EUFRAM

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

Work Package 3

ROLES AND OUTPUTS OF PROBABILISTIC RISKS ASSESSMENTS

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2 EXECUTIVE SUMMARY

The objectives of this Work Package were to:

‘pool data, achieve a common understanding of facts, and develop harmonised proposals for standards and procedures on when to use probabilistic methods, what the outputs should be, and how to use them’

The paper highlights that probabilistic risk assessment does have a role in the environmental risk assessment for pesticides that is carried out under 91/414/EEC. It further points out that there is no clear reason why PRA can not be used for the whole risk assessment process; however, there was a strong desire from Partners involved in EUFRAM to have a simple and easy to use Tier-1 process. Therefore, it was agreed that PRA should primarily be used for refining the risk once a regulatory threshold has been breached.

It was proposed that PRA should follow a standardised format (see WP 6 – Reporting probabilistic assessments). In order to assist in the uptake of PRA in the regulatory forum, it was proposed that, initially, regulatory risk assessments should be conducted using both deterministic and probabilistic approaches.

As regards outputs of PRA, it was noted that current regulatory experience is limited, and hence it was not possible to determine, from a regulatory perspective, what outputs were useful and hence preferred. Potential end users were consulted and a number of various outputs were noted. Several ideas were proposed regarding possible outputs, as well as more general issues involving probabilistic risk assessments. Some of these issues have been considered in the Case Studies (see WP 8). Further development of these issues will be via WP 8 and the End-user Workshops.

3 OBJECTIVES

The objective of Work Package 3 – Role and outputs of probabilistic assessments – is to:-

‘pool data, achieve a common understanding of facts, and develop harmonised proposals for standards and procedures on when to use probabilistic methods, what the outputs should be, and how to use them’
4 BACKGROUND

Currently in the European Union pesticides are assessed via the EU Directive 91/414/EEC (see Anon (1991)). This Directive covers the risk to the operator, consumer and environment. The risk to the environment covers the fate and behaviour (i.e. exposure) as well as the possible effects to non-target organisms. Non-target organisms considered under 91/414/EEC include the following: birds, mammals, aquatic life (including fish, aquatic invertebrates, algae and aquatic plants), non-target arthropods, honeybees, earthworms, soil macro-invertebrates, soil microbial processes and non-target plants.

The risk assessment carried out for non-target organisms is currently predominantly deterministic i.e. it takes single point estimates for both toxicity and exposure. However, it is appreciated that these values, especially the exposure value, are often based on a point from a distribution, for example 90th centile spray drift data used in determining the predicted environmental concentrations in surface water. The ratio between the exposure estimate and the toxicity results in either a ‘toxicity:exposure ratio’ (i.e. TER) or ‘hazard quotient’ (i.e. HQ) which is then compared to a regulatory trigger value in the Uniform Principles of 91/414/EEC (Council Directive 94/43/EC). If the trigger value is breached, then no authorization is granted *unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product according to the proposed conditions of use.* This refined risk assessment usually takes the form of further information on the toxicity of the compound and/or the exposure of non-target organisms to the compound. The refined risk assessment can also incorporate the use of risk management measures, for example buffer zones to reduce the amount of pesticide entering an off-crop habitat via spray drift.

The current deterministic approach uses arbitrary safety, assessment or uncertainty factors and leads to a qualitative final output which tends to describe the risk in terms of ‘margin of safety’, ‘adequate protection’ or by reference to a higher tier study or studies. Examples of regulatory deterministic risk assessments are presented in Table 1. Such assessments do not provide an indication as to the magnitude or frequency of effects. In addition, this type of output does not provide any indication as to the level of certainty associated with either the input parameters or the final output. Therefore, the output from current assessments is potentially very difficult to understand in terms of what may occur under actual use conditions. Or put another way there is no indication as to what is the probability that an effect will occur, the size of that effect and how certain the risk assessor is that it will occur.

Table 1: Examples of some possible outputs from conventional ecotoxicological risk assessments carried out under 91/414/EEC.

<table>
<thead>
<tr>
<th>Area of risk assessment</th>
<th>Possible output from conventional ecotoxicological risk assessment carried out under 91/414/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic life</td>
<td>Regulatory end point (e.g. ecologically acceptable concentration (EAC)) from microcosm and other higher tier</td>
</tr>
</tbody>
</table>
Area of risk assessment | Possible output from conventional ecotoxicological risk assessment carried out under 91/414/EEC
--- | ---
concentration (EAC)) from microcosm and other higher tier studies = 1 µg/l, the ‘predicted environmental concentration’ (PEC) at 1 m is 0.3 µg/l. The resulting ‘toxicity/exposure ratio’ (TER) is 3 and it is considered by scientific assessors that there is sufficient margin of safety between the PEC and the effects end point to permit use of the product without any risk management measures, e.g. buffer zones. Therefore, in this instance, a TER of 3 is considered to address uncertainties, variabilities and unknowns in the risk assessment.
Non-target arthropods | As a result of the Tier-1 risk assessment a ‘hazard quotient’ (HQ) of greater than 2 was produced (see Candolfi et al (2001) for details), however higher tier laboratory data indicate that recovery and/or recolonization of the in-field environment is likely within the required timeframe (Candolfi et al 2001). No effects within an ‘ecologically relevant time period’ are considered likely for the off-field environment.
Birds | Tier-1 assessment according to Anon (2002) indicates high acute risk, i.e. TERs less than 10. Additional information on foraging and feeding behaviour was presented and these permit the revision of the proportion of diet obtained from the treated area (i.e. PT) and/or the proportion of different food types in the diet (i.e. PD) (see Section 5.6 of Anon 2002). The refined risk assessment indicates that the resulting TER is greater than the appropriate Annex VI trigger value.
Earthworms | Tier-1 assessment according to Anon (2002b) indicates high short-term risk, i.e. TER less than 10. However, field trial data were submitted which indicates that under the conditions of the field trial, there is an initial impact but there is recovery by the start of the following season.

