BEFORE THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Estimating Exposure to Dioxin-Like Compounds; Review Draft, June 1994

COMMENTS OF THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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COMMENTS OF THE SOCIETY OF THE PLASTICS INDUSTRY, INC. ON EPA'S REVIEW DRAFT REPORT: *ESTIMATING EXPOSURE TO DIOXIN-LIKE COMPOUNDS*

The Society of the Plastics Industry, Inc. (SPI) is pleased to submit these Comments in response to the Environmental Protection Agency's (EPA) draft document entitled: "Estimating Exposure to Dioxin-Like Compounds" (Reassessment)(June 1994)(External Review Draft). SPI is a 2,000 member not-for-profit trade organization representing all segments of the plastics industry in the United States. The Society's members include processors and manufacturers of plastics and plastics products, suppliers of raw materials, processors and converters of plastics resins, and manufacturers of accessory equipment for the plastics industry. Founded in 1937, SPI is the major national trade association of the plastics industry.

EPA's multi-volume draft report represents the Agency's reassessment of the health risks of exposure to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) and chemically similar compounds. Because the draft reassessment refers to claims that dioxin may be emitted during the production of certain plastics precursors, SPI and its member companies have a substantial interest in the draft Reassessment.

I. SUPPORT OF CMA AND VI COMMENTS

The Vinyl Institute (VI), a division of SPI, is filing comments that focus on those portions of the Reassessment that identify ethylene dichloride, vinyl chloride monomer, or polyvinyl chloride resin (EDC/VCM/PVC) as potential emission sources of dioxins. Consistent with EPA's conclusions, there is insufficient data to make a detailed assessment of the EDC\VCM\PVC industry's role as a source of dioxins. At an August 1994 meeting with EPA, the Vinyl Institute pledged to cooperate with the Agency's efforts to better characterize the industry's status as a potential source of dioxins, and has accelerated its efforts to generate the relevant data for submission to EPA in 1995. However, current analyses indicate that, if the EDC\VCM\PVC industry is a source, it is insignificant. SPI supports the comments and activities of the Vinyl Institute.

SPI also supports the comments filed in this docket by the Chemical Manufacturers Association (CMA) and its Chlorine Chemistry Council, in which many SPI members are active.

II. CLARIFYING AND COMMUNICATING SCIENCE POLICY DECISIONS AND DATA GAPS IN THE REASSESSMENT

For over two decades, the United States has implemented extensive and detailed government policies to control a number of environmental problems. Overall, these efforts have led to real improvements in environmental quality. Yet, despite the demonstrated success of the past, shortcomings exist in all statutory and regulatory programs. Specifically, the focus of environmental laws and regulations, to date, has not consistently shown a basis in sound scientific principles and the comparatively higher risks to society. To accomplish this, the process must include the application of: (1) scientifically sound risk analysis; (2) risk-based prioritization; (3) benefit-cost analysis; (4) flexible, efficient, cost-effective risk management; and, (5) public participation in the process.

A. Recent Guidance on Risk Assessment

EPA has endeavored to produce a sound risk analysis and sought public participation in the Reassessment document itself.[1/] Yet, initial communication with the

[1/] The draft reassessment does not seek to provide a cost-benefit analysis, risk-based prioritization, or thoroughly address risk management issues.

public and published summaries of the draft reassessment gave an appearance of certainty that is unwarranted. From this perspective, in its revision and communication of the final report, EPA should carefully consider the recommendations and insights echoed convincingly in two 1994 publications, described below.

The first publication is by the National Research Council (NRC) Committee on Risk Assessment of Hazardous Air Pollutants, entitled Science and Judgement in Risk Assessment (1994)(1994 NRC Report). The 1994 NRC Report is a response to a Congressional mandate in the Clean Air Act Amendments of 1990 that the National Academy of Sciences (NAS) review the methods that EPA uses to estimate toxicological risk. One of its principal recommendations is that EPA clearly state the scientific and policy basis for each of its "default options" (science policy decisions).[2/]

While not attempting to summarize all of the applicable points in either the 1994 NRC Report, we list several of the NRC recommendations with particular relevance.

- Clearly identify all generic and particular default options and describe the scientific and policy basis for each.[3/]

[2/] 1994 NRC Report at 104.

[3/] Id. at 104-105.

