

EUFRAM

Concerted action to develop a European Framework for probabilistic risk assessment of the environmental impacts of pesticides¹

Work Package 6

5 GUIDANCE FOR REPORTING PROBABILISTIC ASSESSMENTS

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10 Steve Maund (Syngenta, Switzerland)², Pamela Byrne (PCS, Ireland), Paul van den Brink (Alterra, The Netherlands), Sabine Beulke (Cranfield University, UK), Hector Galicia (Springborn, Switzerland), Andy Hart (CSL, UK), Leo Posthuma (RIVM, The Netherlands), Keith Solomon (University of Guelph, Canada).

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² Work Package leader.

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2 SUMMARY

In this chapter, guidance for the reporting of probabilistic risk assessments for EU plant protection products is described. A review of existing recommendations has been conducted and various aspects of the existing guidance have been taken together with expert discussions from the EUFRAM working group to develop a reporting framework. It is suggested that the framework takes the following structure:

- Executive summary
- Problem formulation
- 80 - Effects characterisation
- Exposure characterisation
- Risk characterisation
- Ecological interpretation and other lines of evidence

Recommendations for best practice for reporting these sections of the assessment are included in the sections below.

3 INTRODUCTION

At the EUPRA workshop in 2001 (Hart, 2001), one of the weaknesses identified was that the use of probabilistic risk assessment (PRA) could result in ‘a risk of producing misleading results.’ One recommended action from EUPRA to address this potential weakness was to:

“Establish standard procedures for explicit reporting of assessments, including all the assumptions that are made, to enable a critical evaluation of all stages.”

This chapter aims to develop such standardized procedures that enable appropriate and transparent reporting of PRAs. It reviews existing recommendations, where they exist, and has developed, through discussion with the experts involved in the current EUFRAM project, a set of recommended best practices to be used in the future.

4 REVIEW OF EXISTING GUIDANCE FOR REPORTING RISK ASSESSMENTS

At present, there is no explicit regulatory guidance either in the EU or USA for the reporting of risk assessments for PPPs.

In the USA under the Federal Insecticides, Fungicides and Rodenticides Act (FIFRA), there is no formal requirement for the registrant to submit a risk

105 assessment. Rather, the data required for registration purposes are
submitted to the US-EPA, and the staff at the Office of Pesticide Programs
(OPP) conduct their own evaluation of the compound according to internal
procedures. In practice, however, most companies do submit their own
110 evaluation of the data generated. However, there is no fixed format or
recommendations by which this should be done.

In the EU, under Directive 91/414/EEC Concerning the Placing of Plant
Protection Products (PPPs) on the Market, the registrant is required to
conduct a refined risk assessment of the compound, if the triggers from the
Tier 1 evaluation are failed (EU, 1991). The registrant is required to
115 demonstrate in this risk assessment that the use of the compound would not
result in unacceptable risks under field conditions. However, there is no
explicit guidance in the Directive as to how this evaluation should be
conducted. Some recommendations for the conduct of aquatic and terrestrial
risk assessments are included in the EU Ecotoxicology Guidance Documents.
120 These contain some limited information about the nature of the methods,
endpoints and interpretation of higher tier studies, but could not be considered
to contain a detailed specification of how the risk assessment should be
reported.

125 Whilst at this time, there are no officially adopted reporting requirements either
for deterministic risk assessment (DRA) or PRA, there are a number of
existing recommendations for both DRA and PRA that could be used as a
starting point for developing recommendations for the reporting of PRA for
PPP registration in the EU. These documents are briefly reviewed below.

4.1 ECOFRAM (draft report 2000)

130 The ECOFRAM report contains a number of recommendations on how PRAs
should be reported (ECOFRAM, 2000). Most of this guidance focuses on the
appropriate expression of risk characterisation and description of the
approach used.

135 A generalised framework for reporting PRAs however has been developed,
which might serve as a useful guide for developing more detailed
recommendations for reporting PRAs in the EU. The outline of this framework
is as follows:

- 140 1. A clear description of the problem formulation i.e., identification of the
potential issues in the lower tier risk assessment that requires further
refinement.
2. A description of the effects and exposure characterisation, describing
which exposure evaluation was conducted, using which model for which crop
with which product, use rate and application pattern, and giving an indication
of the representativeness of the use.
- 145 3. A description of the approach taken in the risk characterisation.
Namely, how the exposure and effects distributions described in Point 2 were
combined to show what the likely outcome of the product use would be,
describing the magnitude, duration, organisms potentially at risk, and the
recovery period. The uncertainty associated with these estimates should also
150 be included.

The report also states that:

155 “In all cases, risk assessors must be prepared to justify the assumptions that they have made, and moreover, where information is NOT available for key parameters, they should explain why. Probabilistic risk assessments are complex and only through precise explanations of the underlying data and findings can clarity be achieved.”

160 The report also includes a table (included here as Table 1) which lists the key variables that are associated with each step of the aquatic evaluation. This list of variables is suggested as a potential range of inputs for developing reporting statements for the assessment.

Table 1: Key variables identified with the ECOFRAM process which may provide a framework for reporting aquatic PRAs

Parameter	Tier 1	Tier 2	Tiers 3 and 4
Evaluation type	Deterministic	Probabilistic	Probabilistic
Model	Ideal Tier 1 model (GENEEC)	MUSCRAT 2 (PRZM-EXAMS)	Refined Ideal Tier 2 – describe refinement/approaches
Potential receiving water body	Pond	Pond, headwater stream	Pond, headwater stream, river, reservoir
Proximity	Adjacent to treated fields	Adjacent to treated fields	Varying degrees of removal from edge – includes buffers or mitigation
Crop	“Row crop”, cranberry, rights of way, forestry or rice (ideally crop specific)	Crop specific	Crop specific (perhaps regional)
Region	High exposure scenario	National or relevant regional	National, relevant regional and more specific scenarios
No. of treatments/ application methods	Closest approximation to Tier 1	Specific details from worst case	Worst case and options
Representativeness	Worst-case label	Worst case and/ or “typical case” and/ or mitigated cases	Worst case and/ or “typical case” and/ or mitigated cases
Toxicity study data	Standard study suite	Standard study suite	Standard studies plus additional work as available
Occurrence % of periods	Currently not applicable	Indicated by RADAR or direct from PRZM-EXAMS output	Indicated by RADAR or direct from PRZM-EXAMS output
Periods	Annual return frequency	Pre-specified for taxa, annual, 30 day or seasonal cycle	Pre-specified for taxa, annual, 30 day or seasonal cycle
% uncertainty	Currently not applicable	Probability of exposure available from PRZM-EXAMS	Other information as available
Medium	Water column (sediment desired)	Water column, sediment	Water column, sediment, other water body compartments
Censoring threshold	None	Standard toxicity values and/ or LOEC/ NOEL	Various
Taxa/ species	Fish, aquatic invertebrate	Warm/ cold water fish, benthic invert., water col. Invert., marine fish/ invert., non-target aquatic plant	Warm/ cold water fish, benthic invert., water col. Invert., marine fish/ invert., non-target aquatic plant
Duration	Instantaneous, 21, 60 or 90 day	Instantaneous, 24, 48, 96 h, 21, 60, 90 d	Tier 2 plus intervals as needed
Recovery period	Ignored	From RADAR	From RADAR

165 **4.2 EC DG C: Scientific Opinions - Scientific Steering Committee. First Report on the Harmonisation of Risk Assessment Procedures (published on the Internet 20.12.2000)**

170 In October 2000, the Scientific Steering Committee (SSC) of DG SANCO issued an opinion on the harmonisation of risk assessment procedures (http://europa.eu.int/comm/food/sc/scc/out82_en.html). A working group was established to develop consistent approaches between the various Scientific Committees that advise the Commission in the areas of human and environmental health. Within this report, the SSC also recommends the development of probabilistic approaches. Although it does not deal specifically with PRA, many of the general recommendations in this report could also be applied to the development of reporting standards for PRA.

