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June 4, 2004

William V. Kennedy, Executive Director Commission for Environmental Cooperation North American Free Trade Agreement 393, rue St-Jacques Ouest, bureau 200 Montreal, Quebec H2Y 1N9 CANADA

Re : March 2004 Draft Report Taking Stock: A Special Report on Toxic Chemicals and Children's Health in North America

Dear Mr. Kennedy:

The International Cadmium Association (ICdA) is a not-for-profit trade association of the world's cadmium producers, consumers, processors, recyclers, and end-users headquartered in Brussels, Belgium with a North American office in Washington, DC. Our members include companies and associations in Canada, Mexico and the United States, and we have followed with considerable interest the NAFTA CEC Sound Management of Chemicals (SMOC) program for a number of years.

ICdA applauds the special efforts that the Taking Stock report has made to focus on the specific health concerns of children. The International Cadmium Association is committed to the safe use of cadmium and cadmium products, and to minimizing any impact they may have on human health, particularly those involved with children.

We are, however, concerned with the methodology utilized in this report to assess the risks associated with the production, use and disposal of cadmium and cadmium compounds in products. We are furthermore concerned that the rankings developed for various chemicals appear to bear little or no rigorous scientific linkage between actual exposures to children and carcinogens, developmental toxicants and neurotoxicants. These concerns are detailed in the attached submittal.

Thank you for the opportunity to submit these comments and for considering our concerns. We hope that these comments will be helpful.

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COMMENTS OF THE INTERNATIONAL CADMIUM ASSOCIATION TO THE COMMISSION FOR ENVIRONMENTAL COOPERATION NORTH AMERICAN FREE TRADE AGREEMENT CONCERNING THE MARCH 2004 DRAFT REPORT "TAKING STOCK: A SPECIAL REPORT ON TOXIC CHEMICALS AND CHILDREN'S HEALTH IN NORTH AMERICA"

The International Cadmium Association

The International Cadmium Association (ICdA) is a not-for-profit trade association representing the interests of the cadmium industry all over the world. Its membership includes primary cadmium and cadmium oxide producers, nickel-cadmium (NiCd) battery manufacturers, cadmium pigment producers, cadmium telluride (CdTe) solar cells manufacturers, cadmium electroplaters, cadmium distributors, cadmium-containing end products and cadmium recyclers in North America, Europe and Asia. These members include companies or other associations in Canada, Mexico and the United States of America.

ICdA is pleased to have the opportunity to submit these comments on the March 2004 Draft Report *Taking Stock: A Special Report on Toxic Chemicals and Children's Health in North America.* We share the CEC's concern with the potential human health and environmental effects of cadmium, especially as they may pertain to that of children. Many of the association's programs and efforts are aimed at minimizing any human health or environmental impacts from cadmium, and maximizing the collection and recycling of cadmium products.

Our main concerns with the March 2004 Draft Report stem from a few basic points:

- The utilization of the Environmental Defense Scorecard to rate the carcinogenicity, developmental toxicity and neurotoxicity of cadmium and cadmium compounds;
- The utilization of the Toxic Release Inventory (TRI) and the National Pollutant Release Index (NPRI) data along with the Environmental Defense ratings to establish which chemicals pose the greatest dangers to children's health in North America;
- The lack of any firmly established relationship between cadmium chemicals which are used commercially and reported under TRI and NPRI and the actual chemicals which have been shown to cause human health and environmental adverse effects and;
- The lack of any rigorous scientific risk assessment determinations in evaluating effects on children's health.

Carcinogenicity, Developmental Toxicity and Neurotoxicity

The carcinogenicity of cadmium has been well studied and thoroughly discussed, and yet the conclusions still remain controversial. Carcinogenicity has been well documented in animals exposed to cadmium ions, usually from cadmium chloride, and the major agencies which maintain carcinogenicity ratings for chemicals (IARC, NTP) specify that it is the ionic species of cadmium which is either a known or suspected human carcinogen. Carcinogenic effects in adult humans have been established for long-term, high exposures in occupational settings, but even these epidemiological studies have largely been confounded by the presence of other carcinogenic agents. It has not been conclusively demonstrated that a positive dose-response relationship exists between cadmium exposure and cancer or whether the simultaneous exposure to another known carcinogenic agent is responsible for a positive dose-response relationship.

