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Technical Monograph n°21

Framework for Ecological Risk Assessment of Plant Protection Products

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Framework for Ecological Risk Assessment of Plant Protection Products

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EXECUTIVE SUMMARY

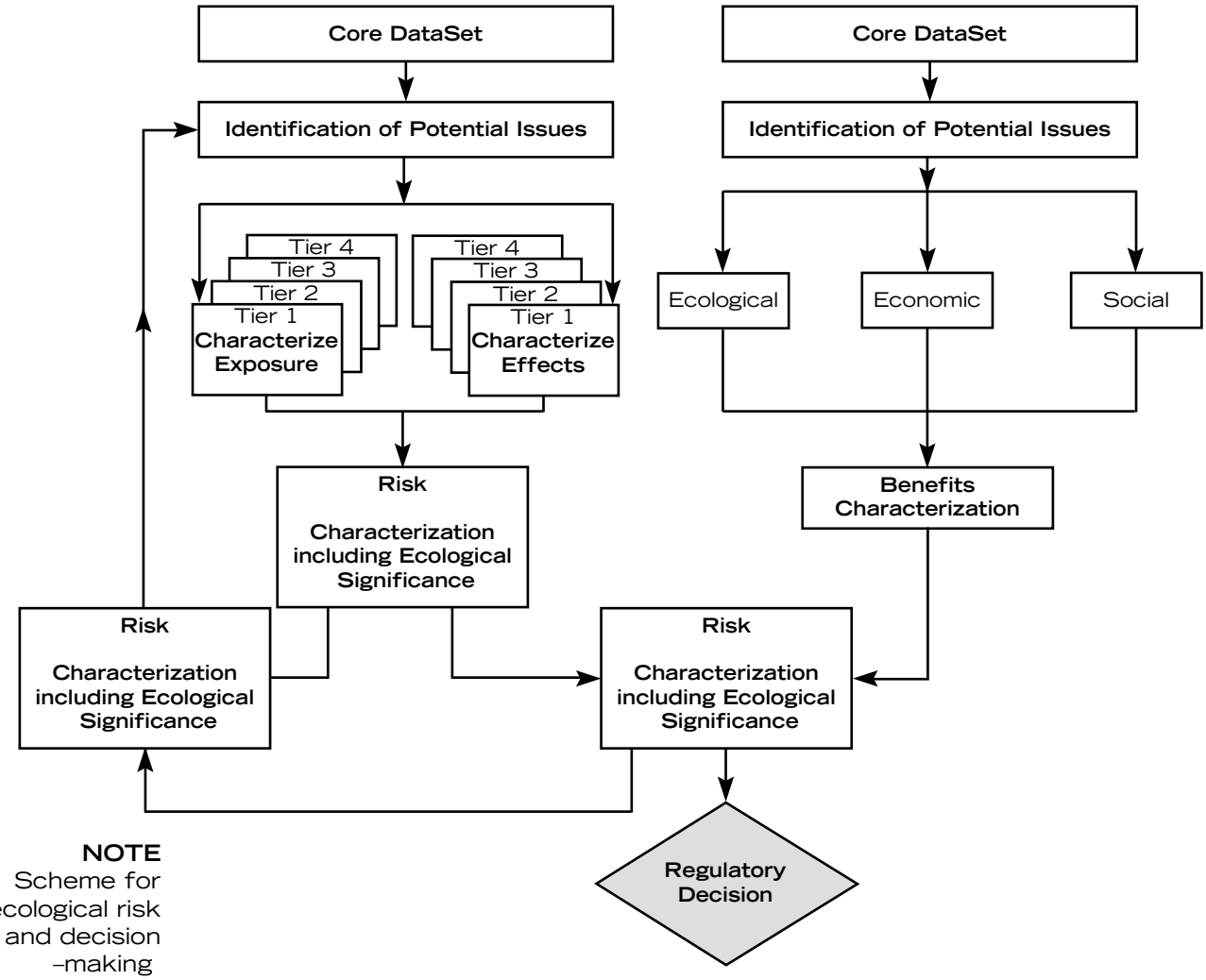
This paper was prepared by the European (ECPA) and CropLife America in response to the growing need to seek a harmonised approach to Ecological Risk Assessment (ERA). This is of particular concern in the context of the registration and use of crop/plant protection products (CPPs or PPPs) such as herbicides, insecticides and fungicides since regulatory decision-making is outpacing the development of ecological risk assessment tools that determine appropriate levels of safety.

A variety of ERA schemes have been developed recently, but all are different since they did not use identical starting points or input criteria in their development. CropLife America and ECPA recognize it is not possible, nor desirable, to have one globally harmonized ERA for PPPs, but it is of considerable value to set forth a set of guiding principles to be used as a framework for the construction of ERAs. A framework approach provides the much needed value of flexibility, allowing users to adapt risk assessment procedures to local needs and conditions without the loss of a sound, scientific approach to ERA.

The ERA framework described in this paper and shown on the next page establishes an iterative and flexible process that uses increasingly specific data to achieve more precise understanding of the nature and degree of ecological risk. Within each iteration, there is consideration of information on effects and exposure that leads to the characterisation of risk. There is an assessment of the risk's ecological significance, and, often ignored by other schemes, there also is a parallel evaluation of benefits stemming from the use of PPPs.

The framework originated from ERA schemes proposed independently by the United Nations Food and Agriculture Organization and the U.S. Environmental Protection Agency. These two schemes were combined to form a new scheme that focuses on:

- the identification of issues,
- the characterization of risks and benefits, and
- the evaluation of risk, its refinement, and its management.



NOTE
Scheme for regulatory/ecological risk assessment and decision –making

The first phase, issues identification, is the all-important first step of determining what issues are of concern so that the risk assessment is designed properly to meet the right needs. This includes a discussion within the regulatory agency and with stakeholders to determine what goals and objectives are relevant to the risk assessment and also meet the needs of the risk manager or environmental decision maker. A core dataset often specified in a formal regulatory document (such as the EU Council Directive 91/414/EEC or USEPA Federal Regulations 40 CFR part 158) can be used to highlight specific concerns and narrow the focus of the ERA objectives and subsequent risk assessment activities.

The next phase deals with the characterization of exposure and effects, the characterization of risk, and the characterization of benefits, so that all may be merged ultimately to identify what ecological risks might be possible and how those risks compare to benefits. The process is an iterative, tiered approach, beginning with an initial Tier 1 assessment that typically makes conservative estimates of exposure and effects so that it serves as a screen to narrow the focus of subsequent "risk refinements" at the higher tiers.

"Risk refinement" has been used in several ways in the context of PPP, environmental, and ecological risk assessment. In the EU the term "further evaluation" is often used in guidance documents. In this paper risk refinement refers to the following:

> A scientific investigation, interpretation, and evaluation performed to characterize in more depth the potential risks arising from an agricultural chemical use pattern once a preliminary (Tier I) risk assessment has indicated an issue may need to be addressed.

Risk refinement activities can be directed towards regulatory purposes and/or internal company product stewardship. It may involve further environmental fate or toxicity research, simulation modeling and/or monitoring studies, and may be performed at many levels of complexity. Higher tiers of refinement utilize probabilistic (e.g., Monte Carlo) modeling techniques in order to identify a "likelihood" of impact on ecological systems and thus aid decision-makers to put the impact into perspective. Highest levels of refinement can take a landscape approach, which correlates temporal and spatial distribution/co-incidence of exposure and toxicity factors to the actual agronomic practices and geographies of specific regions.

One important component of risk characterization at each tier of assessment is that of uncertainty. At Tier 1 uncertainty is higher than in other tiers because numerous conservative assumptions are made to maintain the simplicity and screening nature of the initial tier. The uncertainty arises from an incomplete knowledge of the ecological system being assessed and from the system's inherent natural variability.

Uncertainty analysis attempts to identify and quantify the uncertainty at each stage of the ERA. The analysis is usually descriptive at lower tiers; sensitivity analysis and more complex model (Monte Carlo) simulation are usually reserved for higher tiers. Uncertainty analysis increases the credibility and confidence in ERA through explicit descriptions of the magnitude and impact of the uncertainties on the ERA conclusions. It should be a part of the ERA process.

Benefits characterization is not directly a part of risk assessment, but it is an essential part of the overall risk assessment framework since it provides critical information for the management of risk. Risk management involves decisions often based on non-scientific criteria (e.g., economic, social, and political) with a goal of achieving "acceptable" risks. Therefore, it is essential that possible risks resulting from the use of a particular PPP are measured against potential benefits that accrue due to the use of the product, and that this information be considered during the risk management process.

In the final phase of ERA, all activities are brought together so that risk is evaluated from standpoints of ecological significance and risk versus benefits. It is determined what aspects of risk refinement could be undertaken to define risk in a more realistic and specific fashion, and attention is turned to the management of risk through possible modifications to PPP usage pattern and general agricultural practices for purposes of risk reduction.

A key driver in the risk evaluation process has to be the ecological significance of impact(s) identified during an ERA. To identify the significance of an impact and thus put its risk into proper perspective, the risk evaluation has to differentiate between transient effects of no ecological consequences and long-term adverse effects which may not be acceptable. In determining significance these effects need to be compared to ecological variation due to natural causes and the impact of other human activities.

All of the above needs to be considered when determining the "acceptability" of an ecological impact. "Acceptability" underpins PPP regulatory programs in many countries. The legal definition is vague, but in ecological terms several approaches have been developed, usually defining "unacceptable" rather than "acceptable". The USEPA characterizes "unacceptable" as "widespread and repeated mortality in the face of minor economic benefits to society". German regulatory authorities utilize the principle of population recoverability as criteria of acceptability for soil microbial impacts, and they have proposed that PPP effects on other organisms be compared to fluctuations occurring naturally.

1 INTRODUCTION

This paper has been prepared on behalf of GCPF by the European (ECPA) and American (ACPA) Crop Protection Associations in response to the growing need to seek a harmonised approach to Ecological Risk Assessment (ERA). This is of particular concern in the context of the registration and use of crop/plant protection products (CPPs or PPPs) such as herbicides, insecticides and fungicides where regulatory decision-making is outpacing the development of ecological risk assessment tools to determine appropriate levels of safety.

For many years the impact of a PPP in the environment was considered primarily through effects assessment, based upon the intrinsic toxicity of the product. As our knowledge of both the structure and function of ecological systems has increased, so have we developed appropriate tools to assess/predict the relative impact of PPPs taking into account relevant exposure concentrations. This accounts for the likelihood of an unacceptable event occurring and therefore brings into play the concept of ecological risk.

Several ERA schemes have been developed over the past 10 years but all exhibit differences from one another. This is primarily due to the fact that, invariably, they do not use the same starting points or input criteria at similar stages in the process. It is recognised at the outset that it is neither possible, nor desirable to have one globally harmonised ERA for plant protection products as their varied use patterns give rise to different levels and degrees of exposure, and therefore to their consequential effects. Rather, the approach to ERA developed by ACPA/ECPA and presented in this paper is in the form of a set of principles that may be used as a framework for the construction of specific risk assessments.

From a global perspective this has one important asset --- flexibility. The framework allows for the different levels of resources and data available in a particular situation because it does not prescribe what is needed as building blocks at specific points. It therefore enables the user to apply the framework in a way that meets local needs and circumstances.

This is not to say that there are not types of data/information that may typically be appropriate for different levels of an ecological risk assessment of Plant Protection Products (PPPs), where use pattern (generally based on good agricultural practice) is a pre-requisite. However, there is no reason why the principles embodied within the framework may not be applied to other chemicals and scenarios.

