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SCIENTIFIC COMMITTEE ON PLANTS

SCP/GUIDE-FOC-SW/002-Final

**OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING
THE EVALUATION OF A DOCUMENT CONCERNING FOCUS
SURFACE WATER SCENARIOS IN THE CONTEXT OF COUNCIL
DIRECTIVE 91/414/EEC**

(Opinion adopted by the Scientific Committee on Plants, 17 December 2002)

A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF A DOCUMENT CONCERNING FOCUS SURFACE WATER SCENARIOS IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

(Opinion adopted by the Scientific Committee on Plants on 17 December 2002)

B. TERMS OF REFERENCE

The Scientific Committee on Plants was requested to evaluate and comment on the report of the work of the Surface Water Scenarios Workgroup of FOCUS (FORum for the Co-ordination of pesticide fate models and their USE), "FOCUS surface water scenarios in the EU Evaluation Process under 91/414/EEC" (June 2002), in the context of the Commission's work on the implementation of Directive 91/414/EEC concerning the placing of plant protection products on the market.

In 1996, the FOCUS Steering Committee established a Working Group on Surface Water Scenarios. Its remit was to develop a series of standard agriculturally relevant scenarios for the European Union that could be used with the predictive models to fulfil the requirements for calculating PEC¹s for surface water. The FOCUS Workgroup for Surface Water Scenarios has now developed a tiered system of evaluation to enable prediction of the potential contamination of surface water via spray drift, leaching and run-off events. The system includes 10 scenarios representing major agricultural areas in Europe and uses of four computer models (Drift Calculator, PRZM-3², MACRO³ and TOXSWA⁴), which calculate surface water contamination under specific soil, climatic and crop parameters.

The Commission has not formulated questions on the document and accordingly requested the SCP to make an overall assessment of the document

C. OPINION OF THE COMMITTEE

Opinion:

The Scientific Committee on Plants welcomes this report and sees it as a significant step forward in risk assessment process.

The Committee supports and endorses the overall conclusions and recommendations. However, the Committee recommends that the following four issues should be addressed:

- (1) The proportion of agricultural land represented by each scenario in isolation should be clarified.**
- (2) An estimate should be provided of the combined effect of the various uncertainties affecting the model outputs.**

1 PEC : Predicted Environmental Concentration

2 Pesticide Root Zone Model, revision 3

3 Macropore flow model

4 TOXic substances in Surface WAters

- (3) All three steps of the tiered process should be completed in every assessment until more experience is gained.**
- (4) The reference to the potential for Annex I listing based on passing one scenario needs to be justified.**

The SCP proposes that this stepped approach is adopted as soon as possible by the Commission, provided adequate resources and technical support are in place for its implementation. The SCP also recommends the Commission to consider the wider implications of this work and associated research needs, which have not been fully addressed by the FOCUS Steering Committee.

A. TITLE

OPINION OF THE SCIENTIFIC COMMITTEE ON PLANTS REGARDING THE EVALUATION OF A DOCUMENT CONCERNING THE FOCUS SURFACE WATER SCENARIOS IN THE CONTEXT OF COUNCIL DIRECTIVE 91/414/EEC

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C. 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 development of standardised modelling methodologies 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. In their introductory report, the FOCUS Steering Committee mentioned the need for guidance on the first estimates of Predicted Environmental Concentrations (PECs) required by Annex VI of the Directive 91/414/EEC⁵ using mathematical models. These estimates would be used to assess the potential movement of active substances and their metabolites to surface water, 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.

To answer this need, three working groups were established which subsequently published guidance documents dealing with:

- Leaching Models and EU Registration (FOCUS, 1995⁶);
- Soil Persistence Models and EU Registration (FOCUS, 1997⁷)
- Surface Water Models and EU Registration of Plant Protection Products (FOCUS, 1997⁸)

The guidance document on Surface Water Models included three important recommendations:

- In order to develop typical scenarios for surface water fate modelling including inputs from spray drift, drainage and run-off within the EU and to subsequently assess the distribution of

⁵ OJ L 230, 19. 08.1991, p.1

⁶ Final report of the work of the Regulatory Modelling Working Group of FOCUS, 1995, (4952/VI/95 of June 1995, http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkd/doc/focus/gw_en.pdf)

⁷ Final report of the work of the Soil Modeling Work group of FOCUS (29 February 1997, http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkd/doc/focus/soil_en.pdf)

⁸ Final report of the work of the Regulatory Modelling Working Group on Surface Water Models of FOCUS, 1997, (SANCO/6476/VI/96 of 24 February 1997; http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkd/doc/focus/sw_en.pdf)

‘worst case scenarios’ following use of a plant protection product the development of appropriate EU databases of aquatic environments adjacent to agricultural land, soil types, topography, crops and climate are needed.

