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SCIENTIFIC COMMITTEE ON PLANTS **SCP/GUIDE-B&M/002-Final**

25 April 2002

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE DRAFT GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS UNDER DIRECTIVE 91/414/EEC

(Opinion adopted by the Scientific Committee on Plants, 24 April 2002)

A. Title

DRAFT OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE DRAFT GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS UNDER DIRECTIVE 91/414/EEC
(Opinion adopted by the Scientific Committee on Plants on 24 April 2002)

B. Terms of Reference

The Scientific Committee on Plants (SCP) is requested to give an opinion on the draft Guidance document on Risk Assessment for Birds and Mammals (document SANCO4145/2000)

Without any intention to limit the consideration of the document by the Committee, the SCP attention is drawn to the following points, which were found to be the most challenging ones during the discussion so far:

1. Are the generic indicator species and scenarios selected for the Tier 1 ecologically and agronomically relevant and protective, while at the same time their use will not trigger an excessive number of refined risk assessments?

2. Is the residue per unit dose for insects appropriate?

3. With regard to long-term risk from seed treatments to birds and mammals: Could there be more simple criteria identified, which might be applicable in Tier 1 to eliminate low risk substances? (e.g. NOEL[1] (reproduction) > 1000 ppm, logPow[2] < 3, and DT50[3] from seed < 4 days)?

C. Opinion of the Committee

The Committee welcomes the initiative that has been taken to develop guidance on assessment of risks to wild mammals and birds, and to clarify the way these assessments are currently conducted.

The Committee has considered the whole of the draft Guidance Document in detail. Section 1 of the Opinion relates to the specific issues that were emphasised in the Committee's Terms of Reference. Section 2 of the Opinion lists the Committee's detailed comments on other aspects of the draft Guidance Document.

Opinion on question 1:

Are the generic indicator species and scenarios selected for the Tier 1 ecologically and agronomically relevant and protective, while at the same time their use will not trigger an excessive number of refined risk assessments?

The scenarios selected for the initial assessments are agronomically relevant, but there is a strong argument for adding rice, and perhaps forestry, as separate categories. The Committee recommends that a section on assessment of granular pesticides should be added to the Document.

[1] No Adverse Effect Level
[2] 1-octanol-water partition coefficient
[3] Period required for 50% dissipation

The generic species are ecologically relevant and realistic. However, the Document should emphasise that it is the responsibility of the notifier and assessor to determine whether the standard scenarios and species are appropriate for each particular assessment, and to devise non-standard scenarios and species where necessary. This should be done at the very start of the assessment, and not as a refinement step.

A number of important assumptions in the Tier 1 assessment lack adequate explanation. As a general principle, all assumptions should be justified. They should be based on data where possible, and the source of the data should be cited. Where expert judgement is necessary, the logic of this should be explained. If the assumption involves choosing a single value for a parameter that is variable in nature (e.g. variation between species, crops, pesticides or sites), the reason for choosing that particular value should be explained. If the assumption involves significant uncertainty, it should be stated what allowance has been made for this.

The Question asks whether the species and scenarios selected in the Document are protective. Whilst the Committee recognises the lack of evidence for frequent direct[4] impacts of pesticides on wild bird and mammal populations, the Committee is of the opinion that it is not currently possible to quantify how protective the proposed procedures are, because (a) the assessment outputs (toxicity-exposure ratios) do not have a clear ecological interpretation, and (b) the assessment procedure contains many unquantified uncertainties. Furthermore, existing regulations do not define how protective assessments should be. The Committee has identified two possible approaches to estimating the level of protection afforded by the proposed procedures: one approach using uncertainty analysis, the other involving empirical calibration or validation. Based on these approaches, the Committee makes the following recommendations:

1. **The procedures proposed in the Guidance Document should be revised to take account of the issues raised in all parts of the Committee's Opinion, as far as is practical in the short term. The revised procedures should then be adopted on a provisional basis, until the level of protection can be properly assessed.**

2. **The proposed procedures should be calibrated or validated to the extent that is possible, e.g. by comparing the resulting toxicity-exposure ratios with available information from field studies and incident monitoring.**

3. **The level of protection provided by the proposed procedures should be estimated using uncertainty analysis, in conjunction with ongoing work to implement probabilistic approaches.**

4. **Appropriate policy officials / risk managers should be consulted to determine whether the level of protection (as indicated by the outcome of the preceding recommendations) is set at an appropriate level or, if not, to adjust the proposed procedures accordingly.**

The Question asks whether use of the selected species and scenarios will not trigger an excessive number of refined risk assessments. The frequency of refined assessments is a legitimate concern, both because of the cost in terms of the experimental animals that are used in some types of higher tier study, and because of the cost of refined assessments in money and time. All these costs should be taken into account when determining the level of protection that is appropriate. However, the balance between risk and the various costs is a question of policy, and not within the remit of the Committee.

[4] i.e. Impacts arising from toxic effects of pesticides directly on birds and mammals, as opposed to indirect effects of pesticides such as removal of food supply or habitat.

<u>Opinion on question 2:</u> Is the residue per unit dose for insects appropriate?

The Committee does not consider the residue per unit dose (RUD[5]) values in the Guidance Document to be appropriate for estimating pesticide residues on insects, because (a) there is evidence that the assumption of a linear relationship between dose (application rate) and residues is unsafe, (b) the values are based on measurements that are probably representative of large insects, whereas smaller insects are expected to have higher residues (due to their larger surface area / volume ratio), and (c) the assumption that residues in insects always decline over time is unsafe.

Research is needed to provide a more robust approach. In the meantime, the Committee recommends that different approaches should be used for 'large insects' and 'small insects'. RUDs for large insects should be based on a peer-reviewed analysis of existing residue measurements for insects, taking a percentile which makes reasonable allowance for uncertainty about the linearity of the dose-residue relationship. RUDs for small insects should be based on an appropriate percentile of existing data on forage crops of similar surface area / volume ratio to small insects (a modification of the currently-accepted approach), until sufficient measurements on small insects are available to estimate improved RUDs. In addition, special care should be taken to identify and allow for cases where residues may increase over time.

<u>Opinion on Question 3:</u> With regard to long-term risk from seed treatments to birds and mammals: Could there be more simple criteria identified, which might be applicable in Tier 1 to eliminate low risk substances? (e.g. NOEL (reproduction) > 1000 ppm, logPow < 3, and DT50 from seed < 4 days)?

In theory, it would be possible to identify simple criteria to eliminate in Tier 1 seed treatments posing a low long-term risk to wild mammals and birds. However, to do this in a scientifically-robust way would require resolution of several fundamental and difficult issues affecting the assessment of long-term risks (i.e. which test endpoints to use, how to allow for variation between species, how to allow for variation in exposure over time). Furthermore, the Committee does not agree with the Guidance Document's assertion that 'there is no true long-term exposure or repeated exposure for seed treatments'. This assertion arises from considering a single treated field in isolation ('field scale'). The Committee considers that the likelihood of concurrent and/or repeated exposures in multiple fields should be taken into account when estimating realistic worst-case exposures. As a general principle, the Committee considers the restriction of assessments to single treated fields to be inappropriate.

Research is required to resolve these issues. Until this has been done, the Committee recommends that the first tier assessment for seed treatments should use the same approach as for other substances, because this is more conservative and avoids making unsupported assumptions. Special factors affecting exposure to seed treatments can be taken into account in the higher tier assessment, where appropriate.

<u>Additional comments</u>

[5] Residue per unit dose; generic estimation factors used to estimate concentrations of pesticide residues on food items eaten by wildlife. The estimated residue (mg/kg) is obtained by multiplying RUD by dose (kg/ha). The RUD factors are based on analysis of residue data from field studies with a variety of pesticides applied at different rates.

The Committee also recommends that consideration be given to its detailed comments on other aspects of the draft Guidance Document, which are listed in Section 2 of this Opinion.

A. Title

DRAFT REPORT OF THE SCIENTIFIC COMMITTEE ON PLANTS ON THE DRAFT GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS UNDER DIRECTIVE 91/414/EEC

B. Table of contents

C. Background

In collaboration with experts from all Member States, Germany has prepared a draft Guidance Document. The document is intended to facilitate the review and decision-making concerning inclusion of active substances in Annex I of Council Directive 91/414/EEC.

Source documents made available to the Committee:

1. Terms of reference to the Scientific Committee on Plants, submitted by DG Health & Consumer Protection, 16 November 2001 (SCP/GUIDE-B&M/001).

2. Draft guidance document on Risk Assessment for Birds and Mammals (SANCO4145/2000) November 2001, submitted by DG Health & Consumer Protection, 16 November 2001

3. Compilation of comments from Member States and ECPA, 12 November 2001, submitted by DG Health & Consumer Protection, 16 November 2001.

4. BBA (2001). Discussion paper prepared for the EU expert group on higher tier risk assessment for birds and mammals. Test-Run of the standard scenarios for the tier-1-assessment (rev 5). BBA, Germany. November 2001.

5. INRA (2000). Risk assessment for terrestrial vertebrates (French comments to the Working Group on the draft guidance document on birds and mammals risk assessment). INRA, France. 19 June 2000.

D. Scientific background on which the opinion is based

1. SECTION 1. SPECIFIC QUESTIONS TO THE COMMITTEE

1.1 Question 1.

Are the generic indicator species and scenarios selected for the Tier 1 ecologically and agronomically relevant and protective, while at the same time their use will not trigger an excessive number of refined risk assessments?

<u>Opinion of the Committee</u>

The scenarios selected for the initial assessments are agronomically relevant, but there is a strong argument for adding rice, and perhaps forestry, as separate categories. The Committee recommends that a section on assessment of granular pesticides should be added to the Document.

The generic species are ecologically relevant and realistic. However, the Document should emphasise that it is the responsibility of the notifier and assessor to determine whether the standard scenarios and species are appropriate for each particular assessment, and to devise non-standard scenarios and species where necessary. This should be done at the very start of the assessment, and not as a refinement step.

