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Concerted action to develop a EUropean FRAMework for probabilistic risk assessment of the environmental impacts of pesticides

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WORK PACKAGE 3

PRELIMINARY PAPER ON ROLE AND OUTPUTS OF PROBABILISTIC RISKS ASSESSMENTS

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2. EXECUTIVE SUMMARY

The objective of this Work Package 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'. In order to try and initiate discussions, this preliminary paper focuses attention on the following three areas:

- Where in the assessment procedure could probabilistic risk assessment be used?
- What are the possible outputs of a probabilistic risk assessment?
- Are there any potential obstacles, political or scientific, for PRA under 91/414/EEC?

The first draft of this document was circulated to EUFRAM members prior to the first Project Meeting (PM). The document was considered by all EUFRAM Partners and discussed at the first Project Meeting. The document presented below has been revised in light of these discussions.

In order to stimulate thought and discussion at the PM eight questions were posed in the original draft. Responses to these questions, as well as comments passed during the PM, have been used to produce the detailed plan of action (see Section 8). Other comments have either been incorporated into this draft, passed to other WPs or will be considered in further versions of this document.

3. INTRODUCTION

The objective of this Work Package 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'*

In order to achieve this objective, this preliminary paper covers the following key issues:-

- Does probabilistic risk assessment have a role in the assessment of pesticides under 91/414/EEC?
- Where may probabilistic risk assessment have a role in the assessment of pesticides under 91/414/EEC?
- What are the possible outputs of a probabilistic risk assessment?

Several abbreviations have been used in the document and the definitions have been supplied in Appendix A.

4. REGULATORY CONTEXT

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 both 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 micro-organisms and non-target plants.

The risk assessment carried out for non-target organisms is currently deterministic, taking single point estimates of toxicity and exposure. This results in either a 'toxicity:exposure ratio' (i.e. TER) or 'hazard quotient' (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 relevant trigger value is breached then no authorisation can be 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 'appropriate risk assessment' usually takes the form of further information on either the toxicity of the compound and/or the exposure of non-target organisms to the compound. Outlined below are three very simple examples to demonstrate possible ways in which the risk may be refined.

When the risk to non-target arthropods is determined, laboratory 'worst case' toxicity studies with two indicator species (*Typhlodromus pyri* and *Aphidius rhopalosiphi*) are performed and LR50 endpoints produced (i.e. the application rate ('lethal rate') causing 50% mortality of the test organisms). These

endpoints are then used together with the in- and off-field exposure estimates to determine the 'hazard quotient' (i.e. HQ), i.e. in-field application exposure scenario /LR50. If the resulting HQ, is greater than 2, then it has to be demonstrated by the use of further information, e.g. higher tier toxicity studies or risk management measures, that the risk is acceptable (for further details see Candolfi *et al* (2001)).

When the risk to birds or mammals is assessed, the process as outlined in Anon (2002) is followed. For the first tier assessment, the look-up tables (see Tables 4, 6 and 7 in Anon (2002)) are used to provide the ,'estimated theoretical exposure' (i.e. ETE) for the acute, short-term and long-term assessment respectively. These endpoints are then compared to the appropriate toxicity endpoints. If any of the resulting TERs are less than the appropriate Annex VI trigger values, then the assessment may be refined using the various steps outlined in the document. For example the amount of food obtained from the treated area as well as the proportion of different food types in the diet can be factored into the assessment (see Section 5.6 of Anon (2002)). It is also possible, but not recommended, to refine the acute risk assessment using additonal acute toxicity data (see Section 5.1 of Anon (2002)). Sometimes a weight of evidence approach is used where information from laboratory studies, field trials and wildlife incidents are used to determine the impact of a plant protection product.

When the risk to aquatic life is assessed, the risk to fish, aquatic invertebrates, i.e. a free-swimming invertebrate – *Daphnia magna* and a sediment dwelling invertebrate – *Chironomus riparius*, algae and higher aquatic plant (if the compound is a herbicide) are considered. Currently a standard exposure scenario is used which comprises spray drifting on to a 30 cm deep static water body. The resulting concentration (or 'predicted environmental concentration' (i.e. PEC)) is compared to the appropriate toxicity endpoint. If the resulting TER is less than the appropriate Annex VI trigger value, then the assessment should be refined. Generally refinement takes the form of higher tier toxicity studies (see Section 5 of Anon (2002a)). These studies fall in to two types:- one assesses the effects of the compound on a test species (or range of species) under more realistic exposure scenarios (e.g. mesocosms, see Section 5.4 of (Anon 2002a)), whilst the other type of tests assesses the toxicity of the compound on a wide range of species (see Section 5.3 of Anon (2002a)). The output from these studies is then used to produce a regulatory endpoint. This endpoint may or may not include additional uncertainty factors depending upon the type of study used. This endpoint is then compared to the PEC and an assessment made of its 'acceptability'. In addition, it may be possible to refine the risk by reassessing the exposure issue, however, this has yet to be fully developed with the European context.

