Ecotoxicity and ecological risk assessment

Regulatory applications at EPA

First part of a four-part series

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Most of the laws under which EPA operates require protection of "human health and the environment," or words to that effect. Since its establishment in 1970, EPA has labored mightily to do both—protect health and protect the environment. However, resource constraints have forced many hard choices. Typically, those activities most closely related to identification and reduction of risks to human health have received the higher priority, leaving few dollars or staff for strictly environmental or ecological protection.

Despite these constraints, ecological risk assessment, based on ecotoxicity data, has been an important activity under many programs at EPA. The Office of Pesticides and Toxic Substances, for example, is concerned about potential impacts of pesticides and toxic chemicals on organisms, including aquatic and terrestrial communities. Its legal mandates come from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

The Office of Water is required by the Clean Water Act to restore and maintain the biological integrity of the nation's waters and, specifically, to ensure the protection and propagation of a balanced population of fish, shellfish, and wildlife. EPA also develops methods, including biological monitoring and assessment methods, for establishing and measuring water quality crite-

ria. These statutory requirements have encouraged the Office of Water to develop innovative approaches to ecological assessment.

The Office of Solid Waste and Emergency Response (OSWER) has responsibility for assessment of effects from solid waste and hazardous waste and for remediation of abandoned hazardous-waste sites under Superfund. Historically, OSWER guidance has focused primarily on health risks. However, national and site-specific strategies for remediation are now placing increased emphasis on ecological impacts as well, especially in the Superfund program.

We will now describe current approaches to ecological risk assessment used by the pesticides, toxics, and water programs and sketch new directions being explored by EPA.

TABLE 1

Data sources and assessment factors used by OTS[a] to evaluate need for testing of new chemicals

Data source available	Assessment factor to be applied
Structure-activity derived LC_{50} value	1000
Single LC_{50} value from chemical analog[b]	1000
Single test LC_{50} value for PMN[c]	1000
Two LC_{50} values for same analog (e.g., 1 fish, 1 algal test)	1000
Two LC_{50} values for PMN (e.g., 1 fish test, 1 invertebrate)	1000
Three LC_{50} values for same analog (fish, algae, invertebrate)	100
Five LC_{50} values for same analog (3 invertebrates, 2 fish)	100
Five LC_{50} values for the PMN (e.g., 3 algae, 2 fish)	100
Maximum acceptable toxic concentration for analog	10
Field study	1

[a]EPA's Office of Toxic Substances.
[b]"Analog" is a chemical similar to that proposed for production.
[c]"PMN" is the Premanufacture Notification describing the chemical.

Pesticides and toxic substances

Both programs under the Office of Pesticides and Toxic Substances, the Office of Pesticide Programs (OPP) and the Office of Toxic Substances (OTS), assess risks to ecological resources using an ecotoxicological approach: laboratory toxicity bioassays to determine hazard, determination of exposure either from monitoring data or predicted from models, and a comparison of exposure to hazard using the quotient method. In the quotient method, the exposure value is directly compared with a toxicity endpoint (e.g., concentration in water to an LC_{50} value; 10 ppm/100 ppm), the LC_{50} value being the concentration lethal to 50% of a test population. The closer the quotient is to 1 (or greater), the higher the probability that an adverse effect will occur.

Interpreting this adverse effect, that is, the likelihood that what is observed in the lab will actually occur in the field, is one of the greatest uncertainties in both programs. Although each program derives it differently, the final result is the application of a safety factor to account for uncertainty.

The pesticide and toxic substances programs are similar in their approach to assessing ecological risk, but the quantity of data used to make assessments is strikingly different. TSCA assessments tend to be data-poor, with only limited ecological effects information being provided by the company submitting a premanufacture notification, whereas FIFRA assessments are usually data-rich. Why?

FIFRA is a registration law that gives EPA legal authority to require up-front testing. TSCA is not a registration law but, rather, a "review and approval law." A case must be made that a new chemical is likely to cause adverse health or ecological effects before any substantial testing can be required.

New chemicals under TSCA

Because of the large numbers of industrial chemicals that are assessed by OTS, a method was devised to ensure uniformity and consistency in identifying chemicals for testing to determine ecological hazard. Assessment factors are used in conjunction with the hazard assessment to derive concentrations of concern in aquatic media which, if equaled or exceeded, provide a basis for further testing. Assessment factors are numbers that are used to adjust standard toxicological measurements to derive a "concern level."

An environmental concentration of concern is that concentration at which populations of organisms may be adversely affected under simulated or actual conditions of production, use, and disposal. The assessment factors take into account the uncertainties due to such variables as test species' sensitivity to acute and chronic exposures, laboratory test conditions, and age-group susceptibility. There are four assessment factors currently being used: 1, 10, 100, and 1000. Table 1 summarizes the application of assessment factors *(1)*.

