over the listing of manganese. Regardless of whether this was EPA's intent, it is implied from EPA's current proposal and is completely unacceptable from a due process perspective.

¹³Risk Assessment for the Listing Determinations for Inorganic Chemical Manufacturing Wastes: Background Document, Table 6-16, p. 6-22 (Prepared for USEPA by the Center for Environmental Analysis) (Aug. 28, 2000) (hereinafter EPA Risk Assessment Background Document). EPA generated a HQ for manganese by dividing the Average Daily Dose (ADD), which is calculated based on a risk assessment using Synthetic Precipitation Leaching Procedure (SPLP) and Toxicity Characteristic Leaching Procedure (TCLP) results, by the Oral Reference Dose (RfD) for manganese. Thus, $HQ = ADD/RfD$. The HQ is intended to establish whether an individual has experienced exposure that places him or her either above or below a threshold of concern for a specific health effect. The ADD is the exposure metric and the RfD represents the no-effect level for non-cancer effects that is presumed to be without appreciable risk from chronic exposures over a lifetime. The nominal level of concern for EPA hazardous waste listings is an excess lifetime non-cancer risk HQ of 1. *Id.* at pp. 2-11, 6-4, 6-11.

modifying factor that brings the oral reference dose (RfD) used in this rulemaking well below EPA's reference dose for manganese (0.14 mg/kg/day). In TFA's opinion, EPA's proposal does a disservice to the general public by implication, and due to its failure to clearly communicate that manganese is completely essential for normal development and maintenance of health. To suggest as EPA's proposal does, that the presence of manganese in the environment is hazardous is completely irrational. By establishing a lower level for risk assessment, EPA implies that manganese at higher levels is hazardous. As EPA well knows, at these levels and in these forms, this is not true.

Second, EPA is considering adding manganese to the Appendix VIII group of hazardous constituents due to its alleged toxicity via the oral route. As explained below, the data upon which EPA relies are limited and have several notable deficiencies. Due to the efficient handling of manganese by the human body, it is unclear whether exposure to manganese via the oral route induces toxicity and at what level this could occur.

Third, the design of the conceptual exposure scenarios for both children and adults are flawed. In particular, the use of extended duration exposures for children and the assumption of 100% for the fraction of ingested tap water derived from the contaminated source for adults are questionable.

And, finally, the suitability and calibration of the EPACMPT model are uncertain. There has not been sufficient time, given the short comment period, to thoroughly investigate the peer-review comments of this model or to evaluate the model code.

We now turn to our reasons for objecting strenuously to EPA's proposal on manganese.

Response 13-2: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2a: Manganese is an Essential Element.

EPA states that manganese has been shown to be a neurotoxin with oral exposure in both humans and animals.¹⁴ In the context of human health and nutrition, this conclusion is completely misleading. Manganese is not toxic in the usual sense of that word. Rather, manganese is an essential element in all biological systems, including plants, animals, and humans. Manganese is essential for normal neurological development and function. Accordingly, the hazard and risk assessment process for manganese must be inherently different, because fundamental assumptions normally present are not true. One typical assumption is that lower exposure assures a lower probability of adverse affect. In fact, at some point, for nutritionally essential substances, lower exposure results in greater

¹⁴EPA Risk Assessment Background Document at p. 6-32.

probability of adverse effect.

Secondly, in comparison to many chemical substances, because it is an essential element, human tolerance for widely varying exposure to manganese is much more robust. As discussed below, the biochemical systems that control manganese levels in the body, specifically when exposure occurs via ingestion, are capable of mediating large amounts for long periods of time. These two characteristics of manganese toxicity mean that the usual approach to regulating toxic substances is inherently inappropriate.

EPA's failure to emphasize the critically important role of manganese leaves the impression that one is inherently better off with less exposure to manganese, an incorrect inference.¹⁵ As with all biologically essential chemicals, this is true up to a point; at that point, the lack of exposure can be devastating. Manganese is an essential component of the daily human diet, necessary for such functions as the formation of connective tissue and bone, the metabolism of carbohydrates (sugars and starches) and lipids (fats), and neurological development and function. Manganese is commonly used as a soil amendment essential for normal plant development¹⁶ and is also highly significant for animals. It has been established for more than 30 years that, in animals, manganese deficiency causes impaired growth, skeletal abnormalities, ataxia, defects in lipid and carbohydrate metabolism, nervous system disorders, and reproductive and developmental disorders.¹⁷ Thus, manganese is essential for all forms of life, and deficiency as well as excess can produce adverse effects.

Few, if any, cases of manganese deficiency or over-exposure through oral routes in humans have been reported. However, it is well known that deficiencies in essential chemicals at critical times of development nearly always result in lifelong deficits. Moreover, such effects are often insidious, occurring slowly, and unnoticeably over time, until the deficit is so large that it becomes clinically or biologically significant. Thus, EPA's current characterization of its concern for release of manganese to the environment, which could promote public

¹⁵See, e.g. 65 FR 55763 ("We believe the available studies clearly show that manganese has toxic effects on humans and other life forms."); 65 FR 55687 ("We are also proposing to add manganese to the list of hazardous constituents in Appendix VIII, based on scientific studies that demonstrate manganese has toxic effects on humans and other life forms."); 65 FR 55768 ("Manganese represents significant risk to human health and the environment..."). TFA submits that these references are misleading under any reasonable standard of a full and accurate discussion of the issues, and should be deleted from the final rule.

¹⁶Manganese is necessary for chlorophyll formation. Michigan State University Extension. Soils & Soil Management - Fertilizer - 05209705 (1997). As noted, manganese deficiency in soils is commonly corrected by soil application of the compound. Manganese sulphate and manganous oxide are the most common carriers of manganese to the plant. Manganese sulphate is highly soluble in water. Manganese-The Other Uses. S.A. Weiss. Garden City Press, Ltd., 1997. p. 266-267.

¹⁷Hurley, L.S. and Keen, C.L. 1987. Trace elements in human health and animal nutrition, Vol. 1. Underwood, E. and Metz, W., Eds. Academic Press. New York.

aversion to manganese "exposure," must be revised. As discussed next, manganese intake represented as "high" in EPA's proposal represents completely acceptable levels for the general population, and for individuals at all ages.

Response 13-2a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2b: Homeostatic Mechanism of Manganese.

The way that the human body processes and eliminates manganese is believed to play a critical role in maintaining manganese homeostasis in the face of wide variation in daily or average, short-term manganese intake. Because it is so highly efficient, accumulation of manganese in the body is clearly limited, even in the presence of substantially higher than normal daily dietary intake rates, except in well-defined diseases (e.g., liver ailments).¹⁸ The scientific basis of any proposal to regulate manganese intake, including this proposal, must be questioned if this mechanism is not considered in defining the levels of exposure to manganese that are hazardous, or conversely, without risk.

Manganese deposited in the GI tract is absorbed by passive and active transfer mechanisms across the intestinal wall into capillaries that drain into the portal veins leading directly to the liver. There, the amounts of manganese in the blood stream are regulated by sophisticated chemical control systems.¹⁹ Roels²⁰ described it as follows:

Once entered into the blood circulation, [manganese] is cleared from the blood within a few minutes and concentrates rapidly in the liver where the primary homeostatic mechanism is exerted at the level of excretion via the bile. . . . Part of the [manganese] excreted with the bile probably undergoes hepatic circulation. . . . Whatever the route of absorption, the elimination of [manganese] is almost exclusively via the feces. . . . the normal concentrations of [manganese] in whole blood and in urine are less than 20 ug/L and 30 ug/L, respectively. [Citations

¹⁸Agency for Toxic Substances and Disease Registry. Toxicological Profile for Manganese (ATSDR). 1992. Draft for Public Comment (Update) (hereinafter ATSDR Draft Profile. U.S. Environmental Protection Agency (EPA). 1984. Health Assessment Document for Manganese. Final Draft. Cincinnati, OH EPA. RIN No. 600-83-013F (hereinafter EPA Draft Health Assessment Document).

¹⁹Patty's Industrial Hygiene and Toxicology. 1991. General Principles. 4th Edition. Volume 1, Part A. George D. and Florence E. Clayton, Eds. John Wiley & Sons, Inc.

²⁰Roels, H., Lauwerys, R., Genet, P., et al. 1987. Relationship between external and internal parameters of exposure to manganese in workers from a manganese oxide and salt producing plant. Am. J. Ind. Med. 11:297-305.

omitted]²¹

The important conclusions here are that (1) homeostasis is regulated by the liver, and (2) large excesses of manganese are readily and rapidly excreted by the liver through the bile, with a net amount of 1-5% retained, or about 20-250 micrograms/day, depending on the individual's needs. Indeed, manganese evidences "the highest degree of homeostasis of any metal excreted via the intestine, relatively large quantities are handled efficiently."²²

The hepatic homeostatic control mechanism has an extraordinarily wide range of functional efficacy, dependent on the health status of the individual. This dose-dependent mechanism in humans -- common to all other higher animals -- controls the amount of manganese in the circulating blood via a combination of oral absorption and biliary excretion. The human system is clearly capable of easily controlling absorption and retention from daily intake amounts that range from 2 to more than 9 mg per day, the generally accepted range of normal intake for adults. When dietary supplements are taken, daily intake can easily reach 35 mg or more, representing seven to ten times the average dietary levels,²³ without reports of adverse effect.

Regarding how this mechanism operates in relation to potential routes of exposure, the liver regulates manganese retention in the body via oral ingestion. Absorption of manganese through the skin is not considered to occur to any great extent.²⁴ Inhaled manganese that is non-respirable is eventually absorbed in the GI tract and regulated by the liver as well. In contrast, respirable manganese (which is not relevant to the current RCRA proceeding) deposited in the deep lung can be first absorbed directly into the pulmonary circulation, which is why inhaled particulate is the primary target for control in an occupational setting and in ambient air rules.

Response 13-2b: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2c: Solubility and Ubiquitous Nature of Manganese.

EPA's case for adding manganese to Appendix VIII is further weakened because EPA's survey

²¹Roels reports these levels as 2 and 3 ug/100 mL, respectively. For consistency in this commentary, all data on blood levels are reported in ug/L.

²²Patty's Industrial Hygiene and Toxicology. 1981. Toxicology. 3rd Edition. Volume 2A. George D. and Florence E. Clayton, Eds. John Wiley & Sons, Inc.

²³Bolger, P.M. and Carrington, C.D. 1997. Dietary intake of manganese. U.S. Food and Drug Administration. Washington, D.C. Fifteenth International Neurotoxicology Conference, No. 3.

²⁴Rodier, J. 1955. Manganese Poisoning in Moroccan Miners. Br. J. Ind. Med.12: 21-35.

reports and risk assessment do not reveal the form of manganese that was used in the agency's modeling or discuss how the different forms of manganese affect the potential for exposure.²⁵ This is a critical point. Inorganic manganese compounds are mostly solids and thus are most likely to exist as suspended particle matter. The tendency of soluble manganese compounds to adsorb to soils and sediments can be highly variable, depending mainly on the cation exchange capacity and the organic composition of the soil. The particle size and solubility associated with manganese compounds varies, and directly influences how and where they are deposited and absorbed (Rodier, 1955). For example, certain conditions favor the formation of manganese dioxide, which is insoluble in water at neutral pH.²⁶ Yet, TFA can find no account given to the critical factor of solubility in EPA's proposal and underlying risk assessment models.

Manganese combines with chemicals such as oxygen, sulfur, and chlorine rather than occurring naturally in pure form, and readily changes from one compound or valence state to another (Patty's, 1981). For example, in water or soil of pH greater than 8 or 9, the soluble divalent manganese ion is chemically oxidized to the insoluble tetravalent form.²⁷ Given that manganese compounds vary widely in solubility, this deficiency undermines the unreliability of EPA's risk assessment because solubility is known to affect bioavailability and, therefore, hazard.

Moreover, the treatment standards proposed for manganese in Table IV-1 for K178 are not reasonable based on the amount of manganese present in the environment and because EPA did not account for dilution in the risk assessment model. Manganese in treated leachate and wastewaters will undergo both dilution and absorption prior to contact with groundwater aquifers or surface water bodies. Indeed, TFA found no mention of EPA consideration of background levels in soils or in natural waters.

Manganese is ubiquitous in the environment and the diet. It is the twelfth most abundant element and the fifth most abundant metal, comprising 0.10 percent of the earth's crust. Natural (i.e., background) levels of manganese in soil range from 40 to 900 mg/kg with an estimated mean of 300 mg/kg, with accumulation occurring in the subsoil rather than on the soil surface.²⁸ In a survey of 286 U.S. river water samples, concentrations of dissolved manganese ranged from 0.011 mg/L to more than 0.051 mg/L, whereas river water

²⁵Titanium Dioxide Background Document.

²⁶Most waters have a pH between 4 and 7.

²⁷EPA Draft Health Assessment Document at p. 3-56.

²⁸International Programme on Chemical Safety (IPCS). Concise International Chemical Assessment Document on Manganese and its Compounds (No. 12) at p. 9.

samples in the United Kingdom ranged from .001 mg/L to 0.530 mg/L.²⁹ Groundwaters typically have higher levels of manganese than surface waters due to the more acidic and reducing conditions, with levels as high as 9.6 mg/L at pH 4 and 1.3 mg/L at pH 7.³⁰

For purposes of treating soil and water, the wide range of manganese naturally occurring in both soil and water makes it difficult to determine whether or not treatment procedures would be effective, and raises the possibility that the regulated community would be forced to treat materials that are naturally occurring. Therefore, a greater variability factor should be used to account for these modifications, resulting in a correspondingly higher treatment level.³¹

Response 13-2c: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2d: Evaluation of Oral Exposure Data.

With respect to data cited by EPA that manganese is a neurotoxin with oral exposure in both humans and animals, EPA concedes in its own rulemaking and elsewhere that "the evidence is limited."³² TFA believes that this is because of the nutritional role that manganese plays. EPA's Integrated Risk Information System (IRIS) database summary for manganese indicates that:

In humans, many data are available providing information about the range of essentiality for manganese. In addition, there are many reports of toxicity to humans exposed to manganese by inhalation; much less is known, however, about oral intakes resulting in toxicity . . . rodents do not provide a good experimental model for manganese toxicity, and only one limited study in primates by the oral route of exposure is available.³³

Two noted authoritative bodies have reached similar conclusions. The American Conference

²⁹Id. at p. 9.

³⁰EPA Draft Health Assessment Document at p. 3-56.

³¹65 FR 55768.

³²EPA Risk Assessment Background Document at p. 6-32; see, also, Integrated Risk Information System (hereinafter IRIS) Database Summary for Manganese (USEPA) (Updated May 5, 1998). It is false and misleading to imply, as the proposal does, that there is little evidence on which to base a decision regarding risk of manganese exposure via drinking water. In fact, the data set on manganese from a public health perspective is as near to the optimum as can reasonably be expected, because the literature on metabolism, exposure levels, and other human toxicologic parameters are well known. In fact, the evidence is overwhelming that oral exposure to manganese sufficient to produce adverse effects occurs only rarely and at extraordinarily high doses.

³³Id.

of Governmental Industrial Hygienists (ACGIH) acknowledges that the many attempts to induce toxic effects by feeding manganese compounds have only been partially successful, and have shown that manganese administered by mouth in the inorganic form is slowly and incompletely absorbed in the bloodstream.³⁴ In addition, the International Programme on Chemical Safety (IPCS) has found the evidence for toxicity via oral ingestion of manganese-contaminated water inconclusive, stating that, "the available evidence for adverse effects associated with chronic ingestion of excess manganese is suggestive but inconclusive. (emphasis added).³⁵ The few documented instances of human health effects from oral exposure have involved very high levels of intake.³⁶

In support of its proposed rule and proposed RfD, EPA discusses the toxicity of manganese via oral exposure in connection with two studies where the drinking water was a source of manganese exposure. These are reviewed below.

1. Kawamura et al. (1941).

Kawamura et al. (1941) reported the only epidemiological study describing toxicological responses in humans consuming large amounts of manganese dissolved in drinking water, describing twenty-five cases of classical manganese poisoning with symptoms including lethargy, increased muscle tonus, tremor and mental disturbances.³⁷ The drinking water was reported to contain approximately 14 mg Mn/L when analyzed one month after the symptoms appeared. Retrospective extrapolation estimates that the concentration of manganese in the drinking water at the time of exposure may have actually been 28 mg/L.³⁸ The most severe symptoms were observed in elderly people, while children appeared to be unaffected. It is unclear whether the investigators considered occupational or dietary exposures.