- Explain the basis for departing from the agency's typical default options when this occurs.[4/]

- Establish the predicative accuracy and uncertainty of the methods and models and the quality of data used in the risk assessment.[5/]

- "*Clarify the sources and magnitudes of uncertainties in risk assessment.*"[6/]

- "*EPA often reports only a single point estimate of risk as a final output. . . . . Use of a single point estimate suppresses information about sources of error that result from choices of model, data sets, and techniques for estimating values of parameters from data.*"[7/] EPA should clearly articulate the uncertainties and ranges associated with risk estimation.

4/ Id.

5/ Id. at 137-138.

6/ Id. at 252.

7/ Id. at 184.

- *"Select and validate an appropriate emission and exposure-assessment model for each given implementation in the risk-assessment process."*[8/]

- *"Fully communicate to the public each risk estimate, the uncertainty in the risk estimates, and the degree of protection."*[9/]

The second publication was sponsored by the U.S. Department of Energy (DOE) and prepared for Sandia National Laboratories by Regulatory Impact Analysis Project, Inc. (RIAP/DOE Report), and is entitled "Choices In Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process (1994)." As the RIAP/DOE Report states:

> *Some risks to human health and the environment are provable. Provable risks can be measured or observed directly and include actuarial risks such as those associated with highway or air travel accidents. In contrast, other risks -- such as those associated with low doses of radiation or exposure to chemicals in the environment -- are often too small to be measured or observed directly with existing scientific methods and available resources. Additionally, specific*

8/ Id. at 252.

9/ Id. at 252.

health and environmental effects are often difficult to attribute causes because other competing causes cannot be excluded with reasonable certainty. Such risks are unprovable. However, the fact that a risk is unprovable does not mean that it does not exist. Provable risks can be calculated, whereas unprovable risks can only be estimated through the risk assessment process. Although unprovable risks may be estimated and expressed in probabilistic terms, they are at best educated guesses and do not constitute knowledge or uncontroverted fact. In other words, the ability to produce a numerical estimate of an unprovable risk does not mean the risk is proven.[10/]

Risk assessment is used when risks are unproven or not measurable. "*When risks can only be estimated, the benefits of regulatory programs to reduce those risks also can only be estimated, are not verifiable, and depend on science policy-based assumptions.*"[11/] As detailed below, we urge EPA to clearly state the scientific and policy basis for its science policy decisions and clearly identify the limitations and estimates inherent in the analysis.

[10/] RIAP/DOE Report at xiii-xiv.

[11/] Id. at xv.

B. Defining "Science Policy Decisions"

As used in the RIAP/DOE Report, the term *"science policy issues"* refers to the *"gaps and uncertainties in scientific knowledge and data that rise in the assessment of risks to human health and the environment associated with exposure to substances, conditions, activities, and sites. 'Science policy decisions' are the policy choices made to bridge such gaps and uncertainties."*[12/] The same meaning is derived from 1994 NRC Report.

C. Common Science Policy Issues and Default Assumptions

The RIAP/DOE Report summarized some basic science policy issues and default science policy assumptions used by federal agencies.[13/]

Science Policy Issue	Default Science Policy Assumptions
In the absence of adequate human data, what is the relevance of animal bioassay data to the estimation of human risk?	A substance that is carcinogenic to animals is also a human carcinogen.
Is the occurrence of benign tumors in experimental animals relevant to estimating human cancer risk?	Benign tumors are combined with malignant tumors in animals to establish carcinogenic potential in humans.

[12/] Id. at vii.

[13/] Id. at viii, Table ES-1. SPI does not necessarily endorse all of these assumptions.

Science Policy Issue	Default Science Policy Assumptions
When both positive and nonpositive cancer incidence data exist, should the nonpositive data be used for quantitative risk assessment purposes?	In the presence of positive data, nonpositive data do not indicate safety and should not be used in quantitative risk assessment
What is the relevance of data from animal bioassays conducted with MTD protocols to estimating human risk?	Carcinogenic effects observed at the MTD in animals are predictive of effects in humans at much lower doses
Which animal species should be used to represent humans in terms of carcinogenic response?	The animal species exhibiting the greatest sensitivity is the most appropriate for risk assessment.
When predicting human health risk on the basis of animal data, how should mechanistic variations between species be taken into account?	Differences between species in mechanisms of carcinogenicity are not taken into account when extrapolating data from one species to another.
Data indicate that ingestion of a substance may be associated with cancer. If inhalation exposures are of concern, what is the relevance of the ingestion data to the assessment of risk?	A carcinogen by one route of exposure is a carcinogen by any other route of exposure.
The available data do not demonstrate the absence or existence of a threshold for carcinogens.	There is no nonzero dose below which an increase in cancer risk does not occur.
Data indicate a dose-response relationship at high doses, but few or no data concerning the dose-response relationship at lower levels exist.	The dose-response relationship is linear at low doses.
If data on human exposure are unavailable for a particular substance or site, how can exposures be estimates for purposes of quantitative risk assessment?	chosen values for exposure variables are upper-bound point estimates which, when taken together, do not result in unrealistic exposure estimates.

