

WES Review 2018

WES Methodology: Criteria for the selection of sources for workplace exposure standards, notations and supporting data

Australian workplace exposure standards and advisory notations

Safe Work Australia (2018)



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Criteria for the selection of sources for exposure standards, notations and supporting data

This document is the first part of the methodology for a regulatory framework for recommending and reviewing health-based workplace exposure standards and notations¹.

Aim

The overarching aim for the review of workplace exposure standards for hazardous chemicals is to develop a list of health-based recommendations for workplace exposure standards and notations based on evaluation of available data for individual chemicals.

This part of the methodology aims to identify appropriate domestic and international sources that directly support this overarching aim and process and:

- are credible and trusted
- use scientific evaluation of the results of validated test methods to establish health-based standards, identify points of departure (no observed adverse effect concentrations [NOAEC], lowest observed adverse effect concentrations [LOAEC] or benchmark dose [BMD]²) or human health hazard classifications
- communicate the scientific approach and publish or make available supporting documentation of the scientific evaluations or classifications, and
- incorporate a peer review and consultation process.

Approach

This methodology provides a practical, cost-effective approach to review the workplace exposure standards by utilising relevant standards and supporting assessments that are available internationally and are derived using a systematic, scientific evaluation. Consideration of international information supports the Australian Government's principle to adopt international standards and risk assessments from trusted international sources where appropriate.

Outcome

The outcome of this part of the methodology is a list of domestic and international sources whose documentation can be evaluated to recommend workplace exposure standards and a list of sources whose documentation can be evaluated to recommend notations.

The documentation and classifications developed by these sources can then be collated and evaluated to efficiently recommend or review a workplace exposure standard and notation(s). This approach will ensure the standard and notations recommended are based on a robust weight of evidence.

¹ Notations include those for classification of carcinogenicity and sensitisation and potential for skin absorption.

² This may include no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) depending on the human health endpoint and data available.

Primary and secondary sources for workplace exposure standards

There are various domestic and international standard setting bodies (and organisations) that recommend or establish workplace exposure standards. Each body or organisation implements its own process to determine the basis for its recommendations. Some bodies derive standards from undertaking a scientific evaluation of research findings; others adopt standards from other bodies. Each process has differences reflecting the priorities of the body or organisation.

The processes may vary between bodies due to:

- science based decisions including:
 - point of departure (NOAEC, LOAEC or BMD) selection
 - selection of critical study or critical health effect
 - application of uncertainty factors, or
 - weight of evidence, and
- policy decisions including:
 - risk, and
 - feasibility including economic or technical considerations.

Australian approach to inform evaluations of workplace exposure standards and associated notations

To ensure recommendations are based on consistent decision-making, this framework includes criteria for selection of domestic and international sources of data and integrates secondary sources to fill data gaps and address policy concerns.

A recommendation for a workplace exposure standard will be determined from evaluation of:

- primary sources of data:
 - that will form the basis of decision-making for recommending a workplace exposure standard for a hazardous chemical, and
- secondary sources of data
 - that will be used where there are significant data gaps or in a weight of evidence approach where there is uncertainty arising from primary sources.

The criteria for a primary source of data are consistent with ideal characteristics identified in Deveau et al (2015)³. This approach will lead to harmonisation with standards set internationally.

Only documentation that is publicly available will be used during the evaluation process.

Recommendations for workplace exposure standards will be derived in a consistent manner. It is possible that the final standards derived by a primary source may not be adopted. However, the underlying data and identified critical effects and points of departure may be used to derive a workplace exposure standard.

Sources that do not meet all of the criteria for a primary source may then be considered as secondary sources.

The approach for selecting secondary sources is consistent with that for the primary sources. However, the criteria are less stringent as the data from secondary sources are only intended to be used to supplement the primary source information where it may be lacking for a particular hazardous chemical or if there are concerns surrounding the data or decision-making process.

³ Deveau, M. et al. (2015) The Global Landscape of Occupational Exposure Limits – Implementation of Harmonization Principles to Guide Limit Selection. *J. Occupat. Environ. Hygiene* 12: S127-S144.

Selection of sources of data for workplace exposure standards

Primary sources of data for workplace exposure standards

Primary sources of data provide the basis of decision-making for recommending a workplace exposure standard.

Primary sources of data must satisfy *all* the criteria listed.

Criteria for primary sources of data

Credibility

- Source is either:
 - a multilateral body with critical engagement from a number of countries in the development of outputs, or
 - an internationally respected single country body whose outputs are adopted, recognised or referenced by other countries.

Standards are developed through consensus

- Source develops standards through:
 - a scientific committee consisting of independent scientists from academia and government, or
 - by experts within an agency, and
 - integrates a peer, stakeholder and public review process.

Standards are health-based

- Source must derive health-based standards free from considerations of:
 - socio-economic impact
 - non-scientific policy, and
 - feasibility.