Velazquez and Ru (1994) reviewed Kawamura and note that the "concentration of manganese at the time of exposure was probably at least 28 mg Mn/L" and further that "the

³⁴American Conference of Government Industrial Hygienists (ACGIH). 1996. Supplement: Manganese, Elemental, and Inorganic Compounds.

³⁵International Programme on Chemical Safety (IPCS). , Concise International Chemical Assessment Document on Manganese and its Compounds (No. 12). World Health Organization, Geneva (1999) at p. 9.

³⁶ATSDR Draft Profile. EPA. 1995. Integrated Risk Information System (IRIS) Summary of Manganese. (hereinafter IRIS Summary).

³⁷Kawamura R., Ikuta H., Fukuzumi S., Yamada R., Tsubaki S. Intoxication by manganese in well water. *Kitasato Archives of Experimental Medicine* 1941. 18: 145-171.

³⁸IRIS Summary at p. 5-6.

total intake was at least 58 mg Mn/day.³⁹ Referring to Kawamura, the Agency for Toxic Substances and Disease Registry (ATSDR) states, "[t]hus, while there is no doubt these people were exposed to manganese, there is considerable doubt that all of the features of this outbreak (particularly the deaths) were due to manganese alone."⁴⁰ In the discussion by Velazquez and Ru, it was pointed out that certain effects appeared inconsistent with documented traits of manganism, including rapidity of onset and reversibility. Kawamura reported that zinc was also present in the well water at elevated levels. The presence of zinc is at least suggestive that other constituents, potentially unidentified, are at least partially responsible for effects noted in the study.

2. Kondakis et al. (1989).

EPA cites a second study of manganese in drinking water by Kondakis et al. (1989) that was conducted in three areas in northwest Greece.⁴¹ Manganese concentrations in natural well water were 0.0036 to 0.0146 mg/L in area A, 0.0816 to 0.2526 mg/L in area B, and 1.6 to 2.3 mg/L in area C.⁴² The authors reported that there was a significant difference in neurologic scores between areas A and C even when both age and sex were taken into account. However, differences in occupational exposures and general health status of the subjects in the three test areas were not reported, and could contribute to the differences seen in the neurologic scores. Neither were the exposure metrics adequately described.

Several reviewers of Kondakis et al. have urged extreme caution in interpreting the results of this study. Numerous deficiencies have been identified in the reporting and scoring of the alleged neurological effects, as well as in the evaluation of dietary manganese exposure. Specifically, in ATSDR (1992) concerns with the Kondakis study were based on several issues, including:

1. "No details were reported on which neurological signs or symptoms were increased, so it is difficult to judge if the difference was due to effects characteristic of manganism or to nonspecific parameters",
2. "The weighting factors assigned to each neurological sign were largely arbitrary and it is not clear whether the same results would have been obtained if different weighting factors had been used",
3. "Many of the parameters included in the scoring were subjective (e.g., weakness,

³⁹Risk Assessment of Essential Elements. Mertz, Abernathy, and Olin (1994).

⁴⁰ATSDR Draft Profile at p. 45.

⁴¹Kondakis X.G., Makris N., Leotsindis M., Prinou M., Papapetropoulos T. Possible Health Effects of High Manganese Concentration in Drinking Water. Archives of Environmental Health May/June 1989. 44(3): 175-178.

⁴²Original unit values for concentrations of manganese in water were converted from (g/L to mg/L for comparison purposes among studies discussed.

irritability, insomnia, depression, poor memory), and little effort was taken to avoid bias in the examiner or in the study populations",

4. "As in all ecological studies of this sort, no evidence was obtained to indicate that those individuals who experienced neurological signs did in fact ingest higher levels of manganese than unaffected individuals" and,

5. "The authors reported that the populations in the towns were very similar to each other, but provided little data to substantiate this. In this regard, even small differences in age, occupational exposures, or general health status could account for the small differences observed."

Additionally, a major shortcoming with the Kondakis study is the lack of demonstrable evidence that the manganese concentrations in drinking water, at the levels cited (i.e., up to 2.3 mg/L), were directly responsible for observable health effects. The levels reported in the study could account for no more than approximately 5 mg of additional manganese intake per day (assuming the standard two liters per day ingestion rate for water). This amount is well within the normal variation in daily intake of manganese that would be routinely experienced and, based on current knowledge of manganese, cannot have produced the effects reported. Also, this amount is not considered sufficient for toxic effects to be exhibited.⁴³

Due to the advanced age (over 50) of the study group used in the Kondakis study, the findings may not be applicable to other age groups, such as children. The study group in the Kondakis epidemiologic study included only individuals over the age of 50. The reason that an older subject group was selected for the study was the premise (which may, in fact, not be true) that the neuro-motor and behavioral impacts due to manganese that were assessed are only manifested after chronic, long-term exposure. Acute and subchronic exposures, including exposures to children, would not result in any observable effects. Therefore, extrapolation of these results to younger populations is considered inappropriate.

The presence of other chemicals, especially metals, may have substantially influenced the results and were not accounted for in the study design. The Kondakis study indicated that, in all study groups, the concentrations of all metals, except manganese, were within the maximum admissible concentrations of the EEC directive. While the concentrations of metals other than manganese were not reported, it is noted that the EEC directive that was in use in 1986 (the time of the Kondakis study) specified an allowable lead concentration of 0.05 mg/L and an allowable copper concentration of 3 mg/L. Subsequent to the time of that study, EPA has established an action level for lead of 0.015 mg/L and an action level for copper of 1.3 mg/L. The reason that the 0.015 mg/L action level was established for lead was largely due to neurological effects. It is, therefore, possible that metals other than manganese are present in one or more of the study areas at concentrations that subsequently

⁴³ATSDR Draft Profile. Patty's Industrial Hygiene and Toxicology. 4th ed.. Vol. 1, Part A.

have been determined to have adverse neurological effects, and that the presence of these other metals may have produced the results of the Kondakis study. It is not unusual for several metals to be present in high concentrations in mineral-rich groundwater, such as the groundwater associated with the "high manganese" study group. Unfortunately, the study does not provide information on the concentrations of other metals. It is recommended that EPA determine whether other constituents present in the groundwater could have influenced the outcome of the study.

The differences in the neurological scores also may be due to the random distribution of a few individuals and not the concentration of manganese. This possibility was not examined in the Kondakis study. An examination of the neurological scores published in the Kondakis study (see Table 1 below) suggests that the neurological scores in all study groups and the differences in the mean neurological scores between study groups are largely due to only a few individuals who had high scores. If this is the case, the differences between the study groups may be due, at least in part, to the random distribution of these few individuals. Unfortunately, the study does not provide information on the individual neurological scores needed to assess this possibility.

Table 1. Neurological Scores in the Three Study Areas.*

Study Area	Sex	Number of Subjects	Mean Score	Range of Scores
Low manganese	Males	34	2.4	0-21
	Females	28	3.0	0-18
	Combined	62	2.7	0-21
Medium manganese	Males	22	1.6	0-6
	Females	27	5.7	0-43
	Combined	49	3.9	0-43
High manganese	Males	40	4.9	0-29
	Females	37	5.5	0-21
	Combined	77	5.2	0-29

*After Kondakis (1989) Table 4

An example of how a few individual scores can influence the overall group score is shown when the scores for the male and female groups in Area B are compared. These two groups display the highest and the lowest mean scores of all groups, including the differences between the two Area A groups and two Area C study groups. Kondakis determined that the difference was statistically significant. However, it would not have been anticipated that the largest difference between mean neurological scores was between males and females from the same study area. The reason for the large difference in scores is that one or, at most, a few females in Area B had high scores and no males had high scores. It is anticipated that the reason for this difference was not associated with manganese but instead was associated

with the random distribution of scores. This statistical difference, which was largely ignored by Kondakis, indicates that variables (in this case gender) other than manganese concentrations in well water have been demonstrated to result in statistically meaningful differences in test scores. Because this observation, while not plausible, has been demonstrated in the Kondakis study, it is believed that variables, specifically the random distribution of high scores, have potentially biased the results. It is, therefore, recommended that EPA determine whether the observed differences in neurological scores between the groups is due to the random distribution of a few individuals in the study groups instead of actual differences between the study groups.

To evaluate the actual significant differences, if any, between the study groups, use of parametric statistical test should be considered. Kondakis indicates that non-parametric statistical tests were used to test for significant differences between study groups. Such tests compare the rankings of individuals, but not the actual scores. EPA should determine whether a statistical examination of the actual scores would be more appropriate in assessing the differences in the groups. This is particularly true when dealing with a number of individual scores that are grouped closely together and when the scores are based on subjective, non-quantitative symptoms. It should be noted that EPA does not commonly use ranking tests when evaluating data, but instead uses parametric statistical tests with transformed data, as necessary. EPA should determine whether it is appropriate to use non-parametric test such as the Mann-Whitney, Kuskall-Wallis, and Jonckheere tests on such data sets or whether parametric tests, such as those commonly used by EPA, should be employed.

Differences in age may account, at least in part, for the differences in neurological scores. While Kondakis indicated that "no age differences were observed between areas and/or within sexes", this variable was not considered or adequately evaluated in the study. An examination of the ages and the neurological scores published in the Kondakis study (see Table 2 below) indicates that the highest mean neurological scores are correlated with the highest mean ages. Differences in age may significantly impact differences in neurological scores. If this is the case, the differences between the study groups may be due, at least in part, to age. Unfortunately, the study does not provide information on the individual neurological scores and ages needed to assess this possibility. The study clearly demonstrates that the mean ages of all of the study groups overlap within a standard deviation of one another. However, it is expected that the standard deviations of the neurological scores of all of the study groups (except possibly Area B males) overlap within one standard deviation and Kondakis clearly does not consider that no neurological score differences were observed between areas based on overlapping standard deviations. This appears to be inconsistent with the decision making process used for assessing age differences between the groups. It is recommended that EPA determine whether the observed differences in neurological scores between the groups are due, in total or in part, to differences in the ages of the subjects in the study groups instead of differences in manganese concentrations.

Table 2. Comparison of Ages and Neurological Scores.*

Study Area	Sex	Mean Age	Mean Score	Comparison of Rankings (age-score)**
Low manganese	Males	64.9	2.4	8-8
	Females	66.4	3.0	5-6
	Combined	65.6	2.7	6-7
Medium manganese	Males	63.7	1.6	9-9
	Females	66.8	5.7	4-1
	Combined	65.4	3.9	7-5
High manganese	Males	67.3	4.9	3-4
	Females	68.0	5.5	1-2
	Combined	67.6	5.2	2-3

* From Kondakis (1989)

** From lowest to highest rankings

3. Vieregge et al. (1995).

An ecological cross sectional study of 41 adults studied by Vieregge et al.⁴⁴ contradicts the findings by Kondakis. Vieregge et al. found no clinical, sub-clinical or subjective differences attributable to manganese between a group exposed to drinking water with manganese levels ranging from 0.3 to 2.16 mg/L and a group with drinking water containing 0.05 mg/L manganese. This study used more sensitive tests and did not confirm the Kondakis et al. study. Thus, the Vieregge study offers an additional basis for why the Kondakis study does not support EPA's proposed use of a modifying factor.

In addition to standard questionnaires, neurological examinations and blood tests, Vieregge et al. used instrumental testing including tests for hand tremor and rapidity of motion. No clinical, sub-clinical or subjective differences attributable to manganese were observed in this definitive study. This study used more sensitive tests, and contradicted the Kondakis et al. 1989 study. Kondakis et al. found subjective differences (questionnaire) and hair manganese concentration differences attributed to manganese but did not perform any sensitive instrumental testing for sub-clinical movement disturbances.⁴⁵

The Vieregge et al. study was published in November 1995, after EPA had completed its

⁴⁴Vieregge, P., Heinzow, B., Korf, G., Teichert, H.M., Schleifenbaum, P., Mosinger, H.U. Long term exposure to manganese in rural well water has no neurological effects. *Can J Neurol Sci* Nov. 1995. 22(4): 286-9.

⁴⁵Supra n. 34.

peer-review of the RfD for manganese in July 1995. Because this proposed rule relies almost solely upon the IRIS documentation for support, EPA completely failed to consider the findings of Vieregge et al. in this rulemaking.

Response 13-2d: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-2e: TFA's Response to the Use of a Modifying Factor of 3 for the Proposed RfD for Drinking Water Ingestion.

The IRIS database reflects that EPA has established an oral RfD for manganese of 0.14 mg/kg/day with a recommended modifying factor of 1 for ingestion in the diet.⁴⁶ The value is based on a reported no observable adverse effects level (NOAEL) of 10 mg/day. However, this RfD is apparently restricted to dietary exposure (i.e., solid foods) only. In 1995, EPA recommended that a modifying factor of 3 be applied when using the RfD for assessments involving non-dietary exposures (i.e., drinking water and soil). The proposed rule is using that recommendation in examining manganese in drinking water and soil. Applying a modifying factor of 3 yields a RfD of 0.047 mg/kg/day.

The initial reason provided for the use of a modifying factor of 3 appears due to EPA's concern that the results of one study (Kondakis et al.) raises the possibility of adverse neurological effects at doses "not far from" the range of ESSADI. As detailed in TFA's discussion of Kondakis et al., this has now been shown to be unnecessary and scientifically unsupportable.

In addition, EPA cites results from a study that indicate some degree of increased uptake of manganese from water in fasting individuals as another basis for the use of a modifying factor. This suggestive finding is more indicative of the lack of competing cations (Ca²⁺, Fe²⁺) in the fasting state than of a different chemical form of manganese. At any rate, the oral reference dose for manganese is based on chronic human consumption. It is highly unlikely that a significant portion of any individual's drinking water is consumed in the fasting state (either adults or infants) and therefore, is irrelevant for a lifetime oral exposure risk assessment.

EPA also relies, as a basis for the use of a modifying factor, upon a concern that infant formula, which typically has higher concentrations of manganese than does human milk, could be combined with water with a high level of manganese. Stastny et al. (1984) demonstrated that, although infant formulas contained significantly higher manganese levels than human milk, there were no difference in blood levels manganese levels among infants

⁴⁶EPA Risk Assessment Background Document at p. 4.

fed formula compared with breast fed infants.⁴⁷ Lonnerdal (1985 and 1989) reported that relative manganese absorption from breast milk is much higher than from infant formulas.⁴⁸ This was explained by the presence of lactoferrin in human milk, which may facilitate iron and manganese uptake. High concentrations of casein in cow's milk and cow's milk formulas limit trace element absorption and the presence of phytate in soy formula limits absorption of trace elements.

Cow-milk formulas currently contain 30-75 ug/L manganese and soy formulas contain 100-300 ug/L, down from the 300-1,400 ug/L concentrations a few years ago.⁴⁹ Soy protein isolate formulas still contain 1.5% phytates and all soy-based formulas are now, iron-fortified.⁵⁰ Both the phytate and iron in soy based formulas inhibit manganese absorption. There are no reports in the literature of neonatal manganese toxicity attributable to infant formula or water.

EPA indicates as its final justification for the modifying factor that there is some evidence that neonates absorb more manganese from the GI tract, are less able to excrete absorbed manganese, and that absorbed manganese more easily passes the blood-brain barrier. Manganese is known to be essential for normal skeletal development. Recent studies indicate that significant physiological responses occur during pregnancy and lactation to help assure adequate manganese for the infant. Stastny et al. (1984) demonstrated that mean human milk concentrations decreased with progression of lactation from 6.6 ug/L during the first month to 3.5 ug/L by the third month. Spencer (1999) demonstrated that maternal whole blood manganese levels increase throughout pregnancy and are approximately 3 fold higher in the neonate.⁵¹ Krachler et al. (1999) demonstrated that manganese was 150% higher in cord blood than in maternal blood and that manganese

⁴⁷Stastny, D., Vogel, R.S., Picciano, M.F. Manganese intake and serum manganese concentration of human milk-fed and formula-fed infants. *Am J Clin Nutr* Jun 1984. 39(6): 872-8.

⁴⁸Lonnerdal B. Dietary factors affecting trace element bioavailability from human milk, cow's milk and infant formulas. *Prog Food Nutr Sci* 1985. 9(1-2): 35-62. Lonnerdal B. Trace element absorption in infants as a foundation to setting upper limits for trace elements in infant formulas. *J Nutr* Dec. 1989. 119(12 Suppl): 1839-44.

⁴⁹Lonnerdal B. Effects of milk and milk components on calcium, magnesium, and trace element absorption during infancy. *Physiol Rev* Jul. 1997. 77(3): 643-69.

⁵⁰American Academy of Pediatrics. Soy protein-based formulas: recommendations for use in infant feeding. Committee on Nutrition. *Pediatrics* January 1998. 101(1): pp. 148-153.

