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QUALITY OF LIFE AND MANAGEMENT OF LIVING RESOURCES

EUFRAM

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

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DETAILED REPORTS ON

COMMUNICATION, SOFTWARE, DATABASES & DATA-SHARING

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LIST OF CONTENTS FOR VOLUME 3

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EUFRAM

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

Work Package 7

Communicating the results of probabilistic risk assessments[2]

Version 3, December 2006

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Contents

1 Introduction

To date, the primary focus of research into risk communication has *not* been on the development of dialogue between risk managers and risk assessors, but rather between expert communities and the general public. However, the regulatory adoption of novel risk assessment techniques is contingent on their acceptance by decision makers, which in turn depends on the development of effective communication strategies between assessors and managers. This is likely to become even more important as recent revision of the process of risk analysis has increased the functional, and to some extent structural, separation of risk assessment and risk management (Houghton *et al.*, 2006). As a consequence, there is increased emphasis on the need to develop effective communication between risk assessors and risk managers regarding the interpretation and implications of probabilistic risk assessment approaches. Different experts involved with the risk analysis process may have different expertise bases, and thus bring different perspectives regarding the process and implications of risk assessments. This may be particularly relevant under circumstances where novel risk assessment methodologies are being introduced, and where there may be a need to use different approaches to interpreting the risk assessment data thus obtained. The increased complexity of novel approaches to risk assessment, as well as rapid advances in the field, may have direct consequences for risk analysis as decision-makers may not be trained in technical aspects and interpretation of probabilistic assessments. As a consequence, it becomes more important to develop effective communication from assessors to decision makers, and indeed all interested stakeholders, about the methodologies applied, and interpretation of results (Apostolakis, 1990; Thompson & Bloom, 2000; Thompson & Graham, 1996).

It is, of course, possible that decision-makers are affected by their own risk judgements and biases when considering interpretations of probabilistic data. This process of influence is not dissimilar to that which influences lay understandings of risk. Thus a useful first step in optimising assessor-manager communication may be to examine the principals that guide risk communication in general. Potentially influential factors will be considered in depth in the next section.

2 Principles of risk communication

In general, when individuals want information about a particular hazard, they prefer a clear message from technical experts regarding the potential risks, together with the associated uncertainties, and cross-population variabilities in vulnerabilities. This must include the nature and extent of *disagreements* between different experts (Denis, 2001). The public need this information from the policy community, in an understandable and intelligible format. Decision-makers must themselves be aware of uncertainties and variabilities associated with risk assessments, and should therefore have an interest in supporting research to further understand and reduce uncertainties (Krebs, 2001). A necessary first step to implementing stakeholder debate about risk is to develop effective communication between risk assessors and risk managers.

Risk assessments are often difficult to understand, and are inherently laden with assumptions. They are also the focus of controversy within the community of risk assessment practitioners, where there may be lack of consensus regarding which assessment methods to apply, as well as how to interpret data arising from the assessment. Thus communication about risk assessment to both decision-makers and other stakeholders, including the general public, is laden with difficulties. As a consequence, negative stakeholder and public reactions to regulatory activities, may compromise societal confidence in the process of risk analysis *per se* (Jensen & Sandoe, 2002).

The aim of this paper is to briefly review research into communication about the application and interpretation of novel risk assessment techniques (in particular applied to risk assessment of pesticides), and to identify some key challenges specifically associated with the communication of probabilistic risk assessment and uncertainty to decision-makers. Implications for communication with other stakeholders and the general public will also be briefly discussed. Recommendations will be developed regarding best practice in communication of probabilistic risk assessments, based on case studies provided by the EUFRAM project and beyond. Proof of principles of these recommendations will be provided by applying three case studies to analysis the effectiveness of communication about probabilistic methods to end users and decision-makers within the EUFRAM project

3 Research on risk perception and communication

There is an extensive literature on risk perception and risk communication. For the purposes of the current discussion the main outcomes of research in this area will be summarized (for more extensive reviews, see Bier, 2001; Fischhoff, 1995; Schütz *et al.*, 2000; Slovic, 2000). The way risk is *perceived* by people has been shown to be an important determinant of public responses to different hazards (Fife-Schaw & Rowe, 2000; Frewer *et al.*, 1997; Verbeke, 2001) and possible unintended negative environmental and health impacts of technology (Levidow & Marris). Very generally, an individual’s response to different risks is determined by psychological factors. These include, for example, whether an individual is exposed to the risk on a voluntary basis, whether a risk is controllable by the person who is exposed to the risk in question, and the extent to which the hazard is perceived to be unnatural. These types of factors influence peoples fear and dread of different potential hazards.

Many potential hazards are, at the same time, associated with benefits both for individuals and society. An example includes the use of pesticides in the agri-food sector, where society perceives that there is a trade-off between increased food security and potentially negative environmental impact.

One conclusion is that the process of communication between all actors in the debate about risk needs to be optimised, and that this communication process needs to be interactive. Such a discussion between different stakeholders requires effective communication with end-users and other interested stakeholders about the outcome and interpretation of risk assessments as a starting point.

It is useful to consider particular challenges associated with communicating probabilistic risk assessments and their interpretation, in order to develop a set of practical recommendations regarding best practice in communication.

4 Challenges associated with communicating probabilistic risk estimates

Some specific challenges can be identified which specifically relate to communication of probabilistic risk assessments. For example, one distinction that needs to be made when developing an effective communication framework within which to optimise the communication of uncertainty is that between *outcome* uncertainty and *assessment* uncertainty. Outcome uncertainty refers to understanding *"what might actually happen and with what probability*", and assessment uncertainty "*to what extent are the results of the analysis likely to change with additional information*" (Brown & Ulvilla, 1987). These authors note that *outcome uncertainty* is the only communication issue relevant during a *crisis* where immediate responses are needed. Communication about *assessment uncertainty* is more relevant when there are sufficient time and resources available to facilitate the collection of additional data (Brown & Ulvilla, 1987). From this, it is implied that the information requirements of decision-makers vary according to the immediate time pressures associated with an incident or risk assessment. It is important to communicate information about the differences between assessment uncertainty and outcome uncertainty, as they have different implications for decision-makers, including resource allocation.

Communicators must distinguish between *risk uncertainty* and *risk variability*. Under conditions of risk variability, the risk varies *across* a population but the distribution is well known. Understanding variability may also have implications for the allocation of resources to risk mitigation activities, and this must also be communicated (Morgan & Henrion, 1990). Thompson (2002) notes that *differences in communication needs* between uncertainty and variability, as well as what these mean in terms of policy development.

5 Key principles for communicating risk estimates to decision-makers in the EU regulatory context

The American Industrial Health Council has provided a report summarising what decision-makers ask for in terms of risk information (Table I). This is, of course, of direct relevance to the development of an effective framework for the communication of probabilistic risk assessments.

Table I- What do decision-makers ask for in terms of risk information?

- The presentation of the risk assessment must be comprehensible and understandable
- The applicability of the assessment for public policy decision-making should be clearly stated
- The presentation must be credible and fully defensible
- The risk assessment report should contain a clear and relatively brief summary that includes balanced treatment of all relevant contentious issues
- The basis for the choice of critical assumptions should be described along with discussion and resolution of science issues as far as possible
- Conclusions should be drawn so as to be relevant to the specific risk management policy framework

American Industrial Health Council, 1989, (reported in Bier, 2001)

Reliability of information is likely to be a key issue to decision-makers and, indeed, the public, and thus it is necessary to *communicate the extent to which a particular assessment is reliable or not*. In particular, it is important to communicate sources and magnitudes of *uncertainty* associated with a particular hazard (National Research Council, 1994). It is also useful to provide information to decision makers regarding the most likely public responses to the various decision options under consideration, as well as emerging hazards which may also be associated with high levels of uncertainty. In some cases this may implicate specific research focusing on these issues. Decision-makers must also take public responses to risk uncertainty into consideration, and this is therefore considered in the following section.

Communication between risk decision-makers and risk assessors should also be interactive, in order to ensure that which risks are assessed, and how the assessment process is conducted, aligns with the information needs of risk managers (Bier, 2001).

6 Key principles for communicating risk estimates to the public, and potential public responses

There is, at the present time, increasing societal and political pressure directed towards increased transparency in risk management practices. For this reason, the uncertainties associated with technical risk assessments, upon which risk management decisions are founded, need to be explicitly communicated to all end-users and stakeholders, including the public (Frewer *et al.*, 2002). Public response to communication of uncertainty may also need to be taken into account by decision-makers.

In the past, it has been assumed by experts that the public are unable to conceptualise the scientific uncertainties associated with technical risk estimates, and, moreover, that providing them with this information will have very negative effects on public risk perceptions and related attitudes. This assumption may not be well founded. The effects of various uncertainty conditions, reasons for uncertainty, and risk magnitudes, on lay people's understanding of technical risk estimates have been investigated (Johnson & Slovic, 1995; Johnson & Slovic, 1998). 20% of the sample had difficulties with the concept of uncertainty *per se*, and were unable to distinguish if a reported risk figure was a point estimate or an interval estimate. For some of the remaining respondents, discussion of uncertainty appeared to signal more *honesty* on the part of the communicators, although discussion of uncertainty resulted in lower *competence* ratings of the competent authorities. *Graphical* presentation of uncertainty produced higher *comprehensibility* ratings, but lower *trustworthiness* ratings.

Different types of uncertainty have been found to be important to the general public (Frewer *et al.*, 2003). For example, the public appear to discriminate between *lack of knowledge*, (for example, lack of scientific information regarding a specific risk, or conflicting scientific information or opinion), uncertainty about the *potential impact or extent* of a particular hazard, and the perceived need for *further research to be conducted in order to reduce the uncertainty*. Perceptions that regulatory institutions were *withholding uncertainty information from the public* had a negative impact on public trust in those institutions. The public was more accepting of uncertainty resulting from inadequacies in scientific process *per se* compared to uncertainty associated with the failure of institutions to reduce scientific uncertainty through conducting appropriate empirical investigation (see also van Kleef *et al.*, 2006).

There is ample evidence that decision-making associated with probabilistic risk assessment is not easy for non-experts, and difficulties in interpreting outputs may extend to a range of end-user communities. For example, individuals appear to have difficulties in interpreting low probabilities when making decisions (Kunreuther *et al.*, 2001), and few people tend to seek out probabilistic information under conditions of uncertainty (Huber *et al.*, 1997). Other heuristics, (cognitive decision rules or judgemental biases), may exert influence on interpretation, although it is not known how different individuals, or indeed people with different levels of expertise, are influenced by these (Kahneman *et al.*, 1982). Example of heuristics include *the availability heuristic*, where the easier people experience the recollection of a past event, the greater they estimate the probability of the event occurring in the future, and *representativeness*, where the likelihood of an event is estimated according to the similarity to the class of events of which it is seen as an example.

Public confidence can only be developed if communication from decision-makers explicitly addresses communication of uncertainty and variability. Difficulties in developing a communication strategy, and concerns about public responses to this information, should not be used to prevent best practice in communication being developed, as the information will be in the public domain anyway. Effective communication with the public is contingent on the development of effective communication between assessors and managers, and other interested stakeholders and end-users, regarding the interpretation of probabilistic risk assessment.

7 Developing a strategy for effective communication of probabilistic risk assessments

The principals of *intelligibility*, *applicability*, *credibility*, *balanced treatment*, *critical assumptions*, and the specific risk management *policy framework* in which the communication activity are embedded must be addressed if effective communication strategies between assessors and regulators are to be developed. In particular, where data may be difficult to interpret, the use of a narrative approach, in addition to figures and tables, is invaluable. The presentation of both *best* and *worst* cases may facilitate presentation of a balanced interpretation of data. Explicit interpretation of the outputs in terms of what they mean in terms of environmental impact may be helpful in identifying interpretation in a policy context. For example, consider a risk assessment dealing with the “safe” aquatic concentration of Carbaryl. A narrative approach may facilitate interpretation of what the probabilistic risk assessment as follows.

> “The *risk* to aquatic invertebrates from the use of Carbaryl is X%. This means that *water concentrations of Carbaryl above a safe level can occur in every (100/X)th case.*”

If the “*realistic worst case*” aquatic exposure concentration is applied:

> “The risk to aquatic invertebrates from the use of Carbaryl is X%. This means that *there can be Carbaryl effects on X% of all aquatic species*.”

From this, the narrative approach might adopt the consequences of a fully probabilistic risk assessment. “The risk to aquatic invertebrates from the use of Carbaryl is X%. This means that in every (100/X)th case water concentrations of Carbaryl can be high enough *to result in effects on Y% of all aquatic species*”. What is also needed here, however, is a full explanation of what this means for the local ecology, how serious the exposure to Carbaryl actually was, and whether there was any information in the assessment with relevance for the development of environmental policy.

The credibility of the risk assessment process must be to be demonstrated – the inclusion of a ”*positive control*” may facilitate this process when communicating with decision makers. This does, however, only need to be demonstrated once in practice, and should not be included in every risk assessment.

8 Study 1: Case Study. Risk to aquatic organisms arising from exposure to ‘herburon’ *via* spray drift

The aim of this case study is to demonstrate how probabilistic risk assessment might be undertaken using only baseline fate and effects data. The study was conducted using a hypothetical urea herbicide. First, a deterministic risk assessment was undertaken. Next, probabilistic distribution of exposure is compared with a fixed ecotoxicity endpoint derived from standard laboratory tests. Subsequently, differences in the susceptibility of different test species were considered, and the probabilistic expression of exposure was compared with an ecotoxicity endpoint derived from the species sensitivity distribution. Finally, the uncertainty in generating species sensitivity distributions from a small number of measurements was incorporated into the assessment. A combined probabilistic assessment of exposure and effects was carried out.

A detailed account and comprehensive results are included in the report on work package 8 *(in this report numbered Case Study 3).* Here, however, the focus will be on a selection of preliminary results that were presented to a meeting of an expert panel[3] that advises the UK regulatory authorities on the environmental risks of pesticides, and in particular the reactions of the panel to different ways of

[3] The Environmental Panel of the UK Advisory Committee on Pesticides, meeting of 15 April 2004. The panel were given a 15 page “summary report” in advance and a powerpoint presentation at the meeting

communicating probabilistic outputs. Selected examples of the results presented to the panel are shown in figures 1, 2, and 3; tables II and III; and summary table IV.

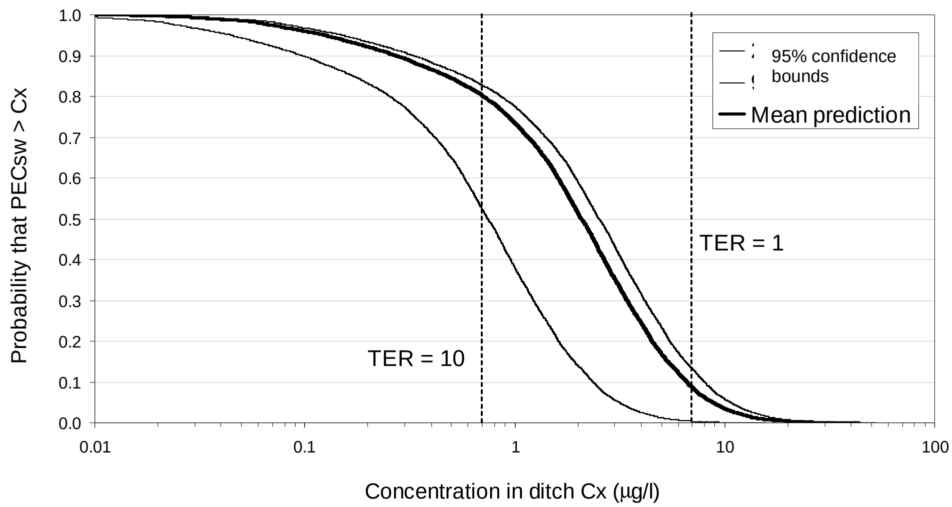


Figure 1: Example of assessment output from Case Study 4 ('herburon'). Comparison between the distribution of PECsw values for ditches in loam landscapes and exposure concentrations equivalent to a toxicity-exposure ratios of 1 and 10 (based on a 120-hr EC50 to Lemna gibba = 7 µg L-1)

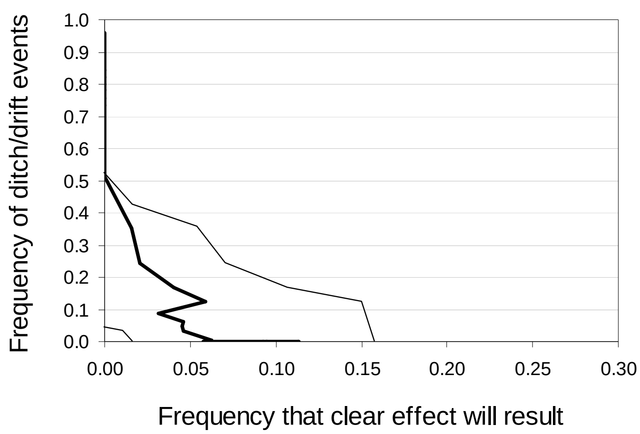


Figure 2 Example of assessment output from Case Study 4 ('herburon'). Joint curve showing the predicted frequency of exceeding a given initial exposure concentration in UK ditches and the frequency that the concentration would result in clear effects on community metabolism in a mesocosm study (thick line = mean prediction; thin lines = 95% confidence bounds)

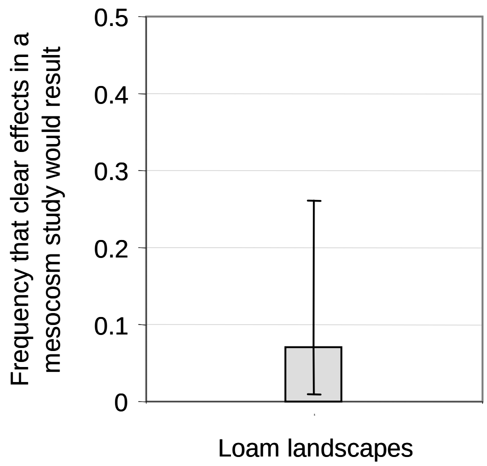


Figure 3 Example of assessment output from Case Study 4 ('herburon'). Overall frequency that exposure of ditches in loam landscapes would result in clear effects on community metabolism in a mesocosm study. Line shows 95% confidence interval.

Table II Example of assessment output from Case Study 4 ('herburon'). Percentiles taken from the distribution of PECsw and TER for exposure to herburon of ditches in loam landscapes via spray drift (Fig. 2).

Percentile	PECsw (µg L-1)		TER	
	Median	95% CI[1]	Median	95% CI
25th	0.93	0.33 – 1.13	7.5	6.2 – 21.2
50th	2.07	0.74 – 2.51	3.4	2.8 – 9.5
75th	3.93	1.41 – 4.77	1.8	1.5 – 5.0
80th	4.49	1.61 – 5.45	1.6	1.3 – 4.3
85th	5.36	1.92 – 6.50	1.3	1.1 – 3.6
90th	6.59	2.36 – 7.99	1.1	0.88 – 3.0
95th	8.75	3.13 – 10.62	0.80	0.66 – 2.2
99th	14.94	5.35 – 18.13	0.47	0.39 – 1.3
99.5th	18.34	6.57 – 22.26	0.38	0.31 – 1.1
99.9th	27.71	9.93 – 33.62	0.25	0.21 – 0.70

[1] CI = Confidence interval

Table III. Textual description of assessment outcome in Figures 1 & 2 – example from Case Study 4 (‘herburon’).

- For potato fields in loam landscapes and assuming that every field is treated and has ditches adjacent, the proportion of ditches where instantaneous concentrations of herburon are predicted to give a TER of less than 10 based on a 120-hr laboratory EC50 for Lemna gibba is 80% (95% confidence interval 70-82%). [Figure 1]
- For potato fields in loam landscapes and assuming that every field is treated and has ditches adjacent, the TER equivalent to the 90th percentile instantaneous concentration of herburon in the ditch is 1.1 (95% confidence interval 0.9-3.0) based on the lowest acute ecotoxicity endpoint (Lemna gibba). [Figure 1]
- The estimated frequency of clear effects on community metabolism with no recovery within 8 weeks is 7% (95% confidence interval 1-26%), assuming that the exposure model is correct and that mesocosm studies directly represent effects in the field. [Figure 2]

Table IV Example of a listing of sources of variability and uncertainty differentiating between those included and excluded in the analysis (from Case Study 4, ‘herburon’).

	Considered	Not considered
Variability in exposure	Measured drift generation and deposition	Wind speed and direction
	Distance from edge of sprayed area to water	Variation in deposition across the water surface
	Interception of drift by bankside vegetation	
	Dimensions of the water body	
Uncertainty in exposure	Errors in application rate	Measurement bias in drift experiments
	Measured drift generation and deposition	Sampling uncertainty in drift experiments
	Deposition on a surface below ground level	Model error for exposure model
	Interception by bankside vegetation	
	Volume of water in the ditch at application	
Variability in effects	Heterogeneity between mesocosm studies	Range of variability in natural habitats and associated assemblages
	Multiple endpoints evaluated	Recovery from any initial effect
	Results from multiple tests included by weighting according to similarity	
Uncertainty in effects	Extrapolation lab to field (semi-field test used for endpoint)	Extrapolation to true field conditions
	Extrapolation single species to population to community (community endpoint used)	

The assessments presented to the panel quantified some sources of *variability* in both exposure and effects, using Monte Carlo simulation. The effect of this variability was shown as distributions (Figures 1 and 2), and as frequencies in bar charts (Figure 3) tables (Table II) and text (Tables III). The paper also included a table listing sources of uncertainty and variability and showing whether they were included or excluded from the analysis (summary Table IV). The paper discussed the nature of the excluded sources of variability, but did not specifically discuss how they might alter the assessment outcome.

The responses of the panel to the paper and presentation included the following points. (Note: the panel comprises mainly scientists and these contributed most to the discussion at the meeting, so the comments are mostly relevant to assessor-to-assessor communication. However, some points relate to other audiences, as indicated below).

