Selecting mechanistic effect models for environmental risk assessment; the link with protection goals and test protocols

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1. Introduction

Environmental risk assessment is the process aiming to assess the impact of chemicals on the environment (or parts thereof). Virtually all risk assessment frameworks assess risks by combining the results from an exposure and an effects assessment. Estimation of exposure concentrations relies heavily on mechanistic fate models, and has done so for several decades already. On the effects side, in contrast, the focus lies on toxicity testing and descriptive statistical treatment of data. Mechanistic effect models do exist, however, and are gaining increasing interest in a regulatory context [1-3]. In 2014, EFSA has even come up with a scientific opinion on 'good modelling practice' for such mechanistic effect models [4]. A wide range of effect models exists at different levels of biological organisation (individual, population, community; see e.g., [5]). These models differ in their degree of complexity, in their underlying assumptions about the biological and toxicological reality, in their 'quality' (as assessed from a good-modelling perspective), and in their data requirements, making it almost impossible to see the wood for the trees.

The selection of the most appropriate models cannot be performed in isolation. A model that passes the requirements of a 'good-modelling evaluation' with flying colours is not necessarily the best to serve the needs of a risk assessment. Model selection is best viewed in conjunction with two other issues: the protection goals and the test protocols (Fig. 1). The protection goals, when explicitly formulated, will make it easy to select (or develop) useful models. And subsequently, the useful models should guide the most efficient design for toxicity testing. The other way around, the range of available models can provide options and guidance for the explicit definition of protection goals. We know what types of output can be delivered by the candidate models, and regulatory protection goals are most useful if they are defined in such a way that they match with a specific type of model output. Model selection, in turn, is constrained by what data can reasonably be obtained. A model that requires a herculean testing effort to parameterise for each compound will be useless in practice.

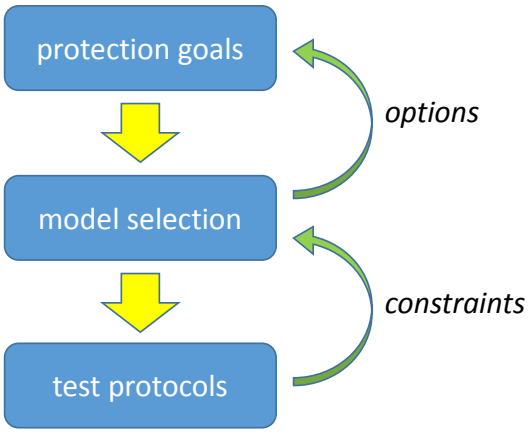

Figure 1. Model selection cannot be performed in isolation, but is determined by the definition of the protection goals. In turn, model selection should shape the test protocols. Thin arrows indicate that this is not purely a top-down control: the range of available models can inform the definition of protection goals, and the testing possibilities constrain the range of useful models.

At this moment, the linkage between the three components in Figure 1 is rather chaotic. Protection goals defined in risk assessment regulations are too vague to be of much guidance (and certainly not for streamlining the effects assessment) [3]. Models are developed by modellers out of scientific interest or addressing (perceived) needs of regulators. Test protocols are designed to deliver data for descriptive non-mechanistic methods (mainly to derive an NOEC or ECx), and are generally quite useless to support parameterisation of mechanistic models. For these reasons, environmental risk assessments needs a more ambitious agenda to redesign the effects assessment, and that requires an integrated evaluation of the three main issues (Fig. 1).

2. Relevant types of protection goals

If protection goals would be formulated in a specific way, the most relevant models will automatically follow from them (or at least it will properly prune the range of candidate models). At this point, I think it is useful to distinguish four broad categories of protection goals at different levels of biological organisation:

1. Protecting properties of individuals (e.g., health or survival).
2. Protecting intrinsic health of populations (i.e., population growth rate).
3. Protecting populations under more realistic conditions (e.g., density dependence and time-varying exposure or food levels).
4. Protecting food chains or communities (i.e., include interaction between species).

Different risk assessment frameworks will make a different choice from this list. Clearly, Type 1 is applicable to human health and the risk assessment for endangered species. However, for plant protection products, individual survival may also be of interest: in an agricultural area, one might accept (temporary) health effects on a species as long as there is no (overt) mortality. Type 2 in fact also focusses on properties of individuals, but only insofar as they affect the population growth rate. This implies a focus on the effects on survival and reproduction, weighed over time: effects early in life impact population growth more than effects later in life. Type 3 includes more ecological realism into the population effects. For example, it may include elements of 'density dependence' where population growth is affected by the density of a population. Or it may include food availability as a time-varying factor (either autonomous or as a result of feeding by the target population), or spatial aspects (e.g., including the details of a landscape). Type 4 goes a step further and explicitly considers multiple species interacting with each other (perhaps also in a landscape).

It should be stressed that including more ecological realism is not necessarily going to improve a risk assessment. As more choices and assumptions need to be made, the data needs and uncertainty increases as well. Furthermore, focussing on one particular realistic scenario may imply that other realistic scenarios are overlooked. For example, the impact of a chemical stress may work out differently when a population is regulated by limiting food availability or by predation.

3. Conclusions

Model selection cannot be performed by only considering the 'quality' of the models. Even though 'good modelling practice' provides sensible guidelines for modellers and users of models, we should not forget that the current procedures for effects assessment are in almost complete violation of these guidelines. Furthermore, the fate models that have been so successfully applied in risk assessment for decades often leave much to be desired in this department as well. Instead of focussing too hard on model 'quality', we need to consider that the task of model selection (or development of novel models) is intricately linked to the regulatory protection goals and to the process of designing test protocols. In this contribution, I will provide several example cases to demonstrate how these linkages might work out. I hope that this contribution can help to streamline the fruitful integration of mechanistic modelling into a regulatory setting.

4. References

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