⁵¹Spencer A. Whole blood manganese levels in pregnancy and the neonate. *Nutrition* Oct. 1999. 15(10): 731-4.

concentrations in colostrum were twice that in maternal serum.⁵² These findings confirm a physiological concentrating effect of manganese throughout pregnancy and more dramatically so in the neonate which is highly suggestive, if not confirming of a vital role in fetal development. Further, there are no reports in the literature of neonatal manganese toxicity or of pediatric manganese toxicity in the absence of total parenteral nutrition or biliary atresia. Thus, available human evidence suggests that, contrary to current conventional wisdom," the very young are the least susceptible population for manganese neurotoxicity. This concern by EPA is not well founded.

Ultimately, EPA's stated reasons to support any safety factor fail for one simple reason. The safe level of ingested manganese in humans for all ages is known to a reasonable medical certainty. Unlike the usual situation, the data on human exposure and human risk at high levels of exposure are known, and a wealth of knowledge about the importance of manganese to children is available. In contrast, EPA has offered no firm evidence that ingested manganese at levels at or immediately above of the RfD is toxic or hazardous. Given the evidence cited above, concern about uncertainty with regard to children is misplaced. Although EPA expresses concern for neonates possibly absorbing more manganese from the GI tract, actual studies with human neonates have demonstrated that plasma levels of manganese in neonates are maintained regardless of the level of manganese intake.⁵³ This indicates that the body's mechanisms are calibrated to retain manganese at a time when its essentiality for proper development could be critical, affirming its importance to infants and children. Thus, contrary to the situation with many chemicals, sufficient knowledge of manganese exists to conclude that no adjustment of oral exposure limits need be made to protect infants and children. Thus, the RfD should not be adjusted on this basis.

Given the essentiality of manganese and that the papers cited above are all studies of human populations, there is no scientific justification for applying any factor to modify the RfD. A safety factor other than one would reduce the allowable drinking water level below the level known to be safe, clearly an unreasonable and irrational result, and one not authorized under law. EPA has offered no reasonable basis for not following the same course in this proceeding as it followed in establishing the oral RfD.

Response 13-2e: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

⁵²Krachler, M., Rossipal, E., Micetic-Turk, D. Trace element transfer from the mother to the newborn-investigations on triplets of colostrum, maternal and umbilical cord sera. *Eur J Clin Nutr* Jun 1999. 53(6): 486-94.

⁵³Wilson, D.C., Tubman, T.R., Halliday, H.L., McMater, D. Plasma manganese levels in the very low birth weight infant are high in early life. *Biol Neonate* 1992. 61(1): 42-6.

Comment 13-3: Changing the RfD to 0.14 mg/kg/day Eliminates the Justification for EPA's Proposed Regulatory Level for Manganese.

EPA's selection of 10 mg/day as the NOAEL appears to be based on three studies of dietary intake for manganese. In a 1989 report, the Food and Nutrition Board of the National Research Council (NRC) determined an "estimated safe and adequate daily dietary intake" (ESADDI) for manganese to be 2 to 5 mg/day. A 1987 study by nutritionists Freeland-Graves et al. suggested a range of 3.5 to 7 mg/day based on human health studies. The third study published by the World Health Organization (WHO) in 1973 reported the average daily consumption of manganese to range from 2 to 8.8 mg/day. In this report the WHO concluded that an intake of 8 to 9 mg/day is "perfectly safe".

In a 1996 document, the WHO reported updated dietary intakes for manganese. In that report the intake range was given as 2 to 20 mg/day. The WHO concluded: "The intake of manganese can be as high as 20 mg/day without apparent ill effects".⁵⁴ The NRC is currently reviewing dietary reference intakes for various micronutrients including manganese. As part of this review, the NRC plans to determine "tolerable upper intake levels" for each nutrient.

The EPA's selection of 10 mg/day as a "NOAEL" appears to be based on the upper end of dietary intake guidelines rather than being based on an intake that is actually safe for human consumption with no observable adverse effects. EPA is not authorized to establish regulatory limits below those levels necessary to protect public health. Therefore, EPA should revise the RfD for manganese based on these data and set a higher NOAEL.

As previously explained, the physiological basis for a higher acceptable level of oral exposure is the fact that most experts recognize that the oral pathway, except for extreme cases of very high exposure, is by and large not a significant health risk.⁵⁵ There are two reasons for this: (1) the rate of absorption of manganese from the gastro-intestinal (GI) tract after oral intake is only three to five percent, and (2) the body has a very effective homeostatic mechanism by which excess manganese is excreted following oral intake.⁵⁶ For the foregoing reasons, the oral RfD of 0.14 mg/kg/day is the more appropriate value for EPA's risk assessment.

The use of a RfD of 0.14 mg/kg/day substantially reduces the frequency of manganese

⁵⁴World Health Organization. 1996. Guidelines for Drinking-Water Quality, 2nd Ed. Vol. 2. Health Criteria and Other Supporting Information. Geneva, Switzerland. pp. 276-284.

⁵⁵Klaassen, C.D. Casarett & Doull's Toxicology: The Basic Science of Poisons. McGraw-Hill. 1996.

⁵⁶ATSDR Draft Profile.

exceeding the HQ at the levels observed in the proposed K178 waste stream.⁵⁷ Based on TFA's calculations, a HQ greater than 1 would only be present at the 99th percentile for adults (1.4). A HQ greater than 1 but less than 2 (1.8) for children would only be present at the 97.5th percentile, and the HQ for children at the 99th percentile would be reduced by 60 percent (8.6 to 2.9). As a result, the risks from the presence of manganese in the proposed K178 waste stream are low. This would be more consistent with EPA's findings for antimony in wastewaters in the titanium dioxide sector.⁵⁸ Table 3 compares the figures used in EPA's risk assessment with the use of EPA's RfD value for dietary exposure, as well as with a more realistic daily consumption estimate for manganese, in deriving HQ values for manganese in the proposed K178 wastestream.

Table 3. Comparison of HQs Based on Different RfDs and Estimated Daily Dose.

HQ at 95th Percentile

	RfD = 0.047 mg/kg/day (3.3 mg/day)	RfD = 0.14 mg/kg/day (10 mg/day)	RfD = 0.285 mg/kg/day (20 mg/day)
Adult HQ	1.6	0.53	0.26
Child HQ	3.3	1.0	0.54

HQ at 97.5th Percentile

	RfD = 0.047 mg/kg/day (3.3 mg/day)	RfD = 0.14 mg/kg/day (10 mg/day)	RfD = 0.285 mg/kg/day (20 mg/day)

⁵⁷Three facilities that produce titanium dioxide via the chloride-ilmenite process commingle their process wastewaters and subsequently generate wastewater treatment solids that EPA is proposing to regulate as not Bevill-exempt. The category consists of solids that drop out in on-site settling ponds or are filtered out of the treated wastewater prior to discharge. Manganese levels were reported at one of these facilities as follows: Total Metals Method: Hillside Pond sludge - 2,890 mg/kg; TCLP Metals Method: Final leachate from Hillside Pond sludge - 47.4 mg/L; SPLP Metals Method: Final leachate from Hillside Pond sludge - 1.5 mg/L. Titanium Dioxide Listing Background Document for the Inorganic Chemical Listing Determination (Aug. 2000) (hereinafter Titanium Dioxide Background Document).

⁵⁸EPA's Risk Assessment Background Document at p. 6-28 states: "Antimony in the chloride process-only wastewaters in the titanium dioxide sector did exceed an HQ of 1 for the child receptor at the 99th percentile. However, given the small magnitude of the exceedance (an HQ of less than 2) and the relatively low probability of occurrence (1 percent or less), risks from this waste are expected to be low."

Adult HQ	2.5	0.84	0.41
Child HQ	5.4	1.8	0.89

HQ at 99th Percentile

	RfD = 0.047 mg/kg/day (3.3 mg/day)	RfD = 0.14 mg/kg/day (10 mg/day)	RfD = 0.285 mg/kg/day (20 mg/day)
Adult HQ	4.1	1.4	0.67
Child HQ	8.6	2.9	1.4

Response 13-3: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-4: EPA's Child and Adult Resident Exposure Scenarios.

Section 5.1 of EPA's Risk Assessment Background Document states that for "cancer risk, the child resident was modeled as a 1- to 6- yr-old, with a variable starting age (for exposure) and cohort aging when applicable (i.e., in assuming lifetime average exposures where the duration of exposure must be considered)." Section 5.1 also states that for "non-cancer risk, the younger child (1- to 6-yr-old) was modeled." Table 5-1 presents the Monte Carlo distributions used in the probabilistic risk analysis. For the child resident's exposure duration, a discrete variability distribution from the 1997 Exposure Factors Handbook was used, but that exposure duration extended beyond 22 years. This is inconsistent with U.S. EPA's Risk Assessment Guidance for Superfund, Volume I -- Human Health Evaluation Manual (Part A), in which the exposure duration for a child resident of this age range would be limited to six years. By definition, the exposure duration for a child aged 1- to 6-yr cannot extend past six years. A more appropriate distribution to characterize the exposure duration for children is a uniform distribution with a minimum expected value of 1 yr and a maximum expected value of 6 yr. For non-cancer risk, the exposure duration should reflect the age of the receptor being evaluated. The child resident exposure duration distribution used by USEPA is inappropriate and grossly overestimates the actual risk that might be posed to the child. An explanation for using the extended exposure duration was not clearly provided in the document.

Table 5-1 also provides the tap water ingestion rates for child up through age 19, based upon U.S. EPA's 1997 Exposure Factors Handbook. Again, using tap water ingestion rates for children older than the 1- to 3-yr-old cohort and the 4- to 6-yr-old cohort is considered inappropriate based upon the defined exposure scenario for children. EPA has introduced

excessive and inappropriate conservatism in the risk assessment by including the 7- to 10-yr-old cohort and the 11- to 19-yr-old cohort in the tap water ingestion rate term.

The child resident and adult resident exposures were apparently based on a fraction of ingested tap water derived from the contaminated source (FI) of 100%. This is implied, because no specific discussion of the FI term, typically included in the ingestion of tap water risk calculation algorithm, was provided. Assuming 100% FI is highly conservative, but appropriate for a point estimate (deterministic) risk assessment. However, it is not considered appropriate for an adult receptor aged 20-yr to 64-yr, because one could justifiably assume that the adult works away from home (drinking water obtained from other sources) for the majority of that 45-yr exposure duration. EPA should consider adding a FI term into their algorithms 5-1 and 5-2. In a Monte Carlo risk assessment, the FI term also should be represented by a distribution. This would decrease the compounded conservatism in the risk assessment. This would result in an overall decrease in the calculated risk for the child resident and the adult resident.

The Adult Exposure Scenario should not be based on a lifetime exposure period. As discussed above, manganese is an essential element, so lifetime exposure is necessary. Moreover, data from occupational settings demonstrates that manganese blood levels correlate best with recent subchronic (measured in weeks or months) exposures. That is, long-term exposure estimates are not predictive of either observed effect or of blood manganese levels, while short term exposures are.⁵⁹ Thus, a more scientifically supportable exposure period for adults is 30-60 days, and one of 180 days is sufficiently conservative for EPA's standard setting purposes.

EPA must revise its risk estimates using the new exposure period. There is no evidence that could be put in the record to support a longer exposure period than that above, because no data in the literature support the conclusion that effects of manganese are cumulative or that a longer exposure period is necessary. Nor can EPA, in the face of the occupational and nutritional data cited above, use a default assumption of a lifetime or cumulative exposure model.

Response 13-4: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion. However, we wish to clarify the general issues raised that are related to EPA's exposure scenario. The commenter

⁵⁹Clewell, H.J. and Crump, K.S. 2000. Unpublished paper. Determination of occupational exposure guideline for manganese using the benchmark method. p. 26 (citing, Cotzias, G.C., Horiuchi, K., Fuenzalida, S., and Mena, I. Chronic Manganese Poisoning, Clearance of Tissue Manganese Concentrations with Persistence of the Neurological Picture. *Neurology* 1968; 18: 376-382; Crump, K.S., Rousseau, P. Results from Eleven Years of Neurological Health Surveillance at a Manganese Oxide and Salt Producing Plant. *Neurotoxicology* 1999; 20: 273-286; and Roels, H., Ortega Eslava, M., Ceulemans, E., Robert, A., Lison, D. Prospective Study on the Reversibility of Neurobehavioral Effects in Workers Exposed to Manganese Dioxide. *Neurotoxicology* 1999; 20: 255-272).

appears to misunderstand how EPA assessed exposures and risks for non-cancer health effects. The exposure duration parameter values listed in Table 5-1 of the risk assessment background document (*"Risk Assessment for the Listing Determinations for Inorganic Chemical Manufacturing Wastes,"* August, 2000) are used only for assessing cancer risks where the lifetime average daily dose (LADD) is used as the exposure metric. The LADD is averaged over an individual's lifetime (assumed to be 70 years). For assessing risks from other, non-cancer effects, EPA used the average daily dose (ADD). As shown in Equation 5-1 of the risk assessment background document, the ADD is not averaged over an individual's lifetime but, instead, is based only on the individual's tap water intake rate (and the concentration of the contaminant in tap water). The distribution of tap water intakes for the child exposure scenario is given in Table 5-7. EPA averaged the tap water intake rates for the 1 to 3 year old and the 4 to 6 years old cohorts to obtain the average intake rates for use in calculating the ADD for the child exposure scenario. A similar procedure was used for adults, as explained in Section 5.5 of the risk assessment background document.

As indicated by the commenter, EPA assumed that substantially all of an individual's tap water is derived from a domestic well impacted by a plume of contaminants from the source of contamination. However, for lifetime exposures (i.e., calculation of the LADD), EPA assumed exposures to contaminated tap water occurred for only 350 days a year rather than the entire year. In addition, EPA used time-averaged ground water concentrations for assessing tap water exposures. For assessing risks other than cancer, EPA used a 9 year average well-water concentration. To the extent that exposure times shorter than 9 years are of interest (e.g., exposures to children ages 1 to 6), EPA may have underestimated the average daily dose (ADD). However, EPA would not expect ground water concentrations averaged over time periods less than 9 years, nor peak ground water concentrations, to greatly exceed the 9 year average concentration. For assessing cancer risks, EPA averaged the well-water concentration over the duration of exposure.

Comment 13-5: EPA's Risk Assessment Model.

Comment 13-5a: Calibration, Validation and Post Audit.

Model calibration is a process that determines if a model is suitable for use as a predictive, decision-support tool. It takes the form of a comparison and/or history matching between model predictions and actual site conditions, given a common set of input variables.

Modeling of human health risk from releases to the environment typically relies on relatively simple closed-form analytical solutions, which have been developed using the human health toxicological dose-response relationship in the scientific body of knowledge. Using these closed-form analytical solutions, the result of modeling human health response to a release to the environment is typically assumed to represent reality, with no supporting calibration to ensure that the model is predicting accurately and representative of actual situational conditions. This assumption, unsupported by calibration is justified in the case of human health, dose-response risk modeling on the basis that it represents the best available scientific approach.

Ground water flow and solute transport models on the other hand, must successfully pass a calibration process to be suitable for making predictions of flow and solute transport scenarios. The best available scientific approach for minimizing any uncertainty of a ground water model's predictive capability is to qualitatively and quantitatively compare model predictions to actual site conditions, using a common set of input variables, e.g., aquifer boundary conditions, geology/hydrogeology, recharge and discharge areas, hydraulic conductivity distribution.

U.S. EPA's "full-scale modeling" effort as described in the risk assessment document comprises numerous deterministic solute transport calculations, using a range of statistically prepared input variables. However, it appears that no calibration was ever performed either for the unsaturated or the saturated flow and transport models that would substantiate the model's use as a predictive tool for determining concentrations at a point downgradient for this study. Site-specific data that could have been used to perform a calibration of the ground water flow conditions were compiled by U.S. EPA, as noted in the report, but were apparently not used for this purpose. At a minimum, the underlying ground water flow model must have successfully undergone a calibration prior to the construction and running of a predictive contaminant transport model. Typically a contaminant transport code uses the result of the ground water flow calculations as inputs to the calculation of contaminant advection and dispersion through the system.

No requirements for future validation/post audit of the model, and/or associated revision in the findings where appropriate, were noted in the risk assessment document. Validation/post audit is a mechanism for reassessing the suitability of the model through time relative to its appropriateness for use in making predictions of ground water flow and contaminant transport. It provides a second check on the capability of the model to accurately predict ground water flow and solute transport scenarios.

If the modeling effort by EPA did include calibration and validation, the information must be made available for outside review under the Administrative Procedures Act if it is to be used and EPA intends to rely on it to support a standard like that in the proposal. In the event calibration and validation were not conducted, EPA must at least describe the technical rationale EPA has provided to support that determination.