175 The report deals with risk assessment in a similarly structured way to the ECOFRAM report, covering the following areas:

1. Hazard identification
- 180 2. Exposure assessment
3. Hazard characterisation
4. Risk characterisation
5. Risk communication.

The report also contains a list of definitions for risk assessment.

185 Under their discussion of risk communication (in which reporting matters are included), the SCC listed some key issues that were required to support the effective reporting of risk assessment findings. Detailed examples of the presentation of results of evaluations are included in Appendix 6 of the report. The SCC recommended that the following areas needed further consideration when reporting risk assessments:

- 190 1. Editorial format – to improve readability
2. Terms of reference – originator of the questions
3. Sources, type of information used and other constraints in the risk assessment, e.g. time
- 195 4. Reference to the assessment process used (regulations, guidelines)
5. Mode of uncertainty expression
6. Wording and expressions used
7. Coherence and transparency
8. Mode of expression of the final risk evaluation
- 200 9. Refusal – impossibility to answer.

This list of issues provides some useful starting points for the development of a framework or recommended procedure for reporting PRAs.

205 4.3 US-EPA Guiding Principles for Monte Carlo Analysis (EPA/630/R-97/001) Mar 1997.

A working group was established under the US-EPA Risk Assessment Forum to develop recommendations on the use of Monte Carlo analysis on risk assessment (US EPA, 1997). Whilst mostly focused on discussions of appropriate Monte Carlo methodologies, this document contains some useful
210 detailed recommendations on how the results of a Monte Carlo analysis should be reported (p. 17). The following steps are recommended:

1. Provide a complete and thorough description of the exposure model and its equations (including a discussion of the limitations of the methods and the results).
- 215 2. Provide detailed information on the input distributions selected. This information should identify whether the input represents largely variability, largely uncertainty, or some combination of both. Further, information on goodness-of-fit statistics should be discussed.
3. Provide detailed information and graphs for each output distribution.
- 220 4. Discuss the presence or absence of dependencies and correlations.
5. Calculate and present point estimates.
6. A tiered presentation style, in which briefing materials are assembled at various levels of detail may be helpful. Presentations should be tailored to address the questions and information needs of the audience.

225 4.4 US-EPA Guidelines for ecological risk assessment (US-EPA 1998)

This document provides a general framework for ecological risk assessment, which is not specific either to pesticides or to probabilistic assessments. Nevertheless it includes guidance that may be relevant to EUFRAM. In particular, Text Note 5-8 in the document lists the following as “Possible Risk
230 Assessment Report Elements”:

1. Describe risk assessor/risk manager planning results.
2. Review the conceptual model and the assessment endpoints.
3. Discuss the major data sources and analytical procedures used.
4. Review the stressor-response and exposure profiles.
- 235 5. Describe risks to the assessment endpoints, including risk estimates and adversity evaluations.
6. Review and summarize major areas of uncertainty (as well as their direction) and the approaches used to address them.
7. Discuss the degree of scientific consensus in key areas of uncertainty.
- 240 8. Identify major data gaps and, where appropriate, indicate whether gathering additional data would add significantly to the overall confidence in the assessment results.
9. Discuss science policy judgments or default assumptions used to bridge information gaps and the basis for these assumptions.
- 245 10. Discuss how the elements of quantitative uncertainty analysis are embedded in the estimate of risk.

The document also offers advice (in Text Box 5-9) on how to ensure that risk characterisation is “clear, transparent, reasonable and consistent”:

For clarity:

- 250
- Be brief; avoid jargon.
 - Make language and organization understandable to risk managers and the informed lay person.
 - Fully discuss and explain unusual issues specific to a particular risk assessment.

255 **For transparency:**

- Identify the scientific conclusions separately from policy judgments.
 - Clearly articulate major differing viewpoints of scientific judgments.
 - Define and explain the risk assessment purpose (e.g., regulatory purpose, policy analysis, priority setting).
- 260
- Fully explain assumptions and biases (scientific and policy).

For reasonableness:

- Integrate all components into an overall conclusion of risk that is complete, informative, and useful in decision making.
 - Acknowledge uncertainties and assumptions in a forthright manner.
- 265
- Describe key data as experimental, state-of-the-art, or generally accepted scientific knowledge.
 - Identify reasonable alternatives and conclusions that can be derived from the data.
 - Define the level of effort (e.g., quick screen, extensive characterization) along with the reason(s) for selecting this level of effort.
- 270
- Explain the status of peer review.

For consistency with other risk characterizations:

- Describe how the risks posed by one set of stressors compare with the risks posed by a similar stressor(s) or similar environmental conditions.

275 **4.5 US EPA Risk Assessment Guidance for Superfund (RAGS), Volume 3A – Process for conducting probabilistic risk assessment (US-EPA, 2001)**

280 The US EPA has developed detailed guidance on the use of probabilistic methods in risk assessment for Superfund sites. Although directed at assessment of contaminated land sites rather than pesticides, many parts of this document are relevant to EUFRAM.

Appendix F of RAGS-3A (Workplan and checklist for PRA) contains two topics of relevance to EUFRAM WP6: guidance on developing a workplan and a checklist for the evaluation of completed probabilistic assessments.

285 **4.5.1 Work plan/problem formulation**

The concept of the work plan in RAGS-3A is closely similar to problem formulation in the US EPA Ecological Risk Assessment Framework. RAGS-3A states that the work plan should document the decisions taken by risk managers, risk assessors and stakeholders in planning the assessment. It

290 also warns that the EPA generally will only accept probabilistic analysis for Superfund if the EPA has approved the work plan in advance. Finally, evaluation of the completed assessment includes checks for consistency with the work plan (see below). Thus documentation of the work plan is considered to be an integral part of reporting the assessment as a whole.

295 RAGS-3A provides an example of the main elements of a work plan:

1. Statement of the ecological assessment endpoints and/or human risk
2. Summary of the point estimate risk assessment
3. Potential value added for risk management by conducting a PRA and proceeding to the subsequent tiers (quantify variability, uncertainty, or both)
- 300 4. Discussion of adequacy of environmental sampling for PRA (e.g., data quality issues)
5. Description of the methods and models to be used (e.g., model and parameter selection criteria)
- 305 6. Proposal and basis for probability distributions and point estimates
7. Methods for deriving the concentration term
8. Proposal for probabilistic sensitivity analysis
9. Method for dealing with correlations
10. Bibliography of relevant literature
- 310 11. Software (i.e., date and version of product, random number generator)
12. Simulation approach (e.g., iterations, Monte Carlo or Latin Hypercube sampling, time step)
13. Proposed schedule and expertise needed.

