



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

SCIENTIFIC COMMITTEE ON PLANTS

SCP/GUIDE-RICE/002-Final

**Opinion of the Scientific Committee on Plants on the draft Guidance document on
Environmental Risk Assessments of Active Substances used on Rice in the EU for
Annex I Inclusion**

(Opinion adopted by the Scientific Committee on Plants on 30/01/2003)

A. TITLE

Opinion of the Scientific Committee on Plants on the draft Guidance document on Environmental Risk Assessments of Active Substances used on Rice in the EU for Annex I Inclusion

(Opinion adopted by the Scientific Committee on Plants on 30/01/2003)

B. TERMS OF REFERENCES

No formal question was asked but the Committee was supplied with a background note from DG SANCO E relating to the draft guidance document on rice scenarios drawn up by the working group "MED-RICE" SANCO/1090/2000 as follows:

Under Point 7 the conclusions read: "Aquatic organisms in the rice paddy itself do not require the same level of protection as those in the non-target water bodies adjacent to the fields. "

The approach taken is outlined in detail under Point 4.2.4. in the document.

The rationale is that paddy fields fall dry anyway at a certain time of the year and all aquatic life comes to an end. On the other hand, species dwelling within the paddy may have a particular ecological FUNCTION during the time they are there - e.g. as a food source for fish, amphibians and birds.

Taking both considerations into account, the (working) group felt that the aquatic risk assessment should focus on maintaining the ecological function of the aquatic species and not necessarily take into account the full range of species sensitivity distributions. In other words, a reduced safety factor may be justified because - as long as there are daphnids, there is food for fish or tadpoles. So, if the risk assessment ensures that Daphnia are protected, some impact can be accepted on possibly more sensitive species of invertebrates because the ecological function of the group is maintained and the tadpoles find something to eat.

This reduced level of protection therefore applies within the paddy. Outside the paddy the uniform principles are applied without derogation.

C. OPINION OF THE COMMITTEE

The Committee appreciates the effort to develop specific guidance for environmental risk assessments in this crop.

There are a number of errors which need to be corrected and further information must be provided to justify the choice of scenarios and some of the guidance provided. Three areas related to the proposed modelling framework are of specific concern.

A number of assumptions are made in the establishment of the Step 1 PEC¹ estimation procedures. Some of these assumptions are considered to be incorrect by the Committee. Other assumptions are implied and all need to be discussed more thoroughly and scientifically justified.

Aspects of the modelling framework proposed by the Working Group need to be more thoroughly considered. In particular, further information should be provided on Steps 2 and 3 in

¹ PEC: Predicted Environmental Concentration

the assessment procedure. Guidance on mathematical modelling options is limited. It is recognised that methodology is currently under development but the guidance offered by the Working Group does not provide advice or references on where further information can be obtained to assist in the development of more complex assessments.

It is recommended that the scientific validity and regulatory consistency of the stepwise procedure should be checked and demonstrated through Case Studies or through illustrations with hypothetical products.

Other issues of concern include exposure to non-target terrestrial compartments next to rice paddies (dikes, banks etc.) which are claimed to be within the scope of the document. However, there is no guidance included on how to calculate PEC's for adjacent non-target terrestrial environments.

The Committee does not support, the proposed data requirements for avian testing, since there is no indication or scientific justification as to which of the proposed or rejected test species would be a better surrogate for the different species exposed in the paddies. Also, the Committee is of the opinion that the argument for using TER² triggers in rice, which are different from those used for other crops, has no scientific justification.

² TER: Toxicity Exposure Ratio

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C. BACKGROUND

The Committee was supplied with a background note from DG SANCO E1 relating to the draft guidance document on rice scenarios drawn up by the working group “MED-RICE” as follows:

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The approach taken is outlined in detail under Point 4.2.4. in the document.

The rationale is that paddy fields fall dry anyway at a certain time of the year and all aquatic life comes to an end. On the other hand, species dwelling within the paddy may have a particular ecological FUNCTION during the time they are there - e.g. as a food source for fish, amphibians and birds.

Taking both considerations into account, the (working) group felt that the aquatic risk assessment should focus on maintaining the ecological function of the aquatic species and not necessarily take into account the full range of species sensitivity distributions. In other words, a reduced safety factor may be justified because - as long as there are daphnids, there is food for fish or tadpoles. So, if the risk assessment ensures that Daphnia are protected, some impact can be accepted on possibly more sensitive species of invertebrates because the ecological function of the group is maintained and the tadpoles find something to eat.