Standards are based on evaluation of appropriate data

- Standards are derived from undertaking a scientific evaluation of research findings
- Includes evaluation of, preferably, peer-reviewed research and publications
- Scientific data that is evaluated is sourced from adequate and appropriate studies that are conducted according to international guidelines for toxicological and epidemiological testing of chemicals, and
- Source must conduct *de novo* evaluations and not adopt standards from other sources.

Documentation of evaluations is accessible and robust

- Source provides documentation of evaluation either freely or available upon request or registration, and
- Documentation:
 - presents and scrutinises relevant epidemiological and experimental studies, especially key studies that present data on the critical effect for the standard
 - describes all observed effects
 - states and describes the establishment of dose-response and dose-effect relationships and points of departure (NOAEC/LOAEC/BMD) for each observed effect
 - identifies and justifies the critical effect in the conclusion
 - includes consideration of mutagenic, carcinogenic, teratogenic and allergic/immunological properties
 - provides a reference list for all studies described, and
 - displays the year of publication, or the year of publication can be readily obtained.

Secondary sources of data for workplace exposure standards

Secondary sources of data will be used when there are significant data gaps or uncertainty arising from the evaluations conducted by primary sources.

When recommending workplace exposure standards, data from secondary sources may be used in a weight of evidence approach. As this process is not intended to be a comprehensive literature review, individual scientific publications are not considered to be secondary sources of data.

Secondary sources for workplace exposure standards have been divided into:

- **Group A sources** will be used:
 - to supplement lacking or unavailable evaluation documentation, or
 - if the exposure standard has not been reviewed by the primary sources since 1995⁴ or since the Australia exposure standards was last revised, and
- **Group B sources** will be used:
 - if key information for recommending a workplace exposure standard is lacking from primary source documentation (for example human health data), or
 - to clarify and resolve inconsistencies in data presented or interpreted by primary sources.

Criteria for secondary sources for workplace exposure standards

Secondary sources of data must meet the following criteria before being considered for group A or B:

Outputs are developed through consensus

Source develops output through:

- a scientific committee consisting of independent scientists from academia and government, or
- by experts, and
- integrates a peer, stakeholder, or public review process.

Then, the secondary source must meet the following criteria for either group A or group B sources:

Group A secondary sources	Group B secondary sources
<p>are bodies that set or recommend exposure standards, and</p> <ul style="list-style-type: none"> • derive or make recommendations on standards from undertaking a scientific evaluation of research findings, but do not satisfy the criteria to be primary sources, or • publish research findings that may be used as the basis of standard setting by undertaking a scientific evaluation of research findings. 	<p>are not exposure standard setting bodies, and</p> <ul style="list-style-type: none"> • output is used or considered by a primary source in exposure standard setting considerations, or • is a reputable domestic or international body that undertakes comprehensive toxicological and/or epidemiological review of hazardous chemicals.

⁴ 1995 has been chosen because this is the date that a majority of the Workplace Exposure Standards for Airborne Contaminants were adopted. This date can be substituted as appropriate.

Selection of sources of data for notation recommendations

Australia's workplace exposure standards are published with advisory notations associated with the hazardous chemical. These notations consist of:

- classification of carcinogenicity
- classification of sensitisation⁵, and
- potential for systemic effects due to skin absorption.

Both domestic and international sources may be considered for recommending notations.

Sources of data for notations will provide the classification to inform a recommendation for a notation or resolve uncertainty. Recommending a notation is not intended to be an in depth literature review, therefore individual scientific papers are excluded.

Criteria for sources of data for notations

Sources of data for notations must satisfy all the criteria listed.

Credibility

- Source is either:
 - a multilateral body with critical engagement from a number of countries in the development of outputs
 - an internationally respected single country body whose outputs are adopted by other countries, or
 - an authoritative domestic body.

Classifications are developed through consensus

- Source integrates a peer, stakeholder, and public review process.

Human health classifications

- Source classifies hazardous chemicals specifically for the following:
 - carcinogenicity
 - skin sensitisation
 - respiratory sensitisation, or
 - toxicity via the dermal route.

Classifications are based on evaluation of appropriate data

- Classifications are:
 - consistent with current state of knowledge of the hazards of the chemical(s)
 - based on criteria that integrates human, animal and in vitro testing data, and
 - based on clear decision logic.
- Scientific data that informs a classification is test method neutral and sourced from adequate and appropriate studies that are conducted according to appropriate guidelines.

Classifications are reflective of intrinsic hazard

- Classifications are based on the hazards arising from the intrinsic properties of the chemical, and
- Classifications are free from considerations of
 - risk
 - socio-economic impact
 - non-scientific policy, and
 - feasibility.

Classifications are accessible

- Classifications are freely available.

⁵ The sensitisation notation does not currently distinguish between skin and respiratory sensitisation.

Next steps

These criteria will be used to identify primary and secondary sources that can be used for recommending workplace exposure standards for hazardous chemicals and the sources for notation recommendations.

The sources will then be used to inform health-based recommendations using a process to review data.