EUFRAM

Concerted action to develop a European Framework for probabilistic risk assessment of the environmental impacts of pesticides[1]

Work Package 6

PRELIMINARY PAPER ON REPORTING PROBABILISTIC ASSESSMENTS

June 2003

Steve Maund (Syngenta)[2], Pamela Byrne (PCS, Ireland), Paul van den Brink (Alterra, The Netherlands), Igor Dubus (Cranfield University, UK), Joanna Jaworska (Procter & Gamble, Belgium), Leo Posthuma (RIVM, The Netherlands), Keith Solomon (University of Guelph, Canada).

1 CONTENTS

1 Contents....................1
2 Executive Summary....................2
3 Background....................2
4 Detailed Objectives (from EUFRAM project specification)....................3
5 Initial Review of Existing Guidance for Reporting Risk Assessments....................3
6 Synthesis of the Existing Recommendations – Framework for Further Development in WP6....................7
7 Proposed Way Forward for Dealing with Issues....................8
8 Timelines....................9
9 References....................9
10 APPENDIX 1 – Discussion Issues for Meeting 1....................11

[1] EUFRAM is coordinated by CSL (www.csl.gov.uk) and supported by European Commission's 5th Framework Programme (www.cordis.lu), contract number QLK5 - CT 2002 01346. Further information and news about EUFRAM is provided at www.eufram.com.
[2] Work Package leader.

2 EXECUTIVE SUMMARY

This paper describes the planned activities of EUFRAM WP6 'Reporting of Probabilistic Risk Assessment'. The existing guidance on the reporting of probabilistic risk assessment will be reviewed. There are several source documents from the US-EPA and European Commission which provide a valuable basis for this. A glossary of terms to be used in probabilistic risk assessment will be developed, based on a number of existing sources. Finally, a framework for reporting PRA will be developed. This will include sections as follows: Executive Summary; Problem Formulation; Effects Characterization; Exposure Characterization; Risk Characterization; Interpretation in the Context of Regulation; Handling of Large Data Sets. The first draft of the chapter will be circulated to the EUFRAM group by end September 2003.

3 BACKGROUND

The use of probabilistic risk assessment (PRA) approaches to assess the potential risks from the use of plant protection products (PPPs) in the environment has attracted increasing interest from regulatory authorities and the PPP industry over recent years. The Aquatic Risk Mitigation Dialog Group in the USA identified PRA as an option for refining risk assessment (ARAMDG, 1994). The United States Environmental Protection Agency (US-EPA) Science Advisory Panel (SAP) made the recommendation in 1996 that the US-EPA Office of Pesticide Programs (OPP) move towards probabilistic approaches. Whilst the SAP endorsed the existing deterministic approach as a suitable screening tool, they suggested that a move towards PRA at higher tiers would allow a better understanding of the potential risks, and also perhaps improve risk-benefit decision-making. As result of this recommendation, OPP established the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) to develop guidance on the development of PRA for aquatic and terrestrial PPP risk assessment methods.

In the EU, interest in PRA approaches has also been developing over the last five years. As part of the Higher-tier Aquatic Risk Assessment for Pesticides Workshop (HARAP, Campbell et al., 1998), the future use of PRA was recommended as a suitable approach for developing higher-tier aquatic effects assessments. More recently, in the EU ecotoxicology aquatic, terrestrial, and bird and mammal Guidance Documents (SANCO/3268; SANCO/4145; SANCO/10329) recommendations (with certain caveats) are made for the future implementation of PRA into the EU evaluation procedure. The Forum for the Coordination of Pesticide Fate Models and their Use (FOCUS), has in its development of guidance for calculating predicted environmental concentrations for pesticides in surface water (Linders et al., 2002) acknowledged that at the higher tiers (Step 4), probabilistic descriptions of potential exposure concentrations may be a suitable means of refining exposure assessments.

In 2001, the European Commission sponsored a workshop on PRA approaches for pesticides in Europe (EUPRA, Hart, 2001). This workshop reviewed the current state-of-the-art of PRA for pesticides and made recommendations about how the science should be further developed. As part of the process, the strengths and weaknesses of PRA were evaluated. One weakness identified was that the use of 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 will review existing recommendations, where they exist, and develop through discussion with the experts involved in the current EUFRAM project begin to a set of recommended best practices to be used in the future.