This reduced level of protection therefore applies within the paddy. Outside the paddy the uniform principles are applied without derogation.

Source documents made available to the Committee:

1. Rice Guidance Document: Terms of Reference, submitted by DG Health and Consumer Protection, 3 May 2002 (SCP/GUIDE-RICE/001).
2. Rice Guidance Document: Comment from Germany, submitted by DG Health and Consumer Protection, 3 May 2002 (SCP/GUIDE-RICE/003)
3. Rice Guidance Document: Comment from ECPA, submitted by DG Health and Consumer Protection, 3 May 2002 (SCP/GUIDE-RICE/004).
4. “Guidance Document for Environmental Risk Assessments of Active Substances used on Rice in the EU for Annex I Inclusion“ (Sanco/1090/2000–rev.0, December 2001) Final Report of the Working Group "MED-RICE".

D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

I. Overall approach and general comments

The Committee, having previously been asked to give separate opinions on risk assessments for several rice herbicides, appreciates the effort to develop specific guidance for environmental risk assessments in this crop.

The draft guidance document provides a thorough overview of the rice growing regions and practices in Europe and highlights the variability in application scenarios that need to be considered in providing general guidance. The current standard data requirements are investigated as to their applicability to the specific conditions, and some changes are proposed. For PEC estimates (surface water, sediment, groundwater and soil), standard scenarios and calculation methods are proposed. Finally, ecological protection goals and the applicability of the decision-making criteria as set down in the Uniform Principles (Annex VI of Directive 91/414/EEC) are discussed, and amendments proposed.

In the Committee's view it is a policy decision to decide how much impact associated with rice (or other) agriculture is acceptable. In the opinion that follows the Committee restricts itself to consideration of the scientific issues involved in assessing risks for non-target species associated with rice paddies.

The Committee has previously expressed opinions on several guidance documents and wishes to refer to those opinions and comments.

Repeated reference in the rice guidance document is made to other existing guidance (e.g.: pp.44, 46 and 48-50). However, only the guidance document on aquatic ecotoxicology (p.48) and three FOCUS documents (p.55) are specifically cited (including revision number) and other guidance documents should be fully referenced to be specific rather than general, and point to the most recent versions, to ensure consistency.

Several flow diagrams are included in the document (p.6 and in section 5) which all end in step 3, without possible outcomes.

For more detailed and further specific comments, see following sections.

II. Specific comments on Risk Assessment (Section 4.2.4)

The document (see also background note from DG SANCO) proposes to protect non-target organisms in the paddy fields not *per se* (as "biodiversity") but only as far as necessary for maintaining an ecological function, e.g. as food source for birds and other vertebrates (p.50). Thus, it is proposed to lower the TER values (which are defined in Annex VI of Directive 91/414/EEC) for aquatic organisms from 100 to 10 (short-term) and 10 to 1 (long-term), respectively. The Committee does not find that there is sufficient scientific justification for modifying the TER values because:

(a) The TER values defined in Annex VI are used as a convention to account for uncertainties. These include, e.g.: extrapolations between species, from laboratory tests to field effects, and from acute LC50 values to NOEC³s. There is no reason to expect that these sources of uncertainty are any less for rice systems than for other aquatic systems, and therefore there is no logical basis, on these grounds, to reduce TER triggers.

³ NOEC: No Observed Effect Concentration

(b) Information from existing databases (e.g. ECETOC⁴ Aquatic Toxicity Database) indicates that a factor of 10 does not consistently cover the range of interspecies variability in acute toxicity, and, on this basis, reducing the short-term TER of 10 is expected to result in impacts on some species for some pesticides.

(c) The claim that the modified TERs would still protect (an) ecological function(s) has no scientific justification. It is a gross simplification of aquatic systems to assume that as long as there are daphnids there is an unimpacted food supply for fish, amphibians and birds. Part of the reason that risk assessments generally aim to protect the most sensitive species in ecosystems is that this should minimise effects on ecological functions (that might arise via indirect effects following from species interactions).

