Research Area: Use of Risk Assessment to Evaluate Chlorine Chemistry

Accurate scientific information, sound risk assessments, and informed regulatory action are central to balancing risks and, therefore, managing and reducing overall threats to human health and the environment. Not properly balancing risks can have devastating public health consequences. In the early 1990's, Peruvian health officials (citing EPA's regulatory position based upon cautious assumptions that any level of chloroform in drinking water increases the risk of cancer) reduced the level of chlorination in drinking water to reduce chloroform levels. This action contributed to a cholera epidemic that spread throughout South America, killing more than 10,000 people and sickening millions. Later, public health officials wrote that this decision "was fostered in part by the misconception that DBPs pose a greater risk to public health than pathogens."[1] This example highlights the importance for health-based policies and regulations to rely upon scientifically-based risk assessments that incorporate available toxicity and exposure data, along with cautious policy 'default' assumptions to use when data are insufficient.

Within the U.S. and Europe, pressure is mounting to use very cautious approaches in risk management when data for risk assessments are incomplete. Some advocates assert that the appropriate application of precaution requires the extremely conservative application of a ban, substitution, or other measures limiting or restricting chemical use when safety cannot be fully demonstrated. One problem with this approach is that we typically lack a full data set on risks/safety associated with the substitutes, as well. Less information does not mean a safer product. Therefore, unless risk management decisions assess the product of concern compared to its alternatives, we cannot assert that public health is improved.

To respond to this need and to provide a basis for better-informed risk management decisions, risk assessments require more and better chemical–specific data as well as better data on risks from alternative (substitute) products/chemicals.

Increasingly, scientists are looking beyond their own specialties to find data and approaches that can advance their research. For example, toxicological studies are used to augment epidemiological studies and vice versa. Studies designed and conducted with a greater awareness of other disciplines may not only augment research but also strengthen and broaden the data used in risk assessments.

Furthermore, most toxicologists believe that improving toxicological assessments requires a better understanding of the contribution of both toxicokinetics and toxicodynamics to dose-response phenomena observed in laboratory studies. Integrated approaches may also help to resolve controversies over which biological endpoints are most meaningful for assessing adverse effects. Finally, integrated pharmacokinetics and pharmacodynamics [PB-PK/PD] approaches may be important to developing better models for predicting dose-response characteristics of chemical mixtures.

Improving the scientific basis of risk management decisions requires incorporating more science into risk assessments, which in turn requires more relevant toxicological data and more refined risk assessment methods. The contributions of science to risk management are optimized when the decision-making process, policy objectives, and management options are clearly elucidated and the critical information requested from science research is identified early in the risk management process.

It is clear that risk assessment is entering a new age with respect to our ability to integrate greater complexity into the process. However, there has been a conspicuous lack of consideration concerning how this information will be communicated to the public. Industry should discuss with EPA and other regulatory agencies about how to inform the public that science-based risk assessments are protective of health and the environment and that such assessments represent an improvement in health policy and decisions, rather than a relaxation or softening, of regulatory standards. The recent outcome of the chloroform drinking water standard confirms the importance of science-based risk assessment by the regulatory community and, at the same time, the case shows the reluctance to use new scientific data, rather than default assumptions, for science-based risk assessments in policymaking. This may be repeated for other compounds as more data becomes available.

RFHEE recognizes the need for research to improve the assessment process and will work, in a supportive role, with others in government and industry [in particular the industry's Long Range Research Initiative]. While RFHEE recognizes the importance of this generic work, the conduct of such research is included as a priority issue in other industry funded research efforts. Therefore, RFHEE will focus its research to studies that are specific to chlorine chemistry.

RESEARCH THEMES:

RFHEE intends to partner with governmental agencies and others to examine, understand, and improve the public health decision-making process and the underlying science supporting these decisions. RFHEE is particularly interested in supporting projects that:

- Contribute to the acceptance of risk assessment in public policies, thus reducing the use of conservative default assumptions in public health policy decisions.
- Contribute to the use of PBPK and mechanism-based risk assessments for key chlorinated compounds.
- Contribute to using existing information [including mechanistic data, PBPK modeling, and genetic data] in science-based decision processes.

CANDIDATE PROJECT AREAS:

SEE SEPARATE LIST

[1] Otterstetter, H. and Craun, G., Disinfection in the Americas: A Necessity, Journal of the American Water Works Association [AWWA], September 1997. p. 8.