1. Overall, the panel preferred bar graphs (e.g. Figure 3) more than cumulative curves (e.g. Figure 1) and tables (e.g. Table II). The panel also considered that a narrative statement of the results should *always* be provided. The panel considered it very important to include confidence bounds with every form of output. Note that these preferences are unlikely to be restricted to the specific examples given here, but to these styles of presentation in general.
2. Figure 1 was considered very difficult to interpret. The panel's view of this was probably influenced by the fact that Figure 1 involves use of an unfamiliar and relatively complex model of effects (PERPEST), and that unlike conventional joint probability plots the curves are non-monotonic (being based on combination of a probability density function with a cumulative density function rather than two cumulative functions). Nevertheless, there was a feeling that graphs with *frequencies on both axes* were generally difficult to understand and communicate.
3. The panel suggested that *different outputs* may be suitable for different audiences, even within the same committee, e.g. tables and cumulative distributions for technical members, bar charts for regulatory staff, and narrative text for lay members. All should thus be included in a report.
4. The panel considered that the level of detail provided in the 15 page summary paper was appropriate for a regulatory committee, but would need to be accompanied by a *full report* to enable detailed evaluation of methods and assumptions when required.
5. The vertical axis of Figure 1 was not easily understood. After additional explanation, the panel felt that Figure 1 could be useful for more technical audiences (e.g. assessor to assessor). This is consistent with experiences in other fields (e.g. human dietary exposure) and points to a general conclusion: cumulative distributions are difficult to explain well to non-technical audiences, and also to technical audiences who are unfamiliar with them.
6. The Panel considered one aspect of Figure 1 especially helpful: the fact that it compares the exposure curve to established, familiar, deterministic risk thresholds (TER=1 and 10). This is consistent with the view (e.g. in the report of work package 3) that it is helpful to present probabilistic assessments *together* with familiar deterministic approaches.
7. The panel was asked not to dwell on the details of the underlying methodology but it was clear that they had questions about many aspects, especially the use of the PERPEST model. This is consistent with the view expressed at EUPRA that combining probabilistic methods with other novel or complex assessment methods adds to the difficulty of communication and acceptance of the overall assessment.

8.1 Communication from Assessors to Risk managers – Conclusions of case studies and recommendations for developing effective communication strategies

An overview of recommendations regarding assessor to manager communication may be useful at this point. Relevant factors are provided in Table V.

Table V Communication from risk assessors to risk managers – conclusions of case studies and recommendations for developing effective communication strategies.

- The use of narrative forms backed up with diagrams (where appropriate) to describe the results of assessments and the associated uncertainties. With respect to diagrams, bar graphs are generally better understood than cumulative curves and tables. Inclusion of confidence bounds is important. In general, the use of cumulative distributions should be avoided, or at least used with care or in combination with other diagrammatic representations in the case of communication between assessors and decision-makers and / or the public.
- Care should be taken in the choice and construction of diagrams. Even for simple diagrams, the axis labelling and units must be easily understandable by the audience. Special care should be taken to explain cumulative distributions and joint frequency plots, as these are unfamiliar to most audiences and difficult to communicate well. From a pragmatic perspective, colour should be avoided if the documentation is to be photocopied.
- Graphs with frequencies on both axes are generally difficult to understand and communicate, unless people have specific expertise regarding interpretation of these.
- Different outputs may be suitable for different audiences, including situations where a particular audience (for example, a regulatory committee) has different areas of expertise. This implies that multiple presentations of the same data in a report may be useful. A concise summary report outlining the main points of the assessment and its key results should be produced. A full technical report should be made available for those who wish to examine the details. Opportunities for interactive discussion of the assessment between assessors and risk managers should be provided.
- The assessor must be transparent about where the uncertainties in the assessment lie. Where possible, uncertainties should be incorporated into the analysis and shown as ranges or confidence bounds on the results. The potential effect of other uncertainties on the assessment outcome should also be described (e.g. how different could the ‘true’ risk be?)
- Explanations should be started with familiar assessment methodologies and subsequently move to unfamiliar assessment approaches (e.g. from quotient –to probabilistic assessments). Novel ideas should be introduced one at a time rather than all at once.
- Inclusion of a “positive control”, the effects of which were already well understood by those involved in the risk analysis process, facilitates communication about new methods. Although this should not be a requirement within individual risk assessments, it could be very useful for:
    - Demonstration/teaching purposes (provided it is not interpreted as a benchmark because criteria for “positive” vary between pesticides/scenarios, and providing a test case for evaluation of new tools (to help build confidence and check consistency between tools)

- Specialist jargon should be avoided whenever possible
- The ecological implications should be explained, (bringing in expertise from other areas such as basic ecology and biology, in order to understand which relevant organisms are affected, the implications for vulnerable or protected habitats, etc.)
- Narrative forms should be used to explain what is not understood as well as identifying what is understood

The same approach may underpin communication with other stakeholders, for example the general public. Narrative approaches, which avoid specialist jargon, are as appropriate for lay people as decision-makers, and the use of analogy is a useful way to explain probabilistic approaches.

9 Study 2: EUFRAM end-user survey

To investigate whether the tools developed within the EUFRAM project were both acceptable to, and successful in communication, to other experts, a survey was conducted among members of the EUFRAM training workshop held in October 2005. Participants of the EUFRAM workshop were part of risk assessment, risk management or other end-user communities. At the end of the first day of the Dublin EUFRAM workshop, a pen-and paper survey was distributed among the participants, during the evening reception. The survey consisted of 11 assignments requesting participants to read a particular value from 8 different graphical presentations of probabilistic risk assessment information. For each type of graphic a question followed about perceived difficulty and adequacy of the information provided by the graphs. Data about individual experience with different probabilistic methods were also collected. The surveys were collected from participants the next morning at 9 o'clock, prior to the first session of day two of the workshop.

As the reception ended at eight o'clock in the evening, many of the participants indicated they did not have enough time to fill out the questionnaire. This may have resulted in a higher than expected number of errors. However, it is arguable that such time pressure may reflect a realistic situation when risk assessors and/or managers have to reach decisions under time pressure.

9.1 Demographics and experience

Fifty six participants contributed to the survey. Two additional participants were excluded, despite answering all the questions correctly, because they handed in the survey only after lunch and thus had much longer to complete the survey compared to the stringent time limit imposed on the other participants. The average age of the participants ranged between 26 and 62 years (mean age was 39 years). However, 11 respondents did not report their age. 19 participants were female, 29 male, and 8 respondents did not report their sex.

In terms of occupation, the breakdown was as follows. Seven participants reported they were academics, 11 were consultants, 19 worked for governmental institutions, 9 were employed by industry, and 1 reported that they were self-employed. Forty four participants reported that the primary focus of their work was risk assessment. One described themselves as a risk communicator, 4 reported they did other work, and 7 did not report their main work type. None of the respondents reported that the focus of their work was risk management. Table VI summarizes respondent's self-reported familiarity with probabilistic risk assessment.

Table VI: Familiarity with Probabilistic Risk Assessment (PRA). All items are scored on a 5 point scale[1], anchored at -2 and 2.

#	Question	Labels	Mean (SD)
1	How familiar are you with PRA?	not at all familiar, a bit, reasonably, familiar, very familiar	-0.6 (1.1)
2	Have you produced PRA's yourself?	never, once, occasionally, regularly, frequently, major part of job	-1.3 (0.9)
3	Have you reviewed or studied PRA's by others?	never, once, occasionally, regularly, frequently, major part of job	-0.8 (0.9)
4	How well do you understand PRA's by others?	not at all, slightly, reasonably, well, very well	-0.2 (0.8)

[1] except items 2 and 3, which originally had 6 levels. To allow comparison with other items in this table, mean and standard deviation, were homologised by multiplying the 6 level item scores by 0.83 (=5/6)

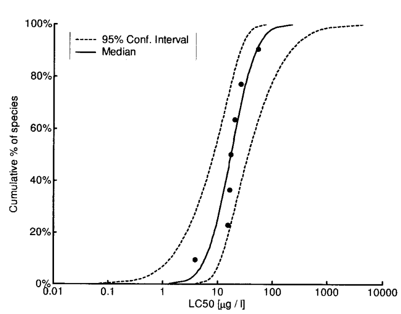
On average, participants reported they were not really familiar with probabilistic risk assessments, and understood them slightly. Furthermore, participants reported that they hardly ever produced a probabilistic risk assessment themselves, and, indeed, had infrequently reviewed reports developed using probabilistic risk assessment generated by others. Taken together, these results indicate that participants did not report a high level of experience with probabilistic risk assessment, which might be expected given their voluntary attendance at a workshop about probabilistic risk assessment techniques.

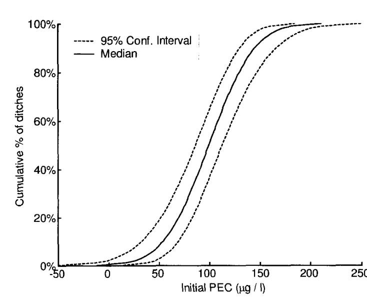
9.2 Correct answers to the questions

The questions addressed four categories of graphical presentation of probabilistic risk assessments (see Figure 4):

- Type 1 – Cumulative functions for effects and exposure (Graphics 1 and 2)
- Type 2 – Exceedance functions for exposure (Graphic 3)
- Type 3 – Overlay, with combined effects and exposure functions in a single graphic (Graphic 4 – cumulative-exceedance; Graphic 5 – cumulative-cumulative)
- Type 4 – Combined risk functions in which hazard and exposure are integrated into a single measure (Graphic 6 – cumulative, Graphic 7 – exceedance[4]

Type 1: Cumulative





[4] Graphic 8 was risk characterisation but has been omitted from analysis[0] due to a technical error

Type 2: Exceedance

Type 3: Overlay

Type 4: Combined

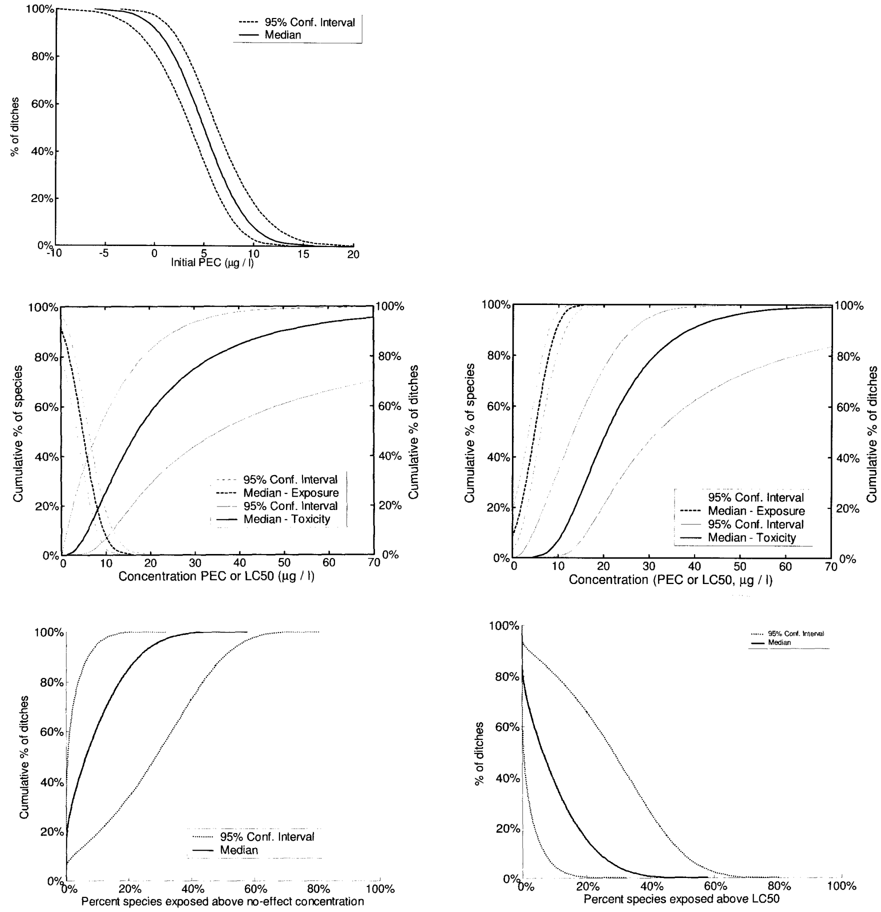


Figure 4: The graphics presented in the end-user survey

In the cases of the first three graphical presentations, respondents were asked to estimate both a boundary percentile, (for example, “What is the 90th percentile exposure”) and answer a question about risk estimates (“What percentage of species have a LC50 lower than 10?”) For the 4th through 8th graphical presentation, only one question of the second type was asked.

Graphics 2 and 3 were tested using two different representation methods. These were a *cumulative function*, (for example, with increasing pollution by the pesticide the number of infected species gradually increases to 100%), and an *exceedance function*, (for example, if a certain % of species are not be affected, which pollution level should not be exceeded). Graphic types 4 and 5 combined either 2 cumulative functions, or a cumulative function and an exceedance function. Graphics 6 and 7 presented an integrated measure this was a *profile plot for risk*. Respondents made a reasonably large number of errors in interpreting the probability functions. First let us focus on the different graphical representations (Table VII).

Table VII: Correct answers per assignment. Effects of experience and age on correct response of the 7 graphs presented

Graph	Assignment	Type of graphic	**Question:** Report the relevant values for a certain probability	**Frequency** correct/ wrong/ missing	**% correct**	**Effects** (logistic regression)
1	1a	Cumulative Distribution Function for hazards	Percentile	55/1/0	98	n.a.[1]
	1b	Cumulative Distribution Function for hazards	Lower than	56/0/0	100	n.a.[1]
2	2a	Cumulative Distribution Function exposure	Percentile	49/5/2	91	n.a.[1]
	2b	Cumulative Distribution Function exposure	Higher than	42/14/0	75	-
3	3a	Exceedance exposure	Percentile	37/12/7	76	Produced previously (p=0.037) and participated / EUFRAM Brussels workshop (p=0.041) positive effect
	3b	Exceedance exposure	Higher than	53/1/2	98	n.a.[1]
4	4	Overlay Exceedance	Percentile	31/16/9	66	-
5	5	Overlay Cumulative Distribution Function	Percentile	33/14/9	70	Self reported understanding (p=0.038) and higher age (p=0.049) positive effect
6	6	Combined Cumulative Distribution Function	Percentile	28/24/4	54	Self reported understanding (p=0.043) positive effect
7	7	Combined Exceedance plot	Percentile	24/27/5	47	Self reported understanding (p=0.009) positive effect

[1] As (practically) all answers were correct, there is little to no variance to explain

Table VIII shows there is a difference between the efficiency with which participants interpreted the graphics, as measured by the number of errors ($\chi^2(4)=13.4$, $p<0.01$). When asked to mark a *specific percentile risk*, participants score better using a cumulative function. When asked for a risk that is *higher* than a certain level, the exceedance function results in fewer mistakes. This implies that the efficacy of a certain type of representation is context dependent.

Table VIII: Counts of errors for the 4 questions posed to type 2 and 3 graphics

	Errors in answers	
Graph type	Percentage	Higher than
Cumulative	5	14
Exceedance	12	1

Furthermore it should be noted that the plots combining different types of information (graphics 4 through 7, the overlay and combined plots) posed serious problems in terms of the ease with which participants could interpret these types of graphs. In some cases participants scored less than 50% correct answers.

Subsequently, we considered the number of correct answers obtained by each participant. Not all participants answered all questions. This may be because of time-pressure, or because participants did not understand the relevant graphic. The percentages of correct and erroneous percentages do not necessarily add up to 100%, as "no response" may not be the result of inability to analyse the question, but rather reflect the time pressure under which respondents were working. These percentages are reported separately in Figure 5.

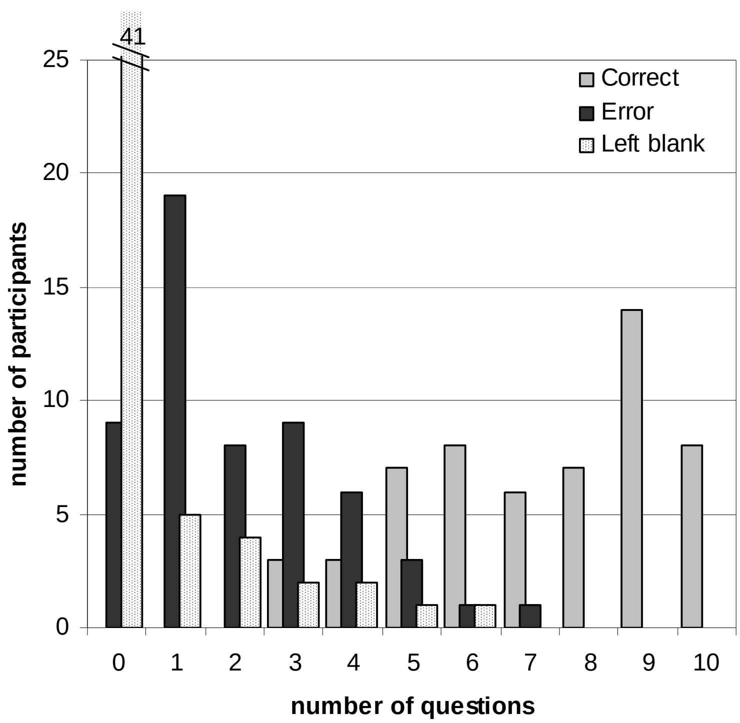


Figure 5: Frequency of the number of participants (N=56) with number of questions (N=10) correctly answered, wrongly answered and not answered at all.

9.3 Estimates of Difficulty and Preference

9.3.1 Reported difficulty

Following the assignments to retrieve information from a graph, participants were asked to rate "How easily could you retrieve the information you needed to answer the question from this graph" on a 6 point scale labelled: very easily, easily, reasonably easy, reasonably difficult, difficult, very difficult (Figure 6).

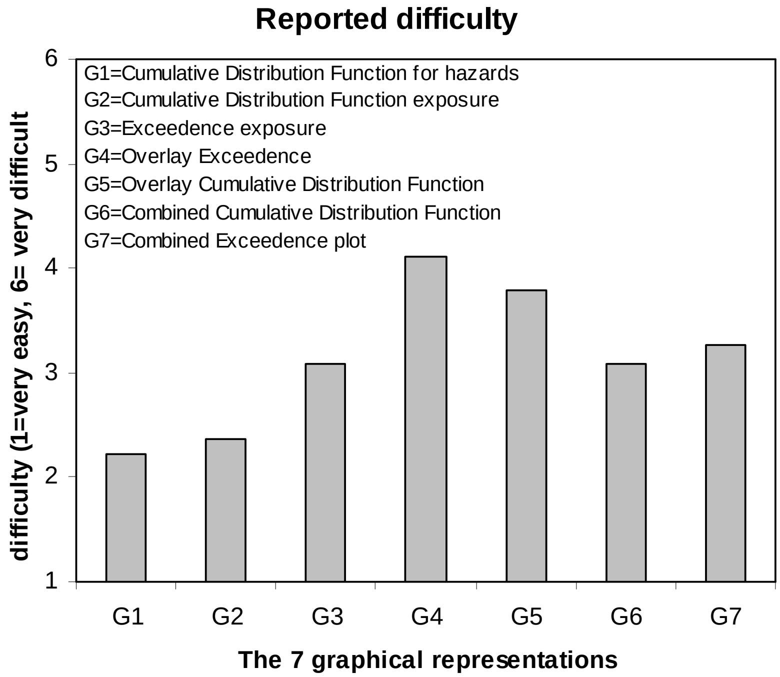


Figure 6: Average reported difficulty to retrieve information from the 7 graphical representations (N=56).

9.3.2 Determinants of reported difficulty

To distinguish whether occupational and experiential factors determined reported difficulty of information retrieval a number of ANOVA's (Fisher F test), was applied. Firstly, we considered whether the sector in which the expert was employed influenced reported difficulty. We focused on the two graphics that were considered difficult to use; the overlay representations (G4 and G5). Consultants and Government employees experienced the Overlay Exceedance (G4) plot as being more difficult than respondents employed in industry or in academia ($F(4,41)=3.8$; $p=0.01$). In the Cumulative Overlay (G5) plot this effect was less pronounced, and only Government employees found this graphic (marginally) more difficult than respondents employed in industry and academia ($F(4,41)=2.4$; $p=0.07$).

Differential perceptions of difficulty may be the consequence of better understanding of probabilistic approaches. However, we should also not rule out a motivational explanation, as experts employed in industry and academia may be more motivated to utilise probabilistic risk assessments than those employed in government. Secondly, we considered whether the four questions about experience and familiarity with probabilistic risk assessment influenced reported difficulty of use (Table IX).

Table IX Effect of previous experience on self reported difficulty

Experience question	Less difficult for type of graph (Question no)	R^2, *p* value for one-sided test
How familiar are you with PRA?	No significant effects	
Have you reviewed or studied PRAs by others?	More often, less difficult on: distribution Function for hazards (G1),	R^2=0.22; p=0.045
Have you produced PRAs yourself?	Overlay Exceedance Function (G4).	R^2=0.28; p=0.037
Have you reviewed or studied PRAs by others?	Cumulative Combined Function (G6)	R^2=0.16; p=0.030
	Exceedance Combined Risk Function (G7), (t=-3.33, p=0.002).	R^2=0.30; p=0.001

9.3.3 Preference

For some assignments, similar types of information were offered as a cumulative distribution functions and exceedance functions. This was the case for exposure graphs G2 and G3, and for the overlay graphs G4 and G5. Participants were asked which of the graphs they liked more (Table X). It was clear that the vast majority preferred cumulative over exceedance. It is also clear that the preference for cumulative representations is less pronounced for the overlay graph. However, we argue that this is more to do with the type of assignment that was chosen for the overlay tasks. As shown previously (Table VIII), 'higher than / lower than' information was better suited for exceedance representation. By introducing the same difference between the exposure function and the overlay function, we could investigate whether the format influenced preference as well as performance. Even if the superior performance of exceedance plots in the 'higher than' situation is taken into account, a *consistent preference for the cumulative plots is found throughout the data.*

Table X: % participants that exhibited preference for cumulative distribution functions over exceedance functions

Type of graph	Type of question	Cumulative	Exceedance
Exposure (G2, G3)	Percentage	92%	8%
Overlay (G4, G5)	Higher than	60%	40%

The lack of preference for exceedance data may be due to the relatively low exposure most people have to this type of graphic. This might be indicated by the observation that regular EUFRAM participants, (who might be assumed to have had more exposure to exceedance graphics), were also more likely to prefer the exceedance plot for exposure $\chi^2(45)=5.3$; p=0.01 (one-sided). Furthermore, those participants who attended the previous (Brussels) workshop were more likely to express preferences for prefer the overlay exceedance plot compared to those who did not attend this meeting $\chi^2(46)=3.4$; p=0.03 (one-sided).

9.4 Was sufficient information provided in the different graphics?

In general, participants agreed that there was enough information present in the graphs (rating varied from between 77%-84% agreement over the different graphs). Of the remainder, this was, in nearly all cases, specified as lack of context for the graphic, either through the provision of textual support ("Chart title", "axis texts", "caption", and "accompanying text"), or through omission of information about the pesticide under question, or the affected species (Table XI).

