#### U.S. Government Comments Draft Report: Taking Stock A special Report on Toxic Chemicals and Children's Health in North America

# Introduction:

The U.S. Government (USG) welcomes contributions to the ongoing dialogue regarding children's health and chemical exposures. With Canada and Mexico, we initiated the Commission for Environmental Cooperation (CEC) *Cooperative Agenda on Children's Health and the Environment in North America* to promote trilateral action to better understand and protect children from environmental risks. This CEC program provides for trilateral work on three children's environmental health priorities: asthma and respiratory disease, lead poisoning, and the effects of exposure to toxic substances.

We believe that the draft report *Taking Stock: A Special Report on Toxic Chemicals and Children's Health in North America,* released April 2004, ultimately has the potential to provide valuable information and insight to the reader regarding children's health, chemicals, and the use of Pollutant Release and Transfer Register (PRTR) data. However, we must stress that we have identified significant and systemic problems with the methodology and content of the draft report that the authors should consider and thoroughly address. We applaud the CEC Secretariat's decision to work with the Parties to convene a scientific peer panel to review the report, along with the set of public comments received. We also agree that the final report should use the most recent PRTR data available.

Our comments are below. They are organized by general comments, then chapter-bychapter comments.

# **USG General Comments**

### USG General Comment 1: Report Purpose, Audience, Disclaimer, and Authors.

The report should clearly state, in the preface, who is the intended audience and what is the purpose of the report. The report should also state that the authors, reviewers and consultants who contributed to the report did so in their individual capacities and not as representatives of the Parties.

### **USG General Comment 2: Citations.**

We believe it is very important that the report provide references to all scientific and factual information. Citations, however, are not consistently provided in the report.

# USG General Comment 3: Toxics Release Inventory (TRI) Data.

The final report should strongly emphasize the following points about the use of TRI data.

First, when analyzing TRI data, it is important to keep in mind that these data reflect chemical releases and other chemical waste management activities, not whether, or to what degree, the public has been exposed to those chemicals. While the current version of the document does identify this shortcoming, it does so in only a cursory way. We believe this issue should receive a much more thorough discussion. In addition, the report should note that none of the TRI rankings are meant to imply that a facility, state or province is not meeting its legal requirements.

Second, the "quantity" of the release of a chemical should not be considered alone without other factors. There are other chemical releases and sources of chemical exposure to children, for example, that are not included in the TRI data base and yet should be considered to get a complete picture of potential exposures.

TRI data, in conjunction with other information, can be used as one possible starting point in evaluating the potential for exposures that may result from releases and other waste management activities which involve toxic chemicals. Determining potential health risk requires knowledge of many factors including the toxicity of the chemical, the fate and transport of the chemical in the environment, the route of exposure (ingestion, inhalation, or dermal) and the amount, frequency, and duration of human or other exposure to the chemical after it is released.

### USG General Comment 4: Use of Chemical Lists.

The USG does not unconditionally concur with the neurotoxicity or developmental toxicity effects cited for the list of known and suspected developmental toxicants or the list of suspected neurotoxicants. We believe that the subsequent presentation of release information based on these health effects-based lists could both misrepresent and misstate potential hazards associated with the chemical release information.

The final lists used in the report should be based on scientifically sound, peer reviewed data pursuant to clearly defined and transparent criteria. The lists of known or suspected carcinogens used in the report are based on scientifically sound, peer reviewed data (i.e., IARC and NTP) and would generally be acceptable to the USG. The California Proposition 65 list also adheres to a set of clear criteria and is based on peer reviewed data. A preliminary review of the use of the Environment Defense lists in this report raised a number of issues. For example, the references for the lists on the Environmental Defense website <www.scorecard.org> do not define what criteria were used to categorize "suspected neurotoxicants" or "recognized or suspected developmental toxicants." Another issue is that the toxicity data described in three predominant references from the website <www.scorecard.org> for suspected neurotoxicants (HAZMAP, NJ-FS, and RTECS) have not been evaluated or peer reviewed, and, in some cases, are not referenced. The validity of the information contained in these sources has not been independently verified and, therefore, should not be regarded as scientific fact. In addition, a preliminary screening of several chemicals on the list were not found in the reference cited in the Scorecard when searched by CAS Number - therefore, the validity

of the chemical's inclusion on the list cannot be evaluated. Finally, page 27 of the draft document states that Environment Defense created the lists used in this report in consultation with other agencies; this sentence as written could be misinterpreted as USG endorsement of the lists, but the USG has not endorsed the Environment Defense lists.

There also appears to be some inaccuracies in the translation of the Score Card lists of chemicals to the PRTR lists used in the report. For example, in some cases the report references a chemical and its compounds, but the Environment Defense Score Card List references only a subset of all compounds considered.

The draft report also includes no detailed information regarding the development process or scientific criteria for each of the lists. This is a serious oversight as this type of information is necessary to understand and evaluate the findings of the report. For each list eventually used in the report, a detailed description of list development process, criteria, strengths and limitations should be provided to the reader. Specifically, are there processes to add or remove chemicals to the list over time. What sources are used? Are there specific criteria applied to list development and has the list undergone scientific peer review? This information is necessary to make informed judgments about the information and better understand the science behind the lists.

Finally, throughout much of the report the text and charts do not routinely distinguish between known and suspected developmental toxicants, although Environment Defense specifically makes this distinction. The same is true for neurotoxicants. This type of generalization and inaccuracy is alarming, diminishes the credibility of the report, and is misleading about the state of scientific understanding.

# USG General Comment 5: The discussion on what is being done to protect children from environmental risks (Chapters 4 and 5) could be improved by highlighting more ongoing activities.

We recommend combining Chapters 4 and 5 and the discussion of what is being done and what could still be done. We also believe that the current content in Chapter 4 does not adequately cover the important ongoing work by many organizations in the U.S. to protect children from environmental risk. We suggest moving away from an outlined list to a more substantive and thorough discussion. This addition will provide the readers a better understanding of ongoing work and enhance any discussions on what could be done next.

We have provided a list of some U.S. activities in our detailed comments below.

USG General Comment 6: The report methodology should be changed to better describe the different types of releases and transfers as well the exposure considerations associated with these different types of releases and transfers.

An important objective of this report is to provide the reader a better understanding of health risks to children by analyzing PRTR data, but the substantive evaluation in the report leads the reader to believe that all releases and transfers result in an equal health impact.

The USG is concerned that the report will lead to inaccurate conclusions regarding actual exposures to children. In particular, we are concerned that the report lumps releases to air and water together with waste disposed of in secure landfills and underground injection wells. There are many critical factors the public should consider when interpreting PRTR data. Disposal and other releases of chemicals into the environment occur through a range of practices that should be distinguished by whether or the extent to which the chemicals are placed in engineered units, as compared to more direct releases. The report should distinguish between these different practices and how they may ultimately affect the potential for human exposure to the toxic chemicals. For example:

- Disposal to Class I Underground Injection wells where toxic and nontoxic fluids are injected into isolated formations beneath the lowermost underground source of drinking water, which limits potential for contamination, and
- Disposal to landfills in which wastes are buried. Many landfills are designed with liners, provisions for daily cover, leak detection systems, and groundwater monitoring systems that limit the potential for human exposure to the contents of the landfill.

Most disposal or other release practices are subject to a variety of regulatory controls designed to limit environmental harm. Please refer to the *Toxics Release Inventory (TRI)* and Factors to Consider When Using TRI Data (www.epa.gov/tri/tridata/index.htm#pdr) for more information on the differences of these data elements.