4 DETAILED OBJECTIVES (FROM EUFRAM PROJECT SPECIFICATION)

The WP on reporting of PRA will:

- review relevant existing guidance on the reporting of probabilistic pesticide assessments and propose a set of key principles, suitable for use in the EU regulatory context, that will ensure clarity and ensure probabilistic assessments are open to full critical evaluation both in official peer review and by other interested parties.
- build on previous work towards a harmonised terminology for risk assessment, e.g. by the EU’s Scientific Steering Committee, and draw on existing publications on how to report Monte Carlo studies.
- identify key issues of reporting and terminology for evaluation and discussion in the next phase of the project.

5 INITIAL 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 assessment. Rather, the data required for registration purposes are submitted to the US-EPA, and the staff at the OPP conduct their own evaluation of the compound according to internal procedures. In practice, however, most companies do submit their own 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 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. The registrant is required to 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. 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.

Whilst at this time, there are no officially adopted reporting requirements either for deterministic (DRA) or probabilistic risk assessments, 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.

5.1 ECOFRAM (draft report 2000)

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

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:

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.

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 be included.

The report also states that:

“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.”

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 in Tier 1	Specific details from worst case	Worst case and options
Representativeness	Worst label case	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 by life cycle	pre-specified for taxa, annual, 30 day or seasonal by life cycle
% uncertainty	Currently not applicable	Probability of exposure available from PRZM-EXAMS	Other information as available
Medium	Water col. (sediment desired)	Water col., sediment	Water, sediment, other water body compartments
Censoring threshold	None	Standard toxicity values and/or LOEC/NOEL	Various
Taxa/species	Fish/Aquatic Invert	warm/cold water fish, benthic invert, water col. Invert, marine fish/invert, non-target aquat. plant	Warm/cold water fish, benthic invert, water col. Invert, marine fish/invert, non-target aquat. Plant
Duration	Instantaneous, 21, 60 or 90day	Instant, 24, 48, 96 hr, 21, 60, 90 d	Tier 2 plus intervals as needed
Recovery period	Ignored	from RADAR	from RADAR

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

In October 2000, the Scientific Steering Committee of DG SANCO issued an opinion of 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 SCC 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.

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

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

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

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:

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.
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.
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.

5.3 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. Whilst mostly focused on discussions of appropriate Monte Carlo methodologies, this document contains some useful 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.

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.

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.

6 SYNTHESIS OF THE EXISTING RECOMMENDATIONS – FRAMEWORK FOR FURTHER DEVELOPMENT IN WP6.

The existing recommendations for reporting DRA are somewhat limited, and specific guidance for PRA, even more so. However, from the available reports which have been reviewed and using the existing recommendations and guidance summarised above, some common themes and challenges in reporting probabilistic risk assessment can be developed.

1. General issues:

- Terminology and definitions of terms used.
- Editorial formats
- Use of tables and figures and other presentation materials
- Methods of effectively reporting large data sets (use of IT tools. e.g. thumbnails, hyperlinks, etc).
- Development of best-practice recommendations for reporting (i.e. something like a template)

2. Areas where specific guidance and recommendations are needed for reporting PRAs:

- Problem formulation
- Exposure characterisation

- Effects characterisation
- Risk characterisation

3. Other issues to be tackled:

- Use of case studies to exemplify reporting approaches
- Potential overlaps with WP3 (when to use PRA, definition of types of outputs needed from PRAs by regulators) and WP6 (guidance on how to communicate the outputs of PRAs).
- Collaboration with WP4 (uncertainty analysis). Effective expression of uncertainty in the assessment is probably a key issue. We need to make sure that we keep in touch with developments in WP4.

7 PROPOSED WAY FORWARD FOR DEALING WITH ISSUES

At the first project meeting on the basis of the discussion points included in Appendix 1, the overall structure of the chapter was agreed by the project team. This will consist of three main parts:

1. A review of existing PRA and DRA reporting guidance
2. Development of a harmonized glossary of terminology to be used in reporting PRA, building on the draft developed by the SETAC Pellston workshop
3. Development of a framework for reporting PRAs.

The work for each of these areas will be developed as follows:

1. Review of existing guidance

Building on this draft paper, the existing recommendations (e.g. ECOFRAM, SSC guidance on harmonization of risk assessment, EPA risk assessment framework, etc) will be further reviewed and developed into a position of the state of the art. Potential similarities and differences between reporting DRA and PRA will be evaluated.

Action: Steve Maund to develop further

2. Development of glossary

Using the available definitions, building principally on the SETAC Pellston glossary, the Workgroup will develop a glossary of terms for reporting PRA. This will be added to the EUFRAM website so that members of other work packages can comment on the proposals, and to facilitate revisions.