From the above, it can be seen that with the current regulatory process the first tier is always deterministic using point estimates for toxicity and exposure estimates usually from distributions, however refinement steps take on a wide range of options. Some of these refinement steps only consider the toxicity component (for example going from single species to multiple species), whilst

others take account of the exposure component (for example moving from an artificial route of exposure to a more realistic one).

5. WHERE IN THE ASSESSMENT PROCEDURE COULD PROBABILISTIC RISK ASSESSMENT BE USED?

As can be seen from the above, the current regulatory risk assessment is a stepwise process starting with a simple deterministic first tier. This first tier is considered to be worst case and often involves several worst case assumptions as well as an arbitrary uncertainty factor. If concern is raised then refinement steps as outlined above may be used. An example of how this tiered process works is presented in Appendix IV of Anon (2002).

It is possible that probabilistic risk assessment could replace or supplement all or part of the above procedure. For example, it could replace the worst case deterministic first tier and hence be used for the whole assessment process. Hart (2001a) has carried out such an assessment where PRA techniques have been used from the first tier. Alternatively, it could be used as a refinement step where concern has been raised as a result of the deterministic first tier. For example in Brown *et al* 2001 a distributed probabilistic assessment has been used once the initial deterministic risk assessment triggered concern.

5.1 The 'pros and cons' of using probabilistic risk assessment (PRA) only as a refinement step.

The US EPA have stated that 'more complex probabilistic assessment...are performed for those pesticides judged at the screening level to potentially pose the most serious risk' (Fite *et al* 2001). At the EUPRA workshop (Hart 2001b) it was envisaged that probabilistic methods would be 'used selectively...as part of a tiered stepwise assessment process'. Therefore, in these cases, PRA has only been seen as a possible way to refine the risk.

In trying to determine the 'pros and cons' of using PRA solely as a refinement step, it has been assumed that the first tier assessment, or screening step, has been used and that concern has been raised, i.e. a TER or HQ has been breached. In a deterministic risk assessment this would trigger the need for further toxicity and/or exposure data (see above) and then these data could be used to recalculate the TER/HQ or carry out a qualitative assessment of the risk. It should be noted that it is not always necessary, or possible, to refine both the toxicity and exposure. Therefore, the following highlights the possible advantages and disadvantages of replacing the standard refinement methodologies with ones using PRA techniques.

Some of the major advantages of using PRA as a refinement step are:

(i) can make full use of all the available toxicity and exposure data (e.g. the slope from the toxicity study as well as the LD50 estimate can be used)

(ii) can provide a quantitative characterisation of the risk and associated uncertainty as well as a quantitative endpoint
(iii) the sensitivity analysis can identify the variables which most effect the estimate of risk and lead to more appropriate refinement steps
(iv) provision of objective methods for combining different types of evidence, e.g. Bayesian updating to combine predicted exposures and effects with data on actual concentrations and impacts from field studies

It should be noted that some of these are advantages of PRA regardless of where is it used in the assessment procedure and hence are applicable to Section 5.2 below.

Some of the major disadvantages of using PRA solely as a refinement step are:

(i) concepts, approaches and outputs unfamiliar and complicated
(ii) difficult to communicate, compared to a qualitative assessment
(iii) undermine the usefulness of the first tier 'screening step'
(iv) currently when a TER/HQ approach is used, the level of protection is unknown, and therefore it could be difficult to refine the risk assessment on a quantitative basis as original protection goal is unknown
(v) loss of continuity and transparency between the first and subsequent tiers
(vi) may indicate false level of accuracy, i.e. the output may give the impression that the output is more accurate and objective than is actually the case.

It should be noted that some of these are disadvantages of PRA regardless of where they are used in the risk assessment process and hence are applicable to Section 5.2 below.

Table 1 outlines the possible disadvantages of using PRA as a refinement step. Included in this table are actions that are required to turn these potential disadvantages into advantages.

