

Environmental Risk Assessment

Background

Environmental risk assessment (EnvRA) is a process that evaluates the possibility that adverse effects may occur as result of exposure of terrestrial and aquatic wildlife, plants, and other organisms to an agent. In general, these agents may be chemical, physical, or biological, and are present in the environment as a result of human activity. Crop protection products are among the agents which could be present in the environment as a result of their government-approved, intended use.

“The risk assessment process is a critical component of pesticide product development and regulatory review. The principles of risk assessment applied to pesticides are fundamentally the same as those applied to bridge and highway design, pharmaceuticals, and innumerable consumer products. The process is directed toward establishing an objective basis on which to assess risk potential relative to the likelihood of injury” (Purdue University, 2005; www.btny.purdue/ppp).

The manufacture, distribution, and use of crop protection products are regulated in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which is administered by the U.S. Environmental Protection Agency (EPA). Manufacturers are required to register these products with EPA by providing scientific studies demonstrating that the use of the product would not cause “unreasonable adverse effects on human health or the environment”.

Extensive scientific studies are conducted to determine the chemical properties of the product, how it changes or behaves in the environment, and its toxicity or unintended impact on plants and animals that are not the original target of the product. Toxicity tests and scientific measurements are conducted in compliance with exacting standards, approved procedures, and strict requirements mandated by EPA.

Results from these studies are incorporated into the EnvRA process to determine potential concentrations of the product in the environment (the level of exposure) and possibility that plants or animals will be adversely affected. For example, the possibility of a reduction in salmon population resulting from exposure to chemicals in surface water is one exposure pathway that could be evaluated in the risk assessment. The EnvRA is conducted in accordance with methodology and guidance established by EPA (www.epa.gov/pesticides/ecosystem/ecorisk.htm).

The EnvRA process can be more complex than the human health risk assessment process because it encompasses more species, such as fish, aquatic invertebrates, aquatic and terrestrial plants, non-target insects, birds, wild mammals, reptiles, and amphibians. Scientists trained in diverse fields including toxicology, wildlife ecology, physiology, and environmental chemistry prepare and review EnvRAs. The EPA may choose to protect ecological organisms at the population, community, ecosystem levels, or at the individual level in some cases of endangered species.

Position

- CropLife America supports the concept and practice of risk assessment as a tool in the registration of products with EPA, which is both protective of crops, and protective of human health and the environment.
- CropLife America supports the efforts of EPA to develop comprehensive, standardized methodology for conducting EnvRAs based upon realistic exposure scenarios, common sense, and sound science.
- “Pesticides provide significant benefits to the American public by controlling pests that invade agricultural crops, industrial sites, homes, schools, restaurants, and hospitals. Public health is enhanced when pesticides are used to combat mosquitoes, ticks, and rodents that carry disease; head lice; fleas; and allergy-producing cockroaches. Antimicrobial products disinfect drinking water supplies and reduce hazards from organisms that cause human diseases such as cholera. The motoring public and transportation industries benefit when herbicides eliminate plants that obscure roadway signs and encroach on rights-of-way. Pesticides are instrumental in protecting native habitats and indigenous flora from non-native plant species. Other pesticides protect and preserve homes, museums, and historic buildings from wood-destroying insects such as termites and carpenter ants” (Purdue University, 2005; www.btny.purdue/ppp).
- CropLife America believes that regulatory decisions should be based upon the balance of risk versus benefit in accordance with FIFRA, and risk assessment is critical to that determination.
- CropLife America recognizes that a “zero” risk level is impossible to achieve, and a level of acceptable risk is necessary in order to offset competing risks and attain societal benefits. For example, accepting some minimal level of risk of an adverse effect to ecological organisms may be necessary when spraying insecticides to reduce mosquito populations and thus reduce the risk to human health of contracting diseases that these insects carry such as malaria or West Nile Virus.
- CropLife America believes that procedures, assumptions, and uncertainties incorporated into the EnvRA procedure should be documented, transparent, based upon the most recent peer-reviewed and vetted scientific data, and capable of undergoing scrutiny such that different risk assessors supplied with the same information would estimate similar levels of risk.
- CropLife America supports the development of scientific data utilizing Good Laboratory Practices and sound data quality.