A number of important assumptions in the Tier 1 assessment lack adequate explanation. As a general principle, all assumptions should be justified. They should be based on data where possible, and the source of the data should be cited. Where expert judgement is necessary, the logic of this should be explained. If the assumption involves choosing a single value for a parameter that is variable in nature (e.g. variation between species, crops, pesticides or sites), the reason for choosing that particular value should be explained. If the assumption involves significant uncertainty, it should be stated what allowance has been made for this.

The Question asks whether the species and scenarios selected in the Document are protective. Whilst the Committee recognises the lack of evidence for frequent direct impacts of pesticides on wild bird and mammal populations, the Committee is of the opinion that it is not currently possible to quantify how protective the proposed procedures are, because (a) the assessment outputs (toxicity-exposure ratios) do not have a clear ecological interpretation, and (b) the assessment procedure contains many unquantified uncertainties. Furthermore, existing regulations do not define how protective assessments should be. The Committee has identified two possible approaches to estimating the level of protection afforded by the proposed procedures: one approach using uncertainty analysis, the other involving empirical calibration or validation. Based on these approaches, the Committee makes the following recommendations:

1. **The procedures proposed in the Guidance Document should be revised to take account of the issues raised in all parts of the Committee's Opinion, as far as is practical in the short term. The revised procedures should then be adopted on a provisional basis, until the level of protection can be properly assessed.**

2. **The proposed procedures should be calibrated or validated to the extent that is possible, e.g. by comparing the resulting toxicity-exposure ratios with available information from field studies and incident monitoring.**

3. **The level of protection provided by the proposed procedures should be estimated using uncertainty analysis, in conjunction with ongoing work to implement probabilistic approaches.**

4. **Appropriate policy officials / risk managers should be consulted to determine whether the level of protection (as indicated by the outcome of the preceding recommendations) is set at an appropriate level or, if not, to adjust the proposed procedures accordingly.**

The Question asks whether use of the selected species and scenarios will not trigger an excessive number of refined risk assessments. The frequency of refined assessments is a legitimate concern, both because of the cost in terms of the experimental animals that are used in some types of higher tier study, and because of the cost of refined assessments in money and time. All these costs should be taken into account when determining the level of protection that is appropriate. However, the balance between risk and the various costs is a question of policy, and not within the remit of the Committee.

Scientific Background on which the opinion is based

The Committee addressed the four elements of this question in turn: agronomic relevance, ecological relevance, level of protection and frequency of refined assessments.

1.1.1 Agronomic relevance

This was interpreted as asking whether the list of 'crop' groupings in Table 1 of the Guidance Document (grassland, cereals, leafy crops, orchard/vine/hops, seed treatment) is adequate to represent EU agriculture, so far as the assessment of risk to wild mammals and birds is concerned.

The Committee considered that:

- There is a strong argument for adding rice, and perhaps forestry, as separate categories of crop type, because the exposure scenarios for these crops is significantly different to the current groupings and likely to give different results.

- Ornamentals and aquatic herbicides also represent significantly different exposure scenarios, but the Committee felt the extent of these uses is sufficiently small that they need not be included in the basic set of groupings.

- Regardless of how many crop types are identified, the Guidance Document should emphasise that it is the responsibility of the notifier and assessor to determine whether the standard scenarios are appropriate for each particular assessment, and to devise non-standard scenarios themselves where necessary. This decision should be based on an assessment of whether the standard scenario is likely to indicate a lower risk than an appropriate non-standard scenario. This should be done at the very start of the assessment, and not as a refinement step (contrary to the implication in the final sentence of paragraph 2 on page 12: 'more tailored scenarios may be employed for refinement'). Otherwise, there is a possibility that the risk might be determined as acceptable in the initial assessment using a standard crop scenario, when a different result would have been obtained with a more appropriate scenario.

- In addition, the Committee noted that the agronomic relevance of the Document is limited by the fact that it gives no guidance on the assessment of risk for uses other than sprays and seed treatments. The most important of the omitted uses is granular pesticides. The Committee recommends that a section on assessment of granular pesticides should be added to the Document. For this purpose, approaches used in the Committee's opinion on fosthiazate (Opinion of the SCP on fosthiazate 2001[6]) may be helpful.

1.1.2 Ecological relevance

The Committee interpreted the question of 'ecological relevance' partly as asking whether the choice of indicator species is appropriate, and partly as asking whether other assumptions used in first tier assessment of the proposed scenarios are appropriate.

1.1.2.1 Choice of indicator species

The Committee interpreted the question of 'ecological relevance' partly as asking whether the list of indicator species in Table 1 of the Guidance Document (small herbivorous mammal, medium herbivorous mammal, insectivorous mammal, granivorous mammal, medium herbivorous bird, large herbivorous bird, insectivorous bird, granivorous bird) is adequate to represent the species likely to be exposed to pesticides used in EU agriculture.

The Committee considered that:

- The choice of species types seems ecologically relevant and their characterisation in terms of body weight etc. seems realistic. They are not literally worst case, but are probably reasonably protective in the sense that there would be few relevant species that would give higher exposure estimates. The Committee made calculations for one additional scenario, involving skylarks feeding on insects in the breeding season. This was found to be less severe (i.e. give higher TER[7]s) than the scenarios in Table 2 of the Document involving large and medium-size herbivorous birds.

- The Document should emphasise that it is the responsibility of the notifier or assessor to determine whether the standard indicator species are appropriate for each particular assessment, and to devise non-standard indicator species themselves where necessary. This decision should be based on an assessment of whether the standard species are likely to indicate a lower risk than an appropriate non-standard species. This should be done at the very start of the assessment, and not as a refinement step, to avoid underestimating the risk.

- The Document should also emphasise that it is the responsibility of the notifier or assessor to determine whether the list of combinations of crop type and indicator species is appropriate in each case. For example, in the case of a seed treatment with systemic action, it would be appropriate to assess the risk for herbivorous mammals and birds as well as granivorous ones.

- If other parts of the Document are changed (e.g. the assumptions regarding residue concentrations, see Question 2) then the selection of species will need to be reviewed, to check that the chosen scenarios are still appropriately conservative.

[6] http://europa.eu.int/comm/food/fs/sc/scp/out121_ppp_en.pdf
[7] Toxicity-to-exposure ratio

1.1.2.2 Appropriateness of other assumptions

The Committee interpreted the question of ecological relevance also as asking whether other assumptions used in first tier assessment of the proposed scenarios are appropriate.

As a general principle, all assumptions should be justified. They should be based on data where possible, and the source of the data should be cited. Where expert judgement is necessary, the logic of this should be explained. If the assumption involves choosing a single value for a parameter that is variable in nature (e.g. variation between species, crops, pesticides or sites), the reason for choosing that particular value should be explained. If the assumption involves significant uncertainty, it should be stated what allowance has been made for this.

The Committee considered that more justification or explanation is required for some of the assumptions relating to the Tier 1 assessment, including the following.

- The assumption that 'in the case of fungicides and insecticides applied in tall growing crops half of the applied amount reaches the ground' is apparently based on assumptions used in the FOCUS[8] Groundwater Document but its use in the context of mammals and birds requires justification (page 11 of the Guidance Document). However, both the Groundwater Document and the current draft of the FOCUS Surface Water Scenario Document list different values depending on crop and growth stage (e.g. 20 – 70% in the surface water document). Consistency between the different EU Guidance documents should be achieved, and justification should be given for deviations from the standard assumption or for – as in this case – the choice of a specific value out of a range.

- The equation used in Table 2 of the Document to calculate daily energy expenditure (DEE) for mammals relates to 'all mammals', whereas the Committee considers the equation for 'other eutherians' (in Appendix I) to be more relevant.

- Many assumptions in Table 2 are based on Appendix I, which cites an unpublished report by Crocker et al. Either this report should be published, or Appendix I should be expanded to include references to the sources of the information and justify the way it is used. Tables 6 and 7 in Appendix I may be deleted, as they refer to particular UK species and are not used in the Guidance Document.

- The equation used to derive food intake rate (FIR[9]) from the other parameters in Table 2 should be stated in the Document, together with the assumptions it implies.

- The document proposes a period of 3 weeks as a convention for use in calculating time-weighted averaged exposures. Some justification should be offered for why this specific length of period is chosen rather any other. For example, when assessing the risk of avian reproductive effects, the choice of time period could be based on information about the mode of action of the pesticide and the reproductive physiology of birds. As the choice of averaging time is stated to be highly uncertain, it would be prudent to set it towards the lower end of the plausible range as a precautionary measure.

- Assumptions relating to the estimation of residue concentrations in Tier 1 are discussed in the Committee's opinion on Question 2 (see later).

- Section 2.3 of the Document assumes that 'for most situations, the principal risk is considered to arise through ingestion, and it is rarely necessary to consider other exposure

[8] Forum for the Co-ordination of pesticide fate models and their Use
[9] Food intake rate related to body weight; eg 0.25 means that an animal takes 25% of its body weight per day; multiplying FIR/bw by concentration results in daily dose

routes in detail'. In fact, even though the issue has received little direct study, there is evidence that non-dietary routes of exposure are important and, in some circumstances, more important than dietary ones (e.g. Driver et al. 1991, Mineau 2001). The approach proposed in the following paragraph of the Document (consider non-dietary routes only in borderline cases) may be adequate if other assumptions in the initial assessment are sufficiently conservative, but should be used only as a short-term solution while research is conducted to develop a more rigorous approach.

- The Committee considers that basing the initial long-term assessment on the 'field scale' (i.e. assuming a single treated field) is unconservative, especially for seed treatments. This should be taken into account in defining the 'time-weighted-average factor' for residue decay, and is discussed in more detail in the Committee's Opinion on Question 3 (see later).