In order to justify such a claim for setting different TERs, it would be necessary to 1) define those ecological functions which are desired to be protected, 2) define the spatial scale for which those functions shall be maintained and assessed (e.g.: for resident populations only, or also birds or fish coming into the paddies to forage there but which are not resident, 3) identify the species and populations both within and outside the paddy which provide those functions and benefit from them, and 4) show that those species and populations are indeed protected by the chosen TER.

(d) The reasoning that rice paddy fields are only temporary environments for non-target species and as such are unique can be questioned for at least two reasons: (1) Paddies are not isolated from the surrounding habitats. Rather, mobile species (birds, fish, larger arthropods) can be expected to visit the paddies to forage. Also, when paddies are drained, aquatic organisms presumably leave the paddies passively and are therefore part of the outside populations. Killing them in the paddy would therefore alter the dynamics of the outside populations as well. (2) The same reasoning could be applied equally to some other crops in relation to certain non-target species. For example arable crop fields after harvest are unsuitable for plant-associated species (which need plants as cover, as direct or indirect food source).

(e) Likewise it is incorrect to conclude that because paddy fields fall dry at certain times of the year 'all aquatic life comes to an end'. In fact, many aquatic species are specifically adapted to temporary water bodies since such habitats exist naturally (Forbes 2002). A number of groups (e.g., rotifers and cladoceran zooplankters) that inhabit such systems have resting stages that can survive buried in the sediment, for months or potentially even years (Ruppert and Barnes 1994, p. 315-316), during dry periods. These stages are critical for recolonisation of the paddies once they are reflooded, and for the outside populations since paddies can not be regarded as isolated entities.

(f) The Committee supports the view expressed in the document that amphibians as non-target organisms are likely to be exposed and that they have to be included in the risk assessment. However, the use of fish toxicity data as surrogate for amphibians in the risk assessment (and with reduced TER's), as proposed, implies a high confidence in the assumption that all life stages of amphibians are less or at worst equally sensitive as the standard fish species, and that exposure would also be the same or less for amphibians as compared to fish. None of those assumptions has been justified by data, although some amphibian data exist (e.g. on *Xenopus*). For a recent review of amphibian ecotoxicology see Sparling et al., (2000).

In addition to the above scientific arguments, the Committee notes that the Guidance document is internally inconsistent. In para. 1 of section 4.2.4 it is stated that "...it is not proposed ...to lower the TERs" and "TER values have to be followed" however, in para. 3 the "modified TER triggers" are put forward.

⁴ ECETOC (1993) Appendix C technical report No 56

In short, the argument for using TER triggers in rice which are different from those used for other crops has no scientific justification (notwithstanding the shortcomings of fixed TERs in general).

III. Specific comments on ecotoxicology (Section 4.2)

III.1 Effects on birds (p. 48):

The Committee shares the view (p. 5) that many bird species may be exposed in rice paddies and that those species probably include different ones from those exposed in a typical "terrestrial" crop. However, proposed modifications to the data requirements are regarded as unnecessarily rigid and prescriptive, since there is no indication which of the proposed or rejected test species would be a better surrogate for the different species exposed in the paddies.

Therefore, for acute oral toxicity, the Committee recommends to retain current practice, i.e. start with one species instead of obligatorily testing two. Also, bobwhite quail and Japanese quail should be equally acceptable.

The Committee does not agree that short-term dietary toxicity tests should always be carried out for both quail and mallard duck. The basic requirement should be for a single species. Furthermore, the Committee notes that the 1999 SETAC avian effects workshop at Woudschoten (Hart et al. 2001) recommended that consideration should be given to requiring short-term avian dietary testing only in those cases, where an adequate short-term TER cannot be derived using information from avian reproduction studies.

For subchronic/ reproductive toxicity, prescription of a specific test species should not be done, unless for specific reasons. For example, the choice of the mallard duck as standard test species appears questionable, unless it is the target of protection or if effects of biomagnification of the substance are to be addressed. Otherwise, considering the range of potentially exposed species, the lack of information on which test species is the better surrogate does not justify a preference for mallard duck over quail.

Apart from different species being exposed in rice paddies, the exposure routes and available food items may also differ from the ones considered typically e.g. for arable crops. The Committee is not aware of existing guidance to assess exposure routes for birds in rice paddies, neither in the rice document nor in the birds and mammals ecotoxicology guidance document (ref. our opinion). It is recommended to address this issue.