Because the report focuses primarily on total releases on- and off-site of chemicals, the report leads the reader to believe that chemicals disposed of in landfills or underground injection wells to be equivalent to releases to air and water. This type of analysis will likely lead readers of the report to draw conclusions about chemical exposures from PRTR data which do not reflect actual exposure. While the report makes the point that facilities release substantial amounts of chemicals to the environment in North America, the particular facilities to which releases are attributed are often not the sources of greatest exposure to the various categories of chemical discussed in the report (carcinogens, developmental toxicants, and neurotoxins.) For example, a number of landfills are listed as accounting for the most "total releases on- and off-site" of known or suspected carcinogens, implying that these are the facilities that should be of greatest concern to the reader. Although the draft report (Page 28) does mention what quantities were released and transferred to air versus to landfills on-site, more information needs to be presented in Chapter 3 that emphasizes to the reader the distinction between disposal to landfills and underground injection wells or other types of releases to ambient media.

We therefore believe that the authors should include an expanded section of the report in Chapter 3 that further explains the many critical factors to consider when using PRTR data. For example, information similar to that presented in the U.S. Environmental Protection Agency's (EPA) "Factors to Consider When Using TRI Data" http://www.epa.gov/tri/2002 tri brochure.pdf) or in Chapter 1 of the TRI Program's annual Public Data Release Report (Pages 1-8 to 1-10, What to Consider When Using TRI Data, http://www.epa.gov/tri/tridata/tri01/pdr/chapter1.pdf) could be incorporated. In addition, the authors should further break down the data in all tables. In other words, don't combine all land releases into one column, rather break them out into landfills, land treatment, etc. This change will allow the readers of the report to see exactly how facilities report the data and allow the user to consider which quantities she wants to include in any further evaluation of the data. Also, in each section of the report that discusses the states/industries/facilities with largest releases or chemicals being released in largest quantities, the report should discuss the releases to the various media separately rather than combining them. This change would allow readers to see which media receive the various releases. Changing the data presentation in the tables and including additional information about the factors to consider when using PRTR data will make it clear to the reader that she must make distinctions between disposal or other types of releases to ambient media

# USG General Comment 7: The report should disclose and distinguish between the relative impacts of chemicals.

While the report does group chemicals by the type of health effect, it does not distinguish between the wide range of toxicities these chemicals exhibit, even within the same health effects category. Thus, a kilogram of copper is equated to a kilogram of mercury in the report, even though the known or suspected health effects from the same amount of chemical may be vastly different.

The report also does not highlight or present any analysis that distinguishes between particular chemicals that are known to cause problems for children and other chemicals.

While reduction measures are certainly important, the report misses an important opportunity to focus attention on reducing those chemicals that are more likely to cause the most serious health problems. The report should highlight such issues so that release information and the relative impacts among chemicals and potential children's health risks are placed in appropriate context.

# USG General Comment 8: Discussion of Health Effects of Chemicals, Health Status of Children, and Presentation of Chemical Releases requires more balance.

Chapter 2 contains a very broad discussion of health effects (e.g., cancer, learning, developmental and behavioral disabilities, endocrine toxicity, birth defects.) This chapter is followed by a chapter presenting data about a set of chemicals known or potentially

associated with three specific health effects. Because Chapter 2 is written so broadly and not directly tied to the PRTR analysis in the report, readers may incorrectly assume that chemical releases, particularly PRTR releases, cause all of the effects discussed in Chapter 2. While the report notes that there are many factors known to influence the health of children and that the effects of many chemical exposures on children remain unknown and require further research, the discussions are cursory and these factors seem understated. Discussion of some important factors affecting the health of children, such as exposure to second hand smoke, violence, and substance-abuse during pregnancy, is absent. We strongly encourage a thorough review of this chapter with a focus on public health messages stated or implied and on how the content relates to the PRTR analysis in the report.

The discussions on health are also weakened by reliance on out-of-date information and lack of explanation of available information sources. For example, Chapter 1 references a 1991 Pan American Health Organization report, although a 2002 report is available. The US also has more recent information available on the health status of children referenced in other parts of the report.

Finally, we believe that Chapter 2 should also include a brief overview of the chemical risk assessment process, including the NRC 4-stage process (hazard identification, dose-response assessment, exposure assessment, and risk characterization) as well as the types of data used to assess potential risks. This change would provide some context for later discussions of HPV, VCEEP, and PRTR. We believe that one purpose of this report should be to clearly explain how we come to understand the health effects of chemicals on children, and currently the report misses this opportunity.

#### **USG General Comment 9: Process Comments.**

We believe this special feature warranted more involvement and consultation with the Parties in developing the methodology for the report. In addition, in some important cases, information on Party programs is dated while other information on a wealth of children's environmental health activities underway in the United States is not included. The children's health agenda in Resolution 02-06 calls upon "the Parties to work together with the Secretariat" on the listed initiatives.

We appreciate the CEC Secretariat's consideration of comments from stakeholders and the Parties as well as the decision to convene a scientific peer review process. The USG believes that these procedures are necessary to ensure that a broad range of views are considered, the credibility of the report methodology is improved, and the content and conclusions of the report are accurate and scientifically sound.

#### **USG General Comment 10: Consistent Presentation and Use of Definitions.**

In select places, the report summarizes Party information, but gives total cumulative numbers for one Party and percentages for the other; this does not present a useful comparison. The same is true with the use of certain definitions and corollary presentation of Party information, for example, relative poverty and poverty. Moreover, "relative poverty" in one Party may not present the same potential health concerns compared to another. We believe the report should recognize in all appropriate places the limitations of comparisons when full comparative numbers or data are not available, including all appropriate assumptions. The report should encourage the generation of high quality, public information.

Finally, the document should be edited to eliminate the use of inappropriate colloquialisms such as "tip of the iceberg"(pviii). This type of language does not fit well in a science-based document.

# **Specific Comments by Chapter**

#### **Executive Summary:**

Comment ES1: Page v, next to last sentence states that "...each year we are adding to the cumulative load of chemicals released into the environment." This is not strictly accurate since many chemicals degrade once released (i.e., the "load" for every chemical is not "increasing" in the cumulative sense implied here). The report should explain this.

Comment ES2: Page xi, second paragraph, first sentence, the phrase "been consistently" should be changed to "often been" since some chemicals may be found to be less toxic upon further analysis.

Comment ES3: Page xi, last sentence, we suggest striking "interacting."

Comment ES4: While there are a few appropriate caveats in the presentation of PRTR release tables on exposure and risk, such disclaimers appear limited in the transition from the summary to the chapters on children's health, e.g., Page viii.

Comment ES5: Page viii, 4<sup>th</sup> full paragraph, Since the summary provides an overview of factors related to children's health, the sentence related to PRTR not reflecting exposures to the public should also include "or children."

Comment ES6: Page ix, The Summary should be revised so that it is more transparent with respect to the methodology used in the report. After stating how it analyzes publicly available PRTR data, it does not provide any detail on how it arrived at selecting the list of chemicals for which it searched PRTR data or that the lists consulted were from non-government sources. Since the report currently consults lists that include a number of chemicals suspected to have certain health effects, it would be an improvement to state in the Executive Summary what percentage of all reportable North American PRTR releases are comprised by the chemicals that are ultimately the focus of this report. This would provide a more complete picture of the releases.

Comment ES 7: The disclaimer related to PRTR releases not necessarily reflecting exposure to the public or children is lost when highlighting percentage releases of chemicals with certain health effects and regions or facilities that have the largest releases of such chemicals based on the report's methodology.

Comment ES 8: The statement "As our knowledge increases, the levels considered 'safe' for chemicals has been consistently lowered" may not be accurate across all bodies of information.

### **Introduction:**

Comment Intro 1: Page 1, Greater context on the link or limitations between the pathways of exposure for children listed and PRTR releases should be provided.