In the guidance documents developed to assist in the evaluation of active substances and their associated products under 91/414/EEC (Anon 2002a and Anon 2002b), some of the above concerns with the current risk assessment techniques are discussed. In Anon (2002b) it is stated that the ‘traditional TER-based approach uses point estimates for the input parameters (e.g. lowest available toxicity figure, highest exposure level) and involves an overall factor (= critical TER) to cover the various sources of uncertainty. Such a deterministic assessment has limitations with regard to the quantification of the risk.’ Anon (2002b) goes on to state that ‘this problem could be overcome by newly emerging probabilistic approaches’. The guidance documents also highlight some of the disadvantages of adopting a probabilistic approach to risk assessment. For example Anon (2002b) notes that ‘for many input parameters reliable information on the distribution is lacking’. It goes on to state that ‘common standard methods for the statistical calculations’ are also lacking and finally
'the result of the (probabilistic risk) assessment appears complex in nature and thus may be more difficult to communicate to non-experts’. It should also be noted that in addition to the pros and cons highlighted in Anon (2002a and 2002b), further assessment is provided in Hart (2001). Therefore, probabilistic risk assessment may present certain advantages, however there are also some associated drawbacks.

In addition to the potential of probabilistic techniques being raised in the EU guidance documents (Anon 2002a and 2002b), the EU Scientific Steering Committee’s Working Group on the Harmonisation of Risk Assessment recommended that probabilistic or quantitative methods of risk assessment be considered for adoption in the area of environmental health (Anon 2000).

In conclusion, current pesticide regulatory risk assessments are predominantly deterministic, comparing a ratio of toxicity with exposure to an agreed trigger value. If this trigger value is breached, then further work is necessary prior to a product being authorised for use. This procedure has several shortcomings, namely, there is no quantification of the risk and no indication as to the level of certainty in the risk assessment. It has been proposed that these shortcomings may be addressed via the use of probabilistic risk assessment.

5 WHAT IS PROBABILISTIC RISK ASSESSMENT (PRA)?

Probabilistic risk assessment is the term used in pesticide risk assessment to describe ‘quantitative risk analysis’ or ‘uncertainty analysis’. In essence it is the use of probability theory to characterize both toxicity and exposure. It is usual to consider the description of toxicity and exposure in terms of distributions. However, as probabilistic methods are a mixture of statistics and mathematics they can be distribution free and therefore would be referred to as ‘descriptions’. These distributions (or descriptions) of toxicity and exposure may then be combined to produce distributions (or descriptions) of the predicted risk or impact. These distributions (or descriptions) of toxicity and exposure demonstrate variability as well as the level of uncertainty.

For purposes of this paper, it is proposed to use the following as a working definition:

probabilistic risk assessment is defined as the use of probabilities or distributions to quantify variability and/or at least one source of uncertainty in the exposure and/or toxicity and the resulting risk.

6 DOES PROBABILISTIC RISK ASSESSMENT HAVE A ROLE IN THE REGULATION OF PESTICIDES ASSESSED UNDER 91/414/EEC?

In trying to determine whether PRA has a role in the regulation of pesticides assessed under 91/414/EEC, we first need to consider whether PRA is compatible
to calculate TERs as well as where to obtain further information as regards
environmental risk assessments (see Annex III Section 10 Introduction). As regards
the Uniform Principles, i.e. Council Directive 97/57/EC, there is reference to
‘appropriate risk assessment’, however it does not provide any details as to how this
should be conducted. Likewise, in 91/414/EEC there is no reference as to how such
a risk assessment should be carried out. Therefore, it is assumed that a risk
assessment should permit the decision-takers (see Section 4 below and Anon
2000a) to determine whether the compound and/or its’ metabolites, and its’
associated product and use, has no unacceptable influence on the environment.

6.1 Where in the assessment procedure can probabilistic risk
assessment be used?

Whilst it can be concluded from the above that there are no procedural or legal
reasons to prevent PRA techniques being used in the regulatory risk assessment
process, there is no indication as to where in the risk assessment process it can be
used. In the EUPRA report (Hart 2001) it is stated that probabilistic methods could
be ‘used selectively...as part of a tiered stepwise assessment process’ once the
trigger value for the first has been breached. Also presented in the EUPRA report is
a proposal that PRA methodologies could be used for the whole risk assessment
process (see appendix 6 of the EUPRA report (Hart 2001).