1.1.3 Level of protection

In order to determine whether the proposed Tier 1 procedure is appropriately protective, it would be necessary to consider (a) the desired level of protection (i.e. the type of effect considered, the acceptable magnitude of effect, acceptable frequency of effect, and the acceptable level of confidence that it will not be exceeded), and (b) the level of protection afforded by the proposed procedure.

What level of protection is required?

As stated on page 23 of the Guidance Document, the level of protection that should be afforded is not explained anywhere in 91/414/EC or its Annexes. The only assessment criteria that are defined for wild mammals and birds are TERs. The text of the Annexes implies that these are intended as screening criteria. In current practice, there is a tendency to treat the TERs in Annex VI as defining the desired level of protection, but they are inadequate for this purpose for several reasons.

- It is stated on page 3 of the Guidance Document that, with the exception of threatened or endangered species, the abundance or persistence of populations is the most relevant assessment endpoint (i.e. the measure of impact most relevant to decision-makers). However, the TER cannot be used to estimate effects on population endpoints because, as the Guidance Document states, the relationship between individual and population responses is not well understood.

- Even as a measure of the response of individual organisms, an acute or short-term TER does not have a defined meaning except when it is equal to 1 (when it implies 50% mortality). This is because it does not take account of the slope of the dose-response relationship. For example, a TER of 2 implies an expected mortality of 27% if the probit slope is 2, but 7% if the slope is 5. The long-term TER also does not define the frequency of effects.

- The TERs do not distinguish level of effect and certainty. For example, neither 91/414/EC nor its Annexes state whether the Annex VI criteria of 10 implies that a TER of 1 is acceptable, with an assessment factor of 10 to allow for uncertainty, or whether a TER of 10 is acceptable without an assessment factor.

- The degree of certainty that would be afforded by the assessment factor is undefined, because it depends on how many toxicity values are used and how exposure is calculated. The type and number of toxicity studies are specified, but the method for calculating exposure is not defined. For example, 91/414/EC and its Annexes do not specify what percentiles to use for residue estimates.

- The lack of a stated rationale in 91/414/EC for the specific values of the TER triggers (5 and 10) causes major difficulties when refining the assessment. For example, it is not defined how much of the assessment factor implied by the trigger value is intended to allow for species differences in toxicity. Therefore, when this source of uncertainty is reduced by means of additional toxicity studies, it is difficult to decide how much to reduce the TER triggers (as is shown by the discussion in section 5.1 of the Guidance Document).

In making these observations, the Committee implies no criticism of the way that the TER triggers in the Annexes were defined. They reflect the state of science at the time, and they were intended only as screening criteria. However, it is clear from the above observations that the TER triggers are unsuitable for use as definitions of the required level of protection.

What level of protection is achieved?

As the required level of protection is undefined, it is necessary first to determine what level of protection the proposed procedure implies (i.e. what the ecological consequences of it are likely to be), and then to consider whether these consequences are acceptable. The former aspect is within the scope of the Committee but the latter aspect (acceptability) is a matter of policy.

Whilst the Committee recognises the lack of evidence for frequent direct impacts of pesticides on wild bird and mammal populations, the Committee is of the opinion that it is not currently possible to quantify how protective the proposed procedures are, for the following reasons:

- The Committee cannot define the level of effect, at individual or population level, that corresponds to any particular assessment outcome. This is partly because, as already mentioned, the TER is a poor indicator of both individual and population responses. In addition, the TER only indicates the risk under one set of conditions, defined by the assumptions used in the assessment. The proposed approach does not quantify how frequently this set of conditions occurs, nor does it show the range of TERs under other conditions.

- Even if the level of effect implied by the assessment could be determined, the degree of certainty could not. There are many uncertainties (stated and unstated) in the proposed procedure, but only two of them are quantified at all (between-species variation in toxicity, and variation in initial residue concentrations).

Possible approaches to ensuring an appropriate level of protection

Two contrasting approaches could be considered.

1. Revise the proposed procedure to define the assessment endpoint more precisely, quantify all the major uncertainties, and combine them to determine the overall uncertainty in the assessment output. It would then be possible to adjust the assumption and trigger values, or define alternative endpoints, so as to achieve whatever level of protection was desired.

2. Use data on pesticide impacts in the field to establish empirical criteria for risk assessment. This type of approach has previously been used to calibrate assessment procedures for earthworms and non-target arthropods (Heimbach 1992 and Campbell et al. 2000 respectively; note that these papers are cited only as examples of the approach – the Committee is not expressing an opinion on their conclusions). It has already been applied to birds by Mineau (2001), who analysed the relationship between acute field impacts on birds and simple measures of toxicity and exposure. Mineau's database of field studies could potentially be used to calibrate the procedure proposed by the Guidance Document for acute avian risks. The procedure would be used to calculate TERs for the pesticide uses

represented in Mineau's database. A judgement could then be made as to whether the level of impact corresponding to TERs in the region of the Annex VI TER trigger of 10 was acceptable. If not, then the input assumptions for the calculation (e.g. the percentile used for pesticide residues) could be adjusted until a TER of 10 was associated with an acceptable level of impact.

The first approach is applicable to acute, short-term and long-term risks to both mammals and birds. It requires detailed examination of the assumptions underlying the proposed procedure. It also requires the use of quantitative uncertainty analysis, which would be difficult in the short term but will become easier if these methods become accepted for use in probabilistic assessments.

The second, empirical approach is only applicable for acute (and maybe short-term) risks to birds, because the field studies and incident data relate mainly to birds and are unlikely to be sensitive to long-term effects. However, it could be done relatively quickly and would represent a substantial advance.

These two approaches are not incompatible. If the first approach (modelling) is used, some form of validation or calibration should also be attempted. This could be achieved by comparison of the predicted risks with data on actual impacts, e.g. from field trials or incident monitoring.

Carrying out either of these approaches is beyond the scope of this opinion, given that the Committee has been asked for a rapid response. However, the Committee recognises the need to establish a practical approach for the short term and wishes to be as constructive as possible. It therefore makes the following recommendations:

1. The procedures proposed in the Guidance Document should be revised to take account of all the issues raised by the Committee's Opinion, as far as is practical in the short term, and then adopted on a provisional basis until the level of protection can be properly assessed.

2. The proposed procedures should be calibrated or validated to the extent that is possible, e.g. by comparing the resulting toxicity-exposure ratios with available information from field studies and incident monitoring.

3. The level of protection provided by the proposed procedures should be estimated using uncertainty analysis, in conjunction with ongoing work to implement probabilistic approaches.

4. Appropriate policy officials / risk managers should be consulted to determine whether the level of protection (as indicated by the outcome of the preceding recommendations) is set at an appropriate level or, if not, to adjust the proposed procedures accordingly.

1.1.4 Frequency of refined assessments

The working group that developed the Guidance Document has carried out two studies to examine how frequently the proposed procedures would trigger refined (higher tier) assessments (BBA, 2001 and INRA, 2000). The frequency of refined assessments is a legitimate concern, both because of the cost in terms of the experimental animals that are used in some types of higher tier study, and because of the cost of refined assessments in money and time. All these costs should be taken into account when determining the level of protection that is appropriate. However, the balance between risk and the various costs is a question of policy, and not within the remit of the Committee.

1.2. Question 2.

Is the residue per unit dose for insects appropriate?

Opinion of the Committee

The Committee does not consider the residue per unit dose (RUD) values in the Guidance Document to be appropriate for estimating pesticide residues on insects, because (a) there is evidence that the assumption of a linear relationship between dose (application rate) and residues is unsafe, (b) the values are based on measurements that are probably representative of large insects, whereas smaller insects are expected to have higher residues (due to their larger surface area / volume ratio), and (c) the assumption that residues in insects always decline over time is unsafe.

Research is needed to provide a more robust approach. In the meantime, the Committee recommends that different approaches should be used for 'large insects' and 'small insects'. RUDs for large insects should be based on a peer-reviewed analysis of existing residue measurements for insects, taking a percentile which makes reasonable allowance for uncertainty about the linearity of the dose-residue relationship. RUDs for small insects should be based on an appropriate percentile of existing data on forage crops of similar surface area / volume ratio to small insects (a modification of the currently-accepted approach), until sufficient measurements on small insects are available to estimate improved RUDs. In addition, special care should be taken to identify and allow for cases where residues may increase over time.

Scientific Background on which the opinion is based

1.2.1 General observations

The general approach adopted in the Guidance Document involves using existing data from field residue studies on a range of pesticides to derive estimation factors called RUDs, that can then be applied to pesticides in general. RUD stands for residue per unit dose (RUD) and is multiplied by the application rate (in kg a.s./ha) to estimate the initial residue on insects in mg a.s./kg. Other possible approaches include trying to model residues on insects from first principles, or requiring field studies. The Committee considers that the use of RUDs is the most practical approach for first tier risk assessment, but does not support the particular values specified in the Document.

The use of RUDs implies an assumption that the relation between application rate and initial residue is linear. This is not supported by a recent analysis of existing data on insect residues (Hart & Thompson, 2001). This analysis showed that, for studies where pesticides were applied at less than 1 kg a.s./ha, measured residues on insects were about an order of magnitude higher than would be expected based on the assumption of a simple linear relationship. Therefore, using the RUDs may substantially under-estimate actual residues at low application rates. This may be caused by factors such as differences between insect types or pesticide types. Research is required to determine how these factors influence residue levels and thus develop a robust method of estimation.

Until recently, RUDs for insects have been based on data on residues measured on plant material of similar surface area to volume ratio, due to lack of appropriate data on insect residues. RUDs for 'large insects' have been based on data for pods and seeds, and RUDs for 'small insects' on data for

forage crops. Newer estimates of the RUD, using data for insects, have given similar results to the plant-based RUDs for 'large insects'. Most of these data derive from samples collected by pitfall trapping, which probably comprised (by weight) mainly of relatively large insects such as beetles. Therefore, the Committee considers that it would be reasonable to use a RUD based on these data to estimate residues on large insects. However, the Committee recommends that this RUD should be based on a peer-reviewed analysis, including additional insect data that are known to exist in regulatory archives, and making appropriate allowance for under-estimation at low application rates.