Table 1: Possible disadvantages of using probabilistic risk assessment as a refinement step only

Possible disadvantages	**Actions required to turn these into advantages**
concepts, approaches and outputs unfamiliar and complicated	Need to ensure that the whole process is transparent and easily understood by all those involved in the process – education of all users.
difficult to communicate, compared to a qualitative assessment	Need to ensure that the whole assessment process is clear and easily communicated to all users.
potential incompatibility with a	Need to make sure that output is

Possible disadvantages	Actions required to turn these into advantages
TER/HQ approach, loss of continuity with the first tier, undermining of the first tier screening step.	compatible with the current regulatory framework, this could involve discussions with policy makers to ensure that TER/HQ approach is appropriate, or developing PRA methods for both TER/HQs as well as % mortality or effect. It will also involve work to ensure that the output is compatible with previous decisions made, e.g. not increasing or decreasing the level of protection. Work is required to provide an indication of the level of protection provided by the current Tier 1 assessments.
may indicate false level of accuracy	Need to make sure that the output is appropriate, and has clear indication of how it should and should not be interpreted. Clear expression of uncertainty is required to indicate to the reader the level of confidence in the output.

5.2 The 'pros and cons' of using probabilistic risk assessment (PRA) for the whole risk assessment process.

As stated above, environmental risk assessments for pesticides have tended to be conducted in a stepwise manner, starting with a first tier which is considered to be worst case. This first tier step is designed to be appropriately precautionary and hence eliminate all pesticides and associated uses which clearly do not pose a risk. It is often considered to be a 'screening step'. This step often combines several worst case assumptions, for example it uses data on the most sensitive species tested, worst case exposure scenario and an additional uncertainty or safety factor. This step is often very quick and easy to conduct and demands little input as regards resources.

Despite the attractions of the worst case deterministic first tier, it is possible that PRA methodologies could be used for the whole risk assessment process. An example of where this has been done is in Hart (2001a). Some of the possible advantages of this approach are:

(i) can make full use of all the available toxicity and exposure data
(ii) can provide a quantitative characterisation of the risk and associated uncertainty as well as a quantitative endpoint, rather than a simple pass or fail of a regulatory threshold or a qualitative assessment of the risk

(iii) the sensitivity analysis can identify the variables which most effect the estimate of risk and lead to more appropriate refinement steps
(iv) can provide transparency and continuity of approach between the first and subsequent tiers of the risk assessment process

Using PRA for the whole risk assessment process, however, may have certain disadvantages. Some of these disadvantages will be the same as those listed above in Section 5.1, however, there will be some disadvantages that are solely related to the use of PRA for the whole assessment procedure, possible examples are:

(i) possible incompatibility with existing legislation
(ii) too costly both in terms of data and time compared to the current 'screening step'
(iii) more complex than the current deterministic procedure

In Table 2 the possible disadvantages of using PRA for the whole assessment procedure are presented. Included in this table are actions that are required to try and overcome these disadvantages.

Table 2: Possible disadvantages of using probabilistic risk assessment for the whole risk assessment process

Possible disadvantages	**Actions required to turn these into advantages**
possible incompatibility with existing legislation	Need to determine if approach is acceptable within current regulatory framework. Check with regulatory authorities, via the use of case studies, as to whether this approach is appropriate from a regulatory perspective. Need also to determine, via the use of case studies, the scientific appropriateness of such an approach.
more resource intensive than the initial first tier risk assessment	Need to demonstrate via the use of case studies that the resources required to carry out a PRA for the whole process is similar to the *status quo*.
increased complexity compared to current process	Require appropriate guidance on how to conduct and present PRAs.

6. WHAT ARE THE POSSIBLE OUTPUTS OF A PROBABILISTIC RISK ASSESSMENT?

In order to answer this question, we first need to consider what should the output from any risk assessment be. In trying to address this, much use has been made of a report produced for the UK Health and Safety Executive by Oxera (Anon 2000).

6.1 What should the output from a risk assessment be?

In order to answer this question, we first need to consider who uses the outputs from risk assessments. In a report produced by Oxera (Anon 2000), for the UK Health and Safety Executive, 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 with an interest in the outcome of a particular policy decision.

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 if there concern has been addressed. Whilst the general public is not explicitly covered by the above categories, their concerns are important and should be considered in deriving an appropriate output. It is also considered that the general public's views should be addressed by one of more of the above categories. 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.

Oxera outlined a model and whilst this model was more focussed on the risk from one off events rather then those associated with pesticide regulatory risk assessment, it does provide some useful ideas. The report states that the 'policy-maker' needs to define what it is they need to know. According to Article 4 point 1(b)(v) of 91/414/EEC Member States shall ensure that a plant protection product is not authorised unless...it has no unacceptable influence on the environment, having particular regard to...its impact on non-target species.' Whilst, on the one hand this objective appears clear and straightforward to answer, on closer consideration, it is extremely difficult to determine. For example, what does 'unacceptable influence' mean? What may be perceived as 'acceptable' by one stakeholder may be unacceptable to another. This leads to the question – who is correct? Acceptability is a combination of social, political, emotional, scientific and economic factors

which are weighed up by the 'policy maker' and 'decision taker' to arrive at a decision. Therefore, in order to carry out an appropriate scientific risk assessment, we, the 'scientific advisers' need to know what the 'decision-taker', 'policy-maker' as well as the 'stakeholder representative' needs to know.

