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SCIENTIFIC COMMITTEE ON PLANTS

**SCP/GUIDE-FOC-GW/002-Final
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**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS
REGARDING THE EVALUATION OF A DOCUMENT CONCERNING
THE FOCUS GROUNDWATER SCENARIOS IN THE EU
REGISTRATION PROCESS**

(Opinion adopted by the Scientific Committee on Plants on 22 September 2000)

1. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF A DOCUMENT CONCERNING THE FOCUS GROUNDWATER SCENARIOS IN THE EU REGISTRATION PROCESS

2. TERMS OF REFERENCE

The Scientific Committee on Plants was requested to evaluate and comment on the report of the work of the Groundwater Scenarios Workgroup of FOCUS¹, final version April 2000.

3. BACKGROUND

The European Commission and the European Crop Protection Association (ECPA) jointly established FOCUS in 1993 to provide guidance to the Member States, the European Commission and industry on the role of predictive modelling in the EU process. The FOCUS working group comprises a number of experts from research, industry and regulatory organisations, which reports to a steering committee. FOCUS was established to develop standardised modelling methodologies and scenarios to derive first estimates of Predicted Environmental Concentrations (PEC's) required by Annex VI of the Directive 91/414/EEC concerning the placing of plant protection products on the market. These estimates would be used to assess the potential movement of active substances and their metabolites to groundwater, as part of the EU process for placing active substances on Annex I, in the context of the Commission's work on the implementation of Directive 91/414/EEC.

In order to prepare its opinion the Committee had access to the FOCUS groundwater report, associated appendices and also a spreadsheet summarising the comments made by Member States, together with the responses from the FOCUS group.

4. OPINION OF THE COMMITTEE

The Scientific Committee on Plants welcomes this report and acknowledges the significant expertise and effort which has been drawn together from a range of interested parties and a number of EU Member States. The Committee supports and endorses the recommendations of the report and proposes that this Tier 1 assessment methodology is adopted as soon as possible by the Commission, provided adequate resources and technical support are provided for:

- interpretation of the model results with respect to Annex I listing,**
- dissemination of the report and the model software, version control of the models and awareness of the dedicated web site,**
- training in the use of the models is provided for relevant regulatory scientists from Member States**
- training opportunities are available for other interested parties,**

¹ Forum for the Co-ordination of pesticide fate models and their Use.

- **ensuring models and their shells have adequate, ongoing expert technical support to ensure queries /problems are resolved efficiently and in a satisfactory manner,**
- **continued efforts to develop model capability/performance and approved updates are incorporated into the Tier 1 methodology.**

The SCP also encourages the Commission to consider the wider implications of this work which have not been fully addressed by the FOCUS Steering Committee, such as:

- **research priorities e.g. improved parameterisation of the models, characterisation of non-equilibrium sorption and incorporation in the modelling, the development of relevant EU databases, how to extrapolate PEC's from 1m depth to a groundwater catchment area,**
- **higher tier assessments e.g. probabilistic approaches,**
- **EU co-ordinated approaches for National assessments of leaching potential.**

The SCP has a number of general and specific comments, which are presented below.

4.1 General comments

This document represents a major contribution to the regulatory procedure and provides an excellent example of the successful co-operation between industry, regulatory and research scientists. The process of developing 'standard scenarios' was fraught with difficulty and many factors needed to be taken into account to derive the representative scenarios presented. It is acknowledged that not all the necessary data was available and expert judgement was required in many cases. It is somewhat surprising that there continues to be difficulty in accessing or establishing databases on cropping, climate and soils/geology in the EU using a scale which is sufficiently sensitive for the resolution of environmental issues.

The names attributed to the scenarios are derived from the original location where data were reviewed; this can create confusion as the scenarios are actually 'virtual ones' based on representative data for a typical agroclimatic region. Whilst there might be some value in applying generic names to the scenarios, it is understood that changes at this stage would represent considerable resource with regard to software and supporting data sets. It is suggested that the FOCUS groundwater group consider including maps of the spatial distribution of each scenario (c.f. FOCUS surface water draft report) to illustrate its extent and to emphasise its agroclimatic identity and importance.

The use of expert judgement is acceptable but there are parts of the report where further clarification might have been more helpful to the reader, for example, a problem arises for the determination of which crops were included for each scenario (Table 2.3). The report does not include any justification for this decision, yet appropriate choice of cropping is clearly critical for the proper use of these scenarios. Some of the recommendations (such as to include Atlantic scenarios for typical Mediterranean crops) are not easily understandable and a very clear rationale for the inclusion of each crop in each scenario is required. In addition, the Good Agricultural Practices (GAP's) also establish if the plant protection product is intended for application in Northern and/or Southern European conditions and therefore it should be quite relevant to have clear justifications on which scenarios must be used for each crop and condition.

The groundwater document has little cross referencing to other relevant FOCUS documents or EU guidance papers e.g. FOCUS surface water, FOCUS soil, soil persistence, relevant metabolites. Is there any formal link proposed between surface water and groundwater documents or interpretation? For example, MACRO will be used extensively in the proposals from the surface water group and is also used for one scenario by the groundwater group.

Little is said about metabolites, particularly in the Forward, yet this is an area where modelling predictions are very important.