Assessment factors are not equivalent to safety factors. A safety factor is usually interpreted as being a margin of safety applied to a no-observed-effect level to produce a value below which exposures are presumed to be safe. Assessment factors are applied to acute or chronic toxicity values based on the type and quality of data available. They are used to arrive at a concentration that, if equaled or exceeded, could cause adverse effects. Assessment factors have been developed solely for the process of reviewing premanufacture notifications to identify those chemicals that require ecological testing to fully assess ecological risks.

Assessing pesticides under FIFRA

OPP follows four steps in a preliminary assessment of ecological risk: review and evaluate hazard data to identify the nature of the hazards; identify and evaluate the observed quantitative relationship between dose and response; identify the conditions of exposure (e.g., intensity, frequency, and duration of exposure); and combine the information on dose–response effects with that on exposure to estimate the probability that nontarget populations will be adversely affected by actual use of the pesticide.

These steps result in the comparison of toxicological hazard data with exposure data. Typically, the toxicological hazard data may consist of acute LD_{50} (the *dose* lethal to 50% of a test population) and LC_{50} values, or chronic no-effect levels for a sensitive indicator species. Exposure data normally consist of model-based, estimated environmental concentrations (EEC) in the media of concern (i.e., water, soil, nontarget organism food items).

If the ratio of these input data (e.g., EEC/LC_{50}) equals or exceeds certain fixed criteria, a risk is inferred, and generally simulated or actual field testing is required to confirm the risk. In Table 2 are ecotoxicological assessment criteria containing specific safety factors that form the regulatory framework developed by EPA in 1975. This framework has been used to estimate the potential hazard of pesticides to nontarget organisms.

TABLE 2

Ecotoxicological assessment criteria for pesticides[a]

Presumption of no hazard	Presumption of hazard that may be mitigated by restricted use	Presumption of unacceptable hazard
Acute Toxicity		
Mammals		
EEC[b] $< 1/5\ LC_{50}$	EEC $\geq 1/5\ LC_{50}$	EEC $\geq LC_{50}$
mg/kg/day $< 1/5\ LC_{50}$	mg/kg/day $> 1/5\ LC_{50}$	
Birds		
EEC $< 1/5\ LC_{50}$	$1/5\ LC_{50} \leq$ EEC $< LC_{50}$	EEC $\geq LC_{50}$
Aquatic organisms		
EEC $< 1/10\ LC_{50}$	$1/10\ LC_{50} \leq$ EEC $< 1/2\ LC_{50}$ EEC $\geq 1/10\ LC_{50}$	EEC $\geq 1/2\ LC_{50}$
Chronic Toxicity		
EEC < Chronic No effect level	N/A	EEC $\geq$ effect level (including reproductive)

[a]Adapted from Reference 2.

[b]Estimated environmental concentration. This is typically calculated using a series of simple nomographs to complex exposure models.

The framework was designed to provide a safety factor that would allow for differential variability among fish and wildlife species *(2)*. Many theoretical questions can be raised about the use of assessment criteria and safety factors in general. Currently, this framework is not used to predict the probability that the pesticide will cause significant adverse effects to nontarget organisms because the framework does not provide a mechanism for estimating uncertainty. Since 1985, the program has developed the weight-of-evidence approach for determining unreasonable ecological risk. This determination includes consideration of the quality and adequacy of the data, as well as the magnitude of the estimated or observed effect.

Both the toxics and the pesticides programs recognize that the ratio method for assessing risk has numerous weaknesses. For example: it does not adequately account for effects of incremental dosages; it does not compensate for differences between laboratory tests and field populations; it cannot be used for estimating indirect effects of toxicants (e.g., food chain interactions); it has an unknown reliability; it does not quantify uncertainties; and it does not adequately account for other ecosystem effects (e.g., predator–prey relationships, community metabolism, structural shifts, etc.). Therefore, the ratio method does not provide for a complete characterization of the magnitude of risk nor the degree of confidence associated with the characterization.

Assessing water quality

The Water Quality Act of 1987 (P.L. 100-4) amends the decade-old Clean Water Act and redirects its focus from the technology approach, based on end-of-pipe standards, to full-scale implementation of the water quality approach, based on ambient receiving water standards. The new act requires detailed national assessments of: trophic status and trends in lakes (Section 314), waters needing additional nonpoint source controls to attain water quality standards (Section 319), and waters not meeting standards due to point and nonpoint sources of priority toxic pollutants [Section 304(l)].

Bodies of water not meeting applicable state standards must be listed in order of priority for control actions and management plans, and control strategies must be implemented to rehabilitate these degraded waters. In addition,

existing regulations are being updated to perpetuate this assessment process and to tighten controls on toxics. Proposed revisions to the Water Quality Management Regulation *(3)* would formalize the listing and reporting of water quality-limited segments, and the Water Quality Standards Regulation *(4)* will likely, for the first time, require all states to adopt criteria for the priority toxic pollutants.

