



ENVIRONMENTAL RESEARCH BRIEF

EPA's Ecological Risk Assessment Research Program October 1985 - March 1988

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By Congressional mandate, the U.S. Environmental Protection Agency must determine whether individual chemicals, either new or existing, can be manufactured and sold in the United States. The evaluation process for each chemical includes an ecological risk assessment.

The number of chemicals requiring review is large. In 1986, for example, the Agency's Office of Toxic Substances (OTS) had more than 60,000 existing chemicals on inventory and also processed more than 1500 new chemicals (Premanufacture Notices). The challenge for OTS is to provide realistic, consistent evaluations within short time frames when only a limited data set is provided. Often, OTS must make screening level decisions when only a chemical's structure, its proposed use pattern, and two to three bioassay results (collected under only one set of laboratory conditions) are available. It is very unusual for OTS to have site-specific information on fate, exposure, or effects for the premanufacture notice process.

EPA's Office of Pesticide Programs (OPP) also has a gigantic problem. More than 50,000 existing pesticide products must be evaluated, with new products being developed each year. Although OPP can require submission of significant amounts of fate and effects information, it still faces the challenge of extrapolating results from one ecosystem to another and from a limited number of test species and exposure scenarios to a myriad of natural populations.


The Office of Pesticides and Toxic Substances (OPTS) recognizes ecological risk assessment as a synthesis of toxicological hazard and environmental exposure. Toxicological hazard is the intrinsic quality of a chemical to cause adverse effects, such as death (characterized by an LC_{50}) or a chronic effect (such as reproductive failure) when

exposure occurs. Environmental exposure is a function of the amount of toxic chemical available to components of ecosystems and the distribution and dynamics of organisms within these ecosystem components. An ecological risk assessment, then, involves systematically combining results from exposure and hazard assessment.

Numerous techniques have been suggested and sometimes used by OPTS for ecological risk assessment. These include fault tree analysis, safety factor evaluation, ecosystem uncertainty analysis, and predictive ecosystem modeling.

The most commonly used technique, however, is the quotient method. This methodology compares a toxicological benchmark (such as LC_{50} , EC_{50} , etc.) to an anticipated level of exposure. The closer the exposure and effects numbers approach each other, the higher the risk value. This technique is simple and straightforward. Its disadvantages are that it does not take into account dose-response relationships, that it provides no basis for predicting population or system-level responses, that it does not account for ranges in hazard and exposure estimates, and that it cannot address indirect effects of chemicals.

To improve capabilities for assessing and predicting risk to ecosystems, the Office of Research and Development (ORD) initiated a comprehensive research program in consultation with OPTS. The research, which began in October 1986, was undertaken by the Office of Environmental Processes and Effects Research's (OEPER's) Environmental Research Laboratories in Athens, GA, Corvallis, OR, Duluth, MN, and Gulf Breeze, FL. The Athens Laboratory was designated as the lead laboratory.



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OPTS and ORD established several goals for this research:

- Identify critical ecological components for assessment.
- Develop techniques for extrapolating laboratory and limited field data to other systems.
- Provide systematic procedures to permit consistent ecological evaluations among analysts.
- Provide insights into "so what" questions (e.g., "so what" if primary productivity in lakes is decreased by 25%).

OEPER's approach to this problem is primarily one of developing system-independent mathematical models and protocols for exposure and hazard assessment and of embedding them in a computer-based "Decision Support System" that provides convenient access to these models, protocols, and databases essential for completing ecological risk assessments. The models and protocols generated in this research have four characteristics in common.

1. They are based on fundamental understanding of primary ecotoxicological processes and, thus, may require specific research to achieve the prerequisite level of scientific knowledge for routine application.
2. They are formulated in "system-independent" terms so that reliable extrapolations among systems are possible; that is, the only use made of observed datasets that are in the output domain of the models is for validation studies.
3. They result in the generation of mathematical formulations and computational algorithms that will be encoded in computer programs, thus providing a formal statement of methods that is objective, reproducible, readily available, and accessible to external peer evaluation and public appraisal.
4. They are linked to specific databases assembled (in each project as appropriate) to provide the maximum feasible geographic coverage; the databases will contain virtually all the collateral (i.e., not specific to the regulatory concern under analysis) data needed to apply the models.

To achieve its goal, OEPER's Ecological Risk Assessment Research Program relies heavily on results from EPA's base chemical exposure and hazard assessment research and development efforts. The major emphasis in the current program is to integrate results from these two areas to provide the scientific basis for assessing ecological risks. The present state of the art of research in chemical exposure and hazard evaluation has not adequately covered all subject areas needed to provide tools for ecological risk assessment. Existing research results, ongoing research in the areas of chemical exposure and hazard evaluation, and complementary new research conducted in this program will provide a foundation for developing a scientifically sound ecological risk assessment capability for the Agency.

Three elements of any risk assessment (exposure analysis, hazard analysis, and the integration of the two into a risk analysis) are addressed in research involving six levels of integration of individual projects. Aside from levels A and B, each succeeding level of the project represents a higher level of integration and, therefore, may derive its mechanistic knowledge and summary descriptive models from results at lower levels. For example, projects at the level of population and ecosystems (level E) may use some of the results of research on toxicological impacts on individual organisms (research level D). The kinds of research projects, their level of integration ("A" through "F"), some correlative toxicological nomenclature, and results to date are provided below.

- (A) Decision Support Systems—computer software and databases that allow an analyst to assemble and deploy the specific array of analytical tools needed for an ecological risk assessment. These "integration" projects assemble the executive software that allows the user to interact with the models, access databases, and provide service functions for all the models eventually in the system.

(No published reports available)

- (B) Exposure Analysis—release, transport, and transformation of xenobiotic chemicals in the physical environment. This research plan does not initiate significant new research in the transport and transformation of pollutants in ecosystems, which is a well-developed field in its own right. In the Ecological Risk Assessment Research Program, we intend to adapt existing models to the needs of the dependent ecological models, and to sponsor such remedial work as may be necessary to bring all the exposure models in the project to a commensurate state of sophistication.

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- (C) Toxicokinetics—exchange of xenobiotics between individual organisms and their environment, and the transport and transformation of xenobiotic chemicals within the organism. These projects encompass the area of mechanisms and processes that translate an initial exposure into a realized tissue dose at a target organ. In human studies, it would include some aspects of both hazard identification and dose-response assessment; wildlife biologists regard the

behavioral response to initial contact with pollutants as an aspect of exposure assessment.

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significantly improved basis for modeling, prediction, and understanding.

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