The U.S. Environmental Protection Agency's Reassessment of Dioxin

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On April 8, 1991, the EPA Administrator, William Reilly announced that the Agency would conduct a scientific reassessment of the risks of exposure to 2,3,7,8-TCDD and related compounds, collectively known as "dioxin." The purpose of the reassessment of dioxin is to ensure that the scientific bases used to evaluate the human and ecological risks associated with the environmental exposures incorporates the most recent state-of-the-art data. The scientific reassessment of dioxin consists of five basic activities as outlined below:

1) development of a biologically-based dose-response model for dioxin,
2) update and revision of the health assessment document for dioxin,
3) laboratory research in support of dose-response model,
4) update and revision of the dioxin exposure assessment document, and
5) research to characterize ecological risks in aquatic ecosystems.

The presentations which following in this session provide insights into the technical aspects and scheduling of each of these activities.

The dioxin reassessment represents a significant departure from the way in which EPA has conducted risk assessments in the past.

- This reassessment is much broader than our previous assessment in 1988, which focused primarily on the cancer potency of 2,3,7,8-TCDD. Our goal in this reassessment is to develop the best scientific bases currently possible for estimating the full range of health risks to humans and aquatic organisms and wildlife resulting from exposure to dioxin and dioxin-like compounds. EPA is making use of all of the available data and developing new data where needed and appropriate. The state-of-the-art data provide a better understanding of the biochemical mechanisms whereby dioxin exerts its effects and will be applied in the development of a new model for estimating risks to humans.

- EPA is making the maximum use of experts from outside the Agency in both the

conduct of the reassessment and its review. We believe that this will ensure both a high-quality product and greater credibility for the conclusions which are finally reached. We have held two public meetings at which we have shared new information and solicited public participation i the reassessment process. At EPA, we are placing our current emphasis on identifying and assessing the scientific issues and have refrained form predicting what the conclusions of the reassessment will be. The conclusions will be generated not by us but by a group of outside experts who will be convened this fall. This approach comes, however, with a drawback, because observers of the process ar free to draw conclusions from the new information well before drafting of the risk characterization begins.

- In spite of the size and complexity of this undertaking, we are conducting this reassessment of an expedited basis. We are keenly aware that delay and uncertainty are particularly undesirable in a situation such as dioxin where numerous regulatory decisions have already been made based on previous assessments of dioxin risk and where there are many such decisions yet to be made in the not so distant future.

- We recognize that there is tension between the expedited nature of this reassessment and our desire to have active participation in the exploration of the scientific issues by all those interested in dioxin science well before the drafting of the risk characterization has been completed. However, we are committed to producing this risk reassessment in a timely manner ~ that is, to have completed peer review and produced the final version no later than the middle of next year.

EPA cannot and will not speculate on the degree and direction of any changes in the estimating of risks relative to environmental exposures or to its regulatory response to these changes until completion of the major activities listed above. Only after a more biologically plausible dose-response model is developed, scientifically peer-reviewed, and applied, will EPA be able to determine the nature and magnitude of the risks associated with dioxin exposure.

In summary, this reassessment has broadened the range of possible outcomes and is providing a more robust base of information from which conclusions will be drawn. This reassessment should not be viewed as a horse race between two competing points of view--namely, that dioxin is as bad as previously concluded or that dioxin is much less harmful than previously thought. Rather, it is a process through which we expect to be able to sort out what is known and not known about dioxin, and through which a scientifically sound, publicly credible, and timely judgement can be reached on the impact that dioxin and dioxin-like compounds can have on human health and aquatic ecosystems.