Technical Issue Paper

Environmental Risk Assessment of Chemicals

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Environmental risk assessment determines the nature and likelihood of harmful effects occurring to organisms such as humans, animals, plants, or microbes, due to their exposure to stressors. A stressor can be a chemical (such as road salt runoff to a lake), exotic species (such as a foreign plant), or a change in physical conditions (such as dredging a channel). Here, we focus on risk assessment of chemicals. The chemicals can be something that is found in nature, such as copper, or something created by humans, such as pharmaceuticals. Depending on whether humans or other organisms or ecosystems are exposed, a risk assessment is called either a "human health" or an "ecological" risk assessment. Here, the term "environmental risk assessment" is used to include both.

Human health risk assessment of chemicals is used to evaluate the health effects chemicals may have on individuals and populations. For example, it predicts the probability of an increase in cancer incidence in a population from exposure to a chemical known or suspected to cause cancer. It is also used to evaluate the likelihood and severity of other non-cancer adverse effects after exposure to chemicals.

Ecological risk assessment of chemicals evaluates the likelihood and magnitude of adverse effects from exposure to a chemical for organisms, such as animals, plants, or microbes, in the environment, which could be water, soil, or air. Effects can be assessed at different levels of biological organization, which is to say in single cells, individuals, populations, ecosystems, or landscapes.

Applications of Environmental Risk Assessment of Chemicals

Environmental risk assessments of chemicals can be used at many scales. They can take place at the small-scale site level (such as a release at a manufacturing plant), at the field-scale level (for example, spraying plant protection products or pesticides on crops), or at a regional level (such as a river catchment or bay). Policy makers, including government agencies, and industries use risk assessments to support environmental management decisions. Risk assessments can help the public make informed decisions, for example, whether to eat certain foods or to decide which household products are safest to use.

A retrospective environmental risk assessment is used to estimate adverse effects from exposure after it has occurred (for example, after chemicals have been released into the air).

A prospective environmental risk assessment is used to predict adverse effects based on estimated

exposure (for example, this would be used to regulate chemicals such as cleaning products before they are permitted for use or for release into the environment through a discharge permit, such as for air emissions or wastewater release). By definition, environmental risk assessment of chemicals is the process of predicting the chance of adverse effects. Additionally, the same process can be used, essentially in reverse, to predict exposure levels associated with limited harm based on toxicity thresholds and expected exposure.

Risk assessment is a valuable tool that can be used to:

- Estimate amounts of chemicals in environmental resources (such as water, soil, and air) that are associated with minimal harm, when used for various purposes (such as drinking, swimming, fishing, and agricultural production);
- Guide environmental management decisions, such as how to best develop an old factory site into a park or residential apartment building.

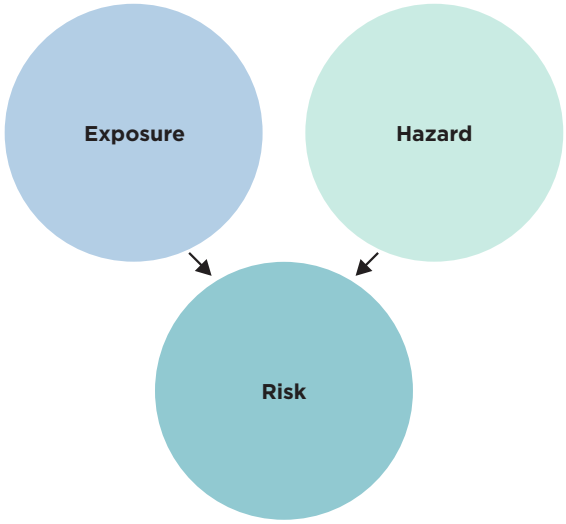
Specific examples of risk assessments include:

- Determining how much pesticide can be applied in an orchard while limiting harm to bees, birds, or other pollinators;
- Recommending or rejecting a new industrial chemical by calculating its potential to contaminate groundwater;
- Evaluating if a chemical found in an environment (example water) could cause adverse effects to an organism in the same environment (example fish);
- Evaluating the benefits of remediation and restoration options at polluted areas.

Environmental Risk Assessment of Chemicals – General Approach

A chemical's capacity to cause adverse effects depends on both chemical exposure and hazard potential. Chemical exposure refers to how much and how often the receptor, such as a plant, an animal, or a human, comes into contact with the chemical. Chemical hazard potential is the inherent (intrinsic) capacity of a chemical to cause harm. A chemical's hazard potential could be based on its environmental fate properties as well as its toxicity.

Hazard is the potential of a stressor to cause harm whereas risk is a function of the likelihood of exposure occurring and the harm caused by that exposure if it occurs.