Based on their higher surface area to volume ratio, small insects are expected to have substantially higher residues per unit mass. This would be consistent with the higher residues found on forage crops, which have a higher surface area to volume ratio than pods and seeds. Therefore the existing data on insect residues (which probably derive mainly from large insects) should not be used to estimate RUDs for small insects, unless an appropriate extrapolation factor can be defined. An alternative approach for small insects would be to continue using estimates based on plant material (e.g. an estimated 90^{th} percentile for forage crops based on the review by Fletcher et al. 1994). Whichever approach is chosen, it should be used only as a temporary measure while appropriate research is conducted to develop more rigorous estimates.

The approach in the Guidance Document also implies an assumption that maximum residues occur immediately after application. Hart & Thompson (2001) found that in a number of existing datasets, the first sampling period did not give the maximum residues. The biggest increases after the first sampling period were seen in studies with organochlorine pesticides (Zaranyika and Mugari 1996), but substantial increases were also seen for other types of chemical, including organophosphorus and carbamate pesticides and a herbicide. Research is required to determine how common such cases are, and to develop appropriate methods to identify and deal with them. In the meantime, some degree of conservatism is advisable when using initial residues to allow for the possibility that higher residues occur later. If there is reason to expect an increase in residues over time, based on pesticide persistence, the mechanism of uptake, or the type and life-stage of insect concerned, then consideration should be given to requiring appropriate field measurements.

In conclusion, the Committee does not consider the RUD values in the Guidance Document to be appropriate for estimating pesticide residues on insects. Research is needed to provide a more robust approach. In the meantime, the Committee recommends that different approaches should be used for 'large insects' and 'small insects'. RUDs for large insects should be based on an appropriate percentile of existing residue measurements for insects. RUDs for small insects should be based on an appropriate percentile of existing data on forage crops. In addition, special care should be taken to identify and allow for cases where residues may increase over time.

The Committee's detailed comments on the derivation and use of RUD values are included in Section 2 of this Opinion.

1.3 Question 3.

With regard to long-term risk from seed treatments to birds and mammals: Could there be more simple criteria identified, which might be applicable in Tier 1 to eliminate low risk substances? (e.g. NOEL (reproduction) > 1000 ppm, logPow < 3, and DT50 from seed < 4 days)?

Opinion of the Committee

In theory, it would be possible to identify simple criteria to eliminate in Tier 1 seed treatments posing a low long-term risk to wild mammals and birds. However, to do this in a scientifically-

robust way would require resolution of several fundamental and difficult issues affecting the assessment of long-term risks (i.e. which test endpoints to use, how to allow for variation between species, how to allow for variation in exposure over time). Furthermore, the Committee does not agree with the Guidance Document's assertion that 'there is no true long-term exposure or repeated exposure for seed treatments'. This assertion arises from considering a single treated field in isolation ('field scale'). The Committee considers that the likelihood of concurrent and/or repeated exposures in multiple fields should be taken into account when estimating realistic worst-case exposures. As a general principle, the Committee considers the restriction of assessments to single treated fields to be inappropriate.

Research is required to resolve these issues. Until this has been done, the Committee recommends that the first tier assessment for seed treatments should use the same approach as for other substances, because this is more conservative and avoids making unsupported assumptions. Special factors affecting exposure to seed treatments can be taken into account in the higher tier assessment, where appropriate.

Scientific Background on which the opinion is based

1.3.1 General Observations

In principle, it would be possible to identify simple criteria to eliminate in Tier 1 seed treatments posing a low long-term risk to wild mammals and birds. However, it would be essential to ensure that the criteria were chosen in such as way as to afford an appropriate level of protection (i.e. an appropriate balance between the various costs of conducting a higher tier assessments and the risk of wrongly approving, at Tier 1, a substance which in fact causes unacceptable impacts).

The Committee has discussed the questions of how to define and achieve an appropriate level of protection in its opinion on Question 1 (above), and the same principles apply here. Appropriate criteria for long-term risk cannot be derived empirically, because there is insufficient empirical data on long term impacts. Therefore it will be necessary to quantify the relationship between the proposed criteria (e.g. NOEL, logPow, DT50) and the assessment endpoint (level of long term impacts), and also quantify the uncertainties affecting this relationship. It would then be possible to determine the critical values that correspond to an acceptable risk.

Defining scientifically-robust criteria for long-term risk will require resolution of some issues that are already recognised as especially difficult and/or requiring new research:

- Which test endpoints to use for long-term toxicity, especially for mammals (Guidance Document for Terrestrial Ecotoxicology, 2000).
- How to allow for variation in long-term toxicity between species (Chapman et al. 2001).
- How to allow for the discrepancy between prolonged, fixed exposure in long-term toxicity tests and shorter, variable exposures in the field (page 17 of the Guidance Document).

Another fundamental issue with an influence on long-term risk from seed treatments is the spatial scale of the assessment. The Guidance Document states (pages 4 and 17) that assessments are conducted at field scale, i.e. by considering a single treated field in isolation. This choice of scale is not justified in the Document, and is not specified in 91/414/EC or its Annexes. The assumption of a single treated field does not affect the first tier acute and short-term assessment, because it is assumed that the animals obtain all their food in the treated field, and that there is no decay of residues. However, the first tier long-term assessment for granivores assumes residue decay with a half life of 10 days, so restricting the assessment to a single field implies that the animal is exposed

to a continuously declining level of residues on treated seed. However, farmers frequently grow the same crop on more than one field, and treat the seed for each field with the same substance. They tend to sow the fields one after another over a period of several days or weeks. Furthermore, seed-eating animals are attracted to newly-sown fields, and may therefore shift their foraging from one field to the next as they are sown. It is therefore unconservative to assume, as the Document does on page 17, that 'there is no true long-term exposure or repeated exposure for seed treatments'. The Committee therefore recommends that assessments should not be limited to single treated fields(this also applies to higher tier assessments for all timescales, as explained in the Committee's general comments in Section 2 of this Opinion). This implies that the 'twa-factor' (time-weighted average factor) in the long-term first tier assessment should include an appropriate allowance for the possibility of concurrent and repeated exposure on adjacent fields. The Committee is not suggesting that first-tier assessments should be spatially-explicit: what is required is a one-time evaluation of the amount by which the twa-factor should be increased to provide simple criteria that achieve an appropriate level of protection. This issue should also be taken into account if simplified criteria were to be defined for initial long-term assessment of seed treatments (e.g. by adjusting the critical value for the DT50).

As a separate point, it may be inappropriate to select a single critical value for the DT50, at least for birds. Pesticides used to treat spring-sown seed are likely to require a much lower critical DT50 than pesticides which are restricted to winter-sown seed, as the latter have more time to decay before the breeding season. Similarly, it would be inappropriate to use a single critical value of log P_{ow} as an index of bioaccumulation potential, because bioaccumulation and delayed toxicity are influenced by many other factors including the mode of action.

The preceding paragraphs show that developing simplified yet scientifically-robust criteria for assessing long-term risks from seed treatments would require resolution of several fundamental and difficult issues. Until this has been done, the Committee recommends that the first tier assessment for seed treatments should use the same approach as for other substances, because this is more conservative and avoids making unsupported assumptions. Special factors affecting exposure to seed treatments, such as incorporation in the soil, loss of active substance from the seed surface, and germination, can be taken into account in the higher tier assessment, where appropriate.

SECTION 2. DETAILED COMMENTS

Section	Location	Comments
1	P 4, para 1.	Restricting the assessment to a single treated field ('field scale') is reasonable when it is possible to assume that the animals obtain all their food there and there is no residue decay, because this will represent a worst case. However, when these assumptions are relaxed, restricting the assessment to a single treated field becomes unconservative. The implications for residue decay of restricting the assessment to a single treated field are discussed in the Committee's Opinion on Question 3, with particular reference to first tier assessment for long-term risk for treated seeds. Therefore, only the implications relating to higher tier assessments are discussed here. In higher tier assessments for all timescales (acute, short and long-term), animals are assumed to divide time between multiple fields

		(Section 5.6 of the Guidance Document). Considering only a single treated field implies that all other fields are untreated. This will significantly underestimate risk in situations where nearby fields are treated with the same substance. If such situations were rare, then it might be reasonable to ignore them. In fact, such situations are not rare, as noted in the Opinion on Question 3. In addition, different fields of the same crop on the same farm are likely to suffer similar pest and disease problems, at about the same time. Even if a substance has a small share of the market, a farmer who uses it is likely to use it on more than one field. Therefore, to avoid underestimating risk, assessments should take account of the potential for individual animals to be exposed on multiple fields. The Committee therefore recommends that as a general principle, assessments should not be limited to single treated fields. This has implications for the estimation of the 'time-weighted average factor' in the long-term first tier assessment (see Opinion on Question 3), and for the way PT[10] is estimated in higher tier assessments (Section 5.6 of the Guidance Document). The text in Section 1 should be altered accordingly, or the final two paragraphs could simply be deleted. Changes to the text would also be required in other places, e.g. Sections 3.3, 3.4 and 5.6, to avoid implying that only a single field is considered.
2.1	First sentence	The text implies that the Directive relates only to direct toxic effects. In fact, Article 4 of the Directive states that authorised products must have no unacceptable influence on the environment, and defines the environment as including '…wild species of fauna and flora, and any interrelationship between them…'. This broad definition includes both direct and indirect effects, although the Annexes to the Directive give no guidance on how the latter could be assessed and it is current practice to ignore them. The guidance document should therefore avoid implying that indirect effects are outside the scope of the Directive.
2.1	P 5, para 2	'such results overrule the previous TERs'. This implies the TERs are completely ignored in the final assessment if other types of data are submitted. This is inappropriate. Usually, such studies address only a narrow set of conditions (e.g. a field study), or a single test species (e.g. an avoidance or secondary poisoning study). Therefore they cannot provide a complete assessment on their own. Instead, the final assessment should consider <u>all</u> relevant information, including the TERs (as is implied in the bottom box in Figure 1).
2.1	Last para	'other data have to be generated by new studies'. This section should mention that it is desirable to minimise animal testing by exploring other options for refinement first, where possible. To do this, it might be appropriate to include a reference to the relevant Directive. Better still, a separate subsection could be inserted which

