WES Review 2018

WES Methodology: Recommending health-based workplace exposure standards and notations

Australian workplace exposure standards and advisory notations

Safe Work Australia (2018)
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Recommending health-based workplace exposure standards and notations

This document is the second part of the methodology for reviewing and recommending health-based workplace exposure standards and associated advisory notations.

Aim

The overarching aim for the review of workplace exposure standards for hazardous chemicals is to develop health-based recommendations for workplace exposure standards and notations.

The document *Workplace exposure standards for airborne contaminants* (Safe Work Australia 2013a; the WES list) contains a list of exposure standards that are mandatory under the model Work Health and Safety (WHS) laws. To comply with the model WHS Regulations, persons conducting a business or undertaking (PCBU's) must ensure that no person is exposed to airborne concentrations of a chemical above the exposure standard at the workplace.

This part of the methodology aims to develop a process for deriving health-based workplace exposure standards and advisory notations for chemicals in the WES list based on information contained in selected primary and secondary sources.

Approach

The first part of the methodology\(^1\) outlines the approach to use trusted domestic and international data sources to inform recommendations for workplace exposure standards.

The second part of the methodology, the part described in this document, outlines how the data available from these sources can be used to determine workplace exposure standards and notations for the chemicals listed.

The third part of the methodology\(^2\) outlines an approach to recommend updates to the composition of the WES list, including making recommendations on which chemicals should be considered:

- to be added to the WES list, and
- for removal from the WES list

The fourth part of the methodology describes the process for consultation on the health-based recommendations, and the associated steps that lead to publication of a revised list of workplace exposure standards.

Outcome

The outcome of this methodology is to establish a process for recommending:

- health-based WES (where possible), and
- associated advisory notations (where relevant).

Rationale

The Australian Government's principle for red tape reduction is to utilise international standards and risk assessments from trusted international sources where appropriate. Therefore, the WES values and advisory notations will be recommended using relevant standards and supporting assessments that are available both domestically and internationally.

\(^1\) WES Methodology: Criteria for the selection of sources for workplace exposure standards, notations and supporting data

\(^2\) WES Methodology: Criteria for the selection of hazardous chemicals to be considered for addition to or removal from the workplace exposure standards list
The basis of the criteria for suitable international and domestic sources of data is that the trusted agency is:
- credible, and
- performs critical, scientific evaluations of appropriate toxicological and/or epidemiological data to derive a standard or provide a hazard profile of a chemical.

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 source data.

### Making recommendations for workplace exposure standards

Recommendations for workplace exposure standards will be derived in a consistent manner. The evaluation process will involve integrating information from the primary data sources (with supporting information from secondary sources where appropriate) to assign WES and notations based on the most up-to-date information within the scope of the work health and safety (WHS) framework. Secondary sources may be consulted at any point during the evaluation process to confirm or clarify detail, or to resolve uncertainty.

It is possible that the final standards published by a primary source may not be adopted. However, the underlying data may be used to derive a workplace exposure standard for Australia.

Following evaluation of the data, the recommendation may be to retain, amend or withdraw the existing WES values and/or notations. Recommendations will be based on the available toxicological and epidemiological data and will not take into account practicality or feasibility considerations.

In some cases, there may be insufficient data or residual uncertainty regarding the data and an interim WES value may be recommended. The interim WES recommendation will be accompanied either:
- by a recommendation for a further, more in-depth assessment of the toxicological and epidemiological data for the chemical, or
- a recommendation for a priority review of the data for the chemical in the next scheduled review of the workplace exposure standards.

A recommendation for a further, more in-depth assessment will only be made if:
- it can be reasonably expected that data to resolve any residual uncertainty or any outstanding data may be found in literature not cited in either the primary or secondary sources, or
- data in secondary sources suggest the available primary source WES values for a chemical may not be sufficiently protective.