Chemical environment fate properties, important to chemical hazard and exposure potential, include issues such as how long it takes for the chemical to break down in the environment (its persistence) and whether it is broken down or builds up when consumed (its potential for accumulating in the organisms or to bioaccumulate) or how likely it is to dissolve in water (its solubility), which can affect toxicity and exposure. A chemical's environment fate properties are described by various measures, such as rates of solubility in fat and water, volatility, degradation, and bioaccumulation. Chemical toxicity is best described as the relationship between the amount (dose) of a chemical and the harm that amount causes (described by a dose–response relationship). Hazard assessment and exposure assessment can provide important insights and can have independent utility, but both must be considered together when estimating risk.

For example, scientists use laboratory tests to determine how much of a chemical a fish can be exposed to before the chemical causes harmful effects, such as a decline in the number of its offspring, as a measure of the chemical's toxicity to fish. On the other hand, the actual amount of a chemical in the water where a fish lives, is a measure of that fish's exposure. Risk refers to the probability of harm occurring and the amount of harm. It could be described as the "probable proportional reduction of the number of offspring" in this example.

Environmental Risk Assessment – Components

Environmental risk assessments are generally made up of a few components, sometimes referred to by different terms.

Problem Formulation

Identifies the scope and objectives of a risk assessment. Lays out the plan and technical approach for conducting the risk assessment. Answers the questions of Who? What? Where? Why? What for? and How?

Exposure Assessment

Evaluates the potential exposure scenarios, and the intensity of exposure (how much and how frequently). When evaluating chemicals, exposure pathways (such as drinking) and routes of exposure (such as oral, dermal, or inhalation) are determined.

Hazard Assessment

Examines if and how a stressor could cause adverse effects and under what circumstances, and it identifies the type and strength of those effects.

Risk Characterization

Combines exposure and hazard information. Results can be presented as a binary yes-or-no response or a probability. They can also be presented as one value (deterministic) or a range of values (probabilistic).

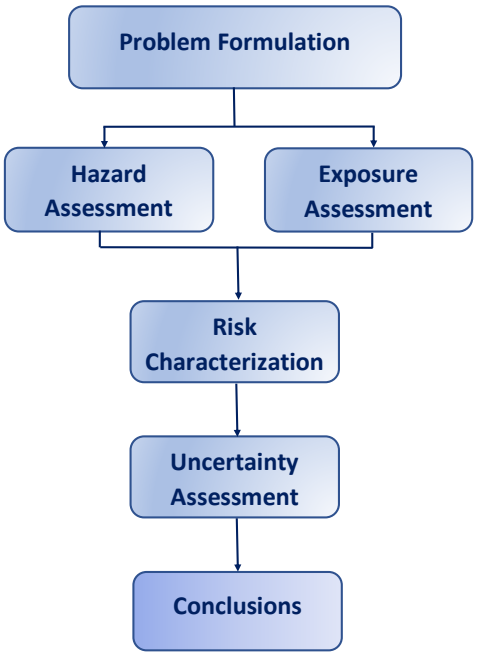
Uncertainty Assessment

Describes sources of uncertainty (such as extrapolating from a laboratory rat to a human and lack of data used in making exposure assumptions).

Conclusions

Integrates the results of the risk characterization and uncertainty assessment, often based on the various outcomes in a systematic weight-of-evidence approach. "Weight-of-Evidence in Chemical Risk Assessment" [1] refers to the process of assembling, weighing, and evaluating evidence, in a risk assessment, to come to a scientifically defensible conclusion. An example would be using chemical concentrations in sediment, water, and plants at a contaminated pond to assess risk to a duck through its diet as one line of evidence and using measured survival of ducklings at the pond as another line of evidence.

This diagram displays how the different components of an environmental risk assessment relate to one another.



Environmental Risk Assessment - The Process

The environmental risk assessment process is designed to be a "tiered" process. The lowest tier, Tier I, requires the least amount of data and can quickly give conservative answers that are health protective. A Tier I risk assessment is often referred to as a screening-level risk assessment and is based on very simple and, therefore, conservative assumptions that may overestimate risk. Therefore, a Tier 1 risk assessment by design will have the highest safety factor.

Often, in a Tier I risk assessment of chemicals, levels of concentrations of chemicals are compared to "screening levels." Screening levels are concentrations that are not expected to be associated with harmful effects. Measured concentrations less than screening levels indicate that adverse effects are not expected, while concentrations greater than screening level indicate the need for more analysis since screening levels are inherently designed to be over-protective. If adverse effects cannot be excluded in a Tier I risk assessment, more data are acquired and more sophisticated models are used to refine the risk estimate as the risk assessment progresses through the subsequent tiers.

[1] View the SETAC Technical Issue Paper: Weight of Evidence in Environmental Risk Assessment at https://www.setac.org/page/TIPS.

Environmental Risk Assessment – Key Players

Risk assessor

An individual or a team with the training and expertise to conduct a risk assessment.

Risk manager

An individual, a team, or an organization with responsibility for or authority to take action in response to an identified risk.

Stakeholder

Any individual, team, or organization interested in, responsible for, or affected by the outcome of a risk assessment.

Environmental scientists

Scientists that generate data used in a risk assessment – specialists in variety of fields, including geology, hydrogeology, chemistry, toxicology, and engineering.