[10] Fraction of diet obtained in treated areas; dimensionless (between 0 and 1)

		emphases the need to minimise animal testing.
2.1	P6, Figure 1	The decision flow control operation "*Did the refinement result in revised TER*" is incorrect (incidentally in formal systems notation, this should be a diamond). Almost all refinements will result in *revised* values, so surely the question is whether the revised TERs are now *acceptable* on the basis of standard triggers? We note that in the scheme there are end states of "*negligible risk*", "*acceptable risk*", and "*characterise risk*" but not one for "*unacceptable risk*". In addition the assumptions and terms in this diagram should be better explained and defined, to ensure it is clearly understood (e.g. the presumption that the initial assessment is conservative, and the meaning of 'refinement' and 'weight of evidence'). The Committee suggests the group developing the Guidance Document considers the potential relevance of guidance on assessing lines of evidence, which has been published in the USA (EPA 1998, Section 5.2.1).
2.2	P 8	'is not appropriate for those treatment groups where a *strong* food avoidance is *obvious*' and 'Case 2….food consumption *moderately/not affected'* and 'Case 3….*distinct* food avoidance'. The meaning of the words in italics are too vague for practical use. These criteria have important consequences for the assessment and need to be more clearly defined, to avoid inconsistencies between assessments. Due to lack of a quantitative basis for these definitions they may need to be based on expert judgement but, provided the reasoning is stated, this would be preferable to the vagueness of the current wording. Also, in Case 3, the actions to be taken are too vague. At least, it should be explained more clearly how a NOEL could be used.
2.3	Para 2	'Inhalation doses, dermal doses and ingestion doses can generally not be combined to give a total dose. One reason for this is that the site or sites of toxic action of a substance within the organisms are often different for the different pathways'. These sentences should be rephrased. It is incorrect to say exposure via different routes cannot be combined, and in principle they should be combined in order to avoid underestimating exposure and consequently risk. This may be complex and requires that (a) they are in same units and (b) take account of differences in absorption by different routes. The second of the quoted sentences makes a generalisation, which is not always appropriate. The site of toxic action may or may not be the same for different routes depending on the chemical in question. It is true, however, that it is not practical to combine exposure via different routes on routine basis. The suggestion of the draft Document (to do it in borderline cases) is a reasonable solution.
2.3	Para 3	'if the initial results are close to the trigger value, then an assessment of the next most important route of exposure is appropriate'. This solution is endorsable, although its practical

		application would require an assessment of all the potential routes in order to identify the most important one according to the exposure scenario. The Guidance Document should ensure that this is actually done (e.g. it should be included in the worked example in Appendix IV, where the final acute TER is stated as 9-14). The Guidance Document needs to say how, in such cases, the exposure via different routes will be combined. Some indications on how to proceed might be gained from human operator exposure procedures including route-to-route modelling.
2.3	Figure 2	The legend includes a single asterisk but there are no single asterisks in the figure.
3	P 10	We suggest changing the definition of PT to 'fraction of diet obtained in treated areas' (plural) to be consistent with a more realistic spatial scale (see also comments on sections 1, 3.3 and 5.6).
3	P 10	The calculation of C[11] for long-term exposures uses a time-weighted average factor. See comments below on section 3.4.
3	P 10-11	Concentration on vegetation and insects. See comments on Appendix II of the Guidance Document (below) and Opinion on Question 2.
3	P 10-11	Is Gonzales-Valero et al. 2001 still in press? The document indicates that estimates of concentrations of PPPs on insects might be based on Fischer & Bowers 1997, but this is an unpublished manuscript. Could notifiers readily obtain it?
3	P 11, para 1	'In the case of fungicides and insecticides applied in tall growing crops…it is assumed that *half* of the applied amount reaches the ground.' The document should cite basis for assumption of 'half', or replace it with an estimate based on data. '….*in case of need* this interception factor may be refined' – this is too vague; the document should specify how to identify cases where this need applies. The same assumption appears again later on (e.g. bottom of page 11). The Committee questions whether using a single default assumption is justified, given the potential influence of many factors including crop type and growth stage and also machinery, application instructions (pressure, dilution, spray to runoff) and formulation details. This requires further consideration.
3	Table 2	The document uses the 'all mammals' equation for estimating DEE. This equation is based on data including desert and marine species and marsupials, which are not relevant to the assessment scenarios and are likely to have different energy requirements. The 'other eutherians' equation should be taken from Appendix 1 instead. The difference between these two equations is substantial. Any changes

[11] Concentration; here: concentration of a substance in food or other material which is ingested by birds or mammals

		to Table 2 will need to be carried through to relevant places in later tables.
3.2	Para 1	The document uses 90th percentiles for the initial concentration in the acute exposure assessment. Therefore the rationale for this should be stated. This rationale would necessarily include a reason for picking the 90th percentile rather than any other percentile. Furthermore, the document should state (and justify) whether the median estimate of the chosen percentile should be used, or a confidence limit for that estimate (both are shown in Appendix II of the Guidance Document but the choice between them is not discussed). These issues are part of the larger and fundamental question of the degree of conservatism in the assessment (see opinion on first specific question to the SCP). In principle, the degree of conservatism to be applied to the residue estimates should take account of the degree of uncertainty present in other parts of the assessment (both effects and exposure) and the overall degree of conservatism desired.
3.2	Para 1	It has become standard practice to base residue estimates on initial residues immediately after application, as is done in the Guidance Document. For both plants and invertebrates, it is implicitly assumed that maximum residues will occur immediately after application. Data for multiple time periods was included in about half the insect residue studies examined in a recent review by Hart & Thompson (2001). Examination of these studies showed that in a substantial minority of cases, the first sampling period did not give the maximum residues. In several cases, substantial increases over time (several-fold) were reported. The biggest increases were seen in studies with organochlorine pesticides (Zaranyika and Mugari 1996). Levels of lindane in crickets increased from 2.86 to 20.06 mg/kg between 14 and 70 days after application, and levels of endosulfan in grasshoppers increased from 4.29 to 28.16 mg/kg between 28 and 70 days after application. These results are consistent with the high persistence of these compounds in the environment. However, substantial increases over shorter time periods were seen for other types of chemical, including organophosphorus and carbamate pesticides and a herbicide (unpublished regulatory studies). The existence of such data indicates that, in some cases, pesticide residues on invertebrates may increase over time after application. Presumably this results from contamination of the insects' diet or by adsorption of residues during locomotion. In such cases, using estimates based on residues at day 0 would result in under-estimating worst-case exposures of insectivorous birds and mammals. Research is required to determine how common this is and, if necessary, to develop ways of dealing with it in risk assessment. It is possible that the frequency and magnitude of increasing residues would be such that the 90th percentile of the initial residue would still provide adequate protection, but this cannot be assumed without further analysis. In the meantime, some degree of conservatism is advisable when using

		initial residues to allow for the possibility that higher residues occur later. If there is reason to suspect an increase over time, e.g. with a persistent active substance, consideration should be given to requiring appropriate field measurements. Note this issue affects the estimation of acute, short term and long term exposure, as all three currently make use of initial residue estimates.
3.2	Para 1	'no MAF[12] is applied for residues in insects'. The argument provided for this is reasonable, but the examples of increasing residues over time (see previous comment) imply that there may be exceptions. Again, research is required on this issue. In the meantime, provided the overall approach is conservative, it seems reasonable to apply no MAF.
3.2	Table 4	The RUD values are taken from Table 10 in Appendix II of the Guidance Document. Comparing the two, it appears that median values are taken for short grass and leafy crops, whereas the upper confidence limit is taken for insects. The justification for this should be explained.
3.3	Para 1	'in the course of some days they (animals) will gather food in an area that is large compared to the spatial scale of residue variation. So averaging of residues is expected to occur and therefore arithmetic means are taken for residues in vegetation and insects.' This approach sounds reasonable but its appropriateness depends on the nature of the data that are being used, the spatial scale at which averaging is done, and the intended interpretation of the results. The individual numbers in the Kenaga, Fletcher and Fischer datasets appear to represent different study sites, whereas the Brewer study refers to one site of citrus and one of alfalfa. Both within and between site variation need to be considered. If one interprets the animal as foraging within a single site it is reasonable to average residues within the site, but not between sites. For this purpose, an arithmetic mean may be more appropriate than a geometric mean, as it is a linear function of the total exposure summed over locations as the animal forages within the site. Between site variation reflects the influence of local application methods and environmental conditions. The value to be taken from the between-site distribution for a deterministic assessment depends on what percentile of sites one wishes the assessment to reflect. If the distribution is lognormal (as assumed in the Guidance Document), then the geometric mean will fall at the 50th percentile. Whether this is an appropriate percentile to use depends partly on the wider issues regarding conservatism in the assessment, discussed earlier. However, it can be seen that the argument in the Guidance Document is confused, because the justification relates to within-site variation whereas the datasets involved comprise between-site variation. It would be helpful for the document to (a) include a discussion of the distinction between within- and between-site variation, (b)