It is not within the scope of this project to source literature outside of the primary or secondary data sources to resolve any of these outstanding data gaps or uncertainties. Should the need arise to source further information, this will be covered in the in-depth assessment.
Introduction to workplace exposure standards and the approach to evaluations

The WES values are airborne concentrations (generally expressed in mg/m³ or ppm air concentrations) of a chemical that are not expected to cause adverse effects on the health of an exposed worker. These adverse effects may be systemic effects associated with inhalational exposure to chemicals or local effects following contact exposure to airborne concentrations of the chemical. The WES values are expected to be protective for both short term (acute) and long term (chronic or subchronic) effects.

The WES values will generally be decided based on the adverse effect that occurs at the lowest airborne concentration of the chemical, or the ‘critical effect’. Protecting for the critical effect is expected to also be protective for all other adverse effects.

There are three WES parameters whose use is generally dependent on the nature of the critical effect:

- if the critical effect is a chronic or subchronic effect
  - 8-hour time-weighted average (TWA)
- if the critical effect is a short term or acute effect
  - short term exposure limit (STEL)
  - peak limitation

In some cases, additional adverse effects may occur at air concentrations of the chemical marginally above the concentration for the critical effect. The WES parameters and values should be sufficient to protect for these additional effects, as well as any other adverse effects, taking into account variations in exposure that may occur even when there is compliance with a TWA or STEL value (both are average concentrations)³.

Therefore, it is possible that a mixture of WES parameters may be assigned for a specific chemical to protect for critical chronic effects (TWA) and short term/acute effects (STEL or peak limitation). Short term parameters (STELs or peak limitations) may also be assigned to protect against the critical chronic effect (or other chronic effects) where the effect is dependent on both time and concentration; higher concentrations for shorter periods may cause similar effects to that observed with chronic exposure and there may be a need to control the concentration and time by assigning a short term limit with a TWA value.

Alternatively, if the value for the short term parameter is close to the TWA value, it may be more appropriate from a practical perspective to assign the short term or acute parameter at the lower of the two concentrations to protect for both short term and long term effects.

Generally, a TWA or a short term parameter will only be assigned if one has been assigned by a primary agency.

The possible combinations of WES parameters are as follows:

<table>
<thead>
<tr>
<th>Possible combinations of WES parameters</th>
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<tbody>
<tr>
<td>TWA</td>
</tr>
<tr>
<td>STEL</td>
</tr>
<tr>
<td>Peak limitation</td>
</tr>
<tr>
<td>TWA + STEL</td>
</tr>
<tr>
<td>TWA + peak limitation</td>
</tr>
</tbody>
</table>

³ In practice, the actual concentration of an airborne chemical arising from a particular process may fluctuate significantly with time. The TWA and STEL parameters allow short term excursions above the standard value provided they are compensated for by extended period of exposure below the standard value in the given time period (eight hours or 15 minutes for a TWA and a STEL, respectively). Given the fluctuations in concentration around a TWA concentration, adverse effects occurring at concentrations at least 10 times the no adverse effect level for the critical effect will be considered for applying a short term or acute parameter (STEL or peak).
The 8-hour time-weighted average (TWA) parameter

The TWA refers to the maximum average airborne concentration of a substance when calculated over an eight-hour working day. TWA values are generally assigned to be protective for long term or chronic effects.

Generally, agencies that set workplace exposure standards will have a parameter equivalent to Safe Work Australia’s TWA; however, the terminology may differ across agencies (Table 1). Consistent with primary sources, TWA values will be assigned at 1, 2 or $5 \times 10^n$ (ppm or mg/m$^3$) unless scientific reasons indicate a more specific value. Further discrimination resulting in proposals falling in-between any two of these integers suggests a precision that is unjustifiable in reality, given the limitations of the databases for the vast majority of the substances considered and the uncertainties involved in toxicological extrapolations (SCOEL, 2013).

