3 July 2018

Environmental Protection Authority
Private Bag 63002
Wellington 6140.

Attn: Lee Bailey, Senior Advisor Hazardous Substances Reassessments.

The following submission is made on behalf of Kiwicare Corporation Ltd, Christchurch, NZ. We have presented submissions on the two documents recently published by the EPA:

- Assessing the Risks of Hazardous Substances – draft for consultation; and
- Risk Assessment Methodology for Hazardous Substances – draft for consultation

Re: Assessing the Risks of Hazardous Substances – draft for consultation

Is the level of detail appropriate?

- This document is generally suitable as an overview/introduction although we feel there are some areas that require clarification (see below).

Are there areas that require additional information or clarity?

- ***Section 3 – Incorporating Maori perspectives:*** Is there a need for all applications (and self-assessments) to consider the risks and benefits from a Maori perspective? The original guidance published for the Act indicated this was critical for new chemicals or actives and those that were publicly notified but would not be needed for a 'Rapid' or Self-assessment, or potentially for a non-notified application.
- ***Section 3, 4th paragraph:*** The statement is made – "If the hazards of a new substance are similar to or less than those of an existing approved hazardous substance then the EPA may choose to make a rapid assessment". This statement suggests that the new substance does not need to have the same use profile or indeed the same active ingredient – this should be clarified.
- ***Section 4, Step 1 – Hazard identification:*** There is a need for the EPA to clarify what data is used to make a hazard assessment and what weighting or priority is given to data from alternative sources. Does the data contained in the CCID take precedence over other data sources? Are company SDSs preferable over generic SDSs from a database such as ChemWatch? Indeed, are SDSs acceptable sources of data?
- ***Section 4, Step 2 – Conceptual model:*** A decision tree or framework would be useful at this point; this would help manage the expectations of applicants and the public.
- ***Section 4, Step 3 – Risk assessment:*** We feel it is important to state that a risk assessment will only be conducted on the hazards identified in step 1. It is also important to consider exposure pathway and frequency and whether the assessment is for a chronic or acute effect/exposure.
- ***Section 5 Approach to assessments:*** Is it worth linking this to the GHS framework, which recognises that hazards and risks for a chemical or mixture change between workplace, consumer and transport (*Globally Harmonised System of Classification and Labelling of Chemicals; 4th Revised Edition, 2011)*?

Re: Risk Assessment Methodology for Hazardous Substances – draft for consultation

Is the level of detail appropriate?

- Kiwicare supports the EPAs initiative in publishing this guidance document and feels that, in general, the level of detail is appropriate but there are some critical areas that need further consideration or discussion. The methodology outlined is ambitious and exceeds the processes undertaken by other jurisdictions and is beyond the scope of current GHS guidelines. While being innovative and leading is commendable this needs to be done following careful consideration. Given the complexity of the issues covered by this document we feel the time and level of consultation is not sufficient and would encourage the EPA to consider industry workshops or one-on-ones.
    - An important consideration that we believe is often overlooked, despite being core to the document as written, is modelling should only be undertaken for hazards identified during classification.

Are the technical aspects correct?

- **Section 3.1:** It is important to consider issues of decay, binding and partitioning between different media (water, soil, sediment, etc.) as well as elapsed time and dilution when assessing exposure. The proposed risk assessment tools tend to consider exposure pathways in isolation – i.e., aquatic toxicity in isolation from sediment binding, or exposure to plant protection products during weeding, harvesting or to toddlers without considering partitioning coefficients between media and rate of adsorption in to foliage, etc. Additionally, some environmental limits (NOAEL, etc.) are applied in isolation of the solubility of a compound in the matrix of concern, this clearly leads to errors in risk assessment that needs to be acknowledged (see Mackay, *et al.,* 2017; Gobas, *et al.,* 2018 for more in-depth discussion).
- **Table 5:** It is important that the EPA recognise the difference between chronic and acute exposure. Chronic exposure limits (ADI and AOEL) can be used as an initial screening tool for acute exposure (i.e., re-entry modelling, bystander exposure and pesticides used outside the home) but the EFSE and the UK, have clearly stated (in more recent studies) that the use of AOEL for acute or even short-term exposure is neither warranted or accurate; they promote the use of a AAOEL (*EU Guidance assessment exposure plant protection products Sante Jan 2017.pdf*) and recommend a tiered assessment be used where AAOEL data is not available (see "*EFSA Tiered approach to exposure modelling.jpg"*).
- **Table 6, Appendix B5.5 and Appendix C.9**: The default foliar dissipation half-life (DT50) used in the EFSA model for risk assessment of herbivorous birds and mammals of 10-days (as quoted in Appendix C.9) has recently been reviewed with a new reduced DT50 of 3.2-days proposed (Ebeling and Wang, 2018[1]).
- **Table 6 and Appendix C.10:** The USEPA pollinator risk assessment model referred to in Table 6 also includes a tiered assessment approach (*USEPA pollinator risk assessment guidance 2014.pdf* and *USEPA guidance exposure effects testing assessing risks bees 2016.pdf*). The USEPA has also published an additional guidance note on when Bee exposure testing is warranted (*USEPA process for requiring Bee exposure and effects testing 2016.pdf*). For an EFSA view, see *2014-EFSA_integrated environment risk assessment Bees.pdf* and Croft *et al*., 2018[2].