Comment Intro 2: The goal statement for the report does not fully reflect the information it provides in that PRTR releases are not necessarily indicative of exposure (as stated on Page viii and with PRTR release tables). While the report discusses potential impacts of these substances on the health of children, it does not fully cover what the Parties are doing to more specifically address threats to children's environmental health, including those that may stem from higher priority risks. The report does not fully describe the limits of its methodology; some impacts based on present data may be overstated (Page 2).

Comment Intro 3: At the end of Chapter 2, a number of reports are mentioned. We believe that it would be good to reference a few other key reports, such as the American Academy of Pediatrics (AAP) Pediatric Environmental Handbook, the AAP Journal Supplement from April 2004, the International Forum on Chemical Safety Children's Health and Chemical Safety publications from November 2004, and the two US domestic children's environmental health indicators reports.

## Chapter 1:

Comment 1-1: We believe that the number of children as percentage of the total population for each Party should be among the listed figures. This number is currently in an appendix (Pages 6-7).

Comment 1-2: There are some critical inconsistencies in the use of definitions and presentation of information in the demographics section. It would be an improvement to draw from consistent, widely-used definitions and to provide consistent context in explanations or information. For example, the report should provide the source of the statement that 20 percent of North American children live in poverty (Page 6). Further issues may also be relevant to ensure accuracy. For example, how does the definition for poverty in that source compare to the next definition when the term "relative" poverty is used (Pages 6-7)? Is this a widely known or used definition? In terms of children's environmental health across the three countries, does living in "relative" poverty present the same environmental health risk or threat to children for each country (Page 7)? This is expanded upon for children in urban and rural areas, but not for the general statement. The discussion continues about poor children, but it would be helpful to know the definition of poor used by the author. Is it the same as children that live in "relative" poverty? Is it the same as that used in the following health discussion and "conditions of poverty" and "poor children" at pages 8-9 and by the cited sources? Do children living in urban or rural areas across the three countries face the same level of environmental health risks (Page 7)?

Comment 1-3: Page 8, last paragraph, should "the Americas" be changed to "North America?" We believe the information should focus on North American trends.

Comment 1-4: In terms of leading causes of death, does the report mean cancerous tumors so that statements on page 10 and page 18 are consistent?

Comment 1-5: Page 10, Last Paragraph. This paragraph presents a number of significant conclusions. However, the report does not provide evidence for all of these conclusions or citations. Please reference USG general comment 2. We believe the report will be strengthened if these kinds of issues are consistently addressed within the report.

## Chapter 2:

Comment 2–1: While chemicals that are produced inadvertently as the result of manufacturing may not be included in screening/testing information, it does not mean that their release may not be controlled through other requirements, e.g., MACT standards (Page 12). It would be useful to note this point.

Comment 2–2: The sentence on page 12 of the draft report concerning the TSCA Inventory should be revised as follows (revised text is bolded): "In the US, the Toxic Substances Control Act Chemical Substance Inventory is a list of approximately **82,000** 'existing' substances." (As of April 2004, there were 81,709 chemicals on the TSCA inventory.)

Comment 2-3, Page 12, Last Paragraph on the new chemicals program requires several revisions as follows:

For the sentence that reads, "A chemical not on the original TSCA Inventory is considered a "new" chemical; between 1,000 and 3,000 "new" chemicals have been submitted to the EPA each year under TSCA. A notice under Section 5 of the . . . ", we suggest reversing the order of the sentences and correcting the number of chemicals in the following manner: "A chemical not on the original TSCA Inventory is considered a "new" chemical. A notice under Section 5 of the . . . new chemical for general commercial use. EPA receives approximately 1,500 notices annually."

The sentence "If EPA determines that the new substance may present an unreasonable risk of injury to human health or the environment, testing and restrictions may be used." should read "If EPA determines that insufficient information exists to evaluate the human health and environmental effects of the substance, and that (1) it may present an unreasonable risk or (2) be produced in substantial quantities, and have substantial or significant human exposure, or have substantial release to the environment, EPA might prohibit or limit activities associated with the new chemical."

Add after "10 percent of the notices filed." the following: "Following the 90-day review period, if EPA takes no action, the submitter may begin manufacturing or importing the chemical. A "Notice of Commencement" (NOC) must be submitted to EPA within 30 days of first manufacture or importation. Following receipt of the NOC, the chemical substance is added to the Inventory. From 1979 to October 2003, approximately 18,100 new substances have been added to the inventory."

Comment 2–4: Page 13, Please include the following changes for the discussion on High Production Volume (HPV) Chemicals:

#### 1st paragraph

"Approximately 2800 chemicals are known as high production...." should read, "**Based on 1990 reporting**, approximately 2800 chemicals are known as...."

"...high volumes there -- at over 1 million pounds..." should read "...high volumes there -- at **or** over 1 million pounds..."

"...or between 4 and 7 trillion pounds annually" We are unsure of the source of these numbers. We suggest that a source be provided if the numbers are used.

#### 2nd paragraph

"lack of basic test data for 93%" should read "lack of **publicly available basic screening** test data for 93%."

"Over 430 companies, some working through 155 consortia..." should read "Over **410** companies, some working through **113** consortia..."

"conduct new testing as required and make the existing data and new tests available to the public " should read "conduct new testing as **necessary** and make the **existing and new data** available to the public "

#### <u>4th paragraph</u>

As written, it sounds like OECD and ICCA programs test all chemicals. Some of the data acquired under these programs will be existing data.

Comment 2-5: It would be useful if the report included a focus on the Voluntary Children's Chemicals Evaluation Program (VCCEP), as well as the HPV Program. The VCCEP is described in brief on page 75. In our latter comments, we propose language for a similar focus and snapshot of the VCCEP. This HPV discussion should also include an internal cross-reference to the VCCEP discussion on page 75 or wherever VCEEP is finally included in the final report. Links to the appropriate activity websites should be added in the references VCCEP. These links are: http://www.epa.gov/chemrtk/vccep/index.htm and HPV =

http://www.epa.gov/chemrtk/volchall.htm .

Comment 2-6: Please address the following comments for page 14:

The next to the last paragraph implies that there are currently no developmental or neurotoxicity data for benzene, toluene, xylene, and trichloroethylene. This is not entirely correct and we suggest that the literature be reviewed and discussed in sufficient detail to allow the reader to have a firm understanding of the toxicological database from which statements about health associations have been drawn.

#### 5th paragraph

"A 1998 EPA review found that no basic toxicity testing was publicly available for..." should read "A 1998 EPA review found that no basic **screening level** toxicity testing was publicly available for a significant portion of **the approximately 2800** chemicals considered to be produced or imported..."

"Six tests are necessary for a basic understanding..." should read "Six **testing endpoints** are necessary for a basic understanding..."

#### 6th paragraph

"According to EPA, only seven percent of HPV chemicals have a complete set of the six tests; almost all of the HPV chemicals (93%) were missing one or more of these basic tests, and just under half of the HPV chemicals were missing all of these tests" should read "According to EPA, only seven percent of HPV chemicals have a complete set of **the six testing endpoints**; almost all of the HPV chemicals (93%) were missing one or more of **these testing endpoints**, and just under half of the HPV chemicals were missing all of the HPV chemicals (93%) were missing one or more of **these testing endpoints**, and just under half of the HPV chemicals were missing all of **the six testing endpoints**."

The second clause of the first sentence should be amended from, "EPA issued the HPV Challenge Program" to, "the HPV Challenge program was announced."