[12] Multiple application factor; exposure level after the last of n applications compared to a single application

		recommend arithmetic averaging within sites (where such data are used), and (c) define and justify a suitable percentile to be taken for between-site variation. This is likely to alter the values recommended (currently, arithmetic averages are used for data representing mainly between-site variation). In the long-term exposure assessment (Section 3.4, para. 1), arithmetic means are again used for residues. The same issue applies here also.
3.4	Para 2 (page 16)	The document proposes using a 3-week time-weighted average for residue concentrations, but gives no justification for the choice of this particular time period. Mineau et al. (2001) suggest a more robust approach - they calculate the length of the time period for which exposure exceeds the NOEL and then use knowledge of mode of action and reproductive physiology to assess whether this period is long enough to cause concern. The Mineau et al. 2001 approach is more scientific than using an arbitrary averaging period of 3 weeks, but implies a more cumbersome assessment (repeating the comparison of exposure and toxicity for multiple time periods). The approach in the document could be strengthened and made more or less equivalent to the Mineau et al. approach if the choice of averaging period could be justified in terms of mode of action and reproductive physiology. As there is obviously considerable uncertainty about this matter, the period should be set on the low side as a precautionary measure. At the very least, the choice of 3 weeks should be justified, instead of just being 'proposed as a convention' without any specific reason.
3.4	P 17	'In the case of insects no default twa-factor (time-weighted-average factor) is employed in the first tier as the time course of residue level is unknown.' This implies an assumption that residues remain constant over time. Although there is evidence that residues increase in some cases (see earlier), this assumption is likely to be conservative in the majority of cases. For active substances of short persistence it will be highly conservative. Given current knowledge the proposed assumption seems a reasonable compromise for a preliminary assessment, but this approach should be reviewed when further research is available.
4.2	P 21	Justify default value of 0.3 for 'F'.
4.3	P21	Calder & Brown 1983 is Calder & Braun 1983 in the references.
4.4	Para 1	'half the skin surface area' – This assumption should be justified. Also, it should be explained whether or not this assumption takes account of the factors modifying dermal exposure, such as the presence of fur and feathers etc. (mentioned in paragraph 1 on page 22 of the Document).

4.4	Last sentence	'See also EPPO[13], 1994'. It would be helpful to be more specific about what the reader is to look for in EPPO – is the document endorsing the whole approach taken to dermal risk in the EPPO scheme?
4.4		No guidance is given on what measure of dermal toxicity to use for birds: it therefore appears that the Guidance Document endorses the approach in EPPO (1994), i.e. 'when no dermal toxicity measurements are available, it is suitable to use a surrogate estimate, calculated as five times the acute oral LD50 (Hudson et al., 1979)'. EPPO provides no justification for this other than the reference to Hudson et al.. The latter paper does not mention multiplying the oral LD50 by five; instead, it appears that the EPPO (1994) approach is based on reinterpretation of Hudson et al.'s Figure 1. This is unsatisfactory as a basis for regulatory guidance. Firstly, the scientific justification for such assumptions should be clearly stated. Secondly, the proposed procedure may not be sufficiently protective. The correlation between oral and dermal toxicity for mallards, reported by Hudson et al., is statistically significant ($r = 0.65$, $P < 0.01$ for the log-log correlation) but highly variable. For example, of 21 pesticides tested by Hudson et al., the dermal LD50 is less than the oral LD50 in 3 cases (ethoprop, fenitrothion and methyl parathion). In the case of fenitrothion, the dermal LD50 is less than half the oral LD50. This suggests that using 5 times the oral LD50 as a surrogate for the dermal LD50 is not sufficiently protective. The Committee recommends that the group drafting the Guidance Document should provide a more detailed description and justification of its proposed approach for estimating dermal toxicity.
4.5	Equations	The Committee notes that the equation for estimating inhalation rate in birds gives lower values than that in mammals. This seems surprising given larger relative size of the respiratory systems of birds, and may merit closer examination. Also, the Document states that passerine birds have a higher inhalation rate than that given by the equation: guidance should be given on how to estimate this higher rate.
4.5	Last para	'If no information on inhalation toxicity is available…it is recommended to compare inhalation exposure levels with five times the acute oral toxicity rather than requiring experimental testing of inhalation exposure (EPPO, 1994)'. This recommendation is wrong and not scientifically justified, because there are no reasons to compare inhalation exposure levels with acute oral toxicity. Inhalation exposure is important with two respects: (a) the absorption through lungs of chemicals that become systemically bioavailable; (b) the direct toxic effect on lungs which may be the critical toxic effect of a substance even in the absence of

[13] European Plant Protection Organisation

		general systemic toxicity. To address point (a), generally absorption through lungs is considered to be 100%, thus the PEC[14] in the air would allow an estimate of the inhalation contribution to the total systemic dose. To assess the point (b), data coming from inhalation experiments and/or data related to chemical-physical properties of the substances are generally used. While it is understood that specific inhalation experiments on birds and several mammalian species are not available, a first level of information can be derived from the inhalation studies in rats which is a mandatory part of the Annex 2 testing list. Therefore the Committee suggests that a first level of assessment of inhalation risk to birds be performed through inter-species extrapolation from inhalation toxicity in rats rather than route-to-route extrapolation from oral toxicity in birds. Another important issue is the relevance of the standard inhalation toxicity test to the field exposure of birds and mammals. Laboratory tests may involve several hours constant exposure, whereas air concentrations in the field are likely to involve a very brief peak (during spray application) followed by a rapid decline, which will be very dependent on vapour pressure and other properties of the pesticides. This must be taken into account to avoid over-estimating risk. The Guidance Document should indicate how to address both this and the preceding issue, and justify any assumptions used.
5.1	Para 1	This paragraph highlights a very important and fundamental deficiency in the current regulations – the lack of a rationale for the 'assessment factors' of 5 and 10 for the TER. This creates significant difficulties in current regulatory practice (as is explained in 5.1 of the Guidance Document). The Committee's suggestions for resolving these difficulties are given in the Opinion on Question 1.
5.1	Para 2	'it can be shown that the use of a fixed uncertainty factor of 10…the overall assessment level for birds is the 25th percentile of the species distribution and for mammals the 13th percentile….'. It should be stated whether this relates to the one-sided left 95% confidence limit for the 25th percentile, or the median estimate of the 25th percentile. Also, a justification should be given for why the chosen value provides an appropriate degree of protection against uncertainty.
5.1	Para 2	Last sentence: suggest add reference to Posthuma et al. (2002) for a more recent account of species sensitivity distribution methods.
5.1	Para 3	The justification given for preferring a 'qualitative' approach is not logical – if modifying the assessment factor is not compatible with 91/414 then this applies equally whether it is done by 'an exact numerical procedure' or 'in a qualitative way'. The science for an explicit statistical approach exists (e.g. Luttik and Aldenberg 1996, Mineau et al. 2001). While there is discussion about the details of these approaches it is clearly better to agree on a consistent explicit approach than to give vague guidance ('a careful reduction…could

[14] Predicted environmental concentration.

		be envisaged') that could be interpreted in different ways by different users. Also, the meaning of 'down from 10 resp. 5' is unclear.
5.1	Para 4	This single sentence introduces a major reinterpretation of the assessment factors in 91/414/EEC without any discussion, because it implies that they are intended solely to account for uncertainty in the extrapolation of toxicity data between species. Any such reinterpretation should be given much more emphasis (e.g. a clearly titled separate section) and discussed and justified in detail. Furthermore, the proposed reinterpretation (while conveniently simple) is scientifically inadequate, because it only considers one source of uncertainty and ignores a host of others (both in exposure and effects), and because it provides no justification for the overall level of conservatism that is implied. The Committee's proposed approach for defining an appropriate level of protection is outlined in the Opinion on Question 1.
5.2	6th bulleted point	'Preferably more than one site should be used…'. This implies that a single site can be acceptable, and that this value would then replace the 90th percentile of the residue distributions used in the initial assessment. This represents a very large reduction in the level of precaution. Although the measured value has the advantage of relating to the pesticide in hand, it could come from anywhere (from the 0th to the 100th percentile) in the distribution for that pesticide. Over the long run of assessments, on average the TER will relate to the average field, so about half of treated fields will have worse TERs. But for a particular assessment, the TER could relate to anything between a 0th and 100th percentile field. This implies a serious lack of control on the level of precaution in the assessment, and therefore substantial inconsistency in the level of precaution applied to different pesticides. Therefore: • the word 'preferably' should be deleted • more guidance should be given on how to determine an adequate number of sites, or the user should be advised to consult a statistician • guidance should be given on how the measured data should be used, including whether to use the average or a given percentile of the measured distribution, and how to account for sampling error especially when the number of sites is small. Note that this percentile should be chosen so as to maintain an appropriate overall degree of conservatism for the assessment as a whole.
5.2	Vegetation	This section should discuss what part of the vegetation should be sampled, and consider how to deal with the fact that data in the residues section of the dossier relate to parts of the plant that are appropriate to human consumer exposure but may not be relevant to wildlife exposure. Similar points are already made in the following

		section on insects, but need to be considered for vegetation also.
5.4	Para 2	The first two sentences of this paragraph could lead to significant underestimation of risk and need to be revised. The current wording says that estimates of AV[15] can be used to calculate a revised TER, but omit to say what types of estimate of AV are suitable for this purpose. The wording implies that any study showing reduced consumption of treated food can be used for this purpose. However, as stated in the previous paragraph, the extent of avoidance is dependent on many factors that may differ between lab and field. Therefore it is essential that any estimate of AV used to recalculate the TER is derived from a study in conditions which represent field conditions appropriately. The type of conditions which may be appropriate are also discussed elsewhere in 5.4. Even though the relevant information appears elsewhere in the section, these two key sentences could produce misleading results if taken out of context. It is therefore important that the words 'under appropriate conditions' are inserted in both the first and second sentences of para 2 (following the word 'measured' in sentence 1 and 'material' in sentence 2).
5.5		'is not an all-or-nothing response': the meaning of this is unclear and further detail is needed – e.g. add 'Even when dehusking occurs, only a proportion of seeds are dehusked.' The paragraph ends without really giving any guidance on what, if anything, should be done about dehusking in the assessment. As this issue is complex, the Guidance Document could usefully refer the reader to the detailed discussion in Prosser (2001) (not Prosser et al. 2002 as stated in the document). The full reference for this work is given incorrectly in the document (see references of this Opinion for correct version). See also important comment on section 2.6 of Appendix II of the Guidance Document (below).
5.6		To avoid the problems discussed above in the comment on section 1, relating to the spatial scale of the assessment, PT should be defined as the proportion of diet obtained in treated areas (plural), not the treated area. Therefore, throughout section 5.6 'area' needs changing to 'areas'. (see also comments on section 3.3 and Appendix IV of the Guidance Document).
5.6	P 30 para 3 and example box	Put 'local' before 'population' in both places, as the type of data discussed refers to local populations around a particular treated area, not larger scale populations (e.g. regional or national).
5.6	P 30	The second bullet point after the example box should place more stress on the quality of data required to justify reductions of PT. The key point is that any reduction should be supported by relevant, reliable data from an identified and verifiable source (e.g. texts on