Response 13-5a: The calibration, validation, and post-audit such as described by the commenter are the processes applied to the development of detailed groundwater models that are used as predictive, decision-support tools at specific sites. Applying such models to a given site takes a long period of time (often years) and requires a very substantial investment in terms of effort expended for model development and data collection and analysis. For practical reasons, such specialized, site-specific models are not particularly useful in the regional site-based, probabilistic simulation modeling approach that EPA believes is appropriate for hazardous waste listing determinations, such as for the inorganic chemical manufacturing listing determination.

The regional, site-based, probabilistic simulation modeling approach represents a screening-level stochastic methodology that predicts the distribution of ground water concentrations for a given chemical at all sites where a particular type of waste is (or could be) managed. In a given realization of such a Monte-Carlo simulation, the site is selected from among the waste management sites retrieved from the site data file. The site data file contains all parameters that are associated with the site location, including waste, waste management unit, soil, aquifer, and climate-based parameters. For the inorganic chemical manufacturing industry, these data often reflect the variability in hydrogeologic conditions anticipated to be present within a region demarcated by a 100-mile radius ring from a given facility.

Chemical transport in ground water at the selected site is simulated using a simplified, physically-based flow and transport model designed to capture the salient characteristics of the flow and transport processes (e.g, general flow direction and approximate speed, dispersion, advection, sorption, degradation, etc.). The flow and transport model used for each site is not calibrated using site-specific hydrogeologic and climatic data. Instead, multiple sets of parameter values (along with various assumptions) are utilized in the flow and transport simulation to account for parameter variability and uncertainty, as well as the simplifications inherent in such a model. Because the data are site-based, correlations among hydrogeologic parameters (e.g., hydraulic conductivity and hydraulic gradient) are taken into account. The result of the model simulation is a distribution of ground water concentrations that is used in the subsequent exposure and risk analysis.

The simplified flow and transport models imbedded in the regional site-based, probabilistic approach are also useful for regulatory analyses because of their computational efficiency. Such analyses would not be possible with detailed, calibrated site-specific models that demand intensive computational resources. For this reason (and the reasons given previously), extensive calibration, validation, and post-audit processes are not appropriate for, nor consistent with, the requirements of many regulatory applications. EPA considers the development of detailed site-specific models (with the processes of calibration, validation, and post-audit implemented as described by the commenter) to be more appropriate for purposes of site management and/or remediation than for the purpose of hazardous waste listing determinations.

EPA has used the EPACMTP ground water model and related data bases in the context of listing determinations for over a decade for modeling fate and transport of contaminants in ground water. The simplified flow and transport model used in the EPACMTP code has been applied to actual site conditions in a limited model validation exercise. Reasonable agreement was found between the observed data and simulation results (Kool et al., 1994).

Kool, J.B., Huyakorn, P.S., Sudicky, E.A., and Saleem, Z.A., (1994). A composite modeling approach for subsurface transport of degrading contaminants from land-disposal units. *J. of Contaminant Hydrology*, V.17, pp. 69-90.

Comment 13-5b: EPA Model Issues That Affect The Agency's Conclusions.

The EPACMTP computer code used by the U.S. EPA does not appear to be in the public domain. A search of the main U.S. EPA web site, and of the separate U.S. EPA technical web sites which are devoted to models and modeling of the environment failed to locate a reference/link which would permit a copy of the code and its technical documentation to be obtained. Only a single reference to a guidance document for the code was identified. If this code has undergone significant peer/legal review since its recent development for the U.S. EPA, no evidence of this was located. This code is a significant technical basis underlying EPA's proposed rule, and must be made available to the public if EPA intends to rely on it in the rulemaking.

For comparison, MODFLOW is a code for modeling ground water flow developed by the US Geological Survey. It is in the public domain and, therefore, readily available for use by anyone. This code is well documented including example input-output cases. Because of its wide availability, MODFLOW has been used extensively worldwide by researchers in government and academia, as well as by practicing scientists in the consulting and industry sectors. It has undergone slight revisions over time in response to technical feedback from the scientific community and has also been subjected to substantial legal review/scrutiny in ground water litigation cases. This code is well established and legally defensible as a tool for modeling ground water. The same cannot be concluded for the U.S. EPA's EPACMTP code based on a lack of available information about the history of the code, as well as the fact that it appears to have been only recently developed for use by the U.S. EPA (mid 1990s).

While there does appear to be some literature on use/evaluation of the code by experts at or affiliated with the U.S. EPA (e.g., James W. Mercer, et al., EPA SAB-EEC-95-010, US EPA Science Advisory Board: Review of EPA's Composite Model for leachate Migration with Transformation Products - EPACMTP), there was not sufficient time during the comment period to review the documents.

Response 13-5b: EPA has used EPACMTP and its predecessor codes for regulatory applications for well over a decade. The model has been reviewed twice by the Science Advisory Board; once in 1990 (EPA-SAB-EEC-90-009) and again in 1995 (EPA-SAB-EEC-95-010). The model has also been reviewed by experts in the field of ground water flow and transport modeling (e.g., by Dr. R. Allen Freeze, University of British Columbia; by Dr. Fred Molz, Auburn University; and by Dr. Frank W. Schwartz, Ohio State University). The EPACMTP code and user documentation are available to the public upon request. In addition, the specific version of the EPACMTP model used in the inorganic chemical manufacturing hazardous waste proposed listings (including the source code, its executable, sample input and output files, and model documentation) is available in the public docket for the inorganic chemical manufacturing proposed rule (F-2000-ICMP-FFFFF).

Comment 13-5c: EPACMTP Model Code Modifications and Re-validation.

Modifications for the EPACMTP computer code that were specifically made for this listing determination were unsupported by any level of code re-validation. U.S. EPA should address the need, or lack thereof, of a code revalidation effort relative to the modifications made to the underlying code. Slight changes to a computer code can sometimes have unpredictable results on the running of the code. This could have an impact on the end point concentration of manganese. Therefore, it is requested that EPA provide a discussion of the model re-validation results developed as part of the modeling effort.

Response 13-5c: As explained in the risk assessment background (“*Risk Assessment for the Listing Determinations for Inorganic Chemical Manufacturing Wastes*,” August, 2000), the modifications of the EPACMTP code were made specifically to the input streams of parameter values to facilitate enhancements in the source data file for use in Monte Carlo simulations. These modifications were tested by conducting model runs with the pre- and post-modified codes with identical sets of parameter values to ensure that no errors were introduced.

Comment 13-6: EPA has not Provided Adequate Notice, an Adequate Record, or a Sufficient Basis for Regulating Manganese.

To place the proposal in context, EPA's proposed rule consists of one hundred pages of text in the Federal Register. On page 3, EPA first indicates that it intends to propose the addition of manganese to Appendix VIII of Part 261. On page 80, EPA initiates a discussion of the presence of manganese in the proposed K178 wastestream. On page 86, EPA explains how it has considered various treatment technologies and the treatment levels they achieve. Finally, on page 87 of the proposal, EPA begins its first discussion of the regulatory implications of the Appendix VIII proposal that extend beyond generators of the proposed K178 wastestream. On page 89, EPA makes a presumption of low impact on the broad industry sector that will be affected and discusses available treatment capacity for absorbing the additional treatment volumes based on a limited set of data.⁶⁰ The failure to adequately consider the broad potential impact of the manganese listing in Appendix VIII and the concomitant failure to highlight the implications of listing manganese early in the description of the proposed standard invalidate the Federal Register publication as adequate notice to the regulated community. TFA only became aware of the proposal indirectly, and recognized its potential importance only after detailed study and discussion. Hidden, as it were, in the ilmenite proposal, the manganese listing could have slipped through without significant comment from those most likely to be affected and to have relevant and accurate information. To paraphrase, this is no way to run a railroad.

Nowhere in the proposed rule does EPA discuss how the proposed treatment levels minimize short-term and long-term threats to human health and the environment as section 3004(m) of RCRA directs. In this final section of its comments, TFA describes how the obscure references to manganese in EPA's proposal do not meet statutory review standards for

⁶⁰65 FR 55771

adequate notice to the regulated community. TFA further contends in this section that EPA fails to meet standards established in its own regulations for adding manganese to Appendix VIII, and for using manganese as a basis for proposing the K178 wastestream. Finally, TFA asserts that EPA's proposed technology-based treatment standards for manganese are invalid under RCRA.

Comment 13-6a: Adding Manganese to Appendix VIII Brings in Stakeholders Outside the Scope of the Consent Order.

EPA's proposal for inorganic chemical manufacturing wastes significantly impacts a group of waste streams that are completely outside the intended scope of this rulemaking: those waste streams containing manganese that are already regulated as hazardous waste due to ignitability, corrosivity, reactivity, or toxicity based on a non-metal component.⁶¹ EPA has only EPA's proposal will also impose added costs on the treatment, storage, and disposal of characteristic metal waste, i.e., those wastes exhibiting the hazardous characteristic of toxicity due to the presence of a metal listed at 40 CFR 261.24. Most, if not all, of these metal waste streams are outside the sectors covered by the consent order driving this rule.

EPA has not adequately considered the broader regulatory impact on affected industries before proposing to include manganese in Appendix VIII of Part 261 and in setting a universal treatment standard for manganese in Part 268. The agency has acknowledged as much by asking for comments on the effects and technical feasibility of the proposed treatment standard for manganese on other industries.⁶² Apparently, EPA has not considered the economic implications that these

⁶¹65 FR 55771. Based on 1997 Biennial Report data and assumptions of waste compositions and their potential for land disposal, EPA estimates an upper bound of 70,000 tons per year of non-wastewaters mixed with other waste codes and their F039 leachate will be affected. EPA estimates that no more than 520,000 tons per year of characteristic non-wastewaters potentially may be affected by the addition of manganese to the F039 and UTS lists. Background Document for Capacity Analysis for Land Disposal Restrictions: Inorganic Chemical Production Wastes (Proposed Rule) (USEPA)(Aug. 2000). EPA believes that these estimates may be overstated and that only a portion of these quantities will contain manganese above the proposed treatment levels. EPA does not expect that waste volumes subject to treatment would significantly increase as a result of the additional requirement to treat for manganese. The agency states: "[t]he volumes of wastes for which additional treatment is needed solely due to the addition of manganese to the F039 and UTS lists are therefore expected to be very small." TFA disagrees. Manganese is only a minor byproduct in the production of titanium dioxide production. In contrast, the production of steel accounts for 85 percent of manganese's use. TFA believes that the limited comment period on this proposal has not afforded EPA or the regulated community time to identify specific waste streams affected by the proposal.

⁶²65 FR 55768, 55771. For example, EPA anticipates that the universal treatment standard for manganese can be achieved through commercially available incineration followed by stabilization or high temperature metals recovery, or, alternatively, combustion technology for the organic constituents. 65 FR 55770-71. However, EPA states that:

We did not study this constituent in the development of the F039 treatment standards in 1990 or UTS in 1994. Furthermore, we lack studies demonstrating treatment effectiveness for highly concentrated manganese non-wastewaters, such as those containing manganese at levels such as those found in

new regulatory burdens will have on the ferroalloy industry and other affected industries.⁶³ One can only conclude that the proposal to add manganese to Appendix VIII is not well thought out. This does not meet current administrative law standards required for notice and comment rulemaking.

Because of the way the proposal has come up, the sixty-day comment period leaves the ferroalloys industry with little opportunity to thoughtfully evaluate and comment upon the long term implications of regulating manganese as a hazardous constituent under RCRA beyond these hurriedly prepared comments. Publication of the proposed rule in the Federal Register does not alone provide adequate notice to interested parties for purposes of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), the Regulatory Flexibility Act (5 U.S.C. 603), or Executive Order 12291.⁶⁴ Based on a review of the proposed rule, accompanying preamble discussion, and supporting background documents, TFA concludes that EPA has not provided fair notice concerning these new requirements for managing characteristic hazardous waste containing manganese and has not established a sufficient technical and economic basis for imposing these requirements.⁶⁵

Response 13-6a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-6b: EPA's Technical Data and Models Must Be Made Available for Comment Before the Record Can Be Closed.

The failure to make technical information available at the start of formal rulemaking is a sine

K178.

If so, EPA lacks a sound technical basis for the proposed manganese standard.

⁶³65 FR 55775; Economic Analysis for Listing of Inorganic Chemicals, Notice of Proposed Rulemaking, Final Report, USEPA (Aug. 2000).

⁶⁴PPG Industries, Inc. v. Costle, 659 F.2d 1239 (D.C. Cir. 1981) (footnote reference to the use of running averages in clean air proposal as a basis for restricting construction of new facilities found inadequate). Although the courts have looked to the opportunity for meaningful comment as one means of curing a defective notice, the lack of information EPA provides on its understanding of the effects of this proposal limits the opportunity of TFA to provide comments on this point.

⁶⁵Rodway v. Agricultural Dep't., 514 F.2d 809 (D.C. Cir. 1975) (successful challenge to proposal for emergency food assistance for disaster victims that failed to mention new allotments or their impact on prices paid by those eligible). See also Lloyd Noland Hospital & Clinic v. Heckler, 762 F.2d 1561 (11th Cir. 1985) (defective notice in proposed rule for medicare provider reimbursement cured when copies of a critical study insufficiently identified in the proposal were sent to representative industry associations prior to publication of the proposal). TFA has not had adequate time to commission a formal cost analysis of this proposal, nor, as described above, has EPA provided key technical documents to interested parties or made them publicly available.

qua non for the process. A regulation, rule, or standard that is based on technical or scientific information will fail if the underlying data and agency analysis are not provided for public scrutiny, review, and comment. Failure to make that information available invalidates the resulting agency action and decisions, and worse, undermines public confidence in the rulemaking process. A long line of cases in the D.C. Circuit and elsewhere have held that "the agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."⁶⁶ As the court stated in *Connecticut Power and Light*:⁶⁷

The process of notice and comment rulemaking is not to be an empty charade. It is to be a process of reasoned decision-making. One particularly important component of the reasoning process is the opportunity for interested parties to participate in a *meaningful* way in the discussion and final formulation of rules. . . . The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rulemaking process. . . . *In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching decisions to impose particular rules. To allow the agency to play hunt the peanut with technical information, hiding or disguising the information it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow meaningful commentary [emphasis added].*

One particularly important component of the process is the opportunity for interested parties to participate in a meaningful way in the discussion and final formulation of rules. [citations omitted].⁶⁸ Clearly, the Court is saying that due process requires that the public have a meaningful opportunity to influence the final outcome of Agency decisions - a concept that goes back to the foundations of modern notions of administrative procedure contained in the Attorney General's manual published in the 1940's - and to have access to all of the information on which the Agency relies in preparing its proposal.

In commenting on the NRC's approach, the court criticized the procedures in coming "perilously close to foreclosing any useful participation whatsoever during the rulemaking

⁶⁶*Connecticut Light and Power v. Nuclear Regulatory Commission*, 673 F.2d 525, 529-530 (U.S. App. D.C. 1982). See also *Portland Cement v. Ruckelhaus*, 486 F.2d 375, 393 (D.C. Cir.1973) ("information should generally be disclosed as to the basis of a proposed rule at the time of issuance."); *U.S. v. Nova Scotia Food Products*, 568 F.2d 240 (2nd. Cir.1977) (FDA's failure to reveal scientific research upon which the agency relied in making regulation constituted "arbitrary and capricious" action in violation).

⁶⁷*Id.*

⁶⁸*Id.* at 527.

process itself." TFA recognizes that the Connecticut Power court in the end determined that the period of notice was adequate, in part because of the five-year period preceding the rulemaking in which the agency directed, negotiated with, and cajoled plant operators to adopt additional fire protection measures. This is not to say that an extended, public, pre-proposal discussion of ancillary issues moots the question of adequate notice and opportunity for comment.

The manner in which the Agency accomplishes these objectives may not be critical, and an agency may, within limits, have considerable "discretion to select procedures which it deems best to compile a record illuminating the issues."⁶⁹ But the agency must make a good faith effort to accomplish the Constitutional objective. In this case, EPA has not participated in a debate about the underlying effect on manganese throughout any period prior to the release of the proposed rule. Neither did EPA provide a 30 day comment period extension, although several parties requested an extension.

Moreover, EPA has recently been taken to task for failing to make the basis of its regulations completely transparent, and along with other agencies actions was the basis for the Congressional decision to require that the underlying data supporting scientific work funded by federal agencies available to the public. See OMB Circular A-10 (1999). Therefore, before EPA can complete this rulemaking, it must make the information cited here available, at least as it related to risk estimates for the manganese standard that is proposed for inclusion in Appendix VIII.