Due to limits in scientific knowledge or available data, science policy is the key to all regulatory programs that rely on quantitative risk assessment. These science policy decisions, particularly when compounded, can lead to conservative risk assessment results. Further, science policy decisions can be made so as to result in desired regulatory outcomes. The RIAP/DOE Report notes, for example, agency decisions that fluoride and unleaded gasoline are not carcinogenic based on departures from default assumptions.

D. The Inseparability of Risk Assessment and Risk Management

Perhaps the major insight of the 1994 NRC Report and the RIAP/DOE Report is that it is impossible to separate "risk assessment" analysis from "risk management" decisions. Separating these two distinct functions was the approach recommended in the landmark 1983 report by the National Research Council entitled, *"Risk Assessment in the Federal Government: Managing Process."* The 1983 NRC report argued for a complete separation of risk assessment and risk management. However, because science policy issues and science policy decisions (part of risk management) must be an inherent part of risk assessment, that complete separation is not feasible. *"At the very least, the impact of science policy decisions on risk assessment should be clearly and completely described."*[14/]

[14/] Id. at 12.

And, that description must be understood not only by the preparers of the risk assessment but also by the agency's risk managers and the public. The 1994 NRC Report highlights the existing problem:

> *The principle of separation of risk assessment from risk management has led to systematic downplaying of the science-policy judgments embedded in risk assessment. Risk assessment accordingly is sometimes mistakenly perceived as a search for "truth" independent of management concerns.*
>
> *EPA should increase institutional and intellectual linkages between risk assessment and risk management so as to create better harmony between the science-policy components of risk assessment and the broader policy objectives of risk management.*[15/]

[15/] 1994 NRC Report at 267.

E. Clearly Note Science Policy Decisions in the Final Reassessment and Related Communications

EPA's draft Dioxin Reassessment needs to be revised to better identify the science policy issues and decisions it contains. Equally important, executive summaries, press releases, and statements by EPA officials should also strive to highlight the key assumptions or policy decisions. In this way, EPA will not only inform the public and the regulated community, it will serve to better educate our society and advance constructive public debate.

As the 1994 NRC Report concludes:

- *EPA does not adequately communicate to its own decision-makers, to Congress, or to the public the variabilities that are and are not accounted for in any risk assessment and the implications for the conservatism and representativeness of the resulting numbers.*

- *EPA should carefully state in each risk assessment what its particular assumptions about human behavior and biology do and do not account for.*[16]

F. Examples of Science Policy Decisions in the Draft Reassessment

In addition to the basic science policy issues and assumptions presented in table form previously, there are a number of critical gaps in the draft assessment which EPA should consistently and clearly highlight. These include, but are not limited to:

- Instances when the data or underlying research is equivocal, such as the case with the carcinogenicity data;

- The dichotomy between EPA estimates of dioxin generation and deposition data;

- Data inconsistencies and gaps in EPA's "incinerator emission-to-leaf-to-animal-to-human" theory, such as the differences between the fingerprint of

[16] Id. at 221.

dioxins believed to be emitted from incinerators and the fingerprint of dioxins on plant leaves and in animals;

- The limited toxicology data for most dioxin and furan congeners, the weakness this creates in the toxic equivalency factors (TEFs) used by EPA to assess the risk of exposure to dioxin-like compounds, as well as the use of different models in projecting the potential toxicity of exposure to various congeners.

III. CONCLUSIONS

As discussed in these comments, SPI supports the comments filed by its Vinyl Institute and by the Chemical Manufacturer's Association and its Chlorine Chemistry Council. EPA should identify and describe the science policy decisions that form the basis for the assessment of the health risks of exposure to TCDD and chemically similar compounds. The agency should take care to highlight these science policy decisions and other uncertainties in press releases, summaries, and other communications relating to the Reassessment.

Finally, in determining what additional steps the agency will propose in light of the final Reassessment, EPA should carefully consider potential benefits and costs in light of data indicating that body burden experienced by the U.S. population is declining.

Respectfully submitted,

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