Table 1 Summary of equivalent TWA terminology

<table>
<thead>
<tr>
<th>Agency</th>
<th>8-hour Time-Weighted Average term</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe Work Australia (SWA)</td>
<td>8-hour Time-Weighted Average</td>
<td>TWA</td>
</tr>
<tr>
<td>American Conference of Governmental Industrial Hygienists (ACGIH®)</td>
<td>Threshold Limit Value-Time-Weighted Average</td>
<td>TLV-TWA</td>
</tr>
<tr>
<td>Deutsche Forschungsgemeinschaft (DFG)</td>
<td>Maximum Concentration in the Workplace Air Value (Maximale Arbeitsplatz-Konzentration)</td>
<td>MAK</td>
</tr>
<tr>
<td>Scientific Committee on Occupational Exposure Limits of the European Commission (SCOEL)</td>
<td>8-hour Time-Weighted Average</td>
<td>8-hour TWA</td>
</tr>
<tr>
<td>Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands (DECOS)</td>
<td>Time-Weighted Average 8 hours</td>
<td>TWA 8 hours</td>
</tr>
<tr>
<td>Occupational Alliance for Risk Science and American Industrial Hygiene Association (OARS/AIHA)</td>
<td>8-hour Time-Weighted Average</td>
<td>8-hr TWA</td>
</tr>
</tbody>
</table>

Short term or acute parameters

Short term parameters may be assigned for either systemic effects, including specific organ effects, central nervous system effects (e.g. narcosis, alertness) and cardiac arrhythmia, or local effects, such as irritancy and corrosivity.

Short term exposure limit (STEL)

The STEL is a 15-minute time-weighted average exposure limit which must not be exceeded at any time during an 8-hour working day, even if the exposure during the full day is less than the TWA exposure standard. Exposures at the STEL must not be longer than 15 minutes and must not be repeated more than four times per day. There must be at least 60 minutes between successive exposures at the STEL (Safe Work Australia, 2013a).

STEL values are generally considered to be protective for short term or acute adverse effects that may not be of a severe or critical nature (compared with a peak limitation, below) or to minimise the likelihood of adverse chronic effects that may occur from shorter duration or higher concentrations, if effects are concentration-time dependent.
The ACGIH®, DECOS, SCOEL and OARS/AIHA (Table 2) assign STELs which, for the purpose of evaluation, are considered to be an equivalent parameter to a STEL assigned by Safe Work Australia. The excursion factors⁴ used by DFG are not considered to be an equivalent parameter to a STEL.

If evidence indicates the need to assign both a STEL and a TWA value, consistent with the approach of most standard setting agencies, the STEL will normally be in the range:

\[ TWA < STEL < 4 \times TWA \]

### Table 2 Summary of equivalent STEL terminology

<table>
<thead>
<tr>
<th>Agency</th>
<th>STEL term</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe Work Australia (SWA)</td>
<td>Short term exposure limit</td>
<td>STEL</td>
</tr>
<tr>
<td>American Conference of Governmental Industrial Hygienists (ACGIH®)</td>
<td>Threshold Limit Value-Short-Term Exposure Limit</td>
<td>TLV- STEL</td>
</tr>
<tr>
<td>Deutsche Forschungsgemeinschaft (DFG)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Scientific Committee on Occupational Exposure Limits of the European Commission (SCOEL)</td>
<td>Short-term exposure limit</td>
<td>STEL (15 mins)</td>
</tr>
<tr>
<td>Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands (DECOS)</td>
<td>Short term exposure limit</td>
<td>15 minutes TWA</td>
</tr>
<tr>
<td>Occupational Alliance for Risk Science and American Industrial Hygiene Association (OARS/AIHA)</td>
<td>Short Term Exposure Limit</td>
<td>STEL or Short-Term TWA</td>
</tr>
</tbody>
</table>

### Peak limitation

A peak limitation is a maximum airborne concentration of a substance determined over the shortest analytically practicable period of time that does not exceed 15 minutes (Safe Work Australia, 2013a). A peak limitation exposure standard must not be exceeded at any time as it is considered to pose undue risk to workers.

