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Environmental Protection Authority
Private Bag 63002
WELLINGTON 6140

submissions@epa.govt.nz

Submission on the EPA's proposed risk assessment methodology for hazardous substances

Thank you for the opportunity for Auckland Regional Public Health Service (ARPHS) to provide a submission on the Environmental Protection Authority's (EPAs) proposed risk assessment methodology for hazardous substances.

The following submission represents the views of ARPHS and does not necessarily reflect the views of the three District Health Boards it serves. Please refer to Appendix 1 for more information on ARPHS.

Yours sincerely,



Jane McEntee
General Manager
Auckland Regional Public Health Service



Dr. Denise Barnfather
Medical Officer of Health
Auckland Regional Public Health Service

1. Describing the risk assessment process

ARPHS considers any risk assessment methodology must be able to produce results that are acceptable internationally. We note risk assessments always involve a process of hazard identification (how a chemical affects the human body), dose-response (an assessment of quantity needed to cause adverse effects), exposure assessment (an assessment of how humans might be exposed, the potential dose, and which groups/populations might be at risk), and risk characterisation (an assessment of the harm caused by the dose to which people/groups could be exposed).

A thorough and complete risk assessment allows organisations to provide appropriate risk mitigation and communication plans. Without a solid health and environmental risk assessment foundation, mitigation is unlikely to be effective and/or appropriate, and people will not be given the correct information about the risk to their health.

In light of this, we consider the risk assessment overview aimed at members of the public (as outlined in the summary document 'Assessing the Risks of Hazardous Substances') fails to clearly describe the key interlocking processes involved in the risk assessment process. The only recognisable risk assessment category outlined in section 4 of the document is 'hazard identification'. This step is then followed by a 'conceptual model' category, which comes closest to an 'exposure assessment', although this is not described clearly enough to be certain. The next category is incorrectly called 'Risk Assessment' because all of the steps 1-3 together comprise what is widely understood to be a risk assessment. We suggest this category be titled 'risk characterisation', although the description is not clear enough to know exactly what is being calculated.

We also consider the risk assessment process outlined in the document 'Risk Assessment Methodology for Hazardous Substances' could be more clearly structured.

Recommendation: Ensure the risk categories used in the final version of the EPA guide to 'Assessing the Risks of Hazardous Substances', matches the internationally endorsed risk assessment methodology terminology¹.

2. "Public" risk assessments

¹ World Health Organisation, International Programme on Chemical Safety, and Inter-Organization Programme for the Sound Management of Chemicals, 2010. Harmonization Project Document No. 8. WHO Human Health Risk Assessment Toolkit: Chemical Hazards. Available at: <http://www.inchem.org/documents/harmproj/harmproj/harmproj8.pdf>

ARPHS appreciates the EPA's aims of improving transparency around how it assesses hazardous substances and empowering the public and applicants to have a better understanding of the processes involved and the information required for assessment. However, we note that conducting a health risk assessment is a complex specialist skill. Not only does it require that people are trained in the scientific method, including reading and interpreting the scientific literature, but it also requires the collection and interpretation of exposure data, an understanding of the chemical literature, a subsequent understanding of the health literature detailing research and biological mechanisms investigating the effects of chemicals, knowledge of toxicology, and the mathematical models and calculations required to assess quantitative risk etc.

We would be deeply concerned if an applicant's risk assessment was relied upon too heavily by the EPA when conducting its own risk assessment for a hazardous substance. It is vital that the EPA's own risk assessment process remains independent, thorough, impartial and reliant on best practice methods.

Recommendation: EPA to ensure that their risk assessment process is independent, thorough, impartial and relies on best practice methods.

3. Weighting given to health risk

ARPHS appreciates that the EPA's risk assessment methodology is framed by the *Hazardous Substances and New Organisms (Methodology) Order 1998*, and that clause 9(c)(v) in Schedule – 'Methodology for making decisions' under Part 5 of the Act states that the EPA must take into account risks, costs, benefits and other impacts associated with the substance or organism in an application which relate to the economic and related benefits to be derived from the use of the particular substance or organism.

While economic and other issues are relevant to policy, they should have no bearing on the scientific assessment determining the health risk posed by a hazardous substance. ARPHS has concerns that the consultation documentation does not make it clear that the risk assessment of health effects should be independently conducted in the first instance before any overall evaluation of a substance (including economic, risk management and mitigation considerations) occurs. Any perception that human health risks can be regularly managed or offset by economic or other benefits should be avoided.

We consider the last sentence in section 3 should be more prominent, and this messaging should also be clear in section 4.

*Recommendation: EPA to ensure that the health risk assessment process includes **only** health risk information in characterizing the risk to human health i.e. hazard identification, dose-response assessment, and exposure assessment, culminating in risk characterisation. EPA to ensure in its assessment of any application that appropriate weighting is given to public health and environmental risks.*

Appendix 1 - Auckland Regional Public Health Service

Auckland Regional Public Health Service (ARPHS) provides public health services for the three district health boards (DHBs) in the Auckland region (Counties Manukau Health and Auckland and Waitemata District Health Boards).

ARPHS has a statutory obligation under the New Zealand Public Health and Disability Act 2000 to improve, promote and protect the health of people and communities in the Auckland region. The Medical Officer of Health has an enforcement and regulatory role under the Health Act 1956 and other legislative designations to protect the health of the community.

ARPHS' primary role is to improve population health. It actively seeks to influence any initiatives or proposals that may affect population health in the Auckland region to maximise their positive impact and minimise possible negative effects on population health.

The Auckland region faces a number of public health challenges through changing demographics, increasingly diverse communities, increasing incidence of lifestyle-related health conditions such as obesity and type 2 diabetes, infrastructure requirements, the balancing of transport needs, and the reconciliation of urban design and urban intensification issues.