"Of the 830 companies making HPV chemicals, 148 had no test results available on their chemicals" should read "Of the 830 companies making HPV chemicals **that EPA analyzed**, 148 had no **endpoint** information **publicly available** on their chemicals"

"The basic set of tests for one chemical costs about US\$200,000." The reference is based on a 1998 report. EPA recommends that a more up-to-date cost figure for the SIDS data set should be used in the draft CEC report We believe the estimated costs as of 2003 was approximately \$290,000.

Comment 2–7: Page 15, under "Pesticides" the end of the last paragraph appears to need a citation. There are other problems with citations in this section as well.

Comment 2-8: The section on pesticides should include a discussion that pesticides are not part of the industrial discharges that are discussed in Chapter 3. Pesticides are products deliberately introduced into the environment and not discharged or released as

wastes. As noted in the report, all pesticides are not for agricultural purposes. Thirty percent are for non-agricultural purposes. (e.g. Donaldson et al, 2002 Pesticides, Industry and Sales and Usage, 1998 and 1999 Market Estimates. USEPA Office of Pesticide Programs, August 2002.)

Comment 2-9: Page 15, middle column, The draft text states "More than 100,000 children in the US accidentally ingest pesticides." The source cited is EPA's publication "Recognition and Management of Pesticide Poisonings" (1998). The version of that document available in 1998 was the Fourth Edition and dates from 1989. The Fourth Edition of RMPP contained no summary data on accidental ingestion of pesticides. The most recent, Fifth Edition of the RMPP, published in 1999, indicates that about 22,000 children a year were poisoned, i.e., exhibited symptoms following exposure. The best information appears to stem from a March 2003 EPA Fact Sheet: "Pesticides and Child Safety." It states "in 2001 alone, an estimated 66,000 children less than six years old were involved in common household pesticide-related poisonings or exposures in the United States." The Fact Sheet relied on data from the American Association of Poison Control Centers. Furthermore, this information should be presented consistently across the Parties, either in percentages or total numbers.

In the right column, the draft text states "Sales of pesticides have increased by 50 percent in the US in the past three decades. Since 1990, they have increased about 6 percent a year, particularly, for 'cosmetic' uses, for example, to make gardens weed-free." The source for this information is an EPA report issued in 1997 on "Pesticide Industry Sales and Usage." The most recent information on this subject appears in EPA's "1998 - 1999 Pesticide Market Estimates." This report is posted on EPA's website at: http://www.epa.gov/oppbead1/pestsales/99pestsales/introduction1999.html

This information only covers the years 1980 to 1999 and indicates that the estimated dollar value of sales went from \$5.8 billion to \$11.1 billion. That works out to be about a 90% increase over two decades. These estimates, however, were not adjusted for inflation. If adjusted for inflation, this represents a smaller percentage change.

The draft text accurately summarizes the change in sales value of all pesticides from 1990 to 1995 (the last year covered in the cited report). Sales grew from \$7.7 billion to 10.8 billion, or 40% over 6 years -- about 6.7% a year (without adjusting for inflation). The report's statement concerning growth as occurring particularly in "cosmetic" use of pesticides is misleading; there is no clear definition of what constitutes a "cosmetic use" and, if there were, the EPA report contains no data addressing that distinction. The draft text provides one example of a cosmetic pesticide use -- weed control in home gardens. The available data indicate that home and garden sales have grown more slowly than total pesticides sales. The Home and Garden market sector grew from \$1.3 billion in 1990 to \$1.5 billion in 1995, or a total of 25%, compared to a growth of 40% in overall pesticide sales during the same time period.

Comment 2-10: Page 17, paragraph preceding bulleted list, change "for carcinogens" to "for some carcinogens" since some carcinogens have a low-dose threshold.

Comment 2-11: Page 17: We recommend inclusion of a statement to indicate that while toxic chemicals released in the environment include metals, some of these metals are considered to be essential elements in the diet. A dietary deficiency would cause similar detrimental effects on the health of children, including the developing fetus. The document could potentially list these essential elements with the required dietary levels (FDA's Recommended Daily Intake) and report both the harmful effects of diets deficient in these elements as well as the harmful effects of amounts exceeding these doses in the diet. It may be appropriate to reiterate both beneficial and harmful dietary effects for these elements in a short statement in Chapter 5. The statements relating to dietary intake will help send an appropriate public health message and should help avoid conclusions about whether these elements are categorically good or bad. This statement of course relates only to dietary intake and does not change appropriate concerns about industrial releases of these metals to the environment from different sectors and the corresponding risks posed to the environment and human health from various exposure pathways. Statements added to discuss essential elements in the diet should not imply that these elements are supplied through pollutant release and transfers; the purpose of the discussion should be to ensure that the readers understand the role of these elements in the diet, as opposed to concerns relating to releases and transfers of these elements as reported under PRTR.

Comment 2-12: Page 17 –The text reads: "In the past, regulations have sought to identify a 'threshold' below which a chemical does not cause health effects. For many chemicals, such a threshold may not exist. For example, on a theoretical bases, for carcinogens, each decrement of exposure down to zero conveys some level of health risk. For other chemicals, a threshold may exist in certain situations." We believe this text should be replaced by the following:

"Chemical risk assessment practice has historically dealt with different methods for assessing cancer and all other non-cancer risks. Risk assessments for non-cancer health effects have been based upon the assumption that there exists a threshold dose below which there is no risk. This dose, known as a Reference Dose or RfD, is calculated by applying uncertainty/variability/safety factors to no-adverse-effect levels (NOAELs) that are derived from toxicology studies. However, as we have become more sophisticated in understanding biological process, it appears that in some cases, for example lead or dioxin, biochemical effects can be found at ever decreasing doses. In these cases perhaps there is no threshold dose below which there is no risk.

Cancer risk assessments have been based on the assumption that as exposure increases, the chance of damaging DNA increases. This has resulted in the use of cancer risk models which involve linear low dose extrapolation from higher test doses to calculate a probability of getting cancer at generally lower levels of exposure. Thus, any exposure, perhaps even exceedingly low exposure, is associated with some calculable risk. For chemicals that cause cancer through mechanisms other than DNA damage, such as hormonal influences, there may in fact be a threshold below which there is no risk of

cancer induction. In these cases, the linear low dose extrapolation would incorrectly predict a cancer risk below the threshold."

Comment 2-13: Page 18, second paragraph states that "In Mexico, mortality statistics may provide a better picture of trends due to under-reporting." Should this say "....due to under-reporting of morbidity data"?

Comment 2-14: Page 19, first full paragraph states "…lead is known to cause reduced attention spans, and increased distractibility and aggressive behavior in children at levels well below those that cause clinical symptoms." Reduced attention spans, increased distractibility, and aggressive behavior, it seems however, would be considered "clinical symptoms." This should be corrected or clarified.

Comment 2-15: Page 19, Endocrine Toxicity, first paragraph states "Endocrine disrupters can work at low doses; they cause effects in the next generation and only during critical windows of vulnerability." While endocrine disruptors may result in adverse health outcomes, the relationship of human diseases of the endocrine system and exposure to environmental contaminants is poorly understood and scientifically controversial. The concluding description for endocrine toxicity on page 19 more precisely describes the level of certainty in this field. The report should also reference ongoing work of the Parties and others to improve understanding of endocrine toxicity.

Comment 2-16: Pages 19-20, the short section titled "Endocrine Toxicity" ends with a balanced quote from the IPCS 2002 report, but this quote is preceded by text that could be misinterpreted as evidence that current environmental levels of potential endocrine disruptors are associated with a wide range of human disease. We believe that this requires further clarification in the report. We also recommend adding the following to the end of the section: "Validated methods for reliable identification of potential endocrine disrupting chemicals are still in the future, with substantial efforts being conducted in the United States and the Organization for Economic Cooperation and Development, among others."