Table XI: Reported information content of stand-alone risk graphics

	About right	Too little	Too much
Cumulative Distribution Function for Hazards (G1)	77%	23%	0%
Cumulative Distribution Function Exposure (G2)	80%	20%	0%
Exceedance exposure (G3)	74%	22%	4%
Overlay Exceedance (G4)	72%	20%	8%
Overlay Cumulative Distribution Function (G5)	80%	15%	5%
Combined Cumulative Distribution Function (G6)	84%	14%	2%
Combined Exceedance plot (G7)	78%	20%	2%

9.5 Conclusions

The participants at the workshop were not experienced in PRA techniques, although this may reflect the self-selection of the sample rather than reflect experience levels more generally. The accuracy of use of the different graphical representations appears to be dependent on whether participants are asked to mark a specific percentile risk, or a risk higher than a certain level. In the case of the former, use of a cumulative function is more efficient, but exceedance functions results in fewer mistakes in the case of the latter. However, combining different types of information in the same plot causes the most problems in terms of interpretation.

The ease with which participants experienced difficulty in interpreting different graphic was dependent, to some extent, on their sector of employment, implying that different communication approaches may be beneficial in different sectors, at least in the early stages of PRA adoption. Although differential perceptions of difficulty may be the consequence of better understanding of probabilistic approaches, experts employed in industry and academia may be more motivated to utilise probabilistic risk assessments than those employed in government. However, a broad conclusion that can be drawn is that a *consistent preference for the cumulative plots is found throughout.* However, there is some evidence to suggest that increased experience with exceedance plots also increases their acceptance by users. However, it is important that graphics be accompanied by additional textual information, particularly in the early stages of end-user adoption of the new approaches.

10 Study 3: Intention to adopt PRA

It is useful to understand why different experts decide to adopt a PRA method, as well as which experts are most likely to be influenced by which elements of communication about PR, if an effective communication strategy is to be developed to facilitate use and interpretation between different expert communities

10.1 Theoretical Approach

People are unlikely to adopt new risk assessment methodologies unless they hold a positive attitude towards the activity or activities involved. Such attitudes may include, for example, a positive evaluation of its utility, perceived ease of application, intention to adopt the new methods or the acceptability of PRA to other risk assessors or managers. The role of attitudes on an individual's behaviour has been extensively studied in the area of social psychology and marketing, and various theoretical approaches were developed to explain the relationships between attitudes and behaviours. An important theoretical perspective which has frequently been applied in this area is the Theory of Planned Behaviour (TPB, Ajzen, 1991). The decision to use a new analytical tool such as PRA may be considered as "planned behaviour", given that experts may reasonably be expected to critically evaluate the advantages and disadvantages of adopting new assessment approaches. To investigate the different determinants of potential adoption of PRA, a survey was conducted based on the Theory of Planned Behaviour (Ajzen, 1991). In this model (Figure 7), the cause of a given behaviour is an individual's intention to conduct that behaviour. Whether intention actually leads to behaviour depends on perceived behavioural control, (that is, whether the person thinks he or she can actually perform the behaviour). Of course, actually performing a particular behaviour is dependent on whether or not the person has the opportunity to conduct the behaviour.

In order for the formation of the behavioural intention to occur, three factors are of importance. The first of these is the persons *attitude towards the behaviour* (i.e. is he or she positive towards the behaviour under consideration), which in turn is partially based on the persons own behavioural beliefs (how much does this person allow his or her tendency to like specific behaviours actually influence whether they conduct the behaviour). The second is the person's *subjective norm*, (i.e. does the person think it is socially acceptable to perform the behaviour, which is partially dependent on the general impact of societal norms on that person's behaviour). The third is perceived behavioural control (i.e. Does the person perceive that they can actually conduct the behaviour). The behavioural beliefs are assumed to influence behavioural intention, which in term has a direct effect on behaviour itself. It should be noted that these different attitudes may be correlated between themselves. As the selection of new analysis methods, such as PRA, can easily be argued to be planned behaviour, in which intuitive and automatic behaviours play a relatively marginal role, we argue that the theory of planned behaviour is a feasible tool to predict whether risk professionals adopt PRA.

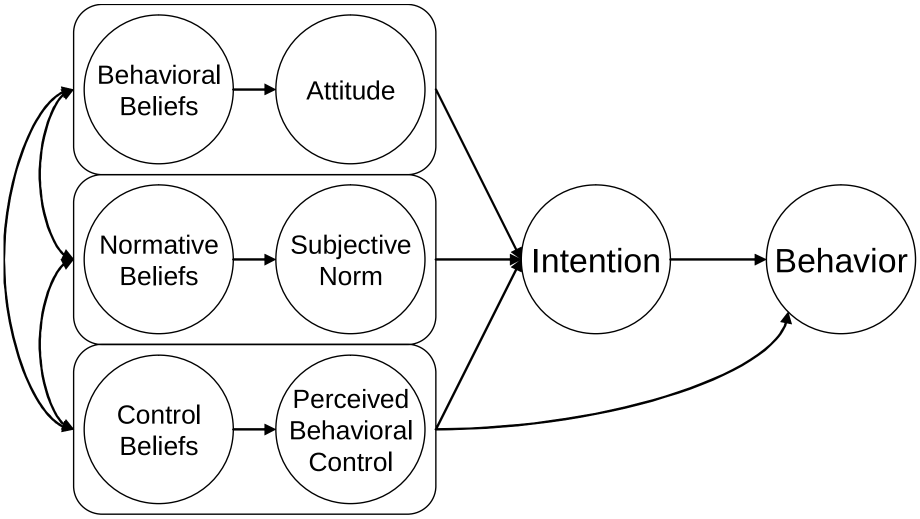


Figure 7: The Theory of Planned Behaviour

10.2 Methods and materials

During the final workshop of the Eufram project, a second survey was conducted. The aims of this survey were to investigate why, or why not, experts working in risk assessment would adopt probabilistic risk assessment (PRA). In particular, the survey focused on whether individuals working in different risk assessment sectors (for example, academia, regulation, industry or consultancy) were differentially motivated to adopt PRA. Analysis was therefore made of potential differences in user uptake, and why these might exist. Comparisons were made between participants employed in government, industry and academia and consultants working in risk assessment.

The survey consisted of 39 items in total. These together comprised of various subscales to assess different attitudinal components relevant to the TPB. These were

- Attitude towards PRA (4 items). Attitude towards a behaviour is the degree to which performance of the behaviour is positively or negatively valued. According to the TPB, an attitude toward a particular behaviour is determined by the total set of accessible behavioural beliefs linking the behaviour to various outcomes and other attributes.
- Subjective norms surrounding adoption of PRA (4 items). Subjective norm is the perceived social pressure to engage or not to engage in a behaviour. According to the TPB, subjective norm is determined by the total set of accessible normative beliefs concerning the expectations of important referents.
- Perceived behavioural control (4 items). Perceived behavioural control refers to people's perceptions of their ability to perform a given behaviour. Within the TPB, perceived behavioural control is determined by the total set of accessible control beliefs, i.e., beliefs about the presence of factors that may facilitate or impede performance of the behaviour. To predict perceived behavioural control norms a five item control belief scale was added, with every item constructed from the multiplication of a belief and a belief strength item.

- Intention to adopt PRA (3 items). Intention is an indication of a person's explicit willingness to perform a given behaviour, and it is considered to be the immediate antecedent of behaviour. The intention is based on attitude toward the behaviour, subjective norm, and perceived behavioural control. To predict subjective norms a three item normative belief scale was added, with every item constructed from the multiplication of a belief and a belief strength item.
- A single item was used to assess self-reported use of PRA.

Additional information was collected relating to demographics, employment and previous experience with PRA. Data were also collected in order to evaluate the extent to which participants felt the Eufram workshops were useful, facilitated networking, and provided high quality materials. The questions asked, together with information about rating scales, are provided are provided in Appendix A. The survey questionnaire was printed and added to the workshop package, which was distributed during registration the afternoon or evening before the main workshop. Participants in the workshop were asked to complete the questionnaire anonymously, and requested to return it during the 1st day of the main workshop. During the opening session, participants were once again asked to complete the survey and return it. A total of 77 surveys were received, 76 of which contained usable data.

10.3 Results

10.3.1 Sample

Fifty nine percent of the total sample was male, 41% female. The average age of participants was 40 years (SD=±9 yrs). Forty nine per cent of participants were employed by government, 18% by industry, 12% in an academic context, and 16% were working on a consultancy basis. Five per cent reported being employed in a different context. The majority described their work to be primarily involved in risk assessment (87%) with only a few participants working in risk management, risk communication or other types work on a daily basis.

10.3.2 Experience with Eufram and PRA

The majority of participants had previously been involved in Eufram activities: 74% participated in the Dublin workshop, 66% participated in the Brussels workshop, and 38% participated in the Eufram project prior to, or outside of the workshops themselves.

In general, participants reported[5] that Eufram workshops helped them gain a better understanding of PRA (M=5.7, SD=±1.1), and that Eufram workshops provided a very good opportunity to contact other PRA specialists (M=6.2, SD=±0.67). They also indicated that that Eufram provide high quality materials (M=5.5, SD=±1.0).

Most participants were familiar with PRA (M=4.7, SD=±1.6), and indicated that they understood the principles underlying PRA). Participants tended to understand the PRA (M=4.7, SD=±1.5) although fewer participants had actually applied PRA in practice (M=2.9, SD=±2.0) or indeed reviewed PRAs by others (M=3.2, SD=±1.9)

[5] All measured on a 7-point scale from 1 to 7 with 1 being an indicator of very low frequency/agreement and 7 an indicator of very high agreement; and 4 being the neutral scale centre.

10.3.3 Planned behaviour

The constructs of the TPB were checked for reliability using Cronbach α, and all proved to be sufficiently reliable to use the mean of the subscales as variables in the analysis. (Attitude items; Cronbach α=0.82; Subjective norm; Cronbach α=0.75; Perceived behavioural control; Cronbach α=0.67; Intention; Cronbach α=0.80; Behavioural belief; Cronbach α=0.76; Normative belief; Cronbach α=0.77; Control belief; Cronbach α=0.82). To investigate differences in TPB components across the different groups of participants we compared the constructs for the different groups (Table XII).

Table XII Mean and (standard deviation) of the main constructs for the different work groups

	n	Attitude	Subjective Norm	Perceived control	Intention	Self-Reported use of PRA
Government	37	4.8 (1.0)	3.8 (1.1)	4.0 (1.2)	4.5 (1.4)	3.0 (1.9)
Industry	13	5.0 (1.1)	3.8 (0.9)	4.4 (1.0)	4.5 (1.4)	3.5 (1.6)
Consultancy	12	4.8 (0.7)	3.6 (0.5)	4.1 (0.9)	4.5 (1.3)	2.8 (1.7)
Academia	8	5.3 (0.7)	4.3 (0.8)	4.8 (1.2)	5.1 (1.0)	4.9 (1.5)[1]

[1] Significantly different from the other groups

As we are primarily interested in the participant's intention to use PRA methods, this construct will be the focus of analysis. By conducting regression analyses, the relations between the constructs of the TPB can be studied. Firstly, the effect of Attitude, Subjective norm and Perceived control on intention to use PRA were investigated. The results are summarized in Tables XIII and XIV.

Table XIII Effects of different determinants on intention (N=76)

	t	*p*	R^2
Model			0.75[a]
Attitude	9.024	<0.001	0.70[b]
Subjective Norm	3.195	0.002	0.44[b]
Perceived Behavioural Control	1.339	0.185	0.20[b]

[a] R^2 for the multiple regression model
[b] R^2 based on zero-order correlation effects

Table XIV Effects of determinants on self reported application of PRA (N=76)

	t	p	R^2
Model			0.24[a]
Intention	3.137	0.003	0.21[b]
Perceived Behavioural Control	1.563	0.123	0.12[b]

[a] R^2 for the multiple regression model
[b] R^2 based on zero-order correlation effects

More general behavioural, normative and control beliefs were only explained by attitude, social norm and perceived behavioural control to a minor extent, which is in the lower margin of previous research using the theory of planned behaviour; although the relations between perceived behavioural control and control beliefs was rather low (Armitage & Conner, 2000) (Table XV). The lack of relationship between control belief and perceived behavioural control may be due to the nature of the Eufram workshop that aimed at introducing the method to a number of experts.

Table XV Influence of general beliefs on specific beliefs (N=76)

	t	p	R^2
Behavioural Belief → Attitude	3.1	<.01	.12
Normative Belief → Social Norm	3.9	<.01	.18
Control Belief → Perceived behavioural control	1.4	.16	.03

Based on above findings we can conclude that the extent to which an individual holds a positive attitude towards PRA methods is the most important determinant of whether they intend to use them or not. The second most influential factor is social norm (i.e. whether colleagues, superiors and project sponsors are likely to endorse the use of the method). Perceived behavioural control does not play an important role, indicating that most participants do not perceive that technical problems in adopting PRA represent a barrier regarding their personal adoption of the method

To investigate how adoption is differentially influenced according to the professional categories of individuals, comparisons were made between the different employment groups (Table XVI).

Table XVI Explained variance in intention within the different professional groups

	n	R^2 Attitude[a]	R^2 Subjective Norm[a]	R^2 Perceived control[a]	Overall R^2 Intention to use PRA[b]
Overall	76	0.70	0.44	0.20	0.75
Government	37	0.63	0.71	0.38	0.76
Industry	13	0.93	0.37	0.01[ns]	0.93
Consultancy	12	0.50	0.11[ns]	0.02[ns]	0.55
Academia	8	0.62	0.22[ns]	0.49	0.83

[a] R^2 based on zero-order correlation effects
[b] R^2 for the multiple regression model

This demonstrates that, for all the professional groups included in the survey, a *positive attitude towards PRA* is an important predictor for intention to use the method. Participants employed in government place the most importance on acceptance by peers. Participants employed by industry rate peer acceptance as important, however they do so to a lesser extent than do people employed in government. Participants employed in government and industry did not perceive any potential difficulties associated with the adoption of the method, but this was not true of participants employed in other areas.

When considering the self-reported use of PRA (Table XVII), the model does not actually predict its use by academics and government officials[6]. Interestingly perceived control of PRA did not play a role in determining whether participants from industry had formed an intention to use PRA, but is a predominant factor determining actual adoption. Against this, consultants who express an intention to use PRA *do* report actually using PRA.

Table XVII Explained variance in self-reported use of PRA within the different professional groups included in the survey

	n	R^2 Intention[a]	R^2 Perceived control[a]	Overall R^2 use of PRA[b]
Overall	76	0.21	0.12	0.24
Government	37	0.16	0.11	0.17
Industry	13	0.08[ns]	0.50	0.57
Consultancy	12	0.55	0.11[ns]	0.60
Academia	8	0.27[ns]	0.15[ns]	0.27[ns]

[a] R^2 based on zero-order correlation effects
[b] R^2 for the multiple regression model

Table XVIII Importance of general beliefs as predictors of specific beliefs (N=76)

	Government R^2	Industry R^2	Consultancy R^2	Academia R^2	Overall R^2
	n=37	n=13	n=12	n=8	
Behavioural Belief → Attitude	0.08[ns]	0.42	0.32	0.35[ns]	0.12
Normative Belief → Social Norm	0.45	0.08[ns]	0.25[+]	0.20[ns]	0.18
Control Belief → Perceived behavioural control	0.09[+]	0.00[ns]	0.02[ns]	0.00[ns]	0.03[ns]

[ns] not-significant, [+] $p<0.05$ one-sided. Other effects significant at $p<0.05$ two-sided.

Finally the relationships between general and specific beliefs were investigated (Table XVIII). The results confirmed that the relationship between *general beliefs* and *specific beliefs towards PRA* was fairly weak. The general normative beliefs are mainly important to participants employed in government.

10.4 Discussion

The differences in the extent to which potential PRA end-users in different types of employment situation, and the potential explanatory factors for these differences, are largely in concordance with the role accorded to different institutions in society. For example, in the context of risk assessment, government may be primarily concerned with regulation aimed at consumer and environmental protection. As experts

[6] The results for participants working in academia may not be significant because of the very small sample involved (n=8)

employed by government tend to seek consensus regarding the views of peers regarding the impact of assessment methods on regulatory activities, it is perhaps not surprising that social norm has a strong influence on behavioural intention. Against this, for those participant employed in industry, personal attitude towards PRA is an important determinant of behavioural intention. However, self-reported *behaviour* is better predicted by perceived *behavioural control*, i.e. whether participants employed in industry believed they actually have the skills to the method, although these participants also take reasonable account of social norms. This is reasonable, as risk assessors in industry are frequently employed in providing assessments which are acceptable to the regulatory community. Adoption of PRA within industry is therefore likely to be contingent on both provision of appropriate training and easily manageable analytical techniques, as well as regulatory acceptance of the methods.

Both consultants and members of the academic community base their adoption of PRA mainly on behavioural intention, which in turn is largely determined by their attitude towards PRA. For those participants working in academia, perceived control of the method is a very important determinant of perceived intention to use the PRA method, perhaps because the subtleties of methods, and indeed their development, are focus of their interest rather than usability alone. This may not be the case for other end-users. In general the academics in the survey had a slightly higher positive view on PRA, and reported using them more frequently. This perhaps suggests that, for many potential end-users, PRA is still regarded as a method under scientific development, and has yet to be applied as a standard within the end-user community more generally.

11 General discussion and conclusions

The report has emphasised various factors of relevance to adoption of PRA by expert assessors in different communities. One conclusion is that a high rate of adoption of PRA methods is unlikely unless effective communication about the method, the interpretation of results, and the final implications for policy development is developed. The case studies and analysis of presentational format has indicated that differences in understanding and application of the methods are contingent on developing an effective communication strategy. Other social factors (for example, peer approval and acceptance of PRA methods) may also influence adoption, although this is contingent on other factors such as employment sector. Thus within the regulatory community PRA will be accepted if there is consensus within the community regarding acceptability of the methods, although it seems not to be contingent on individual understanding of how to actually conduct the analyses. In other sectors, “hands on” experience of actually performing PRA is important.

Thus within the regulatory sector, effective communication might usefully focus on interpretation and comprehension of the outputs.

Simplicity of presentation appears to be an important factor in developing effective communication. The use of communication approaches already familiar to, and accepted by, end-user communities (for example, graphics utilising cumulative rather than exceedance functions are better understood by end-users, although bar chart presentation are the best option if possible) is important. Multiple approaches to delivering the same information are also useful (for example, the use of narrative approaches as well as tables and / or graphics). *Different outputs* may be suitable for different audiences, e.g. tables and cumulative distributions for technical experts, bar charts for regulatory staff, and narrative text for lay people. This must be considered systematically in the process of communication.

Developing end-user confidence in PRA methods is essential if regulatory adoption is to occur. Confidence in the rigorousness of the approach may be developed through demonstrating that unfamiliar probabilistic assessments give similar results to familiar deterministic approaches. Providing understandable interpretations of the implications of the results of PRA is also essential if the utility of PRA is to be demonstrated to end-users. Combining probabilistic methods with other novel or complex assessment methods adds to the difficulty of communication and acceptance of the overall assessment.

In conclusion, the research presented here has indicated that developing an effective communication strategy about PRA is feasible, but must be targeted to the needs of the final end-user. Whilst adoption of PRA as the basis of regulation is not contingent on decision-makers having experience of actually conducting assessments, it is dependent on developing acceptance across the regulatory community about the reliability and utility of the outputs. This can only be achieved through development of an effective communication strategy which explicitly meets the needs of end-users in different communities, including the general public.

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Appendix A: Budapest end user survey:

Introduction

The EU-funded project EUFRAM aims to develop a framework to help risk assessors adopting probabilistic risk assessment methods.

In a number of workshops the results of EUFRAM have been shared with end-users in the risk assessment and decision-making community. However, we would like to know whether the end-user community is now in favour of adopting probabilistic approaches to pesticide risk assessment.

Therefore we kindly ask you to fill out the following questionnaire, during the Budapest workshop. The surveys will be collected during the lunch period on day 2 (Thursday 6 July).

This questionnaire asks for your thoughts on several issues in relation to probabilistic risk assessment.

Some of the questions may seem unexpected or irrelevant. It might also be that some of these questions may appear to be similar, but they do address somewhat different issues.

Please make sure to fill out every question even it seems a bit strange or redundant, as all questions are essential for the analysis

This survey is not a test, it is meant for us to attain a better understanding of opportunities for the use of probabilistic risk assessment. Your answers will be treated confidentially and anonymously.

Filling out this survey is expected to take about 20 minutes.

Please take care that you answer each of the questions.

Thank you very much for your co-operation

Instructions

Many questions in this survey make use of rating scales with 7 places.

You are asked to circle the number that best describes your opinion.

For example, if you were asked to rate "The Weather in Budapest" on such a scale, the 7 places should be interpreted as follows:

The Weather in Budapest is:

bad	1	2	3	4	5	6	7	good
	extremely	quite	slightly	neither	slightly	quite	extremely	

If you think the weather in Budapest is extremely good, then you would circle the *number 7*, as follows:

The Weather in Budapest is:

bad	1	2	3	4	5	6	(7)	good
	extremely	quite	slightly	neither	slightly	quite	extremely	

If you think the weather in Budapest is quite bad, then you would circle the *number 2*, as follows.

The Weather in Budapest is:

bad	1	(2)	3	4	5	6	7	good
	extremely	quite	slightly	neither	slightly	quite	extremely	

In making your ratings, please remember the following points:

- Be sure to answer all items even if the question seems strange– do not omit any.
- Never circle more than one number on a single scale.
- This is not a test, your answers will not be linked to your person in any way.
- We are very grateful for your cooperation as these results may help future application of the Eufram results.

Please answer each of the following questions by circling the number that best describes your opinion. Some of the questions may appear to be similar, but they do address somewhat different issues.

Please read each question carefully.

1) In order for me to gain a better understanding of probabilistic risk assessment the Eufram workshops are

Extremely bad	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely good

2) In order for me to have an opportunity to interact with other specialists the Eufram workshops are

Extremely bad	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely good

3) The information and explanations provided regarding materials on probabilistic risk assessment through the Eufram workshops are

Extremely bad	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely good

4) I am familiar with probabilistic risk assessment

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

5) I have produced probabilistic risks assessments myself

Never	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very frequently

6) I have reviewed probabilistic risks assessments by others

Never	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very frequently

7) I understand probabilistic risk assessments in reports by others

Not at all	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very well

8) Which Eufram activities have you attended?