- Whilst standard scenarios are not available for the assessment of PECs in surface water and sediment, it is recommended that all model calculations make careful and reasoned consideration of the definition of the scenario(s). Justification for all selections must be made.
- Standard scenarios for the European Union should be developed.

Based on these recommendations, the Steering Committee established, in 1996, a FOCUS Working Group on Surface Water Scenarios. Its remit was to develop a series of standard agriculturally relevant scenarios for the European Union that could be used with the predictive models to fulfil the requirements for calculating PECs for surface water. A similar recommendation arising from the Leaching Models report (FOCUS 1995) led to the establishment of a working group to produce agriculturally relevant scenarios for predicting the risk of leaching to Groundwater. The resulting report (FOCUS, 2000) was reviewed by the Scientific Committee on Plants and an opinion published (SCP/GUIDE-FOC-GW/002-Final⁹).

The FOCUS Surface Water Group has now prepared a document (FOCUS, 2002) which recommends the adoption of a step by step procedure for the calculation of PEC_{sw}. The procedure proposes 4 steps:

- the first step being a very simple approach using simple kinetics and a maximum application loading – ‘an extreme worst case loading’
- the second step assumes surface water loading based on sequential application patterns taking into account the degradation of the substance between successive applications
- in the third step more sophisticated modelling estimations of exposure are undertaken using a set of 10 scenarios defined and characterised by the working group and representing ‘realistic worst case’ situations for surface water within Europe. The scenarios consider the target crop, hydrological situation, different surface water bodies, field topography, climatic, soil and management regime.
- the fourth more complex step proposes a higher tier exposure assessment, which is developed by a number of refinement options such as specific and realistic combinations of soil, weather, field topography and aquatic bodies adjacent to fields.

The SCP was requested to evaluate and comment on the FOCUS surface water scenarios document.

In order to prepare its opinion the Scientific Committee on Plants had access to the documents listed below. The Committee was represented at FOCUS surface water workshop of 18/19 February 2002 where the draft report was presented to Member State regulatory specialists and key issues were discussed.

Source documents made available to the Committee:

1. FOCUS Surface Water Scenarios: Terms of Reference, submitted by DG Health and Consumer Protection, 2002 (SCP/GUIDE-FOC-SW/001).

⁹ http://europa.eu.int/comm/food/fs/sc/scp/out75_ppp_en.pdf

2. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, including appendices A-I and K, final draft 6 June 2002, submitted by DG Health and Consumer Protection 2002 (SANCO/4802/2001-rev. 1 of June 2002).
3. FOCUS Surface Water Scenarios, consolidated comments of MS and ECPA and respective reactions, parts 1-3, submitted by DG Health and Consumer Protection 2002 (SCP/GUIDE-FOC-SW/003).
4. FOCUS Surface Water Scenarios, comments of SCP and respective reactions, submitted by DG Health and Consumer Protection 2002 (SCP/GUIDE-FOC-SW/004).
5. Surface Water Models and EU Registration of Plant Protection Products, Final report of the work of the Regulatory Modelling Working Group on Surface Water Models of FOCUS, 1997, submitted by DG Health and Consumer Protection 2002 (SANCO/6476/VI/96 of 24 February 1997).

D. SCIENTIFIC BACKGROUND ON WHICH THE OPINION IS BASED

Opinion:

The Scientific Committee on Plants welcomes this report and sees it as a significant step forward in risk assessment process.

The Committee supports and endorses the overall conclusions and recommendations. However, the Committee recommends that the following four issues should be addressed:

- (1) The proportion of agricultural land represented by each scenario in isolation should be clarified.**
- (2) An estimate should be provided of the combined effect of the various uncertainties affecting the model outputs.**
- (3) All three steps of the tiered process should be completed in every assessment until more experience is gained.**
- (4) The reference to the potential for Annex I listing based on passing one scenario needs to be justified.**

The SCP proposes that this stepped approach is adopted as soon as possible by the Commission, provided adequate resources and technical support are in place for its implementation. The SCP also recommends the Commission to consider the wider implications of this work and associated research needs, which have not been fully addressed by the FOCUS Steering Committee.