Scientifically-based assessments of the developmental toxicity and neurotoxicity of cadmium and its compounds are very sparse. Most major reviews of the health effects of cadmium are inconclusive on these health endpoints. For example, the Agency for Toxic Substances and Disease Registry's (ATSDR)¹ *Toxicological Profile for Cadmium* in section 1.6, page 7 states "Harmful Effects on child development or behavior have not generally been seen in populations exposed to cadmium, but more research is needed. It is also difficult to determine the cause of harmful effects on child behavior or development from exposures to low levels over long periods of time, which are the most likely exposures for children as well (as) adults in the general population. We do not know whether cadmium can cause birth defects in people." Apparently, high doses of injected cadmium ions can produce effects in animals, but similar effects have not been observed in humans.

Similarly, the World Health Organization's (WHO) International Programme on Chemical Safety (IPCS) monograph on cadmium, Environmental Health Criteria (EHC) 134 in section 8.2.6, page 163 notes: "In conclusion, it is not yet possible to say whether cadmium causes mutagenic effects in humans." With regard to transplacental transport and fetal effects, the WHO Cadmium Monograph EHC 134 similarly presents some studies which indicate cadmium effects but also an equal number which indicate that cadmium is not generally transported across the placental barrier.

¹It is curious to note that the ATSDR *Toxicological Profile for Polychlorinated Biphenyls* (*PCBs*) is referenced in the Draft Report but that none of the many other ATSDR reviews on metals (zinc, lead, nickel) are. Most of these documents are well-balanced presentations with often considerable information on carcinogenicity, developmental toxicity and neurotoxicity, yet their consideration appears noticeably absent from the Taking Stock Draft Report, certainly at least in the case of metals.

In spite of these determinations and summaries, as well as other scientifically-based and reputable reviews of the toxicology of cadmium, the CEC Taking Stock Draft Report relies entirely upon the Environmental Defense Scorecard system for establishing the carcinogenicity, developmental toxicity and neurotoxicity of cadmium and its compounds. The Environmental Defense Scorecard rating system, in turn, offers virtually no developmental toxicity or neurotoxicity ratings for any of the 226 cadmium compounds listed in its chemicals data base. Only cadmium metal itself is actually listed directly as a carcinogen, developmental toxin and neurotoxin, and this listing is based solely on the California Proposition 65 listing.

Cadmium oxide and cadmium sulfide, both of which are used commercially, are listed in the Scorecard system as being included under Proposition 65 <u>by Environmental Defense</u> as "Members of a Class of Compounds" which are listed. In other words, Environmental Defense feels justified in extrapolating a carcinogenicity, developmental toxicity or neurotoxicity rating from the element cadmium to all cadmium compounds in spite of the complete lack of any scientific studies on those specific compounds to indicate their carcinogenicity, developmental toxicity or neurotoxicity. It is inappropriate to make such extrapolations, especially for example, in the cases of highly soluble vs. insoluble compounds (cadmium chloride vs. cadmium sulfide) or different ionic species (chromium 3 vs. chromium 6). Carcinogenicity, developmental toxicity and neurotoxicity determinations cannot be generalized to include a metal and all of its compounds.

Furthermore, we question the report's sole reliance on the California Proposition 65 system, in contrast to the weight of the evidence, as reported in the ATSDR *Toxicological Profile on Cadmium*, the WHO IPCS *Environmental Health Criteria on Cadmium*, the International Agency for Research on Cancer (IARC) *Monographs on the Evaluation of Carcinogenic Risks to Humans: Beryllium, Cadmium, Mercury and Exposures in the Glass Manufacturing Industry*, the National Toxicology Program's (NTP) *Annual Report on Carcinogens*, and the U.S. Environmental Protection Agency's *Integrated Risk Information System (IRIS) Cadmium Summary* with respect to the carcinogenic, developmental and neurotoxic effects of cadmium. At the very least, these sources of information should be reviewed along with the California Office of Environmental Health Hazard Assessment's (OEHHA) Evidence on Developmental and Reproductive *Toxicity of Cadmium*. There is also considerable discussion on the carcinogenicity, developmental toxicity and neurotoxicity of cadmium and cadmium oxide in the European Union's draft risk assessment on cadmium and cadmium oxide which should be reviewed and included.

In addition, the Draft Report simply notes whether or not a particular substance is listed as a carcinogen, developmental toxicant or neurotoxicant, and then multiplies this either/or classification by the total releases and transfer number to establish a rating. No system of the potency of the chemical is utilized so that, if a substance is on the carcinogen, developmental toxicant or neurotoxicant list, then it is the level of its releases which determine its final ratings in Tables 3, 7, and 11 in the Draft Report. As pointed out above, cadmium ions from cadmium chloride are listed as known or suspected human carcinogens in several international carcinogenicity ratings. Cadmium oxide, cadmium sulfide and cadmium metal, the commercially utilized materials and the ones which make up the bulk of transfers and releases are not so listed. For the report to have scientific credibility and fulfill its purposes of advising of the risks to children there must be a better system to directly link the scientifically established health effects of cadmium and its various compounds with the specific potency of their effects and the specific levels of the compounds released.

