

Implementing reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Consultation Paper 5

Submission from Cancer Council Australia

July 2017

Cancer Council Australia is the nation's peak non-government cancer control organisation. Cancer Council's Occupational and Environmental Cancer Committee includes members with national standing in relevant disciplines including epidemiology, molecular biology, occupational health, clinical oncology and public health. Comments from the Committee form the basis of this submission and their contribution is acknowledged. Cancer Council Australia welcomes the opportunity to provide comment on the final phase of the NICNAS review.

Contact: Deshanie Rawlings, Public Health Policy Manager, Cancer Council Australia:
deshanie.rawlings@cancer.org.au (02) 8063 4112

Overview

Cancer Council Australia has been involved in NICNAS reforms agenda and has put forward submissions in response to Consultation Papers 2, 3 and 4. In Consultation Paper 4 we highlighted our concerns on the risks of Exempted introductions and risks to the IMAP framework under the proposed reforms. We note that these concerns have not been addressed in Consultation Paper 5. Comments on specific aspects of Consultation Paper 5 and Supporting Material are outlined below.

Intentional human exposure

It is our view that the term 'intentional human exposure' is not appropriate. We suggest that it is replaced with 'recognised human exposure'. The plain language meaning of 'intentional human exposure' relates to a manufacturer's intent and does not follow directly from the defined meaning of the term. The definition provided is inadequate as it does not take into consideration exposure in the course of sale, storage, production and use of the chemical and the definition provides primarily examples rather than providing an explanation.

Cancer Council Australia suggests more satisfactory definition of 'recognised human exposure' would include:

- a) in the course of its usage or manufacture, the chemical (or a metabolite of it) was detected at greater than background level in tissues or bodily fluids of person handling that chemical, or
- b) any specific industrial use of the compound gave rise to a context in which human exposure was recognised to occur.

Information requirements for categorisation

The term 'endpoints' is used throughout Consultation Paper 5, however, this term is not a defined term and in our view it should be. The term should be defined and identify any stage in the production process, including the final stage, at which the chemical is handled, stored or used when there is a reasonable likelihood of human exposure.

The information required related to chemical identity should be expanded to include:

- Physical description: an account of the chemicals state at room temperature and pressure (e.g. a colourless gas, a red/brown viscous liquid etc.)
- Stability: a statement concerning whether the chemical is subject to degradation under normal conditions (room temperature and pressure).

Criteria for human health Hazard Bands

Carcinogenicity is not adequately addressed. While Consultation Paper 5 refers to the GHS classification system, there is no information provided in the Supporting Material. This is inadequate given that there is information provided for characterising chemicals for mutagenicity and genotoxicity in Table 1. The Supporting Material content should be amended to include text and a corresponding table in Section 3 which addresses carcinogenicity and should come ahead of mutagenicity and genotoxicity.

The use of the term 'if known' in relation to carcinogenicity is not appropriate and should be deleted. The term does not add to interpretation or make the meaning more specific.

Cancer Council Australia recommends that IARC is listed and recognised as a trusted prescribed international body.

Exempted chemical introductions

Cancer Council Australia remains concerned about the proposed reforms for Exempted introductions. If this process is implemented, NICNAS will not be able to identify unlisted chemicals introductions in the Exempted category. Our main concern is that there will be no public record of Exempted introductions. While companies are required to keep records of Exempted introductions, the quality of the records cannot be assured. This is particularly important if a chemical self-assessed by industry as low risk is found to be high risk in future. The proposed reforms would make an effective regulatory response to protect the health of the population impossible. One option to ensure NICNAS is able to fulfil its role in protecting the Australian people from toxic injury by industrial chemicals is to require notification of unlisted chemical introductions. Given that a company must keep records of Exempted introductions, entering this information into an online database would not be burdensome. A minimum reported data set including the systematic name and CAS number, molecular formula, quantities imported and use should be required as notification to NICNAS.

Cancer Council Australia does not think it is appropriate that unlisted chemical introductions that fall into Hazard Band D, and therefore possibly carcinogenic, be categorised as Exempted even in Exposure Band 1. A small number of workers may be highly exposed to hazardous chemicals for research and development. We do not support the removal of

nanomaterials from Hazard Band D. The uses of nanomaterials are being researched at present and there is a paucity of in vivo animal and human data on the health effects. Cancer Council Australia recommends applying the precautionary principle for nanomaterials given the insufficient evidence.

Assessed chemical introductions

The information required related exposure and release information (p48) should be expanded. The list of information provided does not cover all issues known to arise from use of industrial chemicals. We suggest a flow diagram in respect of each site where a chemical is to be handled in any context. The flow diagram should describe intake (quantified as 100), storage, conversion or loss (by wastage, evaporation, instability as appropriate), with each outcome quantified with reference to 100 units of intake and the final product (as the chemical or products to which the chemical has been converted (again with reference to the 100 units of intake).

