# IMPORTANCE OF RISK ASSESSMENT IN THE REGULATORY DECISION-MAKING PROCESS

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Risk assessment (RA) is a process of assigning magnitudes, probabilities, and relevance to the adverse effects that may result from a particular activity or set of activities. RA in the regulatory decision-making process for agrochemicals is critical to making the correct decision. The correct decision avoids errors that, on the one hand, may allow the use of products that cause adverse effects on humans and/or the environment or, on the other, reduce the availability of inexpensive and high-quality food and fiber that is produced with maximum efficiency and minimal environmental impacts. In the area of agrochemicals, the process of RA for the protection of humans and the environment is similar but human health RA is intended for the protection of individual humans with a high level of certainty while ecological RA (ERA) is mostly intended for the protection of populations and communities and their function in the environment.

There are two general objectives for RA of agrochemicals. The use of agrochemicals to control pests always occurs after some form of RA has taken place in relation to the particular pest problem. For example, the cost of the agrochemical may be a considered in relation to the benefit resulting from the control of the pest. Thus, an agriculturalist practicing integrated pest management (IPM) may consider the cost of the pesticide or alternatives used to control an infestation of insects in a fruit crop against the benefit resulting from increased value of the crop to the ultimate consumer, be this in improved quality, better storage properties, or greater value. These types of RAs have been used for thousands of years in the agricultural decision making. They are relatively easy to conduct as the risks (loss of the crop, etc.) are measured in financial units and the cost of the control measures are measured in the same units. Thus simple arithmetic can be used to determine if the risk of use (cost) is worth the benefit (profit). This type of RA and the risks and benefits are internalized in the process of agricultural production and are not highly regulated or formalized.

The other level of RA addresses the effects of agrochemicals outside the production system. Here the focus in on humans and environmental organisms within and outside the production unit and the process is more difficult and complex than the in-crop assessments. The basic concepts of the process of RA are well described [1,2] but it is important to recognize that, although all RA methods are essentially similar, they may be used for prospective and retrospective purposes. Thus, RA may be used to set environmental guidelines and criteria for protecting humans and the ecosystem while, in others, it is used to characterize risks in situations where exposures are known and their significance is being quantified (Figure 1). In the first use, the objective is to determine a single "protective" criterion while, in the second, the task is to determine which of one or more measured or estimated exposures to a potentially hazardous substance have caused unacceptable risks.

RAs for agrochemicals are normally conducted in a series of steps or tiers [2-4]. The use of tiered approaches in risk assessment has several advantages. The initial use of conservative criteria allows substances that truly do not present a risk to be eliminated from the RA, thus allowing the focus of expertise to be shifted to more problematic substances. As one progresses through the tiers, the estimates of exposure and effects become more realistic as uncertainty is reduced through the acquisition of more data. Tiers are normally designed such that the lower tiers in the RA are more conservative (less likely to pass a hazardous chemical) while the higher tiers are more realistic, with

assumptions more closely approaching reality. Because lower tiers are designed to be protective, failing to meet the criteria for these tiers is not necessarily an indication of problem but that more data or a more realistic RA may be needed.

The lowest tier of RA for agrochemicals is usually a simple classification or scoring system used to categorize agrochemicals for the purposes of commerce and transportation. The second tier is normally based on the use of hazard quotients. These are simple ratios or quotients of single exposure and effects values and may be used to express hazard or relative safety. The calculation of hazard quotients is deterministic because it makes use of single values for effect data and exposure data. Normally, the toxicity value for the most sensitive organism or group of organisms is compared to the greatest exposure (measured or estimated). This may be made more conservative by division of the quotient by an uncertainty factor (UF) which may range from 1 to 10,000, depending on a number of factors. The quotient approach is most widely used for characterizing risks of agrochemicals to humans. Higher tiers of RA make use of probabilistic techniques to address variance and uncertainty in both the exposure and the toxicity data, thus explicitly addressing uncertainty in the data rather than using simple uncertainty factors. Probabilistic techniques are more commonly used in ERA but have been applied to the characterizing of exposures for RA for the protection of humans.

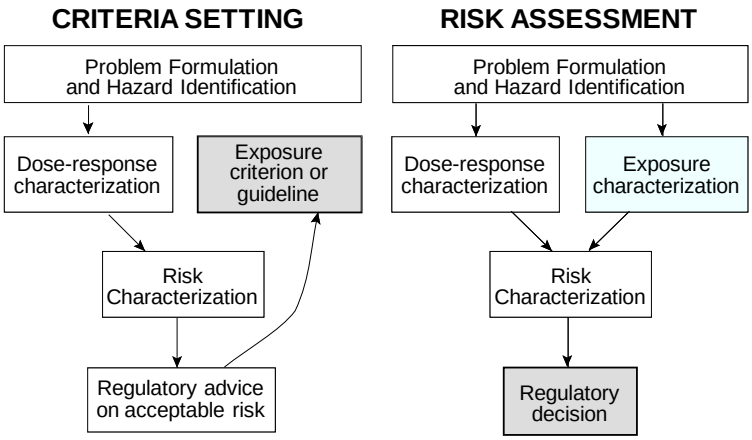


***Figure. The generic framework for developing environmental criteria and for ecological risk assessment.***

All RA requires some type of extrapolation. The most common extrapolation in the process of RA is from laboratory data to the field. Recent studies using microcosms to study the effects of agrochemicals in the field have shown that it is possible to use species sensitivity distributions to develop guidelines that are protective of complex communities in the field. Another important area of extrapolation is from organisms in one location (climatic zone) to another. Most of the testing for pesticides is conducted in temperate zones with organisms typical of that zone. While this is not of significance for human health RA, this is an important question for tropical regions where pesticides may be more widely used and where few data on local species are available. Several studies have been undertaken to address the question of extrapolation from one climatic region to another and the data suggest that, provided the same classes of organisms are considered, there are not significant differences between organisms from temperate and tropical regions in terms of sensitivity to agrochemicals and some other environmental chemicals.

This presentation will summarize recent developments in RA as well as discuss some of the important steps in the assessment process, such as problem formulation and extrapolation from small data sets.

**References**

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