PRA as a risk assessment process was considered in detail in the EUPRA report and
the strengths and weaknesses were highlighted. This assessment was for the
process per se and did not consider whether the strengths or weaknesses
highlighted were more or less relevant to its use as a refinement step or when used
for the whole process. It can be argued that there is no technical difference between
carrying out a PRA for the whole risk assessment process compared to using it as a
refinement step. Therefore the advantages and disadvantages, as highlighted in the
EUPRA report, are applicable regardless of where in the assessment process PRA is
used.

Despite the fact that there is no technical difference between carrying out a PRA for
the whole risk assessment compared to using it as a refinement step, there is
concern regarding the quantity of data required. The reason for this is that the
amount of data presented at Tier-1, compared to that available at higher tiers, is
usually relatively small and hence there would still be considerable uncertainty
regarding the relevant distributions and dependencies. (It is acknowledged that for
certain well-studied compounds considerable data are available and hence there is
reduced uncertainty (e.g. Giesy et al (1999) assessment of chlorpyrifos, Solomon et
al (1996) assessment of atrazine.) However, in reality few pesticides will approach
this level of data.)
Although there is no technical difference between carrying out a PRA for the whole risk assessment process compared to using it as a refinement step, the majority of regulators and risk assessors involved in the pesticide regulatory arena prefer a simple Tier-1 assessment. This preference is based on the need to carry out risk assessments with the most efficient use of resources. The Tier-1 of the assessment aims at identifying compounds that are clearly acceptable and do not require further work, where ‘acceptable’ is defined by the appropriate threshold values presented in the Uniform Principles of 91/414/EEC. Currently, Tier-1 risk assessments use a standardised assessment model, where the outputs from standard toxicity studies are compared to outputs from standard exposure models. The resulting output, either a TER or HQ, is then compared to the regulatory threshold. This Tier-1 assessment, or screening step, is therefore standardised and on one level potentially relatively easy to communicate. The result is normally a pass or fail. However, if an explanation is requested then an explanation of the assessment can be difficult to justify scientifically or quantitatively. In other words, if the Tier-1 triggers are breached an unacceptable risk cannot be excluded, but there is no indication on the magnitude of the actual risk.

When a regulatory threshold is breached, a refined risk assessment is required to better determine a more realistic estimate of what the risk is likely to be. PRA can obviously be used as a refinement step to provide an indication to the decision-taker, what the real impact, in terms of frequency and magnitude, could be. PRA can also provide an indication as to the certainty of the assessment. For this step to be accepted into the regulatory forum, it is essential that it is consistent with the Tier-1, insofar as the output needs to be in line with the regulatory threshold. This does not necessarily mean that the output from a PRA has to be expressed as TERs or HQs, although such an approach may be convenient due to the familiarity of the approach; what it does mean, is that the output needs to be comparable in terms of level of protection (i.e. the number or percentage of species protected by the standard default uncertainty or assessment factors). For example, if the Tier-1 trigger value or threshold provides a certain level of protection, then in order to keep the output from a PRA in perspective, the output needs to be consistent with this. If this issue is not addressed, it is possible that the refined risk assessment may afford a greater level of protection than the Tier-1. Therefore, it is essential to determine the level of protection afforded by the Tier-1 threshold or trigger values.

(It should be noted that the Scientific Committee on Plants proposed that the level of protection should be determined when they considered the bird and mammal guidance document (Anon (2002) (see http://europa.eu.int/comm/food/fs/sc/scp/out125_ppp_en.pdf).)

It should be noted that, as stated above, Tier-1 assessments include a number of worst-case assumptions and safety factors. It will be very difficult to quantify the level of protection afforded by these assumptions and hence it could vary on a case-by-case basis. Therefore, it may be preferable to compare the Tier-1 deterministic assessment with the probabilistic assessment (i.e. Tier-1 deterministic = xth centile of the PRA). The level of protection in the refined assessment (i.e. the centile selected
as a decision criterion) can then be chosen such that the refined assessment is consistent with the Tier-1 assessment.

It should be noted that this work may indicate that the level of protection is not what is required by decision-takers (see Section 7.1) and hence trigger values may be amended upwards or downwards as required.

Work carried out by Mineau for the EPIF Workshop (http://homepage.mac.com/matthiasliess/EPiF/EPiFworkshop.htm) indicated that the Tier-1 assessment used in Anon (2002) may highlight that a compound is of low risk, i.e. TER >10, when in reality incidents may occur in the field. Mineau's assessment was based on an empirical model that was used to predict the likelihood of visible avian mortality (Mineau 2002). When Mineau assessed the risk from a range of compounds, he concluded that the number of ‘false negatives’ was about 5%. Or put another way, for 5% of the compounds Mineau assessed, a low risk was concluded when the risk assessment in Anon (2002) was used. However according to Mineau analysis mortalities were likely to be seen in the field. It should be noted that the number of false positives (i.e. those compounds that failed the Tier-1 but did not cause incidents in the field) was relatively high at 70%. Mineau (2002) highlights that the main reason for the ‘failure’ rate of the Tier-1 is due to some significant routes of exposure not being considered. Whilst this work does not specifically indicate the protection level afforded by Tier-1, it does provide an indication as to the likelihood of incidents that may occur if the risk assessment model is used and assuming the Mineau’s model is correct. Further work of this type is required to try to provide useful information on the level of protection afforded by Tier-1.