State water quality standards form the backbone of the water quality-based approach, and biological endpoints often are the basis of such standards. Because the Clean Water Act declares "fishable/swimmable" as a minimal goal for the nation's waters, EPA, in its oversight of state standards, rarely endorses use designations that do not at least provide for "protection and propagation" of aquatic life. Therefore, criteria that are expressly designed to protect the biota are also the most commonly used endpoints for assessing potential impacts (risks) to designated uses.

EPA criteria are developed as national recommendations to assist states in developing their standards. The endpoints most commonly used in risk assessments are chemical-specific criteria and whole-effluent toxicity criteria *(5)*. Both types of criteria have three components, the first serving as the risk assessment endpoint and the latter two being applied in assessing the exposure:

- magnitude—what concentration of a pollutant (or a pollutant parameter such as toxicity) is allowable;
- duration—the period of time over which the predicted in-stream concentration is averaged for comparison with the criteria concentration (this specification limits the duration of concentrations above the criteria); and

- frequency—how often criteria can be exceeded without unacceptably affecting the community.

Hazard assessments for specific criteria chemicals are conducted in accordance with EPA's National Guidelines *(6)*. Concentrations of these chemicals from individual sources are usually translated into ambient levels using conservative exposure models. The models predict steady-state environmental concentrations that persist for a critical duration and recur at a given frequency. Predicted exposure concentrations are then compared to the criteria—the endpoints of concern—using the quotient method. If the model predicts concentrations that exceed the criteria, the source is considered to pose a significant risk to aquatic life.

Risk assessments for point sources of whole-effluent toxicity are conducted following guidance provided in the Technical Support Document *(7)*. This procedure differs somewhat from that used for specific chemicals. Because a unique battery of toxicity tests may be needed to characterize the hazard posed by each effluent, a tiered approach is used to tailor hazard assessment requirements to the site-specific exposure situation.

Test results from a lower tier (acute tests, few species) are first weighted with uncertainty factors to account for potential variations in species sensitivity, acute to chronic ratios, and temporal fluctuations in effluent quality. Estimated effects thresholds are then compared with expected environmental concentrations using the quotient method. An indication of ambient toxicity can either trigger further testing at a higher tier or implementation of regulatory controls.

The risk assessment procedure outlined above illustrates several of the major improvements that have been incorporated into water quality-based control processes in the last few years. Most notably, whole-effluent toxicity, in addition to chemical-specific criteria, has become a legitimate, enforceable parameter for controlling complex discharges. Exposure duration and frequency, in addition to ambient concentrations, have been acknowledged as important attributes of criteria.

The above example also illustrates several of the approach's shortcomings, many of which have been identified by EPA's Science Advisory Board *(8, 9)*. The primary criticism leveled at this type of risk assessment is that the endpoints, although derived in a rigorous and standardized manner, lack realism *(10)*. Furthermore, they may not relate to ecological endpoints that can be directly measured in the field. It is difficult, therefore, to demonstrate that source controls, essentially derived from single-species response criteria, do in fact produce the desired ecosystem level results.

New directions

Agency-wide. Ecological risk assessment is becoming increasingly important at EPA. The public has learned that chemicals not toxic to humans can have adverse effects on resources we value, including a resource as vital as the global climate. First DDT, which is only slightly toxic to mammals, was shown to jeopardize eagles, other birds, and many species of game fish. Then it became apparent that acid deposition, which has little direct effect on human health, could destroy populations of fish and other aquatic organisms in poorly buffered lakes and might be contributing to the die-back of forests. Most recently, we have learned that compounds as safe as CO_2 and CH_4 can cause global warming with potentially adverse effects on entire regions of the earth. Similarly chlorofluorocarbons (CFCs), used partly because of their stability and low toxicity, have contributed to depletion of stratospheric ozone, increasing chances of skin cancer and vegetation damage.

Responding to such concerns, EPA's Risk Assessment Council (senior managers with significant responsibilities for assessment and reduction of risks) established the Ecotoxicity Subcommittee in 1987, giving it responsibility for development of ecological risk assessment guidelines. The subcommittee has looked at the diversity of EPA's ecological assessment activities and found that they included not only prediction of risks from chemicals but also prediction of impacts from projects, retrospective assessment of site-specific impacts, and monitoring of ecological changes.

The subcommittee has developed an ecological assessment framework based on levels of biological organization from an individual organism to an entire ecosystem. This framework could be used both for "top-down" assessments based on field studies and "bottom-up" assessments based on laboratory bioassays. For example, chemical effects on aquatic communities can be measured by comparing uncontaminated and contaminated streams or predicted by extrapolating from effects on aquatic organisms measured in the laboratory. In 1990, guidelines drafted by the subcommittee for ecological assessments of aquatic populations and communities and terrestrial populations should be released for review *(11)*.