To rely on the rating system of one group which is an advocacy organization rather than a scientific one, and which has based its information on only one review of the data when many are available appears to be questionable policy, and one which will lead to consideration of only one viewpoint when many should be reviewed. The International Cadmium Association urges the Commission for Environmental Cooperation to abandon the Environmental Defense Scorecard system of rating carcinogens, developmental toxicants and neurotoxicants and, at least in the case of cadmium, its complete dependence on the California Proposition 65 evaluations when many others are available. All the best scientific evidence should be considered.

Release and Transfer Data

As noted previously by the ATSDR *Toxicological Profile on Cadmium*, the most likely cadmium exposures for children will be very low dose ones for long periods of time. Almost all human health effects established for cadmium have been as a result of high exposures in the occupational setting which are not conditions encountered by children. Thus, coupling transfer and release data with adverse health effects in children seems inappropriate unless it were demonstrated that either the general population was exposed to high levels of cadmium or that children were employed in the cadmium industry and exposed to occupational levels. While these two conditions are not impossible, they are improbable. Only once in the past 50 years has a high cadmium exposure resulted in adverse human health effects in a general population. In the late 1950s and 1960s, mostly middle-aged women with low zinc and iron stores suffered from Itai-Itai disease in Japan as a result of cadmium contamination of rice fields. Today, however, Japan has rigorous laws governing the cadmium content of rice and drinking water. Similarly, the occupational standards for cadmium around the world have now all been lowered to the range from 2 to 50 μ g/m³ and are considered protective of human health. Thus, not only is the likelihood low of exposures to children but regulations are in place that would preclude the types of health effects on children described in the Draft Report.

Even apart from these common-sense considerations, establishing rating systems for various chemicals based on carcinogenicity, developmental toxicity and neurotoxicity ratings and then matching them to release and transfer data to create a rating system of the worst offenders appears problematic. The three cadmium containing chemicals that are utilized commercially are cadmium metal, cadmium oxide (or hydroxide) and cadmium sulfide. Small amounts of some compounds such as cadmium nitrate, cadmium sulfate, cadmium telluride, and cadmium stearates are also used, but on much smaller scale than the three principal materials – the metal, the oxide or hydroxide and the sulfide. Presumably, most of the releases and transfers for cadmium will be in the form of

metal, oxide or hydroxide, and sulfide. Yet the Draft Report in essence treats all cadmium releases and transfers as if they were the cadmium ions from cadmium chloride which is the compound used in at least 95% of the toxicological testing of cadmium but a vastly smaller proportion of cadmium sold commercially. The toxicity of cadmium sulfide is much lower than that of cadmium chloride simply because the sulfide is virtually insoluble and releases almost no cadmium ions. The bioavailability of cadmium species is not discussed in the Draft Report, and all cadmium releases and transfers are treated as if they are indicative of the worst case cadmium toxicity tests. This factor can be significant in the case of highly insoluble compounds such as the sulfide, the sulfoselenide and the telluride. Even cadmium oxide is moderately insoluble, and certainly develops a lower cadmium ion concentration than cadmium chloride.

Another factor to be considered is that the release and transfer data reflects amounts of cadmium and cadmium compounds that will not represent a true cadmium exposure for children. The amounts of cadmium contained in nickel-cadmium batteries collected and recycled does not represent a cadmium exposure for children. Electroplating sludges, spent anodes and other U.S. EPA F006 electroplating wastes containing cadmium are recycled to recover the cadmium, and the only possible cadmium exposures involved might be occupational ones which are tightly controlled. Similarly, other types of cadmium-containing wastes which are sent for recycling or hazardous waste landfill or chemical fixation do not realistically represent cadmium exposures for children. If release and transfer data will be used, it would be more accurate to remove from the total figures the amounts sent to recycling, hazardous waste landfills or other destinations where they are unlikely to represent a subsequent exposure to children.

Finally, the utilization of the release and transfer data implies that all cadmium exposure to humans and to children in particular arises from industrial releases and transfers. This is simply not the case. For example, 41% of human exposure to cadmium comes from phosphate fertilizers, about 20% from natural sources, and a considerable amount from the processing of materials in which cadmium is contained as a natural impurity. The production of all metals and the specific production, use and disposal of cadmium-containing products accounts for less than 25% of the total of all human cadmium exposure. Thus, transfer and release data are unlikely to reflect any true measure of human cadmium exposure, and the whole question of what measure might be most appropriate for children's health determination needs careful examination.