General comments

Manufacture

Comment - In reading this document it is unclear whether a general release application to EPA for a new hazardous substance/formulation has to include "manufacture" i.e. can an applicant just apply for use in New Zealand?

This is an important point to clarify as it will affect the risk assessment; if a substance is not manufactured in New Zealand then the exposure to production plant workers can be excluded from the risk assessment.

Proposed outcome: EPA to clarify in this document whether manufacture is always included in the risk assessment, even though there is no intention of the applicant ever manufacturing the substance in New Zealand.

Section 2.2.1, Classification using data from scientific studies

Experimental studies on formulated product

Comment - The statement in the first paragraph of this section needs clarification, as it appears to be at "odds" with international approaches to testing of chemicals and animal usage. It is commonly accepted international practice that when safety testing involves animals it is only the "6-pack" acute-type set of studies (acute oral, dermal and inhalation, skin and eye irritation and skin sensitisation studies) which use the final formulation as the test article. The remaining repeat dose toxicity studies are performed on the active ingredient and not individual formulations.

Proposed outcome - amend the wording to clarify the situation i.e to indicate that for repeat dose/chronic toxicity testing studies EPA expect the studies to be performed on the active ingredient and not the individual formulations.

Use of study data from peer-reviewed journals and other international regulatory reviews

Comment – is the EPA approach, as detailed in this document, consistent with approaches of other NZ regulatory organisations e.g ACVM, MOH.

Proposed outcome – EPA to investigate approaches taken by other similar NZ government regulatory bodies so that there is a consistent approach across NZ government. EPA could also explore how other international regulators approach to this issue, with an aim of being consistent, as possible, with other worldwide regulators.

Section 3 – Assessing the risk

Comment – The introductory paragraphs make no specific mention of fauna i.e potential effects on native birds etc.

Proposed outcome – EPA to provide clarity as to what "environment" includes; people are currently explicitly mentioned but animals/fauna are not. By adding clarity may go someway to address the common confusion stakeholders have over the difference in what EPA cover and what MPI/ACVM cover with respect to animals in the environment.

3.2 Qualitative assessment

Comment - Third paragraph, "In addition to the scientific assessment and *unique* to New Zealand…." The use of "unique" is not clear….perhaps "and" should be deleted????

Proposed outcome – EPA to review wording and amend accordingly

Comment – I found this section quite confusing because it is titled "Qualitative assessment" but uses numerical values to explain levels of risk/benefit. A better title would be "Semi-qualitative assessment". I understand the reason for taking the approach explained in this section but strongly feel that for ease of reader understanding the title should more accurately address the procedure being described.

Proposed outcome - EPA to amend the title of the section to more accurately reflect the process being described.

Comment – final paragraph of section 3.2, it is unclear why this paragraph is here. The role of the HSNO Act should be in the first introductory section of this document, rather than tucked away in what appears to be an "add-on" paragraph at the end of a section dealing with more detailed issues than the overall objective of the HSNO Act. In addition, in the first sentence, "reduce" is redundant; the overall objective of the HSNO Act is to adequately managing risks from hazardous substances, which might be achieved by reducing risk.

The possibility of using qualitative risk assessment to consider residual risk should be in the introductory paragraph for this section. The fact that using such an approach may be of value to the decision makers could remain at the end of this qualitative section, although I would question whether such a statement is even needed. I also question the value of the statement "…assuming that these controls are appropriate and are practical for compliance"; it should be a given that any mention of controls means they are appropriate and practical for compliance.

Proposed outcome - remove the redundant word "reduce" from the first sentence. Consider moving reference to objective of the HSNO Act to the document introductory section. Consider deleting the wording around practical controls.

3.2.1 Qualitative descriptors

Comment - Table 1 – rather than just reproduce the 2009 table, this would be a good opportunity to review and update the table. It appears inappropriate to use quantitate descriptors in a section focused on qualitative (non-numerical) assessment e.g. use of "less than ten" in the Minimal examples of Table 1.