2 ECOLOGICAL RISK ASSESSMENT IN AGRICULTURAL SYSTEMS

The rapid development of agriculture and mechanisation of farming techniques has transformed the landscape and changed forever the ways in which food is produced. During the past 50 years improvements in cultivation methods, harvesting techniques, irrigation, crop nutrition, and seeds technology have increased both the quantity and quality of foodstuff, while at the same time reducing their cost. A major contributor to this success has been the development of effective PPPs that have controlled weeds, insect pests, and diseases.

However, it is fair to say that -outside expert circles -little attention was given to the possible environmental side effects of PPPs until the publication of Rachel Carson's "Silent Spring". Whilst this was to many a controversial publication, it completely changed the way the public viewed the benefits of PPPs in the context of food production and led to more rigorous investigations of the environmental consequences of PPP use. It could be argued, however, that, but for the use of PPPs, our understanding of ecotoxicology and the functioning of ecological systems would be diminished greatly. Considerable advances in our knowledge and capabilities to do PPP exposure assessment have been made as a consequence of the need to investigate organism, community, population, and ecosystem responses to PPPs in both terrestrial and aquatic environments. There is a tendency, however, to view the potential ecological impact of PPPs in isolation from farming practices as a whole.

Agriculture itself has altered, and will continue to alter ecological systems. With the development of modern, efficient crop production, a balance has to be maintained between productivity and the protection of indigenous flora and fauna. The days of excessive inputs of nutrients and prophylactic treatments of crops with PPPs are gone. Now we are concentrating on more precise measures to control unwanted pests, weeds, and diseases through the adoption of integrated crop management (ICM) and integrated pest management (IPM) schemes.

Unlike general chemicals, PPPs are placed into the 'environment' intentionally at known concentrations, in specific locations, and within a specific time window. We have a greater understanding of how the behaviour of a PPP may be influenced by, for example, cropping patterns, weather patterns, landscape features such as slope, proximity of water courses, hedgerows etc. This has, in turn, demanded a fresh look at the way environmental impact is determined. Now there is the requirement of a more detailed assessment of levels of effect (responses of non target organisms) and the potential for their exposure to the PPP under the defined conditions of use. This demands knowledge of, for example, the life histories of organisms at risk, their susceptibility to the stressor, exposure routes, and so forth.

Ecological risk assessment for PPPs is typically done in response to a regulatory question. One of the key challenges is to fit ecological risk assessments into a regulatory process that allows for consistency in approach. Answering the questions "does the PPP have an effect, on what, for how long, and to what degree? " always requires an element of scientific judgement because of differing opinions as to what is or is not acceptable. Utilising a stepwise approach to assessing levels of effect has been implicit in PPP regulation for many years but has generally relied on prescriptive data requirements that have not always adequately considered either the nature of any toxic response or the nature of the exposure. Moreover, it is simpler for the regulator to regulate on whether a toxicity value exceeds a certain threshold than to take into account more complex data with associated uncertainties. However, science has and is developing better tools, including modeling, that enable us to provide ways of increasing confidence in estimating ecological risk that fit well within a stepwise approach to risk assessment, particularly in relation to the use of PPPs in agricultural systems.

3 FRAMEWORK FOR ECOLOGICAL RISK ASSESSMENT: PRINCIPLES

The framework for ERA that is described in this paper establishes an iterative and flexible process whereby, through the provision of increasingly specific data a more precise understanding of the nature and degree of risk is achieved. These iterations are carried out only to the extent that there is a need to provide more information to address the issue identified at the outset.

The approach requires the consideration of information on effects and exposure that lead to characterisation of the risk and an assessment of its significance. The process of re-evaluating the risk following the addition of more information, often of higher complexity, is known as risk refinement.

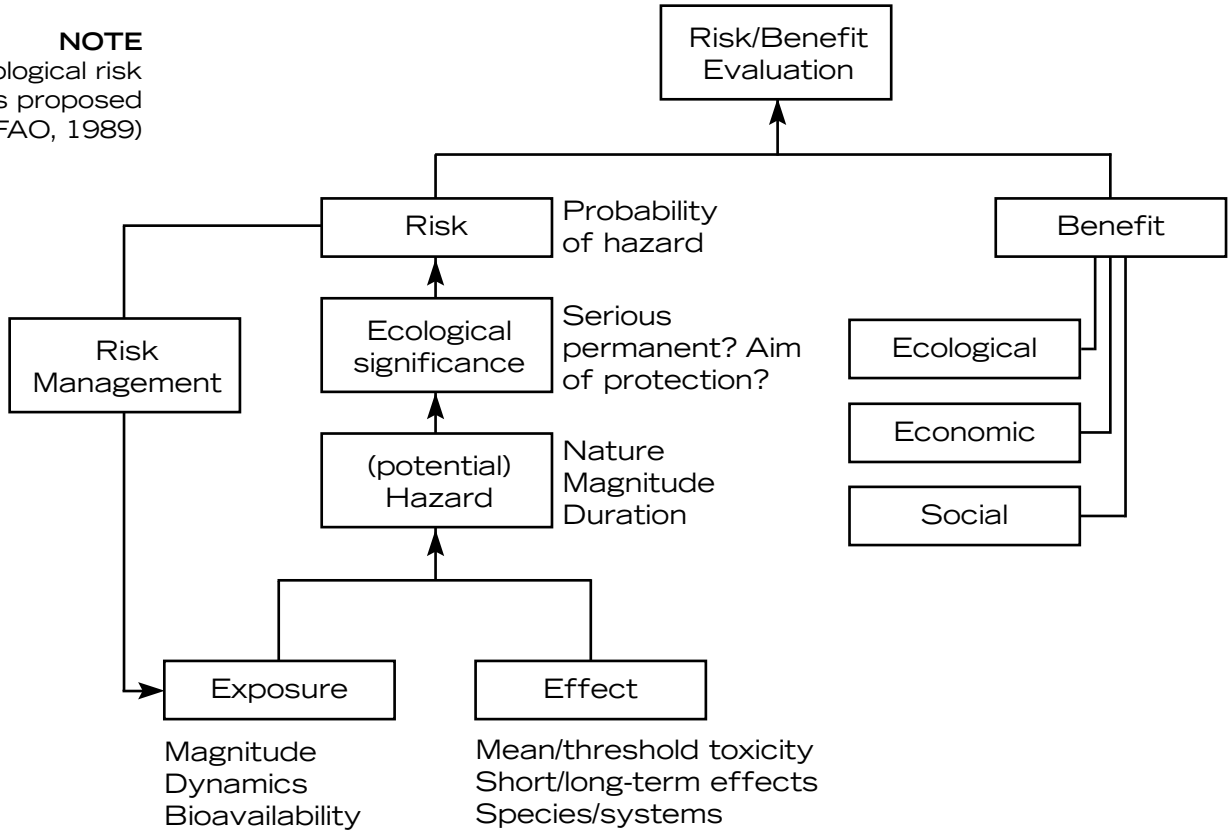
A key element in these proposals, frequently ignored in other schemes, is a proper evaluation of the benefits of the use of the plant protection product and considering these against any potential ecological risk.

3.1 FAO

In 1989 the United Nations Food and Agriculture Organization (FAO) (FAO, 1989) published guidelines on the environmental criteria for the registration of PPPs. These recognized the value of risk assessment as a tool for evaluating the risks of PPPs in the environment. This organization's recommendations on how ecological risk assessment should be carried out are reproduced in Figure 1, which illustrates certain key principles that must be present in an effective ecological risk assessment:

- Exposure assessment
- Effects assessment
- Estimation of potential hazard

- Evaluation of ecological significance
- Estimation of risk
- Iterative process for refinement of risk
- Management of risk
- Risk/benefit analysis



NOTE
Figure 1. Ecological risk assessment as proposed by FAO (FAO, 1989)

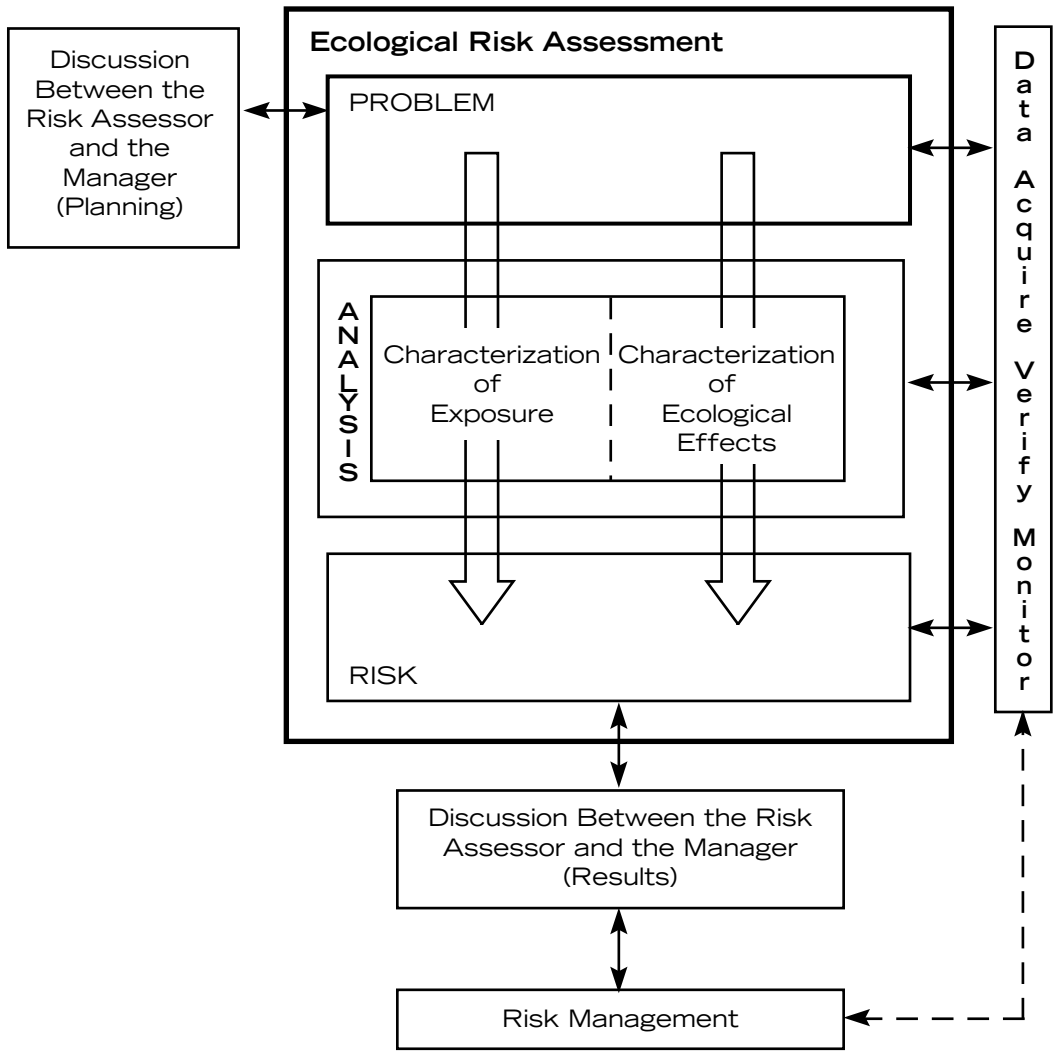
3.2 USEPA

In the United States the U.S. National Research Council for Human Health (USNRC, 1983) developed a general risk assessment framework, which was subsequently modified by the U.S. Environmental Protection Agency in 1992 (USEPA, 1992) and then adopted officially by the Agency in 1998 (USEPA, 1998) as the scheme shown in Figure 2.