Scientific background on which the opinion is based:

General comment

The SCP acknowledges the significant expertise that has contributed to the development of this report. In order for it to be fully effective in its implementation the SCP believes adequate resources and technical support must be in place prior to its adoption. Recommendations are listed below:

- A mechanism should be set up for the dissemination of the report and the model software, version control of the models, supporting documentation 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
- Ensuring models and their shells have adequate, ongoing expert technical support to ensure queries /problems are resolved efficiently and in a satisfactory manner.

The SCP also recommends that continued efforts are made to develop model capability/performance and approved updates are incorporated into the Step 1 to 3 methodology. The work has served to emphasise the need to characterise the aquatic landscape more fully if higher tier assessments or Step 4 assessments are to be made. In many cases the databases do not exist and the contribution of the key parameters which influence / mitigate the PECsw may not be known. The SCP welcomes the establishment of a FOCUS Landscape Ecology and Mitigation group (FOCUS 2002) which will provide guidance (anticipated early 2004) on many of the issues raised, including the need for access to local and regional sources of information.

Specific comments:

Foreword

The foreword to the document states that ‘passing one of the surface water scenarios would be sufficient to achieve Annex I listing within the framework of 91/414/EEC’. This should be justified, taking account of:

- (a) what proportion of the EU agriculture would be protected by a single scenario (see also comments below concerning section 3.5),
- (b) the likely accuracy of the model predictions (see comments below concerning Chapter 8),
- (c) the margin of safety provided by the ecotoxicological evaluation.

Chapter 3: Identification of step 3 scenarios

- The process of developing ‘standard scenarios’ required that many factors needed to be taken into account to derive the representative scenarios presented. It is acknowledged that not all the necessary data were available and expert judgement was required in many cases. Chapter 3 now provides a detailed summary of how the scenarios were selected and characterises their location and relevance. Tables 3.5-4 and 3.5-5 provide very useful information but they are difficult to interpret and may be misleading. A number of issues remain:
 - Figure 3.5-3 assesses the relevance of all of the ten surface water scenarios to EU agriculture, but the relevance of each, in isolation, is not considered.
 - The results that are quoted regarding the percentage of agricultural land represented by the scenarios are derived from the right hand column of Tables 3.5-4 and 3.5-5. However, it appears that the percentages given for some scenarios (e.g. D2) are contingent upon other scenarios having passed. Therefore, these percentages are not valid for individual scenarios. The SCP suggests a look up table should be included to summarise the percentage of agricultural land represented by each scenario in isolation.
 - Note that there are 2 consecutive figures with number 3.5-2.
- FOCUS has identified that there continues to be difficulty in accessing or establishing databases on cropping, water features, climate and soils/geology in the EU using a scale which is sufficiently sensitive for the resolution of environmental issues. The SCP is aware that the FOCUS group on Landscape Ecology and Mitigation will need to address these issues and supports the need for a work programme which will feedback to the FOCUS Steering Group and ultimately provide additional guidance for Step 4 assessments.

Chapter 4 : Characterisation of the scenarios

- Table ES1 includes organic matter contents for the soil types. Table 4.3.1-1 has the same data but is labelled as organic carbon. ES1 should be corrected.
- The SCP believes that upstream uses of plant protection products for the ditch scenario should be included to complete the risk assessment. Member States need to be aware of the potential underestimate of excluding ‘upstream’ applications, particularly when some plant protection products can have widespread use within a catchment. The FOCUS Landscape Ecology and Mitigation could consider the characteristics of a plant protection product application with respect to areas treated and their proximity to watercourses.

- In order to reduce the number of model runs FOCUS selected the 50th percentile hydrological year for each scenario according to annual rainfall totals and assumed a winter wheat crop. For runoff scenarios, hydrological flows vary greatly with the season and three different 50th percentile hydrological years were selected for the spring, summer or autumn seasons. However drainage like runoff, particularly in some scenarios, can be very event driven. Yet, in contrast to runoff, the scenarios do not take this seasonal variability into account. The uncertainty associated with the seasonal distribution of effective rainfall relative to the selection of the 50th percentile year for drainage predictions needs to be explained.