III.2 Effects on the arthropods (p. 50):

For other crops, the ESCORT⁵ 2 workshop (2000) report (which is referenced p. 19 in the Guidance document on terrestrial ecotoxicology SANCO/10329/2002) provides a list of crop-relevant terrestrial invertebrate species which should be tested in tier II if the tier I - tests with 'generic' standard species indicate a risk. Rice-relevant species are not yet included and need to be added in the rice guidance document.

IV. Specific comments on *scenario definition* (Section 3) and *PEC calculations* (Section 5)

The definitions of two standard scenarios, modified data requirements for fate and the approaches taken for PEC calculations are generally supported. However, there are a number of errors which need to be corrected and further information must be provided to justify the choice of scenarios and some of the guidance provided. The Committee has a number of specific comments / suggestions:

⁵ ESCORT: European Standard Characteristics of Beneficials Regulatory Testing

IV.1. Summary:

Environmental compartments to be addressed: There appears to be an inconsistency in the guidance document between the summary and section 5 (PEC Calculations). Section 5 clearly focuses on the paddy field itself (incl. soil and groundwater) and on water and sediment of drainage canals, while the summary (conclusions, p.8) claims that the adjacent non-target terrestrial compartment (dikes, banks etc.) was within the scope of the document. However, there is no guidance included on how to calculate PEC's for the adjacent non-target terrestrial environment.

In Figure ES1 (illustration of the generalised tiered approach) the Step 3 box should say 'refined fate and exposure modelling' as both surface and groundwater assessments need to be made not just 'leaching'.

The detail of the PEC calculations in the summary is unnecessary and equations should be omitted. Little information on normal spray/water management practices and the interaction/description of the paddy with surrounding compartments is provided despite their critical importance.

IV.2. Conclusions :

These contain some irrelevant material and are currently a mix of conclusions and summary statements.

IV. 3. Section 1.0 : Introduction

The second paragraph in quotes does not make sense and should be redrafted.

IV.4. Section 2.0 : Rice Cropping in Europe

Table 2.6.6: It is suspected that the parameter "% OM" (% organic matter) is actually incorrectly cited. This may in fact be % organic carbon. A summary of water management and application practice would be useful in Section 2.7. overview.

IV.5. Section 3.0 : Scenario Definition

The rationale for the choice of the two soil textures is not explained or justified with respect to their significance and extent within the rice growing areas of the five relevant Member States. For example evidence from section 2.4 shows that the rice growing region in the Lombardia region of Italy is predominantly sandy loam and silt loam and covers an area of 94,183 ha which is nearly 25% of the European rice growing area. However, the chosen sand scenario is more severe (5% clay, 0.9% organic carbon) and its infiltration rate is very high (10 mm/d). In addition, hydrology and leaching behaviour will be heavily influenced by the presence of underlying clay/compacted layers. As a consequence, assumptions regarding water retention and infiltration based solely on soil texture may be misrepresentative. This soil texture has been selected on the basis that the associated scenario is more vulnerable to leaching and groundwater contamination. The impact of the 'impermeable' underlying pan needs to be more carefully assessed and its physical characteristics identified for modelling assessments.

The overview of rice cropping in section 2 gave pH values ranging from 4 to 8.5. The choice of a pH 7 for both scenarios has not been justified in the document. The Committee recommends that at least for substances with pH-dependent degradation or sorption, the pH should be chosen to represent worst-case rather than average situations.

Method of application; p.43: The overview of rice cropping in section 2 showed that both terrestrial and aerial application is used in Europe (possibly more terrestrial than aerial). Either it should be justified why the scenarios include only aerial application, or terrestrial application scenarios should be added.

IV.6. Section 4.0 : Data Requirements

Soils used in the flooded aerobic degradation studies should be taken from paddy fields as the microbiology of soils, which are regularly flooded, may differ from drained soils

IV.7. Section 5.0 : PEC Calculations

General Comments

A number of significant areas of general concern were identified during the course of the review. These are discussed in brief here with specific examples highlighted subsequently in this overview.

A number of assumptions are made in the establishment of the Step 1 PEC estimation procedures. These assumptions are often implied and need to be discussed more thoroughly and scientifically justified. Significant examples include assumptions made regarding infiltration behaviour, degradation behaviour in the soil profile and surface water dilution at the conclusion of the closure period.