315 It is important to remember that Superfund assessments are different from pesticide assessments in many ways. Most importantly, each assessment is more or less unique, because a Superfund assessment refers to a specific contaminated site, so a wholly new work plan is needed for each site. In contrast, it may be possible to develop a limited number of generic work plans or problem formulations for pesticide assessments, because the assessment approach will be very similar or identical for different pesticides with the same uses (crop, region, timing, mode of action). For specific assessments, it may then be sufficient to refer to the generic problem formulation that was used, and describe and justify any modifications.

320

4.5.2 Checklist for reviewers

325 RAGS-3A does not include explicit guidance on the preparation of assessment reports, but it does include a checklist for reviewers that indicates in detail what content is required in such reports.

First, the focal areas for the review of a probabilistic assessment are listed, as follows:

- 330 1. Clarity of and conformation to objectives.
2. Scientific basis and documentation of input distributions and assumptions.
3. Model structure and computational mechanics.
4. Results, including, limitations, reasonableness, and clarity of documentation.

- 335 Then, a detailed checklist is provided, organised into four sections
corresponding to the above focal areas. The checklist is reproduced in
Appendix 1 of this paper. Apart from occasional references to the work plan
(which for pesticides can be replaced with ‘problem formulation’) and site
340 (which for pesticides can be replaced with ‘assessment scenario’), this list
appears highly applicable to pesticide assessments, although some additional
points could be considered. These might include, for example:
- relation of assessment endpoints to management goals/decision
criteria
 - expression of the model in mathematical formulae
 - 345 • appropriateness of aggregation and averaging steps in the
assessment
 - the basis for any subjective distributions (especially when
quantifying uncertainty)
 - 350 • identification of conservative assumptions and discussion of their
effect on the outcome, spatial and biological resolution of the
analysis (as well as time steps)
 - identification of excluded variability, uncertainties and dependency
and discussion of their effect on the outcome
 - 355 • evaluation of other lines of evidence (e.g. monitoring data) and their
effect on the overall assessment
 - identification of options for further reduction of uncertainty.

4.6 US-EPA Risk Characterization Handbook (US-EPA 2000)

This is a large document that includes several sections relevant to EUFRAM,
including guidance on the principles and content of risk characterisation, and
360 the needs of different audiences.

Section 3 of the document lists the following as major elements (types of
information) to include in the “technical” risk characterization:

1. Key information (*seems to duplicate points 4-7 below*)
2. Context (comparison with other risks and other assessments)
- 365 3. Sensitive Subpopulations (including sensitive ecosystems or species)
4. Scientific Assumptions
5. Policy Choices (e.g. uncertainty factors, levels of concern)
6. Variability
7. Uncertainty
- 370 8. Bias and Perspective (e.g. conservative assumptions)
9. Strengths and Weaknesses
10. Key Conclusions
11. Alternatives Considered (e.g. risks of alternative risk management
options)
- 375 12. Research Needs

4.6.1 EPA Recommendations for Executive Summaries

380 The above list refers to the “technical” risk characterization which is envisaged as a relatively full account of the process. In addition, the Handbook gives guidance on the provision of other outputs for communicating the risk characterization to different audiences. It states that the products prepared for risk managers are generally in the form of a summary, and states:

385 “Summaries can take various forms and you need to decide which form is the most appropriate for the particular risk manager involved and the needs of that risk manager. In general, risk managers do not need the depth of technical detail found in the technical risk characterization. They want the key issues and conclusions clearly highlighted in the summary. If risk managers want to read and understand the technical details, they can refer to the technical risk characterization or the full risk assessment.”

390 The Handbook suggests that executive summaries should be at most a few pages with some technical detail for audiences with some technical knowledge.

4.7 Assessment summaries in US-EPA submissions to Science Advisory Panel, March 2001

395 As part of its continuing program developing probabilistic approaches for assessing aquatic and terrestrial risks of pesticides, the US EPA Office of Pesticide Programs has made submissions to the FIFRA Science Advisory Panel (SAP) on 3 occasions: an implementation plan in April 2000, prototype models and assessments in March 2001, and refined models in March 2004.
400 The submissions, models and meeting reports are available for downloading at <http://www.epa.gov/scipoly/sap/index.htm>

The submissions for the March 2001 meeting include aquatic and terrestrial assessments for “Chem X”, including executive summaries that may offer some useful ideas for EUFRAM.

405 The summary for the aquatic assessment runs to less than 2 pages, very briefly outlining the assessment scenarios, the assessment methods, the outcome of a deterministic screening assessment, the key outcomes of the probabilistic assessment (only one numerical result is quoted³), excluded effects (indirect, sublethal), excluded uncertainties, included uncertainties,
410 other lines of evidence (fish incidents), and a final summary sentence⁴.

The summary for the avian assessment runs to eight pages, including much more detail on assessment scenarios and results including four tables, a diagram of main model components, and a summary of input data. It ends

³ “...it was concluded that the use of ChemX was expected to infrequently (5% of the time or less) result in significant freshwater fish mortalities, but routinely result in reduced growth and other chronic effects in exposed fish. Substantial mortalities and chronic effects to sensitive aquatic invertebrates were predicted to routinely occur after peak exposures.”

⁴ “...use of ChemX would be expected to pose real and significant risks, acutely and chronically, to aquatic organisms.”

415 with three paragraphs of text conclusions that include numerical estimates⁵. Unlike the aquatic summary it does not mention uncertainties or excluded issues, and includes only an indirect reference to field incidents. The SAP submissions for March 2004 do not include assessment results or summaries.

5 DEVELOPMENT OF A FRAMEWORK FOR REPORTING PRAs

420 As mentioned in the Introduction, the objective of this work package is to:

“Establish standard procedures for explicit reporting of assessments, including all the assumptions that are made, to enable a critical evaluation of all stages.”

425 It is proposed to achieve this objective by developing a **general guidance framework** for reporting PRAs, comprising the elements discussed in the following sections.

430 As a general point, it should be noted that the amount of detail required in individual assessment reports would be greatly reduced if it proves possible to establish a suite of generic, peer-reviewed tools and procedures (e.g. assessment scenarios, models, software, datasets etc.). However, the applicability of standard tools and procedures to each assessment, and any significant modifications to them, should explicitly justified in the assessment report.

5.1 Executive Summary

435 While the aim of the overall report is to provide a comprehensive record of the assessment that can be subjected to detailed technical review (and potentially enables duplication of the assessment by third parties), the aim of the executive summary is to communicate the key points. The selection of those points and the form of the summary (length, language, structure) depend greatly on the audience for the summary, and their information needs.

440 The most common audiences for an executive summary include technical specialists (including peer reviewers) and decision-makers. These roles are not clearly separated in current regulatory practice in Europe, and are partly exercised by committees. In Europe, probabilistic assessments are currently more likely to be produced by industry than regulatory authorities. Technical experts in individual Member States (especially the Rapporteur Member State) and the European Food Safety Authority (EFSA) Scientific Panel On Plant Health, Plant Protection Products And Their Residues (PPR panel), if consulted, will evaluate the detailed technical report, but may they may copy or adapt the summary in their evaluation of the assessment. Committees such as EPCO (EFSA Pesticides Peer review Co-Ordination) and Working Group

⁵ “...high mortality in at least some avian species will occur... Specifically, results show that from 55% to 95% of the bird species using midwestern corn and alfalfa fields treated with ChemX will experience some mortality, on average. Twenty-seven to 90% of the species are likely to experience at least 10% or greater mortality, on average, while up to 23% of the species are likely to experience at least 70% mortality, again on average.”