I attended the Eufram Workshop in Dublin (October 2005) ❍ Yes / ❍ No

I attended the Eufram Workshop in Brussels (March 2005) ❍ Yes / ❍ No

I attended Eufram meetings before March 2005 ❍ Yes / ❍ No

9) My age is ___________ years

10) My gender is ❍ Male / ❍ Female

11) My occupational background is (tick one)

❍ Government / ❍ Industry / ❍ Consultancy / ❍ Academic / ❍ Other: ________________

12) My principal work activity at the present time consists of (tick one)

❍ Risk Assessment / ❍ Risk Management / ❍ Risk Communication / O Other:_______________

13) For me , application of probabilistic risk assessment is

Extremely difficult	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely easy

14) Most people who are important to me in my work think that…

I should not	___1___	___2___	___3___	___4___	___5___	___6___	___7___	I should

…apply probabilistic risk assessment

15) For me to apply probabilistic risk assessments on a regular basis is

Extremely bad	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely good

16) I plan to use probabilistic risk assessment on a regular basis

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

17) Whether or not I use probabilistic risk assessment is completely up to me

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

18) Most of the people in my line of work with whom I am acquainted use probabilistic risk assessment on a regular base

Definitely false	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Definitely true

19) For me using probabilistic risk assessment on a regular basis is

Extremely worthless	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely valuable

20) I am confident that if I wanted to I could use probabilistic risk assessment on a regular basis

Definitely false	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Definitely true

21) It is expected of me that I use probabilistic risk assessment on a regular basis

Definitely false	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Definitely true

22) For me to use probabilistic risk assessment on a regular basis is

Extremely unpleasant	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely pleasant

23) I will make an effort to use probabilistic risk assessment on a regular basis

I definitely will not	___1___	___2___	___3___	___4___	___5___	___6___	___7___	I definitely will

24) For me to use probabilistic risk assessment on a regular basis is

Impossible	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Possible

25) Most people whose opinions I value would approve of using probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

26) For me to use probabilistic risk assessment on a regular basis is

Boring	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Interesting

27) I intend to use probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

28) Generally speaking, how much do you care about what your direct supervisor thinks you should do?

Not at all	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very much

29) Generally speaking, how much do you care about what the sponsor of your project thinks you should do?

Not at all	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very much

30) Generally speaking, how much do you care about what your colleagues think you should do?

Not at all	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Very much

31) Applying probabilistic risk assessment on a regular basis will help me to gain a better understanding of the underlying risk levels associated with pesticide exposure

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

32) Applying probabilistic risk assessment on a regular basis will help me to do well and receive praise for my work

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

33) Applying probabilistic risk assessment on a regular basis will give me an opportunity to interact with specialists and colleagues in the field of risk assessment

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

34) Applying probabilistic risk assessment on a regular basis will help me to keep up with the newest developments in my area of activities

Extremely unlikely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Extremely likely

35) Applying probabilistic risk assessment on a regular basis will help me to develop good research habits, and a feeling a self-satisfaction

Extremely unlikely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Extremely likely

36) Applying probabilistic risk assessment on a regular basis will help me to get information and explanations regarding ongoing issues in risk assessment

Extremely unlikely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Extremely likely

37) Applying probabilistic risk assessment on a regular basis will subject me to tedium and boredom

Extremely unlikely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Extremely likely

38) Applying probabilistic risk assessment on a regular basis will help me to get the best possible results out of my job

Extremely unlikely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Extremely likely

39) How often do you encounter unanticipated events that place demands on your time?

Very rarely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Very frequently

40) How often do you feel ill, tired or listless?

Very rarely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Very frequently

41) How often do family obligations place unanticipated demands on your time?

Very rarely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Very frequently

42) How often does work or employment place unanticipated demands on your time?

Very rarely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Very frequently

43) How often do other assignments place heavy demands on your time?

Very rarely ___1___ ___2___ ___3___ ___4___ ___5___ ___6___ ___7___ Very frequently

44) If I encountered unanticipated events that placed demands on my time, it would make it more difficult for me to apply probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

45) If I felt ill, tired, or listless, it would make it more difficult for me to apply probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

46) If I had family obligations that placed unanticipated demands on my time , it would make it more difficult for me to apply probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

47) If my work placed unanticipated demands on my time, it would make it more difficult for me to apply probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

48) If other projects placed heavy demands on my time, it would make it more difficult for me to apply probabilistic risk assessment on a regular basis

Strongly disagree	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Strongly agree

49) My supervisor at work thinks that I should apply probabilistic risk assessment on a regular basis

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

50) The sponsor of my projects think that I should apply probabilistic risk assessment on a regular basis

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

51) My close colleagues think that I should apply probabilistic risk assessment on a regular basis

Extremely unlikely	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Extremely likely

52) When I have to conduct a risk assessment for my job, I conduct probabilistic risk assessments

Never	___1___	___2___	___3___	___4___	___5___	___6___	___7___	Always

- Did you fill in all the questions?

Please hand this survey in at the entrance to the restaurant at lunch on day 2 of the workshop (Thursday 6 July).

Results will be published in the Eufram documentation. No individuals will be identified.

Once again, many thanks for your co-operation!

Theoretical Framework

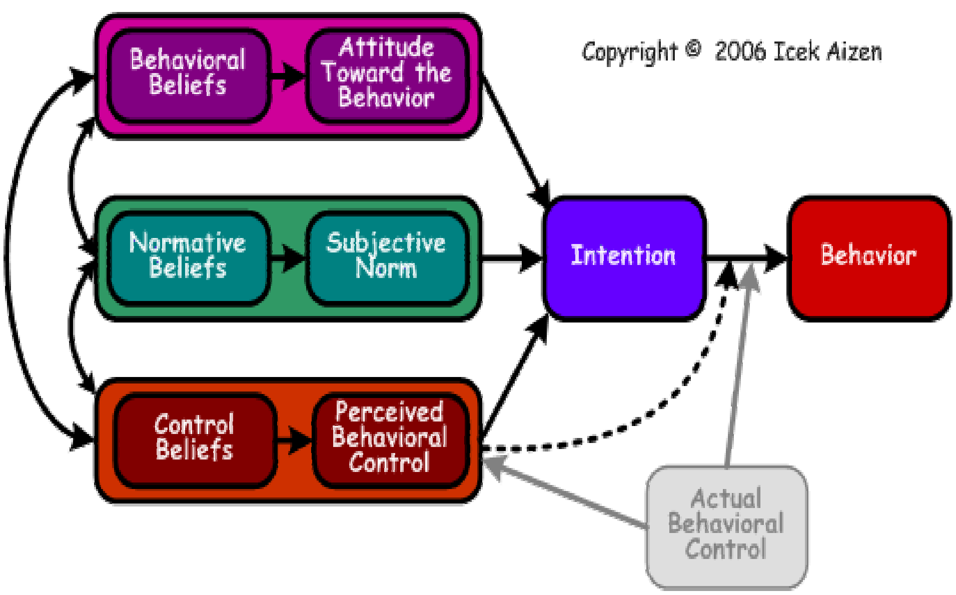
NOT TO BE INCLUDED IN THE SURVEY FORM

We may assume that the choice for an approach to Risk Assessment is planned within a project. Therefore, this behavioural decision can be considered Planned Behaviour. This is expected to fit well within the boundaries of one of the most influential models in social psychology, the Theory of Planned Behaviour (Ajzen, 1991).

In the EUFRAM 2006 survey intention to adopt probabilistic risk assessment as a tool by professionals is measured with a survey based on the classical theory of planned behaviour.

This allows us to identify barriers among professionals for the adoption of probabilistic risk assessment practices as well as the strongest indicators for that adoption.

By adding questions on Eufram and experience (1-13) we will be able to measure the efficacy of the Eufram workshops, and personal experience in the adoption of Probabilistic Risk Assessment. This will be added to the model by investigating the *moderating* effect of items 1-13 on the relations in the model.



Set up of the Current Survey: (underlined phrases relate 1:1 to nodes in the figure above)

Question 1 – 7: General questions on Eufram usefulness and understanding of the method (not in figure – to be used as moderator)

Question 8 – 12: Key experience and demographic variables (not in figure – to be used as moderator)

Question 13 – 27: Measures of Attitude=Mean(15, 19, 22, 26), Subjective Norm=Mean(14, 18, 21,25), Perceived Behavioral Control=Mean(13, 17, 20, 24), and Intention=Mean(16, 23, 27)

Question 28 – 30: Motivation to Comply (not in figure – See below normative belief)

Question 31 – 38: Behavioural Beliefs=Mean(31,32,33,34,35,36,37,38)

Question 39 – 43: Control Belief Strength (not in figure – See below behavioural belief)

Question 44 – 48: Power of Control Factors (not in figure – See below behavioural belief)

Question 49 – 52: Normative Belief Strength (not in figure – See below normative belief)

Question 52: Self reported Behaviour=52

Normative Beliefs α Normative Belief Strength*Motivation to Comply

Or practically: Normative Beliefs = Mean(28*49,29*50,30*51)

Control Beliefs α Control Belief Strength* Power of Control Factors

Or practically: Control Beliefs = Mean(39*44,40*45,41*46,42*47,43*48)

EUFRAM

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

Work Package 10

SOFTWARE AND DATABASES FOR PROBABILISTIC ASSESSMENT[2]

Version 3 of Report on software and databases for probabilistic assessments, August 2006

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Contents

[1] EUFRAM is 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] This document is the responsibility of its publishers and in no way represents the views of the European Commission or its services.
[3] Work Package (co)leaders.

1 OBJECTIVES

Within EUFRAM, one Work Package (#10, Software and Databases) focused on two objectives, viz.:

"…. (to) establish a common methodology for selecting software and databases for probabilistic pesticide risk assessments, *and* evaluate examples currently in use by partners for possible adoption as harmonised standards in the EU" (EUFRAM contract, 2002).

These objectives are largely related to the process of developing the final goal of the EUFRAM-Concerted Action, that is:

"…the development of a framework for probabilistic risk assessment of plant protection products, and the publication of this framework in the format of both a Framework Document and as worked Case Studies that illustrate how the Framework would be useful in practice."

The workpackage on Software and Databases was thus process-oriented rather than in integral part of the framework. The current report therefore provides background information on software and databases; this part of the report is thus not part of the Framework. The list of desirable software and database characteristics, which relates to the key relevance of this workpackage for the Framework is the part of workpackage findings that is taken up in the Framework Document.

The aim of this report is to provide background information, associated to the EUFRAM-developed Framework Document, with regards to issues on software and databases for PRA.

2 BACKGROUND

2.1 General

A workshop on "Probabilistic Risk Assessment for Pesticides in Europe: Implementation & Research Needs" (**EUPRA**) was held in the Netherlands, in June 2001 (Hart 2001). Broadly speaking, the added notion of "probabilistic" (**P**) to the concept of "risk assessment" (**RA**) refers to methods that attempt to quantify variability and/or uncertainty in factors that influence risk, and express risk in terms of the probability and magnitude of adverse effects. The methods currently used for these assessments are predominantly deterministic rather than probabilistic. They use fixed values for exposure, toxicity and risk, and attempt to allow for variability and uncertainty by using worst-case assumptions and safety factors. A probabilistic approach in risk assessment, **PRA**, would allow for variation and uncertainty by using distributions, instead of fixed values, for exposure, toxicity and risk.

Probabilistic methods are common or are being increasingly adopted for various purposes in human society, like insurance industry, safety design of e.g. nuclear power plants, and the design of dams and other constructions. PRA might also be explicitly useful in assessing the impact of plant protection products (pesticides) on the environment. Directive 91/414/EEC and its Annexes require EU member states to analyse these risks before authorising pesticides for sale.

2.2 EUPRA recommendations on Software and Databases for PRA

The EUPRA workshop considered the potential of probabilistic methods for assessment of ecological risks of plant protection products in relation to the above mentioned Directive. The EUPRA workshop reviewed the state of the art, and made detailed recommendations. Together, these recommendations were shaped into the EUFRAM-project, the “Concerted Action to develop a European Framework for probabilistic risk assessment of the environmental impacts of pesticides”.

Amongst others, the EUPRA recommendations specifically addressed the availability and selection of **Software and Databases for probabilistic risk assessment**, since PRA requires software and data sets when the approach is to be practically implemented as assessment approach in the European practice.

This report specifically focuses on the EUPRA recommendations on Software and Databases. The detailed recommendations for this work package, according to Hart (2001), are:

1. that standard software tools for probabilistic assessment should be adopted, at a level of complexity appropriate for users in all parts of the EU regulatory arena.
2. that, in order to avoid duplication of effort, consideration should be given to whether tools developed elsewhere could be appropriate for use in the EU, either in whole or in part.
3. that there is an urgent need to catalogue existing data that would assist the development and operation of probabilistic approaches, and to collate these data in publicly-available, quality-controlled databases. The catalogue of data should include pesticide-specific data (e.g. toxicity, for use in developing SSD methods) and general data (e.g. geographical and ecological data).
4. that databases and software should be made easily accessible, to promote harmonised approaches

2.3 Current situation and problems in Software and Databases for PRA

Regarding the availability of **Software**, the EUPRA report already mentioned the existence of a relevant body of work of US-EPA (http://www.epa.gov/scipoly/sap/index.htm). Although the approaches applied in the US are very valuable for developing the EUFRAM Framework as a whole, the software and databases used in the US-approach cannot be applied directly in the EU-context. This relates both to the differences between the legislations and their historical context, as well as to the scientific consequences these have for the probabilistic modeling and product evaluations.

Regarding the availability of **Data**, it was noted that some data-sharing initiatives are already underway (the RED-project, the SEEM-project, the US-EPA Ecotox database), but that data sharing may be hindered by issues related to commercial interest, confidentiality and data ownership. This situation has not been solved, since there are major economical reasons, especially for companies but also for govenrment-related organizations, to maintain their knowledge bas protected, either in full or in part. Furher information on this subject is provided in the report of Work Package 11, “Pooling data for probabilistic assessments”.

Regarding **Application** of Software and Databases, the existence of an array of technical limitations hampers the application of PRA-techniques in practice. As yet, no single, easily accessible database covering all data sources that are needed has been designed, and it is questionable whether combining a set of existing databases (under the hypothetical assumption of absence of limitations posed by confidentiality and data ownership, e.g., on physico-chemical properties of compounds, of toxicological test results, and of species-specific, biological characteristics of test species) would solve the issue. Similarly, software has mostly been developed for in-company use and for various separate steps in the PRA-process. For various modelling steps, one model can be represented by various software items. However, the existing software programs do not systematically cover all steps that can be identified in a systematic framework for PRA, while arrangements to guarantee broader availability are lacking. Finally, the requirements that usually accompany systematic application within a legal framework are not met.

Solutions for these problems require co-operation between the owners of the data on the one hand and software developers on the other hand. Eventually, sharing data and software would provide benefits to all stakeholders and the ease, reproducibility and transparency of the compound evaluation process. Regarding the need for extra data, the collaboration could indirectly lead to a reduction in the amount of animal testing required in future. These issues are addressed in EUFRAM Workpackage 11.

2.4 Steps taken so far to address prevailing problems

To address the EUPRA recommendations, **EUFRAM Work Package 10** was designed, to focus specifically on Software and Databases. Relating to the major aims of WP10, this report provides a compilation of criteria for evaluating databases and software, and, by using those criteria, and it provides a first evaluation of some of the operational databases and software items currently available.

The work in Work Package 10 has been formatted according to the following steps:

1) The making of an inventory of existing Software and Databases, resulting in a Preliminary paper composed from contributions written by experts in the field (Posthuma *et al.* 2003),
2) The definition of preliminary criteria to select Software and Databases that could be appropriate for any relevant step in the process of PRA (Posthuma *et al.* 2003), and
3) The targeted evaluation of the inventory of Software, Databases and preliminary criteria at an expert workshop on Software and Databases for PRA (held in June/July 2003), in which both the preliminary criteria were discussed and refined, and in which the existing Software and Databases were confronted with the refined criteria, to identify the currently most promising examples for implementation (De Zwart *et al.* 2003).
4) The publication of a final report on Software and Databases, to provide background information on Software and Database issues mentioned in the Framework Document as developed by EUFRAM.

2.5 Contents of this report

This report presents the Work Package results as obtained in the process of EUFRAM until present (August 2006) on the steps 1 – 3, esp. on:

- the common methodology for selecting Software and Databases for probabilistic pesticide risk assessments, that is: to list the criteria to evaluate Software and Database items within the EUFRAM framework
- the inventory of existing software and database items
- the evaluation of the examples that have been presented at the Software and Database workshop of 2003, and that are currently in use by partners, using the evaluation criteria

Note that no further, systematic evaluation of software and databases takes place continuously.

3 IDENTIFICATION OF SOFTWARE AND DATA NEEDS IN PRA

3.1 Schematic overview

Software and databases for PRA of plant protection products will eventually serve within the framework being developed and tested within EUFRAM. Thus, the precise requirements imposed by the EUFRAM-framework will only be clear *after* publication of the Framework to be produced by EUFRAM. Nonetheless, insight in the types of assessments that can be the subject within a PRA is crucial to focus the attention to the right issues. That is: those issues that are likely part of the eventual PRA-process designed by EUFRAM. This Chapter provides the schematic background for the analyses that are made.

Risk of a compound is commonly considered to be present when exposure exceeds a (conceptual) no-response level, or (more general) a relevant sensitivity parameter. This general definition shows that risk assessments consist of both an exposure and an effect assessment.

A general scheme showing the association between the different aspects (potentially) relevant for PRA is given in Figure 3-1. Exposure and sensitivity and associated effects are shown in the central part of the Figure, and are addressed by modelling (either or not validated or verified by measurements in the exposure medium or on effects observed in exposed organisms).

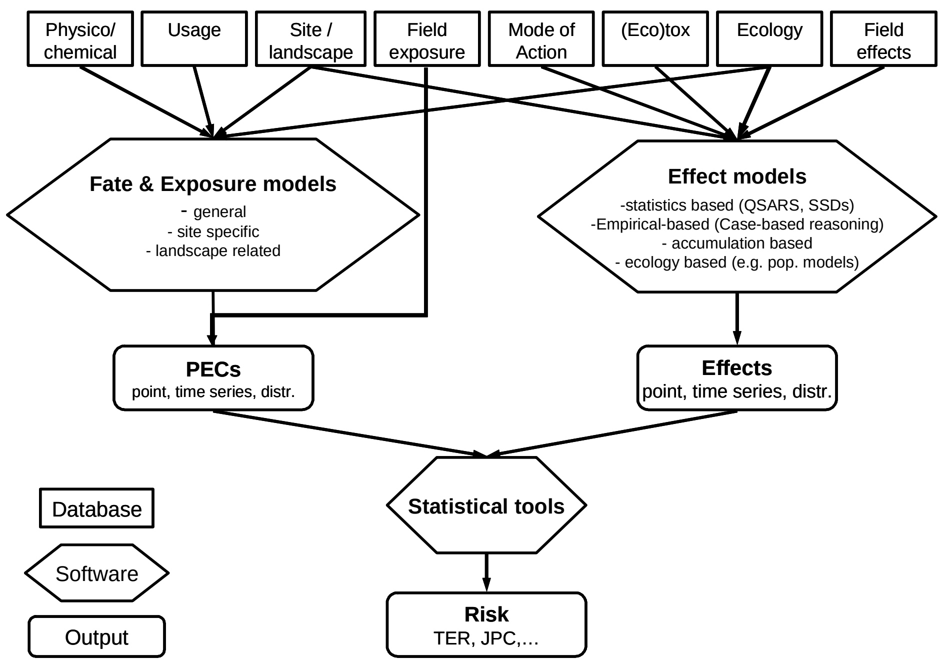

Figure 3-1. Schematic representation of possible steps in risk assessments, identifying the 'position' of Software, Databases and Output. For explanation: see text.

Both exposure and effects are influenced by an array of factors. Conceptually, these range from the physico-chemical properties of the compound, usage pattern, site/landscape characteristics to the ecological niches of the exposed species when considering exposure. When considering effects, the array is from site and landscape data, via the toxic mode of action, ecotoxicological sensitivity, ecological characteristics of the species to field effects (upper part).

For EUFRAM, it is assumed that field data of exposure are usually not available (i.e. for registration of new pesticides), but that exposure is predicted by modelling. Equivalently, the (conceptual) no-response level (or sensitivity of the exposed or target organism) is not known. It can e.g. be predicted from a statistical description of sensitivity data (a Species Sensitivity Distribution, **SSD**), in the derivation of which one may or may not include incorporation of (aut)ecological information to select the species data pertinent to the assessment target.

Both the (statistical) distribution of (predicted) exposure concentrations (**PEC**s, in space or time) and the distribution of effects are obtained by modelling (middle part). In both cases, the model may be using simple assumptions (use only few parameters of the top selection) and approaches, or more complex ones, the latter according to a tiering principle. The PEC data are 'overlaid' with the (statistical) distribution of effects, in most cases an SSD, e.g. of No Observed Effect Concentrations, **NOEC**s) to produce a so-called Joint Probability Curve (**JPC**) and to calculate the final risk parameters, of which various (equivalent) forms exist, e.g. the Expected Total Risk (**ETR**) and the Ecological Risk (Aldenberg *et al.* 2002), (Solomon & Takacs 2002), (Van Straalen 2002) and others). As an example see Figure 3-2.

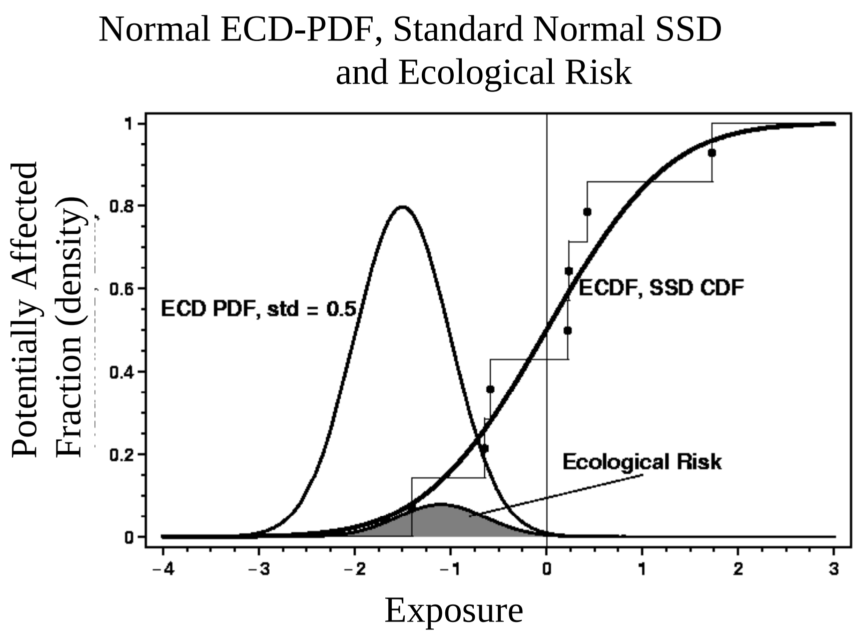

Figure 3-2. An example of a probabilistic approach in ecological risk assessment. Sensitivity data (a Species Sensitivity Distribution-Cumulative Distribution Function, SSD-CDF) are overlaid with exposure data (an Exposure Concentrations Distribution-Probability Density Function, ECD-PDF). The ecological risk is calculated from both distributions according to (Aldenberg *et al.* 2002).

