



NICNAS GUIDANCE NOTE:

RISK ASSESSMENT OF CHEMICALS: ASSESSMENT OF EXPOSURE FROM ALL SOURCES

This Guidance Note provides information on the concepts behind risk assessment and risk management processes within our national chemicals regulatory program.

A key objective of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) (Section 3) is to provide a national system of notification and assessment of industrial chemicals for the purposes of aiding in the protection of the Australian people and the environment by finding out **the risks** to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals.

Thus, NICNAS is a risk based regulatory system.

NICNAS assesses the risks to occupational health and safety, public health and the environment using well established, internationally accepted methodology (International Programme on Chemical Safety, 1999; European Commission, 2003). Risk assessment, when applied to chemicals generally, is the overall process of decision making, taking into account:

- Hazard assessment (including hazard classification and establishment of dose-response relationships);
- Exposure assessment;
- Risk characterisation; and
- Risk management.

Chemical Risk Assessment: Our Approach

1. Hazard Assessment

Hazard assessment establishes the toxicity of a chemical and identifies the set of inherent properties that makes it capable of causing adverse effects. Thus, the hazard assessment step identifies the type of hazard that might occur given the appropriate circumstances.

2. Exposure Assessment

The other major variable in the risk characterisation equation is the estimate of exposure. The purpose of exposure evaluation is to identify the magnitude of exposure to a particular chemical and to determine the frequency and duration of that exposure and all the routes by which exposure occurs over the chemical life cycle.

For the majority of chemicals, exposure assessment is probably the most variable aspect of the risk assessment paradigm. This reflects a variety of contributing factors such as differing and/or unique exposure and use patterns of chemicals across a range of industrial uses, the unique nature of ecosystems, fauna and flora, together with

differing methodologies for exposure assessment as well as differences in dose-response extrapolation methodology.

The exposure assessment is a critical element of the risk assessment and can comprise both direct exposure (ie. workers carrying out manufacture; consumer use of household products etc.) as well as indirect exposure via the environment.

The assessment of both direct and indirect exposures via the environment are important considerations for the risk assessment, particularly for the public health and environmental assessments where exposure to a chemical may arise from several sources such as contact with the raw chemical itself, a preparation or mixture, finished goods containing the chemical (eg. treated fabrics and carpet) or via contamination of the environment (eg. lead and other chemicals in household dust and ambient air).

Where exposure of the population to a chemical is likely or suspected (ie. through biomonitoring data or known chemical properties such as leaching) the risk assessment consideration is extended to include all the sources of the exposure. The release of chemicals into the environment, for example, from articles via leaching, exudation and/or surface abrasion, may occur at any time in the life cycle of the article, including during use, handling, disposal or storage. Hence, NICNAS's risk assessment, whilst focussing on regulating chemical use, may also need to consider the use of a chemical in the production of and release from a finished article. Therefore, information about the possible release of a chemical from an article may be required as part of the exposure information to facilitate the risk assessment of an industrial chemical.

3. Risk Characterisation

The risk characterisation process involves integrating hazard identification, hazard characterisation and exposure assessment outcomes.

The process of interpreting and integrating the information on hazard and exposure to provide a practical estimate of risk is complex and may involve determining what is an acceptable risk and how risk should be managed.

4. Risk Management

Risk characterisation is only part of the risk analysis process. The second major aspect of risk analysis is risk management. Risk management involves risk evaluation, which addresses the fundamental socio-economic problem of determining the optimal level of risk in society based on a trade off between risk, cost and benefit.

The economic and social benefits of any risk reduction action(s) must be balanced with the economic, political and social costs of implementing the risk reduction strategy(ies). Risk management also involves monitoring, evaluating and reviewing the strategies implemented.

References

European Commission (2003) Technical Guidance Document on Risk Assessment. Part 1. Institute for Health and Consumer Protection, European Chemicals Bureau. EUR 20418 EN/1.

Industrial Chemicals (Notification and Assessment) Act 1989. Australian Government, Canberra.

International Programme on Chemical Safety (1999) Environmental Health Criteria 210. Principles for the Assessment of Risks to Human Health from Exposure to Chemicals. World Health Organization, Geneva.