An illustration of the importance of this issue is provided by Dr Hart's experience of the UK Environmental Panel of the Advisory Committee on Pesticides. The Environmental Panel is an independent Panel made up of scientific experts as well as lay representatives. The Environmental Panel's remit is primarily to comment and contribute to scientific discussions and hence, using the definitions above, they would be defined as a panel of 'scientific advisers'. A record of their reactions to two types of PRA are presented in the CSL contribution to this work package, however the key issues regarding outputs were:-

> They expected difficulty using a novel endpoint such as % mortality for decision-making, given the focus of current practice on the TER (toxicity-exposure ratio). They highlighted that it may be more appropriate to compare a deterministic approach with a PRA assessment. However, when this was done it raised further questions regarding the relevance of the TER trigger value.
>
> They were uncertain how to judge the acceptability of any given level of % mortality, given the lack of any established criterion for this.

The above example illustrates the need to try and determine a suitable output from a PRA that 'decision-takers', 'policy-makers', 'stakeholder representatives' as well as 'scientific advisers' can use.

6.2 The *status quo* – possible outputs from a deterministic risk assessment carried out under 91/414/EEC

In order to try and help address the above point, it is worthwhile outlining possible outputs from current regulatory risk assessments. Therefore, outlined below is a summary of a range of some of the possible outputs from a standard deterministic risk assessment carried out according to 91/414/EEC.

In the current regulatory process the output of a first tier assessment is either a 'toxicity:exposure ratio' (TER) or a 'hazard quotient' (HQ). These ratios are compared to the appropriate Annex VI value to determine if further assessment is necessary. If a higher tier or refined risk assessment is carried out then the output of this may be, as indicated above, either a refined exposure or toxicity estimate, or in the case of certain studies a combination of both.

If the toxicity component of an aquatic risk assessment is considered, (e.g. via the use of multiple species studies), then, the Annex VI trigger value may be reduced from 100 to 10. If additional information on exposure is considered, as outlined in SANCO/4145/2000, then the resulting revised TER is compared

to the existing Annex VI trigger value. Sometimes, higher tier studies may be submitted, e.g. extended laboratory studies using non-target arthropods, and the results are then compared to agreed values. Therefore, the regulatory output from these types of assessment are a relatively simple pass or fail, i.e. is the endpoint above or below an agreed value?

Occasionally field data, e.g. non-target arthropod field trials or vertebrate field studies may be submitted and used in the assessment process. It is difficult, if not impossible, to determine a single value from such studies and hence the overall assessment and endpoint, tends to be more qualitative in nature.

It should be noted that in the current deterministic risk assessment, the actual protection goal as well as what is 'acceptable' is not defined. Also there is a lack of consideration uncertainty and variability, and hence the output tends to be of a 'weight of evidence' type, with the overall conclusion being that the risk is acceptable or not.

From the above, it can be seen that the output from conventional risk assessments is variable. Outlined in Table 3 is a summary of some possible outputs from conventional ecotoxicological risk assessments carried out under 91/414/EEC.

Table 3: Summary of some possible outputs from conventional ecotoxicological risk assessments carried out under 91/414/EEC.

Area of risk assessment	Possible output from conventional ecotoxicological risk assessment carried out under 91/414/EEC
Aquatic life	Regulatory endpoint (e.g. ecologically acceptable concentration (EAC)) from mesocosm and other higher tier studies = 1 µg/l, the 'predicted environmental concentration' (PEC) at 1 m is 0.3 µg/l, therefore, it is considered that there is sufficient margin of safety between the PEC and the effects endpoint to permit use of the product without any risk management measures, e.g. buffer zones
Non-target arthropods	High risk identified as a result of the tier 1 HQ assessment, higher tier data indicate that recovery/recolonization of the in-field environment is likely within the required timeframe (see Candolfi *et al* (2001)). No ecologically significant effects are considered likely for the off-field environment.
Birds	First tier assessment indicates high risk, additional information on foraging and feeding behaviour permit the revision of PT and PD (see Anon (2002)) and indicate that the resulting TER is less than the appropriate Annex VI trigger value.
Earthworms	First tier assessment indicate that high short-term risk, field trial data submitted which indicates that under the conditions of the field trial submitted, there is an initial impact. However, recovery is observed and the treated plots recover to control levels by the start of the following season.

6.3 Outputs from probabilistic risk assessments

Outlined in Table 4 are possible outputs from PRA. It is accepted that this list is incomplete, it is also acknowledged that the outputs are summaries and therefore the reader is directed to the relevant paper for further information. Some of the examples are from risk assessments associated with human health, whilst others are related to ecotoxicological risk assessment.