Aldenberg (pers. comm.) has shown that all models in which this type of overlays are produced, though described in different terms, boil down to one, universal statistical approach. Moreover, as linkage to the deterministic approach in risk assessment, the well-known PEC/PNEC ratio approach, or the equivalent Toxicity Exposure Ratio (**TER**) approach used for pesticides in Europe, can statistically be seen as the simplest form of a JPC-approach. That is: one that consists of the ratio of two point estimates, of PEC and PNEC, rather than of broader distributions.

While the JPC-approach is probabilistic in kind, the first principles of this approach do not necessarily reach farther than the use of statistical distributions of PEC and PNEC *per se*. That is: the first principles of the methods do not necessarily use (aspects of) ecological theory to predict risk. In the right part of the Figure, 'ecology-based models', such as population models, are identified. In this case, the risk assessment approach is (at least in part) building forth on ecological first principles. For example, the risk for extinction (or *vice versa*: the probability of maintaining a viable population) can be calculated using e.g. information on birth rate, survival time, juvenile period and death rate (and distributions thereof) under pesticide exposure.

The scheme is worked out below in more detail.

3.2 Aspects of Fate and Exposure

The issue of 'Exposure' (left side of Figure 3-1) is commonly addressed by Fate and Exposure Modelling. Both terms can be used (often interchangeable) in the context of risk assessment. These models (when interpreted in their narrow-sense meanings) capture two processes:

1. Fate modelling: Modelling used to predict the place where compounds used in agricultural practice 'end up' in the environment. That is: to predict the local concentrations in environmental compartments
2. Exposure modelling: Modelling used to predict the level of exposure experienced by an ecological receptor (e.g., an individual, a species, a community), given a certain concentration in an environmental compartment. That is: to predict the biologically relevant concentration of a compound. A compound needs not be completely available for uptake due to partitioning processes (e.g., sorption to the matrix), or due to specific ways in which organisms explore their environment (niche choice, behaviour, food choice).

Fate and exposure models may require the following types of data:

1. Compound-specific data: Data on the inherent physical and chemical properties of the compound, used as key parameters in Fate and Exposure models
2. Usage data: Data on the use of the compound (amounts, crops, periods of use, application methods), used in Fate and Exposure modelling
3. Site-characteristics: Data on the landscape in which the compound is used, including data on matrix properties (e.g., soil type), for Fate and Exposure modelling.
4. Characteristics of exposed organisms: Data on the exposed species, in terms of routes of exposure (food intake rate, et cetera)

Despite the interchangeable use of the terms, the emphasis in modelling is often on fate modelling.

The data (3 – 6) can be obtained only in part from generic databases. Generic databases pertain to the 'universal' (or 'generic') properties of the system, such as pertaining to compound properties like the octanol-water partition coefficient, the fugacity, et cetera. The other part contains modelling parameters that are of interest for site- or species specific assessments, such as in the case of using soil and/or landscape properties of an identified site to predict fate and exposure levels at such a site. Further, 'intermediate' data sets can be envisaged, such as databases on measured crop residues, which may be used in risk assessment next to- or instead of Predicted Environmental Concentrations.

The combination of data from databases with the Fate and Exposure models eventually results in the *predicted fate or exposure*, either in scenario conditions (hypothesised conditions as stand-in for real world possibilities) or in real conditions (an identified site for which an assessment is needed). This can take the format of a single-value estimate, or of a distribution of fate/exposure data in space and/or time.

3.3 Aspects of Effects data

The issue of 'effects' (middle-right part of Figure 3-1) can potentially be addressed in various ways. The more 'refined' a risk assessment should be (higher tiers), the more specific the effects data are needed, and the more realistic the assessment approach is in comparison to the system being assessed.

In lower-tier, generic approaches, statistical distributions of sensitivity data that were generated in laboratory conditions might be considered sufficient as first principles. For example, one can use lab-derived NOECs to construct the relevant Species Sensitivity Distribution (Posthuma *et al.* 2002a) using all available data. In more specific approaches, one might focus on certain species or species types typical for a given landscape, or to the exposure level of interest (e.g., use EC50s to construct the SSD rather than using NOECs, see e.g. (Posthuma *et al.* 2002b). This implies species selection or endpoint selection prior to SSD-construction, which would require a database containing different sensitivity endpoints (NOECs, EC50s, ECx), a database on (aut)ecological preferences of species and a database on biogeographical distribution ranges of species.

In assessments where specific protection endpoints are defined, e.g., in terms of risk for extinction of identified species, attention would be focused on the (aut)ecological characteristics of the species, to fill out how the parameters of the population model respond to exposure.

As final issue, pesticides are often developed to elicit specific toxic action. This relates to the concept of (Toxic) Mode of Action (**TMoA)** - a concept pertaining to the molecular-level interactions between a compound molecule and a receptor molecule inside an organisms' tissues. Risks for organisms possessing the target molecule are expectedly larger than for organisms that lack the receptor site. For the latter organisms, the presence of only baseline toxicity would mark the 'ideal pesticide' in this respect. However, also apparent (secondary) toxicity is possible, whereby the compound molecule interacts with non-target molecules, to cause toxicity to an extent that is often expected to be smaller than for target toxicity. This shows up as different slopes and positions of SSDs constructed of data sets of target organisms as compared to those of non-target organisms (Figure 3-3).

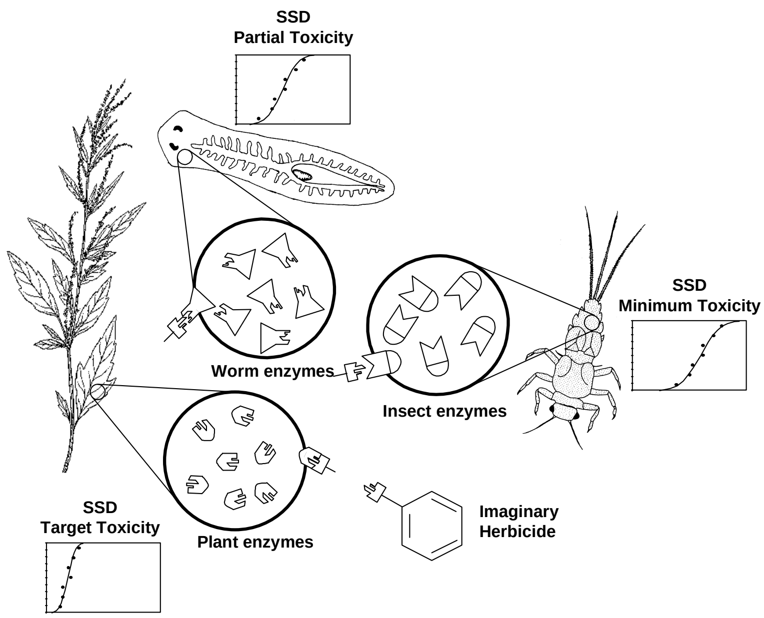

Figure 3-3. Conceptual representation of the influence of TMoA on the shape of the SSD curve when considering classical, toxicological target toxicity, and other effects.

Currently, although the TMoA of a pesticide is often well-defined for the target (pest) organism, it is a matter of further scientific development as to assign primary and secondary (or even tertiary) TMoAs to address non-target organisms. This would be an addition to the concepts of baseline toxicity and primary target toxicity as accepted theories (Posthuma *et al.* 2002b).

The issue of TMoA, and its 'capture' in databases and theory and models has recently gained in importance. In the evaluation of new pesticides, it is useful to consider if data are available for substances with similar TMoA as the compound of concern. Such data are useful to obtain a preliminary view on the risks of a compound, for example by the Case-Based Reasoning approach followed in PERPEST, see www.perpest.alterra.nl (Van Den Brink *et al.* 2002).

3.4 Software and databases potentially needed for PRA

Given the schematic steps that can be part of PRA (Figure 3-1) one can easily deduct the complete set of databases and types of software needed for an assessment of pesticide risks. From the databases, one might apply widely defined data queries to select a large set of data assumed relevant for the assessment. For example, one may select one or all NOEC-data to construct a single sensitivity distribution. From the models, one may choose models founded in statistics, e.g., the distribution of sensitivities (an SSD). Alternatively, one may select models founded on conceptual descriptions of the phenomenon (e.g., population models), on truly mechanistic phenomena (molecular interaction of the pesticide molecule with receptor molecules), or one may use purely empirical models (e.g. Case-based reasoning).

Key to EUFRAM is the notion of 'probabilistic'. This means that distributions of data are modelled rather than point estimates, which asks for specific features of the model, and of the 'software environment' in which the model is implemented. Since there are ‘standard’ software environments (‘shells’) that are specifically designed for probabilistic approaches, those shells can be considered as relevant issue for evaluation within the EUFRAM development process.

Probabilistic approaches also ask for specific attention for options to allow for the required ways of data querying. Usually, an array of data is needed to grasp variability. Further, for the registration of new pesticides, it could be profitable to have options to select data from (toxicologically) related compounds, and highly profitable to have access to (as yet) non-public data.

EUFRAM may eventually develop a probabilistic risk assessment approach based on tiering principles, or not. Decisions on this aspect are taken outside of the scope of this report.

4 SOFTWARE AND DATABASE EVALUATION CRITERIA

4.1 Approaches to define evaluation criteria

Evaluation criteria for software and databases can be taken from different open sources. Gross criteria lists can be found easily, focusing on the general sets of criteria that Software and Database developers apply to optimise their products. The sites http://www.so.cc.va.us/vccsit/Archive/SoftEval.htm and http://www.so.cc.va.us/vccsit/softchek.htm give examples of general criteria and general checklists. These general inventories show that software and database developers focus on an array of checkpoints, under various main headings. The criteria headings range from purely technical criteria for the IT-infrastructure up till criteria focusing on the population of users (e.g., are users trained or not; can training be easily arranged) and legal criteria (administrative requirements, e.g., under EU-regulations).

Since general checklists like those cited above are not tailored to the EUFRAM targets, a tailored inventory of criteria was made amongst current experts in (Probabilistic) Risk Assessment. This process has led to a draft list of potential objective criteria applicable to EUFRAM, as shown in Table 4-1 (for software for PRA) and Table 4-2 (for databases for PRA).

The criteria are grouped under various main ‘headers’, focusing mainly on science and application in PRA-practice (both from a users’ point of view as well as the point of view of the legal context).

Table 4-1. Inventory list of objective criteria that can be used to evaluate the appropriateness of an available software item for the eventual EUFRAM targets.

Category	Criterion	Subcriterion
Science	Model coverage	All PRA aspects
		Part of PRA aspects: fate
		Part of PRA aspects: exposure
		Part of PRA aspects: effects
		Part of PRA aspects: risk
	Model underpinning	Published
		Validation available
	Model specifications	Option to account for variability and uncertainty
		Option to choose optimal model for problem
		Options to shape PRA approach to problem
		Custom-made tools (e.g., in Excel) appropriately execute desired function
		Built-in tools (e.g., in Excel) appropriately execute desired function
Application	Ease of use	'Feeding' of input data
		Exporting of output
		Printing of output
		Screen interface
		Shape of output format: numerical
		Shape of output format: graphical
	Usefulness of output	Option to show confidence bands
	Shell availability	Broadly dispersed and known
		Free availability
		Current dispersal over potential users
		Windows-based
		Web-enabled use possible
	Format	Dependency of executable of shell version
	Technical capabilities	No limitations on required data entry (max. n of rows/columns)
	Future use / legal adoption	Suitability for EUFRAM targets

Merging of the overall ideas from (general) software and database developers and experts in the field provide the list of key criteria on which specific focus is to be put for developing the EUFRAM framework. Such a merging of ideas took place during the Software and Databases workshop organised in the EUFRAM context, June 2003.

The development process (including the workshop discussions) implies that the criteria have been *listed* as a long-list before existing software and database items were exhibited and before some hands-on experience was gained, and that they have been *refined* and *specified for PRA-practice* in the EUFRAM-project *after* gaining hands-on experience.

In the subsequent paragraphs, the criteria for software and databases are addressed. The criteria provided below can be not only interpreted as selection criteria (i.e., to choose amongst existing software and database items), but also as guidance to software and database development. The experts' views provide the general criteria of the ideal software and databases that should be developed in case such matters lack.

Table 4-2. Inventory list of objective criteria that can be used to evaluate the appropriateness of an available database for the eventual EUFRAM targets.

Category	Criterion	Sub-criterion
Science	Data validity	Raw data = data entry
		Quality earmark
	Data aspect	Fate
		Exposure
		Effect
	Data context	Values for modifying factors (contextual data, covariates)
	Data quality	Quality of the study (e.g, GLP, compliance with regulation x)
		Identification of 'doubles'
		Indication of uncertainty on estimated values (e.g., EC50 with C.I.)
		Information on limit of detection
	Data coverage	Allowing for versatile data query / sub-selections
		Wide coverage of existing data
	Database	Published
Application	Ease of use	'Feeding' of new data
		Exporting of output
		Exporting of output selections only
		Printing of output
		Screen interface
		Linkage to software for PRA
	Shell availability	Broadly dispersed and known
		Free availability
		Windows-based
		Web-enabled use possible
	Format	Dependency of executable of shell version
	Technical capabilities	No limitations on required data entry (max. n of rows/columns)
General	Future use / legal adoption	Suitability for EUFRAM targets

4.2 Definition of EUFRAM evaluation criteria

During the workshop, the draft general and 'expert'-biased criteria lists were discussed for software and databases in view of the targets of EUFRAM. Criteria were assigned to the categories 'highly desirable', 'desirable', or 'undesirable' for EUFRAM. In case there were no good 'candidate software or database items' for adoption as EUFRAM standard, these criteria can be of help in the further development of software. The results (refined criteria) are summarised in Table 4-3 for software and in Table 4-4 for database items. It should be noted, that the criteria that were mentioned will not uniformly apply to all models. The scope of the model will eventually determine the criteria that will apply most. For example, if one wants to model a specific habitat, then it is desirable that the model can be recalibrated to obtain the right level of detail. For other modelling problems, recalibration might add too much degrees of freedom for an assessment, e.g., for standard regulatory assessments. The Tables show that the workshop focused on positive rather than negative criteria: many of the EUFRAM-specific criteria were highly desirable or desirable. Only few criteria for software choice and development were characterised as 'undesirable'. The characterisation was, in those cases, addressing the fact that the characteristics would be undesirable in the case of lower-tier, regulatory assessments. In such cases, it is, e.g. in modelling, undesirable to have a wide choice of distributions, since this would lead diversification of results obtained, e.g., dependent on the preferences of the user.

Table 4-3. EUFRAM expert workshop suitability criteria for Software choice and development.

	Highly desirable	Desirable	Undesirable
Scientific characteristics			
Ability to handle different groups of compounds	X		
Multiple Spatial scale (global/regional/local)		X	
Ability to handle (pesticide) mixtures		X	
Ability to handle metabolites		X	
One stop shop (incl exposure, effects and risk		X	
Option to account for uncertainty	X		
Option to account for variability	X		
Option to account for dependencies/correlation	X		
Empirically validated (models only)	X		
Flexible model structure	For research	For higher tier	For lower tier regulatory
Wide choice of distributions	X		For lower tier
Published in the peer-reviewed literature		X	
Expert panel peer review	X		
Option to consider temporal variability/uncertainty	For higher tier/research	X	
Option to consider spatial variability/uncertainty	for higher tier/research	X	
Requires more than typically available data			for lower tier regulatory
Requires recalibration for new regions/countries			X
Contains non-data-derived adjustment factors			X
Technical			
Quality assured software	X		
Version control protocol available	X		
Model fully documented	X		
Input data error checking (incl. units)	X		
Backwards/forward compatible	X		
PC based	X		
Broadly dispersed and known shell	X		
Potential to link to other software/databases		X	
Dependence on other proprietary software			X
Ease of use			
Exporting of output	X		
Reproduce/save past run	X		
Help screens	X		
Intuitive interface	X		
Free of use restrictions	X		
Any windows-based application	X		
Ability to cut/paste/link input data		X	
Roll-over (mouse-over) help		X	
Flexibility in data input (e.g. units)		X	
Reference fields for input data		X	
Default data and worked examples		X	
Differential User-modes (default and advanced		X	
Execution in minutes Vs. hours on Std. PC		X	
Free of costs to user		X	
Web-enabled use		X	
Support and maintenance			
Feedback loops to improve software	X		
Related to regulatory context	X		
Long-term support, updating, and maintenance	X		
User support		X	
User groups		X	

Table 4-4. EUFRAM expert workshop suitability criteria for Database choice and development.

	Highly desirable	Desirable	Undesirable
Scientific characteristics			
Modifying factors (contextual data, covariates)	X		
References for data documented	X		
Quality criteria documented	X		
Identification and handling of 'duplicates'	X		
Information on limit of detection for non detects	X		
Quality measure (e.g. measured / nominal data)	X		
Statistical method described		X	
Indication of uncertainty on estimated values (EC50 with CI)		X	
Quality of the study (GLP, compliance with regulation x)		X	
Reported with original number of digits		X	
Slope of the response lines used to estimate the EC50, LOEC or NOEC		X	
Information to judge the power of tests (e.g. sample size, statistical power)		X	
Raw data included		X	
Links to related compounds		X	
Comprehensiveness of data per endpoint		X	
Comprehensiveness of endpoints		X	
Ease of use			
Exporting of output selections	X		
Free of use restrictions		X	
User friendliness of search terms (common names)		X	
Ability to reproduce past query		X	
Flexibility in data input (e.g. units)		X	
Free of costs		X	
Includes summary tools to qualify sub-selections		X	
Software characteristics – technical			
Broadly dispersed and known	X		
Format remains in exported data	X		
Error checking routines for input	X		
Database documentation	X		
Extensible (by database manager)	X		
Allows for versatile data query / sub-selections		X	
Keeps track of changes to records		X	
No aggregate (text) fields (e.g. min & max instead of range)		X	
Web-enabled use possible		X	
Windows-based		X	
Open design for software access		X	
Support and maintenance			
Feedback loops to improve context of database	X		
Related to regulatory context		X	

Overall, the Tables show that a practice-weighted view on the scientific state-of-art in risk modelling and the data needed for that has been adopted. For the models, this means that the criteria have not been set at a currently and conceptually ideal level, but at a level that can be reached in the near future. The latter also depends on the availability and quality of the available data to 'feed' the models. For example, the idea to have all the raw data of an ecotoxicity study being reported in a database (one of the criteria) could have received universal support as being highly desirable from a conceptual and flexibility point of view. However, this criterion would lead to rejection of the current databases (e.g., for ecotoxicity data currently > 150.000 records), in which commonly only *derived* data are given, such as EC50s or NOECs. Adapting such a database to store the original raw test data would require a major effort, generally viewed as unrealistic. Evidently, the situation described here in the example is already data rich. This means that the ideal model, if any, should also be considered with view on the available data, with reference to both quality and amount.

4.3 Summary properties of ideal software and databases for PRA

The Tables provided in the previous paragraphs during the workshop contain subjective evaluations of criteria being highly desirable or desirable, reflecting the balance of workshop participants' views of their relative importance, weighted by their views of reachable goals. The lists are not intended as absolute criteria for acceptance or rejection of particular tools. Rather, they are intended as criteria that should be considered by prospective users when choosing between existing tools, and as a guide for the development of new or improved tools.

With a view upon the end-users of the software and databases for PRA, the workshop defined a more comprehensive view, superimposed on the separate tables for software and databases. Based on the criteria in the Tables, such an ideal system might be characterised as follows. It would:

1. provide a comprehensive set of models for assessing the ecological risks of pesticides and their metabolites, including both exposure and effects.
2. provide comprehensive, appropriate, referenced, quality-controlled data for all model inputs including pesticide use, physico-chemical properties, toxicity, ecological and landscape factors, and field data.
3. include dynamic links between data and models.
4. include appropriate methods for taking account of uncertainty, variability and dependencies, and for incorporating spatial and temporal variation.
5. offer different modes for different users and purposes, including standardised models and data for lower tier assessments and more flexibility for higher tier assessments.
6. be fully tested and documented, approved by appropriate expert panels, published in peer-reviewed literature and, as far as possible, empirically validated.
7. run efficiently on computer systems typically used by regulatory assessors, or be usable remotely via the internet.
8. have an intuitive user interface including automatic error-checking, extensive help facilities, and convenient methods for input and output of data and results.
9. be provided with long-term maintenance and user support services.
10. be suitable for regulatory use at both national and European level.

Researchers are likely to require more flexibility and specialist tools, that would be difficult to incorporate in a single system, but they would still benefit from the other characteristics mentioned.

It is unlikely that such an ideal system will be achieved quickly, but it is useful to indicate the direction in which developments might be most useful. In the short term, available tools may be judged by the extent to which they meet this ideal, or more specifically the criteria in the Tables (see next Chapter).

5 INVENTORY OF SOFTWARE ITEMS

5.1 Overview

At present (September 2004), 26 software items are considered within the EUFRAM project (Table 5-1.).

The software items can be differentiated into

- general tools (not especially developed fort the risk assessment of pesticides but for analysis of uncertainty and variability),
- models to estimate fate and/or exposure,
- models to predict effects, and
- tools to combine probabilistic fate and effects estimations to calculate risks and calculate Joint Probability Curves.

This differentiation must not seen as an exclusive characterisation, because some tools integrate fate and effect estimation. Fate models are further differentiated with respect to their scale (general, site specific or landscape related), while effect models were divided into statistics based models (e.g. tools to calculate SSDs), ecological models (e.g. population models) and models which consider bioaccumulation.