455 Evaluation rarely work directly with the detailed assessment but instead base
their discussions on the evaluation provided by the Rapporteur Member State
and/or PPR panel. The executive summary is therefore the primary source of
information for this latter type of committee, and should be designed primarily
to meet their needs.

460 The key needs of this audience are to understand the scope and outcome of
the assessment – in terms directly relevant to management goals and the
decisions that need to be made – and to understand the level of certainty and
credibility that can be attached to it. If there are several management options
(e.g. approval with or without mitigation measures), then results for each are
likely to be needed. In addition, if requiring additional data is one of the
options open to decision-makers, it would be helpful to have information on
the most promising options (e.g. types of studies) for reducing uncertainty.

465 With these needs in mind, the following elements are suggested for the
executive summary:

1. Title - Pesticide active substance, type of risk (aquatic, avian etc.).
2. Assessment author and affiliation.
- 470 3. Peer review status (after the document is finalised, further peer review
would need to be documented separately).
4. One sentence summary of assessment outcome, taking account of both
the probabilistic assessment and other evidence, and including an
indication of the degree of certainty. The key elements to communicate
475 are severity/magnitude, frequency (e.g. in time or space), and
(un)certainty. In plain language, “how bad, how often, how sure”. If
appropriate, express in terms that can be directly compared with relevant
regulatory criteria⁶.
5. Formulation and uses considered (short summary of crops, timing,
480 regions, maximum rate, maximum number of applications – possibly as a
table if decision-makers need to identify exactly which uses are covered).
6. Type of ecological receptor assessed (taxonomic group, habitat).
7. Type of impact assessed (e.g. direct, acute/chronic, population etc.).
8. Measure of impact (assessment endpoint, e.g. TER) and how this relates
to management goal/decision criteria.
- 485 9. Reference to standard assessment protocols followed (if non-standard
just say so). Brief outline and justification of any significant modifications
to standard approach.
10. Primary result – text statement incorporating key numerical result and
confidence bounds.

⁶ The choice of endpoint for the one-sentence summary is difficult and should be discussed with the decision-maker in advance. Existing regulatory criteria (e.g. TER triggers) are designed for deterministic screening assessments and incorporate uncertainty factors, so although they provide familiar reference points they may not be suitable as decision points for probabilistic assessment. It may therefore be desirable to expand the one (two?)-sentence summary to include in addition an alternative endpoint, e.g. frequency of mortality, or a qualitative statement incorporating other lines of evidence.

- 490 11. Secondary results if important to the decision, including different assessment endpoints (e.g. TER vs. others), different uses, regions, management options, with confidence bounds. Consider using a table for this.
- 495 12. Summary of factors omitted from the quantitative assessment – e.g. exposure routes, effects, variability, uncertainties and dependencies – and how this might affect the assessment outcome (decision-makers cannot evaluate these for themselves, so assessors need to indicate how different the “true” risk might be).
13. Summary of other lines of evidence and their bearing on the assessment.
- 500 14. Summary of any arguments concerning implications for higher-level/longer-term ecological endpoints or management goals.
15. Brief indication of most promising options that could be considered for reducing uncertainty.

505 The list above assumes that other lines of evidence and implications for higher-level ecological endpoints are considered within the same report as the probabilistic assessment. If this is not the case, and they are dealt with in separate documents, then they would be omitted from all elements of the executive summary.

510 The list above does not include any statement concerning the acceptability of risk or the relative acceptability of different management options. Deciding between management options is a risk management responsibility, and involves a balancing of ecological risk with many other factors (human health, economic, agronomic, social, cultural etc.). These factors are not considered in an assessment restricted to ecological risk, so the conclusions and

515 summary of such an assessment cannot legitimately pronounce upon them. Therefore the executive summary of a risk assessment should be limited to characterizing the level of risk⁷. Note that, when decision-makers communicate risk management recommendations, it would be appropriate to include statements concerning the acceptability of risk, together with an

520 overview of how the various factors (ecological, health etc.) were taken into account.

If expressed in plain language without jargon, a summary of the type proposed above might also be useful for those stakeholders (including NGOs and members of the public) who take an active interest in the assessment.

525 However, different approaches should be considered for other audiences (see Work Package 7).

⁷ This distinction between the roles of risk assessment and risk management is formalised in the EU Food Regulation and the Codex Working Principles on Risk Assessment, and discussed at length in various publications including the US-EPA Risk Characterisation Handbook and a recent EU workshop report (Hart, 2004). It has recently been reiterated by the Director-General of SANCO (Opening address to the inaugural joint meeting of the members of the non-food scientific panels, 7 September 2004, available on SANCO website).

5.2 Problem formulation

5.2.1 Introduction

530 Problem formulation is a phase of the risk assessment in which the goals of the assessment are defined and the methods for achieving those goals are specified. The six main components of problem formulation (see Section XX –general introduction) should be clearly described in the risk assessment report. Some guidance on suitable information to include is described below.

5.2.2 Objective

535 This should be a short section stating the objective of the assessment (e.g. to estimate the acute risk to X organisms from the use of Y pesticide in Z crops) and explain the reason why it was initiated (e.g. as a result of potential risks identified in a screening assessment). If the assessment was intended to focus on particular factors (e.g. a more realistic exposure assessment,
540 perhaps refining some specific parameters but not others) then this should be explained.

5.2.3 Problem formulation process

The advantage of describing the formulation process is that it provides
545 transparency about the choices that were made, which may have influenced the outcome. This would imply summarising the people and organisations who were consulted, at what stages they were consulted, and on which aspects. It may also be desirable to indicate to what extent the final assessment approach represents a consensus and explain any areas of disagreement. Such transparency is increasingly important to the credibility of the risk
550 assessment process (see Work Package 7), although currently the need for it is more keenly felt in relation to food safety than environmental issues.

This section might also be a good place to provide a summary list of any standard guidelines, protocols, models, datasets, etc. that have been used in the assessment, and identify any significant deviations/modifications or novel
555 approaches. More detailed description and justification of deviations and novel approaches should be provided in other sections of the assessment report, which deal with the aspect concerned.

5.2.4 Assessment scenarios

560 This section should present all information necessary to specify the context, scope and boundaries for the assessment, including:

- Specification of the pesticide use and formulations considered, and the mode of action
- A complete list of the use conditions considered in the assessment, including regions, crops, timing, application rates, maximum number of
565 applications, minimum interval between applications
- Description and justification of the types of ecological receptor selected for assessment (taxonomic group, habitat, indicator species if applicable).
- Description and justification of the types of impacts selected for assessment (e.g. direct, acute/chronic, population etc.)

570 In reality, every different combination of use conditions, habitats, species etc.
will generate a different risk. In theory, this variation could be incorporated in a
probabilistic risk assessment, but in practice such an assessment may
become unwieldy to construct and communicate. For this reason, it may be
preferable to devise a limited number of scenarios for assessment, each of
575 which represents a subset of the overall distribution of scenarios in the real
environment. If this approach is adopted, it is essential to report and justify the
detailed specification of each scenario, and also to evaluate where in the
overall distribution of real scenarios the assessment scenarios fall so that the
decision-maker can understand how protective they are. An example of this
580 approach (albeit in a deterministic context) is provided by the FOCUS Surface
Water Scenarios report (FOCUS, 2003) and further developments of this can
be found in the FOCUS Landscape and Mitigation report (FOCUS, 2005). As
described by the FOCUS reports, it should be possible to develop suites of
generic scenarios that can be applied to a wide range of pesticides and uses,
585 from which relevant scenarios can be selected (with justification) for particular
assessments.

