

Appendix B: Summary checklist for model evaluation by the risk assessor

Appendix to: EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues); 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 93 pp. doi:10.2903/j.efsa.2014.3589

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This checklist aims to help the risk assessor conduct a comprehensive evaluation of the model to be used as support for risk assessment. The checklist follows the evaluation process as described in section 10 (see Figure 13 for an overview of this process). The risk assessors should base their evaluation on documentation provided by the modeller. Each question can be answered with “Yes” or “No”. It is recommended that a justification for each answer be provided. It is acknowledged that not all the points have a similar weight for decision-making.

ASPECT OF THE MODEL TO BE EVALUATED BY THE RISK ASSESSOR		Yes	No
1. Evaluation of the problem definition			
The problem definition needs to explain how the modelling fits into the risk assessment and how it can be used to address the specific protection goals (section 4). Please check if due attention is paid to:			
(a)	The available knowledge and data relevant to the risk assessment question		
(b)	The regulatory context in which the model is run		
(c)	The question that has to be answered with the model		
(d)	The outputs required to answer these questions including performance criteria for the regulatory model		
(e)	The species to be modelled (use the checklist in section 5.3)		
(f)	Requirements for the environmental scenarios to be used in the risk assessment		
2. Evaluation of the supporting data			
The supporting data should be of sufficient quality and be relevant to the risk assessment problem. Please check the following items (see section 10.1 for explanation and section 3 for background information):			
(a)	Are the data fit for purpose in view of the problem definition?		
(b)	Has the quality of the data used been considered and documented?		
(c)	Have all available data been used? If not, is there a justification why this information has not been used?		
3. Evaluation of the conceptual model			
The conceptual model provides a general and quality description of the system to be modelled. Please check the following items (see section 10.2 for details and section 6 for background information):			
(a)	Are the specific protection goals sufficiently well addressed by the model?		
(b)	Are the modelling endpoints relevant to the specific protection goal?		
(c)	Is the modelling approach justified?		
(d)	Is the conceptual model logical?		
(e)	Are the processes included in the model relevant to the addressed issue?		
(f)	Are the links between different processes to the variables logical?		

(g)	Are the temporal and spatial scales relevant in regard to the problem definition?		
4. Evaluation of the formal model			
The formal model contains the equations and algorithms to be used in the model. Please check the following items (see section 10.3 for details and section 7.1 for background information):			
(a)	Are the most important model assumptions justified by the modeller?		
(b)	Are the most important mathematical equations described?		
(c)	Is there a description of the variables and parameters including their meaning and unit?		
(d)	Is a justification provided if the complexity of the model is appropriate in view of the problem formulation and the available data?		
(e)	Are references supporting the equations been provided?		
5. Evaluation of the computer model			
The next step is to convert the formal model into a model that can run on a computer (the computer model). Please check the following items (see section 10.4 for details and section 7.2 for background information):			
(a)	Is there a comprehensive and transparent description of the computer model?		
(b)	Is the computer code well readable and is it available?		
(c)	Is it demonstrated that the mathematical model is correctly implemented (model verification)? The following items could be checked: – Has the model been compared with a benchmark? – Has the internal consistency of the model results been checked and reported? – Has a reality check been carried out?		
6. Evaluation of the regulatory model—the environmental scenario			
The environmental scenarios determines the environmental context in which the model is run. The scenario determines the conservatism of the scenario and should therefore be thoroughly evaluated (see section 10.5.1 for explanation and section 8.2 for background information). Please check the following items:			
(a)	Is the scenario representative for the risk assessment under consideration?		
(b)	Has the modeller justified the general biological, abiotic and environmental parameters that constitute the scenario?		
(c)	Has the modeller ensured that the scenario covers the most relevant exposure pathways for the area under consideration?		
(d)	Is the level of conservatism placed into the scenarios appropriate? The level of conservatism is to a large extent determined by the spatio-temporal dimensions of the protection—see point (iv) in section 10.5.1.		
7. Evaluation of the regulatory model –parameter estimation			
Parameter estimation is a crucial step since it determines the behaviour of the regulatory model and hence its applicability for regulatory assessments. Please check the following items (see section 10.5.2 for explanation and section 8 for background information):			
(a)	The model parameter estimation has been adequately documented?		
(b)	Was the quality of the data supporting parameter estimation (literature or experiment) sufficient?		
(c)	Were the estimated parameter values realistic?		
(d)	Are the data sources sufficiently documented?		
8. Evaluation of the sensitivity and uncertainty analysis			
Sensitivity analysis identifies subsets of parameters that have a strong effect on the model outputs. Uncertainty analysis aims at identifying how uncertain the model output is. Please check the following items (see section 10.6.1 for explanation and section 9 for background information):			
(a)	Has the sensitivity analysis been adequately documented?		
(b)	Is the sensitivity analysis applicable to the situations identified in the problem formulation?		