A number of comments have been raised concerning the derivation of the realistic worst case scenarios by combining 80th percentile soil and weather data to achieve an overall target of 90th percentile vulnerability. The SCP considers that the approach is defensible and agrees for the purposes of Annex I listing that it would not be appropriate to adopt extreme case situations. These situations should be addressed at Member State level if it is shown that they are agronomically important for the target crop and the product is likely to be applied.

Whilst it is acknowledged that it is outside of the scope of the present FOCUS report, the Commission should now consider issues concerning the interpretation of the modelling results. It is inevitable that there will be differences in predictions and these will become important when concentrations are close to 0.1µg/l. In addition there may be lack of consensus between Member States when a substance only marginally passes the Annex I listing criteria. The SCP recommends that a transparent procedure be developed which assists the interpretation of such data.

A potential solution could be to move from deterministic (a set of single PEC values) to probabilistic (a probability function) approach. The combination of the soil and climatic conditions developed for each scenario could provide a good basis for constructing a probability curve for worst case conditions (combining the soil and climatic conditions of each scenario, after excluding those considered clearly not relevant). This information is relevant for decision making and risk management measures.

There is a clear need to determine the intended uses and users of the scenarios. Product registration is the responsibility of the Member States and National scenarios are an obvious route. In order to maximise the value of the work of the FOCUS group, the same principle should be applied to Member States and there is scope for a co-ordinated approach to minimise duplication and to maximise the value of the modelling activity.

4.2 Specific Comments

- Insert '(PEC)' 3rd line of second paragraph of 'Background' in the Forward.
- The executive summary table does not include the system of soil textural classification. A footnote is suitable.
- '*et al*' does not always appear in italics.
- It is not clear if the recommendation is for users to always run MACRO at Châteaudun to provide a PEC whereby preferential flow is accounted for.

- It may be helpful to clarify the use of the term ‘groundwater’ and provide relevant definitions and cross referencing to other Directives e.g. at section 2.1.3.
- Why is there a temperature range for the mean annual temperature in Table 2.1?
- There is throughout the report some mixing of units re soil water pressure/suction. All should be kPa (SI unit) and then refer to table 5.1 for those other units. [NB there is an ISO standard for the measurement of soil water retention curves.]
- Insert a ‘t’ on ‘no’ in the last sentence of paragraph 2 in 2.1.7.
- Table 2.3 is inconsistent in the crop column, some lower case is used.
- Paragraph 2 of ‘model output’ in 2.1.9 does not specify leaching volume (water) and substance losses in leachate.
- The ‘critical water content’ in 2.2.3 is not defined.
- ‘kc’ is not defined in 2.2.3 under the ‘climate soil and crop database’ section.
- Graph definition in black and white is still poor for some columns e.g. Tables 4.7 and 4.8.
- Field capacity or wilting point are not defined in 2.3.2.
- There is a format error in the caption for Figure 2.5.
- There should be a definition of ‘substance’ at the beginning of 2.4, i.e. active substance and metabolites.
- Table 4.5 should include a heading ‘year’?
- Assuming Table 5.3 refers to ‘Topsoil’ volumetric water contents, untitled table just below could provide correct MAFF reference for the soil texture classification.
- Section 5.4.5: There is scope to vary predictions by altering the active substance/metabolite input parameters and the timing of application. The document should stress that a full justification for the choice of input parameters should be provided.

5. DOCUMENTATION MADE AVAILABLE TO THE COMMITTEE

1. Note from the SCP Secretariat to the Scientific Committee on Plants, 12 May 2000 (Doc. SCP/GUIDE-FOC-GW/001).
2. FOCUS groundwater scenarios in the EU plant protection product review process. Report of the work of the groundwater scenario Workgroup of FOCUS, final version April 2000 (Doc. SCP/GUIDE-FOC-GW/003).

3. Appendices to FOCUS groundwater scenarios in the EU plant protection product review process. Report of the work of the groundwater scenario Workgroup of FOCUS, final version April 2000 (Doc. SCP/GUIDE-FOC-GW/004).
4. Appendix E. Parameterisation of pearl: appendix to FOCUS groundwater scenarios in the EU plant protection product review process. Report of the work of the groundwater scenario Workgroup of FOCUS, final version April 2000 (Doc. SCP/GUIDE-FOC-GW/005).
5. FOCUS groundwater scenarios in the EU plant protection product review process. Spreadsheet summarising the comments made by Member States (Doc SCP/GUIDE-FOC-GW/006).

6. ACKNOWLEDGEMENTS

The Committee wishes to acknowledge the contributions of the Joint working group that prepared the initial draft opinion:

WG Environmental assessment/Toxicology: Prof. A. Hardy (Chairman), and Committee members: Dr. M-P Delcour-Firquet, Mr. H. Koeppe, Prof. M. Maroni, Dr. A Moretto, Dr. H-G Nolting, Prof. K. Savolainen, Prof. A. Silva Fernandes, Dr. T. Sherratt and invited experts, Dr. J. Boesten, Dr. A. Carter, Prof. E. Dybing, Dr. V.E. Forbes, Dr. C Lambré, Dr. R. Luttik, Prof. J. Rueff, Prof. M.S. Slakinoja-Salonen, Dr. J.V. Tarazona and Prof. M. Vighi.