Table 4: Possible outputs from PRA

	Output	Source
1	The probability that the intake of carbaryl from the consumption of unpeeled apples by toddlers will be greater than 10% of the acute reference dose is 3.8%	Hamey P.Y. and Harris C.A. (1999) Hamey P.Y. (2000)
2	Under the scenario for aerial application to corn at the lowest application rate, the range of mortality for the complex of avian species exposed, on average, is between 0 and 88%.	Fite *et al* (2001)
3	On average (1) 70% of the exposed species may experiencing an average mortality due to Chem X exposure, with 30% of the species experiencing no mortality, (2) 35% of the species are expected to experience 10% mortality or greater, and (3) 10% are experiencing 70% mortality or greater, which may range up to 88%	Fite *et al* (2001)
4	For red-winged blackbirds, 24% mortality of the exposed birds is expected to result, on average. Mortality is expected to be 10% or greater in the majority of cases (95% probability)). However, in a few cases (5% probability), the mortality is expected to be between 45-50% at the lowest application rate.	Fite *et al* (2001)
5	Results show that from 55% to 95% of the bird species using midwestern corn and alfalfa fields treated with ChemX will experience some mortality, on average, 27% to 90% of the species are likely to experience at least 10% or greater mortality, on average, while up to 23% of the species are likely to experience at least 70% mortality, on average	Fite *et al* (2001)
6	In UK orchards treated with chlorpyrifos there is a 19% chance that mortality of blue tits living around orchards exceeds 1%.	Hart A (in press)
7	Analysis indicates that 19% of species with similar feeding and bevaviour profile to bluetits will experience mortality greater than 1%.	Hart (in press)

	Output	Source
8	For a hypothetical scenario involving geese grazing cereals in a coastal region, it was concluded that for 80% of treated fields, acute TERs lay between 11 and 126. The Annex VI trigger value of 10 was breached in 7% of fields, with 95% confidence limits of 0 and 28%. The confidence limits represent the effect of uncertainty in estimating use of treated fields by geese, but exclude other sources of uncertainty.	Hart (2002)
9	As regards the acute aquatic risk assessment for the atlantic silverside in the farm pond scenario, the best estimate of expected mortality would be 32 (24-40)% across the range of exposure concentrations and sensitivities for the given species. 95% of the time, mortality would be expected to exceed 25 (17-33)% whilst for 5% of the time mortality would be expected to exceed 49 (36-63)%	Gallagher K. *et al* (2001)
10	In the given scenario, the NOEC for the rainbow trout was exceeded less than 7 and 5% of the time for all peak and 96 hour exposures.	Gallagher *et al* (2001)
11	The probability of exceeding 0.1 µg/l in groundwater based on simulation of concentrations at 1 m depth for 20 years for the Okehampton leaching scenario when accounting for the uncertainty in Koc and DT50 values was 53.5% on average	Dubus I.G. *et al* (2002)
12	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 contaminating groundwater at concentrations greater than 0.1 µg/l was 1.3%.	Example supplied by PCS
13	'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	Example supplied by PCS

From the range of outputs outlined above it can be seen that some concentrate on focal species (eg no 4, 6 and 8) or groups of species in the habitat or scenario under consideration (eg no 3, 5 and 7). These examples

give an indication of the level and frequency of mortality (or exceedance of an endpoint(s)). No 8 gives an output in terms of where a certain percentage of TERs lie. Some of the above example select a NOEC as the toxicity endpoint, whilst others select an EC50, LC50 or LD50. None of the above assessments appear to consider community level effects.

When consulted on the above issue RIVM highlighted the following points (further detail is provided in their contribution to this Work Package):

> If only exposure uncertainty is present, the output of the PRA are the distributions of the toxicity to exposure ratio (TER). For any toxicity endpoint, if the exposure is uncertain, a distribution of these ratio's is generated. When these distributions are plotted as a cumulative distribution, they are called Risk Characterization Ratio curves (RCR curves).
>
> These TER curves are not necessarily easy to interpret; what is lacking in our view is guidance on how to interpret them. By deciding on trigger values or cut-off values of the RCR (as often specified in EU or national legislation), the probability that certain safety levels are guaranteed can be calculated. Decision making can then be based on the acceptance of certain levels of effect exceedance (risk).
>
> In other studies, overlap between exposure distributions and species sensitivity distributions was plotted as the joint probability curve (i.e. JPC see Cardwell *et al* (1993)). The final probability of effect is indicated as 'expected ecological risk' or EER.
>
> Since 'all species' are taken together in the effect distribution (the SSD), it may be unclear what type of ecological risk is calculated with the EER. It may be useful, just as in any modern SSD analysis, to subdivide species based on the mode of action of the pesticide, habitat consideration etc. In that way, the EER becomes more meaningful for pesticide risk analysis.