(c)	Have the results of the sensitivity analysis been presented so that they allow identifying the most sensitive parameters?		
(d)	Has the uncertainty analysis been adequately documented?		
(e)	Is the uncertainty analysis applicable to the situations identified in the problem formulation?		
(f)	Have the results of the uncertainty analysis been presented so that they allow identifying the most uncertain parameters?		
(g)	Uncertainty is propagated to the model results?		
(h)	Have confidence intervals been estimated and has this information been used in further model use?		
<p>9. Evaluation of the model by comparison with data from independent measurements The performance of the model is usually evaluated by comparing relevant model outputs with measurements. Please check the following items (see section 10.6.2 for explanation and section 9.3 for details):</p>			
(a)	Have the performance criteria for the model been predefined in the problem definition?		
(b)	Are the model outputs that are compared relevant in view of the problem definition?		
(c)	Have the data with which the model is compared been subjected to quality control and is a description of the data available?		
(d)	Is the dataset relevant in view of the problem definition?		
(e)	Is the fit of model output to the data good enough?		
(f)	Has the performance of the model been reported in an objective and reproducible way?		
<p>10. Evaluation of model use When using a model for regulatory purposes, the risk assessor needs to input the pesticide properties and the application regime of these pesticides. In this stage, it is important that the model is well documented and that it is clear how the model works. Please check the following items (see section 10.6.2 for explanation and section 9.3 for details):</p>			
(a)	Is a user manual available? The user manual should contain at least the items described in section 10.7.		
(b)	Have all aspects of the modelling cycle been documented? The documentation should contain at least the items described in section 11.2.		
(c)	Has a summary sheet been provided by the modeller? The summary sheet should provide quick access to the comprehensive documentation (see section 11.3).		
(d)	When applicable—is the regulatory assessment described? Please check the following: <ul style="list-style-type: none"> – Have the pesticide properties been obtained in a justifiable way? – Have commonly agreed standards been used? – Do the application patterns/regimes reflect good agricultural practice? – Is a baseline assessment available? – When applicable, have appropriate assessment factors been used? 		
(e)	Have appropriate conclusions been derived from the risk assessment? Section 12.3 and Appendix B are intended to help the risk assessor in decision-making.		
<p>11. Evaluation of the suitability of the model for regulatory purposes Once a model has been used for regulatory purposes, an evaluation of the suitability of the model for regulatory purposes needs to be carried out. This can lead to recommendations for model improvement. Please check the following items (see sections 12.4 and 12.5):</p>			
(a)	Is there a possibility for dialogue between the modeller and the risk assessor? The items described in section 12.4 could facilitate this process.		
(b)	Is a version control system implemented? See section 12.5 for details.		
<p>12. Overall judgement Based on the results of the checklist, the evaluator could give an overall judgement of the suitability of the model for regulatory purposes. The number of questions answered with “yes” and “no” could be taken in consideration when giving this overall judgement. It is, however, difficult to give a general indication of the</p>			

number of negative answers that are considered acceptable since not all questions have equal weight.			
(a)	Overall, is the modelling judged suitable for regulatory purposes? Please provide a justification for this overall assessment.		