[1] Ebeling, M. and Wang, M. (2018). Dissipation of plant protection products from foliage. *Environmental Toxicology and Chemistry, 37:1926-1932.*

[2] Croft. S., Brown, M., Wilkins, S., Hart, A. and Smith, G.C. (2018). Evaluating EFSA protection goals for honey bees (*Apis mellifera*): what do they mean for pollination. *Integr Environ Assess Manag. 20 June 2018 (Manuscript online).*

- **Appendix B, Table B.6:** This table quotes the default turf transfer coefficient is 20,000cm^2/h; the Operator Exposure Guidance for Amateur (Home Garden) Pesticides indicates a figure of 5,200cm^2/h should be used when modelling children's dermal exposure (see *"amateur-use-models POEM.pdf"*).

Are there any areas that need more guidance?

- We support the use of a flexible approach as outlined in Section 1.4 but feel this could be agreed in a collaborative manner with the applicant as part of the pre-assessment or pathway determination phase of the application process. A criticism of the current process is that concerns may only be raised at the decision stage and no opportunity is provided for the applicant to clarify.
- Can the EPA confirm that analysis of risks will be based on the hazardous properties (HSNO classification), use profile and life stage; recognising that risks change according to workplace, consumer and transport as outlined in *Globally Harmonised System of Classification and Labelling of Chemicals; 4th Revised Edition, 2011*?
- Recognising that risk assessment is primarily done to define the appropriate controls (which may include a refusal to approve) - will quantitative modelling always be conducted, or will quantitative modelling only be conducted where controls are uncertain based on life-cycle stage and qualitative risks (bullet point 3 section 1.4).
- Section 2.5 – Can the EPA provide additional guidance on the ranking of data? For example: a suitable priority might be: data contained in the CCID should be used where available; then data from the NZOC and other (identified) regulatory datasets (APVMA, ECHA, USEPA, etc.); data from scientific publications; and finally, data from supplier SDS's.
- Table 9: Why is the EPA proposing RQs of less than 1 in relation to levels of concern when the modelling used to derive a RQ is generally recognised as conservative especially where end-points for chronic exposure (i.e. ADI or AOEL, etc) are used for acute or short-term chronic exposure modelling.

Do you consider that there are any other matters that should be addressed as part of this methodology?

- As indicated, the EPA appears to be applying risk modelling at a level far greater than other regulators. Many of these regulators have recognised that some of this modelling in particular the end-points used to generate risk quotients (RQs) or define level of concerns (LOCs) need refinement. There are several recently published scientific papers that should be carefully reviewed by the EPA before it finalises policy. A selection of publications is:
    - Simon, T.W., Zhu, Y., Dourson, M.L. and Beck, N.B. (2016). Bayesian methods for uncertainty factor application for derivation of reference values. *Regulatory Toxicology and Pharmacology 80 (2016): 9-24.*
    - Mackay, D., Celsie, A.K.D, Parnis, J.M, McCarty, L.S., Arnot, J.A. and Powell, D.E. (2017). The Chemical Exposure Toxicity Space (CETS) Model: Displaying Exposure Time, Aqueous and Organic Concentration, Activity, and Onset of Toxicity. *Environmental Toxicology and Chemistry, 36(5), 1389-1396.*
    - Gobas, A.P.C, Mayer, P., Parkerton, T.F., Burgess, R.M., van de Meent, D. and Gouin, T. (2018). A Chemical Activity Approach to Exposure and Risk Assessment of Chemicals. *Environmental Toxicology and Chemistry, 37(5), 1235-1251.*
- It is recognised that most formulated products, not just plant protection products (PPPs), are mixtures, yet traditional risk assessment looks at chemicals in isolation. The need to consider risks associated with mixtures has led to several recent publications on the subject including those from the European Commission, Joint Research Centre – Institute for Health and Consumer Protection and others:

- Kienzler, A., Bopp, S.K., van der Linden, S. and Berggren, E. (2016). Regulatory assessment of chemical mixtures: Requirements, current approaches and future perspectives. *Regulatory Toxicology and Pharmacology 80 (2016) 321-334.*
- Bopp, S., Berggren, E., Kienzler, A., van der Linden, S. and Worth A. (2015). Scientific methodologies for the assessment of combined effects of chemicals – a survey and literature review. *JRC Technical Reports; JRC97522, 2015. 64pp*.
- Bopp, S.K., Kienzler, A., van der Linden, S., Lamon, L., Paini, A., Parissis, N., Richarz, A-N., Triebe, J. and Worth, A. (2016). Review of case studies on human and environmental risk assessment of chemicals mixtures. *JRC Technical Reports; JRC102111, 2016. 89pp.*
- Sarigiannis, D.A., and Hansen, U. (2012). Considering the cumulative risk of mixtures of chemicals – A challenge for policy makers. *Environ Health, 2012; 11(Suppl 1): S18. 17pp.*
- EFSA Scientific Committee (Hardy, *et al.*). (2017). Update: use of the benchmark dose approach in risk assessment. *EFSA Journal 2017; 15(1):4658. 41pp.*
- Altenburger, R., Backhaus, T., Boedeker, W., Faust, M and Scholze, M. (2013). Simplifying Complexity: Mixture Toxicity Assessment in the last 20 Years. *Environmental Toxicology and Chemistry, 32(8), 1685-1687.*

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