October 25, 2004

William V. Kennedy
Executive Director
Commission for Environmental Cooperation
393, rue St-Jacques Ouest
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Dear Mr. Kennedy,

Several organizations and individuals previously submitted comments regarding the use of Scorecard's list of chemicals in *Taking Stock: A Special Report on Toxic Chemicals and Children's Health in North America*, a draft report by the Commission for Environmental Cooperation (CEC). Most of these prior comments reflect a lack of familiarity with the extensive materials included directly in Scorecard detailing Scorecard's data sources and methods. Accordingly, this document quotes extensively from Scorecard with regard to issues raised by prior commenters, including:

- "recognized" versus "suspected" toxicants;
- peer review of Scorecard;
- sources of data used in Scorecard;
- timeliness of Scorecard's data on toxicant releases; and
- designation of "essential" elements as toxicants.

Recognized vs. Suspected Toxicants

Unlike Scorecard itself, the *Taking Stock* report combines release figures for recognized toxicants with those for suspected toxicants. Scorecard explicitly distinguishes between these two types of listings: "Chemicals with health hazards that are widely recognized by authoritative scientific organizations are listed separately from the chemicals whose hazards are only suspected on the basis of more limited data." See http://www.scorecard.org/about/txt/caveats.html. Scorecard does not recommend commingling these two types of listings, and does not itself do so.

- *Recognized Toxicants:*

As stated on the Scorecard website, "Chemicals are identified as recognized toxicants based on the hazard identification efforts of authoritative national and international scientific and regulatory agencies." Specifically, Scorecard designates substances as recognized toxicants if they have been included on California's Proposition 65 list, which has been subjected to significant peer review. Cancer, reproductive toxicity and developmental toxicity are the only health effects for which lists of recognized toxicants are given.

- *Suspected Toxicants:*

Scorecard contains a lengthy description of how the lists of suspected toxicants are compiled, which is reproduced in its entirety in the Appendix to these comments. As that description makes abundantly clear, the Suspected Toxicants lists are prepared by reviewing key governmental databases using a peer-reviewed hazard identification methodology developed by researchers at the Oak Ridge National Laboratory to identify suspected reproductive toxins. That methodology requires evidence of adverse impacts on an organ system that had positive findings in humans or two different mammalian species exposed by a relevant route of exposure.

Peer Review

Several comments were made asserting that Scorecard is not peer-reviewed. But as Scorecard itself expressly notes, "Scorecard integrates over 400 scientific and governmental databases to generate its customized profiles of local environmental quality and toxic chemicals. Since Scorecard draws all of its data from authoritative sources and combines them using state-of-the-art informatics, users can be confident they are receiving credible information that reflects the best available science. All data sources are clearly cited on Scorecard, with hyperlinks back to online references whenever available." (http://www.scorecard.org/about/txt/data.html). In sum, Scorecard is itself largely comprised of peer-reviewed materials.

Sources of Information

Again, numerous comments were made concerning the sources of data used by Scorecard. Sources for Scorecard include scientific organizations and regulatory agencies and are always explicitly identified. For example, references for the developmental toxicants include the U.S. EPA, the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction, and the California EPA. The main source of data for developmental toxicants is the Proposition 65 List of Developmental Toxicants which is updated annually by the California EPA. The health hazards cited on Scorecard have been obtained from medical texts, scientific literature, and regulatory agency sources. See http://www.scorecard.org/about/txt/caveats.html. As Scorecard itself notes, Scorecard's risk estimates are useful for ranking purposes, but are not necessarily predictive of any actual individual's risk of cancer or other disease.

Validity, Timeliness, Criteria

Updating the information on Scorecard

As stated on the site, “Scorecard is regularly updated whenever contributing data sources are revised. Some of Scorecard's sources provide close to real-time data (air quality profiles, for example, are based on monitoring of smog and particulates levels in the previous year); other sources provide information that is updated less regularly (hazardous air pollutant profiles, for example, are based on 1996 emissions inventories.)” See http://www.scorecard.org/about/txt/FAQS.html. The health effects information for Scorecard was last updated in December of 2003. (See http://www.scorecard.org/about/txt/FAQS.html#update).

Scorecard expressly indicates the relevant year for all release data, and uses the most-recent source wherever possible. It should be noted that many governmental sources release data only after a significant lag time. For example, EPA typically releases Toxic Releases Inventory data many months after the close of the reporting year. In part, this is because the statutory reporting deadline is not until July 1 of the following year, but Environmental Defense has long criticized the EPA for taking many additional months - typically 10 or more - to make the TRI dataset publicly available. For example, EPA released the 2002 TRI Data on June 23, 2004. Scorecard must then conduct additional cleanup of the EPA TRI datasets, which takes another few months, before posting the data. The 2002 TRI data were posted on Scorecard earlier this month.

Essential Elements as Toxicants

Some commenters complain that some of the substances included on the suspected toxicants list, such as manganese, copper, and zinc, are essential trace elements in the human diet. However, the fact that an element is essential at trace levels does not indicate it lacks toxicity at higher doses or through different routes of administration.

For example, although manganese is a trace dietary element, it is also a well-recognized neurotoxicant by inhalation, as noted in the Agency for Toxic Substances and Disease Registry's peer-reviewed Toxicological Profile (which is in turn cited in Scorecard). Moreover, copper is ranked as "more hazardous than most chemicals" by several ranking systems reported in Scorecard, including EPA's *Risk-Screening Environmental Indicators* system, EPA's *Waste Minimization Prioritization Tool*, and one developed by Purdue University's Indiana Clean Manufacturing Technology and Safe Materials Institute. Similarly, zinc is ranked as more hazardous than most chemicals under the evaluation system developed by the University of Tennessee's Center for Clean Products and Clean Technologies. ATSDR's Toxicological Profile for zinc notes that it can cause reproductive and developmental effects at high dose.