As regards non-target arthropods, the HQ approach and resulting trigger value of 2 has been determined to justify ‘harmlessness’ (see Candolfi et al 2001). Therefore, it could, tentatively, be argued that the level of protection provided by the Tier-1 risk assessment is already known as Candolfi et al showed that rate/response tests with T pyri and A rhopalosiphi together would detect 95% of effects that ever occurred in any of the species tested under the ESCORT 1 recommendation. However, this work only concentrated on beneficial arthropods and not all arthropods. Therefore, the level of protection for all non-target arthropods can not be determined from this work as no equivalent work has been carried out on species that are not beneficial species.

Once work is done to try and determine what the level of protection is, it should be possible to develop simple models that use PRA techniques. The development of such models could cover Tier-1 risk assessments as well as refined risk assessment and hence increase the level of realism associated with the whole risk assessment.

From a regulatory perspective, the development of models, whether for the whole risk assessment process or simply for refined risk assessment is extremely important. Regulation requires a consistent and equitable approach to ensure that the process and decision reached for one compound and its associated use is equivalent to...
another. Therefore, to ensure that this is possible and also to aid in the uptake of PRA it is important to have standardised scenarios with agreed underlying assumptions.

PRA presents a scientifically more robust assessment process than the status quo. From a scientific perspective, PRA can be used for the whole risk assessment process. However, it is considered by some, that it is more appropriate to use PRA only as a refinement step, rather than across the whole risk assessment process. Wherever it is used, it will be necessary to ensure that the level of protection in a conservative Tier-1 is sufficient, and that subsequent tiers are not less precautionary than accepted levels.

7 WHAT ARE THE POSSIBLE OUTPUTS OF A PROBABILISTIC RISK ASSESSMENT?

7.1 Who uses the output from PRA?

In order to determine what the possible outputs of a PRA could be we first need to consider who the audience is. In a report produced by Oxera (Anon 2000a), for the UK Health and Safety Executive, it is stated that there are four functions in the scientific advisory process:

- **decision-taker** – a person with the authority to take a policy decision. This may be a government Minister, or a person or body with the delegated authority to take a decision in the name of a Minister;
- **policy-maker** – a person or organisation charged with assisting a decision-taker in reaching a decision by providing policy analysis, generating policy options, or by conducting risk assessment (policy has been interpreted to include regulation);
- **scientific adviser** – a person or organisation responsible for providing scientific input to ‘policy-making’ or ‘decision-taking’. This includes both scientists expert in narrow disciplines relevant to the problem in question, and more broadly-based scientists able to integrate several disciplines, and those within and outside the civil service;
- **stakeholder representative** – a person or organisation representing the interests and opinions of a group such as farmers, industry, and non-government organization with an interest in the outcome of a particular policy decision. The section can also include members of the public.

If it is accepted that scientists carrying out a regulatory risk assessment fit into the science adviser role, then the output from their assessment would be used by the
policy-maker to help the decision-taker in reaching an appropriate conclusion. It should be appreciated that in reaching any decision the 'decision-taker' would consider several other areas, e.g. economic and social issues. The output would also be used by the stakeholder representative to enable them to determine whether their concern has been addressed. Therefore, the output from a risk assessment has to be sufficiently transparent to be used by non-scientists in deciding, along with other information, the policy to follow.

Individuals or organisations are not referred to by the above titles in the current EU regulatory process. However, it is possible to compartmentalise either individuals or organisations into the above categories. Outlined in Table 2 is how each organisation or individual fits in.

Table 2: Characterisation of decision-taker, policy-maker, scientific adviser or stakeholder representatives.

<table>
<thead>
<tr>
<th>Title</th>
<th>Organisation/individual</th>
</tr>
</thead>
<tbody>
<tr>
<td>decision-taker</td>
<td>Commission and Member States (MS) at the Standing Committee on the Food Chain and Animal Health (Pesticides Legislation) (SCFA) or Council.</td>
</tr>
<tr>
<td>policy-maker</td>
<td>Individual MSs regulatory organisations and associated Ministries and Departments, Commission services.</td>
</tr>
<tr>
<td>scientific adviser</td>
<td>European Food Safety Authority (inc EPCO process and the Panel on plant health, plant protection products and their residues (PPR)), scientific specialists from individual MSs.</td>
</tr>
<tr>
<td>stakeholder representative</td>
<td>Non-governmental organisations, conservation organisations, European Crop Protection Association, farmers and growers etc.</td>
</tr>
</tbody>
</table>

In the EU regulatory process, the ultimate end-users are representatives from the Commission or MSs who sit on the SCFA. However, as can be seen from Table 2, there are many specialist and non-specialist organisations involved in the overall assessment/decision making process and it is essential that each are content with the output from PRA.