Factors that favour assigning a peak limitation instead of a STEL include:

- the health effect is severe
- the health effect is immediate, intolerable or irreversible, or
- there is a very steep concentration-response or dose-response relationship (i.e. there is a narrow margin between a no effect concentration and a concentration that causes a severe adverse effect).

That is, the concentration should be strictly controlled to minimise the risk of adverse effects that may occur if there are acute fluctuations in airborne concentrations of the chemical, despite compliance with a 15-minute average reading.

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⁴ Also called peak limitations. These parameters are not considered equivalent to either STELs or peak limitations according to the definition (and derivation) used by Safe Work Australia. The peak limitations assigned by DFG are multiples of the MAK (TWA equivalent) value and are not assigned on chemical-specific health data.
The ACGIH®, SCOEL, OARS/AIHA, DFG⁵ and DECOS assign peak limitations, though with differing names (Table 3). For the purpose of evaluation, all are considered equivalent to Safe Work Australia’s peak limitation.

If a peak limitation is assigned in conjunction with a TWA value, the Peak limitation will normally be in the range:

\[ TWA < \text{peak limitation} < 10 \times TWA \]

<table>
<thead>
<tr>
<th>Agency</th>
<th>Peak limitation term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe Work Australia (SWA)</td>
<td>Peak limitation</td>
</tr>
<tr>
<td>American Conference of Governmental Industrial Hygienists (ACGIH®)</td>
<td>Threshold Limit Value-Ceiling (TLV-C)</td>
</tr>
<tr>
<td>Deutsche Forschungsgemeinschaft (DFG)</td>
<td>Momentary value</td>
</tr>
<tr>
<td>Scientific Committee on Occupational Exposure Limits of the European Commission (SCOEL)</td>
<td>Ceiling value</td>
</tr>
<tr>
<td>Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands (DECOS)</td>
<td>Ceiling Limit</td>
</tr>
<tr>
<td>Occupational Alliance for Risk Science and American Industrial Hygiene Association (OARS/AIHA)</td>
<td>Ceiling</td>
</tr>
</tbody>
</table>

### Specific chemical groups

**Non-threshold based genotoxic carcinogens**

For carcinogens that act via a mutagenic mechanism, it is generally accepted that a no effect dose (or threshold) at the cellular or molecular level does not exist and there is a linear relationship between tumour incidence and dose that goes through a zero dose. Any exposure, no matter how small, carries a finite risk for carcinogenic effects.

The TWA value for a confirmed or assumed non-threshold based genotoxic carcinogen will be set at a minimal cancer risk level. Further details about non-threshold based genotoxic carcinogens and deriving a WES for them are provided in the document *Non-threshold based genotoxic carcinogens*.

For confirmed or assumed non-threshold based genotoxic carcinogens, the recommended TWA value should be protective for all adverse effects, including short term/acute effects, and thus a STEL or peak limitation evaluation will not be performed for these chemicals.

**Respiratory sensitisers**

‘Sensitisation’ is defined as a condition of acquired specific alteration in the responsiveness of a biological system, initiated by exposure to a sensitising substance and, after an incubation period, characterised by evocation of enhanced reactivity upon re-exposure to the same or a closely related substance (SCOEL, 2013).

There are two phases that characterise the immune response to allergens (Dotson et al., 2015):

- the sensitisation (or induction) phase where the immune system initially encounters the allergen, and

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⁵ DFG assigns ‘peak limitations’ or excursion factors which is not considered an equivalent parameter to either STELs or peak limitations according to the definition (and derivation) used by Safe Work Australia. Momentary values assigned by DFG are equivalent to a Safe Work Australia peak limitation.
• the elicitation phase where re-exposure of a sensitised individual to an allergen triggers an enhanced immune-mediated response.

