Integrating Bioaccumulative Results into EPA's Decision-Making Process

Thomas Murray
U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC

Premanufacture Notifications (PMNs) are required under section 5 of the Toxic Substances Control Act (TSCA) from anyone who intends to manufacture or import a new chemical substance. A new substance is defined as one not on the Chemical Inventory created under TSCA section 9. Once the U.S. Environmental Protection Agency (EPA) receives a PMN document, Agency staff normally have 90 days to review it. First, the PMN substance is sent through an initial screening-level risk assessment process. A major objective of this review process is to determine whether the PMN substance may present an unreasonable risk of injury to human health or the environment during its lifetime.

The Office of Pollution Prevention and Toxics (OPPT) uses a similar process for those chemicals already in the marketplace. Priorities are established for selecting existing chemicals from the chemical inventory for review. There is no statutorily imposed time schedule for these reviews.

Coming out of the screening-level risk assessment process, those chemicals which are found to present the potential for unreasonable risk to human health or the environment are scrutinized more thoroughly. OPPT sometimes requires testing in response to identified concerns before reaching a decision for a chemical under review.

Professionals from many different disciplines take part in reviewing the various aspects of the life cycle of a chemical under review. In his remarks, Maurice Zeeman describes those things considered when assessing risk to ecological communities. My remarks will focus on the human health exposures.

When a chemical is introduced into OPPT's risk screening process, a Structure Activity Team convenes to discuss its potential health and ecotoxicity concerns. This Team provides direction to the review process that follows. Of concern to us in this discussion are those chemicals which result in human exposures through surface water. Here, OPPT engineers quantify surface water releases of these chemicals from point sources or estimate these releases where monitoring data are absent. We do not routinely assess nonpoint sources. OPPT chemists then assess the fate of these chemicals and describe likely or known transport processes. Assessors then use these fate estimates to assess the potential human health risks associated with the expected releases.

The process of evaluating each potential route of exposure can be complicated. To perform the calculations necessary for exposure evaluations, assessors make use of simple formulas, complex mathematical models, and a number of basic assumptions. Sound monitoring data are always preferred but are rarely available. Much of the work involved in the assessment process involves frequently encountered exposure scenarios. This has allowed OPPT to standardize most of the assessment process. A number of thresholds have been developed which help determine whether a given chemical or exposure route will present significant potential exposures. OPPT relies heavily on the efforts of other EPA program offices and academia in updating its exposure assumptions and models.

Sediment/Bioaccumulation Results

When a chemical under review is believed to have the potential to pose a risk to human health through the surface water pathway, several exposure assessment steps are set in motion. First, a fate review is done to determine, among other things, how much of the chemical is likely to be removed in the wastewater treatment process. With an estimate of chemical loading to the receiving stream, instream processes (hydrolysis, photolysis, biodegradation, etc.) are explored to assess the ultimate fate of the chemical. Exposure models are then deployed to track the chemical downstream to drinking water facilities. The fate chemists will also calculate the Bioconcentration Factor (BCF) for the chemical if exposure through fish ingestion is indicated. Potential Dose Rates are calculated through this pathway only when the log BCF is greater than 2. When the BCF is less than 100 (or the log BCF is less than 2), the resulting human exposure is considered negligible. If the log K_{ow} is greater than 8, human exposure is not calculated. Values for log K_{ow} that are higher than 8 are considered

