



Proposed risk assessment methodology for hazardous substances

Please submit your comments to submissions@epa.govt.nz on this form in Word document format or use the on-line submission form at www.epa.govt.nz

Feedback on	Proposed risk assessment methodology for hazardous substances
Name (optional)	
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Proposals and submission form

The EPA is seeking your views as interested parties on the proposals presented in the *Assessing the Risks of Hazardous Substances* and *Risk Assessment Methodology for Hazardous Substances* documents. The EPA is consulting you to be transparent in how we do things as a proactive regulator, and as part of our Customer Centricity themes *Keep me informed*, *Engage with me* and *Be helpful & treat me fairly*.

Please use this form to provide your written feedback and send it to submissions@epa.govt.nz in Word document format no later than 5pm on Friday 6 July 2018. Alternatively, you can use the online submission form on the EPA website at www.epa.govt.nz

The consultation document poses a series of questions that we would like your feedback on. Your response to the questions in the table below are welcomed. You may focus on the questions that are relevant to you, as you are not required to answer all of them.

When providing your comments, please provide your rationale and any additional information you consider is relevant. This information will help us more fully understand the effects the proposed methodology will be likely to have if introduced as currently proposed.

Your feedback is important as it will enable the EPA to make more informed decisions on the final content of the proposed methodology. Please take this opportunity to have your say.

Feedback may be made publicly available

The Environmental Protection Authority (EPA) may publish all or part of your feedback on its website at www.epa.govt.nz. Providing feedback implies that you consent to such publication, unless you clearly specify otherwise in your feedback.

Privacy

The Privacy Act 1993 establishes certain principles with respect to the collection, use, and disclosure of information about individuals by various agencies, including the EPA. Any personal information you supply in the course of making a submission will be used only in conjunction with the matters covered by this document. We may also use your contact details for the purpose of requesting your participation in customer surveys. You may request that your personal information (other than your name) be withheld from publicly available information.

Disclaimer

This document does not alter the laws of New Zealand. The EPA does not accept any responsibility or liability to any person, whether in contract, equity or tort, or any other legal principle, for any direct or indirect losses or damage arising from reliance on the contents of this document.

For the “Assessing the Risks of Hazardous Substances” summary document:

Question number	Question	Page number	Your comments/notes and rationale
1	Is the level of detail appropriate?		
2	Are there any areas that you would like more information on?		

For the main text of the “Risk Assessment Methodology for Hazardous Substances” document:

Question number	Question	Page number	Your comments/notes and rationale
3	Is the level of detail appropriate?		
4	Are the technical aspects correct?		
5	Are there any areas that need more guidance?		
6	Are there any other matters that should be addressed as part of this methodology?		

For the technical appendices of the “Risk Assessment Methodology for Hazardous Substances” document:

Question number	Question	Page number	Your comments/notes and rationale
7	Are there alternative groundwater models that the EPA could consider as part of a revised groundwater risk assessment framework?		
8	Is the level of detail appropriate?		
9	Are the technical aspects correct?	page 42 B 4.8.	EPA: “A number of parameter values from the 2014 EFSA operator, worker, resident and bystander exposure model (EFSA, 2014) are used as they are more recently available. This model is not currently used because of concerns over the applicability of the assessment of bystanders from aerial applications to the use patterns in New Zealand.” This statement does not give a sufficient argumentation why the EFSA model is not used because neither the AOEM nor the UK version of the BBA model include any recommendations for calculating operator or bystander exposure during aerial applications.
		page 44 B 5.3.	EPA states that a default foliar half life of 10 days can be used according to EFSA 2014. However, EFSA 2014 proposes to use a default foliar half life of 30 days. The default proposal of US EPA is a 10% dissipation of foliar residues per day. A default foliar half-life of 10 days is proposed by FOCUS 2003 (as stated in Table B.5).
10	Are the requirements practical and achievable?	96	<p>The 0.1µg/l limit for pesticides/relevant metabolites is arbitrary and not risk-based as implied by the section header (“Risk”). It is highly recommended to follow a scientifically, health-based approach for deriving thresholds in groundwater. The WHO proposes such a reasonable approach (http://www.who.int/water_sanitation_health/publications/2011/dwg_guidelines/en/). For pesticides it is suggested to calculate a guideline value (GV) that should not be exceeded in groundwater (drinking water):</p> $GV = \frac{ADI \times bw \times P}{C}$ <p>where: ADI: acceptable daily intake</p>

Question number	Question	Page number	Your comments/notes and rationale
			<p>bw = body weight (adult: 60 kg)</p> <p>P = fraction of the ADI allocated to drinking-water (20%)</p> <p>C = daily drinking-water consumption (adult: 2 l)</p> <p>The guideline value can in turn be compared to the result of the groundwater leaching model. If the predicted environmental concentration in groundwater is smaller than the GV, the health risk assessment for groundwater (drinking water) is successfully passed. Otherwise further refinement options or adjustment of the use pattern may be required.</p>
11	When used in conjunction with the external guidelines for each model, is any further clarification required to be able to perform a risk assessment?	page 39 B 4.2.	EPA does not give any recommendation how to calculate operator exposure for aerial applications. For estimating the exposure during aerial application, we recommend to follow the approach proposed by the US EPA. Dermal and inhalation unit exposures for mixing and loading from the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" can be applied (https://www.epa.gov/sites/production/files/2016-11/documents/handler-exposure-table-2016.pdf).
12	Are the parameter values used by the EPA relevant and correct?		
13	Are the models used by the EPA relevant and correct?	page 39 B 4.2.	EPA proposes to use the UK CRD version of the BBA Operator Exposure Model. However, in the past years, the AOEM was developed as the appropriate operator exposure model to be used in Europe. It includes state-of-the art application techniques and compared to the BBA model, is based on a more robust dataset. All other criteria listed on page 39 with regard to a suitable operator exposure model also apply to the AOEM. Therefore, we propose to use the AOEM rather than the BBA model for operator exposure calculation.
		page 47 B 6.2.	EPA recommends a combination of the EFSA model and the US EPA model for residential exposure to calculate exposure to bystanders after commercial pesticide use. However, in our opinion, combining different assumptions from different models does not seem very appropriate. We propose to follow the US approach for residential exposure. The US EPA Residential SOPs use the most reliable scientific data available. The potential risk estimates from residues depositing on surfaces can be calculated using drift modelling (AG Drift) for all application scenarios (aerial, groundboom, airblast) coupled with methods employed for residential risk

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			assessments for turf products (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide ; https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPP-2013-0676-0003&contentType=pdf)
14	Are there any alternate models (other than that for the effects on groundwater) that the EPA could consider?		