[15] Avoidance factor: dimensionless, between 0 (complete avoidance) and 1 (no avoidance)

		natural history or published research studies). This requirement is implied (e.g. 'needs to be justified') but is undermined by the example: 'For example in Tier 1 it is assumed that small insect eating birds spend 100% of their time in a treated crop, however if on refinement it is considered that they only spend 50% of its time in the treated crop, then the TER can be amended appropriately.' The words 'it is considered' should be replaced by something like 'reliable evidence shows'.
5.6	P 30	In the example box, the 95th percentile of a distribution for PT is used, but it is not clear whether it is intended that the 95th percentile should be taken as standard when working with PT. Text should be added somewhere in section 5.6 to offer guidance and justification on this point. (This is the same general issue as was raised in comments on section 5.2, above).
5.6	P 30	The second bullet point after the example box: the final 2 sentences (top of page 31) propose a form of sensitivity analysis, which is an excellent idea for uncertain variables of this type – 'it is also essential that a range of PTs are calculated….'. This 'essential' step needs to be added to the example in Appendix IV of the Guidance Document (currently it is only done for PD[16]).
5.6	P 32	The second bullet after the example for PD should say 'PD should always sum to 1' (not equal 1). Also, it would be useful to add an extra bullet saying 'data on dietary composition should be converted to dry weights before using it to estimate PD' (otherwise significantly misleading results could be obtained).
5.6		The exposure equations given in this document are based on some presented in the ECOFRAM[17] report, and imply that PD is the same in treated and untreated parts of the overall habitat. However, the ECOFRAM report also includes a more complex version of the equations which recognise that this may not be true. The example in Appendix IV of the Guidance Document describes such a case (see comments below) and shows that the simplification can lead to inappropriate specification of PD and PT. To avoid this, an extra bullet should be added to the list at the end of section 5.6, saying: 'if dietary composition differs between treated and untreated areas, PD should be based on the diet taken within the treated areas'.
5.7	First sentence	'The aim …is to predict effects on the population level…'. This is too definite a statement, given that this is not defined in 91/414 and is subject to caveats about endangered species etc as discussed in Section 1 of the document. For the purposes of section 5.7 it would be adequate to write 'One aim…'
5.7	Para 5.	It states that the "NOEL is based on statistical significance". More precisely, it is based on *lack of* significance. This section makes the

[16] Fraction of food type in diet; dimensionless (between 0 and 1)
[17] Ecological Committee on FIFRA risk assessment methods

		valid point that a statistically significant effect may not be biologically significant, if the study is of high quality and capable of detecting very small differences. The document should also point out that a statistically insignificant effect does not necessarily imply an absence of biologically significant effects, if it is a poor quality study with low precision.
5.7	Para 6	'If reproductive effects in a mammalian multi-generation study are more pronounced in the second generation whereas in practice exposure will be restricted to a short time period then the reproductive NOEC after the first generation should be used as a possible refinement step.' Second generation effects might be caused by first generation exposure, for example by an endocrine disruption mechanism. It sometimes will be possible to come with a qualified guess about the cause of the observed effect one of many being an endocrine disruption. However, in most cases it will not be possible to say with any certainty whether the observed effect in the second generation derives from an impact occurring during the exposure of the parent generation, the F1-generation or the pups of the F1-generation. The NOAEL from such studies is the lowest dose for a relevant toxicological effect irrespective time of occurrence / observation.
5.8		This section could usefully refer to EUPRA workshop report (Hart, 2001).
5.8	Para 2	'not compatible with the TER concept'. Firstly, this is not true – see page 93 of the EUPRA report for a worked example showing one possible way of applying probabilistic methods to the TER approach. Secondly, if the TER concept prevents us developing improved methods then the use of the TER concept should be reconsidered (see comment on section 5.1 para 1, and Opinion on Question 1).
5.8	Para 2	First bullet point 'generic data are often missing' applies equally to deterministic approaches – as is shown by the discussions in this document about the limited information that exists for estimating PT, PD, etc. In fact, it can be argued that lack of data is a positive reason for using probabilistic methods, because they provide an objective means of accounting for the resulting uncertainty.
5.8	Para 2	Second bullet point – 'suitable procedures are poorly described' – lack of consensus is also a problem.
5.8	Last sentence	'It is advisable to focus on those parameters where reliable information on distribution is readily available rather than to try to consider all parameters.' This is untrue. The usual recommendation is to focus on those parameters which have most influence on the risk. It is clearly not advisable to ignore an important parameter just because information on it is not readily available.

5.9		This section is excellent in emphasising a number of important limitations on the interpretation of incident data. However, it would be helpful to indicate some positive uses that can be made of incident data. For example: if incidents have been reported, (a) it confirms that effects occur at least under some circumstances, (b) the nature of the effects or circumstances may give some clues about how to refine the assessment, or for practical options for reducing risk.
6		'consult regulatory authorities' – add 'well in advance'. Also add sentence at end 'This is important, to minimise the unnecessary use of test animals and resources.'
6.1		Can the Document provide contact details for Barfknecht and Leopold (cited as pers. comm. for unpublished protocols)?
6.2		This section emphasises a conservative aspect of pen studies – animals being confined to the treated area – but does not mention others that are unconservative – e.g. energy expenditure and hence food requirement are reduced, and feeding rate is likely to be lower than in the wild. Because of these latter factors, it is probably not true that 'if no effects are recorded under these conditions then the result indicates a certain margin of safety'. What is more, there is published evidence of examples where pen studies have shown no effects for a pesticide that causes substantial mortality in the wild (Mineau et al. 1994). A more balanced discussion and conclusion is therefore needed in this section.
6.3	Final sentence	'Integrated endpoints (breeding success, biomarker of effects) will supersede the TER.' All relevant evidence should be considered in the final assessment, so the word 'supersede the TER' should be replaced by 'can be used together with the TER in a weight of evidence approach'.
7	Para 2	'If seed is incorporated availability to birds and mammals will be reduced and hence if an acute risk has been highlighted then this will be reduced as birds and mammals will take longer to find and consume treated seed.' The text should be amended to emphasise that it is necessary to provide good evidence that the reduction in risk will be sufficient. The regulations imply that this should be done by revising the risk assessment so that it applies to the use of the product as proposed, including any risk management option. The SCP opinion on fosthiazate provides an example of this, examining the effect on the TER of different degrees of incorporation for a granular product.
43	Glossary	DEE, ETE, SE, BAF, Feeding rate, Assimilation efficiency could be included here.
App I		The report Crocker *et al.* is currently being revised into a manuscript for publication and will hopefully be available on PSD website by

		the time the SCP opinion is finalised.
App I	Tables 1 & 2	Need to state units for equations in legend.
App I	Table 4, 5	In table 4 and table 5 (page I-2 and I-3), are the quoted values in percentages? Delete 'see accompanying spreadsheets' in Table 4 legend.
App I	Tables 6 & 7	Suggest these tables are deleted as they are not used at all in the document and are specific to UK (and related) conditions.
App II	Insect residues	See draft opinion on the second specific question submitted to the SCP, regarding residues on insects.
App II	Section 1.	States that nomogram is still playing an important role in USA. This is incorrect – the US EPA has officially adopted the revised estimates of Fletcher et al. (1994).
App II	Section 2.4	The last sentence states 'This finding (the Brewer et al. study) is inconsistent with the potential concern that Fischer and Bowers data are biased on the low side due to the use of pitfall traps as a collection method.' However, the Brewer et al. study does not address all potential biases: for example, one concern is that residues based on pitfall trapping will be biased towards large insects, which are expected to contain lower residues than small insects (based on the difference in surface area to volume ratios). Most of the insects used by Brewer et al. were also relatively large, so they do not represent a test of this bias (the size of the armyworm larvae is not given by Brewer et al., but they do state that these larvae inhabit the underside of leaves during daylight hours and therefore, are less likely to receive direct spray). It therefore remains possible that Fischer and Bower's data underestimate residues on small insects by a significant margin. Furthermore, the Kenaga, Fletcher and Fischer datasets include data from many sites, and are used in risk assessment to represent between-site variation, whereas the Brewer et al. study used only two sites. It is likely that Brewer et al. would have found wider variation had they examined more sites; therefore their data are also not inconsistent with distributions including higher values. This study therefore does not provide a means of deciding between the estimates of Fischer and Fletcher. Finally, the derivation of the summary statistics in Table 6 of Appendix II of the Guidance Document needs checking: the n of 5 appears inconsistent with the use of 3 replicates in the original study, and in the second row the maximum is stated to be less than the mean.
App II	Section 2.5	The literature data summarised in Table 7 also refer mainly to large insects and therefore do not bear on the issue of small insects. Note that the ranges shown in Table 7 may partly represent within-site variation or, in the case of the laboratory studies, variation between