It should be up to the applicant/author to justify the level/time period for each category. If you put numbers in that's what people will focus on and it will become at least a semi-qualitative assessment.

N.B. the above comments become redundant if the title of the section is amended to "Semi-qualitative".

Proposed outcome - Remove quantitative descriptors e.g. "less than ten" from Tables 1 and 2. If not removed, then a similar approach should be taken for all levels of risk.

Comment – Table 1 - Example for "Moderate"; for social disruption it is unclear what is meant by "people delayed"?

Proposed outcome - EPA to include some more context to this example.

3.3.1 Quantitative models used by the EPA

Comment – second paragraph, "….and have been validated or used by other regulators", this could be read that EPA will use models which are used by other regulators but which haven't necessarily been validated.

Proposed outcome - revise sentence to reflect that EPA only use models used by other regulators which have been adequately validated i.e. models used by other regulators are subject to the same overall validation procedures as required for other publicly available models.

Comment - Fourth paragraph, Table 6 – error message. Following sentence "is" should be are, as it refers to "details".

Proposed outcome - EPA to fix the error message so the link to Table 6 is functional. Correct grammatical error.

Comment – sixth paragraph, it would be helpful if EPA provided brief details on how an applicant/interested party could check whether new models have been "approved" for use by EPA. Will this be done by amending this document or some other method? Currently paragraph 6 seems to be of little value to this document.

Proposed outcome - either remove the sixth paragraph or amend it so it provides the reader a mechanism of checking for updates.

3.3.2 Selecting inputs for quantitative models

Comment – Fourth paragraph wording implies that this document is only for Applicants.

Proposed outcome – Revise the paragraph so it is clear that the requirements relate to an application/applicant.

3.3.3 Understanding uncertainty in quantitative models

Comment – first paragraph, last sentence, it isn't definitive that "all the steps help to improve the assessments made"; rather it is the "aim" of the steps to improve the assessment.

Proposed outcome – amend sentence to reflect the aim rather than a definitive outcome.

Comment – second paragraph, last sentence "This is known as "knowledge uncertainty" – or gaps in knowledge……." This sentence seems to be in the wrong place, as it is not clear what "This" refers to.

Proposed outcome – EPA to review positioning of sentence within the second paragraph or rewording of the sentence so it makes sense to the reader.

Comment – paragraph 5, my understanding is before the most conservative toxicology value is selected the study with the "highest value of confidence" is selected i.e. there may be a very conservative toxicity value but if the data are not reliable then a less conservative toxicity value may be chosen from a more reliable study/data source.

Propose outcome - The first sentence of paragraph 5 should be re-written to put the emphasis where it belongs i.e. on the data quality/confidence.

Comment - paragraph 6, "type and quality of studies…." are important for both human health and ecotoxicity studies.

Proposed outcome - amend section to reflect the above.

Comment – paragraph 6, “at risk” species have been omitted, to be consistent with Section 3.3.4 “at risk” should be included.

Proposed outcome - include “at risk” along with “threatened”

3.3.4 Threatened and “at risk” species

Comment –there is no guidance provided as to when the applicant needs to consider doing addition risk assessment for endangered/threatened species. Due to the diversity of New Zealand and the use of hazardous substances/pesticides is not region/location specific it is likely that for some application sites there is a threat to endangered/threatened species, whereas at other application sites there is no such risk. It isn’t clear how EPA expect this type of scenario to be addressed.

Proposed outcome: EPA to provide guidance on when risks to specific endangered/threatened species should be undertaken.

3.3.5 Standardising terminology and using quantitative model outputs

Comment – paragraph 2, after introducing risk quotients it would be helpful to include its’ abbreviation “RQ”

Proposed outcome – include RQ after “risk quotients”

Comment - paragraph 4, to make it clear to the reader that this paragraph is no longer about human health the paragraph should start out with such an indicator.