Allergens are commonly grouped into two categories based on their mass and the nature of their interactions with the immune system:

• Low molecular weight (LMW) allergens
  o molecular mass less than 5000 Daltons
  o form hapten-protein complexes
• High molecular weight (HMW) allergens
  o molecular mass >5000 Daltons (e.g. proteins)
  o direct recognition by the immune system

Hypersensitivity reactions in the respiratory system can include allergic rhinitis and allergic asthma. Continued exposure can lead to worsening of the symptoms and the effects may become irreversible.

Currently, there are no validated animal models to assess respiratory sensitisation and data to determine if a chemical is a respiratory sensitisir will predominantly rely on data from human subjects.

As a significant percentage of workers who become sensitised are likely to develop an allergic respiratory disorder, workplace exposure standards should be assigned to be protective of the sensitisation phase (Health Council of the Netherlands, 2008; Dotson et al., 2015).

Some agencies who set exposure standards consider that there is no threshold for effects for respiratory sensitisers (or a subset of them) and hence do not assign a workplace exposure standard for these chemicals (i.e. a health-based limit cannot be set). However, there is no consistent policy across international agencies (Table 4).

Table 4 Comparison of respiratory sensitisir policies across agencies

<table>
<thead>
<tr>
<th>Agency</th>
<th>Policy regarding respiratory sensitisers</th>
<th>Is a WES value assigned?</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Conference of Governmental Industrial Hygienists (ACGIH®)</td>
<td>Assumes a threshold</td>
<td>Yes</td>
</tr>
<tr>
<td>Deutsche Forschungsgemeinschaft (DFG)</td>
<td>No threshold for all respiratory sensitisers</td>
<td>No</td>
</tr>
<tr>
<td>Scientific Committee on Occupational Exposure Limits of the European Commission (SCOEL)</td>
<td>A threshold may exist for some respiratory sensitisers, but not others (those that act via an immunological mechanism)</td>
<td>Yes or No (substance-specific)</td>
</tr>
<tr>
<td>Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands (DECOS)</td>
<td>A threshold exists but it may be very low</td>
<td>Yes</td>
</tr>
<tr>
<td>Occupational Alliance for Risk Science and American Industrial Hygiene Association (OARS/AIHA)</td>
<td>No respiratory sensitisers have been assigned</td>
<td>—</td>
</tr>
</tbody>
</table>

As with all other toxicological end points, with the exception of non-genotoxic carcinogens, Australian WES values for respiratory sensitisers will be derived by consideration of data from all available primary and secondary sources in a weight of evidence approach using expert toxicological judgement. The chosen WES value will be supported by a robust scientific justification.

If there is any residual uncertainty with respect to the WES value, an interim WES value will be assigned and there will be a recommendation for a priority review of the data for the chemical in the next scheduled review.
The WES value for all respiratory sensitisers will be accompanied by a RSEN advisory notation (see Introduction to advisory notations) and the supporting documentation will state that:

- the WES value is not expected to be protective for individuals who are already sensitised, and
- exposures to individuals should be kept as low as reasonably practicable

International policies for setting WES values for respiratory sensitisers are evolving and the approach by Safe Work Australia described above should be reviewed, when new policies develop. These reviews should be performed at the regular reviews of the workplace exposure standards.

**Irritants**

Some chemicals can irritate the eyes, mucous membranes of the respiratory tract, and skin. The severity of the irritation is chemical and concentration dependent.

Irritation may be considered an adverse effect, depending on severity. Eye irritation can impair a worker’s ability to function and perform optimally and may lead to accidents in the workplace. Respiratory irritation can impair respiratory function. Chronic irritation may lead to severe, irreversible effects, such as cancer.

While individuals may easily be able to sense irritation, there are inter-individual differences in tolerance towards irritation, and some workers may persist working in an environment despite an overt sense of irritation to the eyes, respiratory tract or skin. To remove this subjectivity and not place the responsibility of sensing a threshold for irritation on the individual worker, a WES value may be assigned based on irritation as the critical effect, provided it is also considered a critical effect by a primary agency.

