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NEW DEVELOPMENTS IN ENVIRONMENTAL EXPOSURE ASSESSMENT IN THE EU PESTICIDE REGULATORY PROCESS

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The paper discusses key aspects of the European Union (EU) regulatory policy for environmental exposure assessment of agricultural pesticide active substances (a.s.) in soil and water, which is examined in the context of the EU Authorisations Directive (91/414/EEC). For agricultural pesticide regulation within EU Member States (MS), the Authorisations Directive will gradually replace existing national systems. Discussion is concentrated on this directive, looking in particular at the Uniform Principles therein and the possible ways that these decision-making guidelines are being developed into a workable regulatory framework. The aim in this process of negotiated development involving the Member States, the Agrochemical Industry and the European Commission (EC), is to identify any questions or data requirements that will be needed for agricultural pesticides.

Keywords: Agricultural pesticide; European regulation; Environmental exposure assessment

INTRODUCTION

This paper is intended to provide some European regulatory background on the current initiatives for development of procedures for environmental exposure assessment in soil and water for agricultural pesticides. The paper will discuss key aspects of the European Union (EU) regulatory policy for agricultural pesticide active substances (a.s.), which will be examined in the context of the EU Authorisations Directive (91/414/EEC) [1]. Discussion will be concentrated on this directive, looking in particular at the Uniform Principles therein [2] and the possible ways that these decision-making guidelines are being developed into a regulatory framework.

For agricultural pesticide regulation within EU Member States (MS), the Authorisations Directive will gradually replace existing national systems and in this directive, contrast is made between trigger values for performing different types of study in the data requirements in Annexes II and III [3], and the Uniform Principles for decision-making in Annex VI [2]. In certain cases the decision-making criteria in

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the Uniform Principles represent only a basic statement of regulatory intent, which then requires further interpretation before it can be used for final decision-making for individual pesticides within the EU. It is worth emphasizing that this represents regulation by risk assessment and possible effects, rather than use of cut-off values or similar schemes.

In the past 10 years, discussions and meetings between MS, the European Commission (EC) and industry have taken place in order to progress the issue of regulation beyond the present position given in the Uniform Principles of Directive 91/414 in order to develop a workable system of regulatory decision-making, involving the preparation of EU guidance documents on a number of key subjects. Certain of these guidance documents have recently been finalised and issued by the EC – Terrestrial Ecotoxicology [4], Aquatic Ecotoxicology [5] and Soil Persistence [6]. Other guidance documents are in preparation – e.g. Assessment of Relevant Metabolites [7].

CURRENT INITIATIVES AND DEVELOPMENTS

Environmental Fate/Exposure Assessment

As part of the EU regulatory assessment process for agricultural pesticides, the predicted environmental concentration (PEC) is calculated for each intended field use of the pesticide, both for the a.s. and for any breakdown products or metabolites. The EU Authorisations Directive recognises five distinct PEC, as follows:

PEC_{soil} – used for comparison against ecotoxicological data for risk assessment;
PEC_{gw} – used for assessment against the EU drinking water standard of 0.1 µg/l;
PEC_{sw} – used for comparison against ecotoxicological data for risk assessment;
PEC_{sed} – used for comparison against ecotoxicological data for risk assessment;
PEC_{air} – no guidance available at present.

(*Note:* gw = groundwater, sw = surface water, sed = sediment).

All of the standard assumptions used to calculate these PEC are very precautionary and tend to over-estimate the likely exposure concentrations in the various environmental compartments. It should be realised that the (1st tier) exposure estimates and PEC calculations do not necessarily represent reality. The EU environmental exposure assessment and PEC methodology is a regulatory decision-making tool only, produced in an agreed way in all EU MS for all agricultural pesticides.

One of the key features of the PEC methodology is the use of computerised simulation modelling of environmental exposure concentrations, particularly in the soil, groundwater and surface water/sediment compartments.

A UK guidance document on computerised environmental fate and exposure modelling is available [8], which can be obtained from the PSD web-site.

FOCUS

FOCUS is the acronym for “FORum for the Co-ordination of pesticide environmental fate models and their USE” and is an initiative organised under the auspices of the EC. The various FOCUS technical work groups are multi-disciplinary and consist of experts in computerised modelling, industry scientists, government regulators, independent researchers and representatives of the EC. The work groups recommend suitable com-

puter models to use and have also developed standard environmental exposure scenarios which represent various relevant combinations of soil/crop/climate parameters for agriculture in the EU.

FOCUS work groups have been formed to deal with the key environmental compartments of soil, groundwater and surface water/sediment. The EU MS fully support and actively participate in all the EU FOCUS initiatives and FOCUS groundwater and surface water/sediment scenarios and models will be used by EU MS as the basis for regulatory environmental exposure assessment. The FOCUS groundwater report was issued in December 2000 [9] and is now in full use. The FOCUS surface water/sediment report is currently in preparation with a first draft issued at end-2001. The FOCUS Mediterranean-rice group report is also in preparation, again with a first draft issued at end-2001. A FOCUS web-site has been established at the Joint Research Centre of the EC at Ispra in Italy to help co-ordinate activities and act as a help-line for regulatory users in industry and government across the EU.