The EPA framework adds to the principles espoused by FAG, the concept of three formal "phases" of ERA that must be carried out:

- **Phase 1** Problem Formulation
- **Phase 2** Exposure and Effects Analysis
- **Phase 3** Risk Characterization

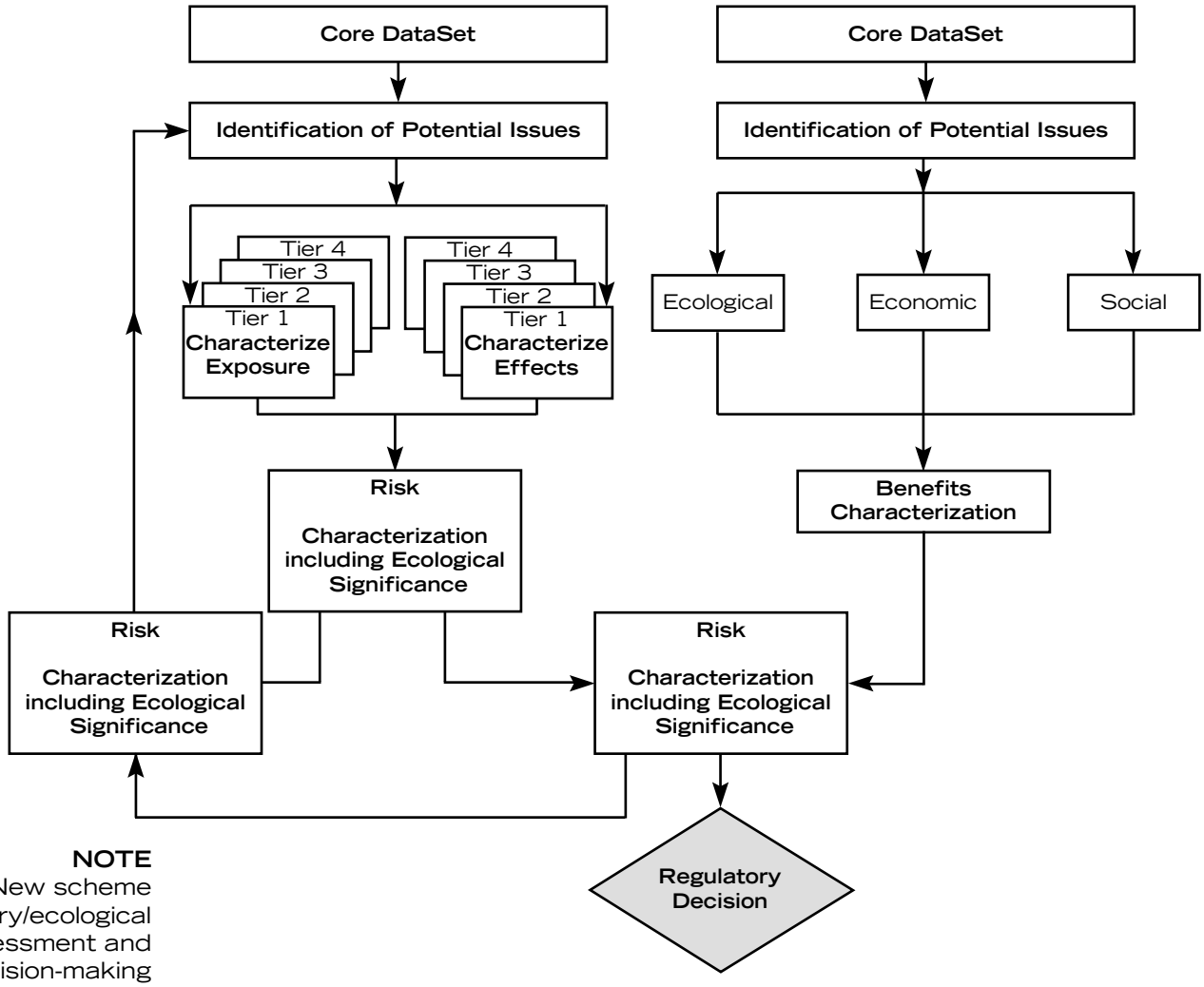
NOTE
Figure 2. EPA framework for ecological risk assessment (USEPA, 1992)



with heavy emphasis on the problem formulation phase, i.e., identification of the issues of public and ecological concern, which often get ignored in most risk assessments. The culmination of these activities is a discussion of the results between the regulators and registrants, who then decide on next courses of action through collection of additional data or mitigation of risk through risk management.

4 PROPOSED SCHEME

The FAD and USEPA schemes have been combined into Figure 3 to form a new scheme that incorporates the main ingredients of both, and serves as the basis for the proposal in this document.



NOTE
Figure 3. New scheme for regulatory/ecological risk assessment and decision-making

This new scheme embodies a new set of key principles for ERA according to the following:

- Issue Identification
  - ★ Assemble core dataset for consideration in problem identification
  - ★ Problem formulation discussion between stakeholders (i.e., regulatory authorities, industry, and when necessary independent experts)

- Risk/Benefit Characterization
  - ★ Characterization of exposure and effects
  - ★ Characterization of risk
  - ★ Characterization of benefits

- Risk evaluation, refinement, and management
  - ★ Characterization of ecological significance
  - ★ Risk Refinement through a tiered process (when necessary)
  - ★ Risk management of exposure/effects issues
  - ★ Evaluation of significance of risk via risk/benefit analysis

A key message inferred by Figure 3 is that it is essential to integrate the results of the scientific disciplines, as well as the steps in the process. At the same time, some flexibility must be maintained since flexibility is required in evaluating the risks and benefits of specific pesticide uses, and their acceptability.

The entire process of ecological risk assessment needs to be comprised of the phases of integrated steps illustrated in Figure 3, with culmination in the form of decisions. These phases are described in more detail in the subsequent sections, beginning with the first phase of an assessment, which is "Issue Identification".

5 PHASE 1: ISSUE IDENTIFICATION

This is an essential first task within sound environmental risk assessment. There are two major steps:

1 Assessment is made (where appropriate with the respective government regulatory body) of the issue(s) of concern. The broad areas to be assessed, (e.g., safety to fish, aquatic invertebrates, birds, honeybees, plants) may be highlighted through an examination of regulatory criteria such as those of the European Union (EU) Directive 91/414/EEC (EU, 1991) or the USEPA Federal Regulations 40 CFR part 158 (USEPA, 1995). The initial data set required to meet these requirements is then defined in a formal document like the EU annexes to Directive 91/414/EEC or USEPA 40 CFR.

2 The initial data set is used to carry out Tier 1 risk assessments. From this initial assessment any key issues are identified for further, more detailed evaluation.

6 PHASE 2: RISK/BENEFIT CHARACTERIZATION

When the identification of issues is completed, ERA activities enter the next phase of the process described as "Risk/Benefit Characterization". For PPPs this phase characterizes the levels of effects (i.e., toxicity) for a range of indicator organisms, and describes the possible routes and levels of exposure to which the organisms may be exposed. Other activities characterize the benefits side of PPP usage (discussed in section 6.5).

Figure 3 shows the risk characterization phase as an iterative set of exposure and toxicity refinement tiers. The tiers progress from simplistic, initial screens to complex, probabilistic upper tiers. Tier 1 of the iterative process will be discussed first, and subsequent tiers will be considered under the third phase of ERA, presented later in Section 7, because progression to higher tiers is based on decisions made after tier 1.

6.1 Characterization of Exposure

Exposure characterization is the process used to determine the concentration or dose of a compound to which an organism or ecological receptor is likely to be exposed. This receptor is typically an individual organism, although ERA strives to address exposures at the population, community, and ecosystem levels. In Tier 1 exposure characterizations, Expected Environmental Concentrations (EECs) or Predicted Environmental Concentrations (PECs) are derived for the US and EU, respectively. EECs and PEGs can range from the highly simplistic, using the total amount of a particular plant protection product applied at one time (i.e., total load; no degradation, no application interval) to modeling in which peak or maximum, average, or time weighted average (TWA), Estimated Theoretical Exposure (ETE) or Estimated Theoretical Residue (ETR) concentrations are generated. Application interval, degradation rates in the environment and other generally available parameters can be input into relatively simple models to obtain worst case exposure values. Although bioavailability can be used to modify the estimates at this tier, 100% bioavailability is often assumed, for example, in the aquatic environment.

In order to provide common ground in terms of exposure potential, certain assumptions are made so that the EEC or PEG values can be derived. These assumptions include:

- Amount of the compound present on terrestrial foodstuffs (Hoerger and Kenaga, 1972, as refined by Fletcher et al., 1994 and Pfleeger et al., 1996; Urban and Cook, 1986) and soil based on the amount applied per acre or hectare
- Percent deposition onto target areas (e.g., 100%, 60%) -- based on type of application and not due to spray drift
- Amount of spray drift onto nontarget areas (e.g., 5% or less; Ganzelmeier, 1986, 1987) -- based on type of application (e.g., ground spray)
- Percent runoff into streams and ponds (e.g., 5%, 2% or less) --based on water solubility and areas of application (e.g., sloped, furrow, etc.)

Standard exposure scenarios are under development in the US and EU (primarily region specific) to facilitate the consistent derivation of likely exposure levels. Tier 1 exposure calculations invariably overestimate the actual exposure level, resulting in a conservative estimate of the levels to which an ecological receptor is exposed.

6.2 Characterization of Effects

The characterization of effects identifies and quantifies potential adverse effects of compounds on ecological receptors through laboratory testing or field observation (van Leeuwen and Hermens, 1995). In a Tier 1 ERA, the effects are typically obtained from laboratory studies (see Table 1) ranging from 2 to 3 days (algae, daphnid, fish) to several months (fish early life stage or avian reproduction). The ecotoxicological data used to derive the effects characterization can be the LD_{50}, LC_{50} or EC_{50} from an acute study; an EC_{50} from an algal study; or the NOEC (or LOEC) from a subchronic or chronic study.

These values describe the concentration to which an organism could be exposed without the expression of potential harmful effects. Often these concentrations are used as the basis for labeling the toxicity (sometimes referred to as hazard) of agricultural chemicals, but they are wrongly assumed to represent a measure of the risk of a compound. This situation is incorrect because the toxicity addresses only the effects side of the ERA equation. In order to have a risk, exposure to a substance must occur.