Actions:

Andy Hart to contact SETAC to ask for permission to use the data

Keith Solomon and Pamela Byrne to develop and liaise with Joe Crocker regarding the web site.

3. Development of reporting framework

The draft framework will be developed using the areas outlined below. For each area, a check list of what should be included in the report will be developed. WP members will also develop recommendations for good reporting practice, including examples of presentation materials (e.g. tables, graphs, summary statistics) that will facilitate communication of the data.

- Executive Summary (check what is available from EPA via Ingrid Sunzenauer) – Andy Hart to liaise with Ingrid, and Pamela Byrne to develop
- Problem formulation – Andy Hart and Igor Dubus to develop
- Effects characterization – Hector Galicia to develop
- Exposure characterization – Igor Dubus to develop
- Risk characterization – Leo Posthuma to develop
- Interpretation in the context of regulation – Keith Solomon to develop
- Handling of large data sets – Steve Maund to develop

8 TIMELINES

- The next draft of the chapter will be prepared ahead of the WP8 meeting in mid October.
- WP members will complete their contributions to the revised draft by the end of August.
- They will be compiled by SJM and will be circulated to the group for comments by mid September.
- SJM will then revise the draft accordingly, and circulate to the whole project team by end of September to allow review ahead of the WP8 meeting.
- Subsequent to the WP8 meeting, the draft will be revised. Timelines for this will be agreed after the meeting.

9 REFERENCES

Campbell, P.J., Arnold, D.J.S, Brock, T.C.M., Grandy, N.J., Heger, W., Heimbach, F., Maund, S.J., Streloke, M, 1999. Guidance document on higher-tier aquatic risk assessment for pesticides (HARAP). SETAC-Europe, Brussels, 179pp.

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

ECOFRAM. 2000. Guidance Document on Risk Assessment Methods for Aquatic Ecological Risk Assessment. Draft of June 2000.

Hart A (ed). 2001. Probabilistic risk assessment for pesticides in Europe: Implementation and Research Needs. Report of the European workshop on Probabilistic Risk Assessment for the Environmental Impacts of Plant Protection Products (EUPRA).

Linders, J., Adriaanse, P., Allen, R., Capri, E., Gouy, V., Hollis, J., Jarvis, N., Klein, M., Lolos, P., Maier, W.-M., Maund, S., Pais, C., Russell, M., Smeets, L., Teixeira, J.-L., Vizantinopoulos, S., Yon, D., 2002. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. SANCO/4802/2001-rev.1 (June 2002), 228pp

SANCO/4145/2000. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC.

SANCO/10329/2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC.

SANCO/3268/2001. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC

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

10 APPENDIX 1 – DISCUSSION ISSUES FOR MEETING 1

10.1 General issues

10.1.1 Terminology and definitions of terms used.

This area is potentially a mine-field, and re-inventing the wheel should be avoided as far as possible. Before we meet, please could all WP members review the Glossary of Terms included in the EC First Report on the Harmonisation of Risk Assessment Procedures, Appendix 1 (http://europa.eu.int/comm/food/sc/scc/out82_en.html)? I suggest that we use this as a starting point. It is quite broad, and I expect we will also need to decide whether we need to go into more detail. Does anyone have any other suggestions for references which have terminology which we could adopt? There is an OECD Monograph on risk assessment that has definitions that we could potentially use, but it is perhaps a little dated.

10.1.2 Editorial formats

I'm not sure how deeply we need to get into this. I certainly think we should avoid the minutae of font size, spacing, etc. etc. Any thoughts on whether this is something we should tackle, or just leave for coverage in a proposed template (see below)?

10.1.3 Use of tables and figures and other presentation materials

We should discuss how best to summarise the inputs and outputs of the PRA with effective use of tables and figures. Again this will overlap with WP8 and WP3. It might be a good idea to start compiling examples of presentation materials that the work group members think have been effective. Could all WP members bring along examples of any presentation materials that they think could get us started with this?

10.1.4 Methods of effectively reporting large data sets (use of IT tools. e.g. thumbnails, hyperlinks, etc)

One of the key challenges in reporting PRAs will be how to most effectively report the often large datasets that are associated with these sorts of assessments. For example, what is the best way of capturing and enabling relatively easy access to something like a 36 year run of PRZM/EXAMs calculations. It may be that some of the available IT tools like pdf thumbnails, and the effective use of hyperlinks in reports (i.e. linking references in the main body of the text to the detailed data-table in the appendix) will facilitate this. There is also the more general question of paper versus electronic presentation.