The EPA Water Program. Recent initiatives in the water quality-based approach have been targeted at enhancing its overall ecological relevance. Guidelines have been developed on assessing the ecological potential of a given body of water to support aquatic life, and procedures have been defined for modifying the national criteria for specific sites *(12)*.

Furthermore, it has been shown that better exposure assessments of both specific chemicals and whole effluent toxicity are possible *(13)* and that sediment *(14)* and wildlife *(15)* criteria are needed for more comprehensive and realistic risk assessments. Perhaps most importantly, "biocriteria" have been developed *(16)* that quantitatively express water quality standards in terms of the resident aquatic community's structure and function *(17)*. Biocriteria are measures of "biological integrity" that can be used to assess cumulative ecological impacts from multiple sources and stress agents *(18)*. Biocriteria thus provide a means of evaluating whether regulatory actions based on predictive risk assessments are actually protective enough of aquatic ecosystems.

Pesticides and Toxics Programs. Building on a quotient method, the Office of Pesticides and Toxic Substances is actively investigating other methods to improve ecological risk assessments. OTS is exploring population and ecosystem modeling techniques, and an expansion of Quantitative Structure Activity Relationships (QSARs) capability is envisioned as a logical next step in the ecological assessment process. [OTS has recently published a manual on the use of QSAR *(19)*]. A collection of life histories will be compiled to assist in the use of surrogate species data. Improved capability to assess the effects of multiple toxicants is needed, as these chemicals are seldom discharged into the environment in isolation.

OPP has published standard evaluation procedures for many of the laboratory studies of indicator organisms such as invertebrates, fish, and birds required by the pesticide assessment guidelines. OPP has moved to strengthen its risk assessment capabilities in the terrestrial area by issuing a guidance document on terrestrial field studies *(20)*; in the aquatic area it has published a guidance document on aquatic mesocosm tests *(21)*.

Most recently OPP has proposed cancellation of all uses of granular carbofuran, which has been found to kill birds—including bald eagles and other raptors—in excessive numbers when used on corn according to label directions. At this writing, the agency's risk assessment findings were affirmed after public review by a panel of experts.

Hazardous-waste policy studies and technical guidance. EPA's Office of Policy Analysis has completed a study of the scope and nature of ecological problems at hazardous-waste sites. The study identified key areas for improving technical analysis, policy guidance, and ecological risk management for the programs of the Office of Solid Waste and the Office of Emergency and Remedial Response *(22)*.

Abandoned hazardous-waste sites qualify for remedial actions by inclusion on the National Priorities List (NPL) through a series of progressively more detailed assessments. Sites are scored by the Hazard Ranking System (HRS), which currently includes limited ecological factors (essentially the HRS scores the distance from a site to the nearest "sensitive" environment). EPA has proposed revisions to the HRS *(23)* that expand the list of sensitive environments and incorporate scores that better reflect potential ecological hazards.

Also, EPA has recently issued new guidance on ecological assessment at hazardous-waste sites. Detailed guidance on performing the Remedial Investigation/Feasibility Study (RI/FS), used to characterize the risks posed by the site and to investigate appropriate remedies, requires new information for a "baseline" ecological investigation *(24)*.

This RI/FS guidance refers remedial project managers to a new environmental evaluation manual *(25)*, which provides a science policy framework for performing the ecological effects portions of the baseline risk assessment. From an ecotoxicological perspective, perhaps its most important mandate is that ecological factors are to be considered "up-front" in the assessment process.

Test methods and protocol references can be found in a new compendium of ecotoxicological methods published by EPA's Corvallis Environmental Research Laboratory (CERL) *(26)* as a companion volume to the Superfund ecological assessment guidance. The CERL document outlines specific laboratory and field tests to be employed during ecological investigations of CERCLA and RCRA sites.

Looking ahead

Despite many demands on limited resources, EPA has developed the capability to assess ecological risks and impacts. Contributions to this capability have been made by programs such as the Water, Toxics, Pesticides, Superfund, and other programs, with the support of the Office of Research and Development. Now there is increasing public interest in, and concern about, ecological effects. Therefore, EPA's programs will continue to expand their efforts to identify, quantify, and reduce adverse impacts on populations, communities, and ecosystems.

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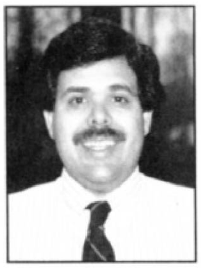

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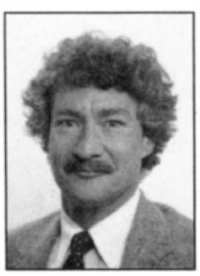

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