Note that assessment scenarios need to be developed in consultation with
decision-makers (and potentially stakeholders) to ensure that they are
relevant to the management goals (e.g. types of species and habitats to be
590 protected) and to the decision options (e.g. types of mitigation measure
available).

5.2.5 Assessment endpoints

Assessment endpoints have a crucial role in decision-making and need to be
specified in consultation with decision-makers and stakeholders. Clear
595 specification of the assessment endpoint(s) is therefore a pivotal part of the
assessment report, without which the results may easily be misunderstood or
misused.

US-EPA (1998) defines assessment endpoints as measurable ecosystem
characteristics that represent management goals, defining (a) the entity to be
600 protected and (b) an attribute of it which is potentially at risk, important to
protect, measurable and has easily discernible meaning. In practice, the
endpoint of the assessment (literally speaking, the quantity which is
estimated) is often an abstract index of risk (e.g. TER) that is not a
measurable ecosystem characteristic and represents management goals only
605 in an indirect way. Such endpoints are convenient and effective if there are
established criteria for using them in decision-making. It may be desirable to
move towards assessment endpoints more in keeping with the US-EPA
definition, but that is an issue outside the scope of this work package. If the
assessment uses endpoints that are not directly representative of the
610 management goals, then it will be advisable for the relationship between the
endpoints and goals to be discussed in the assessment report.

Often in a probabilistic assessment, the assessment endpoint will be a
distribution representing variability in exposure and effects, or a statistic
derived from such a distribution (e.g. the mean TER, or a particular centile of
615 the distribution of TERs, or the percentage of TERs exceeding a particular
value, depending on what is of interest to the decision-maker). It is important

to specify this in advance so that the appropriate outputs can be generated for the report.

620 It is also vital, when the assessment endpoint is derived from a distribution representing variability, to specify the population or ensemble to which the distribution refers, and the time period over which the assessment is to be made. For example, if the endpoint for an aquatic assessment was % of ditches with TER<10 then it is essential to specify the ensemble of ditches on which it is to be based (e.g. all ditches, or just ditches adjacent to treated fields) and the time period over which the percentage is assessed (e.g. per pesticide application, or per year).

625 Finally, if the assessment separates variability and uncertainty then it is necessary to specify what centile confidence bounds are required for the assessment endpoint.

630 **5.2.6 Information sources**

Any limitations on the information utilised (e.g. due to quality criteria) for the assessment should be specified. Examples might include limitation to GLP studies, and limitation to studies published after a certain date or submitted before a certain date. Any criteria used to select or prioritise information should be stated. Ideally, the report should include (perhaps as an annex) a complete listing of all studies and publications considered, so that the information base for the assessment is explicit.

635 **5.2.7 Conceptual model**

Conceptual models consist of two principal components (US-EPA, 1998):

- 640 • A set of risk hypotheses that describe predicted relationships among stressor, exposure, and assessment endpoint response, along with the rationale for their selection
- A diagram that illustrates the relationships presented in the risk hypotheses.

645 Examples of risk hypotheses given by EPA (1998) are textual (e.g. 'birds die when they consume recently applied granulated carbofuran'). For a quantitative risk assessment it may be preferable to express risk hypotheses using mathematical equations. However, it may be preferable to present equations in the parts of the assessment report that describe the exposure and effects assessments and risk characterisation, so here we concentrate on graphical representations of the conceptual model. The purpose of the equations is to document the precise structure of the model (e.g. so that it could be duplicated by third parties) whereas the primary purpose of graphical representation is to facilitate comprehension and communication of the assessment.

655 Various approaches have been used in drawing conceptual model diagrams, and two examples can be seen in one of the case studies in the paper from Work Package 8 (pages 76 and 83). Suter (1999) makes a number of recommendations that may be helpful:

- 660 • that conceptual model diagrams be constructed as a cascade of alternating processes and states,

- that exposure-response relationships be shown as distinct components of model diagrams,
- 665 • that more complex problems be represented by a hierarchy of conceptual models, with each lower level containing states and processes that are aggregated at the next higher level.
- 670 • that conceptual models be developed in a modular way; standard modules being developed to represent states and processes that occur repeatedly in many assessments. Once accepted for general use these would not require detailed description in every assessment report.

In addition, it may be useful to extend the conceptual model to show the relationships between the modelled states and processes and the types of information that will be used to quantify them. This is useful because, often, model parameters are not measured directly but are estimated from other information (e.g. historically, residues on insects have been estimated from data on residues on seeds). Including this in the conceptual model makes the extrapolation explicit, and recognises the associated uncertainty, although it will make the diagrams more complex.

680 In some assessments, there may be substantial uncertainty about the structure of the conceptual model, for example about which routes of exposure are important, or how they should be aggregated. Presenting alternative conceptual model diagrams may be a helpful way to communicate the alternative hypotheses and the resulting uncertainty.

685 It may also be useful to include in the conceptual model other lines of evidence that are relevant to the assessment endpoint, to facilitate understanding of their contribution to the overall assessment outcome.

5.2.8 Other products of problem formulation

690 Many more detailed elements of the assessment may or should be developed as part of the problem formulation process, including lists of the model parameters and their associated uncertainties and inter-dependencies, definition of the smallest biological, temporal and spatial units to be considered in the analysis, specification of any aggregation or averaging steps that are needed to arrive at the assessment endpoint, and decisions on aspects of the analysis plan (e.g. methods for uncertainty propagation and sensitivity analysis). In principle these things could all be reported under the heading of problem formulation. However, it may be best to document them together with the model equations, in the parts of the assessment report that describe the exposure and effects assessments and risk characterisation.

700 Another decision that should be considered, although not finalised, as part of problem formulation is the choice of methods for communicating the results (various types of graphs, tables and narrative text); however, the outcome of this choice will be self-evident in the results sections of the report and does not require separate documentation.

5.3 Effects characterisation

705 5.3.1 Introduction

Effects characterisation is the term that is generally used to describe the synthesis and analysis of the toxicity data used in the risk assessment. Effects data may include both standard regulatory acute and chronic toxicity studies, and also higher-tier studies which may be modifications of standard studies, or population- or community-level studies (e.g. semi-field or field studies)

710 Effects characterisation can be uncertain and variable. For lower-tier risk assessment of PPPs, relatively small sets of data are generally available, and consequently uncertainties arise regarding the representativeness of these data. Similarly, the complexity (and hence robustness or resilience) of natural ecosystems is not included in lower tier ecotoxicological studies. Such factors also therefore lead to uncertainty in predicting effects in the real world. In field studies, data generated may be of limited applicability to other circumstances. Consequently, it is important express the potential influence of uncertainty and variability on the outcome of the effects assessment.

715 At the lower tiers of risk assessment in the EU, uncertainty factors are applied to toxicity exposure ratios to take these (and other) factors into account. At higher tiers, where additional laboratory or field data may be available, it is generally accepted that increasing the degree of realism of the test system and/or increasing the number of species tested should lead to a reduction in the magnitude of the uncertainty factor (e.g. Campbell et al., 1999) to be applied. It is therefore important that the selection, interpretation and use of effects data are clearly justified and discussed when reporting a probabilistic risk assessment. Some guidance for reporting effects data is presented in the sections below.