In the development of a step-wise approach to calculation of PEC values it is important that the refinement with the introduction of greater complexity is consistent and clearly demonstrated. It is recommended that this could be demonstrated through Case Studies or through illustrations with hypothetical products. This would provide evidence that the proposed procedures have been thoroughly checked (both in terms of scientific validity of calculations and regulatory consistency). This demonstration would also aid notifiers and regulatory experts alike in the correct interpretation of the guidance provided by the Med-Rice Working Group.

Aspects of the modelling framework proposed by the Working Group need to be more thoroughly considered. A more thorough discussion of the correct interpretation of input parameters would be welcomed. In particular, the more advanced tiers in the assessment procedure, where guidance is limited and mathematical modelling options are required, needs to be discussed in more detail. It is recognised that methodology is currently under development but the guidance offered by the Working Group does not provide advice or references on where further information can be obtained to assist in the development of more complex assessments.

Estimation of Surface Water PEC Values

No guidance is provided on the calculation of PEC's for compartments outside of the rice paddy.

A dilution factor of 10 is used for the closure period in Equation 3 at p.58 and in Eq. 7 at p. 59 also in definition p. 53. This value is nowhere justified.

It is questionable whether Step 1a for the surface water calculations is sufficiently worst-case for persistent compounds with weak sorption. This step is restricted to the initial exposure whereas the exposure resulting from the flooding period is ignored. It cannot be excluded that during this flooding period the highest concentrations in surface water occur if the dilution factor of Eq. 3 at p. 58 would be less during the flooding period than during the closure period.

In Section 5.2.2, methods are proposed for step-wise calculation of PEC values in surface waters:

- Step 1a assumes neither degradation nor sorption.
- Step 1b assumes degradation occurs but no sorption.
- Step 1c assumes both degradation and sorption occur.

However, it is not clear in the Step 1b description what the endpoints of the PEC calculation are: the course of decline in the concentration in surface water between application and closure time or simply the concentration in surface water at the closure time. Eq. 7 suggests the latter. If so, Step 1b as described here is not sufficiently worst-case because the initial exposure via spray drift appears to be ignored. For rapidly degrading compounds, the initial exposure via spray drift may lead to significantly higher concentrations.

Similarly, in the description of Step 1c (Section 5.2.2) it is not clear what the endpoints of the PEC calculation are: the initial concentration (Eq. 11), the concentration at the closure time (Eq. 14) or the time-weighted average concentration (Eq. 15).

In Eq. 9 (calculation of mass fraction dissolved in the water phase) in the description of Step 1c (Section 5.2.2) the interstitial water present in the sediment or soil is ignored. This is neither discussed nor justified. It is noted that the same omission is made in the subsequent discussions of Step 1 methods for calculation of PEC values in groundwater (see Eq. 3 in Section 5.3.2) and soil (see Eq. 1 in Section 5.4.3).

When discussing Step 1c calculations of surface water PEC values, the potential for sorption to paddy soil and sediment is introduced by assuming equilibrium with a certain soil or sediment layer. However, no guidance is provided on the thickness of these layers. These layers must be very thin (e.g. a few mm) to ensure a realistic worst-case approach (especially for strongly sorbing compounds). A discussion of available models for use at Step 2 and 3 is included in Section 5.2.4. but no references are provided from which further information can be sought.

Estimation of Groundwater PEC Values

In the discussion of Step 1a methods for calculation of groundwater PEC values (Section 5.3.2) the depth of the soil is an important parameter (See Eq. 3). However, no guidance is provided on the thickness of this layer. The layer must be thin (e.g. a few mm) to ensure a realistic worst-case approach.

The outflow parameter in Eq. 9 (calculation of PEC value in paddy water at the conclusion of the flooding period) in Section 5.3.2 is not defined. Section 5.1 states that it is “rate of water outflow from the paddy field” but gives as unit d^{-1} , which is not consistent with rate of water outflow.

In Eq. 13 (calculation of annual average groundwater PEC value) of Section 5.3.2 it is assumed that the pesticide mass that leaches from the top layer of the paddy soil:

- is completely mixed in a water layer that is 365 times the daily infiltration rate;
- is degraded during 365 days at a rate equal to the rate in paddy water.

These assumptions are not mentioned anywhere and consequently also not justified.