		individual insects or batches of insects. This variation is not directly comparable to the datasets of Fischer and Fletcher, which represent between-site variation. A more detailed examination of the original studies in Table 7 would be required for a rigorous comparison with these datasets.
App II	Section 2.6	'For birds with a body weight smaller than 50 g a dehusking factor of 0.13 should be used'. This approach is not appropriate. It is true that most of the pesticide is on the husk, as indicated by the data in Table 8. However, field studies by Prosser (2001) show that, although some birds with a body weight less than 50g dehusk seeds, this only applies to some species and not to all individuals in those species. Even those individuals which do dehusk, do not dehusk every seed. Small seeds are less likely to be dehusked than large ones. Dehusking behaviour is therefore very complex and it would be misleading to attempt to account for it using general assumptions. The particular approach proposed here would seriously underestimate exposure of most small seed-eating birds.
App II	Section 3	'The research carried out by Fischer and Bowers, Brewer et al. and Joermann showed that the residue levels proposed in earlier days for small and large insects by Kenaga, and still used nowadays in the hazard/risk assessment, are in most cases too high.' This statement is not supported by the evidence. First, as stated by the authors themselves in section 2.3 of Appendix II of the Guidance Document, regarding the Fischer data, 'Measurements at foliar sites were close to the Fletcher nomogram model estimates for fruits which EPA has assumed are a surrogate for large insects'. The Joermann and Brewer et al. data are also not inconsistent with the EPA approach for large insects. The most parsimonious explanation for this is that the available data relate mainly to large insects. The EPA approach assumes smaller insects have higher residues: this cannot be refuted by the existing data as none of it is known to relate to small insects. This conclusion is consistent with a more recent analysis, combining Fischer and Brewer's data with additional published and proprietary data (Hart & Thompson 2001). Furthermore, Hart & Thompson show that there is doubt about the fundamental assumption that insect residues are linear function of application rate (underlying the Kenaga, Fletcher, Fischer, EPA and EPPO approaches and that in the draft Guidance Document). Hart & Thompson show that, for studies where pesticides have been applied at less than 1 kg a.s./ha, measured residues on insects are significantly higher than would be expected based on the assumption of a simple linear relationship. Among the possible explanations for this are (a) the studies below 1 kg/ha involved different active substances with different environmental fate properties, (b) samples in the studies below 1 kg/ha contained a higher proportion of small insects, (c) the relationship between residue and application rate is actually non-linear. Hart & Thompson conclude that, until the factors affecting insect residues are better understood, no firm basis can be given for revising the current residue estimation factors.

App II	Section 4	The reasons given for assuming a lognormal distribution are (a) 'The ECOFRAM report (1999) suggests that the data probably are lognormally distributed.' (b) 'Fletcher et al. (1994) give the percentage of values that exceed the upper Kenaga limit, and indeed these percentages better match the lognormal parameters than the linear parameters (pers. Comm. G. Joermann).' Although it is likely that the distribution will be approximately lognormal it would be desirable to check this statistically. Furthermore, the statements quoted above relate to residues on plants, not insects. Future approaches for insect residues should ideally be based on a definitive statistical examination of insect data, with particular attention to the tails of the distributions as these can be very influential in risk assessment. When this is done, it is recommended that the assumption of a linear relationship between application rate and residues should also be critically evaluated, as there is evidence that it does not apply to insect residues (Hart & Thompson, 2001).
App II	Section 4, p II-9	The text in Appendix II of the Guidance Document recommends the 90^{th} percentile for acute assessments and the mean for short and long term assessments, but does not give any justification. Nor does it state whether the median estimates or confidence limits should be used (both are given in Table 10 of the Appendix). A justification should be given for the percentiles proposed for use in risk assessment, and for the use of median estimates or confidence limits.
App III	Table 1	The feeding rate estimates are given without reference to any supporting data and are inconsistent with the feeding rates used in other parts of the Guidance Document. The data in Appendix I of the Guidance Document show that the rates proposed in Appendix III of the Guidance Document are underestimates; they will therefore lead to underestimation of risk. (N.b. The estimates in Appendix III appear similar to those cited in Note 8 of the EPPO scheme published in 1994, except that EPPO makes clear they relate to dry weight whereas Appendix III states they are wet weight).
App III	P III-3	'PEC food is estimated using the model of Hoerger and Kenaga' – this is inconsistent with the main Guidance Document and Appendix II of the Guidance Document, and should be replaced accordingly.
App III	P III-5	PEC predator (insectivores) is calculated for consumption of earthworms, whereas most insectivores feed predominantly on insects. The text should explain the reason, and state whether a calculation for insects would give lower or higher results.
App III	P III-6	'For episodic or intermittent exposures, the steady state calculations are not appropriate and the equations must be substituted by the first order kinetic equations.' Episodic or intermittent exposures are likely to be common and perhaps the normal case. Therefore, is it desirable to give more guidance on how to use the first order kinetic

		equations?
App IV	P IV-2	'the Notifier has generated some real residue data'. As the example proceeds to use the data, it is implied that the data meet the criteria given in section 5.2 of the main document. This should be stated explicitly in the example. In particular the example should state that there were sufficient study sites, to remind the reader of the importance of this issue.
App IV	P IV-3	As mentioned in the comments on section 5.6, the equations in the document imply that PD is the same in treated and untreated parts of the overall habitat. However, this is not always true. In the example, the various paragraphs on page IV-3 appear to imply 3 sources of food, each offering different types of food: cereal fields containing cereal shoots, other arable fields containing harvest spoil and waste grain, and the intertidal area of the coast which contains aquatic plants. As mentioned in the comments on section 5.6, if dietary composition differs between treated and untreated areas, PD should be based on the diet taken within the treated areas: in this case, cereal fields. Therefore, PT should be an estimate of the proportion of feeding time that is spent on treated cereal fields, and PD should be an estimate of the proportion of food obtained there that is cereal shoots. If any other foods containing residues are taken on cereal fields, they would need to be accounted for separately using different values for PD and C and then added to the exposure via cereal shoots. The approach for PT described in the example does not distinguish between cereal fields and fields with harvest waste and is therefore not strictly an estimate of 'proportion of food obtained in treated areas'. On the other hand, the approach for PD in the example gives data for the proportion of diet comprising grass. In one place it is mentioned that the remainder of the diet is made up of grain, potato spoil and turnips. Therefore, the distinction between treated and untreated areas is partly being made by PD (in distinguishing grass from other foods). In this example the end result may be reasonable, but the logic is confused and in other cases might lead to misleading results. This, together with the following two comments, emphasises the great care that is necessary in using PT and PD.
App IV	P IV-3	The approach for PT described in Appendix IV of the Guidance Document offers a rather simplistic basis for estimating time spent in the intertidal area. Information on tide cycles and the position of different plants within the intertidal zone is readily available, and would give a different answer (at some points in the tide cycle, the intertidal feeding areas may be available for well under half the daylight hours). Given that estimates of PT should 'always be fully justified' (page 31), the Appendix should set a stronger example of the level of justification required.
App IV	P IV-3	The arguments and literature citations presented in support of the estimate of PD provide a better example of the level of evidence that

		should be given for these variables. However, (a) the example uses data on grass consumption to estimate cereal shoot consumption, and (b) intertidal foods are absent from the diets reported by the cited studies. The estimates used for PD imply assumptions about these two issues, which should really be discussed explicitly. Similarly, there is an implied assumption that all cereal fields are treated concurrently, which should also be discussed.
App IV	P IV-4	The result of the acute assessment (TER = '9.0 – 14.4') clearly matches the criterion 'close to the trigger value', implying that an assessment of the next most important route of exposure is appropriate according to the statement at the bottom of p. 8 in section 2.3 of the guidance document. In this case, with a scenario of geese feeding on newly-sprayed cereals, dermal exposure through the feet might make a significant contribution.
App IV	P IV-4	Only a single value of PT is considered. Section 5.6 states: 'It is also essential that a range of PTs are calculated for each bird to determine whether this is a pivotal factor in reducing the risk. If this refinement step is deemed to be pivotal then depending upon the reliability of the exposure data used, further data may be necessary.' This implies that a range of values should have been considered for PT in the example. It is also clear that the refinement of PT and PD are pivotal (given that it increased the TER from 4.3 to 9.3-14) and that the data used for them is far from ideal, so it would seem reasonable to invoke the final part of the statement quoted above and require further data.
App IV	P IV-4	The term 'the risk has been adequately addressed', while commonplace (including in previous Opinions of this Committee), is ambiguous. On the one hand, it could mean that the evidence shows the risk is actually lower than is implied by the TER calculations. On the other hand, it could mean that in this case, it has been decided that a TER of 9 would be acceptable. The former is a scientific judgement, the latter a policy (risk management) judgement. As a general principle, the terminology 'adequately addressed' should be replaced by more explicit and less ambiguous statements of the assessment outcomes. In this case, there is an implied judgement about the possibility that the TER might be between 9 and 10; this judgement should be made explicit and justified. In view of the two preceding comments, concerning the potential contribution of non-dietary routes of exposure and uncertainties regarding PT and PD, the conclusion may be difficult to defend. As mentioned earlier, it is important that the Guidance Document sets an appropriate example for the level of evidence required in these areas of judgement.
App VI	VI-2	The Committee considers Appendix VI of the Guidance Document to be a poor example of a weight of evidence assessment, partly due to lack of detail. Appendix IV of the Guidance Document needs a

		weight of evidence assessment, which it currently lacks, but the calculation of TER's in Appendix IV has a better level of detail than that in Appendix VI. The Committee therefore recommends that the drafting group should delete Appendix VI and add a weight of evidence discussion at the end of Appendix IV. The Committee's specific concerns on Appendix VI were as follows: • Insufficient detail is given of the pesticide and its use pattern. • Persistence is a significant part of the argument but is not mentioned in the conclusion. • Acute and short-term toxicity are mentioned in the conclusion, but were not part of the preceding argument and do not necessarily imply low reproductive toxicity. • Part of the argument concerns lack of herbaceous layer but many IPM programmes encourage planting of such layers. • It is argued that because of the potential for recovery after exposure ends, there will be no long-lasting effect. However, if the effect is to delay breeding then birds may miss the opportunity until the following year. This could result in a population level effect. Overall, the Committee considers that the arguments provided in Appendix VI of the Guidance Document are insufficient to outweigh the concern indicated by the very low TER value.

E. References

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