NOTE
Table 1. Examples of regulatory indicator species and test endpoints

Organism	Study Length	Endpoint
Aquatic:		
Algae	72-96h	EC_{50}, NOEC -growth, biomass
Lemna	7-14d	IC_{50} -frond number
Cladoceran	48h	EC_{50} -mortality, immobility
	21d	NOEC -growth, reproduction
Mysid shrimp	96h	EC_{50} -mortality, immobility
	28d	NOEC -growth, reproduction
Bivalve	96h	EC_{50} -shell growth
Chironomid	10-30d	EC_{50}, NOEC - development, emergence
Fish	96h	LC_{50}
	35-95d	NOEC - hatch, growth
	200+d	NOEC -growth, reproduction
Terrestrial:		
Soil microflora	28d %	Reduction -respiration & nitrification
Earthworm	14d	LC_{50}
Plants	14d	EC_{25}, EC_{50}, NOEC - emergence, vigor
Avian	14d	LD_{50}
	8d	LC_{50}
	chronic	NOEC - growth, reproduction
Mammal	14d	LD_{50}
	chronic	NOEC - reproduction

The representative levels of ecotoxicity, shown in Table 1, can be manipulated using uncertainty factors of 5 to 100 (consistent with the EU approach to regulating agricultural chemicals), deriving concentrations deemed to be "safe" for chronic exposure to terrestrial and aquatic communities. In the U.S. scheme under FIFRA, the LC or EC_{50} is divided by 5 or 10 for nonendangered terrestrial and aquatic species, respectively. Endangered species, which are regulated under the U.S. Endangered Species Act are protected by an uncertainty factor of 10 and 20 for terrestrial and aquatic matrices, respectively. However, the NOEC for subchronic and chronic effects is used directly without modification by any uncertainty factor.

Consistent with the U.S. approach to chronic effects assessment, the EU regulatory scheme for PPPs uses these values directly. However, the uncertainty factors are built into the Toxicity/Exposure Ratios (TER) which the risk comparison must exceed in order to function as a flag for further investigation (e.g., progression to higher tiers; discussed in more detail in Section 7 dealing with risk evaluation, refinement, and management).

6.3 Characterization of Risk

The characterization of risk at a first level of assessment (Tier 1) is typically highly conservative, both from an exposure and effects characterization perspective. Tier 1 generally results in the comparison of one exposure level to one ecotoxicity benchmark or effect level. This comparison results in a quotient, a Risk Quotient (RQ) in the United States under FIFRA (Urban and Cook, 1986) and a Toxicity/Exposure Ratio (TER) in the European Union (Council Directive 91/414/EEC, 1991). This quotient is then compared to acceptable levels designated by the particular jurisdiction. In the initial screen, acceptable risk quotients (ratio of effects to exposure) are set at a very conservative level i.e., at a level where there is a very low probability of a PPP causing harm to that group of organisms. If the conservative value for the RQ is exceeded (or TER is not exceeded) then a more detailed risk assessment might be required.

6.4 Characterization of Uncertainty

Uncertainty is a component of risk inherent at each stage of the ERA. In Tier 1 ERAs, uncertainty is likely to be higher than in other tiers because of the numerous assumptions required to complete the assessment and the issue of conservative input values. Uncertainty arises from an incomplete knowledge of the system being assessed (van Leeuwen and Hermens 1995), inherent variability, and is associated with the following aspects (Rowe 1994; UNEP 1996):

- measurement error
- accuracy, how close the measurement is to the true value
- inherent variability
- model error, both conceptual and mathematical
- assumption error, lack of understanding around data gaps
- lack of data

Uncertainty analysis or characterization identifies and quantifies to the extent possible or necessary for the tier and use of the ERA the uncertainty in each phase of the ERA (UNEP 1996). The analysis is usually descriptive in this lower tiered ERA; sensitivity analysis and more complex model (such as Monte Carlo) simulation are not usually completed at Tier 1. The credibility of and confidence in the ERA is increased through explicit descriptions of the magnitude and impact of the uncertainties on the ERA conclusions (USEPA, 1996).

6.5 Characterization of Benefits

Although not directly a part of the process of risk assessment, risk/benefit evaluation is an essential part of the overall risk assessment framework that provides critical information for the management of risk (Suter, 1993; SETAC, 1994; Solomon, 1996). Risk management involves decisions that are often based on non-scientific criteria (e.g., economic, social, and political) with a goal of achieving "acceptable" risks. Therefore, it is essential that the risks that may result from the use of a particular plant protection product (and the risks of alternative activities that would result if the product were not used) be measured against the potential benefits that accrue due to the use of the product, and that this information be considered during the risk management process.

It is clear that the most important demographic trend that currently impacts the risk vs. benefit decision is the rapid increase in world population and the resulting challenges that this trend creates in terms of food production. It is estimated that the world population will reach 6.5 billion by the year 2000 and could reach 10-12 billion by the year 2100 (Stetter, 1993). The need to feed the future world population with current crop yields would require a drastic, unacceptable, increase in agricultural land usage that would have devastating effects on ecosystems worldwide. Exacerbating this trend is the tendency for people in emerging countries to upgrade their diets (higher protein/increased meat consumption), with a concomitant decrease in efficiency inherent with animal production. Therefore, increasing agricultural productivity and safeguarding crop yields are critical for feeding the future population.

Plant protection products are, and will continue to be, one important tool for increasing agricultural productivity. As with all technologies, and human activities some degree of risk must be accepted in order to realize the benefits of increased food production and decreased habitat destruction. The risk/benefit analysis is a process by which these factors are examined, and a decision is reached regarding the risk vs. benefit balance. Any risk management decision that results from the risk/benefit analysis, must therefore be aimed at reducing risk.

Risk management decisions should not be driven by artificially determined "cut-off' exposure levels or other "bright-line" criteria that are not focused on risk reduction. When the benefits from use of a product outweigh the risks (or when the risk of alternative activities produces even higher risks), then the proposed use is justified. However, when the risks outweigh the

benefits, then the proposed use is not justified and risk mitigation options should be considered to reduce the risks. In the extreme case, where risk management measures fail to provide an adequate reduction in risk, the proposed use is not justified and, in this case, should not be allowed. It is, however, important to recognize that a risk/benefit analysis and any parallel or consequent risk management strategy is scenario-specific.

6.6 Types of Benefits

The following are examples of various types of benefits derived from the use of plant protection products:

- Economic -higher crop yields, increased quality, lower (and stable) food prices
- Economic -control of specific pernicious pests/diseases or weeds
- Ecological -less land area needed for food production due to higher yields; control of non-indigenous, noxious species for wildlife habitat preservation and increased biodiversity, reduced soil erosion via reduced tillage
- Social (Human health/nutrition) -increased supply and lower cost of fresh fruits and vegetables
- Social (Public health) -controlling insect vectors for infectious diseases (e.g., mosquito control to prevent the spread of malaria)
- Allows people to enter more rewarding professions by releasing them from the drudgery of low-paid manual weed control
- National security -ensuring the ability to produce sufficient food to feed the population (even under conditions of high pest pressure)

A detailed discussion of benefit assessments and risk/benefit analyses as related to pesticide use can be found in reference (USNRC, 1980).

7 PHASE 3: RISK EVALUATION, REFINEMENT & MANAGEMENT

In the last phase of an ERA, the risks are quantified based on a comparison of the exposure level to the effect or no-effect level, resulting in an RQ, PEC/PNEC ratio or TER. No-effect-leveis (NEL), Levels-of-Concern (LOC) or Predicted-No-Effect-Concentrations (PNEC) are similar terms which describe community responses and include safety factors translating single laboratory or field studies to environmental situations.

Although not always understood nor addressed, the exposure and effects levels must agree both temporally and spatially. Temporal agreement (e.g. comparison of an aquatic 96 hour PEC TWA to a fish 96 hour LC_{50}) can be easily dealt with using models described above. However, spatial agreement, having the appropriate ecotoxicity result for a particular exposure scenario (e.g., birds eat seeds and the LC_{50} study was completed using laboratory avian feed or the species is not typically present during the spray activity, but assumed to be present) is difficult early on in an assessment (e.g., Tier 1) because only laboratory toxicity studies are usually available at this tier and calculated exposure levels are based on laboratory data and modeling.

In the US, Tier 1 RQ values for nonendangered species must be = 0.2 or 0.1 for terrestrial and aquatic matrices, respectively. For endangered species, these levels must be = to 0.1 or 0.05, respectively. Chronic RQs and algal RQs must be = 1.0. In the EU, TERs for terrestrial acute effects must be = 10 and aquatic short-term effects = 100. Chronic and subchronic TERs = 5 and 10 for terrestrial and aquatic species, respectively, are acceptable.

If the Tier 1 ERA does not pass on any of the above risk criteria, then the ERA needs to be refined and iterated back to the initial stages of the ERA, but at the next higher tier. Occasionally, because the ERA is sensitive to a few input parameters, any or all of the sensitive parameters in the Tier 1 assessment can be refined in a higher tier (either through assumption or additional study), and the assessment can pass the required levels of risk (i.e., meet the risk management objectives detailed during the issue identification phase of the ERA). TER or RQ values from a Tier 1 assessment should not be considered safety factors or risk levels, but as parameters that determine the need for additional evaluation. Values which do not pass the risk characterization stage should not lead to the conclusion that unacceptable risk exists.

7.1 Refinement of Risk

The term "Risk Refinement" has been used in several ways in the context of plant protection product, environmental, and ecological risk assessment. In the EU the term "further evaluation" is often the practical term used in guidance documents. For the purposes of this paper, the definition of risk refinement is stated as:

> A scientific investigation, interpretation, and evaluation performed to characterize in more depth the potential risks arising from an agricultural chemical use pattern once a preliminary (Tier I) risk assessment has indicated an issue may need to be addressed.

As such, risk refinement can be directed towards regulatory purposes and/or internal company product stewardship. It may involve further environmental fate or toxicity research, simulation modeling and/or monitoring studies and may be performed at many levels of complexity.

7.1.1 Risk Refinement as a Tiered Process

The initial screen at Tier 1 may show that there is no need for further evaluation of some groups of organisms. For other groups it might be necessary to carry out a more refined risk assessment. This refined assessment might also include an evaluation of how any risks can be minimised, particularly by reducing the exposure of the organisms.

In a regulatory context, the process of risk refinement must be an integral part of the **tiered** risk assessment scheme. As described previously in this paper, the essential concept of a tiered scheme is that in the initial tier ("Tier 1 "or screening tier), very conservative assumptions about key variables are made and the potential for risks to the system of interest is made using an inherently conservative model and comparing the output with single point regulatory RQs (USEPA) or TERs (EU). If the potential for risk is acceptable, no further work is conducted; but where the issue is unclear or potentially "adverse", a risk refinement/further evaluation process is triggered whereby increasingly more realistic and/or comprehensive sets of data, assumptions and models (Tiers 2 - "n") and/or mitigation options are used to re-examine the potential risk until the predicted risk no longer generates concern. An example tiering scheme for USEPA and developed under the auspices of SETAC is shown in Figure 4 (SETAC, 1994).

An essential feature of a tiered approach to ERA is an agreed mechanism to determine when no further work is needed. For example, work on risk, refinement/further evaluation may be considered complete for a number of reasons:

- The more sophisticated exposure models used in higher tiers provide estimates of risk that show further regulatory concern is unnecessary.
- Additional field, laboratory, or monitoring studies provide new and/or additional data or "weight of evidence" that replace more conservative assumptions used in earlier tier/step evaluation or reduce uncertainty such that the predicted risk decreases to "acceptable" levels.
- The registrant initiates use pattern mitigation steps that result in reduced predicted risk.

For the process to work as a credible regulatory tool, the registrant should have the option to choose between proposing/accepting a product and/or label mitigation to reduce potential exposure **AND** conducting additional risk refinements that may include additional laboratory or field studies.

Equally, the regulators must have the option to impose limits on the risk refinement process to ensure that the timeframes of "further evaluation" remain appropriate. The extent to which risk refinement has to be carried out and the criteria that have to be met are largely driven by the nature of the product and its use pattern. However, there is a diversity of opinion about what is required, when it is required, and what it demonstrates.