Chapter 6 : Test runs using the scenarios and tools

- The Step assessments are now refined such that for all test compounds the Step 2 PEC is always lower than for Step 1. However it was found that in limited cases, for certain test compounds, Step 3 PECs can be higher than for Step 2. Regulators should be aware as applicants may avoid refinements of the modelling process in preference of more favourable data. All 3 steps should be carried out until there is confidence in the overall process.
- The SCP recommends that the FOCUS Steering Group should evaluate the on-going performance of the surface water modelling process as it becomes integrated into the regulatory process.
- Section 6.4 provides a comprehensive summary of empirical data but it does not make it clear how well these data agree with the models with the exception of a few specific instances, e.g. the finding reported in section 6.4.2 that PRZM predictions for individual run-off events were typically within one order of magnitude of associated field measurements.
- TOXSWA PEC's have not been compared against any field monitoring data. Data sets are available and therefore the SCP recommends that validation of the model needs to be an urgent priority.

Chapter 8 : Uncertainty issues

- Chapter 8 offers a detailed discussion of the uncertainties affecting many aspects of the approach. It includes a simple form of sensitivity analysis in Tables 8.7.4-1 and 8.4.7-2, in which the effect of particular changes in various parameters are shown when they are altered one at a time. However, it is not clear how the changes in the Tables relate to the full range of uncertainty in each parameter, so it is not clear if the effects shown are worst case. Spray drift, a key source of uncertainty, is not included in Table 8.7.4-1 (see below)
- The uncertainty associated with the characterisation of spray drift, particularly that associated with different crops is of concern since this is a key pathway of pesticide movement to surface water. The SCP recommends that support is given to the ISO working group which has been established to standardise methods for measuring drift deposition and drift reduction. Once this guidance is available further monitoring studies should be carried out to provide reliable spray drift data.
- The development of standardised test methods will not remove the need to take account of local variation in agricultural practice. For example, the difference identified between German and Dutch spray drift data introduces considerable uncertainty, implying that models could underestimate drift by a factor of 5 due to variation in nozzle type and boom height.
- The derivation of the factor 3 applied to the ditch scenario to account for upstream treatment should be explained and justified.
- It would be helpful if the concluding section of chapter 8 provided a clearer indication of the overall effect of the uncertainties on the accuracy and precision of models outputs, even if this were very approximate. For example, the various indications regarding uncertainty in the model outputs could be drawn together. First, PRZM output differ from field

measurements by up to one order of magnitude, as already mentioned (section 6.4). Second, several of the uncertainties explored in Tables 8.7.4-1 and 8.7.4-2 could generate PEC increases in the region 2-4x. Third, there is the 5x uncertainty regarding spray drift, already mentioned. Taken together, these points would suggest that the overall uncertainty in the model output could be at least one order of magnitude.

Future considerations

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

- It is likely that there will be differences in the interpretation of the stepwise predictions and these will become important when concentrations are close to ecotoxicological end-points. The SCP recommends that there needs to be transparency of procedures concerning procedures to interpret the pass/fail criteria for the scenarios, especially for higher tier assessments. There may be lack of consensus between Member States in a number of situations, for example:
 - when a crop is only represented by a single scenario, e.g. cotton, whether additional factors need to be considered,
 - whether one 'safe use', as demonstrated by the modelling procedure, is sufficient to achieve Annex I listing.
 - when an active substance or its metabolites only marginally fail or pass the TER criteria or other ecotoxicological endpoints.
- Guidance needs to be provided on how relevant additional information, e.g. surface water monitoring at the field or catchment scale should be assessed in conjunction with the modelling data.

As research/reviews lead to an improved understanding of the pathways, processes and management practices which influence the fate of a pesticide, it will be important for the Commission to ensure that there is a mechanism to take account of the information for improved model development and parameterisation. This should, for example, include the recommendations of the FOCUS degradation kinetics group.

E. REFERENCES

FOCUS (1997) Surface Water Models and EU Registration of Plant Protection Products. European Commission Document SANCO/6476/VI/96

FOCUS (2000) FOCUS Groundwater Scenarios in the EU Plant Protection Product Review Process. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000, 197pp.

FOCUS (2001) FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 Draft version 21 December 2001, 168pp.

FOCUS (2002) Project Definition For The Focus Work Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document reference SANCO/10571/2002 rev 2 of 25 June 2002.

Opinion of the Scientific Committee on Plants regarding the evaluation of a document concerning the focus groundwater scenarios in the EU registration process, adopted by the Scientific Committee on Plants on 22 September 2000 (SCP/GUIDE-FOC-GW/002-Final).

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