How Do Environmental Risk Assessments of Chemicals Relate to Environmental Management?

Environmental risk assessments of chemicals are typically conducted to assess the effects of environmental exposures to chemicals on receptors and provide input to environmental management decisions. Other considerations may include the availability of technical solutions, benefits, equity, costs, legal mandates, and political issues.

For example, a course of action that has the least ecological risk may be too expensive or not technologically feasible. So, while a risk assessment provides critical information to risk managers, it is only part of the whole environmental decision-making process.

Example 1 – An Environmental Risk Assessment After a Release

An accident results in the release of a large quantity of a chemical into a river upstream of a city. There are reports of affected shellfish in the vicinity of the release site. Officials immediately start implementing emergency response actions. The city stops using the river water as drinking water and prohibits swimming in and fishing at the river while they evaluate the release. At the same time, scientist are called to delineate the level of impact and need for cleanup. They collect shoreline soil, sediment, and river water samples. They also collect vegetation and fish tissue samples. The samples are analyzed for the chemicals in the released material. After several weeks, most of the released substance is removed from the river. After the clean-up, samples are collected to conduct a retrospective environmental risk assessment, and the results are used to assess the effects of any remaining chemicals on humans and the river's ecosystem and to evaluate if further remediation is necessary.

The human health risk assessment evaluates the effects of the residual substance on hypothetical children and adults who may get exposed under several exposure scenarios, specifically use of the river water as drinking water, recreational use of the river (wading and swimming), and consumption of fish. The toxicity (dose–response relationship) of the substance to humans is identified from refined values developed by regulatory agencies. In this example, the scientists find that the substance does not cause cancer but affects the nervous system at high exposure levels. The exposure level that is not associated with any expected adverse effects (the reference dose) is well understood and was developed from laboratory studies. The potential intake dose of the substance is calculated using measured concentrations in water and fish and default exposure assumptions (such as body weight and drinking water intake rates). The exposure assumptions used in this case are specifically selected to represent "reasonable maximum exposure." Finally, the risk to the public is estimated by comparing the potential (exposure) dose to the reference (toxicity-based) dose. If the potential dose is less than the reference dose under all exposure scenarios, the risk is found to be acceptable, and consequently, the city once again begins using the river water for potable water and allows use of the river for recreational purposes.

The ecological risk assessment evaluates the effects of the residual substance to aquatic plants and organisms in the river, such as fish and shellfish, as well as birds and mammals that feed on them. The toxicity of the substance to mammals and aquatic organisms is well understood; however, its toxicity to plants and birds is not well known. The potential of adverse effects to

ecological receptors is estimated – using measured concentrations in water, sediment, soil, and fish – with the understanding that there is more uncertainty in the estimates for plants and birds. Results indicate that while there were some reported adverse effects to some ecological receptors immediately after the spill (shellfish die off), adverse effects to ecological receptor populations in the area from any of the chemical left after the clean-up are not expected, confirming that the clean-up was effective. However, since there were some adverse effects in the immediate vicinity of the release to the shellfish community, shellfish species from an un-impacted location upstream were introduced in the impacted area after clean-up to help restore the community.

Example 2 – An Environmental Risk Assessment for a New Product

A company has developed a new formulation for a pesticide and needs to conduct a prospective assessment of its risk to determine effects to humans and the environment as part of the product research and development process. The product's hazard potential has been thoroughly investigated. The physical characteristics of the product are well understood; it degrades rapidly in the environment and has low potential to accumulate in the food web. The toxicity of the product is also very well understood due to extensive laboratory toxicity studies done on soil dwelling organisms (represented by earthworms), plants (represented by alfalfa), mammals (represented by mice), fish (represented by fathead minnows), and omnivorous birds (represented by quail). Concentrations in soil, runoff water, and air after application at a hypothetical agricultural farm are estimated based on the recommended application rates and the physical parameters of the product. Concentrations in shallow groundwater at the hypothetical farm and in a stream near the farm are then modeled. The potential exposure to hypothetical receptors under various exposure scenarios is calculated using estimated concentrations in environmental media and default exposure assumptions (such as body weights and ingestion rates). The product's hazard potential is combined with the expected dose for each receptor exposure scenario to assess risk. Results indicate that adverse effects to almost all receptors are not expected, except for adverse effects on shellfish in the hypothetical stream near a hypothetical farm cannot be ruled out based on the information available. Therefore, the company decides to conduct a battery of toxicity tests on a variety of aquatic species, including several types of shellfish, to obtain more refined risk estimates before making a decision about the future of the product.

Resources

European Chemical Agency. Committee for Risk Assessment.

European Food Safety Authority. Science Work.

International Organization for Standardization (ISO). 2009. ISO 31000:2009. Risk Management.

United States Environmental Protection Agency. Risk Assessment Guidelines.

Government of Canada. Health Canada. Environmental and Workplace Health.

Please contact setac@setac.org for guidance on relevant SETAC publications and experts in the subject.

Acknowledgments

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