NOTE
Figure 4. SETAC tiered risk assessment scheme for aquatic ecosystems (SETAC, 1994)

TIER 1 (DETERMINISTIC)

EEC ESTIMATION	RISK ASSESSMENT	DATA REQUIRED
Single-event EEC based on a high-exposure scenario (direct overspray of a pond 2 m deep or 1-10 % runoff from a 10 ha field into a 1 ha pond)	Is the EEC < the LC5 for the most sensitive species? And, where chronic toxicity data are available, is the EEC < the chronic no observed effect concentration (NOEC) for the most sensitive species?	Acute toxicity and slope data for three species of freshwater (and saltwater) aquatic animals, (as currently required) and one species of aquatic plant and (ifrequired) chronic studies on four species of aquatic organisms

If "yes", no further assessment necessary. If "no", go to Tier 2

TIER 2 (PROBABILISTIC)

EEC ESTIMATION	RISK ASSESSMENT	DATA REQUIRED
Reasonable high-exposure EECs modeled from a small number of soil/climate scenarios, each representing the upper 10th percentile of runoff yield (sediment and water) for 10-year return for each market	Identify each market the for which upper 10th percentile annual maximum EEC (for the duration of interest) for its reasonable high-exposure soil/climate scenario is < the lower 10th percentile of the distribution of the LC5 estimates from acute tests. Or, is this EEC < the lower 10th percentile distribution of the NOECs from chronic tests?	Additional acute toxicity tests on four species selected from the group of organisms (fish, algae, etc.) observed to be most sensitive in Tier 1 data. If triggered (by other criteria such as persistence), chronic studies on four species of aquatic organisms

If 'yes", no further assessment necessary. If "no", go to Tier 3 or to mitigation.

TIER 3		
EEC ESTIMATION	**RISK ASSESSMENT**	**DATA REQUIRED**
More scenarios to define geographical as well as climate-driven EECs (so problem areas within each market that fail Tier 2 can be identified) and to assess mitigation options	Identify each of the soil/climate scenarios within each market for which the upper 10th percentile annual maximum EEC (for the duration of interest) < the lower 10th percentile distribution of the NOECs from chronic tests?	No additional toxicity data required

If "yes", no further assessment necessary. If "no", go to Tier 4 or to mitigation.

TIER 4		
EEC ESTIMATION	**RISK ASSESSMENT**	**DATA REQUIRED**
Based on site-specific EECs (pulsed exposures) or landscape modeling (to assess position of treated areas in relation to surface waters or percentages of land used for a particular chemical)	As for Tier 3, or use more realistic toxicity tests	Regulator or registrant may require or furnish additional (field-derived) toxicity data that are more realistic, or special tests for pulse exposures or compounds with very short half-lives may be used to obtain a better estimate of the toxicity distribution

If "yes", no further assessment necessary. If "no'" mitigate.

7.1.2 Risk Refinement Approaches

In practice, risk refinement most often involves making an increasingly detailed assessment of anticipated exposures or conducting additional laboratory or field studies aimed at adjusting exposure related parameters. However, in principle, risk can be refined by modifying either the exposure (including bioavailability) component of the ERA or the effects component by making a more careful analysis on sensitivity, variability, and population dynamics of potentially exposed species (usually performed first).

Some of the approaches available at Tier 2 and beyond are summarized in Table 2, which provides more detail on the process shown in Figure 3; supportive text is provided later in this section. The table assumes that the risk refinement process has been triggered by a Tier 1 risk assessment following an issue identification process involving the different stakeholders that established the nature of the regulatory concern, the assessment endpoint and information needs.

Each time the risk refinement process generates a toxicity/exposure ratio of potential regulatory value, the documentation must describe the full methodology used and include a list (with justifications) of models used with their assumptions and input variables. For both the exposure and effects components of the ERA, definition of the most sensitive factors and an indication of key causes of uncertainties in the measurements are also important.

A necessary consequence of risk refinement is a revisiting of the issue identification phase of the assessment. This is because the generation of new data or the refinement of existing data may modify the issue of concern or generate a new issue.

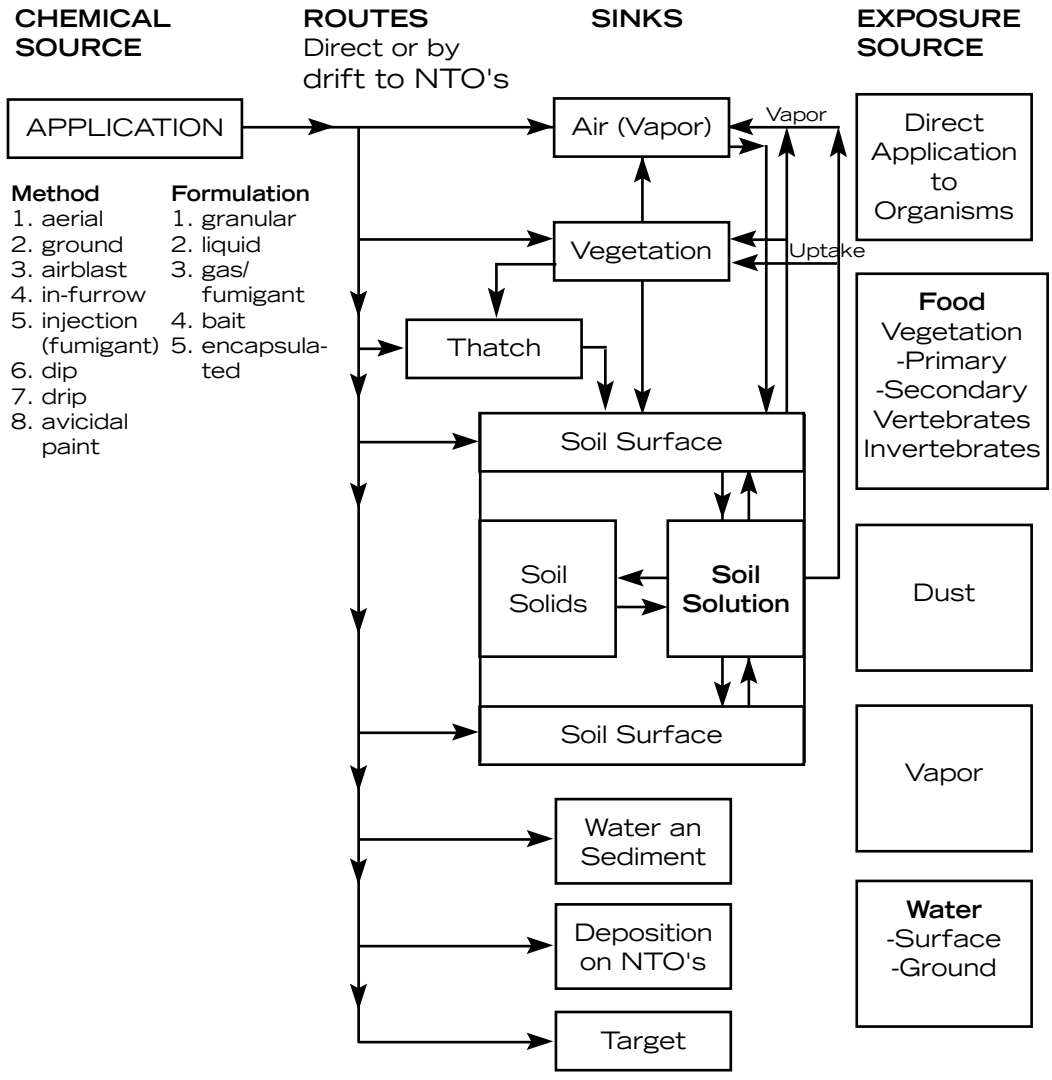
TABLE 2. Risk refinement concepts and approaches.

Concept	Approach
Characterize the transport/fate process(es) leading to exposure with this product use pattern.	Determine which of a series of standard exposure scenarios are appropriate.Use more sophisticated exposure model algorithms.Determine probability distributions of exposures.Determine frequencies, durations and timing of exposures.Analyze variability and uncertainty associated with exposure estimates.
Characterize the biological dynamics and effects on individuals, populations and ecosystems expected to result from this compound	Determine distribution of sensitivities within and between species likely to be impacted.Investigate Dose response curves.Determine likelihood that short term effects may have an impact at an ecosystem level.Analyze variability and uncertainty associated with toxicity estimates.
Perform probabilistic risk assessment to combine characterized exposure and toxicity inputs and associated uncertainties	Compare characterized probabilistic exposure with single point toxicity estimates.Compare probabilistic distributions of toxicity and exposure.Evaluate implications of uncertainty.

Concept	Approach
Iterate the procedures above as needed as shown in Figure 3, i.e., refine exposure and/or effects	Apply concepts at increasing levels of detail.Where necessary reassess to incorporate the potential impacts of mitigation steps that are likely to be acceptable to growers and regulators.If necessary move to Landscape level of risk refinement.
Investigate spatial and temporal scale of risk	Consider watershed/catchment level exposure rather than edge of field estimates.Identify spatial/temporal distribution of potentially significant environmental concentrations or susceptible species/ecosystems.
Investigate spatial and temporal co-occurrence with species/ecosystem of concern	Determine joint probability of co-occurrence of species/ecosystems of concern with exposures likely to cause effects.
Investigate potential for use of mitigative factors (Risk management)	Determine extent, probability and potential impact of factors such as vegetative buffers, actual size/depth of water bodies, drift reducing tree lines, and other factors that tend to reduce actual exposure levels.
Develop monitoring data during limited use to determine if predicted exposure estimations are conservative	This option is always available to a registrant to avoid the multiple iterations and uncertainties associated with the full risk refinement process.

7.1.3 Terrestrial vs Aquatic Risk Refinement

A major difference between aquatic and terrestrial environments is the exceptionally heterogeneous distribution of chemical stressors within a terrestrial system. Therefore, refinement of exposure in terrestrial environments must focus more attention on the pattern of chemical usage, the routes of exposure to relevant organisms including bioavailability, in addition to the organisms' habit patterns. These are all highly determinant to actual exposure levels a terrestrial organism encounters in its real-world environment.



NOTE
Figure 5. Compartmental view of a terrestrial environment showing the interdependency between a PPPs pattern of use, its initial application or release, its transfer to other terrestrial compartments, and ultimately its exposure to terrestrial organisms.

NTO= Non-target organisms

This complexity is illustrated in Figure 5, which provides a compartmentalized view of the terrestrial environment. The figure describes how the method of application and initial placement of a PPP influences the exposure to a nontarget organism through direct contact, or by transfer of chemical from one environmental compartment to another as dictated by expression of the environmental properties of the PPP over time.

As a result, a PPPs initial concentration and subsequent fate are different within each compartment, according to the pattern of use and the interaction of the product's intrinsic physico-chemical properties with the surrounding environment. The net effect is a very wide range of potential exposures for organisms that inhabit or associate with some but not all compartments. Refinement of terrestrial exposure must take these differences into account and designate which exposure routes are of toxicological relevance. It could then quantify probabilistically the levels and frequency of chemical stressor concentration encountered within a compartment of interest.

7.2 Key Tools Required for Effective Risk Refinement

In order to apply the concepts and approaches for risk refinement given earlier in Table 2, a regulatory infrastructure is required to ensure the resulting refined risk assessment meets the needs and standards of regulators and that a regulatory decision is possible based on the results. Key areas where agreement must be achieved are listed below along with some explanatory text and examples of how the approaches are already being employed.