Comment 2-17: Page 19, With respect to the asthma discussion, it should be noted that within the U.S. progress has been made with ozone alerts to help address some of these concerns.

Comment 2-18: Page 20, under Asthma, the first sentence should be changed as it implies that asthma is always caused by "environmental triggers." We recommend giving a more accurate clinical definition of asthma and noting that factors which can exacerbate asthma include rapid changes in temperature or humidity, allergies, upper respiratory infections, environmental pollutants, exercise, stress, or cigarette smoke, including environmental tobacco (second-hand) smoke.

### Chapter 3:

Comment 3-1: Page 22, the distinction is between "prevent pollution" and "reduce waste generation" is unclear. Some clarification would be useful. It might be useful to highlight recycling here as well.

Comment 3-2: Page 23 Box and elsewhere, the document makes general statements like "North American factories...released and transferred over 3.3 million tonnes of chemicals in 2000." However, we have no data on Mexico, so "North American" is really incorrect. Is there some way to fix this semantic error which may lead to misinterpretations by readers?

Comment 3-3: The list of sources seems incomplete on this page. We may also want to reiterate that sources not included in the analysis include 1) chemicals deliberately introduced into the environment, 2) chemicals released from products, and 3) legacy chemicals in the environment. This helps provide context to the analysis.

Comment 3-4: Page 23, last two bullets say the same thing and should be combined.

Comment 3-5: Pages 24-27, discussion on PRTR analysis should describe if there is an adjustment made to the data to address the possibility of double counting releases. In *Taking Stock 2001* this issue is addressed in section 2.2.5 "adjustment of total releases in North America" and the issue should be addressed in this report as appropriate."

Comment 3-6: The report should include a text box about the US Risk-Screening Environmental Indicators (RSEI) model. The Risk-Screening Environmental Indicators model overcomes a limitation of TRI data by showing the chronic human health risks implied by the releases reported to TRI. In its current form, the model addresses relative risks from the air and water media, not land. RSEI only addresses releases in the U.S, i.e., those reported to TRI, i.e., it has not been set-up with Canadian data on population, air dispersion, water intakes, etc. Please include an informational box on this model on or following page 23 in Chapter 3 of the report so that readers are informed of RSEI.

The Risk-Screening Environmental Indicators (RSEI) Version 2.1 is a computerbased screening tool for the evaluation of toxic chemical emissions and transfers from industrial facilities. RSEI can quickly assess important factors related to potential chronic human health risks from industrial pollution and waste management (those chronic effects that are associated with low-level and longterm exposure). Whether a pounds-based, hazard-based, or risk-related perspective is chosen, the RSEI model delivers results in a matter of minutes or hours that previously would have required weeks, months, or even longer to produce. RSEI can help identify opportunities with the greatest potential for hazard or risk reduction, while saving considerable analytical resources.

RSEI Version 2.1 provides a risk-related perspective for air and water releases (including those from certain off-site transfers) for the 1988-2000 TRI reporting data. It also provides other valuable perspectives for all release pathways and other waste management activities at industrial facilities, such as pounds of

release and pounds of release weighted by toxicity (for a hazard-based perspective). RSEI also provides results for important groups such as children, men and women of reproductive age, and the elderly.

Please visit the RSEI Home Page at <u>http://www.epa.gov/oppt/rsei/</u> for additional information on the RSEI methodology, the comprehensive peer review of RSEI, important caveats, the strengths and limitations of the model and to request copies.

Comment 3-7: Page 25, center column notes that the RETC program is voluntary. We recommend clarifying that the program is becoming mandatory.

Comment 3-8: Page 25, center column, mid page states that dioxins and furans are not part of this report; however, Table 20 and the associated text address this issue.

Comment 3-9: Page 26, Figure 4, we suggest stating the year from which these data were drawn.

Comment 3-10: Page 27, center and right columns. We suggest stating who the other agencies are.

Comment 3-11: Page 28, 3<sup>rd</sup> column, Kennecott Utah Smelter and Refinery - the number should be "7,655" not "7654".

Comment 3-12: Why are table 4 (pages 31-32), table 8 (pages 38-39), and table 12 (pages 46-47) formatted differently? All three are presenting largest total releases by state/province yet they have different column headings. In addition, although the report briefly describes the different categories of PRTR information on page 27 and graphically on page 26, in order to be transparent about how the data are calculated, the report should have footnotes that describe exactly from what particular columns are calculated. For example, in table 8, there should be a footnote that explains how the columns called "transfers to disposal (except metals)" and "transfers of metals" were calculated. At the very least, the discussion on page 27 needs to be more detailed to explain the different tables so that the reader can understand how the data presented in the tables were calculated. Also on page 27, the report states that metals sent to treatment, sewage and energy recovery are considered off-site releases; however, the text does not explain why this is the case. The reason is that the metal has no heat value and thus cannot be combusted for energy recovery and cannot be treated because it cannot be destroyed.

Comment 3-13: Table titles are inconsistent for no apparent reason. See table 5 (page 33), table 9 (pages 41-42), and table 13 (page 48) all present the same type of information so the table titles should be the same (i.e., either "largest releases (on- and off-site)" or "largest total releases.")

Comment 3-14: Table footnotes are not consistent and they should be. For example, tables 5, 9, and 13 all present the same type of information (i.e., industrial facilities with largest total releases), yet they had different footnotes when they should all be the same. One sentence in particular should be in the footnotes for all three tables: "None of the rankings are meant to imply that a facility, state or province is not meeting its legal requirements." In addition, this sentence may need to be placed in the footnotes for other tables as well.

Comment 3-15: Page 49, right column sates that the authors looked briefly at the trends in the group of chemicals "....that fall into one, two or all of the three categories." The report then goes on to look only at the combination of all three.

Comment 3-16: Page 52, last paragraph says that "Health Canada states that Canadian children are most likely to be exposed to lead from food, then air, then drinking water." The document then goes on to say that estimates of daily lead exposure for preschoolers are 1.1 ug/kg from food and 2-10 ug/kg from air, and 2.9 ug/kg from drinking water (making air first, water second, and food last). This should be clarified.

Comment 3-17: The data show significant increases in lead "releases" (Page 52), and the report correctly indicates that blood lead levels in children have declined (Page 55). In the text, the discussion acknowledges that the reduction in air releases is likely responsible for this improvement. Clarification is needed here. In addition, the discussion on dioxins/furans highlights air releases, since that's the only likely source of exposure to the Arctic populations being discussed (Page 63), but the report does not acknowledge the general importance of relative exposures from different types of releases.

Comment 3-18: Page 56, first full paragraph, we suggest changing "for one year" to "up to one year."

Comment 3-19: Page 56, first line, "Organic mercury (usually called methyl mercury)" is not completely accurate as there are other forms of organic mercury. We believe the report should say "mostly in the form of methyl mercury" for this sentence.

Comment 3-20: Page 56, last paragraph first line, the report may want to note that both children and adults are primarily exposed to methyl mercury through this route.

Comment 3-21: Page 57, 1<sup>st</sup> column, the sentence says "However, because many municipal incinerators do not report to TRI..." This sentence is misleading; municipal incinerators are not covered by TRI so no municipal incinerators report to TRI unless there are a few that are doing so voluntarily.

Comment 3-22: Page 53, Delete the sentence: "This was similar to the US mean of 3.52  $\mu$ g/dL." According to the Centers for Disease Control (CDC), the U.S. figures indicate a U.S. geometric mean of 2.7  $\mu$ g/dL for 1991-1994. It is unclear whether the CEC is using arithmetic or geometric means. Absent a clarification, the sentence should be deleted.