Response 13-6b: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion. However, EPA notes that the commenter does not identify specific technical information which it believes EPA failed to make available at the start of the comment period. To the extent the commenter is suggesting that the Administrative Procedure Act requires us to make information available to the public as soon as it starts to develop a proposal, EPA disagrees. The cases discussed above show that courts will consider early public contacts when deciding whether an agency has provided adequate notice of a proposal. They do not, however, indicate that pre-proposal notice is required.

Comment 13-6c: EPA Has Not Met the Criteria of 40 CFR 261.11(a)(3) for Listing the Proposed K178 Wastestream Based on Manganese.

TFA respectfully submits that EPA has not met the criteria for listing the proposed K178

⁶⁹Natural Resources Defense Council, Inc., et al., v. United States Nuclear Regulatory Commission, 547 F.2d 633, 178 U.S.App.D.C. 336 (CA DC 1976).

hazardous waste pursuant to 40 CFR 261.11(a)(3) in relation to manganese.⁷⁰ Section 261.11(a)(3) permits EPA to list a solid waste as a hazardous waste if:

It contains any of the toxic constituents listed in appendix VIII and, after considering the following factors, the Administrator concludes that the waste is capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed . . .

The regulations go on to list eleven factors for consideration. EPA has failed to make a compelling case that manganese presents a risk of toxicity from oral exposure at levels that are otherwise within the recommended dietary exposure range. Therefore, EPA has failed to show that manganese is capable of posing a substantial hazard to human health, and manganese at the specified levels in the proposal cannot be used as the basis for determining that the proposed K178 meets any of the eleven factors in the rule.

Response 13-6c: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-6d: EPA Has Not Met the Criteria of 40 CFR 261.11(a)(3) for Adding Manganese to Appendix VIII.

Moreover, EPA has not met the criteria for including manganese in Appendix VIII. To be included in Appendix VIII, as stated at the end of 261.11(a)(3):

Substances will be listed on appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms.

The data summary EPA relies upon in IRIS and in EPA's Listing Background Document does not support a finding that manganese has been shown to be toxic via the oral route of exposure at the levels of exposure identified in the proposed rule. EPA instead proposes to add manganese to Appendix VIII based on a risk assessment that somehow concludes that levels shown to be safe in humans are toxic. Good stewardship compels EPA to ensure that the Agency does not mislead the public into believing that exposure to manganese should be avoided at levels that are acceptable in the human diet. Further, manganese is also essential for plant and animal life, and EPA has not shown that the levels proposed are necessary to prevent injury to ecosystems or animal life. Accordingly, EPA has not demonstrated a risk of adverse effects on the environment or on humans necessary to support its authority to act.

⁷⁰The listing criterion of section 261.11(a)(1) does not apply in this case because EPA has not determined that the waste stream exhibits a hazardous characteristic. The criteria of section 261.11(2) also are not applicable since EPA made no finding regarding acute hazard, increased risk of serious irreversible, or incapacitating reversible illness, or death.

EPA was able to reach its conclusion only because the Agency failed to account for the essentiality of manganese in the diet; more recent studies which bring earlier oral exposure data, which was already limited in nature, more into question; the ubiquitous presence of manganese in soil and water; the homeostatic control mechanism of the human body for processing manganese; and differences that the solubility of various forms of manganese can have on uptake in water and soil. These combined deficiencies make a compelling case that manganese should be dropped from EPA's proposed rule altogether. EPA has failed to show that manganese is capable of posing a substantial hazard to human health or the environment.

Response 13-6d: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-6e: EPA's Proposed Technology-Based Treatment Standards for Manganese are Invalid under RCRA.

EPA cannot go forward with the treatment standards for manganese in the proposed rule, because they do not relate to levels at which short-term and long-term threats to human health and the environment are minimized. Section 3004(m) of RCRA directs:

(1) Simultaneously with the promulgation of regulations under subsection (d), (e), (f), or (g) of this section prohibiting one or more methods of land disposal of a particular hazardous waste, and as appropriate thereafter, the Administrator shall, after notice and opportunity for hearings and after consultation with appropriate Federal and State agencies, promulgate regulations specifying those levels or methods of treatment, if any, which substantially diminish the toxicity of the waste or *substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized.* (emphasis added).

As the basis for the treatment standard for non-wastewaters, EPA selected a high temperature metals recovery technology that vitrifies manganese in slag and achieves a treated manganese concentration of 1.3 mg/L TCLP. EPA applied a standard variability factor of 2.8 to these data to calculate a proposed treatment standard of 3.6 mg/L TCLP.⁷¹ For wastewaters, EPA selected a sedimentation technology that results in a final effluent concentration of 6.1 mg/L and applied a variability factor of 2.8 to obtain a proposed treatment standard of 17.1 mg/L. Alternatively, EPA has asks for comments on setting a treatment standard for manganese non-wastewaters identical to the level for thallium of 0.20 mg/L TCLP based on stabilization. EPA also asked for comment on the similarity of manganese non-wastewater and wastewater treatment to the treatment of other RCRA-

⁷¹65 FR 55768.

regulated metals that appear in the UTS. It is clear from EPA's discussion that the Agency is simply grasping for a treatment level that industry will not oppose. EPA fails to make any case at all regarding whether these levels meet the "substantially diminished" standard for migration to minimize short and long-term threats to human health and the environment. That is not the legal standard EPA must meet in adopting these kinds of proposals

Hazardous Waste Treatment Council v. EPA, 886 F.2d 355 (D.C. Cir. 1989), cert. denied, 498 U.S. 849 (1990), supports TFA's contention that EPA is precluded by law from setting a treatment level for manganese that is below an established level of hazard. In that case, the Chemical Manufacturers Association (CMA) challenged EPA's treatment standards for solvents and dioxins, claiming that EPA's decision to forego the use of health-based standards and rely solely on technology-based treatment levels violated section 3004(m) of RCRA. The CMA argued that "treatment for treatment's sake" would result, contrary to the less rigorous minimization of risk standard of the statute. In upholding EPA's ability to select either technology-based or health-based standards in implementing section 3004(m), the court issued a strong caution that:

This is not to say that EPA is free, under 3004(m), to require generators to treat their waste beyond the point at which there is no "threat" to human health or to the environment. That Congress's concern in adopting 3004(m) was with health and the environment would necessarily *make it unreasonable* for EPA to promulgate treatment standards wholly without regard to whether there might be a threat to man or nature.⁷² [Emphasis added].

EPA has proposed treatment levels for manganese that are neither truly technology-based or truly health-based. The proposed levels are not tied to any achieved reduction of migration of manganese into soil or water, or to any minimization of short-term or long-term health or environmental hazard or risk. Moreover, EPA purports to offer flexibility by listing a variety of treatment methods, which may achieve the desired treatment levels, but specifies none.

Response 13-6e: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 13-7: Conclusion and Requested Remedy

EPA cannot legally or scientifically go forward with those aspects of this rulemaking that relate to manganese. The agency has not identified a health concern level that makes sense, and has not adequately identified or considered the regulatory, economic, and technical effects of including manganese in Appendix VIII for industry stakeholders other than titanium dioxide manufacturers. TFA appreciates EPA's consideration of these concerns, and formally

⁷²886 F.2d at 362.

requests that EPA withdraw those aspects of the proposed rule that relate to manganese. If EPA decides to proceed with the proposed rule inclusive of manganese, TFA hereby requests a hearing on this matter.

Response 13-7: EPA denied TFA's request for a hearing; it felt that written comments presented the issue sufficiently. However, EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment ICMP-00014, Doe Run Company

Introduction

I am submitting these comments on behalf of The Doe Run Company (Doe Run). We are a mining, milling, and smelting company with 22 operations in Missouri, Washington State, Arizona, Texas, and Peru. In addition to our primary lead, copper and zinc mining and smelting operations, we are also in the lead recycling and fabrication business. We produce and market ten different metals worldwide including antimony trioxide. In this letter, we are commenting on the Antimony Trioxide production rules.

We do not currently produce Antimony trioxide in the United States, although we might at some time in the future. We do, however, operate such facilities in Peru. We have several concerns about this rule.

Comment 14-1: First of all, the production of antimony trioxide may be a normal part of a continuous integrated smelting facility and as such should be treated under the smelting framework of rules and exemptions. While the process and its residuals may not qualify by the size of its waste stream alone as a RCRA Bevill waste, when reintroduced or recycled back into a integrated lead smelting operation whose slag wastes do qualify, the slag should not imprint the whole slag as hazardous. It would probably be more appropriate to simply leave the material to be considered as a characteristic waste when discarded.

More importantly to us, however, than having the material excluded by reason that it may be a Bevill waste is that the agency carefully discusses the management of the materials in the rule so that these material streams do not end up in a landfill when they should be recycled. If an antimony trioxide material stream is an intermediate product or a byproduct, the rule should be quite clear that it can be recycled within the smelting facility or another primary metal non-ferrous smelter without being managed as a hazardous waste. If they are not free from regulation, the act of listing them may make it impossible or impracticable to recycle because of the regulatory burdens in which they become encumbered.

Response 14-1: The Agency specifically wrote the K177 listing to apply only to slags associated with antimony oxide production that are disposed or speculatively accumulated. As long as the lead smelters use slags from antimony oxide production that were never disposed of or speculatively accumulated, these slags are not included in the scope of the listing.

Comment 14-2: In the final preamble the agency should clarify that Baghouse filters and the associated dust contained therein can be recycled in any non-ferrous smelter furnace without being regulated as a hazardous waste. This exclusion should not be limited to being recycled in the same furnace in which it is generated, as it may or may not be technically appropriate. The antimony, lead, and cadmium contained within will substantially but not quantitatively report to products or other byproducts that will be exempt if further processed or recycled.

Response 14-2: EPA responded to the facts presented in the questionnaire responses and follow-up conversations and evaluated only those practices that were reported. We were not aware of instances where filters containing antimony dust are sent to non-antimony smelters and did not evaluate potential risks associated with this practice.

Comment 14-3: The same exemption should apply for Antimony trioxide slag. The exemption says it is for slag that is discarded but the Agency has from time to time defined something that momentarily leaves the circuit as "being discarded" and since you have taken the position that this material may not be a Bevill material it is necessary to explicitly restate that it is okay to recycle the material in other portions of the smelter in which it is generated or any other metal smelter without regulation as a hazardous waste. Thank you for your consideration of these comments. It is important to make these distinctions clear.

Response 14-3: We will make this clarification in the preamble to the final rule.

Comment ICMP-00015, American Chemistry Council

Introduction On behalf of the members of the American Chemistry Council (ACC), I am submitting these comments on EPA's recent proposal to add manganese as a RCRA hazardous constituent for the purpose of listing proposed K178, nonwastewaters from the production of titanium dioxide by the chloride-ilmenite process. ACC strongly opposes the inclusion of manganese as a constituent of concern for the listing of titanium dioxide nonwastewater streams (or any waste streams), and believes the regulation of manganese would be an inappropriate and unnecessary use of Agency and industry resources. We also support the comments separately submitted by E.I. du Pont de Nemours and Co., Eastman Chemical Company, the Ferroalloys Association, and the American Chemistry Council's Titanium Dioxide CHEMSTAR Panel.

In the September notice, the Agency proposes to add manganese to RCRA Appendix VII and Appendix VIII as well as establish wastewater and nonwastewater LDR treatment standards for the metal. Most important to ACC members would be the effects from the addition of manganese to the list of Universal Treatment Standards and F039 multi-source leachate on both production and remediation wastes.

Comment 15-1: Manganese is Insufficiently Toxic to Warrant Inclusion on RCRA Appendix VIII.

Under EPA rules, a substance can be added to "appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. 40 CFR § 261.11(c)(3). DuPont, Eastman, and the Ferroalloys Association discuss in some detail the toxicity, or rather lack of human ingestion toxicity, presented by manganese. We summarize some of their most important points below.

Comment 15-1a: Manganese is Essential for Health:

The Food and Nutrition Board of the National Research Council (*Recommended Daily Allowances*, 10th edition, 1989) established an estimated safe and adequate daily dietary intake of 2-5 mg/day for manganese to foster adequate dietary consumption of this essential trace element. Manganese is used by the body as a cofactor for many enzymes to facilitate different metabolic processes. Manganese concentrates in bones and metabolically active organs such as the liver, kidneys, and pancreas⁷³ and is necessary for the formation of connective tissue and bone, the metabolism of carbohydrates and lipids, and neurological development and function. Manganese concentration in the body is homeostatically controlled, primarily through the bile and, ultimately, the feces⁷⁴ to prevent its concentration at levels that could be toxic.

⁷³ Understanding Nutrition by *Whitney and Rolfes* (1999)

⁷⁴ U.S. EPA IRIS Substance file - Manganese and TLVs and Other Occupational Exposure Values CD-ROM, ACGIH, Cincinnati, OH, 20000

Response 15-1a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-1b: Manganese is naturally occurring in many common foods, soils, and even humans

Nuts, whole-grain cereals, dried legumes and tea contain >20 ppm manganese; vegetables and fruits contain 1-5 ppm⁷⁵. Noncontaminated soils in the western U.S. contain 30-5,000 ppm manganese, with a mean of 380 ppm. The range in the eastern U.S. is <2 - 7,000 ppm, with a mean of 260 ppm. In Europe, the mean of manganese in ordinary soils ranges from 233 ppm (Denmark) to 1,405 ppm (England)⁷⁶. "The average adult contains about 12 mg of manganese. The skeletal system contains about 43%, with the rest in soft tissues including liver, pancreas, kidneys, brain, and central nervous system."⁷⁷

Response 15-1b: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-1c: Manganese is generally considered an inhalation, not an ingestion, hazard

EPA admits in the Risk Assessment Background Document supporting this proposal that ". . . there are many reports of toxicity to humans exposed to manganese by inhalation; much less is known, however, about oral intakes resulting in toxicity (emphasis added)⁷⁸. We do not dispute that manganese can present an inhalation hazard; hence, it's regulation under OSHA and as a hazardous air pollutant under the Clean Air Act. However, the concern in this listing proposal is oral ingestion via groundwater, for which the Agency seems to be relying on a Japanese study conducted in 1941 and a Greek study in 1989. Both studies are based on unusual and extreme exposure scenarios, and cannot be easily extrapolated to

⁷⁵ *Introductory Nutrition*, 2nd Edition, 1975, Helen Andrews Guthrie, The C.V. Mosby Company, St. Louis

⁷⁶ U.S. soil data: ATSDR Health Assessment Guidance, July 1990, with its reference source the U.S. Geological Survey. Source for Europe data: "A Perspective on Metals in Soils," *Journal of Soil Contamination*, 5(4): 329-359, 1996

⁷⁷ *Hazardous Materials Toxicology, Clinical Principles of Environmental Health*, Chapter 85, "Manganese and Magnesium," edited by John B. Sullivan, Jr. and Gary R. Krieger, 1992, Williams & Wilkins, Baltimore, MD.

⁷⁸ *EPA Risk Assessment Background Document* at p. 6-32; see, also, *Integrated Risk Information System (IRIS) Database Summary for Manganese* (USEPA), updated 5 May 1998.

a reasonable exposure scenario from TiO₂ wastes⁷⁹. We also find it perplexing that EPA would rely on a 50 year old study, a study that seemingly has not been replicated in the intervening years, while ignoring the conclusions of the American Conference of Governmental Industrial Hygienists (ACGIH) and the International Programme on Chemical Safety of the World Health Organization. Those two bodies have been generally unsuccessful at inducing toxic effects by oral ingestion and have concluded that “The available evidence for adverse effects associated with chronic ingestion of excess manganese is suggestive but inconclusive.”⁸⁰ We would also note that, while EPA has established a *secondary* drinking water standard of 0.5 mg/l⁸¹, this is based on aesthetic changes in water clarity⁸² and the potential for the oxidized forms to stain clothing and plumbing fixtures⁸³. Neither stained fabric nor piping can be considered a toxic effect.

Response 15-1c: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-1d (summary): ACC and the Panel believe EPA has failed to demonstrate that manganese meets the RCRA 40 CFR 261.11 standard for adding hazardous constituents to RCRA Appendix VIII. While EPA does not place any limitations on the rule relating to placing substances on Appendix VIII, it is not reasonable to read it in any other way because *all* substances can be considered toxic if the dosage is high enough. Manganese is not carcinogenic, mutagenic or teratogenic, and the evidence for neurotoxicity is inconclusive. For this reason, ACC and the Panel request that EPA eliminate manganese as a potential listing criteria for proposed FK178 nonwastewaters from the production of titanium dioxide by the chloride-ilmenite process.

Response 15-1d: EPA is deferring final action on all elements of our proposal that are

⁷⁹The Ferroalloy Association and DuPont comments discuss the weaknesses in these studies in great detail.