7.2.1 Standardized Approaches to Improve Exposure Modeling

Each Risk Refinement process should be focused on the specific needs/issues for the particular combination of toxic effect and exposure route identified in tier I; this can be achieved by revisiting the issue identification step described earlier but with a focus on the more specific issues being addressed in the further evaluation.

While the concepts involved in risk refinement are straight-forward and therefore offer many possible approaches, the scope of the individual scientific approaches is guided by the product and its use pattern. It is likely that the best way to maintain a consistent but sufficiently flexible approach to permit risk refinement for the wide range of potential chemical/crop/environmental combinations will be to agree upon a series of standard exposure scenarios for higher tier exposure modeling that address key ecological settings usually based on regions/climatic zones. As referred to earlier, there are currently efforts by the FIFRA Exposure Modeling Work Group in the U.S. and the FOCUS (**FO**rum for the **C**oordination of pesticide fate models and their **US**e) Group in the EU to develop sets of standard scenarios.

Current efforts underway to improve confidence in the exposure models used for regulatory determinations (FIFRA Exposure Model Validation Task Force in USA and FOCUS in EU) have identified that variability between modelers in the selection of exposure model input parameters may be one of the most significant sources of variability in exposure estimation. Accordingly, in addition to the design of standard scenarios, parallel development of clear and strict guidance for model parameter selection along with model "shells" to minimize the number of inputs that have to be selected are important goals to improve the refinement of exposure estimates for aquatic as well as terrestrial systems. Ideally, modeling using these standard exposure scenarios should be performed by the registrant and submitted in a standardized reporting format to facilitate regulatory review.

7.2.2 Use of Probabilistic Exposure Assessment

At higher tiers, the exposure of nontarget organisms to plant protection products should not be expressed by a single value unless there is some statement of probability associated with that value. This is because exposure levels are highly variable since they depend heavily upon climate, pattern of usage, habits of the organism of interest, and interaction of chemical with the surrounding environment.

Analysis of exposure must capture this variability and express it probabilistically before there can be effective refinement of risk. Regulators need to agree on how this variation in exposure levels is to be characterized, and then on how the Subsequent probabilistic information will be used in a risk assessment process.

Probability describes the likelihood of an organism encountering a certain level of exposure, and this can be stated in a variety of ways. The SETAC aquatic example cited earlier as Figure 4 in Section 7.1.1 (SETAC, 1994) is used for purposes of the following discussion. In a tiered risk refinement process, such as SETAC's, the first tier of refinement can provide a simple statement of the probability that a specified exposure level is achieved. There is heavy dependence on definition of standard scenarios that provide discreet estimates of the frequency of occurrence of levels of exposure (return frequencies). The scenarios specify weather patterns, agronomic practices, topography, and soil characteristics; they are selected in such a way as to generally represent various geographic areas within a chemical's usage area. For example, these exposure "return frequencies" may be derived from multiple years of weather impacting on the concentration of a product in surface waters. Higher levels of refinement can involve greater numbers of scenarios to provide an understanding of variability across a product Use area.

SETAC has defined key return frequencies in regard to levels of exposure, so that levels of conservatism in an ERA can be communicated to subsequent managers of risk who have the responsibility for regulatory decision-making.

These return frequencies are defined in the following manner:

Typical Case	= 50th Percentile (1-in-2)
Reasonable Worst Case	= 90th Percentile (1-in-10)
Extreme Worst Case	= 99th Percentile (1-in-100)

Definitions such as these are a necessary part of effective ERA so that the assessment can be placed in proper perspective.

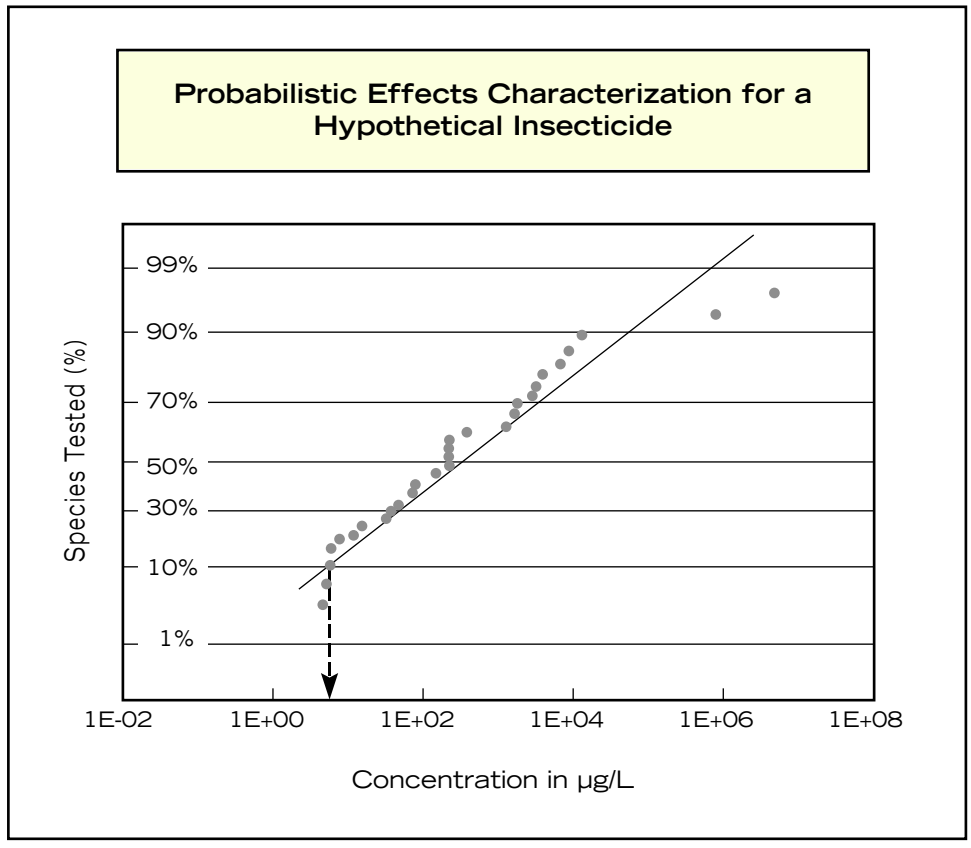
7.2.3 Use of Probabilistic Toxicity (Effects) Assessment

Recently, it has been proposed that screening assessments for aquatic species be refined by a second tier in which the overlap of a distribution of toxicity values of various test species with a distribution of PEGs is evaluated (SETAC, 1994). A major advantage of a probabilistic approach to effects characterization is that it uses all relevant single-species toxicity data, and when combined with exposure distributions, allows for quantitative estimations of risk.

In probabilistic effects characterizations, acute toxicity values (such as LC_{50}, LC_5, EC_{50}, etc.) or chronic toxicity values (such as NOECs, MATCs or LOECs) for the species that have been tested are ordered into a cumulative frequency distribution. A plot of species percent ranks versus chemical concentration typically approximates a log-normal relationship (see Figure 6). If it is assumed that this distribution is indeed log-normal with respect to concentration, and that the susceptibilities of the species that have been tested represent the universe of species that one is concerned about protecting, then it is possible to calculate from the resulting regression line the threshold toxicity value expected for an nth percentile species (e.g., 10th percentile). This could lead to an estimate of the concentration threshold which, if not exceeded in the aquatic environment, would limit adverse effects to no more than a certain percentage of species (e.g., 10%), and conversely, should not affect the remaining species (e.g., 90 %). Likewise, given a specific concentration predicted to occur (i.e., a PEG), the percentage of species expected to be adversely affected may be calculated. This information could then be used in a risk-benefit decision. This type of approach to effects characterization is especially applicable to regulatory use when the primary societal goal is to maintain overall biodiversity and ecosystem integrity, rather than to protect each individual species or population.

NOTE

Figure 6. Normalized frequency distribution of threshold toxicity values of aquatic species tested with a hypothetical insecticide plotted against log of chemical concentration. From the regression line, the threshold concentration for a species at the nth percentile on the susceptibility distribution may be calculated. The arrow indicates the 10th percentile le vel. If this was the PEC, one would predict that 90% of the species (data points to the right of the arrow) would be unaffected while 10% (those to the left) may be affected.



The are several issues with the probabilistic approach to effects characterization that need to be considered. First, the underlying assumption that the susceptibilities of species tested are representative of the universe of species in the environment may not generally hold. Doubtless, species chosen for testing are not a random sample of those in the environment. Indeed, species used in standart laboratory toxicity tests have been chosen largely on the basis of their ability to survive and reproduce under laboratory conditions and previously demonstrated sensitivity to chemical stressors (e.g., Daphnia magna). Species susceptibility distributions derived from laboratory tests may therefore tend to be skewed toward lower concentrations. If so, this would result in an overestimate of the percentage of species in the environment predicted to be affected at a given toxicant concentration.

The second issue is the tacit assumption that protection of a certain percentage of species will preserve ecosystem structure and function, and that effects on a small proportion of species are acceptable. It may be difficult to reach consensus on the choice of the protection level (e.g., 90% of species). Some may view 90% as being overprotective, while others may view that level of risk as unacceptable, especially if the 10% of potentially affected species includes species of high ecological, commercial, conservation (e.g., endangered species), or recreational significance. A final problem is that the number of data points (i.e. test results) needed for probabilistic effects characterizations may be unreasonably large, given time and resource limitations and animal welfare concerns. For example, conduct of toxicity studies with >8 species was recently recommended as a minimum data set for a probabilistic aquatic effects assessment (SET AC, 1994). While this represents only a modest increase in the number of acute studies compared to current regulatory requirements, requirement of a similar number of chronic studies may not be technically feasible (test methods have been developed for relatively few species) and would greatly increase data development costs.

Thus, one challenge in probabilistic risk assessment is to find suitable ways of representing the combination of probabilities of return of exposure levels with a probability of toxicity across or within species. The probabilistic approach to ERA proposed in SETAC (1994) is currently undergoing a rigorous review by a series of working groups sponsored by USEPA (Ecological Committee on FIFRA Risk Assessment Methodology - ECOFRAM). The ECOFRAM process is attempting to address the inclusion of probabilistic approaches within both terrestrial and aquatic risk assessments. Important issues such as the best way of expressing combinations of probabilistic distributions are under evaluation by both U.S., Canadian, and EU scientists and regulators. The outcome of this process will be a series of tools to simplify and codify the use of probabilistic approaches to risk refinement in the context of a regulatory framework. It is expected that these tools will be generally applicable to ERA as applied under various regulatory frameworks.

7.2.4 Uncertainty Factors and Regulatory Endpoints

In addition to selecting the appropriate percentiles of each distribution to consider in the Risk Assessment, accepted additional "regulatory uncertainty factors" need to be available to provide appropriate margins of safety for especially sensitive resources. These levels of acceptability may differ from one country or region to another, based on relevant risk/benefit assessments and local needs.

This is the area where individual regulatory authorities must independently evaluate the social, scientific and financial factors pertaining in their region to determine a series of trigger values to define what happens as a product proceeds through the tier system. Trigger values will determine when a risk refinement can be agreed to have reached completion. Critical here is a clearly defined and predictable approach that properly accounts for risk and benefits.