The inventory shows that for each of the options needed in a PRA-scheme, as conceptualised in Figure 3-1, one or more software items have been developed:

- Crystal Ball (MS-Excel add-in) and Risk Calc form general shells for e.g. uncertainty analysis,
- an array of fate and exposure situations is addressed,
- various ways of effect prediction can be chosen, and
- 9 software items can be chosen to calculate risk from the knowledge of exposure and sensitivity.

All this does, however, *not* mean that adopting (few) models from the set solves the problem, that is: there is no set of current models that, even when combined, fits the description of the ideal set of EUFRAM modelling tools (see previous Chapter). The software items have been developed in different ‘languages’, which may or may not correspond to each other. Software may, in its implementation, be very specific for particular targets, excluding direct use in the EUFRAM framework.

In order to be able to investigate whether the set of models can be used as basis for further developments, the next paragraphs provide:

1) information on the software items addressed in the inventories and discussed so far
2) the confrontation of the software items to the criteria as defined earlier, showing results of the workshop

Evidently, an array of models has not been evaluated. These models were considered of too limited importance for further development for EUFRAM.

Table 5-1. Software reviewed for the use in probabilistic risk assessment within EUFRAM (status September 2004)

Acronym	General tool (e.g. uncertainty analysis)	Fate and exposure prediction			Effect prediction			Risk prediction (e.g. JPC calculation)
		General model	Site / situation specific	Landscape related	Statistics based	Ecology based	Bioaccumulation based	
Crystal Ball	X							
Risk Calc	X							
FOCUS MACRO			X					
FOCUS PEARL			X					
FOCUS PELMO			X					
FOCUS PRZM			X					
MCPELMO			X	X				
SimpleBox		X	X					
AQUATOX			X			X	X	
Daphnia						X		
DEMETRA					X			
PERPEST					X	X		
RAMAS ecotox						X	X	
Secondary Poisoning						X	X	
SimpleChain						X	X	
SSWD					X			
Zebrafish						X		
Busy	X				X			X
ETX					X			X
GPS1						X		X
PRAT2					X			X
ARRA			X		X			X
TIM			X		X			X
USES		X			X		X	X
WEBFRAM			X		X	X		X
IQ-Tox			X		X			X

Description of Software items

The following short descriptions were extracted from the summary and fact sheets of a meta-database developed for EUFRAM-WP10 in which all model and programming information is stored for detailed reference. For more information this meta-database with more specific information can be downloaded from the EUFRAM web site (www.eufram.com in the directory of this report (deliverable database)). Specific attention is given to the aspect “probabilistic”. This aspect is judged as “yes” when the software has an explicit probabilistic design, as a whole, or in major sub-models.

5.1.1 General tool: Crystal Ball

Purpose:

Forecasting and risk analysis taking uncertainty and variability into account

Characteristics:

Crystal Ball is a simulation program that allows analysis of risks. CB considers uncertainty (amount of data or lack of knowledge) and variability (natural/intrinsic) by means of a two-dimensional simulation for characterising risk. The ‘Two-dimensional Simulation’ tool runs an outer loop to simulate the uncertainty values, and then keeps constant the uncertainty values while it runs an inner loop of the whole model to simulate the variability. The primary output of this process is a chart depicting a series of cumulative frequency distributions.

CB is implemented as an add-in to Microsoft EXCEL and utilises Monte Carlo and Latin Hypercube sampling. The program allows creating several alternative scenarios for each model. Forecast, trend, and overlay charts can be generated into reports. A sensitivity analysis option is available.

Availability:

Commercial software of Decisioneering Inc., Standard edition 882 € in September 2004. Website: http://www.crystalball.com

Probabilistic:

Yes.

5.1.2 General tool: Risk Calc

Purpose:

General tool to support probability bounds analysis, standard fuzzy arithmetic, and classical interval analysis.

Characteristics:

Risk Calc does not require specification of precise details of statistical distributions and their dependency relationships when empirical data are lacking. Risk Calc uses traditional methods such as probability theory and interval analysis and the newest techniques such as probability bounds analysis and fuzzy arithmetic to quantify uncertainty in risk assessments.

Standalone Windows program, includes a book that explains how to use the software and supplies examples from reliability engineering, human health assessment, and environmental and ecological risk analysis

Availability:

Commercial software of Applied Biomathematics, available from Lewis Publishers (149.95 $). Website: http://www.ramas.com/riskcalc.htm

Probabilistic:

Yes.

5.1.3 Fate and exposure: SimpleBox

Purpose:

Developed originally in the 1980's as a scientific tool for researchers of environmental fate processes, SimpleBox has formed the regional distribution module in the EUropean System for Evaluation of Substances (EUSES) since 1996.

Characteristics:

SimpleBox is a multimedia (air, water, soil) compartment model of the so-called Mackay type and performs mass balance calculations for the environmental compartments considered (40 in all). The mass balance terms are: emissions into each compartment, advection with air and water, intermedia exchange (atmospheric deposition, volatilisation from water, soil and vegetation, soil run off and erosion, sedimentation and re-suspension), and removal (leaching from soil to groundwater, burial in deep sediments, degradation in all compartments). SimpleBox solves the set of mass balance equations in two different modes: steady-state (Mackay level 3) mode, or quasi-dynamic (Mackay level 4) mode. SimpleBox takes the nesting approach to accounting for spatial variability: it models a small area of high emission intensity (hot spot) as a local scale, nested inside a regional scale, which is nested inside a continental scale, and so on.

SimpleBox is written in MS-Excel spreadsheet format, allowing the user full access to system parameters and process formulations. Probabilistic inputs can be handled via Monte-Carlo simulation software (e.g. Crystal Ball).

Availability:

Report: http://www.rivm.nl/bibliotheek/rapporten/719101029.html

Free available from ha.den.hollander@rivm.nl or d.van.de.meent@rivm.nl

Probabilistic: Can be, but needs additional software.

5.1.4 Fate: FOCUS Models

Purpose:

FOCUS is FOrum for the Co-ordination of pesticide fate models and their USe. The organisation is an initiative of the European Commission to harmonise the calculation of predicted environmental concentrations (PEC) of active substances of plant protection products (PPP) in the framework of the EU Directive 91/414/EEC. FOCUS is based on co-operation between scientists of regulatory agencies, academia and industry.

Characteristics:

The FOCUS **groundwater** scenarios are a set of nine standard combinations of weather, soil and cropping data which collectively represent agriculture in the EU for the purposes of a Tier 1 EU-level assessment of leaching potential. The scenarios and their derivation are described in detail in a published report. The scenarios have been implemented as sets of input files for four simulation models:

- MACRO is a physically-based one-dimensional numerical model of water flow and reactive solute transport in field soils.
- PEARL is an acronym of Pesticide Emission Assessment at Regional and Local scales. It is a one-dimensional numerical model of pesticide behaviour in the soil-plant system.
- PELMO is a one dimensional simulation model simulating the vertical movement of pesticides in soil by chromatographic leaching.
- PRZM (Pesticide Root Zone Model) is a one-dimensional non-deterministic compartment model for the prediction of chemical movement in unsaturated soils by vertical chromatographic leaching.

The FOCUS **surface water** scenarios are used to assess the potential contamination of active substances and metabolites of plant protection products to surface water. They form a part of the review process for active substances in the EU.

The FOCUS concentration estimation methodology was developed as a tiered approach with four levels of assessment. The Step 1 has been defined as a relatively simple calculation based on a maximal loading and a fixed scenario, while the Step 2 allowed multiple applications and regional variation across Europe.

The program STEPS1-2 in FOCUS is a stand-alone Surface water Tool for Exposure Predictions -Steps 1 & 2 for the derivation of PEC values in water and sediment based upon the chosen scenario. The tool requires a minimum of input values (molecular weight, water solubility, DT50soil, Koc, DT50sediment/water, number of applications, application interval and application rate) and is designed to evaluate both active substances and metabolites.

Step 3 of the approach consists of the scenarios developed, while Step 4 allows a detailed site-specific approach in case all Steps fail. The FOCUS surface water scenarios are a set of ten standard combinations of weather, soil and cropping data and water bodies, which collectively represent agriculture in the EU for the purposes of a Step 3 EU-level assessment of concentration estimation. The scenarios and their derivation are described in detail in a published report (FOCUS 2001, see Documentation in FOCUS Surface water).

The scenarios have been implemented as sets of input files for three simulation models estimating the influence of drainage, run-off and fate on the final concentration estimations:

- The model MACRO is used to estimate the drainage as a sub-surface loading to surface waters,
- the model PRZM accounts for run-off as a superficial loading to surface water and finally
- the model TOXSWA, which takes into account the dissipation processes in surface waters itself.

The results of the MACRO-model or the PRZM-model are used as input into the model TOXSWA in addition to the drift input. The resulting concentrations from TOXSWA are used in the risk assessment process to calculate the Toxicity Exposure Ratios (TER) for aquatic organisms.

To minimise the influence of the user on the outcome of the PEC estimation as many as possible of the input variables have been fixed, leaving only the dossier data as main input data. To take care of this input process and to guide the user through the correct scenarios to run depending on the use of the PPP a computerised shell is developed as well. This shell, called SWASH, helps the user through the exposure assessment.

FOCUS models are not developed for probabilistic risk assessment. However, in PRZM, series of daily weather data over a period of 20 (40, 60) years can be used as inputs to calculate 80th percentile of concentrations.

Availability:

All models and documentation can be downloaded at http://viso.ei.jrc.it/focus/index.html.

Probabilistic:

Some modelling aspects have probabilistic elements.

5.1.5 Fate: MCPELMO

Purpose: Stochastic prediction of the vertical movement of pesticides in soil by chromatographic leaching

Characteristics:

The temporal variability of weather conditions and the spatial variability of soil properties in Germany served as inputs into Monte-Carlo simulations using stochastic version of PELMO 2.01 respectively FOCUS PELMO. For example, MCPELMO allows calculation of the probability to exceed threshold levels of pesticides in groundwater for different scenarios in Germany.

Availability:

Email contact: michael.klein@ime.fraunhofer.de

Probabilistic:

Yes.

5.1.6 Fate and Effects: AQUATOX

Purpose:

Analysis and prediction predict of the effects of chemical pollutants and other stressors on aquatic ecosystems.

Characteristics:

AQUATOX is an ecosystem model that simulates the transfer of biomass and chemicals from one compartment of the ecosystem to another. It does this by simultaneously computing important chemical and biological processes over time. AQUATOX can predict not only the fate of chemicals in aquatic ecosystems, but also their direct and indirect effects on the resident organisms. Therefore it has the potential to help establish the cause and effect relationships between chemical water quality, the physical environment, and aquatic life.

Required input data are loading to the water body, general site characteristics, chemical characteristics of any organic toxicant, and biological characteristics of the plants and animals. AQUATOX comes bundled with data libraries that provide default data. This is of particular importance for the biological data, which are probably the most difficult for a user to obtain.

Latin hypercube facilitates uncertainty analysis with choice of 4 distributions of any or all model parameters and loading.

Availability:

Free download of the program and detailed information at http://www.epa.gov/ost/models/aquatox/

Probabilistic:

Yes.

5.1.7 Effect: Daphnia

Purpose:

Extrapolation from effects on life table data of *D. magna* to the population level considering variability between individuals

Characteristics:

Daphnia describes the population dynamics of the water flea *Daphnia magna* by means of a detailed model of the individual life histories of the animals driven by available food levels and toxicant concentrations. The model focuses on the demographic stochasticity due to the different life table properties of the simulated individuals. The model was validated based on population experiments under flow-trough conditions at different constant concentration of a toxicant (3.4-dichloroaniline).

Daphnia is a stand-alone Windows program. Documentation of the model is only available in German.

Availability:

Free on request from udo.hommen@ime.fraunhofer.de

Probabilistic:

Yes.

5.1.8 Effects: DEMETRA

Purpose:

Prediction of toxicity of pesticides and related compounds (such as metabolites) from chemical structure of the compound.

Characteristics:

DEMETRA is a project (Start 2003-01-01, end 2006-06-30), clustered with EUFRAM. This project developed software that gives a quantitative prediction of the toxicity of a molecule, in particular molecules of pesticides, candidate pesticides, and their derivatives. The input is the chemical structure of the compound, and the software algorithms use “Quantitative Structure-Activity Relationships” (QSARs).

Five endpoints have been selected for prediction: Trout, Daphnia, Quail (acute and dietary toxicity), Honeybee. The data set to build up and validate the model includes 420 pesticides (the number is increasing for inclusion of further compounds for testing. Basics of the SW will be a collection of hybrid systems addressing a single endpoint. Five different hybrid systems have been developed for the five endpoints above indicated. Each hybrid system integrates several QSAR models.

Availability:

Web based tool, will be available at http://www.demetra-tox.net

Probabilistic:

Probabilistic elements present.

5.1.9 Effects: PERPEST

Purpose:

Prediction of the Ecological Risks of PESTicides in freshwater ecosystems

Characteristics:

PERPEST predicts the effects of a particular concentration of a pesticide on various (community) endpoints, based on empirical data extracted from the literature. The method that it uses is called Case-Based Reasoning (CBR), a technique that solves new problems (e.g., what is the effect of pesticide A?) by using past experience (e.g., published microcosm experiments). The database containing the "past experience" has been constructed by performing a review of freshwater model ecosystem studies evaluating the effects of pesticides. This review assessed the effects on various endpoints (e.g. community metabolism, phytoplankton, macro-invertebrates) and classified them according to their magnitude and duration.

The PERPEST model searches for situations in the database which resemble the question case, based on relevant (toxicity) characteristics of the compound. This allows the model to predict effects of pesticides for which no evaluation on a semi-field scale have been published. PERPEST results in a prediction showing the probability of classes of effects (no, slight or clear effects, plus an optional indication of recovery) on the various grouped endpoints.

Availability:

Free download of the Windows program as well as the documentation at http://www.perpest.alterra.nl

Probabilistic:

Yes.

5.1.10 Effects: RAMAS ecotox

Purpose:

Shell to develop (structured) population and food web model including simple fate models

Characteristics:

Models of population dynamics and toxicant kinetics are constructed using a simple Windows interface, and linked to bioassay data. Parameters can be specified as scalars, intervals or distributions, to take account of environmental variability and ignorance. Monte Carlo simulations are then used to predict future population trajectories, and calculate the risk of adverse events such as extinction's or algal blooms.

Availability:

Commercial software 395 $ (academic), 595 $ (non-profit) or 995 $ (regular). Website: http://www.ramas.com/ecotox.htm

Probabilistic:

Yes.

5.1.11 Exposure and effects: Secondary Poisoning

Purpose:

Probabilistic calculation of bioaccumulation risks for terrestrial foodwebs of predators

Characteristics

The model uses a species-specific approach to estimate the bioaccumulation potential in terrestrial food webs. Four birds of prey (Sparrow Hawk, Kestrel, Barn owl and Little owl) and two mammalian predators (Badger and Weasel) were modelled. Bioaccumulation factors (BAFs) for major food items of predators were collected and it was assumed that the available data were a sample of a log-logistic distribution. Critical intake levels are collected from NOECs. These were corrected for differences between laboratory animals and animals in the wild: metabolic rate, caloric content of food, and food assimilation efficiency. The model compares food intake concentrations with critical food concentrations to estimate risk to top predators. The model was applied to DDT and Cadmium.

The model is written in Mathcad.

Availability:

Free on request from tp.traas@rivm.nl

Probabilistic:

Yes.

5.1.12 Exposure and effects: SimpleChain

Purpose:

Calculation of effect of persistent compounds on competition within trophic levels and effects on overall ecosystem function

Characteristics:

Generic trophic levels were modelled: primary production (as input), microbial degradation, detritivore invertebrates and carnivorous invertebrates. The model was applied to Copper and Zinc. Model structure can be easily adapted for the number of competing species within trophic levels (limited by computer memory). The model uses ecological parameters (max uptake rate, half saturation constants, assimilation efficiency, production efficiency, death rate, and for detritus: decay rate) to construct parallel food chains of the most efficient producers. Efficient is defined as a more efficient resource utilisation (higher production efficiency). These are combined randomly with species sensitivity, sampled from species sensitivity distributions. The SSD parameters (mean, stdev) can be calculated from toxicity databases.

The software is implemented in Matlab.

Availability:

Not yet decided, in development. Contact: tp.traas@rivm.nl

Probabilistic:

Yes.

5.1.13 Effects: SSWD (Weighted SSDs)

Purpose:

Calculation of Species Sensitivity Weighted Distributions (SSWD) and hazardous concentration (HCx)

Characteristics:

SSWD offers a procedure in which ecotoxicity concentration data can be weighted to account for redundant data for each species or genus and for the disproportion in the data number between the taxonomic groups or trophic levels was developed.

Three distributions (log-empirical, log-normal and log-triangular) can be selected at the same time. The preceding weights are accounting for the calculation of the distribution's parameters and the hazardous concentration. Confidence limits are estimated by bootstrap and the number of bootstrap samples can be defined by the user. The goodness of fit (for log-normal and log-triangular distribution) is tested by a Kolmogorov-Smirnov (KS) test with Dallal-Wilkinson approximation. The SSWD procedure is a Macro ".xla" of Excel.

Availability:

SSWD.xla can be free loaded from the http://chimie.ineris.fr . Email contact: philippe.ciffroy@edf.fr

Probabilistic:

Yes.

5.1.14 Effects: Zebrafish

Purpose:

Extrapolation from effects on life table data of *Danio rerio* to the population level considering variability between individuals

Characteristics:

Zebrafish is an Individual Based Model, which simulates a small laboratory population of the zebrafish *Danio rerio*. The model includes stochastic descriptions of reproduction and foraging behaviour and allows analysis of the consequences of effects on the individual level to the level of the population.

Zebrafish is a stand-alone Windows program. Documentation of the model is only available in German.

Availability:

Free on request from udo.hommen@ime.fraunhofer.de

Probabilistic:

Yes.

5.1.15 Risk calculation: Busy (Bayesian Uncertainty System)

Purpose:

Uncertainty analysis in Ecological Risk Assessment using Bayesian statistics

Characteristics:

Busy provides a flexible and easy to use set of probability distributions to carry out Probabilistic ERA. This includes kernel density estimation to account for non-symmetric and/or multi-modal data sets. The SSD part of Busy focuses on the (species) toxicity data only, while extending the analysis to secondary (2-D) distributions. This is done through Bayesian statistics. Bayesian Logistic Dose-Response modelling implements a small-sample approach to uncertainty analysis of dose-response data sets.

Busy is implemented in the computer programming system Mathematica. In order to run Busy, Mathematica (4.2) must have been installed on your computer. However, there is no need to learn Mathematica. Busy is run through so-called Notebooks that can be coupled to MS-Excel for exchange of data.

Availability:

Developed in the framework of the CEFIC/ACC Long Range Research Initiative Project: Uncertainty Analysis in Ecological Risk Assessment. It will become freely available to CEFIC members, as well as others interested. No web site, email contact: tom.aldenberg@rivm.nl.

Probabilistic:

Yes.

5.1.16 Risk calculation: ETX (various versions)

Purpose:

Derivation of risk limits and/ or estimate % species affected (PAF) by means of SSD-theory.

Characteristics:

The software fits standard distribution functions (normal SSDs) to a set of data. From the SSD, either percentile values on the concentration axis (e.g. the 5th percentile, the HC5), or the fraction of species exposed above the relevant toxicity endpoint can be estimated. This fraction is called the 'potentially affected fraction', PAF. Each quantity estimated with the software is given with a confidence interval, based on normal statistics (Aldenberg & Jaworska, 2000). Different test for the goodness of the SSD fit to a log-normal distribution are implemented, results are given as tables and diagrams. If a set of PECs is entered, Joint Probability Curves are calculated.

Availability:

ETX-2.0 is available as executable and associated RIVM-report, to replace older versions (Van Vlaardingen, 2004). Email contact: tp.traas@rivm.nl or tom.aldenberg@rivm.nl, and/or (autumn 2004) http://www.rivm.nl/bibliotheek/rapporten/*.*.

Probabilistic:

Yes.

5.1.17 Effects: GPS1 (General Population Simulator)

Purpose:

Estimation of effects and recovery using a simple population model

Characteristics:

The General Population Simulator estimates effects of toxicants on populations and the possible recovery by means of the logistic population growth model. Exposure is modelled as exponential decay after single or multiple application of a toxicant, while population dynamics is simply described by growth rate and carrying capacity. Toxicity data are given as LC50 or inhibition of (population) growth rate. Uncertainty about the input parameters can be handled via Monte-Carlo-Simulation while temporal variability can be considered by stochastic modelling of the carrying capacity.

GPS is a stand-alone Windows program.

Availability:

Free on request from udo.hommen@ime.fraunhofer.de

Probabilistic:

Yes.

5.1.18 Risk calculation: PRAT2

Purpose: Calculation of SSDs, % of species affected (PAF), and Exceedence Profiles

Characteristics:

PRAT2 is a simple Excel sheet to fit log-normal distributions to toxicity data and/or environmental concentrations and to calculate the % of species affected for a given PEC or Exceedence Profiles (Joint Probability Curves) showing the probability that the toxicity threshold of a certain proportion of species is exceeded.

PRAT2 uses only the implemented functions of Excel without any macro programming and it is restricted to log-normal models.

Availability:

Free as email attachment from ksolomon@uoguelph.ca

Probabilistic:

Yes.

5.1.19 Exposure, Effects, Risks: Aquatic Level II Refined Risk Assessment (ARRA 2.0)

Purpose:

Estimation of the likelihood and magnitude of effects on aquatic species that are vulnerable to pesticide exposure in edge-of-field situations

Characteristics:

US-EPA is developing a software tool (**A**quativ Level II **R**efined **R**isk **A**ssessment) that facilitates execution of the exposure simulation. It uses an exposure module based on the Agency's PRZM model (used here as a run-off model) linked with the VVWM (Varying Volume Water body Model) .A toxicity data analysis module calculates measurement endpoints and species sensitivity distributions for fish and invertebrates. The effects and exposure data are integrated using a two-dimensional Monte Carlo analysis in the probabilistic risk module, yielding estimates of the probability and magnitude of effects to aquatic organisms, as well as estimates of uncertainty associated with those predictions.

Availability:

Latest information can be found at http://www.epa.gov/oppefed1/ecorisk

Probabilistic:

Yes

5.1.20 Exposure, Effects, Risks: Terrestrial Integration Model (TIM 2.0)

Purpose:

Estimation of the risk of acute effects on birds due to exposure to pesticides in-crop

Characteristics:

The revised Level II **T**errestrial **I**ntegration **M**odel is a multimedia exposure/effects model that can be used to address acute mortality levels in generic or specific species over a user-defined exposure window. The spatial scale is at the field level, such that the field and surrounding area are assumed to meet habitat requirements for each species. As an overall simplifying assumption, contamination of edge or adjacent habitat from drift is assumed to be zero.