Back

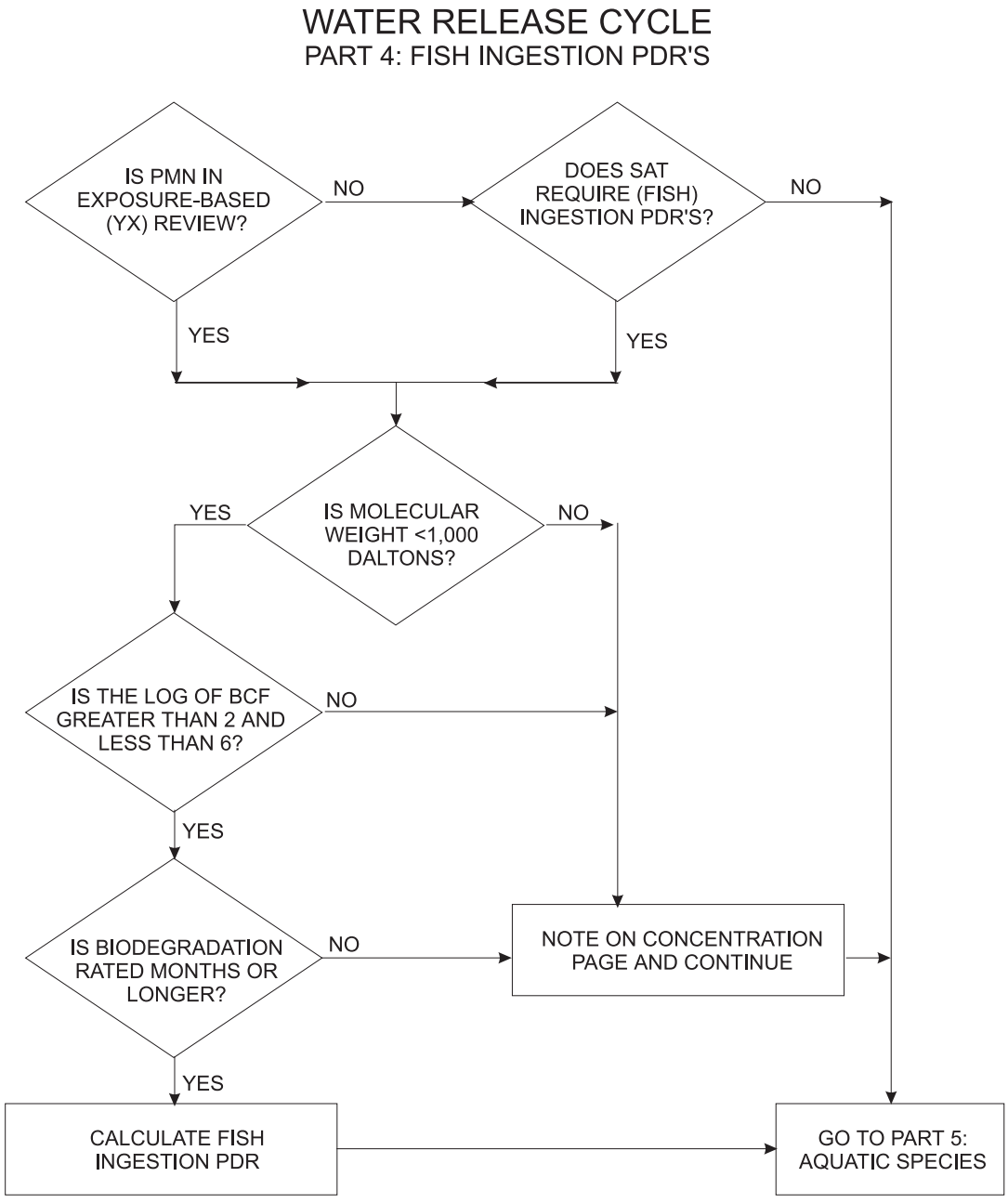
unreliable; therefore, the BCF estimate is deemed unreliable and is not used.

OPPT has also determined that in addition to having the potential to bioaccumulate, the chemical must also remain in the environment long enough to be absorbed into fish tissue. For our purposes, degradation of the chemical must be estimated to take months or longer to allow uptake by fish tissue to occur. Potential dose rates (PDR, a measure of exposure) for fish ingestion are calculated using the stream concentration of the chemical at mean flow (see pages 7-33 and 7-34). For discharges to saline waters, chronic mixing zone dilution factors are used, when available. OPPT currently assumes a fish ingestion rate of 16.9 grams per day. To be consistent with the most recent draft of the *Exposure Factors Handbook*, we will adjust this rate. For subsistence fishers a rate of 140 grams per day can be used; for sport fishers 39 grams per day is reasonable.

Where our calculations indicate that potential exists for unreasonable risk to humans through fish ingestion, we can reach several decisions. Oftentimes, we will require testing by the industry to refine our fate estimates. Dialogue with industry is routinely employed and frequently leads to other refinements in our assessment process. In extreme cases where sufficient risk is anticipated and uncertainty low, TSCA allows OPPT to initiate actions to limit or ban the production or use of a chemical.

Most recently, where potential risk is indicated, we engage industry in discussions designed to encourage voluntary efforts to reduce or eliminate the risk. These range from suggestions to recycle waste or seek disposal practices other than wastewater discharge to intensive efforts to work with industry to redesign their processes to eliminate problems upstream in the process through chemical substitution or process change.

As science advances our understanding of the fate and transport processes of chemicals in the environment and as new testing protocols are developed and standardized, OPPT will embrace these new developments and, where appropriate, will update its assessment process accordingly.



NOTES:

Calculate fish ingestion PDRs for releases to saline, tidal, or "still" waters using chronic mixing zone dilution factors when available.

$$PDR_{fi} = C_{sw} * ING_{fis} * BCF * FQ * 1E^{-6}$$

where

C_{sw} = concentration in surface water (ug/l)

ING_{fis} = ingestion rate

BCF = As calculated

FQ = frequency of exposure (days/year)

Decisions

- Testing
- Dialogue
- Voluntary Actions
- TSCA Regulatory Actions

Next