720 5.3.2 Data Summary and Selection

For the EU registration process, the summaries of studies produced in the EU Annex I dossier (active substance and a representative formulation) or those prepared for member state submissions for Annex III (country-specific end-use product) provide a very detailed description of the studies to be used in the risk assessment. It should therefore generally not be necessary to reproduce this level of detail in a PRA report for EU registration, but should be possible to cross-reference that data.

735 Nonetheless, it may be helpful to summarize (perhaps in tabular form) the basic laboratory data that are used for the risk assessment, including perhaps *i.a.* information on:

- Organism tested (species, sex, age, life-stage, etc.)
- Test guideline followed
- Measurement end points (e.g. median effective/lethal concentration/dose/rate; no observed effect concentration) and confidence intervals
- Measured or nominal concentrations

- 750 - Whether study was conducted with the active substance (AS) or with a formulated product (PPP). If endpoints are mixed then justify why the one surrogates the other one(s).

For higher-tier laboratory and semi-field or field studies, a brief description of the study design and results should also be included. This should generally be limited to two to three paragraphs, and should then cross-reference the more detailed summary in the dossier.

- 755 A full justification should then be given for the selection of the data that are used in the PRA. If data are excluded, clear reasoning should be given for their exclusion.

'Surrogate' data may be used on occasion in PRA. Examples of surrogacy include:

- 760 - using acute to chronic ratios to allow estimation of chronic effects from acute data
- combining data from organisms from different habitats (e.g. saltwater and freshwater species)
- 765 - using endpoints from substances having a comparable mode of action (adjusted as necessary for relative potency).

If surrogate data are used, a robust rationale should be clearly specified, including reasons for surrogate use and any expected influence on the PRA

5.3.3 Effects data analysis

- 770 If further analysis of the effects data are to be conducted, for example the construction of a species sensitivity distribution, the approach used needs to be clearly documented, bearing in mind the detailed technical recommendations included elsewhere in this report. It should be noted that further data analysis may not necessarily always be needed, e.g. where a single endpoint is available from a semi-field or field study. The PRA report should include:

- 775 - A justification for the selection of the data processing and description of the software
- A brief description of the methods used (cross-referencing if appropriate more detailed technical texts)
- 780 - A description of the uncertainties of the analysis
- A description of the variability of the analysis (e.g. confidence intervals)

5.3.4 Presentation of the results

- 785 If further data analysis is conducted specifically for the effects characterisation, it is useful to consider presenting the data graphically. A number of options include:

- Cumulative density function (CDF) showing the effect concentration on the x-axis and the frequency on the y-axis. It is often helpful if the axes are scaled such that the cdf is linearized, e.g. for a log-normal distribution using a log x-axis and probability y-axis.

- 790 - Summary tables stating any selected endpoint from e.g. an SSD (various centiles and their confidence intervals)

5.4 Exposure characterisation

5.4.1 Introduction

795 Exposure characterisation is an important part of the risk assessment process. For EU registrations, predicted exposure concentrations (PECs) in soil, surface water and groundwater must be estimated. Relatively simple calculations are made to estimate concentrations of pesticides in soil, whereas complex simulation models are used to calculate concentrations in groundwater and surface water. Exposure characterisation is uncertain and
800 variable due to:

- Difficulties in measuring some model input parameters
- Uncertainty and variability in experimental and analytical procedures involved in measuring model input parameters
- 805 - Variability in space and time of important factors influencing pesticide behaviour (e.g. degradation and sorption behaviour, hydraulic soil properties, climatic conditions, cropping)
- Simplifications in the process descriptions included in the model

This uncertainty is not explicitly accounted for at lower tiers of the EU-registration process. Instead, a number of worst-case assumptions are
810 included in exposure assessments and a single concentration is calculated for each compartment. A safety factor is introduced when these concentrations are compared with ecotoxicologically relevant concentrations.

At higher tiers of the assessment scheme, the uncertainty and variability in exposure concentrations can be taken into account using Monte-Carlo
815 analysis. This involves:

- Analysing available data for each selected model input parameter and assigning a statistical distribution
- Sampling a large number of different values from the distribution
- Running the model for each value
- 820 - Analysing model output and generating probability distributions

From output distributions, concentrations at selected percentiles (e.g. 95th percentile concentration) or the probability of exceeding a certain threshold concentration can be derived. Due to the large number of parameters, probabilistic assessments tend to focus on those parameters which have a
825 large effect on the calculated exposure concentration (e.g. degradation and sorption properties).

Probabilistic assessments carried out by several individuals can give different results due to user subjectivity (e.g. selection of the model, initial
830 parameterisation, selection of parameters to be varied). Often, only a small number of measurements exists for each parameter and assumptions must be made on the underlying distribution. Differences in results can also be caused

835 by differences in tools used for data analysis and Monte-Carlo sampling. To ensure transparency and reproducibility of probabilistic assessments, each step should be reported in detail. Recommendations for recording this information are include in the sections below.

5.4.2 Justification for the selection of a specific exposure model

840 Often, a number of different models are available to calculate exposure concentrations in the environmental compartment of interest. The selection of a particular model can influence the result of a probabilistic modelling exercise. Simplifications in the model descriptions introduce further uncertainty into the exposure assessment and the suitability of the selected model for the situation at hand should be evaluated.

- Name of model, version and date
- Rationale behind the selection of the model
- 845 - Model description
- Suitability of the model to describe the situation at hand
- Validation status
- Important processes not accounted for in the modelling and implications for the results of the PRA

5.4.3 Detailed description of the initial parameterisation of the model

850 Details of the initial parameterisation and modelling assumptions should be given, including:

- Environmental compartments simulated
- Routes of exposure (e.g. leaching, runoff, drift, drainflow)
- 855 - Key processes (e.g. sorption, degradation in soil, plant uptake, volatilisation, degradation in water and sediment, sorption to sediment and suspended solids, bioaccumulation)
- List of relevant model input values including information on (where applicable) soil, receiving water body, climate, key parameters determining
- 860 leaching, drift, drainflow and runoff/erosion, crop, pesticide application (amount, frequency and timing; crop interception), pesticide properties, mitigation options
- Length of simulation period
- Relevance of scenario (e.g. national, regional)
- 865 - Conservatism of is the scenario

5.4.4 Sensitivity analysis for the model

870 A sensitivity analysis should be performed wherever possible to guide the selection of parameters to be included in the probabilistic assessment. Only parameters which have a significant influence on the model output should be included. Other parameters can be kept at their initial values. A sensitivity analysis specific to the modelled scenario is preferred over a generalised analysis as the sensitivity of one model parameter depends on the settings of other parameters. Details of the sensitivity analysis should include:

- Whether it is generalised or site-specific analysis
- 875 - Details of the initial modelling scenario used in the sensitivity analysis
- Details of the approach used
 - o Which parameters were varied and within which range?
 - o Parameters varied one-at-a-time or simultaneously?
 - o Parameters varied manually or automatically?
 - 880 o Relationships between parameters
 - o Which output variables were selected?
- Key results
- Relevance of the results for the current probabilistic exposure assessment

5.4.5 Justification of the inputs selected for probabilistic analysis

- 885 - Which inputs were varied and why?
- Type of variability and/or uncertainty reflected (*e.g.* spatial variability of properties within an agricultural field; uncertainty introduced by differences in experimental and analytical conditions in the laboratory)