It should be noted that whilst the above section deals with people or organizations who may use the output from a PRA, it should also be considered who will actually carryout the assessment, i.e. the Registrants or Notifiers. It is assumed that Registrants or Notifiers will use PRA as a tool to illustrate the risk from their product and they will therefore use the output in much the same way as Regulators etc.

7.2 What could the outputs of PRA be?
A wide variety of outputs have been used in PRA and some of these were presented in Section 6.2 of the preliminary paper produced for this Work Package. Whilst it was acknowledged that some of these outputs had been considered in the regulatory arena, what was not known was whether any of these outputs were useful to stakeholders and especially decision-takers. In order to address this issue Members of this Work Package (WP), along with representatives from WP6, 7 and 8 were requested to consult potential stakeholders in order to obtain views on potential outputs. Responses were forwarded on to WP8 (Case Studies) so that they could consider the views and incorporate them into the case studies.

Following on from this, WP members were consulted regarding the following issues:

1. What types of output do you want?

2. What scale should be used for the assessment and output (field, landscape, country or EU level)?

Responses on the above questions are presented below.

### 7.2.1 What types of output do you want?

In order to address this question, the views of some of the key organisations, as outlined in Table 2, as well as Work Package Members were sought on approaches used in the regulatory context.

It was clear from the responses received that there is, at present, extremely limited experience of PRA in the environmental regulatory context. As regards decision making at the EU level experience seems limited to examples 1, 2 and 3 in Table 3. In example 1, a species sensitivity distribution approach was used to reduce the uncertainty factor from 10 to 1. This refinement step indicated that the worst case surface water PEC would be equivalent to the NOEC for 0.5% of species. In example 2, concern was initially raised regarding the risk to groundwater. However, on the basis of a spatial assessment the risk was refined to indicate the percentage of crop area that was potentially at risk. In addition to this refinement step, weather data were also used to provide a temporal element to the assessment. These two assessments use limited PRA techniques to refine the risk assessment. However, both were considered by the Commission Working Group Evaluation meeting and used to reach a positive recommendation as regards Annex I listing. It should be noted that these assessments only use PRA methodologies to a very limited extent. They do not consider fate and effects, nor do they separate uncertainty and variability or make an attempt to quantify all the uncertainty or variability as far as possible.

Despite these shortcomings, the use of these approaches have been considered appropriate in the regulatory forum to make decisions regarding the appropriateness of Annex I listing.
In example 3 a PRA was carried out by the Notifier to quantify the risk to birds from a granular formulation of aldicarb. The assessment indicated that an impact at the local level was predicted, however it was considered that effects at the population level were unlikely (see [http://europa.eu.int/comm/food/plant/protection/evaluation/exist_subs_rep_en.htm](http://europa.eu.int/comm/food/plant/protection/evaluation/exist_subs_rep_en.htm) and [http://www.pesticides.gov.uk/acp.asp?id=303](http://www.pesticides.gov.uk/acp.asp?id=303)).

The above deals with the EU Annex I assessment process, but it is possible to use novel techniques to assess particular uses at the MS level. Example 4 provides such an illustration of this. When the risk assessment was carried out at MS level, a risk to aquatic macrophytes from the active substance entering surface water via drainflow was identified. Tier-1 risk assessment indicated that the TER based on a *Lemna* spp study and an initial estimate of drainflow (based on the UK drainflow model – see [http://www.pesticides.gov.uk/psd_pdfs/registration_guides/data_reqs_handbook/env_fate.pdf](http://www.pesticides.gov.uk/psd_pdfs/registration_guides/data_reqs_handbook/env_fate.pdf)) was below 10. Therefore a refined risk assessment was required. This assessment examined the exposure component and determined the risk in terms of the frequency that a ‘safe concentration’ is exceeded. The ‘safe concentration’ was defined as the regulatory end point from a *Lemna* study divided by an uncertainty factor of 10. This approach has been used in the UK and considered by the UK Advisory Committee on Pesticides (The ACP is a statutory body set up by Ministers under the Food and Environment Protection Act 1985 to advise them on all matters relating to the control of pesticides.) Whilst, the ‘frequency of exceedence’ approach has been used, it should be noted that the acceptability of the frequency that a ‘safe’ concentration is exceeded is a risk management one and not a scientific one.

Table 3: Outputs from PRA used in either the regulatory risk assessment process for Annex I listing or product authorisation a MS level.