⁸⁰Both the Ferroalloy Association and DuPont comments support this point. The quotation is from the International Programme on Chemical Safety, *Concise International Chemical Assessment document on Manganese and its Compounds (No. 12)*; World Health Organization Geneva 1999) at p. 9.

⁸¹ National Secondary Drinking Water Regulations (NSDWRs or secondary standards) are non-enforceable guidelines regulating contaminants that may cause cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water.

⁸²*Hazardous Materials Toxicology, Clinical Principles of Environmental Health*, Chapter 85, “Manganese and Magnesium,” edited by John B. Sullivan, Jr. and Gary R. Krieger, 1992, Williams & Wilkins, Baltimore, MD

⁸³Chemical and Biological Removal of Iron and Manganese from Drinking Water, Thesis Defense by Arthur Hall Lundquist, M.S. Environmental Engineering, November 22, 1999, The Center for Biofilm Engineering, an NSF Engineering Research Center at Montana State University-Bozeman

specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-2: EPA's Impact Assessment Has Not Considered the Collateral Effects of Adding Manganese to Appendix VIII.

ACC and the Panel are certainly concerned about the scientific and technical support for EPA's proposal to list K178 for the presence of manganese. Since K178 is generated by only one company at only one site, our comments would generally stop with the concern over manganese toxicity. However, listing the waste for the presence of manganese results in the element being included in other aspects of the RCRA program with the potential to affect a significant number of our members. Our concerns primarily center on the collateral effects of establishing a Universal Treatment Standard for manganese that could then be considered an underlying hazardous constituent for characteristically hazardous wastes, F039 multi-source wastewaters, and contaminated media.

Comment 15-2a: Establishing a Universal Treatment Standard for Manganese Could Significantly Affect Current Hazardous Waste Management Processes.

Currently generators do not evaluate hazardous wastestreams for the presence of manganese; however, manganese is a significant component of stainless steel and is also used in catalysts. As a result, we would expect that certain streams could pick up small concentrations of manganese either from the catalyst or from steel reactors, tanks and piping. The manganese would not be a component of the waste as generated, but might have to be considered an underlying hazardous constituent for land disposal restriction purposes. Depending on the other UHCs in the stream, this may or may not create a problem. For streams containing other metals, the addition of manganese may not cause a problem. However, for streams that do not contain metal UHCs, the presence of manganese could require significant additions to the current treatment train.

Response 15-2a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-2b: Adding Manganese to the Treatment Standard for F039 Multi-Source Leachate Could Also Affect Current Practices.

Because of the broad definition, the actual composition of a multi-source leachate is far ranging. As described above, F039 streams that already contain metals may not be significantly affected. However, those with only non-metal hazardous constituents could have to significantly modify their treatment train to accommodate the metal.

Response 15-2b: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-2c: Including Manganese to the UTS and F039 Lists Could Slow Progress and Increase Costs of Remediations.

Manganese, much like iron, is a common element in nature and its chemical fate depends on the acidity and redox conditions of the surroundings. Its concentration in aqueous media, for example, will not reflect its concentration in a waste, but rather is entirely dependent on other chemical attributes (pH and Eh) of the environment where it resides. Depending on the natural chemistry of the system, there could be an abundance of manganese in a waste, but little in the water contacting the waste. Conversely, there could be essentially no manganese in the waste, but due to the Eh-pH of the system and its natural presence in the Earth's crust, its concentration in water could be quite high. This phenomenon could have a significant impact on remediation projects.

We do recognize that characteristically hazardous remediation wastes, because of the HWIR-Media rule, would only have to be treated to a 90% reduction in concentration or 10 times the UTS limit⁸⁴. Similarly, groundwaters are not required to meet universal treatment standards for underlying hazardous constituents if the wastewater is managed in a Clean Water Act permitted system or a Class I hazardous injection well. However, any sludge generated by the CWA system *would* have to meet the new manganese UTS. Considering that manganese is ubiquitous in the natural environment and that its chemical fate depends on the acidity and redox conditions of the environment, remediation sludge could be expected to contain manganese.

Since generators do not currently analyze their waste streams for manganese, we can only speculate on the potential effect of its listing on current waste management and remediation activities in the chemical industry. Based on the use of manganese in so many industries,⁸⁵ we believe its listing could have significant ramifications in many industry sectors. These are potentially important and costly effects of the Agency's proposal and should be addressed in the associated economic impact analysis.

Response 15-2c: EPA is deferring final action on all elements of our proposal that are specifically

⁸⁴We do point out, however, that as of September 30 of this year, 18 states have adopted the rule and none are yet authorized.

⁸⁵ Manganese and manganese compounds are used in the manufacture of dry cell batteries as a depolarizer, and also in paints and varnishes, inks, dyes, matches and fireworks, bleaching agents, laboratory reagents, motor oils, fertilizers, disinfectants, welding rods, and in the synthesis of hydroquinone, the green-colored potassium manganate and the purple-hued potassium permanganate. Manganous acetate is used in dyeing, leather tanning, and fertilizers and as a drier of linseed oil. It [is] also used as a decolorizer and coloring agent in the manufacture of glass and ceramics. Manganese carbonate is found in the pigment manganese white. Manganese sulfate is a red pottery glaze and fertilizer for vines and tobacco. *Hazardous Materials Toxicology, Clinical Principles of Environmental Health*, Chapter 85, "Manganese and Magnesium," edited by John B. Sullivan, Jr. and Gary R. Kreiger, 1992, Williams & Wilkins, Baltimore, MD

related to manganese. See Section IV.B of the final rule for further discussion.

Comment 15-3: ACC Supports EPA's Proposal Not To List 13 Other Wastes

We support EPA's determination not to propose to list as hazardous waste streams from the 13 other inorganic chemical manufacturing processes. We are particularly pleased at the situations in which EPA reflected the fact that a stream was already characteristically hazardous, and therefore already being managed as a hazardous waste (e.g., certain wastes from manufacture of barium carbonates, cadmium pigments, inorganic hydrogen cyanide, phosphorus pentasulfide, phosphorus trichloride, potassium dichromate, and sodium dichromate) or had already been evaluated as part of a separate listing (certain hydrogen cyanide wastes). We also appreciate the way the Agency reflected current waste management practices - those associated with both hazardous and nonhazardous waste - in the risk assessment.

Response 15-3: EPA acknowledges ACC's support for the rule.

Comment ICMP-00016, U.S. Antimony

Comment 16-1: When Robert Maxey with U.S. Environmental Protection Agency (USEPA) made his site inspection on September 23, 1999, he informed us that a report would be written covering the findings of his visit. United States Antimony Corp. (USAC) was never notified of the completion of the report. Mr. Maxey had indicated we would receive a copy of the report upon completion. Had we not been working closely with our own state's department of environmental quality for a number of years, we would have not had a chance at all to respond to this Federal Register Document nor its accompanying report entitled "Antimony Oxide Listing Background Document for the Inorganic Chemical Listing Determination". It was Robert Reinke, Solid and Hazardous Waste Specialist, with the Montana Department of Environmental Quality (MDEQ) that alerted us to the existence of these documents.

Response 16-1: EPA met its legal obligations for notice and opportunity to comment by publishing a notice of proposed rulemaking in the Federal Register. To try to increase notice, we also posted a copy of the proposal on its web site and e-mailed a copy to each potentially affected facility (including US Antimony). We feel that these outreach efforts were sufficient. We note that US Antimony timely submitted comments after it learned about the proposal.

Comment 16-2: There is already a program in place to monitor and regulate hazardous materials. This program is overseen by USEPA and administered by MDEQ. We feel the information utilized to form the proposed amendments of regulations for hazardous waste management under Resource Conservation and Recovery Act (RCRA) to be incomplete and incorrect.

Response 16-2: Primary responsibility for determining which wastes are listed as hazardous under the RCRA program rests with the Office of Solid Waste (OSW) in EPA Headquarters. Since listing new wastes as hazardous broadens the scope of the RCRA program, States are required to adopt newly listed wastes into their regulations once EPA has finalized a listing. The presence of an implementing state program does not preclude EPA from making national listing determinations.

We address below all of the commenter's specific concerns relating to inaccuracy or incompleteness. We conclude we continue to have a rational basis for considering the data to be reasonably valid and representative. We note that the sampling information we used in the risk assessment has gone through a Quality Assurance process and has been validated. See our response to comment 16-8.

Comment 16-3: The K176 baghouse filters used in the production of antimony oxide and the K177 slag from the production of antimony oxide that is speculatively accumulated (page 9 of 182) are being designated hazardous waste based on the report titled: "Antimony Oxide Listing Background Document for the Inorganic Chemical Listing Determination" dated August, 2000. On page 12 of the above mentioned document under "Assessment of

Management Scenarios" the following statement is made; "Per data presented above in Table 3.4 the analysis of samples LI-1-AO-03 and AC-1-AO-03 indicates that this waste fails the TC for lead and arsenic". Review of the table reveals that neither LI-1-AO-03 nor AC-1-AO-03 fails the TC for arsenic and only LI-1-AO-03 fails the TC for lead. The Federal Register Document dated September 14, 2000 (volume 65, number 179) page 42 of 182 reports the results of LI-1-AO-03 in Table III-4 -characterization of Baghouse Filters F in which the TCLP lead concentration exceeds the total concentration of lead in the sample. Furthermore, note that Table 3.4 includes a sample designated AC-1-AO-06 in which arsenic is above the regulations for TC. Either the sample number is incorrect or the data listed below is incorrect for the sample number. AC-1-AO-06 was a sample of slag from our reduction plant furnaces. AC-1-AO-07 was a sample of a baghouse filter also from our reduction plant. In either case, this plant is not part of the antimony oxide production facility. This plant is a facility in which we manufacture antimony metal, and it is therefore not subject to the RCRA3007 survey/study. We were informed on September 23, 1999 during the site inspection that the reduction facility was not considered a part to the listing for antimony oxide production by Robert Maxey.

Response 16-3: Table III-4 of the proposal (p. 55704) contains the analytical results and preamble discussion for baghouse filter samples LI-1-AO-03, AC-1-AC-03 and AC-1-AO-07. The analytical data and the sampling labels are correct. The data clearly show exceedences of the TCLP for lead (LI-1-AO-03) and arsenic (AC-1-AO-07). As noted by the commenter, AC-1-AO-07 is a sample of the reduction baghouse filter. We cannot find any reference to a sample designated AC-1-AO-06 in Table 3.4 in the preamble. Perhaps the commenter intended to refer to Table 3.4 in the Antimony Oxide Listing Background Document.

The statement in the background document (p. 11 in the docket copy) should have read, "Per the data presented above in Table 3.4, the analysis of samples LI-1-AO-03 and AC-1-AO-07 indicates that this waste fails the TC for lead and arsenic." The third sample in Table 3.4 should have been labeled AC-1-AO-07 not AC-1-AO-06. The background document correctly noted the sample number at the top of page 11 in the first sentence under Waste Characterization. A revised version of the background document has been sent to the docket to correct this error.

The Agency makes listing determinations on a national basis. Therefore, it is appropriate for us to consider analytical results from more than one facility in our listing determination. In the case of the antimony oxide baghouse filters, two of three samples indicated exceedences of the Toxicity Characteristic (TC). However, none of the four major producers categorized the baghouse filters as characteristic waste. Therefore, we must consider non-hazardous disposal of the filters as a plausible management scenario for the antimony oxide industry. Because samples showed exceedences of the TC, the Agency decided to list the waste as hazardous under 261.11(a)(1). See our response to comment 16-9 for a discussion of the commenter's oxidation baghouse filters.

We regret the fact that the comments of an EPA employee during the sampling visit may have given the commenter an incorrect view of the scope of the listings. As described below, we have carefully considered the substance of the commenter's concern and we are convinced that it is

reasonable to include within the listings filters and slag from the reduction furnace when the product of the furnace is used as an intermediate in the production of antimony oxide.

During follow up conversations with U.S. Antimony, company personnel indicated that ninety percent of the antimony metal produced in the reduction furnace is sent to the oxidation furnace to produce antimony oxide and the antimony metal production is run on a batch basis. In cases when the antimony metal is used as an intermediate in the production of antimony oxide, the Agency has determined that the oxidation and reduction furnaces are steps in a single, integrated process designed to produce antimony oxide. Therefore, the reduction furnace slag and baghouse filters are included within the scope of the listing when generated during the production of antimony metal that is used in antimony oxide production. However, EPA agrees with the commenter that when the antimony metal production is not used for antimony oxide production, the antimony metal is not a process intermediate for antimony oxide production. The slags and filters from such batches are also not associated with antimony oxide production and, therefore, are not included in the scope of the listing as long as they are not commingled with the listed wastes.

During the site visit on September 23, 1999, EPA sampled the reduction furnace slag to assess slag from the production of antimony oxide. EPA has determined that when the metal is used as a process intermediate in the production of antimony oxide, the slag from the metal production fall within the scope of the listing. Since the vast majority of the antimony metal production (90%) is associated with antimony oxide production, EPA believes that our samples of the reduction furnace slag are representative of the listed slag⁸⁶. The majority of the remaining ten percent of the metal production which is not associated with antimony oxide production is produced on a contract basis for another facility. U.S. Antimony and this second facility have an agreement in place that when metal is produced on a contract basis, both the metal and the slag are returned to the second company. Therefore, we believe there is a reasonable basis for concluding that the slag we sampled was associated with antimony oxide production.

Comment 16-4: Concerning K177 and the potential for groundwater contamination, the two samples of slag analyzed from USAC's Thompson Falls Facility were determined not to show any hazardous TC characteristics. The report states that our slags exceed the HBLs for antimony, arsenic, boron, selenium, and vanadium. Neither of the reports state what a HBL is nor what constitutes the threshold limits for these compounds. We consulted with Robert Reinke with MDEQ and Mr. Reinke was also unable to enlighten us with what an HBL is nor what thresholds limits apply to an HBL.

Response 16-4: The preamble section E.3 page 55696 and the risk background document discuss the Agency's development and use of Health Based Levels (HBLs) in support of the proposed rule. In addition, the specific HBLs used for the antimony oxide listing determination can be found in association with our sampling data for the sector on pages 8 and 11 of the Antimony Oxide Listing Background document and on pages 55702 and 55704 of the preamble. HBLs are waste concentration levels in environmental media that would not exceed EPA's risk thresholds given

⁸⁶ See notes from conference call with U.S. Antimony dated February 28, 2001

conservative assumptions regarding exposure. In many cases, the HBLs used throughout the proposal are drinking water MCLs or Superfund Soil Screening levels.

Comment 16-5: Table 111-2 in the Federal Register Document is incomplete and does not reflect the results reported by the analytical laboratory for the total concentration levels for the elements boron, selenium, and vanadium.

Response 16-5: Table III-2 of the preamble, Table 3.2 of the background document and Table 2 of the Waste Characterization Report all report the total concentration for boron, selenium and vanadium as below the detection limits. The high content of other metals (i.e., antimony, calcium, iron, and sodium) in the wastes required the samples to be diluted for the totals analysis. The AC-1-AO-01 sample was diluted 100 times and the AC-1-AO-06 sample was diluted 500 times. This dilution step results in increased detection limits for the less prevalent constituents such as boron, selenium, and vanadium. In this case, the dilutions caused the total concentration for these three constituents to be below the detection limits. However, as discussed in the preamble on page 55702, the critical data in this table are the TCLP and SPLP values which show the leachate concentrations. We use these leachate concentrations, not the total concentrations, as inputs in our risk assessment. These values show that leachable levels for the samples for boron, selenium and vanadium are above the HBLs for these constituents, which is why they were included in the modeling for the slag.

Comment 16-6: The Federal Register Document identified "4 residential wells with in several miles of the facility" and went on to say "one well is located 1.4 miles directly down gradient". There are however, no residential wells 1.4 miles down gradient of the facility. There are no residential wells down gradient within 4.5 miles of the facility. There is one private residential property approximately 1.5 miles up gradient of the facility. The private residential property down gradient have 8 to 10 wells 2 of which are my own.

Response 16-6: EPA reviewed the water contour maps for the facility and we believe that our original analysis of water flow direction is correct. For the proposal, the Agency relied on well data from the Montana Bureau of Mines and Geology GWIC database through the Internet to determine if there were any domestic groundwater wells in the area⁸⁷. However, based on this comment, the Agency further investigated groundwater use and well placement data for the area. We spoke with Montana DEQ's RCRA inspector for the site as well as staff from U.S. Forest Service district ranger station in charge of special use permits⁸⁸. Based on these discussions, we agree with the commenter that there is no residential well in the down-gradient location described in the proposal. According to these sources, the closest in-holding down-gradient is another mine which is 3.5 miles away. It is another mile before additional in-holdings are found which are

⁸⁷ See *Antimony Oxide Listing Background Document* in the docket for the proposed rule for the Internet excerpt from the database.