5.4.6 Description of the Monte Carlo analysis

890 Probabilistic exposure assessment involves the analysis of available data for the parameter of interest (*e.g.* degradation rate). A statistical distribution is assigned to these data. A large number of values is sampled from the distribution and used as input data for modelling. The methodology selected by individual modellers can strongly influence the result and each step should be clearly documented:

- 895 - Type (*e.g.* uniform, normal, log-normal) and parameterisation (*e.g.* mean, standard deviation, percentiles, truncation) of the probabilistic distribution assigned to the model inputs
- Details on how the distributions were derived:
 - 900 o Methodology and results of experimental studies on which the distributions were based
 - o Relevance of the data for the questions identified in the problem formulation
 - 905 o Critical evaluation of experimental data (quality of dataset; number of measurements, mean, median, outliers, variability, statistical testing for a number of probability density distributions and justification of the decision made)
 - o Details of literature information used
- Tool used to sample from the distributions
- 910 - Number of values sampled
- Seed number:
 - o Fixed or random
 - o Number of different seed numbers tested
- Parameters varied simultaneously or individually

- 915 - Correlation between parameters accounted for in the sampling procedure. How strong and of which type (e.g. positive, negative, linear, non-linear) was the correlation? What was the basis for the assumptions made?
- Relationships between sampled values for one parameter and input values for another parameter (e.g. 1000 values sampled for parameter A; parameter B calculated as 0.5 x value for parameter A).
- 920

5.4.7 Method used to run the model

Simulation models provide a range of output variables. These include concentrations of the pesticide in different compartments (e.g. soil, water), at different locations within each compartment, and at different times within the simulation period. A large number of simulations are carried out using the sampled values for each parameter as model input and the selected output is analysed for each run. Sometimes, the output provided by the model needs to be processed, for example to calculate averages or maxima over selected periods. The handling of model input and output and running the model can be time-consuming and automated methods are available to facilitate the procedure. The methodology used for this purpose should be documented:

925

930

- Number of runs carried out
- Tool used to automatically run the model with the sampled input values
- Additional differences in model settings between the probabilistic and deterministic assessment
- 935 - Model output selected
- Method used to record output values
- Further processing or calculations (e.g. discharge of drainflow and associated pesticide into a standard ditch)

5.4.8 Evaluation of model output

Probability distributions of the output are generated. From these distributions, concentrations at selected percentiles or the probability of exceeding a certain threshold concentration can be derived. The results of a probabilistic assessment may depend on the assumptions made during the analysis and settings in the tools used for Monte Carlo sampling. Where possible, the repeatability of the assessment should be evaluated:

940

945

- Method used to analyse the output
- Detailed information and graphs for each probability distribution function
- Table with key percentiles (e.g. 50th, 90th, 95th, 99th percentile)
- 950 - Comparison with results from deterministic modelling
- Repeatability (influence of the seed number used in the random sampling)

5.4.9 Discussion points

- How much confidence can be assigned to the results?
- How large is the uncertainty associated with the model inputs varied in the assessment (e.g. type and parameterisation of the probability distribution)?
- 955

- How large is the variability in results from PRAs (e.g. arising from the selection of different seed numbers).
- How large is the uncertainty associated with input parameters which were not varied in the assessment.
- 960 - Other sources of uncertainty not accounted for in the PRA (e.g. model error, user subjectivity)
- Representativeness of the PRA

5.5 Risk characterisation

965 **5.5.1 Introduction**

In the lower tier risk assessment scheme in the EU, risks are characterised according to the criteria set out in Annex VI of Directive 91/414. Trigger values are specified for the various risk quotients (e.g. TER, HQ) for acute and chronic endpoints. In general, it is recognized in the EU ecotoxicology guidance documents, that at the higher-tiers, reducing the uncertainty factors used in this process can be achieved by generating more data (e.g. additional species testing) or through the use of semi-field or field studies. Evaluation of the appropriate degree of reduction of the uncertainty factor tends to be assessed on a case-by-case basis, depending on the type of potential risk identified and the quality of the available data.

The objective of risk characterization in probabilistic environmental risk assessment is to estimate the potential extent of effects of toxicants by comparing a distribution of exposure concentrations with either a single endpoints (e.g. for a field study) or a distribution (e.g. a species sensitivity distribution). A detailed technical discussion of the possible methods for combining exposure and effects distributions is included in WP4. Some guidance on how such analyses should be reported are included in the section below.

5.5.2 Reporting recommendations

985 Approaches to reporting probabilistic risk characterisation should include i.a. the following:

- A clear description of the method used, either referencing a peer-reviewed or standard method, or if bespoke, a transparent and detailed description of the methods used (including appropriate equations) so that the calculations can be reproduced in full by a third party.
- 990 - Description of the probabilities of exceeding the appropriate effects thresholds (as described in the problem formulation), the magnitude of the effect and its duration, the organisms likely to be at risk, and the recovery period (if known).
- 995 - A restatement of the sources of uncertainty and variability in the risk characterisation, and their potential influence on the outcome of the assessment.

5.6 Ecological Interpretation and Other Lines of Evidence

5.6.1 Introduction

1000 As well as the 'mathematical' components to PRA, the assessment should
include a discussion of the likely ecological consequences of the potential
risks identified, and also include other lines of evidence which may help with
interpretation. Some considerations for these aspects of the report are
described below.

1005 5.6.2 Ecological background

The interpretation of PRA depends very much on the regulatory framework
and the protection goals or objectives. Thus the reporting of the PRA needs
to be tailored to the needs of the regulatory mandate and applicable laws. In
risk assessment for pesticides, as for all risk assessments, there are several
1010 possible protection goals. Since the properties of ecosystems vary in time
and space, it is important to have quantifiable and broadly accepted ideas of
what constitutes an ecologically important effect, what constitutes a
sustainable ecosystem, and what protection goals are appropriate to use
(Calow 1998, Brock and Ratte 2002). In ecotoxicology, except in the case of
1015 socially-valued species, the protection goals and endpoints for risk
assessment are directed to populations and communities in their natural
environment. Overall, the intention is that populations, communities, and
ecosystem functions should be sustained in the natural environment.

To keep or restore ecosystems in a pristine condition is generally more
1020 important for certain environmental uses such as nature reserves than for
agriculture and forestry, however, it is recognized that these activities also
provide habitat for organisms valued by society. The interest of ecological risk
assessment of pesticides is to also contribute to sustainable management of
these agricultural and forestry ecosystems

1025 5.6.3 Categories of effect

Within the context of sustainability of communities and ecological functions
and services, there three general categories of undesirable effects of
substances in the environment. These relate to ecosystem structure, function,
and aesthetic value to humans. Structure of an ecosystem is a combination of
1030 which organisms are present and how many there are. Function is basically
what the organisms do or what services that perform in the ecosystem. The
choice of protection goals (and by extension, assessment endpoints) may be
based on ecological knowledge or on human value judgements. For example,
there is a general tendency to select functional protection goals and
1035 assessment endpoints when the populations of the potentially affected
organisms may change rapidly for natural reasons, recover from effects
rapidly, or are difficult to characterize. Examples of these are bacteria and
fungi in soil and sediment or algae in aquatic systems. In populations that
have lower recovery potential or are easily characterized, there is a tendency
1040 to use structural protection goals such as absolute population numbers.
Examples of these are birds, fish, or terrestrial mammals. Choices of
protection goals may also be determined on the basis of value judgments, for
example, if the risky activity brings great benefits, structural changes may be