<table>
<thead>
<tr>
<th>Output</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ‘From the probabilistic distributions, it was calculated that less than 0.5% of fish species would have a NOEC value less than the worst case PECsw from multiple application at 1 m. This indicates that at the worst-case PECsw, less than 1 in 200 species of fish would be expected to demonstrate any mortality whatsoever. Given that there are only approximately 190 fish species in Europe, it can be concluded that the NOEC values from the fish toxicity studies conducted will be protective of the vast majority of fish species.’</td>
<td>Example supplied by PCS</td>
</tr>
<tr>
<td>2 On the basis of FOCUSgw modelling, it was established that for the target crop growing area in the region being considered, the overall probability of the active substance</td>
<td>Example supplied by PCS</td>
</tr>
<tr>
<td>Output</td>
<td>Source</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>containing groundwater at concentrations greater than 0.1 μg/l was 1.3%.</td>
<td>Example from the Council Decision of 18 March 2003 concerning the non-inclusion of aldicarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance.</td>
</tr>
<tr>
<td>Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing aldicarb satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to its possible impact on non-target organisms. It is appropriate to take this decision in view of the high risk of aldicarb in its present granular formulation in particular to small birds. Data submitted by the notifier for the proposed representative uses indicate that granules will remain on the soil surface after treatment. The possibility of a lethal intake of granules by small birds cannot be excluded. A probabilistic risk assessment was prepared by the notifier and evaluated by the rapporteur Member State who concluded that effects on national populations would not be expected although some local impact might occur. It must be taken into consideration that agreed criteria for the interpretation of such a probabilistic risk assessment are not yet consolidated and it would not be appropriate, in view of the possible risks, to delay decision-making further until such criteria are agreed.</td>
<td></td>
</tr>
<tr>
<td>‘A frequency of exceedance X of a TER Y was considered to be acceptable on the basis of an exposure estimate that covered z% of the UK wheat growing area. Toxicity data from a <em>Lemna</em> study were used to generate the TER, however reassurance was obtained from toxicity data on additional species.</td>
<td>Example from PSD</td>
</tr>
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</table>

When the views of the WP Members were requested on which type of output they preferred, it was highlighted, that the output should be what decision-takers want or need rather than what the scientific assessment wants to supply.

With the above issue in mind, Case Study 3 (see Work Package 8) was presented to the UK Environmental Panel of the ACP. The Environmental Panel is a sub-committee of the ACP and is made up of expert ecologists, ecotoxicologists, fate and behaviour specialists as well as lay representatives and policy advisers. Using the terminology presented in Section 7.1 above, they are predominantly scientific.
advisers. However, as they also contain lay people and policy advisers they provide an extremely useful forum to discuss the appropriateness of the regulatory approaches. Therefore, it was considered appropriate to seek their views on the appropriateness of outputs from probabilistic risk assessment. The Panel considered that the frequency of exceedence approach was more scientific than the toxicity-exposure ratio used at the Tier-1. However, the Panel highlighted that such an output required careful and interpretation to ensure that decision-takers make appropriate and consistent recommendations or decisions.

In addition to the above views were submitted on various PRA approaches that had been used within the regulatory forum, but were not related to specific authorisations. These views are presented in Table 4.

**Table 4: Outputs of PRA not related to specific authorisations.**

<table>
<thead>
<tr>
<th>Output</th>
<th>Comments</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exceedance plot showing probability of exceedance on y axis and % mortality of birds on x axis.</td>
<td>Result of research funded by UK PSD/Defra. The outputs have been used in presentations to conferences and the UK Environmental Panel of the ACP, and in published paper (Hart, 2003). Exceedance plots need significant amount of explanation. This can be done, for example, by putting arrows on to the graph to show how to read across and down at different points. However, it is likely that the output will also need to be explained in detail.</td>
<td>The assessment relates to the local population of blue tits around treated orchards and is presented in Hart, A. 2003. Probabilistic assessment of pesticide risks to birds. <em>In:</em> Environmental Fate and Effects of Pesticides, J.R. Coats and H. Yamamoto, eds., Chapter 16. ACS Books, Washington, DC. pp. 271-286.</td>
</tr>
<tr>
<td>Table showing average % mortality of blue tits around treated orchards, and probabilities that this exceeds 1% and 10%.</td>
<td>Origin of this work is as above. Probably more easily understood than exceedance curve. But only show results for three points (average, 1% and 10%). (It should be noted that the word average is misleading as the assessment assumes there is one true value for % mortality. It should</td>
<td>As above.</td>
</tr>
<tr>
<td>Output</td>
<td>Comments</td>
<td>Example</td>
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<tr>
<td>be replaced with the 5th, 50th and 95th centile estimates for % mortality.) The disadvantages of a table is that it is less visual than a graph and there needs to be agreement on the end points of interest. This latter point means that the ‘decision-taker’ needs to specify the level of protection before the assessment is done.</td>
<td></td>
<td>Appendix 2 in Hart, A. 2002. Project PN0920: UK case studies on quantitative risk assessment. Final report to DEFRA. York, Central Science Laboratory. Available at <a href="http://www.pesticides.gov.uk/">http://www.pesticides.gov.uk/</a></td>
</tr>
<tr>
<td>Tables showing % TERs &lt;10, and 10th and 90th centile TERs. In one version, with 95% confidence bounds on each. Also showed deterministic TER based on same data.</td>
<td>The UK Environmental Panel of the ACP considered it was appropriate to compare deterministic and probabilistic results side by side. They liked that the distribution of TER’s was easy to compare with the deterministic TER. But they also complained that a TER wasn’t ecologically meaningful. This suggests that showing all 3 types of result together could be a good strategy until people gain familiarity – i.e. deterministic and probabilistic TERs and a more ecologically meaningful probabilistic endpoint.</td>
<td></td>
</tr>
</tbody>
</table>

WP members indicated that both the distribution of TERs and an output showing severity, frequency and likelihood of effects were desirable. It was considered desirable to have both approaches for the same assessment as this could aid the incorporation of a novel risk assessment technique into the regulatory forum.