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6 The timing for review is yet to be determined. However, the model WHS laws must be reviewed every five years and it is expected that this will be the maximum timeframe. This will be covered in a separate methodology document (still in draft form).
Introduction to advisory notations

Australia’s workplace exposure standards are published with advisory notations associated with the hazardous chemical. The notations are provided with the exposure standard for information only, so a PCBU and workers can take informed action to minimise exposure and risks.

A notation will only be recommended if a WES value (or an interim WES value) has been recommended. These notations consist of:

- classification of carcinogenicity (carcinogen)
- classification of sensitisation (respiratory and/or dermal sensitiser)
- the potential for systemic effects due to skin absorption (skin), and
- Immediately Dangerous to Life or Health (IDLH).

The abbreviations for these notations are shown in Table 5.

**Table 5 Advisory notations that may be assigned together with the WES**

<table>
<thead>
<tr>
<th>Notation</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogen</td>
<td>Carc. Cat. 1A</td>
</tr>
<tr>
<td></td>
<td>Carc. Cat. 1B</td>
</tr>
<tr>
<td></td>
<td>Carc. Cat. 2</td>
</tr>
<tr>
<td>Respiratory sensitiser</td>
<td>RSEN</td>
</tr>
<tr>
<td>Dermal sensitiser</td>
<td>DSEN</td>
</tr>
<tr>
<td>Skin notation</td>
<td>Sk.</td>
</tr>
<tr>
<td>Immediately Dangerous to Life or Health</td>
<td>IDLH</td>
</tr>
</tbody>
</table>

Carcinogenicity notation

Chemicals on the WES list that meet the criteria for classification as a carcinogen according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) will be assigned one of three GHS categories (Table 6). This classification will be consistent with the classification listed for the chemical in the Hazardous Chemical Information System (HCIS).

**Table 6 GHS hazard categories for carcinogens**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description of Hazard Statement</th>
<th>Advisory Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1A</td>
<td>Known to have a carcinogenic potential for humans; the placing of a substance is largely based on human evidence</td>
<td>Carc. Cat. 1A</td>
</tr>
<tr>
<td>Category 1B</td>
<td>Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence</td>
<td>Carc. Cat. 1B</td>
</tr>
<tr>
<td>Category 2</td>
<td>Suspected human carcinogens; the placing of a substance is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1</td>
<td>Carc. Cat. 2</td>
</tr>
</tbody>
</table>

If data presented in either the primary or secondary sources for WES suggest the classification in HCIS may be incorrect, this will be noted during the evaluation.

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7 Database located on the Safe Work Australia website that provides information on chemicals that have been classified in accordance with the GHS.
Sensitiser notations

Previously, for chemicals on the WES list, a differentiation between respiratory and skin (dermal) sensitisers was not made, both were assigned the ‘Sen’ notation. Moving forward, the notation will provide further information by differentiating between skin (dermal) sensitisers (DSEN) and respiratory sensitisers (RSEN), recognising that different mechanisms may be involved in these two immunological reactions. The notation will be based on the GHS sensitiser classification (excluding hazard sub-categories) for that chemical (Table 7).

Table 7 GHS hazard categories for sensitisers

<table>
<thead>
<tr>
<th>Type of sensitiser</th>
<th>Classification criteria</th>
<th>Advisory Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory sensitiser</td>
<td>A substance is classified as a respiratory sensitiser; (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test</td>
<td>RSEN</td>
</tr>
<tr>
<td>Skin sensitiser</td>
<td>A substance is classified as a skin sensitiser; (a) if there is evidence in humans that the substance can lead to sensitisation by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test</td>
<td>DSEN</td>
</tr>
</tbody>
</table>

‘Skin’ notation

The WES values are generally assigned to be protective for toxicity by the inhalational route. However, dermal exposure to some airborne chemicals may also significantly contribute to the total systemic exposure to the chemical. Where significant exposure and toxicity may occur as a result of dermal absorption from airborne concentrations of the chemical, a skin notation (Sk.) will be assigned.