RIVM conclude by saying that : 'It is our feeling that the EER can be useful in communicating the results of PRA. Trigger values of the EER can be established for either 'no concern' or 'high concern', i.e. higher tier follow-up, just as for the RCR curves. It can be extended in the individual distributions and the resulting JPC if needed. It is our experience that the full JPC curve is not very easy to communicate in first tier assessment, neither in the original Cardwell/Ecofram version nor in the revised form by Aldenberg c.s'

All of the outputs outlined above are verbal representations of graphical information. Examples of possible graphical outputs are presented in the paper from WP4.

Two issues that become apparent when considering the above range of possible outputs are (i) scale of the assessment and (ii) consistency of the endpoint. These issues are briefly discussed in Section 7.

In trying to determine what the outputs of a probabilistic risk assessment should be, we need to consider, as stated above in Section 6.1, who will be using it.

7. ARE THERE ANY POTENTIAL OBSTACLES, POLITICAL OR SCIENTIFIC, FOR PRA UNDER 91/414/EEC?

In trying to determine whether there are any political or scientific obstacles, we first need to consider whether PRA is compatible with 91/414/EEC (Anon (1991)). In Annex III of 91/414/EEC there is guidance on how 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 an assessment should be carried out. Therefore, it is assumed that a risk assessment should permit the 'decision-takers' to determine whether the compound, and its associated use, has no unacceptable influence on the environment. Therefore, PRA should be compatible with the principles of 91/414/EEC. However, whilst an assessment procedure may be compatible with the legislation, it does not necessarily mean that the risk assessment procedure will not face 'political' obstacles.

Some potential political and scientific obstacles that may face PRA are outlined below:

Derivation and acceptance of appropriate model scenarios: Over the last few years much work has been done to develop standardised risk assessment strategies. Most of this work has concentrated on harmonising the way in which MSs and Notifiers determine the exposure and hence risk from the use of plant protection products. The current process is not finalised and is continually undergoing revisions. The continual development of risk assessment scenarios and guidance has been perceived by some as delaying the authorisation process. If a new risk assessment methodology is proposed, it may be seen as diverting valuable resources from assessing compounds in the regulatory process. On the other hand, devising a new risk assessment framework could be perceived as being an opportunity to address several shortcomings of the current process and hence ensure that they are addressed appropriately. One example of this issue is the scale at which the assessment should be conducted, i.e. should it be at the field or landscape scale. Therefore, in order to gain wide scale acceptance, there ideally needs to be accepted model scenarios. In the UK, PSD/Defra has recently sponsored a suite of research and development projects which are developing web-based risk assessment scenarios. For further information see projects PS2301 to PS2307 on http://www2.defra.gov.uk/research/project_data/projects.asp?SCOPE=0&M=PSA&V=PH%3A040.

Regulatory risk assessments need to be consistent in their approach. This enables Regulators to make consistent decisions between assessment. If a new risk assessment procedure were to be developed, it would be desirable, if not essential, to have consistent models.

Derivation and acceptance of appropriate outputs: Currently the output from most regulatory risk assessment is either a pass or fail, i.e. the TER or HQ is either breached or not. Occasionally, higher tier data are required and a qualitative assessment is made (see above). 'Policy makers' and 'decisions takers' have become comfortable with the TER/HQ pass or fail approach as well as the qualitative outputs from higher tier assessment. A change to PRA will mean that 'policy-makers' and 'decision-takers' will need to consider what the overall protection goals are, and hence what is and is not acceptable. A PRA assessment will give an output that there may be an exceedance of either a certain toxicological threshold, or a level of mortality. Whilst from an ecological or population point of view this may not be of importance, this type of output may make 'policy makers' and 'decision takers' feel uncomfortable. For example, the perception that the approved use of a plant protection product may result in the deaths of farmland birds may cause the product or use not to be approved as the adverse public reaction may be too great, regardless of the real impact of the compound. Therefore, in order to derive appropriate outputs that are likely to be accepted by all potential users, it is important to obtain a clear indication as to what potential users need or want.

Perceived need for more data: It is often considered that PRA requires more toxicological and exposure data in order to work effectively. This is, in part, due to the case studies that have used large amounts of exposure and toxicity data in order to run (eg Hart 2001b).

Perceived complexity of the assessment process: The current assessment procedure is relatively simple and the endpoint or output is one that is 'understood' by all concerned, (i.e. the TER and associated trigger value has become accepted as 'regulatory language'.) PRA, on the other hand, is more complex hence 'policy-makers', 'decision-takers' and 'stakeholder representatives' are naturally more cautious of an assessment system that they do not fully understand.