In addition to the above, general views were obtained, and these are summarised below:-

1. **Assessments should be as simple as possible** – Simplicity would ensure that results would be more likely to be taken up by stakeholders. The concepts used in any regulatory risk assessment should, ideally, be as simple as possible. It is important that all potential end-users are familiar with concepts being used and agree with their use. It is also important that all the underlying data are from acceptable regulatory studies.
2. **Assessments should use standardised and agreed scenarios** – As highlighted above, from a regulatory perspective, approaches need to be consistent, therefore, it is ideal, where possible, to have a set of agreed scenarios. Standardised scenarios would reduce the likelihood of rejection by regulators due to novel or unknown approaches being used.

3. **Assessments should be to an agreed format** – The presentation of probabilistic risk assessments, including consideration of uncertainty and variability, should be presented in a standardized manner. Standardised reporting would, as (2) above, reduce the likelihood of rejection by regulators due to novel or unknown approaches being used.

4. **Comparison of conventional deterministic approach with PRA approaches** – Regulatory probabilistic risk assessment should be accompanied with a deterministic assessment. This should allow for a comparison of the techniques and outputs and should also ensure that regulators and other end-users become familiar with the new methodology whilst working with the status quo.

(NB Point 3 is considered in WP 6 – Reporting probabilistic assessments)

It was felt that it was essential to address these general issues, as failure to do so could prevent the adoption of PRA techniques in the regulatory arena. As a result a range of different outputs have been used in the case studies and it is proposed to determine the usefulness and hence acceptance of these at the End-user Workshops.

7.2.2 **At what scale should the assessment be carried out?**

Views on the appropriate scale that an assessment should be carried out at were obtained from the same sources as above. The responses indicated that the scale should be relevant to the scale of concern. It was also noted that there should be the ability to put the assessment into a wider context. Relevant scale was defined in landscape terms, e.g. vulnerable soils as well as in genetic terms, e.g. scales relevant for population genetics.

In examples 2 and 4 in Table 3, the output can indicate the frequency of exceeding a ‘safe’ concentration for all water bodies, or for just those vulnerable water bodies. Decision-takers may be interested to know both levels of risk prior to making a decision. As regards avian risk assessment, Anon (2002) indicates that the Tier-1 is at the field-scale; however, when refining the risk assessment it may be more relevant, depending upon the focal species being considered, to assess the risk at the landscape scale. As a general principle, exposure should be assessed over the spatial and temporal scale relevant to the individual, i.e. their foraging range. Effects should then be aggregated over whatever spatial scale is considered relevant to the population of concern (e.g. local, regional, national etc). This means that, although exposure of each individual should be assessed within its own range, this needs to be repeated for each individual.
7.3 Conclusion

From the above, the following can be concluded:-

1. Regulatory experience of PRA in the decision making process is currently very limited.

2. Regulatory approaches are currently limited to spatial scale assessments, frequency of exceedence of a ‘safe concentration’. ‘Species sensitivity distribution’ have been used in the regulatory forum to reduce uncertainty or assessment factors.

3. Regulatory risk assessment should follow a standardised format, using where possible, agreed models, assumptions and refinement steps.

4. Assessments should be conducted using deterministic and probabilistic approaches, as this will allow for comparison of techniques and outputs.

8 CONCLUSION

The objectives of this Work Package were to:

‘pool data, achieve a common understanding of facts, and develop harmonised proposals for standards and procedures on when to use probabilistic methods, what the outputs should be, and how to use them’

The paper highlights that probabilistic risk assessment does have a role in the environmental risk assessment for pesticides that is carried out under 91/414/EEC. It further points out that there is no clear reason why PRA can not be used for the whole risk assessment process; however, there was a strong desire from Partners involved in EUFRAM to have a simple and easy to use Tier-1 process. Therefore, it was agreed that PRA should primarily be used for refining the risk once a regulatory threshold has been breached.

It was proposed that PRA should follow a standardised format (see WP 6 – Reporting probabilistic assessments). In order to assist in the uptake of PRA in the regulatory forum, it was proposed that, initially, regulatory risk assessments should be conducted using both deterministic and probabilistic approaches.

As regards outputs of PRA, it was noted that current regulatory experience is limited, and hence it was not possible to determine, from a regulatory perspective, what outputs were useful and hence preferred. Potential end users were consulted and a
number of various outputs were noted. Several ideas were proposed regarding possible outputs, as well as more general issues involving probabilistic risk assessments, e.g. standardized formats and scenarios. Some of these issues have been considered in the Case Studies (see WP 8). Further development of these issues will be via WP 8 and the End-user Workshops.