Ideas have been put forward for possible future FOCUS workgroups, as follows:

- degradation/dissipation kinetics to assist in the calculation of the various degradation rate parameters used as input data for environmental exposure modelling and to update the persistence guidance document [6].
- PEC in air (as required by the EU Authorisations Directive, but not yet developed).
- mitigation and landscape-level factors (to assist in performing MS differentiated risk assessments and defining suitable risk mitigation measures).

Groundwater

For pesticide a.s. and all laboratory soil major metabolites (occurring at > 10% of applied a.s.), the regulatory applicant company must submit data that enable estimates of soil degradation and sorption to be made. For use as input data to groundwater leaching models, degradation rate estimates based on first order kinetics are definitely preferred by EU MS (even if other curve fitting approaches better describe the decline). If using field dissipation rates as pesticide modelling input parameters, the applicant must make sure that the model is set so processes such as volatilisation and photolysis are not double counted [10]. The FOCUS groundwater scenarios [9] should be used by the applicant for all EU first tier groundwater assessments. Other scenarios or model settings will be accepted but will be considered higher tier.

For local regulatory groundwater assessments in the UK, associated with applications for product approval, the UK government expert committee has agreed in principle to the use of the following FOCUS groundwater scenarios for 1st tier assessments in the UK – Chateaudun, Hamburg, Kremsmunster, Okehampton; with PEARL, PELMO and PRZM groundwater leaching models with FOCUS shells (see [9] for further details of models and scenarios) to support decisions on product approvals in the UK.

Further consideration is still needed on whether and how preferential flow should be included in the decision-making process for UK PEC in groundwater. At this time, the UK does not intend to develop its own groundwater modelling scenarios. This area of activity is still under development, but all proposals will be fully consulted with interested parties.

Surface Water and Sediment

PEC for surface water/sediment is required for all pesticide a.s. and major metabolites representing > 10% of the applied a.s in the water phase of the standard regulatory laboratory water/sediment study. The EU regulatory assessment procedure for environmental exposure of surface water/sediment recognises three potential routes of exposure, as follows:

- atmospheric spray drift;
- sub-surface drainflow or lateral flow;
- surface run-off or overland flow.

At the present time, for spray drift calculation, the EU MS use a harmonised procedure outlined in EU Guidance Document on Aquatic Ecotoxicology [5] and according to German data from Ganzelmeier *et al.* [11]. However, this procedure is now under revision and it is clear that the FOCUS surface water/sediment report when finalised will recommend that spray drift is calculated according to more recent data generated in Germany. In the past, sub-surface drainflow and surface run-off have been considered as MS issues in the EU procedure and these potential routes of pesticide contamination have been less well documented in regulatory terms. However, the forthcoming FOCUS report on surface water/sediment scenarios will help to harmonise this area by making proposals for standard exposure calculations for spray drift, drainflow and surface run-off. The initial draft report was available at end-2001.

A harmonised EU regulatory method for calculating the PEC in sediment is currently not available, and the FOCUS report is awaited to bring some order to this area. It is not actually a stated requirement of the Authorisations Directive, however a risk assessment to sediment dwelling organisms must be completed by the applicant. If accumulation in sediment from the proposed use is unlikely, then water spiking effects tests are appropriate and PEC_{sed} is not required. If spiked sediment effects tests are required, PEC_{sed} must also be calculated.

DISCUSSION

In addition to the development of EU guidance documents based on the Uniform Principles, the FOCUS environmental exposure modelling initiative is extremely important. The groundwater scenarios report was issued in December 2000 and a number of training workshops for MS and industry have already taken place. Work on the surface water scenarios is less advanced, but should be complete by end-2002.

The European Commission Co-Ordination (ECCO) peer review process, jointly organised by the EC, the German regulatory authority and the UK PSD has successfully brought together experts from all the MS and great progress in mutual understanding has been made in the area of environmental exposure assessment. The production of harmonised tables of environmental fate critical end-points and PEC values has been particularly beneficial in aiding decision-making between the MS.

We can now look forward to further increasing our understanding of the EU pesticide regulatory policy and process. In the area of environmental exposure assessment, we await with interest the finalisation of all the FOCUS modelling initiatives and the associated development of harmonised EU guidance for calculation of the various PEC values for soil, groundwater, surface water, sediment and air.

CONCLUSIONS

In the EU now we are bound by the Authorisations Directive for the regulation of agricultural pesticides, with its data requirements and decision-making schemes. However, the Uniform Principles, which are the expression of the decision-making schemes, only provide part of the answer. The remainder must be developed through mutual understanding and discussions amongst the EU MS, industry and the EC – helped by appropriate inputs from learned experts and members of the research community.

In this paper we have seen in the area of environmental exposure assessment, that computerised modelling is rapidly becoming more important in regulatory decision-making and has helped the harmonisation and mutual understanding process within the EU. The FOCUS initiatives are key developments, with the groundwater models and scenarios already in use and the surface water/sediment models and scenarios at a final development stage.

Disclaimer

The author emphasises that what is presented here is purely and simply his personal view and does not necessarily represent the view of any particular organisation.

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