8. DETAILED PLAN OF ACTION

The above paper was circulated to EUFRAM Partners prior to the first Project Meeting (PM1). Comments received have been incorporated into the above text.

In the initial draft of this paper 8 questions were posed in order to stimulate discussion and aid the development of a detailed plan of action. Outlined below in Table 5 are the original questions as well as a summary of the key responses. These have been further developed into a detailed plan of action. Also included in this table is a timetable indicating when certain action should be completed.

Table 5: Detailed plan of action

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
1	Are there any more potential disadvantages of using PRA as solely a refinement step? If so what are they and what work is required to turn these in to advantages?	The list of potential disadvantages presented in Section 5.1 has been amended in light of comments received.	Completed

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
2	Considering the responses to question 1, what further work is required to determine whether it is appropriate to use PRA solely as a refinement step for pesticides?	One key issue that was highlighted during the discussion at PM1 was the potential incompatibility of PRA with deterministic risk assessment (DRA) and in particular the level of protection afforded by Tier 1. It was acknowledged that in order to address this point, the uncertainty in the current Tier 1 assessments should be quantified. It was, therefore, agreed that this was probably best addressed by the use of case studies. As regards other possible disadvantages highlighted in Table 1, it was felt that the issues would be addressed by other WPs, for example issues concerning the education of users will be addressed by 'end-user workshops' (WP12). Likewise most disadvantages would be considered as part of the case studies (WP8). It was also agreed that in order to determine where in the assessment process PRA could be used, it was necessary to determine what the 'customer' wants or needs (see Qu 5).	WP8 to consider the level of uncertainty in the Tier 1 assessment and produce case studies as appropriate. The issue of where in the assessment process PRA could be used should be considered by WP3 Partners – see Action under Question 5.

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
3	Are there any other possible disadvantages of using PRA for the whole risk assessment process? If so what are they and what work is required to turn these into advantages?	The list of potential disadvantages presented in Section 5.2 has been amended in light of comments received.	Completed

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
4	Considering the response to Question 3, what further work is required to determine whether it is appropriate to use PRA for the whole risk assessment process for pesticides?	One issue that was noted and discussed was the potential incompatibility with the current legislative framework, especially trigger values. It was, therefore, agreed that in order to determine the scientific and regulatory appropriateness of using PRA for whole risk assessment procedure it was necessary to run a DRA and PRA side by side. As regards other possible disadvantages highlighted in Table 2, it was considered that case studies (WP8) and the 'end-user workshops' (WP12) would address these concerns It was also agreed that in order to determine where in the assessment process PRA could be used, and especially whether it could be used for the whole assessment process, it was necessary to determine what the 'customer' wants or needs (see Qu 5).	The scientific and regulatory appropriateness will be assessed once case studies have been produced by WP8. and considered by WP3 and other WPs. The issue of where in the assessment process PRA could be used should be considered by WP3 Partners – see Action under Question 5.
5	How should we determine what the 'decision-takers', 'policy-makers', 'stakeholder representatives' as well as 'scientific advisers' want in terms of an	It was agreed that in order to determine what the 'decision-takers', 'policy-makers', 'stakeholder representatives' as well as the 'scientific advisers' want, it was necessary to ask them. It was agreed that in order to try and progress this issue it would be best to present relevant people with case studies. It was felt necessary to obtain the answer to this question relatively quickly so that further work would be appropriately focussed. Therefore, prior to the first Case Study	Prior to CSM1 WP8 will supply relevant information on problem formulation etc to WP3. MC will produce set of questions in consultation with WPL 6, 7 and 8 for

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
	output?	Meeting (CSM1) WP8 will provide WP3 Partners with partially completed case studies as well as relevant information on problem formulation so that they can elicit feedback from relevant people. Questions will be supplied to WP3 Partners by Mark Clook (MC) (in consultation with WPL 6, 7 and 8) to aid them in obtaining appropriate feedback (for example – what do they want from assessments?). Responses to these questions will be collated by MC and forwarded on to WP8. These responses will be considered and incorporated into subsequent case studies by WP8 and will be discussed at CSM2. Along with the above issue, it was also felt necessary to ask 'decision-takers', 'policy-makers', 'stakeholder representatives' as well as the 'scientific advisers' their views on how they use, or could use, information on uncertainty in assessments. This question stems from work carried out in WP5. Due to time-tabling issues, it will not be possible to ask relevant people their views prior to the CSMs, therefore, it is proposed to seek views immediately after CSM2. It is planned that by this time a well worked example should be available that can be used to elicit appropriate responses from relevant people.	WP3 Partners to elicit information from relevant people. Responses will be fed into WP8 after CSM1. Prior to CSM2, case studies will be circulated to WP3 to elicit further information from relevant people. All feedback to be with WP8 to enable full consideration and ensure that WP8 can deliver report by 30-6-04. WPL of WP3 will circulate case study after CSM2 to WP3 Partners, together with set of questions related to how relevant people deal with uncertainty. Responses will be fed back to WP5 and 8. This consultation will take place during May 2004, with response back