Comment 3-23: Page 54, The current elevated blood lead level is  $10 \mu g/dL$ . Revise to read: "The current elevated blood lead level in children is defined as  $\geq 10 \mu g/dL$ . Add: "Between 1999--2000, 434,000 children (95% confidence interval = 189,000-846,000) or 2.2% of children aged 1-5 years had blood lead levels  $\geq 10 \mu g/dL$ . Special attention is given to blood lead levels  $\geq 10 \mu g/dL$ . Many studies point to a link between blood lead levels  $\geq 10 \mu g/dL$  and harmful health effects, in particular in learning disabilities and behavior problems. The Department of Health and Human Services' *Healthy People 2010* initiative has set a national goal of eliminating blood lead levels  $\geq 10 \mu g/dL$  among children aged 1-5 years by 2010.

Comment 3-24: Page 54, The document uses the confidence interval instead of the geometric mean for blood lead levels. The correct numbers from the same reference should read: "Between 1976 and 1980, the average blood lead level was 14.9  $\mu$ g/dL, which decreased to 3.6  $\mu$ g/dL between 1988 and 1991, and then to 2.2  $\mu$ g/dL in 1999-2000 (CDC 2003b)."

Comment 3–25: Page 54. The report should use the information from a more current (2002) source rather than the 1997 source, for the number of homes with low income families. Revise the document to read: "Twenty-four million housing units had significant lead-based paint hazards. Of those with hazards, 1.2 million units housed low-income families (<\$30,000/year) with children under 6 years of age." (Jacobs, D. E. *et al*, 2002. The Prevalence of Lead-Based Paint Hazards in U.S. Housing. *Environmental Health Perspectives*. 110(10):A599-A606.)

Comment 3-26: Page 58, left column (and Table 18), text in this section does not explain why the trends analyses stop with 1999 when the data sets go to 2000. At the beginning of this section, report needs to explain that the data are presented in different tables because the reporting threshold for mercury changed in 2000 for the US TRI Program, thus making the data not comparable. This is explained on page 61 for the PCB data but is not explained in the mercury section. In addition, the last sentence in the note in table 18 should be deleted because it refers to 2000 and that table only presents data on 1995-1999.

Comment 3-27: Page 62, second column is misleading when it states that TRI does not currently report using i-TEQs and that all facilities that report to TRI also report dioxins and furans. On the first point, the Form R does contain a section for reporting the distribution of dioxin and each dioxin-like compound for the total quantity that the facility is reporting. This distribution must be reported if the information is available from the data used to calculate thresholds, releases, and other waste management quantities. The distribution must also either be the distribution that best represents the distribution of the total quantity of dioxin and dioxin-like compounds released to all media from the facility or the facility's one best media specific distribution. Thus, while it is correct to say that the TEQ amount is not reported, it is misleading to suggest that there is no data from which some inference about TEQs might be drawn.

Comment 3-28 Page 62, Under health effects, 3rd line "generally" should be taken out as 2,3,7,8-TCDD is the most potent of the dioxins and furans (1,2,3,7,8-Pentachlorodibenzo-p-dioxin is equi-potent, having been also assigned a TEF value of 1).

Background information: TEF/TEQs were developed to account for "dioxin-like" (those chemicals have a mechanism of action similar to 2,3,7,8-TCDD, binding to the AhReceptor, and bioaccumulate) polyhalogenated aromatic hydrocarbons (PHAH). The PHAHs are a broader category than merely dioxins and furans; it additionally includes PCBs, azo/azoxy benzenes and naphthalenes. Only those chemical congeners with 2,3,7,8-TCDD or "dioxin-like" activity were assigned TEFs. Not all dioxins, furans and PCBs have been assigned TEFs. Because of this, complex mixtures of PHAHs will contain dioxins, furans and PCBs which are not accounted for by the TEQ methodology. This may lead to underpredicting the toxicity of the mixture.

Comment 3-29, Page 62, Recommended language for second column, second paragraph, in lieu of the first sentence:

Dioxins, furans and dioxin-like PCBs are found in the environment as complex mixtures. Because of this, a method was created to assign a toxic equivalency factor (TEF) to chemicals with mechanisms of action similar to 2,3,7,8-TCDD (van den Berg *et al.*, 1998; Birnbaum, 1999; Birnbaum and DeVito, 1995).

Comment 3-30: Dioxin references for this section:

1. (required) van den Berg, M., Birnbaum, L., Bosveld, A., Brunstrom, B., Cook, P., Feeley, M., Giesy, J., Hanberg, A., Hasegawa, R., Kennedy, S., Kubiak, T., Larsen, J., Leeuwen, R.v., Liem, D., Nolt, C., Peterson, R., Poellinger, L., Safe, S., Schrenk, D., Tillitt, D., Tysklind, M., Younes, M., Waern, F., and Zacharewski, T. (1998). Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. *Environ Health Perspect.* **106**, 775-792.

(optional) Birnbaum, L.S., and DeVito, M.J. (1995). Use of toxic equivalency factors for risk assessment for dioxin and related compounds. *Toxicology*. 105, 391-401.

3. (optional) Birnbaum, L.S. (1999). TEFs: A practical approach to a real-world problem. *Human Ecol Risk Assess.* **5**, 13-24.

Comment 3-31: On the second point, a facility only has to report dioxin if it meets all three criteria for reporting (i.e., it is a covered facility, it has 10 employees, and most importantly, it manufactured, processed, or otherwise used 0.1 grams of dioxin). If these criteria are not all met, no reporting of dioxin is required, regardless of whether the facility is reporting for another chemical. The sentence in report should be rewritten to say "TRI has a different approach, requiring any facility that is in a covered industry

sector, has 10 or more employees, and manufactures, processes, or otherwise uses 0.1 gram of dioxin and dioxin-like compounds over the calendar year to report to TRI"

Comment 3–32: Page 63, Citations are needed for this box. In the second to last sentence of the second paragraph, does the report mean to say "United States standards" instead of "United States studies"? In the last sentence, "have been" should be changed to "are being."

# Chapter 4:

Comment 4-1: Chapter 4 consists of an outline of national programs to help protect children's health, but the outline format is not particularly useful for discussion and analysis. The format also results in an inaccurate perception that many important children's environmental health programs are not underway.

Comment 4-2: Page 69, call out box, the first and second sentences taken together imply that all persistent chemicals are POPs. To clarify this statement, change first sentence to read, "Some organic chemicals." To be a POP, the chemical must be organic and display characteristics of toxicity, bioaccumulation, and transport. Not all persistent chemicals are organic. Please clarify that the phrase "know no boundaries" means that these chemicals can be transported long distances in the atmosphere, through water, etc. The text box may also want to reference LRTAP POPS and other appropriate protocols as well.

Comment 4-3: We would like to share a few examples of programs in the US that help protect children from environmental risks. This is not an exhaustive list but it does highlight the range of ongoing efforts.

National Academy of Sciences (NAS) Evaluation of Future Approaches to Toxicity Testing for Risk Assessment: An internal review of EPA's practices for assessing chemical toxicity concluded that existing testing guidelines result in numerous gaps, especially with respect to understanding mechanisms of toxicity and possible early life-stage sensitivity. EPA has signed a contract with the NAS to assess and advance current approaches to toxicity testing and assessment to meet regulatory data needs. In the first part of the study (12 months), the committee will prepare a report reviewing selected aspects of several relevant reports by EPA and others on this topic. In the second part of the study (24 months), to be funded separately at the government's option, the committee will prepare a second report presenting a long-range vision and strategic plan for advancing the practices of toxicity testing and human health assessment for environmental contaminants. In developing the vision and strategic plan, the committee will consider evolving regulatory data needs; current toxicity testing guidelines and standards used by EPA and other federal agencies; the use of emerging science and tools (e.g., genomics, proteomics, transgenics, bioinformatics, computational toxicology, in vitro testing, and other alternatives

to animal testing); and the challenges of incorporating more complex understanding of toxicity (e.g., toxicokinetics, mechanisms of action, systems biology) into human health risk assessment.