The Committee finds these assumptions unacceptable for the following reasons:

- it is unlikely that the water infiltration rate during winter is equal to that during the rice cropping period because there is no water layer on the soil in winter so the diluted volume of water is too large;
- assuming complete mixing with clean water is a best-case assumption which is not consistent with Step 1a;
- assuming a 365 days period available for degradation before groundwater is reached, is not a realistic worst case;
- assuming that degradation in soil proceeds at the same rate as in paddy water is also not a realistic worst case: microbial populations in subsoil may be less active than in the paddy water.

To illustrate the above problem, the Committee made the following calculation. Scenario proposal 2 (see Table ES.1 at p. 4) is most vulnerable for leaching. During the cropping period the total water percolation is about 1000 mm (based on a rate of 10 mm/d during about 4 months). The average penetration depth of a mobile pesticide which is applied at the start of the cropping period is at the end of this period thus about 5 m (assuming a volume fraction of water of 0.2 as is recommended at p. 69). The consequence of the proposed procedure is thus that leaching to groundwater is evaluated at some 10 m depth. This does not seem defensible in the first step of a tiered approach.

Again, it is noted that a significant proportion of water will be subject to lateral flow when encountering an impermeable layer. This could have a critical influence on the degree of leaching to groundwater. Consequently, these assumptions may misrepresent the degree of risk.

These points apply also to Step 1b because this step is also based on Eq. 13.

The Step 1b calculation of groundwater PEC values in Section 5.3.3 is based on the assumption of piston flow. The one but last sentence of this section claims that this is a worst-case assumption for assessment groundwater concentrations. This is not considered defensible because piston flow is a best-case assumption (see for instance Fig. 9 of Jury & Gruber, 1989). The approach followed in Step 1b is, therefore, not considered defensible.

The calculation of the residence time in Eq. 18 of Section 5.3.3 is not correct: the right-hand side has to be multiplied with the volume fraction of water in the horizon (assuming that “depth” in the equation is the thickness of the horizon as is suggested in the preceding sentences). This error may have a large effect on the result, as this volume fraction is 0.2 for Scenario 2.

Section 5.3.4 refers to Step 2 methodology, which appears to be under development, and is not fully referenced. The advice for Step 3 calculations is similarly very scant and either more detail should be supplied or a statement made to indicate that this level of assessment has not yet been developed.

Section 5.3.5 refers applicants to the FOCUS leaching models for Step 2/3 predictions of $PEC_{\text{groundwater}}$ but cautions potential model limitations if they are applied to paddy scenarios. The SCP considers that while these models have the capability of simulating relatively complex hydrology and soil physical conditions, the simulating of water and pesticide behaviour in rice paddies is recognised as presenting a significant modelling challenge that should be addressed with due care. Assumptions that are commonly applied to simulations in more traditional European agricultural scenarios may not be applicable when considering rice paddies.

Estimation of Soil PEC Values

In Eq. 2 of Section 5.4.3 it is assumed that the PEC_{soil} is restricted to the sorbed fraction of the total amount. The most common procedure is to base the PEC_{soil} calculation on the sum of the amounts present in the pore water in soil and sorbed to the solid phase. This common procedure is indeed followed in Eq. 5 of Section 5.4.3.

It would have been helpful if the PEC calculations would have been illustrated with calculations with example compounds (as was done in the FOCUS scenario reports). This would also have been a check on the consistency between the steps (see FOCUS Surface Water for example). In general the Committee is not convinced that the steps are consistent (i.e. later steps lead to lower PEC values than earlier steps).

Appendices:

The role of the Appendices is not clear (Summary, p7, Use of the Guidance: this refers to ‘easy use’ spreadsheets for estimating PEC values to ensure consistent and convenient application). Further information on the use of these spreadsheets is required. More generally, detail is also needed on the availability of the ‘model’, its interpretation, and any training, dissemination, or support to be provided.

E. REFERENCES

Comment from Germany on the Confidential Draft Working Document „Guidance Document for Environmental Risk Assessments of Active Substances used on Rice in the EU for Annex I Inclusion“ (Sanco/1090/2000-rev.0).

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Acknowledgements

The Committee wishes to acknowledge the contribution of the working group that prepared the initial draft opinion.

Environmental assessment WG: Prof. Hardy (Chairman) and Committee members: Mr. Koeppe, Prof. Leszkowicz, Prof. Papadopoulou Mourkidou, Prof. Silva Fernandes, invited experts: Dr. Boesten, Dr. Carter, Prof. Forbes, Dr. Hart, Dr. Luttik and D. Auteri.