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
			by 31-5-04.
6	How should appropriate PRA models be derived and agreed?	It was appreciated that this was closely linked to Qu 5 and hence once case studies have been produced and potential users consulted, further appropriate models/examples can be produced along with guidance on how to produce 'real' assessments. It was highlighted that issues such as what scale should the assessment be carried out at, needed to be considered by the case studies. It was also noted that a programme of action is required to assist in implementing PRA methods in a way that is suitable for use in the EU regulatory context. It was noted that this programme should include the following: • Establish general principles (this should be covered by WP3-11 of EUFRAM) • Develop specific models for the range of scenarios needed in EU assessments – these PRA models should be in line with current regulatory approaches in terms of the assessment endpoint, the model structure, and the data inputs, and to concentrate initially on quantifying uncertainty and variability within that context. • Implement the models as accessible, user-friendly software tools. • Provide opportunities for training and testing by end-users (planned for 2005-6 in EUFRAM WP12) • Initiate longer-term research to generate (a) improved generic input data, e.g. residue distributions, ecological parameters etc (b) refined models to take account of new issues as necessary (e.g. population endpoints).	WP3 Partners will provide comments on case studies to WP8.

Qu No	Question	Conclusion of comments and discussion	Action required to progress issue
7	How should we address the perception that PRA requires more data?	It was agreed that the case studies should compare DRA with PRA. It was acknowledged that case studies using normal size datasets should be used to determine whether they could account for the uncertainty resulting from limited data. It was also acknowledged that there should be consideration of the current DRA approach and how it deals with uncertainty compared to PRA. It was agreed that this issue should be addressed by the action point under Qu 5 above. It was also noted, some of the above issues should be addressed by running a PRA with a conventional dataset and this should be addressed by WP5 and WP8.	WP8 to note the need to compare DRA with PRA and hence include this in case studies.
8	How should we address the perception that PRA process is complex?	It was noted that if all stakeholders and potential users have been consulted then the approaches and especially the outputs should be what is wanted and hence this should go, at least in some part, to addressing issues regarding complexity. It was noted that implementation needs to be via 'user friendly' software that is easily available to all possible end users. It was agreed that PRA should be accepted as being more complex, but it was felt important to try and determine how much more complex it was compared to DRA. It was agreed that this, in part, could be addressed by the case studies (i.e. the case studies could provide an indication on any potential increase in data, complexity in the assessment and hence interpretation of the output.)	WP8 to note concerns and try to include this issue in the relevant case studies. WP3 to assess case studies and hence determine level of increased complexity.

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APPENDIX A

Abbreviations

Abbreviation	Definition
CSM	Case Study Meeting – meetings to discuss the case studies are planned and organised by WP8
DRA	Deterministic Risk Assessment
DT50/DT90f	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.
EAC	Ecologically Acceptable Concentration
EC	European Community
EC50	Effective Concentration 50 – the concentration at which there is 50% effect (eg immobilization of *Daphnia magna*) of the test population
EER	expected ecological risk
ESCORT	European Standard Characteristics of Non-target Arthropod Regulatory Testing
ETE	Estimated Theoretical Exposure
EU	European Union
EUPRA	European Workshop on Probabilistic Risk Assessment for the Environmental Impact of Plant Protection Products.
HQ	Hazard quotient, i.e. exposure/toxicity – used in honeybee and non-target arthropod risk assessment
JPC	joint probability curves
LC50	Lethal Concentration 50 – the concentration at which there is 50% mortality on the test population
LD50	Lethal Dose 50 – the dose at which there is 50% mortality on the test population
LR50	Lethal Rate 50 – application rate causing 50% mortality of the test population
MS	Member State
NOEC	No Observed Effect Concentration – highest concentration in a dose response test which is not statistically different from the control
NOEL	No Observed Effect Level – highest dose in a dose response test which is not statistically different from the control
OECD	Organisation for the Economic Cooperation and Development
PM	Project Meeting – the first Project Meeting of EUFRAM was held at Alterra in May 2003.
PEC	Predicted Environmental Concentration
PRA	Probabilistic Risk Assessment
RCR	risk characterization ratio
SSD	species sensitivity distributions
TER	Toxicity-Exposure Ratio

US EPA	United States Environmental Protection Agency
WP	Work Package – describes a unit of work within the EUFRAM project, each WP is lead by a 'Work Package Leader' (WPL).