- Cancer Guidelines/Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens: The final draft Cancer Guidelines are currently undergoing final review within EPA. The Supplemental Guidance is also being reviewed by EPA's Science Policy Council (SPC). Agency approval of both documents will be sought at the June 7 Special SPC meeting. The Supplemental Guidance will then undergo an cross federal review under the auspices of the White House's Office of Science & Technology Policy through the Committee on Environment and Natural Resources (CENR) during the summer of 2004.
- **National Children's Study:** The National Children's Study will examine the effects of environmental influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. The goal of the study is to improve the health and well-being of children. The study defines "environment" broadly and will take a number of issues into account, including:
  - Natural and human-made environment factors
  - Biological and chemical factors
  - Physical surroundings
  - Social factors
  - Behavioral influences and outcomes
  - Genetics
  - Cultural and family influences and differences
  - Geographic locations

Researchers will analyze how these elements interact with each other and what helpful and/or harmful effects they might have on children's health. By studying children through their different phases of growth and development, researchers will be better able to understand the role of these factors on health and disease. The study will also allow scientists to find the differences that exist between groups of people, in terms of their health, health care access, disease occurrence, and other issues, so that these differences or disparities can be addressed. The National Children's Study will be one of the richest information resources available for answering questions related to children's health and development and will form the basis of child health guidance, interventions, and policy for generations to come.

• Non-Road Diesel rule: On May 11, 2004, the Clean Air Non-road Diesel Rule was signed. The rule will cut emission levels from construction, agricultural and industrial diesel-powered equipment by more than 90 percent. The rule will also remove 00 percent of the sulfur in diesel fuel by 2010. EPA predicts that when

the full inventory of older non-road engines have been replaced, the non-road program will annually prevent up to 12,000 premature deaths, one million lost work days, 15,000 heart attacks and 6,000 children's asthma-related emergency room visits. The overall benefits of the nonroad diesel program are estimated to significantly outweigh the costs by a ration of 40 to 1. The rule compliments the Clean Diesel Truck and Bus Rule of 2000 and the voluntary programs that focus on vehicles and equipment in use today, including the Clean School Bus USA Program, the Voluntary Diesel Retrofit Program and the SmartWay Transport Partnership. More info is available at www.epa.gov/cleandiesel.

- **PBDE'S:** The Agency is developing an action plan for polybrominated diphenyl ethers (PBDE's), a class of chemicals used as flame-retardants. PBDE's have been in the scientific news because several PBDEs have been observed in US human breast milk and environmental samples and there is increasing evidence that they may be developmental neurotoxicants. The current work is a follow-up to the recent voluntary phase-out of penta-BDE and octa-BDE by the only US manufacturer. It is hoped that the action plan will help the Agency to better understand these chemicals, identify and assess the risks of substitutes for penta-BDE and octa-BDE, and to identify any additional steps that may be necessary to address potential risks presented by the PBDEs.
- **Fish Advisory:** On March 19, 2004 the EPA and FDA issued a joint consumer advisory on mercury in fish and shellfish. The advisory is for infants, children, nursing mothers, pregnant women and women that may become pregnant. It highlights the nutritional value of eating fish and shell fish and advises the previous groups of people to (1) avoid some types of fish including: Shark, Swordfish, King Mackerel, or Tilefish; (2) eat up to 12 ounces of a variety of fish with lower levels of mercury per week except for albacore tuna it is higher in mercury and therefore only 6 ounces of albacore tuna should be consumed in a week; and finally (3) consult local advisories for fish friends and family catch themselves. State and Tribal governments also issue fish advisories specific to local issues.
- International Walk to School Day: Multiple federal agencies, including EPA, participated in the 7th annual International Walk-to-School Day event in Washington, D.C. on October 8, 2003. The celebration was established to encourage children, parents, schoolteachers and community leaders to walk to school when possible. For the first time, the celebration highlighted the <u>air quality</u> benefits of walking to school. Nationwide, over 300 million people participated.
- Children's Health Month, October 2003 and 2004: As part of Children's Health Month, cities and states across the nation declared October 2003 Children's Health Month. Alabama, Kentucky and North Carolina issued state proclamations during formal signing ceremonies. The National Conference of Black Mayors adopted a resolution acknowledging the importance of protecting children from environmental health risks and recognizing October as Children's

Health month. Additionally, seven mayors including: Mayor Ralph Moore -Union City, GA, Mayor Lucinda Daily - Beaumont, MS, Mayor Edward Brown -St. Joseph, LA, Mayor Frank Anderson - Terrell, TX, Mayor William Ward --Chesapeake, VA, Mayor John Street, Philadelphia, PA, Mayor Brenda Lawrence -Southfield, MI, issued Children's Health Month proclamations. Procter and Gamble's October brandSAVER publication was dedicated to Children's Health Month and highlighted tips to protect children's health. Planning for 2004 is under way, with the theme of "Protect children where they live and learn."

- The Environmental Council of the States (ECOS) and Association of State and Territorial Health Officials (ASTHO) developed a national agenda to reduce environmental triggers of childhood. This project brought state environment and health agencies together for the first time. Five states are currently conducting pilot projects to implement the national agenda, *Catching Your Breath: Strategies to Reduce Environmental Factors that Contribute to Asthma in Children.*
- National Conference of State Legislatures (NCSL): NCSL represents state legislators and staff in all 50 states. NCSL produced a video designed specifically for state legislatures on children's environmental health, developed an on-line tracking system of pending state legislation and enacted statutes on various children's environmental health topics, and provided technical assistance to state legislatures. A legislative options guide will be published in April 2004 with fact sheets on individual topics soon to follow.
- Global Children's Environmental Health Indicators: A group of multilateral organizations, governments, and non-government organizations have agreed to develop global children's environmental health indicators, as first proposed at the World Summit on Sustainable Development. WHO regional offices are taking the lead to design and implement country pilots, and the CEC is the lead for the North American effort.
- **Comprehensive Healthy School Environments Assessment Tool:** EPA is funding a multi-media effort to develop a flexible a comprehensive software tool for school districts to use in conducting facility-specific environmental assessments that integrate all EPA environmental guidance and requirements and which will also be capable of integrating a wide range of other health and safety assessment issues of interest and concern to school districts.
- APA Pediatric Environmental Health Fellowship Program: The Ambulatory Pediatric Association's (APA) developed competencies as well as this year's Pediatric Environmental Health Scholars meeting for the Pediatric Environmental Health Fellowship Program which is primarily supported through private funding. This program is developing the next generation of experts in the field of pediatric environmental health.