10.2 Development of best-practice recommendations for reporting (i.e. something like a template)

This is an area where we will have to work in close cooperation with WP8 (case studies). I think that we should consider whether it would be sensible to develop some sort of template which could be used for reporting PRAs. Part of the problem here will be that the assessments from different discipline areas are likely to be quite different from each other, depending on what the aim of the assessment was. Perhaps we can pull out some general themes from the different areas?

10.3 Areas where specific technical guidance is needed for reporting PRAs.

I see this as the real nitty-gritty of what our work group should be developing. I think we need to break this up into subsections and allocate people to work on them. Some proposals for the areas to be covered by this below:

10.3.1 Problem formulation

The start of the report of the risk assessment should set out in very clear terms the issues that it is trying to address. This should include:

- A clear description of the potential concern identified at the lower tier of the assessment.
- Discussion of the factors in the lower tier assessment where further evaluation of the inputs and/or methods used could help to refine the risk assessment.
- Statement of the purpose and scope of the assessment
- Definition of the assessment questions and endpoints
- Definition of the spatial and temporal scale to be covered

We should discuss and refine these sections, and perhaps generate some examples of the sorts of things that would be expected here. Again, examples from the case studies group will help.

10.3.2 Exposure characterisation

We need to develop a list of recommended reporting criteria for both the inputs and outputs of the exposure assessment. This should include:

- A description of the methods that are used to refine the exposure assessment (e.g. inclusion of a range of inputs parameters (different DT50s, Kocs,etc), inclusion of spatial and temporal variation (e.g. time spent in crop, proximity of environment of concern to area of application, weather data), inclusion of any uncertainty analysis).
- A description of and rationale for the data used in the assessment. This could potentially be a very long list, so we need to agree what sort of level of detail is needed. There should also be a discussion of the uncertainty of the data used in the assessment (e.g. what was the variability of measurements, how robust were the data – strong or weak data sets, how representative are the data for the questions identified in the problem

formulation, other factors that could influence the outcome of the assessment).

· A clear description of any models that have been used, including if appropriate, clear description of the key equations on which the model is based, and any assumptions that have been made.

· A description of the sensitivities of the model.

· A detailed discussion of the statistical methods that have been used to process the data. For example, if a Monte Carlo analysis has been conducted to generate exposure distributions, details of the methods and software used should be provided (EPA guidance described above has much of this covered already).

· Discussion of the sensitivity of the exposure calculation to the inputs and any assumptions that are made. We need to discuss to what sensitivity analyses should be conducted and reported.

10.3.3 Effects characterisation

A similar list to the exposure characterisation needs to be developed.

· A description of the methods that are used to refine the effects assessment (e.g. inclusion of a range of inputs parameters, inclusion of spatial and temporal variation, inclusion of any uncertainty analysis). Clear identification of the endpoints of concern, and perhaps some discussion of their ecological relevance.

· A description of and rationale for the data used in the assessment. Uncertainty of the data used in the assessment (e.g. what was the variability of measurements, how robust were the data – strong or weak data sets, how representative are the data for the questions identified in the problem formulation, other factors that could influence the outcome of the assessment).

· A clear description of any models that have been used, including if appropriate, clear description of the key equations on which the model is based, and any assumptions that have been made.

· A description of the sensitivities of the model.

· A detailed discussion of the statistical methods that have been used to process the data. For example, if a Monte Carlo analysis has been conducted to generate exposure distributions, details of the methods and software used should be provided (EPA guidance described above has much of this covered already).

· Discussion of the sensitivity of the effects endpoints and any assumptions that are made.

10.3.4 Risk characterisation

The risk characterisation will describe how the exposure and effects distributions have been combined, and will then summarise the potential concerns identified. Points to cover include:

- The method used for combining the exposure and effect distributions, including equations, software, etc.

- A description of the potential risks likely to accrue from the use of the product. This should cover the likelihood of certain magnitude of effects occurringm their potential duration, a description of the sorts of organisms that would be potentially affected, and an indication of the likely recovery period.

- The uncertainty of the assessment should also be described.

10.4 Other issues to be tackled

- Use of case studies to exemplify reporting approaches

- Potential overlaps with WP3 (when to use PRA, definition of types of outputs needed from PRAs by regulators) and WP6 (guidance on how to communicate the outputs of PRAs).

- Collaboration with WP4 (uncertainty analysis). Effective expression of uncertainty in the assessment is probably a key issue. We need to make sure that we keep in touch with developments in WP4.