The following information should be required in relation to release:

- Exposure of the local community (within 5km of the plant) under normal operation
- Circumstances of foreseeable risk in respect of failed normal operation for (a) employees and (b) the local community
- The steps being taken to avoid the emergence of a contaminated site

Unlisted chemicals introduced at the nanoscale

Cancer Council Australia's preference is for Option 3 to be incorporated into the categorisation criteria for intentionally manufactured materials. Option 3 is practicable, the chemical should be assessed unless the nanoscale material is incidental. This would allow importation of fine materials such as Zinc Oxide, where nanoscale particles are present.

There is evidence that the small particle sizes may have different toxicological effects from those of larger particles. If only a small proportion of a chemical is nanoscale, these are potentially of concern. Therefore size-dependent properties should be included as a criterion for categorisation. Nanoscale carbon fibres have similar physical characteristics to asbestos and there is suggestive animal data that cancers are associated with exposure to these particles.^{1,2,3}

The categorisation into Exempted introductions should not be allowed for nanomaterials where the particle count and/or surface area mean that the chemicals may have a very different toxicological outcome.

E-cigarettes

The inclusion of electronic cigarettes (e-cigarettes) in Consultation Paper 5 is of concern. The health effects of e-cigarettes are currently unknown and these products are not harmless.^{4,5} Products inhaled directly to the lung are normally only approved after extensive safety and efficacy evaluation due to the serious issues that can potentially arise with this form of substance delivery.⁶ A formal approval process also ensures that consumers are provided with specific guidance on safe and appropriate use. E-cigarettes currently on the market in Australia have not gone through these kinds of assessment processes.

Cancer Council Australia and the National Heart Foundation are calling for a ban on non-nicotine e-cigarettes from retail sale for both adults and children, unless their use has been approved by the Therapeutic Goods Administration.

In the absence of a ban it is our view that unlisted chemical introductions in the case of e-cigarettes should only be categorised as Assessed. There is insufficient toxicological data available to make a true health hazard assessment of most substances contained in e-cigarettes. E-cigarettes contain a number of ingredients which may have been proven safe for ingestion, but not for inhalation (for example, diacetyl). The National Health & Medical Research Council advises that “e-cigarettes may expose users to chemicals and toxins such as formaldehyde, heavy metals, particulate matter and flavouring chemicals, at levels that have the potential to cause adverse health effects”.⁷ Propylene glycol and glycerin when overheated can produce dangerous levels of the carcinogens formaldehyde and acetaldehyde.^{8,9} Harms from chemical exposure take time to present and cannot be fixed retrospectively. Chemicals contained in e-cigarettes are of particular concern given that the long-term health effects of inhaling these chemicals are unknown. Given the potential risk, the health and safety of the population should be the first priority.

Conclusion

Cancer Council Australia appreciates the opportunity to comment on Consultation Paper 5. The ability to use evaluations from reputable sources such as ECHA is an appropriate measure. However, we remain concerned about the issues outlined above. Cancer Council Australia trusts that the suggestions put forward in this submission will be incorporated into the delegated legislation. We hope that NICNAS will be adequately resourced to continue the important work of evaluating grandfathered chemicals on the Australian Inventory of Chemical Substances. Cancer Council Australia recommends a line is included in the legislation that ensures NICNAS will be funded to conduct NICNAS initiated assessments.

References

1. Poland CA, Duffin R, Kinloch I, Maynard A, Wallace WA, Seaton A et al. Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. *Nature nanotechnology*. 2008;3(7):423-8.
2. Hobson DW, Roberts SM, Shvedova AA, Warheit DB, Hinkley GK, Guy RC. *Applied Nanotoxicology*. *International journal of toxicology*. 2016; 35(1):5-16.
3. Pacurari M, Lowe K, Tchounwou PB, Kafoury R. A review on the respiratory system toxicity of carbon nanoparticles. *International journal of environmental research and public health*. 2016; 13(3):325.
4. Callahan-Lyon P. Electronic cigarettes: human health effects. *Tobacco Control*. 2014; 23(2):ii36-ii40.
5. Pisinger C, Døssing M. A systematic review of health effects of electronic cigarettes. *Preventive Medicine*. 2014;69(0):248–60.
6. World Health Organization Study Group on Tobacco Product Regulation. Report on the scientific basis of tobacco product regulation: third report of a WHO study group. Geneva, Switzerland: 2009 WHO Technical Report Series 955.
7. NHMRC CEO Statement: Electronic Cigarettes (e-cigarettes). Australian Government National Health and Medical Research Council; 2017 [Accessed 29 June 2017] Available from https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/ds13_nhmrc_ceo_statement_ecigarettes.pdf
8. Kosmider L, Sobczak A, Fik M, Knysak J, Zacierka M, Kurek J, et al. Carbonyl compounds in electronic cigarette vapors: effects of nicotine solvent and battery output voltage. *Nicotine & Tobacco Research*. 2014;16(10):1319-26.
9. Jensen RP, Luo W, Pankow JF, Strongin RM, Peyton DH. Hidden formaldehyde in e-cigarette aerosols. *New England Journal of Medicine*. 2015;372(4):392-4.