I hope these observations help clarify the nature and scope of the information presented in Scorecard.

Very truly yours,

(sent electronically)

John Balbus, M.D., M.P.H.
Director, Health Program
Environmental Defense

APPENDIX:

Scorecard's Project to Identify Suspected Health Hazards

(Verbatim from Scorecard at http://www.scorecard.org/health-effects/gen/sushazid.html).

Substantial amounts of animal and human toxicity data have never been systematically reviewed to identify chemicals with the potential to adversely effect human health. This is particularly true for health effects like neurotoxicity or immunotoxicity that have not been the focus of authoritative hazard identification efforts. After compiling lists of suspected toxicants from the scientific and regulatory literature (which often focus on the same small set of well-studied toxicants), Environmental Defense initiated a research project to supplement available hazard identification with the results of a review of two large toxicological databases: the National Institute for Occupational Safety and Health's Registry of the Toxic Effects of Chemical Substances (RTECS) database and the Carcinogenic Potency database (CPDB).

Environmental Defense's lists of suspected toxicants from RTECS and CPDB represent a screening-level evaluation of a chemical's capacity to adversely effect human health. Chemicals listed have been shown to cause target organ toxicity in either humans or two mammalian species, by a relevant route of exposure. This amount of evidence of reported adverse health effects is sufficient to comprise a strong "hazard signal" that warrants further action. Such action should include compilation of an adequate screening information dataset, a more comprehensive and authoritative evaluation of whether the chemical could cause adverse effects in humans, and appropriate exposure or risk reduction measures.

Environmental Defense adopted the hazard identification methodology developed by researchers at the Oak Ridge National Laboratory to identify suspected reproductive toxins. In their 1996 paper, A Screening Method for Occupational Reproductive Health Risk, Jankovic et al. compiled a list of reproductive toxins by identifying chemicals from the RTECS database for which adverse reproductive/developmental effects have been found in humans or in at least two mammalian species tested via the routes of exposure considered most relevant to humans (i.e., inhalation, ingestion or dermal exposure). Using the same criteria, Environmental Defense searched the RTECS and Carcinogenic Potency databases to identify chemicals that exhibit specific target organ toxicities.

To be identified as a suspected toxicant, a chemical must have undergone relatively extensive toxicological testing and been reported to exhibit adverse effects on the same organ system in at least two mammalian laboratory species. Chemicals reported to cause toxic effects in humans were also included on the appropriate suspect list, whether or not these effects were also documented in laboratory species.

DATABASE REFERENCES AND NOTES
CPDB: Carcinogenic Potency Database. Lawrence Berkeley Laboratory Berkeley, CA. http://potency.berkeley.edu/cpdb.html

The Carcinogenic Potency Database (CPDB) contains the results of chronic, long-term animal cancer tests. Both qualitative and quantitative information on positive and negative experiments are given, including all bioassays from the National Cancer Institute/National Toxicology Program (NCI/NTP) and results from the general literature that meet a set of inclusion criteria. The database covers 5152 experiments on 1298 chemicals

Environmental Defense reviewed this compilation of results on carcinogenicity in rats and mice and selected all chemicals with positive results in at least two species by a relevant route of exposure. Chemicals that met these screening criteria and that had not already been authoritatively identified as recognized carcinogens under Proposition 65 were added to the Scorecard's list of suspected carcinogens.

RTECS: Registry of Toxic Effects of Chemical Substances. National Institute for Occupational Safety and Health, Cincinnati, OH.
http://www.cdc.gov/niosh/rtecs.html. RTECS is available through various vendors. Environmental Defense utilized Chem-Bank CD-ROM (August 1997).

The Occupational Safety and Health Act requires NIOSH to list "all known toxic substances...and the concentrations at which... toxicity is known to occur". To fulfill this mandate, NIOSH has been compiling a database since 1971 that now contains records on over 130,000 chemicals. Six types of toxicity data are included: (1) primary irritation; (2) mutagenic effects; (3) reproductive effects; 94) tumorgenic effects; (5) acute toxicity; and (6) other multiple dose toxicity.

Environmental Defense reviewed RTECS and abstracted all records of adverse effects for the following Toxic Effects Codes:
Cardiovascular or Blood: G (cardiac), H (vascular), and P(blood)
Endocrine: N (endocrine)
Gastrointestinal or Liver: K (gastrointestinal) and L (liver)
Immunotoxicity: S (immunological including allergenic)
Kidney: M (kidney, ureter, bladder)
Musculoskeletal: Q (musculoskeletal)
Neurotoxicity: A (brain and coverings), B (spinal cord), C (peripheral nerve and sensation), E (autonomic nervous system), and F (behavior)
Respiratory: J (lung, thorax, or respiration)
Skin or Sense Organs: D (sense organs and special senses) and R (skin and appendages)

These records were analyzed to select just those chemicals with evidence of adverse impacts on an organ system that had positive findings in humans or two different mammalian species exposed by a relevant route of exposure. Chemicals that met these screening criteria were added to the suspected list for the relevant health effect.

HAZARD IDENTIFICATION METHOD REFERENCE
Jankovic, J. and F. Drake. A Screening Method for Occupational Reproductive Health Risk. American Industrial Hygiene Association Journal 57: 641-649. 1996.