The major parameters addressed in the model are multimedia estimates for different routes of exposure; food habits of defined generic or selected specific species, hourly ingestion/inhalation rates of food, water, and air and dermal residue transfer rates from contaminated vegetation as a function of body weight, frequency of feeding and drinking on the sprayed field, distribution of residues on/in vegetation, water (dew and puddles), and air, degradation/dissipation rates of pesticide residues in each environmental media considered and acute toxicity dose-response relationships.

Availability:

Free download from http://www.epa.gov/scipoly/sap/index.htm#march.

Probabilistic:

No.

5.1.21 Exposure, Effect, Risks: USES 4.0

Purpose:

Initial and refined risk assessment of industrial chemicals and pesticides.

Characteristics:

USES is a decision-supporting instrument enabling rapid and efficient assessment of the risks attached to new and existing substances, and agricultural and non-agricultural pesticides. The PC program, manual and background document, are mainly intended for use in the Netherlands. USES is intended mainly for initial and refined risk assessment rather than comprehensive analysis. Interpreting estimated risks for risk management is also beyond its scope. Risk assessment with USES takes account of international policy on substances and the associated regulations. The USES 4.0 risk assessment system for new and existing substances is fully equivalent to EUSES. USES 4.0 also incorporates, as much as possible, the EU Uniform Principles referred to in Directive 91/414/EEC concerning the placing of plant protection products on the market and Directive 98/8/EC concerning the placing of biocidal products on the market.

For probabilistic assessments, additional tools like Crystal Ball are needed.

Availability:

See http://arch.rivm.nl/csr/risk.html

Probabilistic:

No.

5.1.22 Exposure, Effects, Risks: WEBFRAM

Purpose:

Development of a web-integrated model (WEBFRAM), for the assessment of ecological risks from pesticides.

Characteristics:

Ongoing project, sponsored by DEFRA (PS2304). Report available in December 2006

Availability:

No own web site yet, information from:

http://www.silsoe.cranfield.ac.uk/ecochemistry/research/project/ps2304.htm

Probabilistic:

Not clear yet

5.1.23 Exposure and Effects: Instrument for Quantification of toxic pressure (IQ-tox)

Purpose:

Multi-criteria evaluation of multi-substance exposure data, with corrections for bioavailability of compounds (hence: an exposure element), using functions of matrix/media characteristics. No fate modelling.

Characteristics:

IQ-Tox is a dedicated MS Access application with VBA procedures and custom made graphics procedures for evaluating site-specific exposure or monitoring results. Very flexible and versatile program for quantitative multi-criteria analysis. Unlimited sets of environmental and response variables can be defined and grouped to form different environmental quality indices related to predetermined human activities. Ecotoxicity related indices can be calculated according to the mixed model ms-PAF (multi-substance Potentially Affected Fraction) approach for mixture toxicity. Any variable that can be quantified and rated for environmental acceptability can be incorporated. Several options and weighting procedures are open for grouping.

IQ-Tox has no probabilistic components yet.

Availability:

An Access *.mbe file can be obtained from d.de.zwart@rivm.nl

Probabilistic:

No.

5.2 Confronting Software items with criteria

The following results when the software items are confronted with the criteria developed during the workshop Table 5-2. The Table shows, regarding the scientific aspects of the software for PRA:

- that various software items were not confronted to the full list of criteria developed during the Software and Database workshop. Therefore, contact persons were asked after the workshop to check the criteria for “their” software. This is an ongoing process (see Recommendations chapter). Other items were not available at the workshop (these items do not have evaluation entries).[4]
- that software items that address the *same* type of issues (e.g., calculating SSDs) differ with regards to the apparent suitability for further development in the EUFRAM framework.
- that software items can undergo substantial evolution. Experience over the last year shows that major changes in development status may occur within a year. An example is the evaluation of EXT(2000), a dedicated Excel program, at the workshop in 2003, while a versatile stand-alone executable is available in autumn 2004.
- that the evolution of software appears to take place in line with the criteria as established for part of the studied items

and that, regarding the operational features:

- some items obtain positive remarks on many aspects, whereas others obtain mainly negative marks. Note that this suggests large differences in the purpose of the designer (own use versus planned multi-usage by third parties), and not scientific weakness of the latter.

Given these observations, and the large variability in judgement on the individual criteria for each software item, the workshop was crucial to gain overview. To that end, a SWOT analyses were made. The results are presented in Table 5-3. Note that the SWOT provides a preliminary overview on the proposed and evaluated items, and that the Recommendations (see Chapters 8 and **Error! Reference source not found.**) suggest to continuously update the views that are presented. Note further that the Tables are the results obtained in the June 2003 workshop. The ideas shown are to be seen as a wish list.It is likely that various wishes are not fulfilled for the existing software, or that they are difficult to be fulfilled in the near future.

[4] Owners of software and databases are asked to provide further facts as items develop..

Table 5-2. Overview of the confrontation of the software items with the criteria for software development.

	SimpleBox	AQUATOX	Daphnia	DEMETRA	PERPEST	SSWD	Zebrafish	GPS1	IQ-Tox
Scientific characteristics									
Ability to handle different groups of compounds	+	+	+	+	+	+	+	+	+
Multiple Spatial scale (global/regional/local)	+	-	-	-	-		-	-	-
Ability to handle (pesticide) mixtures	+	+	-	-	-	-	-	-	+
Ability to handle metabolites	-	+	-	+	-		-	-	+
One stop shop (including exposure, effects and risk characterisation)		-	-	-	-		-	-	+
Option to account for uncertainty	+	+	-	+	+	+		+	-
Option to account for variability	+	+	+	+	+	+	+	+	-
Option to account for dependencies/correlation	+		-		-		-	-	-
Empirically validated	+	+	+		+		+	-	-
Flexible model structure	+	+	-	+	-		-	-	-
Wide choice of distributions	+	+	-	-	-	-	-	-	+
Published in peer-reviewed literature	+		-	+	+	+	+		-
Expert panel peer review	+	+	-	+	+		-	-	-
Temporal variability/uncertainty	+	+	-	-	+		-	+	-
Spatial variability/uncertainty	+	-	-	-	+		-	-	-
Requires more than typically available data	-	-	-		-		-	-	-
Requires recalibration for new regions/countries	-	-	-		-		-	-	-
Contains non-data-derived adjustment factors	-		-		-		-	-	-
Technical									
Web-enabled use possible	-		-	+	+	-	-	-	-
Quality assured software		+	-	+	+		-	-	-
Version control protocol available		+	-		+		-	-	-
Model FULLY documented	+	+	-	+	+	+	+	-	-
Input data error checking (incl. units)	-	-	-		+		-	-	+
Backwards/forward compatible		-			+		-	-	-
PC Based	+	+	+	+	+		+	+	+
Broadly dispersed and known shell	+	+	+	+	-	+	+	+	+
Potential to link to other software/databases	-	+	-	+	-		-	-	-
Dependence on other proprietary software	-	-	-	+	+	+	-	-	+
Ease of use									
Flexibility in data input (e.g. units)	+	-	+		+	+	+	+	-
Free of costs	+	+	+	+	+	+	+	+	+
Exporting of output	+	+	+		+	+	+	+	+
Reproduce/save past run	+	+	+		+	+	+	+	+
Help screens	-	+	+		+		+	-	-
Intuitive interface	+	+	+	+	+	+	+	+	+
Free of use restrictions	+	+	+	-	+	+	+	+	+
Any windows-based	+	+	+		+	+	+	+	-
Ability to cut/paste/link input data	+	+	+		+		+	+	-
Roll-over (mouse-over) help	-	+	-		-		-	-	+
Reference fields for input data	-	+	-		-		-	-	-
Default data and worked examples	-	+	+	+	-		+	+	-
Differential User-modes (default and advanced user modes)	-	+	-		+		-	-	-
Execution in minutes Vs. hours on Std. PC	+	+	+		+	+	+	+	+
Shape of output format: numerical		+	+	+	+	+	+	+	+
Shape of output format: graphical		+	+		+	+	+	+	+
Option to show confidence bands	-	+	+		-	+	+	+	-
Support and maintenance									
Related to regulatory context	+	+	-	+	+	+	-	+	-
Feedback loops to improve software		+	-		+		-	-	+
Long-term support/updating/maintanenence	-	+	+		+		-	-	+
User support	-	+	-		-		+	-	+
User groups	-	-	-		-		-	-	-

Table 5-3. Results of the SWOT analyses for the software items (restricted to items presented at the workshop). Suitability 1 = directly usable in EUFRAM, 2 = with modification, 3 = not suitable, 0 = not ranked during the workshop).

Acronym	Probilistic module included	Research tool	Potential for regulatory use	SWOT summary / Remarks	Suitability for EUFRAM
Crystal Ball	X	X	X	+ user friendly and flexible tool - expensive Excel add-in, limited sample size, lack of Bayesian methods, limited sensitivity analysis	0
Risk Calc	X	X	X	+ flexibility: statistical freedom in the treatment of distributions, automatic check of units - people not (yet) familiar with p-bounds, complex tool, not free available	0
FOCUS PELMO	(X)		X	+ developed especially for EU registration, quality checked, user friendly - fixed scenarios, not really probabilistic yet	2
SimpleBox	(X)		X	Included in EUSES + simple, generic model, well studied, free available, flexible excel sheet - global or regional scale only, steady state, not dynamic, formulars not protected, requires expert user, uncertainty not included (but possible with Crystal Ball)	2
AQUATOX	X	X	X	Higher tier tool + state of the art dynamic ecosystem model(s), flexible, very user friendly, calibration and validation continues, used by US EPA, free on web - model equations fixed, complex	2
DEMETRA	(X)			Clustered with EUFRAM, under development, will allow to predict toxicity values with uncertainty reported	0
PERPEST	X	X	X	Database based, only regulary update necessary + new approach to use knowledge from exisiting micro-/mesocosm studies to estimate ecological effects of new compounds, user friendly interface, peer reviewed, free on the web - limited flexibility (input of new data), restricted to substance with MoA covered in the database	1
RAMAS ecotox	X	X		Shell, higher tier tool + focus on ecological endpoints, user friendly model builder interface, flexible - not free available (commercial), parameters dificult to assess	2
Secondary Poisoning	X	X	X	Potentially useful + simple trackable algorithm, clear structure, free on request, - depends on Crystal Ball	2
SimpleChain	X	X	X	+ simple mechanistic model - depends on Matlab, not user friendly	2
SSWD	X			not available at the workshop	0
Busy	X	X	X	Under develeopment + powerful statistical tool - complex, not clearly user friendly, needs Mathematica	0
ETX	X		X	Simple Excel based tool + complete SSD and JPC tool, user friendly, free - diagrams might be improved	1
GPS1	X		X	+ simple population model to analyse effects and recover , user friendly interface - restricted to single population, software not quality checked and documented	2
PRAT2	X	X	X	Teaching tool + simple SSD and PEC distr. tool, easy to use, free - no detailed statistics (e.g. confidence limits)	2
ARRA	X		X	+ all-in-one: includes different tools (e.g. fate/ exposure models, dose-response models, SSDs,…); especially developed for regulation of pesticides , user friendly interface, straightforward package for basic PRA - specific to US-EPA, use of not S.I. u	2
TIM	X		X	+ integrates fate and effects, user friendly interface (Excel based), dose-response orientated, free on the web - restricted to birds & mammals, no insects, no beneficial arthropods, no chronic data, US-EPA scenarios only, little flexibility, adaptation	2
USES	(X)		X	+ focusses on many aspects, linked to regulation, accepted in EU (EUSES), tested over the years, can be adapted for pesticides - not yet probabilistic (needs Crystal Ball)	2
WEBFRAM	(X)		X	Under development + comprehensive models, linked to current legislation, strong links to EUFRAM, free, web based - not necessarily probabilisitic, UK rather than European focus (only UK scenarios)	0
IQ-Tox			X	+ user friendly interface, AMOEBA presentation, creates simpe to interprete output, für site specific RA - not realy probabilistic	3

From the latter Table, it can be concluded that most software items obtain the rating "2", implying that the item has to be adapted to the general design criteria to a smaller or larger extent. Only two programs were considered sufficiently adapted to the EUFRAM criteria that they gained the rating "1", which implies that those items only need undergo minor adaptation when they would be adopted in the EUFRAM framework. Various programs obtained the remark that they were especially suited to a lower or higher tier of an eventual risk assessment scheme. A small number of items has already been adopted in an official, sometimes EU-level, risk assessment framework (e.g., EUSES).

6 INVENTORY OF DATABASES

6.1 Characteristics / types of Database items

At present (September 2004), 12 database items are considered within the EUFRAM project (Table 6-1). The databases address different parts of a risk assessment framework, focusing on:

- physicochemical properties (e.g., in RIVM e-toxBase)
- ecotoxicological sensitivities (e.g., in US-EPA Ecotox and RIVM e-toxBase)
- ecological properties (e.g., Assiwerk/Enerwerk)
- field conditions (e.g., POND-FX)

Like in the software item classification, this differentiation must not be seen as exclusive. Some databases store data of different kinds, for example, the RIVM e-toxBase can store test data as variable as physico-chemical properties of a compound, ecotoxicity test data (NOECs, EC50s, BSAFs), Mode-of-Action data, metabolite data, and taxonomic information.

Table 6-1. Databases reviewed for the use in probabilistic risk assessment within EUFRAM (status September 2004)

	Compound			Biota		Field		
Acronym	Physico-chem. properties	MoA	Usage	(Eco-) toxicity	Ecology	Site charac-teristics	Fied exposure	Field effects
EPA EFD	X						X	
RED				X			X	
RIVM e-toxBase	X	(X)		X				
ECOTOX-EPA				X				X
COMET				X				
NTP	X							
ECOTOX CD				X	X			
MINAMB	X			X			X	
SEEM			X	X				
Assiwerk / Enerwerk					X			
Pond-FX					X	X		
SEISMIC						X		

6.2 Descriptions of Databases

The following short descriptions were extracted from the summary and fact sheets of a meta-database developed for EUFRAM-WPR10 in which all model and programming information is stored for detailed reference. For more information this meta-database with more specific information can be downloaded from the EUFRAM web site (www.eufram.com/xxx).

6.2.1 Fate: EPA EFD (Pesticide Environmental Fate Database)

Purpose:

This is an environmental fate database containing studies describing what happens to pesticides in the environment after they are applied. The database contains fate and transport data.

Characteristics:

EPA's Office of Pesticide Programs (OPP) collects and reviews a variety of environmental fate studies submitted by pesticide manufacturers in support of the registration of pesticide products. Environmental fate studies describe what happens to a pesticide in soil, water, and air after it has been applied and include the following types of studies: product chemistry, metabolism, hydrolysis, photolysis, field dissipation, bioaccumulation, adsorption/desorption and leaching. After reviewing the data in these studies, OPP scientists summarise the information in Data Evaluation Reports (DERs), Reregistration Eligibility Decision Documents (REDs), science chapters, Emergency Use Exemptions, and other environmental fate reports. In 2000, OPP initiated the development of a pesticide environmental fate database which will allow the user to search and view the data, query the fate database, and print reports that are found in these summary reports. The database contains environmental fate and transport data for about 250 pesticide active ingredients. The Pesticide Program plans to complete the initial version of this database by the end of 2002 and will be adding additional active ingredients during the next two years.

Availability:

The Pesticides Environmental Fate Database will be put in service by the US EPA in late spring or early summer 2003, as Microsoft Access database. For more information: Liu.Larry@epa.gov. Website (only descriptive as yet: http://www.epa.gov/oppefed1/general/databasesdescription.htm

6.2.2 Ecotoxicity and metabolites: RED

Purpose:

Compilation of a European Reference Database for Ecotoxicology Data on Plant Protection Products and their Metabolites

Characteristics:

Council Directive 91/414/EEC requires extensive ecotoxicological testing of active substances and plant protection products. For an overall ecotoxicological assessment it is insufficient to evaluate a limited number of endpoints in an isolated way. Comparative assessments of different substances and/or probabilistic assessments of the variability of data sets or analyses of sensitivity distributions of different species become increasingly important not only in the scientific community but also in the context of regulatory decision making. In order to perform such comparative or probabilistic assessments a body of validated data is required. The goal of the RED project therefore is to initiate the development of a database containing this type of data which is freely accessible and which will allow the statistical distributions of the ecotoxicological effects of active parent compounds and their metabolites to be explored.

Availability:

Under development. See further:

http://www.silsoe.cranfield.ac.uk/ecochemistry/research/project/red.htm

6.2.3 Ecotoxicity, metabolites and physico-chemical data: RIVM e-toxBase

Purpose:

Development of the RIVM e-toxBase started in 2000, in order to provide an array of RIVM ecotoxicity-related projects with a tool to store, handle and retrieve data in an efficient and reproducible way. The database now covers more than 166,000 entries, including Toxic Mode of Action information, and is ready for internal use.

Characteristics:

The RIVM e-toxBase is a server-based relational database with strict integrity rules, ensuring a reliable and unambiguous means of storing and retrieving ecotoxicity data. Access to the database is user-restricted. Depending on their specific rights, users can read, qualify, store and export data in the RIVM e-toxBase.

Both the database itself and the interface were originally developed in MS Access. By now, the database has been transferred to a robust, server-based environment (a stand-alone application in Visual Basic). The database is currently “open” for all personnel working at RIVM; that is: RIVM-personnel can obtain “read/download” rights. Storage rights are restricted to RIVM-personnel, that is: to those responsible for an RIVM project, or to those persons assigned by the project leader, within a project.

The internal RIVM interface has three main functions: selecting and viewing data, easy export of a selection of data to a MS Excel sheet and entering new data. A range of selection criteria like test type (EC50, NOEC), substance, species name and literature references are available for querying the data in the RIVM e-toxBase. After a selection is made, a user is immediately presented with the remaining number of tests. Advanced search options are available, like the “taxonomy browser”, which allows a user to select test results for entire taxonomic groups. Using the flexible export function to MS-Excel, any field from the database can be selected for export. The entry of new tests is restricted to certain users within RIVM.

Currently, data coverage concerns mostly aquatic ecotoxicity data, pesticides included. Compound characteristics (e.g., Kow), and breakdown products (parent/metabolite) can however also be stored. The database can store scientific entries as well as meta-data (which include literature references but also an array of quality statements, which may differ between the scopes of the different RIVM-projects). The largest source of data is the US EPA ECOTOX database. Data from the ECOTOX database have first been ‘cleaned’ in order to fit the strict integrity rules of the RIVM e-toxBase. New data are added each day, as RIVM projects generate or store ecotoxicity data. Some of the RIVM data sets are (at least in part) confidential. In the latter case, access to the data is restricted to certain users.

The data model design of the RIVM e-toxBase is highly flexible, so that new types of data can be stored without having to make major structural modifications to the database. The user-friendly interface (and in future web-interface) offers access to the database to a wide audience, without requiring any special knowledge of ecotoxicology or databases.

Availability:

To be decided, currently only RIVM-internal use. Development of a web-enabled searching technique is underway, and is currently being tested with partners in ongoing projects outside RIVM. Data retrieval functions and screen interfacing required the development of new approaches, since the access via de web slowed the functions beyond desirable limits.

6.2.4 Ecotoxicity: Ecotox-EPA

Purpose:

The ECOTOXicology database (ECOTOX) is a source for locating single chemical toxicity data for aquatic life, terrestrial plants and wildlife. ECOTOX is a useful tool for examining impacts of chemicals on the environment.

Characteristics:

Peer-reviewed literature is the primary source of information encoded in the database. Pertinent information on the species, chemical, test methods, and results presented by the author(s) are abstracted and entered into the database. Another source of test results is independently compiled data files provided by various United States and International government agencies. ECOTOX was created and is maintained by the U.S.EPA, Office of Research and Development (ORD), and the National Health and Environmental Effects Research Laboratory's (NHEERL's) Mid-Continent Ecology Division. The development of the ECOTOX was started in 1995, and in March of 1996, it was released to governmental users through talnet access procedures. In February, 2000 ECOTOX was released as a web based interface system. The ECOTOXicology database (ECOTOX) is a source for locating single chemical toxicity data from three U.S. Environmental Protection Agency (U.S. EPA) ecological effects databases; AQUIRE, TERRETOX, and PHYTOTOX. Aquatic data in AQUIRE are limited to test organisms that are exclusively aquatic (saltwater and freshwater). Species that are associated with the water but do not have gills, such as ducks and geese, are included in the terrestrial database. Amphibians are included in both AQUIRE and TERRETOX databases, with the life stages that exist exclusively in the water (e.g., tadpole) located in AQUIRE and the terrestrial life-stage (e.g., adult) in TERRETOX. Bacteria and virus are not included in the ECOTOX database. TERRETOX is the terrestrial animal database. It's primary focus is wildlife species but when data gaps exist for a particular chemical, data for domestic species are included. PHYTOTOX is a terrestrial plant database.

Availability:

The ECOTOX database can be accessed using your web browser software via the Internet at http://www.epa/gov/ecotox. For more detailed information regarding field data definitions, refer to the pertinent coding guidelines.

6.2.5 Ecotoxicity: COmputerized Molecular Evaluation of Toxicity (COMET)

Purpose:

The data set has been prepared within the EC funded project COMET (Computerized Molecular Evaluation Of Toxicity), ENV4-CT97-0508. It includes 235 pesticides. On the basis of these pesticides predictive models for toxicity have been evaluated, for trout, daphnia, quail, and rat.

Characteristics:

COMET includes a data set with toxicity values for trout, daphnia, quail, and rat. Values have been taken from the Pesticide Manual, RTECS, ECDIN, AQUIRE, HSBD. Min, max and suggested values are indicated. Suggested value is the minimum value, unless it is an outlier. COMET also developed QSAR models, calculating chemical descriptors with various software types, such as CODESSA and Pallas. Data coverage pertains to several chemical classes of pesticides; trout, daphnia, quail, and rat. Mathematical algorithms are used for QSAR models: linear multiregression, neural networks, fuzzy logic, B-spline and genetic algorithms.

Availability:

Excel for toxicity data and chemical descriptors. Available at request: Benfenati@marionegri.it.

6.2.6 (Eco)toxicity: NTP (National Toxicology Program database)

Purpose:

Federal and State Regulatory Agencies use the NTP study data in considering the need for regulation of specific chemicals to protect human health. The National Toxicology Program (NTP), amongst other tasks, provides information about potentially toxic chemicals to health regulatory and research agencies, the scientific and medical communities, and the public.