⁸⁸ See notes from conference calls with Montana DEQ and the U.S. Forest Service at Lolo National Forest dated _____.

residential property. As the commenter indicates, there is one private residential property with a well 1.5 miles up-gradient from the facility that we noted in the supporting documentation for the proposal. We also note that U.S. Antimony's operating permit under the mining program indicates that on-site water production wells are used to supply the laboratory and administrative buildings.

In the development of the proposal, we did not model a specific well in our risk assessment for this site. Instead, we used the logic that because there is documented domestic groundwater use in the immediate area (within 1.4 miles), there is the potential for wells to be drilled closer to the site in the future under another patented land. In discussions with the Forest Service, we see no reason to change our assumptions that new patents could be made closer to the facility. Should people move closer to the facility, groundwater plausibly could be used as the drinking water resource. The facility's on-site well noted in the preceding paragraph also supports the conclusion that use of groundwater for drinking water in the immediate area is plausible. Although our risk assessment is conservative for current groundwater use patterns, it predicts risks for potential future receptors.

Comment 16-7: There is a sulfide deposit containing lead and zinc approximately 3 miles down gradient of the facility known as the Montana Standard, owned by another company and many sulfide deposits of antimony, lead and arsenic just up gradient of the facility. Groundwater levels of antimony up gradient of the facility exceed the drinking water standards for antimony by as much as 130 times. These levels are the baseline levels for the area.

Response 16-7: Our risk assessment analysis utilized the SPLP leaching data from the wastes. The waste leached antimony at levels up to 35,000 times the health-based level. These leachate levels also exceeded drinking water standards for antimony. Our risk assessment examined potential risk from the waste alone. If there is a high background level of antimony, that only increases the potential impact of antimony leached from the waste.

Comment 16-8: The sampling techniques used by the USEPA did not represent the slag and refractory samples collected. The levels of antimony reported by the USEPA were markedly different from our in-house slag analyses. This leaves us to believe the results to be biased high. The drums that were sampled appeared to be high graded. No attempt was made to collect a representative sample of the slag. One or two sample points hardly constitutes data from which any conclusion can be drawn.

Response 16-8: According to our sampling plan and our waste characterization report (WCR), EPA's objective was to sample slag that was categorized by the facility as both low antimony content (<5%) and high antimony content (5-10%). The WCR states that sample AC-1-AO-01 was from a drum containing slag with <5% antimony and sample AC-1-AO-06 was from a drum containing slag with 5-10% antimony. The sampling data results support these statements. The totals concentration for AC-1-AO-01 is 11,500 mg/kg. The totals concentration for AC-1-AO-06 is 127,000 mg/kg. (Note that since we determined that refractory was outside the scope of the consent decree, we did not evaluate it for listing purposes. Therefore, the sampling comment on

the refractory waste is not relevant to this rulemaking.)

We believe that the two slag samples provide an adequate measure of the constituents of concern in the wastes under evaluation. We used the analytical results from both samples in our risk analysis and found that the constituent of concern was antimony. The total levels of antimony in the samples ranged from 11,500 mg/kg (equates to 1.1% antimony) to 127,000 mg/kg (equates to 12% antimony), which indicates that our assessment took into account the variability in these wastes. U.S. Antimony did not provide any data in their comments to compare with EPA's data. In the absence of any data from the commenter to the contrary, we continue to believe that our sampling results adequately represent the slags.

Comment 16-9: We believe that the industry wide listing of antimony oxide baghouse filters and slag from our reduction facility to be another unnecessary mandate on our industry that makes the United States less competitive in a world market. The fact remains that hazardous waste has well defined definitions and regulations already in place. We feel that the report is suspect because; (1) samples were taken from the reduction facility which is not a part of the antimony oxide plant, (2) the slag samples were not representative and appear to be biased high, (3) the baghouse bags from USAC's antimony oxide plant do not fail the threshold limits for any elements on the TCLP analysis, (4) baghouse filters are recycled in our facilities to recover any antimony residues (5) slag from the reduction plant is already being regulated by MDEQ.

Response 16-9: We are listing baghouse filters as a hazardous waste because the industry as a whole does not consistently manage them as characteristic hazardous wastes in accordance with applicable hazardous waste regulations. As discussed above under comment 16-3, we believe the waste from the reduction furnace operations fall within the scope of the listings when the antimony metal is used in antimony oxide production. We conducted QA/QC evaluations of our samples and have concluded that the data are valid and representative.

The State of Montana does not regulate the slag as hazardous waste. The State would regulate the reduction baghouse filters as characteristic hazardous waste, if disposed. However, as stated by the commenter, the facility is recycling the filters to recover antimony. We noted in the preamble that if any or all of the commenter's filters are recycled in ways that are not regulated under our definition of solid wastes, they will not be subject to this listing.

We do not agree that we should exclude from the listing filters from the commenter's oxidation furnace because our sample of these filters did not exhibit the TC. Our sampling data for the Montana oxidation filters shows TCLP lead levels (2.8 mg/L) that are very close to the TC regulatory lead level (5.0 mg/L). The commenter submitted no additional data supporting the assertion that its oxidation furnace filters do not fail the TC. Given likely variability in the waste, it is quite possible that other samples would have exhibited the TC for lead. Further, we sampled filters from a similar oxidation furnace at a second production facility in La Porte, TX. The La Porte filters contain lead at levels exceeding the TC (8.5 mg/L). The lead levels for both the La Porte facility and the Montana facility are close, within the same order of magnitude. Therefore,

based on these factors, we think it is reasonable to assume that the filters from oxidation furnaces will exceed the TC for lead frequently enough to warrant listing, even at the Montana facility. The criteria in 261.11(a)(1) provide generally that EPA can list a solid waste as hazardous if it exhibits any of the characteristics of hazardous waste. We believe our data sufficiently demonstrate that the oxidation filters meet the 261.11(a)(1) test.

Although not directly relevant to a listing under 261.11(a)(1), we also note that the leachable antimony content of the baghouse filters from both oxidation furnaces exceed EPA's antimony health-based level (HBL) for human drinking water consumption by a significant margin. The Montana oxidation furnace filters contain up to 15% antimony and leach 700 times above the drinking water HBL. The La Porte oxidation filters contain up to 9% antimony and leach 1,550 times above the drinking water HBL.⁸⁹

⁸⁹ See Waste Characterization Reports for U.S. Antimony, Thompson Falls, MT and Laurel Industries, La Porte, TX that are in the docket for the proposed rule.

Comment ICMP-00017, International Association of Color Manufacturing

Introduction

On behalf of the members of the International Association of Color Manufacturers (ACM), we submit these comments on the proposed amendments to the regulations for hazardous waste management under the Resource Conservation and Recovery Act (RCRA) that propose to list as hazardous three wastes generated from inorganic chemical manufacturing processes. 65 FR 55684 (14 September 2000). IACM objects to the proposed addition of manganese to the Universal Treatment Standards (UTS) Table codified at 40 CFR Sec. 268.48. 65 FR 55768.

IACM is the international association of color additive manufacturers. IACM's members manufacture and market the vast majority of color additives (certified and exempt from certification) that are incorporated into foods, drugs and cosmetics in the United States. These color additives are extensively regulated by the U.S. Food and Drug Administration (FDA) as described at 21 CFR Parts 73 and 74, and have been thoroughly evaluated to assure that they are safe for inclusion in foods, drugs, and cosmetics.

Comment 17-1: IACM Objects to the Inclusion of Manganese in the UTS Table

Manganese is present in minute amounts in a wide variety of foods, drugs, and cosmetics, and is an element essential to human health. The Agency's Integrated Risk Information System (IRIS) database provides a thorough review of the available toxicity data on manganese. The data in the IRIS database clearly demonstrate that the most significant risk to humans from manganese is as a result of inhalation exposure, and not oral ingestion.

Response 17-1: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 17-1a: IACM objects to the inclusion of manganese in the UTS Table codified at 40 CFR Sec. 268.48. 65 FR 55768. As noted by the Agency in the preamble to the proposed rule, universal treatment standards for manganese have not yet been developed, and are just now being proposed in this same proposed rule. 65 FR 55768. The Agency also noted in several instances in the proposal that it has not yet collected a significant amount of data on treatment effectiveness for manganese nonwastewaters.

Response 17-1a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 17-2: Requested Actions

The inclusion of manganese in the UTS Table is likely to have significant effects outside of the inorganic pigments industry, and affect far more companies than just the producers of

titanium dioxide. We request that if the Agency wishes to proceed with listing manganese in the UTS Table, that it do so in a separate rulemaking so that the supporting data can be carefully and fully considered, and comments solicited from industries other than the inorganic pigments industry.

If the Agency proceeds in the development of treatment standards for manganese, then IACM requests that we be allowed to participate in the development of such standards.

Response 17-2: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 17-3: As noted in the proposal (65 FR 55768), we also request that we be notified of future changes that may be made in the UTS based on newly submitted data.

Response 17-3: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment ICMP-00018, The Ferroalloys Association

Request for Comment Period Extension

The members of The Ferroalloys Association (TFA) Manganese Committee request that you formally extend the comment period on the recently proposed rule to list certain inorganic chemical manufacturing wastes for 30 days to December 13, 2000.⁹⁰

The proposal has significant regulatory implications for the manganese industry and thus affects a much larger industry group than just the titanium dioxide sector. EPA's intent to include manganese in Subtitle C programs under the Resource Conservation and Recovery Action (RCRA) was not well-known prior to publication of the proposal; TFA only found out about it indirectly. Based upon an initial review, we found that there is little analysis of manganese in the record of the proposed rule to which to respond. Thus, comments on the proposal are requiring a substantial amount of data development by industry.

We recognize that EPA is under court order to finalize the inorganic listing proposal, but we believe that due process justifies an extension in this case. With an extension, we expect to provide EPA with TFA's understanding of the volume and types of waste streams that might be affected by the proposal, expected costs, and how the essential nature of this element and its physical/chemical properties affect EPA's risk assessment and proposed treatment levels. We believe this information will be valuable to EPA and is necessary in reaching a carefully considered decision on these aspects of the proposed rule.

Response 18-1: EPA denied TFA's request for an extension of the comment period on November 7, 2000. See the response to TFA's written comments above in section 13. These written comments were sufficient for the Agency to understand the commenter's concerns. EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

⁹⁰ 65 FR 55684, September 14, 2000; Dkt. No. F-2000-ICMP-FFFFF. The TFA Manganese Subcommittee is composed of a wide cross-section of the Manganese Industry. In addition, the TFA Manganese Subcommittee includes several allied organizations including the International Manganese Institute, the American Feed Industry Association, and the National Electric Manufacturers Association.

Comment ICMP-00019, National Mining Association

Request for Comment Period Extension

The National Mining Association (NMA)⁹¹ by this letter requests that the Environmental Protection Agency (EPA) extend for thirty (30) days the comment period on the September 14 proposed Inorganic Chemical Manufacturing Wastes listing rule.⁹² Such an extension would place the new comment deadline at December 13, 2000.

As you know, NMA members are greatly interested in any proposed regulatory actions that could affect the status of RCRA's Bevill Amendment coverage of this industry's wastes. Of equal concern is the question of whether or not the materials proposed for listing are even wastes in the first instance. Furthermore, the proposed addition of manganese to RCRA Appendix VII and VIII, along with establishment of LDR treatment standards for the wastewater and nonwastewater forms of the metal, is of concern because of the ubiquitous nature of the naturally occurring metal.

Any one of these major issues would, by itself, justify a comment period considerably in excess of 60 days. The September 14 proposed rule is a lengthy complex and highly process-specific rule combining these three and other significant issues. The allotted comment period is simply inadequate; we cannot conduct a reasonable, thoughtful examination of the proposed rule and its record documents, and provide the agency with a well-reasoned response within the allotted 60 days.

NMA has no wish to delay appropriate EPA action. By the same token, however, NMA and its members believe that a proposal of this magnitude must be carefully considered, and that such consideration simply is not possible given the current deadline.

Response 19-1: EPA denied NMA's request for an extension of the comment period on November 13, 2000. See the response to NMA's written comments above in section 12. These written comments were sufficient for the Agency to understand the commenter's concerns. EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

⁹¹ NMA is comprised of the producers of most of the nation's coal, metals, agricultural and industrial minerals; the manufacturers of mining and mineral processing machinery, equipment and supplies; and the engineering and consulting firms, financial institutions and other firms serving the mining industry.

⁹² "Hazardous Waste Management System; Identification and Listing of Hazardous Waste. Inorganic Chemical Manufacturing Wastes: Land Disposal Restrictions for Newly Identified Wastes: and CERCLA Hazardous Substance Designation and Reportable Quantities". 65 FR 55684, September 14, 2000.

Comment ICMP-00020, Steel Manufacturer's Association et al

Request for Comment Period Extension

On behalf of the Steel Manufacturers Association ("SMA"), American Iron and Steel Institute ("AISI"), and Specialty Steel Industry of North America ("SSINA"), we hereby request a 30 day extension of the comment period on the identification and listing of certain inorganic chemical manufacturing wastes. 65 FR 55684 (Sept. 14, 2000). SMA AISI, and SSFNA are particularly concerned with the proposed establishment of a universal treatment standard ("UTS") for manganese, as well as its identification as a hazardous constituent in Appendix VIII of 40 CFR Part 261. *Id.* at 55767-769. If the extension request is granted, comments would be due on December 13, 2000.

SMA, AISI, and SSINA together represent almost 100 percent of the structural and specialty steel manufacturing in the United States. Manganese may naturally be present at relatively low levels in steel products, including slag. Accordingly, SMA, AISI, and SSINA are interested in the potential regulation of manganese under the Resource Conservation and Recovery Act.

The proposed actions involving manganese have potentially significant impacts on industries other than inorganic chemical manufacturing, including the iron and steel industry and member companies of SMA, AISI, and SSINA. Manganese is an essential micronutrient for human health and a ubiquitous element that is likely to be found at most remediation sites, regardless of whether it is present in a particular hazardous waste. Thus, identifying manganese as a hazardous constituent subject to a UTS will have serious ramifications for remediation activities.

Because the manganese proposals were embedded in a 98-page rulemaking notice specific to inorganic chemical manufacturing, SMA, AISI, SSINA, and other industry stakeholders were unaware of these significant actions until recently. An extension of the comment period is necessary, to enable these stakeholders to evaluate the potential effects of the proposed manganese proposals and collect data to assess the validity of the specified UTS.

Response 20-1: EPA denied SMA/AISI/SSINA's request for an extension of the comment period on November 7, 2000. See the response to SMA/AISI/SSINA's written comments below in section 25. These written comments were sufficient for the Agency to understand the commenter's concerns. EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment ICMP-00021, Millennium

Introduction

Millennium Inorganic Chemicals Inc. ("Millennium") appreciates the opportunity to comment on the proposed rule issued by the United States Environmental Protection Agency ("EPA") regarding the classification of certain inorganic chemical manufacturing wastes under the Resource Conservation and Recovery Act ("RCRA"). 65 FR 55683 (Sept 14, 2000).

Millennium, along with its non-U.S. affiliates, is the second largest producer of titanium dioxide ("TiO₂") in the world. Millennium has two titanium dioxide manufacturing facilities in Baltimore, Maryland and two titanium dioxide manufacturing facilities in Ashtabula, Ohio. One of the facilities in Baltimore, Maryland manufactures TiO₂ by the sulfate process; the other three facilities use the chloride process.

Millennium is filing these comments in support of EPA's proposal not to list as hazardous waste under RCRA any of the waste streams from the manufacture of titanium dioxide by the sulfate process or the chloride process.

SUMMARY

Millennium commends EPA for a thoughtful assessment of the potential risks associated with the management of wastes generated from the production of titanium dioxide by the sulfate process and by the chloride process. As noted below, EPA used a screening approach to risk assessment that incorporated sufficient conservatism to establish a sound foundation for concluding that a waste did not warrant further evaluation for listing as a RCRA hazardous waste. In many instances, the wastes generated at the Millennium facilities were removed from further consideration based on this conservative screening approach. Even with a screening methodology that significantly overestimated the risk associated with these wastes, EPA was able to conclude that management of these waste streams does not pose any significant risk to human health or the environment.

In a number of instances, EPA proceeded to a more complete modeling of the potential risks associated with several of the waste streams generated at the Millennium facilities. This more complete assessment, while still sufficiently conservative to overstate any potential risks, also yielded a determination that none of these waste streams warranted listing as hazardous wastes under RCRA.