- Giant Food Education Campaign: Giant Food (food chain in mid-Atlantic region) is conducting a year-long campaign to educate their customers about protecting children from environmental health risks. Giant Food launched the campaign during March 2004 by educating consumers about the hazards of mercury thermometers. Giant offered discounts for the purchase of digital thermometers; created a "Kids Corner" placemat with puzzles and games for children on mercury; displayed information on how to safely deal with and dispose of mercury thermometers on their web site and in their stores; included articles on mercury in their weekly circulars; and participated in a local radio show.
- EPA Strategy for Research on Environmental Risks to Children: This document provides the strategic direction for EPA's research program in children's health. EPA prepared the Strategy for Research on Environmental Risks to Children to strengthen the scientific foundation of the EPA risk assessments and risk management decisions that affect children. The Strategy for Research on Environmental Risks to Children includes a stable, long-term, core program of research in hazard identification, dose-response assessment, exposure assessment, and risk management, as well as problem-oriented.
- Understanding Economics of Children's Health and Environmental Risks: Under Executive Order 13045 and Agency policy, EPA assesses health risks that may disproportionately affect children. Benefit-cost and other economic analyses of these risks is a critical aspect of this assessment, including the evaluation of planned regulations and policies and feasible alternatives. The *Children's Health Valuation Handbook*, was developed as a reference tool for analysts conducting economic analyses of EPA regulations and policies that may affect risks to children's health. This handbook focuses on valuing changes in risks to children's health caused by environmental improvement or degradation. The USG is also funding research in this area.
  - **Pediatric Environmental Health Units:** EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) support Pediatric Environmental Health Specialty Units (PEHSUs) that provide education and consultation services to health professionals, public health officials, and the public on children's environmental health issues. The Units are located in each of the 10 EPA/ATSDR Regions as well as one in Mexico and one in Canada. Each U.S.based PEHSU has a toll-free number and a Web site dedicated to providing Region-specific information on children's environmental health issues of concern.

**Working with Farm Families:** The USDA has chemical exposure safety programs throughout its agencies. The Cooperative State Research, Education and Extension Service include the Pesticide Safety Education Program and the Healthy Homes Initiative. The Animal and Plant Health Inspection Service provides resource materials on safety topics such as: Essentials of Proper Chemical Storage, Pesticide Use and Protective Clothing, Understanding Material Safety Data Sheets, and Biological/Chemical Safety Plans. The report may also

want to reference projects associated with the NAFTA Technical Working Group on Pesticides that are focused on chemical safety and pesticide risk reduction.

# Chapter 5:

Comment 5-1: Chapter 5 of the draft report describes various activities to reduce children's exposure to toxic chemicals (including many that are outlined categorically via chapter 4). We look forward to discussing these and other activities among the Parties and with Partners under the CEC's Cooperative Agenda for Children's Health and the Environment in North America.

Comment 5-2: Page 72, In paragraphs 1 and 2, the authors may wish to reiterate that PRTR releases and industrial releases are not the only source of chemical exposures to children. The second paragraph also seems to be drawing conclusions about PRTR releases that have not been clearly supported earlier in the text. The problem may stem from imprecise language, but we believe the authors should evaluate this.

Comment 5-3: Page 73, center column, last sentence, we suggest rewriting this sentence. A PBT cannot re-enter the environment from soil and sediment as soil and sediment are part of the environment. It may be useful to talk about sinks of pollution from which chemicals can be released over time to other environmental media.

Comment 5-4: Page 73, right column, the next NATA is scheduled for release in 2004, not 2003.

Comment 5-5: The report may also want to consider some other important actions that individuals can take to reduce risks and exposure to chemicals and pesticides. For example, steps such as reading and following labels on consumer and agricultural use chemicals. We note that misapplication of household and agricultural chemicals can lead to serious risks to the health of children. Various educational campaigns exist on this issue.

Comment 5-6: Page 75 briefly mentions EPA's Voluntary Children's Chemical Evaluation Program (VCCEP). Please include a focused discussion similar to that included on the HPV program on page 13 as follows:

The Voluntary Children's Chemical Evaluation Program (VCCEP) is intended to provide data to enable the public to understand the potential health risks to children associated with certain chemical exposures. EPA asked companies which manufacture and/or import 23 chemicals which have been found in human tissues and the environment in various monitoring programs to volunteer to sponsor their chemicals in a pilot of the VCCEP. Thirty-five companies and ten consortia responded and volunteered to sponsor 20 chemicals.

The VCCEP consists of three tiers of assessment which a sponsor can commit to

separately. EPA asked companies to volunteer to sponsor chemical(s) they manufacture or import in Tier 1 of the VCCEP pilot. As part of their sponsorship, companies collect and/or develop health effects and exposure information on their chemical(s) and integrate that information in a risk assessment. A "Data Needs Assessment" is also developed by the sponsor. The Data Needs Assessment discusses the need for additional data, which could be provided by the next tier, to fully characterize the risks the chemical may pose to children.

The information submitted by the sponsor is evaluated in a Peer Consultation which is a group of scientific experts with extensive and broad experience in toxicity testing and exposure evaluations. The Peer Consultation evaluates the adequacy of the assessments and the need for development of any additional information to fully assess risks to children. EPA considers the results of the Peer Consultation and announces whether additional higher tier information is needed. If additional information is needed, sponsors will be asked to volunteer to provide the next tier of information. If additional information is not needed, EPA and the sponsors will cooperate to conduct appropriate risk communication and, if necessary, risk management.

#### 23 CHEMICALS IN THE VCCEP PILOT:

CAS No. 67-64-1	Chemical Name Acetone	CAS No. 108-88-3	Chemical Name Toluene
71-43-2	Benzene	108-90-7	Chlorobenzene
75-35-4	Vinylidenechloride	112-40-3	n-Dodecane
78-93-3	Methyl ethyl ketone	123-91-1	p-Dioxane
79-01-6	Trichloroethylene	124-18-5	Decane
80-56-8	a-Pinene	127-18-4	Tetrachloroethylene
95-47-6 100-41-4	o-Xylene Ethylbenzene	541-73-1 1120-21-4	m-Dichlorobenzene Undecane
106-46-7	p-Dichlorobenzene	1163-19-5	Decabromodiphenylether
106-93-4	Ethylene dibromide	32534-81-9	Pentabromodiphenyl ether
107-06-2	Ethylene dichloride	32536-52-0	Octabromodiphenyl ether
108-38-3	m-Xylene		

#### HAZARD AND EXPOSURE INFORMATION REQUESTED:

The health effects information is submitted in three tiers in VCCEP. Tier 1 tests are the same as those requested in the HPV Challenge Program. Following are the health effects tests in the VCCEP listed by tier:

Tier 1	Tier 2	Tier 3	
Acute toxicity	Subchronic toxicity	Neurotoxicity	

		screening battery
Repeated dose toxicity with reproductive and developmental toxicity screens	Prenatal developmental toxicity	Carcinogenicity
	Reproductive and fertility effects	Developmental neurotoxicity
Bacterial reverse mutation assay	Immunotoxicity	
<i>In vitro</i> <u>or</u> <i>in vivo</i> chromosomal aberrations <u>or</u> <i>in vivo</i> micronucleus test	<i>In vivo</i> chromosomal aberrations <u>or</u> <i>in vivo</i> micronucleus test	
	Metabolism and pharmacokinetics	

EPA also requested exposure information to be submitted so that the likely extent of children's exposure to the VCCEP chemicals can be determined. The exposure information needed for this evaluation program includes population groups exposed, sources of the exposure, as well as frequencies, levels, and routes of exposure. The exposure information submitted at Tier 1 may be readily available screening level information with more detailed analyses submitted at upper tiers.

More information on VCCEP can be found at: http://www.epa.gov/chemrtk/vccep/index.htm

Comment 5-7: Page 77, center column, second bullet point, the bullet should read "For criteria air contaminants and air toxics, see the National Emissions Inventory...".

Comment 5-8: Page 77, we suggest adding the following references to the "general information about children's environmental health" listings:

SEPA Office of Children's Health Protection (http://yosemite.epa.gov/ochp/ochpweb.nsf/homepage)

SAmerican Academy of Pediatrics document *Pediatric Environmental Health* <u>http://www.aap.org/bst/showdetl.cfm?&DID=15&Product\_ID=1697&CatID=132</u>

-"Tips to Protect Children from Environmental Risks"

Comment 5-9: The reference to the American Academy of Pediatrics Handbook of Pediatric Environmental Health should include a reference to the second edition as well.