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# STATUS OF DIOXIN-RELATED ACTIVITIES AT THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (U.S. EPA)

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## Introduction

Dioxins are a group of chemical compounds inadvertently created through a number of activities including: combustion, certain types of chemical manufacture, chlorine bleaching of pulp and paper, and other industrial processes. Dioxin is produced in very small quantities compared to other pollutants (around 30 pounds TEQ annually in the U.S.); however, because it is highly toxic, it has been treated as a significant environmental pollutant since the early 1970's. U.S. EPA first took action against dioxin as a contaminant of the herbicide 2,4,5-T in 1979. Since then, EPA has expanded its dioxin control efforts to each of its major programs.

In 1985 EPA published a scientific review of the health effects of 2,3,7,8-TCDD, the most toxic of the dioxin family of compounds. That assessment has served as the scientific basis for dioxin risk estimates for all U.S. EPA programs. In April 1991, EPA announced that it would conduct a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA has undertaken this task in light of significant advances in our scientific understanding of mechanisms of dioxin toxicity, significant new studies of dioxin's carcinogenic potential in humans and increased evidence of other adverse health effects. The reassessment is part of the Agency's goal to improve its research and science base and to incorporate this knowledge into EPA decisions. In September, 1994, EPA released a "public review draft" of its dioxin reassessment. This release marks a mid-point in EPA's effort to reevaluate the scientific understanding of dioxin. While the reassessment has been underway, EPA has continued to move forward in implementing its dioxin control programs. EPA has taken a number of actions to control the risks of dioxin.

## Science Reassessment

In September 1994, the EPA released the public review draft of the full reassessment. The reassessment consists of two documents, each about a thousand pages long, and each published in several volumes. One of these documents addresses the human health effects of dioxin; the second focuses on sources and levels of exposure. The reassessment is a scientific document and does not address policy or regulatory issues. Volume three of the health effects document is the Risk Characterization chapter . This chapter integrates the findings

of both the effects and exposure documents, and describes the potential risks posed by dioxin.

The draft study not only updates the 1985 document, but also represents an ongoing process to build a broad scientific consensus on dioxin's toxic effects. To help foster this consensus, EPA has worked to make each phase of the dioxin reassessment an open and participatory process. These efforts have included the involvement of outside scientists as principal authors of several chapters, several public meetings to take comment on our plans and progress, and publication of earlier drafts of our work for public comment and review. We are continuing this participatory process by making the current draft available for public comment and full scientific review. When this process is completed, we anticipate having an up-to-date and thorough scientific assessment of dioxin that is at the cutting edge of environmental toxicology.

Regarding health risks, the draft study reaffirms the association of dioxin and cancer. In its 1985 assessment, EPA concluded that dioxin is a proven animal carcinogen and a probable human carcinogen. The current draft report reaches the same conclusion, but with greater confidence. Based upon both animal and human evidence, EPA's estimate of dioxin's cancer potency is essentially unchanged from that of 1985.

The draft reassessment differs significantly from the 1985 document in its evaluation of dioxin's non-cancer effects. Today we have a stronger body of evidence to suggest that at some dose, dioxin exposure can result in a number of non-cancer health effects in humans. These effects may include developmental and reproductive effects, immune suppression, and disruption of regulatory hormones. We have no direct evidence to show that any of these non-cancer effects occur in humans at everyday levels of exposure. However, we can infer from the data that average everyday exposures are close to exposures that are known to cause such effects in laboratory animals.

The draft study also identifies dioxin sources that are known to contribute to environmental contamination. Waste combustion accounts for about 95% of all the known U.S. emissions, with medical and municipal waste combustion dominating the combustion sources. It is likely that there are a number of unidentified sources of dioxin in the U.S. and that we do not have sufficient information about emissions from known sources to provide precise estimates. It is also possible that much of the dioxin that contributes to human exposure results from past dioxin emissions recirculating in the environment. Although there are some natural sources of dioxin, such as forest fires, it seems clear that dioxins are primarily a product of modern industrial society.

The draft reassessment adopts the hypothesis that the pathway for exposure to humans is primarily via airborne dioxins that settle on plants and accumulate in the food chain and associated particularly with fat. Food (and particularly animal fat) is the primary pathway for dioxin exposure, but the U.S. federal government continues to emphasize that the benefits from a balanced diet far outweigh any theoretical risks from dioxin exposure.

The U.S. EPA will be taking public comments on the draft document from September, 1994 to January, 1995. During the public comment period, public meetings will also be convened to take formal comments on the draft documents. These hearings are being planned for the first two weeks of December in five areas around the U.S.

The draft documents also will receive scientific peer review by EPA's Science Advisory Board. This meeting will be held after the public comment period has ended, early next year. Following SAB review, comments and revisions will be incorporated and final documents will be issued. We anticipate completion and release of the final reassessment about one year from now in the fall of 1995.

**Regulatory Activities**

While the reassessment has been underway, U.S. EPA has continued to move forward in implementing its dioxin control programs. U.S. EPA has taken action under each one of its major statutes to reduce dioxin emissions. Recent actions taken by EPA include proposing air emission standards for municipal waste incinerators, proposing water effluent standards for pulp and paper mills. Additionally, U.S. EPA will propose air standards for reducing dioxin and other emissions from medical waste by February, 1995.

While the science of the reassessment is undergoing peer review, U.S. EPA is examining the policy implications to determine what changes, if any, are needed in existing programs. U.S. EPA is committed to developing an agency-wide strategy for managing dioxin risks, concurrent with completion of the dioxin reassessment. As with the reassessment, the U.S. EPA will provide an opportunity for early public input into our policy evaluations. In Spring 1995, U.S. EPA will hold dioxin policy workshops to explore the policy implications of the reassessment. The details of these workshops will be widely announced.

**Research and Data Collection**

This massive scientific effort has made it clear that there are significant data gaps that are critical to our understanding and effective management of dioxin. As a consequence, U.S. EPA has begun a major initiative to expand the understanding of dioxin sources, environmental pathways and human exposure. The highest priority will be to identify additional data to improve the reassessment; however, the exposure initiative will extend beyond the reassessment into future years.

As a part of this effort, the U.S. EPA is calling on all parties to submit any data that can help us better understand dioxin exposure. The Agency is requesting that industry, public interest groups, state and local governments, academia, and hospital facilities examine their files for existing data. Needed information includes data on dioxin sources, releases and levels in air, water, soil, food, animal feed, and human tissues. In addition, U.S. EPA is calling on industries that are potential dioxin sources to voluntarily work with the Agency to devise and implement emissions testing programs.

**Conclusions**

The reassessment represents a major expansion of U.S. EPA's scientific understanding compared to our previous assessments of dioxin toxicology. Because many of the studies included in the reassessment have only recently been part of the scientific literature and our integration of this evidence is entirely new, it is important that the reassessment undergo thorough public and scientific peer review. At the same time, because the general thrust of the reassessment is consistent with our past scientific basis, the Agency feels confident in aggressively pursuing its ongoing dioxin control efforts. This report, once it has completed peer review sometime next year, will give us the best scientific basis possible to guide our continuing efforts to curb dioxin risks.