Proposed outcome – start the paragraph with a statement such as “For environmental assessments the models and equations…..”

Comment – paragraph 7, to ease understanding suggest an example of a toxicology value which is being referred to is given.

Proposed outcome – include an example

Comment – paragraph 7, error message for Table 6

Proposed outcome – address error message

Comment – Table 9 no explanation of “LOC”

Proposed outcome - provide an explanation for the abbreviation “LOC”

4. Controls

4.1. The purpose of controls

Comment – first paragraph, third line, “safe” is inappropriate and misleading. The aim of HSNO is to manage risk to an acceptable level, not to necessarily make them safe for all, sometimes the risk to vulnerable cohorts is outweighed by the benefits to the majority. Using terms such as safe can give a false sense of “security” to those cohorts which lie outside the general population.

Proposed outcome – remove the comment with regard to a product being safe for all.

Comment – paragraph 3, last sentence, it is unclear who the "you" refers to as this document isn't just aimed at Applicants. In addition, the sentence doesn't seem to add value to the paragraph; it is unclear of the purpose of the sentence in the context of the whole paragraph.

Proposed outcome – amend the sentence to clarify who is "you" or delete the sentence completely.

5. Benefit assessment

5.3 What to include in a benefits assessment

Comment – first paragraph, third sentence, use of "your"

Proposed outcome - remove "your" and merely indicate the information needs to be in the application.

Appendix A Glossary

Comment – Active ingredient, this should also be in the plural form as there may be more than one active ingredient in a formulated product

Proposed outcome – amend entry to reflect that there may be more than one active ingredient

Comment – Evaluate, the explanation contains "evaluation" which is basically using "evaluate" to explain "Evaluate"

Proposed outcome – improve the explanation by not using "evaluation" e.g. summing up or bringing together the combined assessments of the risks, costs etc

Comment - exposure assessment explanation includes water but not air or soil, this seems inconsistent.

Proposed outcome – consider including air and soil for completeness

Comment – risk quotient, explanation does not mention human health although RQ's are used in human health risk assessment.

Proposed outcome – include human health in the explanation.

Comment – it would be of value to also include such terms as "AOEL", "PDE", "ADE", "TER", "TV" for completeness and value; having these terms in one place makes it easier for the reader to check their meanings, and also it would it would help the reader to appreciate the differences in the values. For a "non-expert" it is difficult to grasp the difference in the terms AOEL vs ADE vs PDE etc. Another approach would be for the document to contain a separate appendix explaining the terms and their associations (or not). This comment also applies to acronyms used for environmental/ecotoxicity parameters.

Proposed outcome - add terms as suggested above

Comment – it would be of value to include a definition of "environment" in the glossary

Proposed outcome – include "environment" in the glossary.

B.1 Introduction to human health modelling

Comment – paragraph 2, it would be of value to include RQ and AOEL after mention of these terms, or just use the acronyms.

Proposed outcome - add acronyms

B.2 Acceptable Operator Exposure Level

Comment – it would be of value to explain the derivation of the "100" assessment factor (AF), as well as to give an example as to when such a value may need varying.

Proposed outcome – consider including above suggestions

B.3 Dermal absorption

Comment - paragraph 2, third sentence, "physco" needs to be spelt correctly

Proposed outcome – correct spelling "physico"

B.4 Commercial pesticide operators

B.4.1. Exposure linkage assessed

Comment - is "assessed" correct here?

Proposed outcome – amend "assessed" to "assessment"

B.4.2 Model used

Comment – the third bullet point doesn't make sense

Prosed outcome – review wording and amend as appropriate

Bodyweight default values

Comment - Table B.2 gives a bodyweight default value of 70kg, whilst Table B.10 gives a default value of 60Kg. It would be of value to have an explanation as to the reasons for the differences in these default values. It would also be of value to have a default bodyweight for toddlers, and an associated explanation.

Proposed outcome – Inclusion of the above-mentioned explanations and values.