The concept of applying uncertainty factors is used frequently. Two possible approaches to risk assessment are often encountered -in one, conservative assumptions are compounded in the exposure assessment to generate extreme overestimates of exposure which nevertheless are considered to offer a large Margin of Safety for risk assessment by virtue of their acknowledged overestimation. The alternative approach is to use more reasonable, realistic scenarios and parameter estimations during the exposure modeling and then to ensure a margin of safety by setting appropriate "pass/fail" criteria (e.g., TER or RQ). Because of the complex and somewhat arbitrary nature of the socio-economic factors that are considered before regulating a plant protection product, it is more reasonable to adopt the latter approach because it reflects better science in the estimate of exposure. For example, it is thought that some exposure models propagate proportionally greater errors when run under exceptional conditions of slope or weather and so less uncertainty will be associated if the models are run under conditions more representative of those used to generate their underlying algorithms.

The regulatory community needs to develop agreed approaches to making decisions based on risk-refined data. This could involve at its simplest level, agreement to lower TERs and RQs when certain exposure data are provided, particularly field data, or where additional species data add confidence to the distributions of sensitivity to the stressor. Again, the activities within ECOFRAM may provide guidance in these areas.

7.2.5 Consideration of Landscape Factors

Even with the use of standardized scenarios, appropriate comparison of exposure and toxicity will still tend to suggest potential exposures and concomitant risks that are not supported by the "weight of evidence". This arises because the nature of the risk assessment process adds worst case upon worst case -for example the frequent assumption in regulatory modeling that 100% of a watershed/catchment is planted to the crop of interest and that strong winds always blow towards sensitive ecosystems when chemicals are applied.

At a lower tier this is an acceptable underlying assumption, but during risk refinement, it may be necessary to perform a more detailed analysis. This comparison must take into account the need for co-occurrence in both time AND space of significant concentrations of the stressor and susceptible receptors for risk to occur.

At this point, a landscape-level risk characterization may be required to examine the joint probabilities of concurrence of the expected exposures and toxicities. To implement this level of analysis, a thorough understanding of agronomy, the ecological processes in the system of concern and the temporal and spatial distribution/ co-incidence of exposure and toxicity factors is essential. To perform these analyses, Geographic Information Systems (GIS) are necessary to perform the spatial mathematical analyses -data for this type of approach may come from maps or even from remote sensing images.

7.2.6 The Communication of Risk Refinement Output

One of the most difficult issues in regulatory risk refinements is how best to document, interpret and explain the concepts of probabilistic exposure and toxicity data sets. This is a dual problem impacting the regulated community when they present risk refinements to regulatory authorities not yet fully familiar with the approach and, perhaps more so, for the regulators who have to explain their findings to a public not at all familiar with the concepts of probabilistic risk assessment.

Because of the increasing complexity of data and interpretation (model outputs, statistical analysis) it is evident that electronic media will become the normal means for reporting to regulatory authorities. Authorities and the registrant will essentially use the same tools to carry out risk assessment; hence the Use of electronic media will facilitate the process.

The use of models as tools for simulating environmental fate and behaviour and distribution of effects/effect levels is an essential ingredient for effective risk refinement, but interpreting and understanding the outputs where the results are expressed in probabilistic terms requires specialized expertise that may not be readily available. A collective assessment of the data may therefore be required (with experts) to ensure that decisions can be made based on sound scientific judgement. Past experience in the interpretation of large-scale aquatic mesocosm studies, for example, demonstrates the difficulty that such data present when attempting to express them in terms of potential ecological risk. As proposed in Section 5 for issue identification, discussing the design of higher tier studies with the regulatory authority prior to implementation can help to identify the critical endpoints and their potential ecological significance. From this discussion a set of clear objectives can then be established that may at least help in communicating the purpose and results of the risk assessment to interested parties.

7.3 Management of Risk

7.3.1 Product Management; Good Agricultural Practices

The proper management of a plant protection product (PPP) is imperative in order for the grower to obtain the maximum benefit from the use of the product while providing safety to humans and the environment.
Management of the product starts with the product label, which describes:

- the intended use of the PPP (e.g., specific crops)
- the pests against which the crop is protected
- the rate of application at which those pests are controlled or suppressed
- the application methods (e. g., application equipment, air blast, ground spray) under which conditions, the product can deliver the desired control while maintaining safety to the applicator, bystanders and the environment
- the frequency of use which may be necessary to control various pest infestations
- precautionary measures that have to be taken

This information is the agreement reached between the manufacturer of the product and the regulatory agency granting the registration of the product's use and sale in a given country. The specific uses and management of the product under agricultural conditions has been termed "good agricultural practices" (GAPs) in the EU.

7.3.2 Mitigation as a Risk Management Tool

In cases where a potential risk may exist, the PPP manufacturer, with the regulatory authority, will develop mitigation approaches to manage these concerns. Mitigation is essentially the process of reducing the frequency or degree of contact (real or estimated) between a PPP and nontarget organism in order to reduce the level of potential effect and/or the probability of an effect occurring. Mitigation measures can be applied at different tiers because information gained at a higher tier may either confirm risk management approaches identified from the levels of uncertainty at a lower tier or permit a reassessment of these measures if the level of uncertainty about the risk is reduced (i.e., confidence increases).

Mitigation inevitably has a cost element, for example in the removal of a particular use pattern of a product, the imposition of label restrictions (e.g., buffer zones), or a change in the nature (formulation) of a PPP.

In implementing any mitigation practice, account has to be taken of the widely varying cropping patterns, landscape features, and methods of agricultural chemical application in different regions where significant differences in mitigation/risk management processes will apply.

Mitigation as a risk management process should as a rule be implemented at the local level applying criteria appropriate to the conditions of use. Where necessary, mitigation measures may be applied at larger scales e.g., catchment (watershed) or landscape level. Mitigation at larger scales must, however, be implemented on the basis that scenarios are similar. Examples here may include runoff protection measures where buffer strips be imposed where the slope of the land to a receiving water course has an in cline of greater than 'x' degrees.

Risk management at a local level that requires users of agricultural chemicals to assess the environment potentially 'at risk', can only be a good thing. Local environmental risk assessments would require the factoring in of knowledge that can only apply at the point of use. In this context mitigation against, for example, spray drift could include accounting for wind speed/ direction, spray engineering controls to reduce drift, natural or artificial barriers to drift (trees, hedgerows screens, etc).

Mitigation methods are discussed in greater detail for aquatic (SET AC, 1994) and terrestrial systems (Dulka and Kendall, 1994) elsewhere.

Mitigation, in order to be successful, must integrate measures for crop pest control and exposure to PPPs with a thorough understanding of crop production and agricultural economics. The following approaches have been organized following those suggested by Dulka and Kendall (1994). These include:

- improved grower awareness, (product sele ction, IPM)
- modifications of product use (e.g., use rate, application - requency, number of applications, timing of application)
- formulations (e.g., formulation types, additives)
- packaging (closed filling systems, water soluble bags etc)
- modifications of product delivery (spray volume, droplet sizes, application equipment)
- improved management practices (e.g., avoiding contamination of streams and ponds with equipment washings)
- farm management strategies (e.g., planting practices, enhancement of wildlife habitat, grower incentives)

Various methods involving grower education, good agricultural practices, modification of product use and application, and farm management practices are available to provide the safe use of PPPs.

7.4 Ecological Significance

7.4.1 Overview

The goal of environmental protection is to sustain the variety and functioning of ecosystems in the agricultural environment, including the maintenance of soil fertility which is essential for sustained agriculture.

According to the Chemical Manufacturers Association (CMA, 1996):

> "Ecological risk assessment evaluates the likelihood that physical, chemical and biological stresses will alter the variety and functioning of ecosystems. The goals of ecological risk assessment should be to: (1) determine the function of an ecosystem and how the function can be measured, and (2) describe the probability and magnitude of the impact of existing or projected human activities on ecosystem function."

The importance of ecological significance in a refined risk assessment of plant protection products was addressed by the FAO in its "Revised Guideline on Environmental Criteria for the Registration of Pesticides", and guidance was given on the aspects to be considered (FAO, 1989):

> "The ecological approach requires an adequate knowledge of the presence and fate of the pesticide in the environment, a sound and professional biological background, which includes experience from ecological field work and agricultural practice, and a clear definition of which type of environment and which biological community should be protected. Environments where agricultural pesticides are applied are sites of more or less intensive agricultural activity. It should be remembered that human activity, in particular agriculture, has in some instances created types of environment which are now considered worthy of protection.
>
> Ecological evaluation has to differentiate between transient effects, which have no significant ecological consequences, and long-term adverse effects which may not be acceptable. Attention should be given to effects that may occur outside the agricultural vicinity, e.g., when pesticides move outside the treated area. The mobility of wild–life species must also be considered.
>
> The ecological importance of environmental effects caused by pesticides has to be evaluated in comparison to:
>
> - Natural abiotic variations: drought, freezing, flooding, temperature changes often have drastic effects on organisms.
> - Biotic fluctuations: the abundance of food will determine the population size of feeders.
> - Re-population potential: organisms with a high intrinsic rate of natural rincrease and dispersal may quickly compensate occasional depressions,' however, care should be taken if organisms with a low re -population capacity are affected.
> - Rarity of the species.
> - Ecological impact of other human activities including agriculture.
> - The definition of the aims of protection and conservation.

The aims vary widely and different answers will be appropriate in different cases and countries. However, the final aim of the environmental hazard evaluation is adequate protection and conservation of the environment".

The difficulties in practical application of such principles are recognized, but the need for their use increases with increasingly complex registration procedures like in Europe, where "acceptability" of potential side effects is the key of environmental evaluation (see analysis of actual concepts by DFG, 1994). This is also a legal requirement in many countries.

7.4.2 Aim of protection: Species and sustained function

Contrary to human toxicology, environmental toxicology normally does not aim at the protection of individuals, but of species or higher taxonomic levels (populations, communities, ecosystems), and at the sustainability of ecological functions. No evaluation of acceptability of effects on the environment is possible without a clear definition of the protection goal. Unfortunately, even in certain legal directives such as the European 91/414 Registration Directive (Council Directive 91/414/EEC, 1991), terms such as species, populations, organisms, groups of organisms, individuals and functions are sometimes used inconsistently. The consequence can be the tendency of some risk assessors to aim at the protection of individuals (in order to achieve "zero-risk" for populations), with a maximum or even "precautionary" protection level (equivalent to a very low probability of hazard). This explains very restrictive registrations or very high use restrictions (e.g., by means of large precautionary buffer zones), to an extent which sometimes jeopardizes efficient agricultural production.

The approach to protect species by protecting individuals is logical but appears neither fully realistic nor justified from an ecological point of view. It is not realistic because biologically active substances must have biological effects (even if they are short-term and reversible) on at least some individuals or populations in the area where they are applied and in a limited area of transition at the border line. No protective measure - whether chemical, mechanical, biological - can be without direct or indirect effects on at least some non-target organisms.

7.4.3 Ecological Weighting of Effects

Ecologically, differences in biology, strategies of reproduction, mode and speed of recovery and resettlement are huge, and so are the ecological consequences of seemingly similar toxicological endpoints like an LC/EC_{50} for different types of organisms. A short-term exceedance of the acute LC_{50} of a fish species can result in fish kill; a similar exceedance of algae EC_{50} will be without major consequences. The exceedance of an LD_{50} dose for birds related to a certain surface area (e.g., one square foot or one square meter) is not an appropriate measure for risk; birds have a natural mechanism of food tasting and selection driven by palatability, color, size, etc. -without this very efficient learning and avoidance behaviour they would not be

able to survive in a natural environment where food sources change frequently and have to be tested for palatability.