Characteristics:

The database presents written summary information on test reports. Currently, data coverage concerns mostly: compounds identification (CAS number, chemical formula, ect..), physical-chemical properties (solubility, volatility, stability, etc..), toxicity data (LD50 on several species mainly mammals, carcinogenicity, mutation data, teratogenicity, etc..) and other data. Some information is reported in the text form; some data are not numerical ones.

Availability:

The NTP database can be accessed using your web browser software via the Internet at http://ntp-server.niehs.nih.gov/

6.2.7 Ecotoxicity: ECOTOX CD (CD Ecological Modelling and Ecotoxicology)

Purpose:

The ECOTOX-CD provides extensive tables, data and parameters needed by modellers, theoretical scientists, environmental managers, ecologists and toxicologists to carry out estimations and calculations. Information on the environmental effects of chemical substances is also included.

Characteristics:

The original print edition - the Handbook of Ecological Parameters and Ecotoxicology - contains data and references from the scientific literature in a web-based search environment. Examples of data include: growth parameters, lethal concentrations (LC50), modelling equations, emissions, degradation of chemical substances, background concentrations, concentration factors, biological effects, octanol/water partition coefficients, excretion and uptake rates and compositions of living organisms. Examples of the models include: eutrophication models, models for dispersion of chemical compounds, models for growth and competition of different organisms, and models describing the global environmental cycles.

Availability:

Commercial, www.elsevier-ecotox.com

6.2.8 MINAMB

Purpose:

The MINAMB database stores physico-chemical characteristics, ecotoxicological and mammal toxicological data as well as environmental fate data and information about metabolites for around 450 substances.

Characteristics:

The data are organized in an Access database.

Availability:

Not yet decided, contact: domenica.auteri@icps.it

6.2.9 Effects: Database for pesticides and their metabolites (SEEM)

Purpose:

The SEEM database was commissioned by de European Commission, DG Health and Consumer Protection and contains ecotoxicity data for pesticides and pesticide metabolites. It is currently ready for use by ICPS and DG-SANCO. The main objectives for its establishment were the relationship between acute and chronic toxicity, the relationships between sensitivities of individual endpoints of parent substances and their metabolites, and the relationship between toxicity for Daphnids and sediment dwellers.

Characteristics:

The SEEM-database consists of data on 200 active ingredients and 130 metabolites in and Excel spreadsheet.

Availability:

Restricted (EU Commission), see also http://www.icps.it/

6.2.10 Ecology: Assiwerk/Enerwerk

Purpose:

Database of assimilation efficiency, water content and energy content of food for birds and mammals. The RIVM database is extended by information from the Central Science Laboratory (York, UK) and from Franz Bailain (Germany).

Characteristics:

The database contains data in Excel format and can be used to express dietary information into exposure data for birds and mammals (e.g., a diet of 100% insects for a 15 g passerine bird is *x* gram food per day).

Availability:

Contact person is C.E.Smit@RIVM.NL. Website: http://www.rivm.nl/csr, new site under construction.

6.2.11 Ecology (Field): Pond-FX

Purpose:

In order to better predict the likely effects of a pollutant (pesticide, or otherwise) on the "health" of natural resources such as farmland ponds, the original research project focused on the need to understand how the ecology of the pond life can alter, or mediate, the effects that might be expected purely from the results of toxicity tests. A prerequisite for such investigations is to collect information about the various life history characteristics thought to play a role in mediating the risk that a population of organisms will be both: (a) exposed to the pollutant, (b) unable to recover from any adverse effects within an acceptable period of time.

Characteristics:

The Pond-FX web site provides ways to access the data. Most of the information is contained in a relational database which, although somewhat complex, means that there is great flexibility in how the information may be explored. The links offer selected starting points for exploring the database but do not restrict the information that can be accessed. You will find that most of the information on a page will be linked to the other areas of the database. The data coverage is: 1. A classification of the types of pond found on farmland around Britain and the invertebrate pond life found in them. 2. Information about the life history of pond organisms (including dispersal ability, preferred water body types, feeding habits, etc.). 3. Miscellaneous information such as rarity status, common names and photographs of some of the pond animals.

Availability:

http://www.ent.orst.edu/PondFX

6.2.12 Spatial Environmental Information System for Modelling the Impact of Chemicals (SEISMIC)

Purpose:

SEISMIC is an environmental information system designed to provide detailed soil and weather data necessary to parameterise a wide range of chemical fate models for any environmental scenario in England and Wales.

Characteristics:

SEISMIC is programmed in MS Visual Basic and utilises MS-Access databases and ESRI MapObjects technology. It does not require additional GIS software to run. SEISMIC contains both spatial and parameter data, on climate, agricultural crops, soil types and aquifer types. Further, it contains weather data.

Availability:

Under licence, Annual lease fee or one-off payment, http://www.silsoe.cranfield.ac.uk

6.3 Confronting Database items with EUFRAM Criteria

The following Table results when the Database items are confronted with the criteria developed during the workshop (Table 6-2). The Table shows, regarding the scientific aspects of the Databases for PRA:

- that the database items were not all tested / presented at the Software and Database workshop (some items do not have evaluation entries) and that the criteria list developed during the workshop could not be applied to the items there (input from developers / contact persons is necessary)

- that there are various databases available for a single purpose, e.g. collecting ecotoxicity data in US-EPA Ecotox and RIVM e-toxBase
- that databases have highly different purposes, such as an embedded target of predicting toxicity based on stored toxicity data (e.g. QSAR, embedded formulae) *versus* pure storage and retrieval functions

and that, regarding the operational features:

- some items obtain positive remarks on many aspects, whereas others obtain mainly negative marks. This suggests large differences in the purpose of the designer (own use versus planned multi-usage by third parties), and not scientific weakness of the latter.

Given these observations and the large variability in judgement on the individual criteria for each software item, the workshop was crucial to gain overview. To that end, a SWOT analyses were made. The results are presented in Table 6-3. Note again that the SWOT provides a preliminary overview on the proposed and evaluated items, and that the Recommendations (see Chapters 8 and **Error! Reference source not found.**) suggest to continuously update the views that are presented.

Table 6-2. Overview of the confrontation of the database items with the criteria for database development.

	EPA EFD	RED	RIVM e-toxBase	ECOTOX-EPA	COMET	NTP	ECOTOX CD	MINAMB	SEEM	Assiwerk / Enerwerk	Pond-FX	SEISMIC
Data characterististics												
Modifying factors (contextual data, covariates)			+									
References for data documented			+									
Quality critera documented			+		-							
Identification and handling of 'duplicates'			+									
Info on limit of detection for non detects			-									
Quality measure (e.g. measured / nominal data)			+									
Statistical method mentioned			-									
Indication of uncertainty on estimated values (EC50 with CI)			-		-							
Quality of the study (GLP, compliance with regulation x)			+		-							
Reported with original number of digits			+									
Slope for EC50, LOEC for NOEC			-									
Info to judge tests (e.g. sample size, power)			+									
Raw data included			-									
Link to related compounds			-									
Comprehensiveness of data per endpoint					+							
Comprehensiveness over endpoints												
Technical characteristics												
Format remains in export			+									
Error checking routines for input			+									
Database documentation			+									
Extensible (by db manager)			+									
Allowing for versatile data query / sub-selections			+									
Keep track if records have changed			+									
No aggregrate (text) fields (e.g. min & max instead of range)			+		+							
Web-enabled use possible			-		+							
Windows-based			+		+							
Open design for software access			-									
Ease of use												
Exporting of output selections			+									
User friendliness of search terms (common names)			+									
Reproduce past query			+									
Flexibility in data input (e.g. units)			+									
Free of costs					+							
Includes summary tools to qualify subselections												
Feedback loops to improve context of database												
Related to regulatory context												

Table 6-3. Results of the SWOT analyses of the databases presented at the Software and Database workshop (suitability 1 = directly usable in EUFRAM, 2 = with modification, 3 = not suitable, 0 = not ranked during the workshop)

Acronym	SWOT summary / reamarks	Suitability for EUFRAM
EPA EFD	+ many data on fate, metabolites included, goodqueries, continued entry - restricted to chemicals registered by US-EPA, not yet freely available	1
RED	not available at workshop	0
RIVM e-toxBase	+ integrates different data sets, large number of endpoints, influenced by the EU registration procedure, user friendly interface, flexible,fate and physicochemical data can be added - not yet available for public, dependece on US-EPA for update	1
ECOTOX-EPA	+ large data base of ecotox data, flexible queries, web based, free - quality check not done properly, different units, no slopes given for EC-values	1
COMET	QSAR models and input data + toxicity values given with min and max, metabolites included, free available - includes all tests, regardless of use of standardised methods	2
NTP	not available at workshop	0
ECOTOX CD	not checked at workshop	0
MINAMB	not available at workshop	0
SEEM	+ brings many different high quality data together, includes metabolites, easy to use - not yet availble for public, only species used in EU dossiers considered, no real database with user interface (Excel file)	2
Assiwerk/Enerwerk	+ large DB for bioaccumulation related parameters, raw data included - no relational database (Excel files), no user-interface, restricted to bird and mammals, limited availability	2
Pond-FX	+ user friendly web application - no output/export device, no info about quality and source of data, no updates	2
SEISMIC	not available at workshop	0

From the latter Table, it can be concluded that most databases obtain the rating “2”, implying that the item has to be adapted to the general design criteria to a smaller or larger extent. Three databases were considered sufficiently adapted to the EUFRAM criteria that they gained the rating “1”, which implies that those items only need undergo minor adaptation when they would be adopted in the EUFRAM framework. A specific difference between the two items, being both ecotoxicity databases, is that the US-EPA Ecotox database currently allows for web-enabled searching and data collection by any thrid party, whereas the RIVM e-toxBase is currently for in-house use only. Various databases were not evaluated after obtaining hands-on experience during the workshop.

7 CONCLUSIONS REGARDING THE EUPRA RECOMMENDATIONS

The detailed recommendations for this work package, according to Hart (2001), are, as repeated from the introductory pages of this report:

1. that standard software tools for probabilistic assessment should be adopted, at a level of complexity appropriate for users in all parts of the EU regulatory arena.
2. that, in order to avoid duplication of effort, consideration should be given to whether tools developed elsewhere could be appropriate for use in the EU, either in whole or in part.
3. that there is an urgent need to catalogue existing data that would assist the development and operation of probabilistic approaches, and to collate these data in publicly-available, quality-controlled databases. The catalogue of data should include pesticide-specific data (e.g. toxicity, for use in developing SSD methods) and general data (e.g. geographical and ecological data).
4. that databases and software should be made easily accessible, to promote harmonised approaches.

As to these recommendations, it can be concluded that (regarding the various issues) the following remarks apply:

1. Availability of suitable software and databases is as yet not sufficient:
    - various software tools are available for the various necessary steps that can be envisaged for a tiered protocol for risk assessment;
    - the set of tools do not show the required "inter-linkage" as needed for a 'protocolised' risk assessment scheme in neither the technical (IT-technique) nor the logical (scientific rationale) way;
    - not all possible assessment steps are covered; and
    - most items require further development, according to the set of defined criteria, to move into the direction of optional regulatory adoption.
2. Adoption of tools requires close fit to the (eventual) regulation; developments seem unavoidable from this perspective.
3. There is as yet no open data source for all relevant types of data, this is except for the databases that can as yet be queried via a web interface (e.g., the US-EPA Ecotox database). This implies that part of the data is hidden or unavailable for use, either due to technical reasons or due to use limitations imposed by data(base) ownership. In addition, the databases that are available, at best provide data which are of limited use for the risk assessment of new pesticides (i. e. ecotoxicity data), and when data are available they were mostly collected for lower tier assessments. Especially, data that might be useful for risk assessment of different pesticides are difficult to obtain, e.g. databases about landscape characteristics and species ecology.
4. Efforts are needed to adapt the existing set of software and database items to the probabilistic risk assessment framework being developed in EUFRAM. These efforts can be focused by:

(1) seeking complete coverage on the *types* of software and database items needed (e.g., do we cover the complete cause-effect chain), and

(2) seeking the best implementation format per assessment step, by e.g. adapting the best candidates towards functioning in a formalised scheme as targeted in EUFRAM.

With regards to the latter, note that most software programs are relatively simplistic in the ways that they can deal with uncertainty, and that many practical issues need to be addressed when adopting any program for implementation (e.g., handling data, account for uncertainty, other distributions that the log-normal distribution, et cetera).

8 RECOMMENDATIONS FOR THE INTEGRATED FRAMEWORK

The EUFRAM framework for probabilistic risk assessment is formatted according to the insights obtained of various feedbacks to drafts of the Framework Document and worked case studies, and draft Work Package reports, as well as from three End User Workshops. This is to merge sound science to practical approaches. It is recommended to incorporate the list of desirable software and database characteristics in the Framework Document, e.g. as an Appendix, to underscore that the development of software and databases that is needed for the operation of the framework as an operational approach would profit from a set of characteristics as described. By putting the criteria in the Framework Document, the information is not lost, and it may be therefore of help in guiding software and database development in the long term.

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EUFRAM

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

Work Package 11

POOLING DATA FOR PROBABILISTIC APPROACHES

November 2007

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1 CONTENTS

[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 INTRODUCTION

One of the statements at the 2001 EUPRA workshop was: "probabilistic methods are data hungry" and as possible solutions were proposed:

a) the sharing of generic data

b) "Promote the use of unpublished proprietary data in the development of generic databases"

The remit for work package 11 can be considered as the result of these ideas:

This paper will identify the main type of existing data that might be useful for developing probabilistic methods and identify those types for which data access is difficult, e.g. data generated by industry for registration purposes, which could without prejudice to current pesticide authorisations be pooled for meta-analyses that are needed to support the implementation of probabilistic approaches. The paper will also propose a plan of action to investigate ways of pooling these data, including calendar for consultation with data owners and investigating the roles that might be played by organisations such as OECD, the EU Environment Agency and industry associations.

3 GENERAL APPROACH

The general approach taken was to collect the information on the data where accessibility is an issue, to identify the data owners and their interest and to explore which options for pooling exist.

The inventory was discussed with EUFRAM partners at project meetings to check for completeness and technical suitability.

Discussions with data owners began in year 1 and continued through to year 4. Evolution of the EUFRAM framework and case studies (see Work Packages 1-10) focussed discussions on two specific types of data access: (a) access to data used in an individual probabilistic assessment, for the purpose of peer reviewing the assessment; and (b) access to data for the purpose of deriving general estimates for use in multiple assessments. These two situations differ in the issues they raise and in their potential solutions.

4 ENTITIES

4.1 Data required for probabilistic approaches

Principally the data required for probabilistic risk assessment can – for the purpose of data access - be categorized as follows:

Generic data

geographical

biological/ecological

meteorological

agronomical

Substance specific data (incl. metabolites)

Chemical

e-fate

ecotox & biological

Product specific data

Market data

Use data

4.2 Categories how pooled data can be used

1. Input data for characterising generic assessment scenarios

(e.g. the use of soil, climate data etc to define probabilistic versions of the FOCUS scenarios). These data are required if we are to develop robust probabilistic methods for representing spatial and temporal variability.

2. Data to develop generic or surrogate estimates for substance or product specific data

a. Estimation of pooled variances for SSDs (Luttik and Aldenberg 1996)

b. QSARs to replace toxicity data

c. acute/chronic ratios

d. uncertainty or extrapolation factors for parent/metabolite toxicity

These data may reduce the number of new studies required (e.g. by enabling estimation of an SSD with very few studies, or avoiding the need for testing metabolite toxicity),

3. Data for validation or testing of probabilistic assessments

a. Measured concentrations to compare with PEC distributions,

b. Data on impacts in mesocosms or field studies to compare with predicted impacts.

This can help by building confidence in probabilistic methods (if predictions are confirmed), and enabling us to detect and correct model components that lead to poor predictions.

The nature of the benefits differs between these types of use. This will on one side influence the willingness of data owners to share, on the other side this will have a profound impact on the techniques that can be used for data pooling.

4.3 Data owners

In a similar way the owners of the data can be grouped by their interest into:

Research Institutions

a) publicly funded

b) privately funded

c) mixed funding (might today be the rule for public research institutions)

Public service institutions

(e.g. meteorological offices)

Other commercial enterprises

Agrochemical Industry

Government and supranational agencies (including regulatory bodies)

In this it is of special interest, to clarify precisely what the limitations are on the use that EU and member state regulatory authorities can make of data submitted by companies. These are essentially legal questions and it may well worthwhile to clarify how far the legal situation in the European community, respectively the individual member States provides any scope for use of submitted data in research to improve probabilistic approaches. In the USA, the Freedom of Information Act may provide some scope for accessing regulatory data for research purposes.

4.4 Issues with data accessibility

Data accessibility can be restricted by several and interlinked factors: These can be categorized:

Legal

property rights

data protection

data confidentiality

licensing and copyright law

competition law

Commercial

cost of data generation

profit from data use

damage from data misuse

Technical

data formats (e.g. non digitized "paper" data)

Immaterial value (e.g. value of a database for a research institute as basis for future research projects)

In all data accessibility discussions it is very important, to consider that the value of the data to the data holder may far transcend the costs for their generation. This holds true for all commercial enterprises, for which the data either support their present business or are a source of future business. But this is also true for a research institute which intends to use a database as a basis for future research.

4.5 Pooling options

Depending on the type of data, the interest of the data owner and the purpose for which the data are to be used, different option might exist to resolve accessibility issue:

Cost sharing (e.g. acquisition or generation of data by an industry association for use by a group of companies)

Sharing of interest

> This solution might be favoured, when the commercial value of a data package is difficult to assess (e.g. several agrochemical companies exchanging regional soil, wheather and topographical or ecological data on a quid pro quo basis).

Technical solutions

> anonymization of data
>
> generation of meta data

For each of these options the applicability to the different data types and data owners needs to be analysed, determining the technical, practical and legal restrictions (e.g. competition law) that exist for them.

Some of the issues which arise from data sharing arrangements are given below:

- What would happen in a data-sharing arrangement if only some companies participated? Would other companies not be allowed to use the pooled data? Would they be charged a fee?
- How will a data-sharing arrangement cope with some partners having more data to share than others? Could it be assumed that those with more to share probably have more actives and therefore get more benefit? Or would one need some accounting of contributions and benefits?
- Would owners be more likely to contribute to a project with a defined plan for analysing the data and generating specific outputs? This could then be viewed like a joint research project than a data pooling exercise. For example, one could envisage a FOCUS-style project to develop probabilistic exposure scenarios, including data pooling but perhaps also data collection (e.g. satellite data). Another example might be a joint project to estimate extrapolation factors for metabolite toxicity, with companies contributing existing tox data for parents and their metabolites. There are funding programs that could contribute to the costs of such projects (e.g. LINK in the UK, and EU schemes).

4.6 Quality assurance

A very general issue is the quality assurance of pooled data. While it will in all cases be necessary, to establish confidence, that the pooling procedure did not introduce artefacts which have a significant impact on the use of the data and that the pooled data properly reflect the original data set and are not biased either due to a selection of the data used in the pooling procedure or due to the pooling procedure itself. This will be especially difficult in those cases, where pooling was choosen to maintain the confidentiality of the original data, since in these cases no retrospective check will be possible, and the suitability of the pooled data will have to be established a priori.

A few examples may illustrate the different kinds data may be biased due to a pooling procedure:

- Frequently studies are targeted towards problem areas and therefore give a biased representation of the full data. This is especially true for monitoring studies but also other studies may only
- Some data holders may have an interest to include only data “favourable” to a certain position.
- The pooling procedure itself may introduce statistical artefacts. This is especially important for procedures which involve the generation of meta data. A well known example are weather generators, which are calibrated with a limited set of real weather data and then used to generate large volumes of simulated weather data for use in exposure models. While these algorithms give generally good estimates of the normal range of weather conditions, they are far less satisfying where the frequency and amplitude of extreme events is concerned. In this case such a program may therefore not be suitable, where the extremes of the distribution curve are of prime interest (i.e. run-off events) whereas they may be very well useable in other cases where extreme events are less important.

In all cases, where access to the original data is restricted, special care will have to be taken, that the procedures are properly documented and define the use areas for the data thus generated.

5 CONCLUSION

Probabilistic methods will most certainly increase the incentives for data pooling. Currently, assessments are deterministic and there is only limited incentive for reducing uncertainty. Probabilistic assessments up to now have mostly concentrated on quantifying variability (especially in exposure) as a means of relaxing worst-case assumptions – this favours sharing of generic data but perhaps not specific data. In future, probabilistic assessments may do more to quantify uncertainty (in both exposure and effects). In theory, this would provide a clear incentive for sharing all types of data, as reductions in uncertainty would be fully recognised. In praxis however, large obstacles are still to overcome, since on one side data owners have legitimate concerns regarding the proper sharing of costs and benefits, the protection of intellectual property and commercial interests on the other side the users of pooled data must be assured that these data are “fit for purpose” and not biased due to the underlying selection and pooling procedures.

Detailed discussions were held with data owners to seek practical solutions that would enable data-sharing. However, it is clear that there is no general solution to the major obstacles mentioned above, and that instead **agreements for data-sharing must be established on a case-by-case basis**. These will generally be formal confidentiality agreements between the parties giving and receiving data, controlling what purposes the data can be used for and in what ways (if any) it can be published or transferred to third parties. It is not practical to produce a standard template for such agreements as the data-owner organisations generally have their own formats which they will require to be used.

At the conclusion of the project, the situation regarding four types of data sharing may be summarised as follows:

1. Input data for characterising generic assessment scenarios: Significant data-sharing agreements have been established between groups of data-owners for some types of scenario data, e.g. data on ecological parameters required for modelling avian exposure.
2. Data to develop generic or surrogate estimates for substance or product specific data. Databases of toxicity information have been developed by some research and regulatory organisations for use in their own work or research. In some cases, access has been granted to other parties for use in specific research projects.
3. Data for validation or testing of probabilistic assessments. Field studies and toxicity data have been made available by some data-owners for one research project investigating the relationship between probabilistic risk estimates and impacts in the field.
4. EUFRAM partners agreed in principle at project meeting 6 that data and computer programs used in EUFRAM case studies would be made available to other organisations for the specific purpose of evaluation and peer review on a case-by-case basis, subject to the establishment of suitable confidentiality agreements between the parties concerned.

In conclusion, although a more general, open sharing of data might ideally be desirable, in practice it is not achievable. However, case-by-case data sharing under formal confidentiality agreements has proven feasible and is making important contributions to the development and validation of probabilistic approaches.