- 1045 tolerated if functions are unaffected. These three ecological response categories are discussed below (modified from Brock and Ratte 2002).
- 1050 Changes in structure are generally expressed in terms of overall species richness and densities, quantified as the number of taxa, or diversity indices. Changes in structure blend into functions in ecosystems when they relate to populations of keystone important ecological species that play a major role in ecosystem performance, productivity, stability, and resilience. These include species that are critical in trophic cascades such as piscivorous fish and large herbivores or species which are supply ecological structures or habitat such as rooted submerged macrophytes. A special case for protecting structure are those species protected by law and endangered species.
- 1055 Changes in ecosystem functioning and functionality are expressed as negative effects on biogeochemical cycles and energy flow. Examples are oxygen depletion, changes in primary productivity, and changes in the processing of nutrients such as mineralization of organic matter or fixation of atmospheric nitrogen.
- 1060 A third category relates to how humans value the aesthetic properties or appearance of the ecosystem/landscape. Examples are disappearance of species with a popular appeal such as dragonflies, songbirds and butterflies, noticeable mortality of individual vertebrates or other valued ecosystem components, unpleasant taste or odor problems and symptoms of reduced ecosystem functions, such as algal blooms in lakes and clarity of water.
- 1065

5.6.4 Suggestions for good reporting practice for PRA

These suggestions are based on the premise that the output from the will be a probabilistically derived estimate of the likelihood of adverse effects. The output should have the following characteristics:

- 1070
- The intensity of the effect and its variation is known or predicted with respect to:
 - Types of environments or habitats affected,
 - Temporality, and
 - Spatial extent of the effects.
- 1075
- The effects are segregated by class of organism and the function of these organisms in the ecosystem and their recovery potential is known or predicted.
 - The likelihood of affecting specially protected areas is known or predicted.
 - The likelihood of affecting socially important (endangered) organisms is known or predicted.
- 1080

These data can then be used to classify and apportion the effects into the categories shown in Table 2.

Table 2: Criteria for classifying know or predicted effects of pesticides in the ecosystem.

Class	Criterion^a	Description
1	Effect not likely	No statistically significant effects (< 5% probability of any responses) known or predicted as result of the use of the pesticide.
2	Slight effect	Known or predicted effects slight or transient (> 5% < 20% probability of occurrence either spatially or temporally) with recovery occurring within 2-3 or generations of the affected organisms or in less than a season (until the following spring or normal use period of pesticides for pest management purposes).
3	Pronounced but restricted short-term effect	Known or predicted effects pronounced but transient (> 20% < 50% probability of occurrence either spatially or temporally) with recovery occurring within 2-3 or generations of the affected organisms or in less than a season.
4	Pronounced and widespread short-term effect	Known or predicted effects pronounced but transient (> 50% probability of occurrence either spatially or temporally) with recovery occurring within 2-3 or generations of the affected organisms or in less than a season.
5	Pronounced long-term effect	Known or predicted effects pronounced (> 50% probability of occurrence either spatially or temporally) with recovery occurring in more than 1 season.
^a Effects may be structural, functional, or aesthetic.		

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US-EPA 2001. Risk Assessment Guidance for Superfund: Volume III – Part A, Process for Conducting Probabilistic Risk Assessment. Available at www.epa.gov/superfund/RAGS3A/index.htm.

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1135 **APPENDIX 1**

Table F-1 (Example of a Generic Checklist for Reviewers) from the US-EPA Risk Assessment Guidance for Superfund, Volume 3 Part A – Process for Conducting Probabilistic Risk Assessment (US-EPA 2001).

Focal Point	Evaluation criterion
Objectives and Purpose	
Assessment endpoints	Are the human and/or ecological assessment endpoints clearly stated and consistent with the workplan?
Benefits	Are the rationales for, and the benefits of, performing the PRA clearly stated and consistent with the workplan?
Site conceptual model	Is there a description or graphic representation of the receptors and pathways considered in the assessment? Has the PRA addressed each of the pathways for completeness (e.g., sources, release mechanisms, transport media, route of entry, receptor)?
Separation of variability and uncertainty	What is the modelling strategy for separating variability and uncertainty in the PRA? Is this consistent with the assessment endpoints?
Model structure and computational mechanics	
Flow chart	Is a diagram of the computational sequence provided so that the pathways of inputs and outputs and data capture can be understood and easily communicated?
1-D MCA, 2-D MCA	Is a 1-D MCA or 2-D MCA being implemented in the PRA? What is represented by either or both dimensions?
Algorithms	Are all algorithms used in the model documented in adequate detail to recreate the analysis?
Integration	Are the algorithms used in numerical integration identified and documented?
Dimensional analysis	Has a unit analysis been conducted to ensure that all equations balance dimensionally?
Random number generator	What random number generator is used in model computations? Is it robust enough? What reseeding approach is used to minimize repeated sequences?
Input distributions and assumptions	
Variability and uncertainty	Is there a clear distinction and segregation of distributions intended to represent variability from distributions intended to represent uncertainty?
Data sources	Are the data or analysis sources used in developing or selecting the distributions documented and appropriate for the site?
Distribution forms	Are the analyses used to estimate the distribution parameters adequately documented?
Distribution parameters	Are the analyses used to estimate the distribution parameters adequately documented?
Distribution tails	Do the estimation methods precisely depict the tails of the input distributions; how was this evaluated? Is there sufficient

	information to depict tails for empirical distributions? Are these estimated as exponential tails with bounding values?
Truncations	Are any input distributions truncated? Do these truncations make sense? Should truncations be applied to any of the distributions?
Concentration term	Is the derivation of a point estimate or distribution for the concentration term adequately documented? Is sufficient information provided to enable the reviewer to recreate the concentration term?
Variable correlations	Have variable independence and correlations been addressed? Has the methodology for representing variable correlations in the model been documented and is it reasonable in terms of the variables, the site and the statistical approach?
Time step	Has the basis for the time step used in the model been documented? Is a single time step used, or do the variables have different time steps? Are the time steps conceptually reasonable for the variables; for the site? Has the time step been evaluated in the sensitivity analysis?
Sensitivity analysis	Has a sensitivity analysis been conducted? Are the methods used in the analysis statistically valid? What did the analysis reveal about uncertainties in the assessment and the relative contribution of input variables to uncertainty?
Results of modelling	
Completeness	Are all the exposure routes identified in the site conceptual model and workplan addressed in the model results? Has the PRA fulfilled the objectives and satisfied the purpose stated in the workplan?
Point estimate calculation	Has a point estimate calculation using mean or median values of the input distribution been performed? How do these results compare with the central tendencies calculated with the probabilistic model? How do the reasonable maximum exposure (RME) estimates compare? Have the similarities or differences between risk estimates from the point estimate and probabilistic approaches been adequately addressed?
Stability of output tails	Has the stability of the high-end of the risk distribution been adequately evaluated? How stable are the estimated tails (in quantitative terms)? Is this level of stability adequate to support the risk management decisions that the model is intended to support?
Significant figures	Is the number of significant figures used in the output reasonable and consistent with model uncertainty?
Limitations	Are the strengths and weaknesses of the PRA methodology and limitations of the results for decision making clearly presented?
Clarity	Are the results and conclusions clearly presented and consistent with model output?
Graphics	Are there graphics included that show both the risk distribution and PRA results?

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