This notation will inform PCBUs and workers that maintaining airborne concentrations of the chemical at the workplace exposure standard may not be sufficiently protective as significant additional exposure may occur via the dermal route.

The criteria for a skin notation are provided in Criteria for assignment of a skin notation. Data to inform a skin notation will be located in the primary and secondary sources for WES as well as primary sources for notations.

Immediately Dangerous to Life or Health (IDLH) notation

The Immediately Dangerous to Life or Health (IDLH) notation is a new addition to the advisory notations associated with the Australian WES list.

The IDLH parameter was developed by the US National Institute for Occupational Safety and Health (NIOSH) to represent an airborne concentration of a chemical capable of:

- causing death or immediate or delayed permanent adverse health effects to a worker, or
- impeding their escape from such an environment (NIOSH, 2013).

An IDLH is not considered an exposure standard as it represents a concentration that may cause harm, rather than a concentration at which no adverse effects are expected in nearly all workers.

However, it could provide PCBUs and workers additional safety information for non-routine workplace situations, such as working in confined spaces, industrial accidents (for example, chemical spills or explosions) or other uncontrolled-release scenarios and may help guide accident prevention and emergency response planning in the workplace.
The IDLH values will be adopted directly from NIOSH. The underlying scientific data will not be scrutinised. However, not all NIOSH IDLH values will be adopted. For a further discussion regarding this parameter including when an IDLH value will not be adopted, see New Advisory Notation Proposal: Immediately Dangerous to Life or Health.

Evaluation Process

Overview of the evaluation process

The basis of the evaluation is to examine the information contained in the documentation for a particular chemical from primary agencies and, where necessary, secondary agencies, to obtain a toxicological profile of a chemical that will be used to recommend WES values and advisory notations. The WES values and parameters available from primary sources will be used to help guide the most appropriate WES parameter(s) and WES value(s) that should be recommended for a particular chemical.

An overview of the evaluation process is shown in Figure 1. The process can be divided into five stages (below). Not all stages are necessary during the evaluation of each chemical.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| Stage 1 | Assessment of whether the chemical is a non-threshold based genotoxic carcinogen:  
• If yes, recommend a TWA value according to cancer risk and proceed to Stage 5  
• If no, proceed to Stage 2. |
| Stage 2 | Evaluate to recommend a TWA value if SWA has an existing TWA value or any primary agency has assigned a TWA value:  
• Proceed to Stage 3 if SWA has an existing short term or acute limit or any primary agency has assigned a short term or acute limit  
• Proceed to Stage 5 if neither SWA nor any primary agency has an existing short term or acute limit. |
| Stage 3 | Evaluate to recommend a short term or acute limit:  
• Proceed to Stage 4 if a combination of a TWA or a short term or acute limit appears warranted, else  
• Proceed to Stage 5. |
| Stage 4 | Recommend the best combination of WES parameters |
| Stage 5 | Recommend advisory notations where appropriate |

If neither SWA nor any primary agency has an existing WES value assigned to a chemical, neither a WES value nor an advisory notation will be recommended for a particular chemical. Determining a WES value directly from toxicological data is considered out of scope for this project. A further more comprehensive review will be recommended.

Terms relevant to the evaluation process

Critical effect

The critical effect is the adverse health effect that the WES is assigned to primarily protect against; the adverse effect that occurs at the lowest airborne concentration or dose. More than one critical effect may exist if a number of adverse effects occur at similar low doses or concentrations.

For a given chemical, the critical effect may differ between agencies due to

• the assessment of different datasets, or  
• different interpretations of the same dataset.
Point of departure (PoD)

A PoD is the point on a toxicological concentration-response or dose-response curve, established from experimental or observational data, corresponding to an estimated low effect level or no effect level. The PoD for the critical effect is the starting point for deriving WES values. Commonly used PoDs are the:

- no observed adverse effect concentration (NOAEC)\(^8\)
- lowest observed adverse effect concentration (LOAEC)\(^8\), and
- benchmark dose (BMD) or concentration – a dose or concentration that produces a predetermined change in response rate of an adverse effect compared to background or the lower 95% confidence interval of this benchmark dose value (BMDL).

