DOW CHEMICAL HUMAN HEALTH RISK ASSESSMENT PROPOSAL
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BRIEFING PURPOSE

To provide background on the hazardous constituent contamination of the Saginaw Bay Watershed (SBW) originating from the Dow Chemical (Dow) Midland, MI facility; to describe Dow's proposed methodology for human health risk assessment (HHRA); and to describe Region 5's position on the proposed HHRA.

FACILITY BACKGROUND

The Dow facility is a 1,900 acre chemical manufacturing plant located in Midland, Michigan. Dioxins were byproducts formed during the manufacture of chlorine-based products. Past waste disposal practices, fugitive emissions, and incineration at Dow have resulted in on and off-site dioxin/furan (D/F) contamination.

D/F contamination of the SBW extends over 50 miles, into Saginaw Bay. The highest dioxin concentration detected to date is 110,000 ppt TEQ. For comparison purposes, the MDEQ's residential direct contact criteria is 90 ppt. The ATSDR Action level is 1,000 ppt.

The health risks from fish consumption and the geographic extent are comparable to the Hudson, Fox, and Kalamazoo Rivers which are major Superfund sites. Unacceptable risks to human health exist with cancer risks of one in a thousand (using old dioxin cancer slope factor), and non-cancer risks (reproductive, immune) 10 times acceptable levels for adults and 25 times acceptable levels for children. The University of Michigan Dioxin Exposure Study has found that frequent fish consumers have elevated dioxin blood levels.

In 2003, MDEQ issued an Operating License to Dow which includes corrective action requirements requested by EPA for the Tittabawassee and Saginaw Rivers, their floodplains, and Saginaw Bay.

This issue has attracted a high level of interest by Federal and State legislators, citizens, environmental groups, and the media.

HHRA BACKGROUND

As part of Remedial Investigation Workplans (RIWPs) for the City of Midland and the Tittabawassee River, Dow proposes to conduct site-specific human health risk assessments. The risk assessments may identify exposure pathways and likely exposure scenarios, and make estimates of intake doses. The intake dose estimates may be combined with chemical-specific dose-response factors (i.e., toxicity factors), and the resulting cancer risk and non-cancer hazard estimates may be used to calculate cleanup goals.

DOW'S HHRA PROPOSAL

Dow proposes to follow a Probabilistic Risk Assessment (PRA) methodology which includes:

- Replacing single point/deterministic estimates for many exposure parameters and exposure factors (e.g., body weight, soil ingestion rate, food and water intake rate, exposure duration) with statistically-derived distributions known as Probability Distribution Functions (PDFs).
- Generation of PDFs for exposure factors from published studies on human characteristics and behaviors, such the EPA Exposure Factors Handbook.
- Extending the PRA methodology to include all of the chemical-specific dose-response data used to derive chemical-specific dose-response factors (i.e., Cancer Slope Factors, Reference Doses, Toxic Equivalence Factors).
- Generation of PDFs for chemical-specific dose-response factors by reviewing all available scientific literature on the toxicology of contaminant chemicals to describe the variability and uncertainty associated with the toxicological responses
- PRA methodology for dose-response factors would cover many other site contaminants in addition to D/F (est. 50-60).
- Calls for Independent Peer Review of many aspects of its PRA Risk Assessment; (Dow wants these reviews to be separate and independent from Agency review.)
- Dow projects that PRA risk assessment will require 3.5 years to complete; (not including additional time projected for incorporating the findings of risk assessment into site-specific remedial goals for the SBW.)

EPA REGION 5 POSITION

- EPA Region 5 has significant concerns about the long time frame proposed by Dow to complete site-specific PRA risk assessment; significant evidence already exists to suspect elevated D/F exposure through the food chain pathway, especially for at-risk populations such as pregnant women, children, subsistence hunters and fishers, and Native Americans.

- Development of PDFs to describe uncertainty and variability of dose-responses for chemical contaminants is not in accordance with EPA published guidance. EPA only recognizes toxicity factors developed by HQ through a peer reviewed, national consensus based process.
- Dow has not provided the methodology for mathematically combining the results of numerous toxicological studies to create PDFs. Establishing and performing such a methodology will likely unnecessarily delay the completion of risk assessments.

- Methodology proposed by Dow is outside the normal EPA national risk assessment program (e.g., ORD, NCEA, Risk Assessment Forum).
- With regard to applying PRA to risk assessments, the EPA site remediation program (i.e., OSWER - Superfund/RCRA) has made a clear policy decision that chemical-specific dose-response data will not be recognized as a valid and appropriate part of the PRA process.
- Region 5 is not aware of any peer reviewed or widely accepted scientific consensus methodology available for applying PRA to chemical-specific dose-response factors or deriving PDFs for such factors.
- In formal guidance on PRA, OSWER stated:
    - "This guidance does not develop or evaluate probabilistic approaches for dose-response in human health assessment and, further, discourages undertaking such activities on a site-by-site basis. Such activities require contaminant specific national consensus development and national policy development. Parties wishing to undertake such activities should contact the OERR to explore ways in which they might contribute to a national process for the contaminant of interest to them." (Risk Assessment Guidance for Superfund; Process For Conducting Probabilistic Risk Assessment; December 31, 2001)."
- For the assignment of dose-response factors, EPA regional toxicologists/risk specialists do not have the authority to change, or reach a new consensus with outside parties on dose-response factors for chemicals that currently have listed IRIS factors or that have equivalent factors published in EPA regulations. For inquiries on the use of alternative toxicity factors, Regional toxicologists will refer these cases to the appropriate EPA Headquarters program (e.g., OSWER, ORD, OPPT) for a national expert review in which the Region could participate.
- EPA Region 5 turned down a similar request at the Kalamazoo River PCB Site (March, 2003) under the Superfund program.