Based on its review of the proposed rule and associated background materials, Millennium concurs with and supports EPA's decision not to list as "hazardous" wastes from the manufacture of titanium dioxide by the chloride process and the sulfate process. However, as discussed below, Millennium recommends that EPA revise certain aspects of its discussion of the Bevill status of various waste streams in the context of the final rule.

Comment 21-1: EPA Properly Determined Not To List as Hazardous Any Wastes From the Production of Titanium Dioxide by the Sulfate Process or the Chloride Process

Pursuant to the consent decree entered in EDF v. Browner, D.D.C. Civ. No. 890589, EPA was required to consider whether or not to list as "hazardous" wastes from a wide range of inorganic chemical manufacturing operations, including "titanium dioxide production wastes (except for chloride process waste solids)." In this proposed rule, EPA has set out the results of its assessment of the risks associated with titanium dioxide production wastes and its conclusion that none of the wastes from the production of titanium dioxide by the sulfate process or the chloride process warrant listing as hazardous waste under RCRA. As discussed below, Millennium believes that EPA has made an accurate assessment of the absence of any significant risk to human health or the environment from these wastes.

Response 21-1: EPA acknowledges Millennium's support for the rule.

Comment 21-1a: EPA's Use of A Conservative Risk Assessment Methodology Underscores the Absence of Any Risk Warranting Listing

As part of its risk assessment methodology for these listing determinations, EPA decided to use a variety of screening methodologies rather than conduct full-scale risk assessment modeling for all of the waste streams under consideration. EPA reasoned that the use of demonstrably conservative screening assumptions would provide a sound scientific basis for determining that some waste streams did not present sufficient risk to warrant listing while also conserving the time and resources of both industry and the Agency. 65 FR 55694.

Millennium supports the decision to use screening methodologies to sort out which wastes might warrant a more comprehensive risk assessment. Based upon its review of the Federal Register discussion and the related background documents, Millennium believes that the EPA did use sufficiently conservative exposure and fate and transport assumptions to be able to conclude with complete certainty that the wastes that were screened out would not pose any significant risk to human health or the environment.

In fact, Millennium urges EPA to include in the final rule a more direct discussion of the manner and extent to which this approach results in an extremely conservative, i.e., higher, assessment of potential risk than is actually present. While EPA has made substantial progress in its "plain English" presentation of risk assessment methodology, many readers would benefit from a summary explanation of how the compounding of conservative assumptions (in lieu of real world data) results in significant overestimates of potential risk.

The Agency's approach to reviewing actual waste management practices and assessing the likelihood of changes in current waste management practices was realistic and well supported. Where facilities have invested in and presently use specific equipment or technology to manage waste streams and secondary materials on-site, i.e., on-site landfills

or treatment or storage tanks, it is reasonable and appropriate to conclude that facilities will continue these present waste management practices rather than shift to practices that would not recoup the benefit of the investment (i.e., continued use of a tank for its effective life) or would be less cost effective (i.e., off-site disposal at a third-party or municipal landfill).

With respect to the evaluation of risks through specific exposure pathways, EPA appears to have successfully identified and focused on the units and locations where it would expect the potential exposure and risk to be the highest. Under this approach, the Agency considered multiple factors, including the concentration of particular constituents in a waste and proximity of particular units to off-site receptors. The Agency then made a series of further assumptions designed to build a further degree of conservatism into the risk assessment (e.g., assuming that a groundwater well would be present downgradient of the facility and located within a contaminant plume regardless of site-specific circumstances.)

Based upon its knowledge of its facilities and operations, and its review of the overall approach taken by the Agency, Millennium is convinced that the risk assessment methodology used by the Agency for the listing decisions provided a sound but also demonstrably conservative basis for the evaluation of the potential risk associated with the wastes generated from the production of titanium dioxide by the sulfate and chloride processes.

Response 21-1a: The Agency acknowledges the commenter's support. A description of our screening assumptions is provided in the background documents supporting the proposed rule.

Comment 21-1b: EPA Properly Determined Not To List As Hazardous Any Wastes From the Production of Titanium Dioxide by the Sulfate Process or Chloride Process

In the proposed rule, EPA considered whether or not to list waste streams separately generated by the production of titanium dioxide by the sulfate process and by the chloride process, as well as two waste streams that consist of commingled wastes from both sulfate and chloride process production operations.

Millennium believes that EPA properly determined not to list as hazardous any wastes from the production of titanium dioxide by either the sulfate process or the chloride process. Consideration of the Agency's approach to one such waste is illustrative of the conservatism in the Agency's risk assessment methodology. With respect to gypsum waste from the sulfate process, EPA correctly screened out all potential exposure pathways with the exception of the groundwater and surface water pathways from the landfilling of gypsum. Further modeling of that waste management scenario again confirmed that the landfilling of this material did not pose any significant risk to human health and the environment, even given what EPA characterized as "a number of conservative assumptions that likely overstate these marginal risks" (i.e., existence of drinking wells were there are none and assuming a groundwater flow

not known to occur). 65 FR 55755.

Millennium has similarly reviewed the factual descriptions and exposure and fate and transport assumptions used by the Agency with respect to the other waste streams generated by its operations. While Millennium has identified a number of other assumptions which it believes led the Agency to significantly overestimate the potential risks attributable to these waste streams, Millennium has concluded that the Agency's approach has simply underscored the legitimacy of its determination that none of these waste streams warrant listing as hazardous wastes under RCRA.

Response 21-1b: The Agency acknowledges the commenter's support.

Comment 21-1c: EPA Properly Determined Not To Use Dioxins and Furans as Appendix VII Constituents in this Rulemaking

As EPA noted in the proposed rule, the Agency has not sufficiently evaluated the potential significance of any risk attributable to the presence of dioxins or furans in any of the waste streams addressed in this rulemaking. EPA also correctly determined not to use these constituents as Appendix VII constituents in this rulemaking. Furthermore, such action would have, in many instances, required the Agency to address wastes beyond the scope of the consent decree.

Response 21-1c: See our response to comment 22-9g-2.

Comment 21-2: Comments Regarding EPA's Approach to Application of the Bevill Exemption

An essential aspect of EPA's assessment of wastes from the production of titanium dioxide was evaluation of whether particular waste streams were exempt from listing consideration due to the Bevill exemption. In fact, the consent decree which required EPA to undertake this rulemaking activity specifically recognized the Bevill exemption by acknowledging that "chloride process waste solids" were excepted from this rulemaking activity. 65 FR 55688. As noted below, Millennium believes that EPA needs to be careful in the final rule to guard against inadvertently altering how the Bevill exemption is applied.

Comment 21-2a: Bevill Determinations Need To Consider Site-Specific Factors

As EPA noted in the preamble to the proposed rule, it is "not always simple" to determine whether a particular waste stream is a Bevill exempt waste:

We found it sometimes difficult to determine whether a particular facility's waste fit within one of the exempt categories. For example, the mineral processing exemption

for titanium dioxide covers only solid materials from an initial step in the production process. It was not always easy to tell whether particular waste solids were generated from the portion of the process that would make them exempt, or from later production steps. (65 FR 55688.)

At the same time, EPA asserted that it was not in any way altering or reopening any earlier Bevill decisions regarding the scope of the exemption. The Agency stated that it sought in this rulemaking only to make assessments of "whether particular wastestreams fall within any of the exempt categories."

EPA has construed the exemption in the consent decree for "chloride process waste solids" to be a direct reference to the mineral processing waste exemption for "chloride process waste solids from titanium tetrachloride production" set out in 40 CFR § 261.4(b)(7). As EPA noted in the preamble, "each facility using the chloride or the chloride-ilmenite process generates its exempt solids in slightly different ways." Millennium agrees with this statement, but does not believe that EPA has fully considered the significance of this fact. Millennium is concerned that the generic statements, and in particular the "general principles" listed by EPA on pages 55750 and 55751 of the Federal Register notice, will be taken as having absolute regulatory force and effect and will be improperly applied to the differing process scenarios present in the industry. Millennium recommends that EPA modify this discussion and acknowledge more explicitly the need for site-specific evaluations of the scope and effect of the Bevill exemption.

As discussed below, Millennium believes that a site-specific approach is particularly warranted in those instances where the manufacturing stream at issue may not be "solid waste" and hence may be outside EPA's jurisdiction for purposes of this rulemaking.

Response 21-2a: Today's rule does not alter the Bevill status of waste solids from the production of titanium tetrachloride. As noted in prior Bevill rulemakings, where appropriate, Bevill opinions are based on site-specific and fact-specific bases.

Comment 21-2b: EPA's Failure to Address "Solid Waste" Determinations Should Not Be Allowed to Affect the Agency's Approach to the Bevill Exemption

As EPA acknowledges in the preamble to the proposed rule,

RCRA gives EPA jurisdiction only over materials that are discarded. EPA's current definition of discard is set out in the definition of solid waste at 40 CFR 261.2. Under this approach, process residuals (or "secondary materials") destined for recycling are solid wastes within our jurisdiction if the recycling closely resembles waste management. Conversely, if the materials are recycled as part of an ongoing manufacturing process, they are not solid wastes. (65 FR 55693.)

For purposes of the proposed rule, however, based on recent court decisions,⁹³ EPA made a conscious decision not to evaluate whether secondary materials addressed by the proposed rule were "solid wastes" under RCRA:

For almost all of the residual materials from these manufacturing processes which are re-used or recycled in some way, we decided not to attempt to determine whether the recycling practice is not subject to regulation under the court decisions and regulations Such determinations can be very time-consuming, particularly where we find recycling practices that appear not to be regulated, and then need to determine whether or not such recycling practices are legitimate. Consequently, we decided that it would be more efficient to examine first the potential risks posed by the reported recycling practices. If we found no significant risks, we would decide not to list the material. If, on the other hand, we found risks, we evaluate the recycling practice prior to making a listing decision. (65 FR 55694.)

Millennium concurs with the Agency's assessment that evaluation of the regulatory status of secondary materials in these circumstances is complicated, time-consuming and best addressed on a site-specific basis. Thus, Millennium agrees that it would be inappropriate for EPA to seek to make generic determinations regarding the potential "solid waste" classification for various secondary materials addressed under the proposed rule.

However, Millennium is concerned that EPA's presentation of this issue in the proposed rule has potential to create confusion and a presumption that certain streams are "solid wastes," when in fact no such assessment has been made by the Agency. For various streams that are reused or recycled, the preambular discussion contains conclusory statements that the secondary materials being discussed are not Bevill exempt and are therefore potentially subject to regulation. However, these materials may in fact fall outside the definition of "solid waste" and hence the Bevill exemption would not even be relevant. By discussing the Bevill status of these materials, the Agency creates a misleading impression that it has already concluded that these materials are "solid waste" and hence appropriate for evaluation with respect to the Bevill exemption.

Given that EPA's stated approach to these streams was to focus primarily on whether a risk is present that would warrant further assessment, Millennium recommends that EPA limit its discussion and analysis to the potential for risk. If the Agency does conclude that it needs to make some statement regarding the potential Bevill status of recycled or reused secondary materials, then the Agency should include in that specific discussion a clear caveat that the Agency has specifically refrained from making any assessment of the potential "solid waste" classification of those materials. The discussion should further note that a determination that

⁹³ In particular, EPA has expressed concern about the potential impact on its jurisdiction of the recent decision in *Association of Battery Recyclers, Inc. v. EPA*, 208 F.3d 1047 (D.C.Cir. 2000).

these secondary materials are not "solid wastes" for purposes of RCRA also places the materials outside the reach of the "hazardous waste" regulations as well.

Response 21-2b: See our response to comment 9-2c. The Agency wishes to clarify that the Bevill exclusion only applies to solid wastes. If a material is excluded from the definition of solid waste, it is not subject to the Bevill exclusion.

Comment 21-2c: EPA Acted Properly In Assessing Risk Only for the Non-exempt Portions of Waste Mixtures

As EPA acknowledged, there are a number of waste mixtures generated at titanium dioxide manufacturing facilities that consist of combinations of wastes which are and are not Bevill exempt wastes. In evaluating these waste mixtures for purposes of this rulemaking, EPA decided to assess only the risks associated with the non-exempt portions of the waste mixtures. Millennium agrees with this approach. Any approach by the Agency that did seek to evaluate or attribute risks to the exempt portions of these waste mixtures would have been inconsistent with the purpose and intent of the Bevill exemption.

Response 21-2c: The Agency acknowledges the commenter's support.

Comment 21-3: Manganese Should Not Be Added to EPA's List of RCRA Appendix VIII Hazardous Constituents

EPA is proposing to add manganese to the list of hazardous constituents in Appendix VIII to 40 CFR Part 261. 65 FR 55687. The criteria for adding constituents to Appendix VIII are set out at 40 CFR § 261.21: "Substances will be listed on Appendix VIII only if they have been shown in scientific studies to have toxic, carcinogenic, mutagenic, or teratogenic effects on humans or other life forms." As discussed below, EPA has not adequately demonstrated that manganese meets these criteria.

Comment 21-3a: Manganese is an Essential Mineral

Greger (*NeuroToxicology, 1999*) quotes other references stating that manganese is an essential element.

According to the 1999 edition of the most widely used basic nutrition college text in the United States, *Understanding Nutrition* by Whitney and Rolfes:

The human body contains a tiny 20 milligrams of manganese, mostly in bones and metabolically active organs such as the liver, kidneys, and pancreas. Manganese acts as a cofactor for many enzymes that facilitates dozens of different metabolic processes. For example, manganese metalloenzymes assist in urea synthesis, the conversion of pyruvate to a TCA cycle compound, and the prevention of lipid

peroxidation by free radicals.

The Food and Nutrition Board of the National Research Council (*Recommended Daily Allowances*, 10th edition, 1989) has established an estimated safe and adequate daily dietary intake for manganese to foster adequate dietary consumption of this essential trace element.

Response 21-3a: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.

Comment 21-3b: EPA Has Not Demonstrated Via Scientific Studies that Manganese Has Toxic, Carcinogenic, Mutagenic, or Teratogenic Effects on Humans When Ingested In Drinking Water and Therefore Has Not Shown that Manganese Warrants Addition to Appendix VIII

EPA has compiled an extensive health assessment in support of inhalation hazard in the 1996 IRIS substance file for manganese used as the basis for the addition to Appendix VIII in the proposed rulemaking. The inhalation hazard described by EPA and ATSDR is already addressed via the inclusion of manganese as a Hazardous Air Pollutant under the Clean Air Act.

However, neither the IRIS substance profile nor the ATSDR draft *Toxicological Profile for Manganese* (September 1997) establish a conclusive link between manganese in drinking water ingestion and toxicity to humans.

One reason for the apparent lack of manganese toxicity to humans via oral ingestion is that iron and calcium in the diet or in dietary supplements limit manganese absorption (Whitney and Rolfes, 1999). Greger (*NeuroToxicology*, 1999) elaborates, "... the body is protected against manganese toxicity by low absorption and/or rapid presystemic elimination of manganese by the liver but not the kidneys."

The IRIS substance file (page 6 of 37) refers to a 1941 report by Kawamura et al (*Kitasato Arch. Exp. Med* 18: 145-169) as "the only epidemiologic study describing toxicologic responses in humans consuming large amounts of manganese dissolved in drinking water." Velazquez and Ru (in *Risk Assessment of Essential Elements*, Mertz, 1994) review the Kawamura paper and note that the "concentration of manganese at the time of exposure was probably at least 28 mg Mn/L" and further that "the total intake was at least 58 mg Mn/day". Referring to the study by Kawamura, ATSDR states, "Thus, while there is no doubt these people were exposed to manganese, there is considerable doubt that all of the features of this outbreak (particularly the deaths) were due to manganese alone." (p. 45)

The IRIS substance file also discusses neurological effects suggested to be related to chronic intake of drinking water containing 1.8 to 2.3 mg/L of manganese in northwest Greece (p. 4

of 37). ATSDR (p. 47) reviews the same study by Kondakis et al (*Arch. Environ. Health*, 1989) and concludes, "Thus, this study supports but does not prove that chronic oral intake of manganese can lead to neurological changes in humans."

Furthermore, Vieregge et al (*Can. J. Neurol. Sci.*, 1995) directly contradict the Kondakis study by demonstrating that long term exposure to rural well water containing 0.3 to 2.16 mg/L has no neurological effects.

The International Programme on Chemical Safety of the World Health Organization (*Concise International Chemical Assessment document on Manganese and its Compounds*, 1999) sums up the overall situation stating, "The available evidence for adverse effects associated with chronic ingestion of excess manganese is suggestive but inconclusive."

Response 21-3b: EPA is deferring final action on all elements of our proposal that are specifically related to manganese. See Section IV.B of the final rule for further discussion.