Environmental modelling for risk assessment – Current state of the art and future challenges

The requirements for plant protection product registration under the Regulation 1107/2009/EC are changing constantly. As well as becoming more complex, they are leaning towards conservatism to ensure a higher likelihood of safety for humans and the environment. Modelling is one of the more stringent tools.

In a Scientific Opinion from 2014 dedicated to Good Modelling Practice (GMP), EFSA clearly indicated that sooner or later modelling will play a greater part in Environmental Risk Assessments (ERAs). This stance goes hand in hand with the willingness of the authorities to decrease both vertebrate and higher tier (field) testing which may be replaced and/or supported by modelling approaches due to the benefits of this approach.

This will likely impact an agro-chemical manufacturer in a variety of ways, for example, fish testing requirements may be reduced in the future if it can be demonstrated by non-testing alternatives such as Quantitative Structure–Activity Relationship (QSAR) models that the biological activity of a substance can be extrapolated from its chemical structure. Another example would be the inclusion of the landscape scale into standard risk assessment schemes as intended for non-target arthropods based on the current EFSA Scientific Opinion from 2015. Instead of performing field studies on landscape scale (which is very difficult to realize when considering, for example, replication), modelling of the landscape would be performed and combined with local scale field studies.

There is no doubt that the regulatory scientific community is focussing more on fate and effect modelling in countless workshops, conferences and academic publications, but the time frame for implementation of specific models into the ERA, apart from those that are already widely accepted (such as the FOCUS models), is still unclear. Fate modelling in general is already fairly advanced with regards to acceptance for ERA and we are now starting to see potential refinement options such as subnational registration approaches based on soil types. In contrast, effect modelling is still in its infancy; models are being developed but the standard implementation, especially for population- and ecosystem-models on local or landscape scale into the ERA, is pending. Reasons for this include the lack of data or the restricted access to valuable data from authorities to validate the already developed models and the need for determining specific protection goals for several organism groups. Also, authorities can be reluctant to accept models developed by industry (e.g. BEEHAVE) even while lacking capacity for in-house model development.

Although the establishment of a standardized application scheme may still be years away, the use of models is already widespread and will perhaps become a universal tool in ERA. This is why it is advisable to consider challenges at an early stage - manufacturers, consultants and authorities need to assess potential impacts and consequences as soon as possible. It may seem like an uphill struggle ‘but’ challenges connected with modelling can be broadly divided into different categories such as the process of model development (design, analysis, documentation and communication), implementation into ERA (modelling framework), utilization and interpretation by the user and acceptance of results by risk managers.

In the following table, some major challenges from each category are listed.

Table 1. Current and future challenges divided into the process, the implementation, the utilization/interpretation and the acceptance of models in ERA.

Category	Challenges
Process of model development	Clarification of the issue which shall be tackled by the model Consideration of parameters to be included Level of detail Scale (organism, population, landscape, …) Linkage between Specific Protection Goals (SPGs) and model output
Implementation into ERA	Validation of the model (e.g. by monitoring data) Need for a general framework
Utilization & Interpretation by user	User interface ('one-button-model' or understanding of the mechanism required?) Scope and restrictions of the model Interpretation of output (one value or detailed interpretation)
Acceptance of results by authorities	Harmonisation between member states Regional specificities (different parameters for different countries)

Unfortunately, modelling seems to be something that stakeholders are reluctant to engage with. This is surprising considering that models possess the ability to transform complex processes, which can be biological, physical or chemical, into simpler structures by only considering the relevant parameters for a specific issue – this can provide the user with valuable information which would be difficult, if not impossible, to be generated via experimental studies. As an example, to determine the concentrations of a substance in surface water after application of a plant protection product (PPP) without having FOCUS models it would be necessary to actually apply the PPP and afterwards measure the concentration in every single example of surface water in Europe.

This is of course not possible and this is where FOCUS models come into play. Measured weather data recorded in previous years from specific locations, representative for most of Europe are used to predict the environmental conditions at the intended time of PPP application and then combined with information on the soil properties of those locations and the measured environmental behaviour of the substance in water and soil (e.g. based on the half-life or sorption properties).

To allow the end-user (typically the risk assessors and decision makers) to understand the mechanisms behind the model as well as its scope and restrictions, it is crucial to establish some form of communication between developers of models, users and other stakeholders. Furthermore the practical implementation into ERA must be transparent and comprehensible for the final stakeholders such as manufacturers. Finally, the developers of the model require peer-review by other experts and also participatory modelling from end-users and final stakeholders. The EFSA Scientific Opinion on Good Modelling Practice (2014) is really useful guidance aiding the consistency and transparency in regard to reporting and explaining modelling approaches.

In summary, taking into account our considerations, the most urgent points to be tackled are:

- Determination of SPGs for all organism groups to establish models with quantitative output
- Validation of already existing models with available data/generation of required data
- Creation of an overall framework for implementation of models into ERA
- Establishment of a communication scheme
- Development of a harmonized guidance on interpretation of models

For nearly all of these points the authorities (EFSA and member states) are seen as the main lead institution, potentially accompanied by working groups from industry and academia. A sole applicant

cannot be expected to develop and integrate modelling approaches into ERA knowing the high levels of uncertainty in acceptance by regulatory bodies.

In conclusion, Eurofins fate and ecotox modellers recommend that applicants have this topic in mind and potentially start considering modelling approaches in their regulatory strategies, but, before relying on models in ERA, it may be advisable to have case-by-case discussions with the concerned member states.

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