These few examples make it clear that simple quotient methods alone are insufficient for assessing a hazard or a risk and totally unsuited for judging the "acceptability" of side effects; even highly scientific assessments of various types of effects are worthless if there is no defined "aim of protection" and no "scale" against which ecological and general acceptability of effects can be measured.

7.4.4 Natural and Area-Characteristic Variations

A very meaningful comparative scale for the evaluation of acceptability of effects is the natural range of variations of populations and of species communities. In addition, certain agricultural activities like type of crop, ploughing and harvesting, irrigation and drainage have a major influence on population dynamics and species composition. Wildlife habitats (biotopes) in populated areas are necessarily influenced by human uses of the area. The biocoenosis (community of species) is not "natural" in the sense of "not influenced by humans"; it can be called use- or area-characteristic. The typical flora and fauna changes over time with the use pattern of the area irrespective of the use of PPPs.

7.4.5 Acceptability

"Acceptability" is the key of registration schemes in many countries. The legal definition is vague, but in ecological terms several approaches have been developed, usually defining "unacceptable" rather than "acceptable". The USEPA, for instance, characterized as unacceptable ecological impacts "widespread and repeated mortality in the face of minor economic benefits to society" (USEPA, 1993).

In the EU acceptability criteria are only "harmonised" for the authorisation of an active substance (PPP) in order to achieve Annex I listing (EU, 1991). For the products themselves, member states may apply caveats to restrict use in their own country or regions on the basis of their own legislation and definition.

An example of a test guideline which provides guidance on acceptability is the test on microbial activity in soil, a test on metabolic function (BBA, 1990; OECD, 1996). For other organisms as well, it was proposed by the German BBA (Rothert et al., 1988, 1990; Brasse et al. 1990) to compare possible effects from pesticide treatments to naturally occurring fluctuations. The principle of "recoverability" (potential of recovery) at the population level applies in Germany (Klingauf, 1991), where the species is clearly defined as the "aim of protection". Generally, as for all human activities, risks have to be weighed against benefits.

7.4.6 Endangered Species

Species are endangered if they are reduced to small populations in small areas within in their potential area of distribution, and when the size of the population or the foreseeable future of the remaining area threatens the sustained existence of the species. Habitat competition and predation are also issues that must be considered. Clearly, such situations can only be managed by local protection of the basic elements necessary for the survival of that species and by protecting at the individual and not the population level (e.g., US Endangered Species Act). This is the task of nature conservation and cannot be addressed in the context of pesticide evaluation and registration. The registration evaluation can however provide guidance on which organisms have to be protected locally.

REFERENCES

Avery, D. T. 1993. Biodiversity: saving species with biotechnology. Hudson Institute. Indianapolis, IN.

BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig): Richtlinie für die amtliche Prüfung von Pflanzenschutzmitteln Teil VI, 1-1, März 1990, Auswirkungen auf die Aktivität der Bodenmikroflora.

Brasse, D.; Ehle, H.; Heimann-Detlefsen, D.; Joermann, G.; Kokta, C.; Köpp, H.; Laermann, H.- Th. (1990): Requirements for assessing effects of pesticides on non-target organisms in the Federal Republic of Germany. Pest. Outlook 1 (5), 29-32.

CMA (Chemical Manufacturers Association). 1996. Ecological Risk
Assessment. A tool for decision making. Washington, DC. 19 pp.)

DFG (Deutsche Forschungsgemeinschaft). 1994. Ökotoxikologie von
Pflanzenschutzmitteln, Sachstandsbericht (Expert Report on Ecotoxicology of Plant Protection Products). Chapter 6. VCH Weinheim. 414 pp.

Dulka, J. J. and Kendall, R. 1994. Chapter 10, Avian Risk Management Strategies for Agricultural Products. In: Assessing Pesticide Impacts on Birds: Final report of the Avian Effects Dialogue Group, 1988-1993. RESOLVE, Inc., Washington, D.C.

EU (European Union). 1991. Council Directive 91/414/EEC.

FAO (Food And Agriculture Organization of the United Nations). 1989. Revised guidelines on environmental criteria for the registration of pesticides. Rome.

Fletcher, J. S., Nellessen, J. E., and Pfleeger, T. G. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. Environ. Toxicol. Chem. 13 (9): 1383-1391.

Ganzelmeier, H. 1986. Abtriftmessungen beim Ausbringen von Staübepräparaten im Vergleich zur Konventionellen Ausbringetechnik (Sprühen, Spritzen) im Obst-und Feldbau. Landesanstalt für Pflanzenschutz, Stuttgart. Juni, 1986.

Ganzelmeier, H. 1987. Untersuchungen im Rahmen der Überwachung von Pflanzenbehandlungsmitteln im Acker- und Obstbau sowie zur Bienentoxizität, 1984/85/86. Landesanstalt für Pflanzenschutz, Stuttgart. Juni, 1987.

Hoerger, F. D. and Kenaga, E. E. 1972. Pesticide residues on plants: Correlation of representative data as a basis for estimation of their magnitude in the environment. In: Coulston, F. And Korte, F. (eds). Environmental quality and safety: Chemistry, toxicology, and technology. Georg Thieme Publishers. Stuttgart, Germany. pp. 9-28.

REFERENCES

Klingauf, F. 1991. In: Kurzprotokoll (Nr.13 bzw. 15 S. 17-22) der gemeinsamen Sitzung der Bundestagsausschüsse für Umwelt, Naturschutz und Reaktorsicherheit und für Ernährung, Landwirtschaft und Forsten, 25.9 1991.

Knutson, R. D., Hall, C. R., Smith, E. G., Cotner, S. D., and Miller, J. W. 1993. Economic impact of reduced pesticide use on fruits and vegetables. American Farm Bureau Research Foundation.

Pfleeger, T. G., Fong, A., Hayes, R., Ratsch, H., and Wickliff, C. 1996. Field evaluation of the EPA (Kenaga) nomogram, a method for estimating wildlife exposure to pesticide residues on plants. Environ. Toxicol. Chem. 15(4): 535-543.

Rothert, H. and Köpp, H.. 1988. Ecological effects assessment: Experience with pesticides. DECD Workshop on Ecological Effects Assessment. Washington, DC.

Rothert, H., Brasse, D., and Bode, E. 1990. Abwägungs- und entscheidungsprozesse bei der Zulassung von Pflanzenschutzmitteln im Hinblick auf deren Auswirkungen auf terrestrische Fauna. Ges. Pfi. 42:29-33.

Rowe, WD. 1994. Understanding uncertainty. Risk Analysis. 14(5):743-750.

SETAC. 1994. Final Report: Aquatic Risk Assessment and Mitigation
Dialogue Group. SETAC Press, Pensacola, Florida.

Solomon, K. R.. 1996. Ecotoxicological risk assessment of pesticides (short-course training manual).

Stetter, J. 1993. Trends in the future development of pest and weed control - an industrial point of view. Reg. Tox. Pharma. 17:346-70.

Suter, G. W. 1993. Ecological risk assessment. Lewis Publishers, Chelsea, Michigan. p. 9.

Taylor, C. R. 1995. Economic impacts and environmental and food safety tradeoffs of pesticide use reduction on fruit and vegetables. American Farm Bureau Research Foundation.

Urban, D. J. and Cook, N. J. 1986. Hazard Evaluation Division standard evaluation procedure ecological risk assessment. U.S. Environmental Protection Agency. EPA-540/9-85-001. Washington, DC.

UNEP. 1996. Environmental Risk Assessment for Sustainable Cities. Tech. Publ. 3. United Nations Environmental Programme.

REFERENCES

USEPA (U.S. Environmental Protection Agency). 1992. Framework for ecological risk assessment. Risk Assessment Forum, U.S. Environmental Protection Agency. Washington, DC

USEPA. 1993. Implementation of the policy decisions of the ecological effects and environmental fate task force, Memorandum D.D. Campt, Washington 25.08.1993.

USEPA. 1995. Protection of environment. EPA Regulations 40 CFR, Parts 150 to 189.

USEPA. 1996. Draft proposed guidelines for ecological risk assessment. Risk Assessment Forum. U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-95/002B.

USEPA. 1998. Guidelines for ecological risk assessment. Risk Assessment Forum. U.S. Environmental Protection Agency. Washington, DC. EPA/630/R-95/002F. Final.

USNRC (U.S. National Research Council). 1980. Regulating pesticides. (Committee on Prototype Explicit Analyses for Pesticides, Environmental Studies Board, Commission on Natural Resources, National Research Council). National Academy of Sciences. Washington, DC.

USNRC (U. S. National Research Council). 1983. Risk assessment in the federal government: Managing the process. Prepared by the National Research Council Committee on the Institutional Means for Assessment of Risk to Public Health. National Academy of Sciences. Washington, DC.

van Leeuwen, C. J. and Hermens, J. H. 1995. Editors. Risk assessment of chemicals: An introduction. Dordrecht, The Netherlands. Kluwer Academic Press.

Williams, T. 1997. Killer weeds. Audubon. March-April 1997.

LIST OF DEFINITIONS

Definition of Terms

The following definitions are proposed. Industry will work with the IPCS/OECO group working on the harmonisation of terminology.

Assessment Endpoint: Something tangible that is to be protected e.g., an individual species or ecosystem (EPA)

Benefits: The desirable effects arising from the use of a product in terms of ecological, economical and social advantages.

Degradation: Transformation of a molecule into products by biotic or abiotic means.

Dissipation: The summation of all processes that result in the loss of a compound from a system.

Ecological Risk Assessment: The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors, e.g., exposure to a PPP (EPA).

Ecological Risk Management: The process of deciding what actions to take in response to a risk (Suter)

Ecologically Significant Effects: Changes that cause sustained impact on ecological systems.

Exposure: The process by which an organism comes into contact with a substance resulting in a dose (the amount of a chemical either in the organisms as a whole or in a target tissue). (OECO)

Exposure Assessment: The determination of the emissions (i.e., sources), pathways and rates of movement of a substance in the environment, and its transformation or degradation, in order to estimate the concentrations/doses to which ecological systems and populations are or may be exposed. (OECO)

Exposure/ Toxicity Quotient: The quotient of exposure divided by toxicity (the inverse of the EU's Toxicity/Exposure Ratio TER) - the values should reflect similar time periods.

Hazard: The combination of an inherent property(s) of a chemical stressor with a particular level of exposure, potentially causing harmful effects at this level.

LIST OF DEFINITIONS

Level of Concern: A regulatory criterion against which an exposure/toxicity quotient is compared.

Measurement Endpoint: A measurable ecological characteristic that is related to the valued characteristic chosen as the assessment endpoint.

Potential Effects: The level of toxic response arising from the potential exposure of a susceptible organism to a stressor.

Probability Factor Selection: Selection of a point value from a known distribution:

Extreme Worst Case	9th percentile
Reasonable Worst Case	90th percentile
Typical Case	50th percentile

Risk: The probability of a harmful effect occurring. Risk involves three components, toxicity, exposure and probability.

RQ: The quotient of exposure divided by toxicity, where either or both numerator and denominator have probabilistic connotation.

Stressor: Any physical, chemical or biological entity that can induce an adverse response (EPA).

TER: The quotient of toxicity divided by exposure.

Toxicity: Expression of an inherent property(s) of a substance which results in harmful effects in the organism.

Uncertainty Factors: A factor applied to an exposure (dose), effects concentration or the level of concern to correct for identified sources of uncertainty (Suter).

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