9 RECOMMENDATIONS FOR INTEGRATED FRAMEWORK

Following consideration of the above at Project Meeting 2 (PM 2), it was proposed that the following topics be included in the Integrated Framework:

Definition of PRA

The following definition was agreed at PM2:

*Probabilistic risk assessment is defined as the use of probabilities or distributions to quantify variability and/or at least one source of uncertainty in the exposure and/or toxicity and the resulting risk*

It was also agreed that there should be a definition of variability and uncertainty as well as a lay persons definition of PRA and DRA in the Integrated Framework.

Does PRA have a role in pesticide risk assessments carried out under 91/414/EEC?

As regards whether PRA has a role in pesticide risk assessment, the following was agreed:

- Primary use is as a refinement step once Tier-1 risk assessment raises concern, i.e. TER or HQ thresholds breached.
- Can also be used for the whole risk assessment process but is aspirational rather than a practical option.
- PRA can be used to quantify the level of protection provided in the Tier-1 (eg Case Study 5 and Focus Step 1, 2 and 3 comparison.)

What are the outputs of PRA?

As regards the outputs of PRA the following was agreed:

Who uses PRA?
What types of outputs are required?

- TERs?
- Others?
  - % mortality in focal species
  - % species affected
  - Exceedance of safe concentration
  - Effects lasting more than x days

In addition to the above the following key issues were also agreed:

- It was noted that if a distribution of TERs was used as an output then there needs to be a description of what it means.
- Regulatory probabilistic risk assessments should, where appropriate, be conducted to take account of spatial, temporal, effects, exposure and between species variability.
- Regulatory assessments should include an evaluation and characterization of quantifiable and unquantifiable uncertainties.
- Assessments should address – how bad, how often and how sure?

What scale should be used for PRA?

It was agreed that the assessment should be conducted at a scale that is relevant to the problem formulation and that assessments should, where appropriate, be to an agreed format, calculation methods, scenarios and outputs.

Finally, it was considered important that regulatory probabilistic risk assessments should be accompanied with a deterministic assessment as this will allow for comparison of techniques and outputs and will also ensure that regulators and other end-users become familiar with the new methodology whilst still working with the status quo.
10 RECOMMENDATIONS FOR FURTHER WORK

From the above the following further work has been identified:

1. Level of protection afforded by Tier-1 needs to be determined in order to aid the interpretation of the output from the PRA. This is required regardless of whether PRA is used as a refinement step or for the whole process.

2. Suitable models or procedures need to be developed that can be used in regulatory risk assessment. This is to ensure that decision-taker or takers have consistent and hence comparable risk assessments on which to base their decisions on.

11 REFERENCES


## 12 ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>DT50/DT90f</td>
<td>Disappearance time 50% (90%); the time it takes in a dissipation study until 50% or 90% of the initial amount or concentration has disappeared. The subscript f denotes field.</td>
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<tr>
<td>EAC</td>
<td>Ecologically Acceptable Concentration</td>
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<td>EC</td>
<td>European Community</td>
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<tr>
<td>EC50</td>
<td>Effective Concentration 50 – the concentration at which there is 50% effect (eg immobilization of <em>Daphnia magna</em>) of the test population</td>
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<tr>
<td>EER</td>
<td>expected ecological risk</td>
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<tr>
<td>ESCORT</td>
<td>European Standard Characteristics of Non-target Arthropod Regulatory Testing</td>
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<tr>
<td>ETE</td>
<td>Estimated Theoretical Exposure</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>HQ</td>
<td>Hazard quotient, i.e. exposure/toxicity – used in honeybee and non-target arthropod risk assessment</td>
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<td>JPC</td>
<td>joint probability curves</td>
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<td>LC50</td>
<td>Lethal Concentration 50 – the concentration at which there is 50% mortality on the test population</td>
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<tr>
<td>LD50</td>
<td>Lethal Dose 50 – the dose at which there is 50% mortality on the test population</td>
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<tr>
<td>LR50</td>
<td>Lethal Rate 50 – application rate causing 50% mortality of the test population</td>
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<td>MS</td>
<td>Member State</td>
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<tr>
<td>NOEC</td>
<td>No Observed Effect Concentration – highest concentration in a dose response test which is not statistically different from the control</td>
</tr>
<tr>
<td>NOEL</td>
<td>No Observed Effect Level – highest dose in a dose response test which is not statistically different from the control</td>
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<tr>
<td>OECD</td>
<td>Organisation for the Economic Cooperation and Development</td>
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<td>PEC</td>
<td>Predicted Environmental Concentration</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>PRA</td>
<td>Probabilistic Risk Assessment</td>
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<tr>
<td>RCR</td>
<td>risk characterization ratio</td>
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<td>SSD</td>
<td>species sensitivity distributions</td>
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<td>TER</td>
<td>Toxicity-Exposure Ratio</td>
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<td>US EPA</td>
<td>United States Environmental Protection Agency</td>
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