Information collection

A comprehensive pharmacokinetic, toxicological and epidemiological profile of a chemical does not need to be documented. Only information relevant to recommending a WES value, the most appropriate WES parameter and advisory notations is necessary. Examples of relevant information include:

- for WES values/parameters:
  - critical effects, points of departure and uncertainty factors
  - data relating to cancer risk for non-threshold based genotoxic carcinogens, and
  - any additional data relevant to interspecies comparisons
- for advisory notations:
  - data relevant to assignment of a skin notation
  - information regarding skin or respiratory sensitisation, and
  - IDLH values.

These data can be sourced from primary and/or secondary source documentation.

Weight of evidence approach

If the WES value and parameter for a chemical are the same across primary agencies, this value and parameter will be recommended for adoption by SWA unless there are data to suggest the value is not sufficiently protective. However, there will be times when primary agencies have assigned different WES values and/or parameters for the same chemical. This can arise as a result of:

- differences in the datasets used to derive the WES value
- differences in the interpretation of the same dataset used to derive the WES value, or
- differences in the derivation of the WES value using the same dataset.

When this occurs, expert judgement using a weight of evidence approach will be applied to recommend a WES value for SWA. This judgement will take into account:

- the age of the data used by the primary agencies
- the assessment of the quality of the data by the primary agencies
- the interpretation of the data by the primary agencies
- the use of uncertainty factors and the justification provided by the primary agencies, and
- secondary agency documentation for the chemical that may help resolve any uncertainty or conflicting conclusions or interpretations by the primary agencies.

A robust scientific justification for the selected WES value will be provided in the evaluation report.

Grouping of chemicals

In most cases, evaluations will involve the assessment of data for an individual chemical (rather than a group of chemicals). A group assessment of chemicals will occur if the toxicological profile of the grouped chemicals can be attributed to the common component for each of the chemicals, for example a common ion, and (generally) group assessments were performed by the primary agencies. The outcome of the assessment will be a recommendation on the WES and notations that will cover the group of chemicals.

\(^8\) If there are no adequate inhalational studies that can be used to derive a WES value, data from studies using other routes of exposure (e.g. the oral route) may be used provided the toxicological profile by the alternative route of exposure is expected to be similar to the inhalational route, taking into account the pharmacokinetic profile as well as possible local effects of the chemical. The PoD for non-inhalational studies may be the no observed adverse effect level (NOAEL) or the lowest observed adverse effect level (LOAEL).
Figure 1: Summary flowsheet of the overall evaluation process
Stage 1: Deriving a TWA value for a non-threshold based genotoxic carcinogen

If a chemical is characterised as a non-threshold based genotoxic carcinogen and data are available, a TWA value at a minimal cancer risk level (or determined by applying a large uncertainty factor) will be recommended. A short term or acute limit will not be assigned for these chemicals.

The process for determining if a chemical is an assumed or confirmed non-threshold based genotoxic carcinogen and the method for recommending a TWA value for these chemicals is shown in Figure 2 and provided in Non-threshold based genotoxic carcinogens.

Where there are insufficient data to calculate a concentration at a minimal cancer risk level, an interim TWA value will be recommended from identified points of departure and applying an uncertainty factor. The choice of the uncertainty factor will be made by expert judgement and will be dependent on the available data for an individual chemical. A justification for the uncertainty factor will be provided in the evaluation report.

Next steps

After assigning a TWA value based on cancer risk (or by the use of a large uncertainty factor), assumed or confirmed genotoxic carcinogens will be assessed for advisory notations (Stage 5).

For chemicals that do not meet the criteria for an assumed or confirmed non-threshold based genotoxic carcinogen, WES values will be determined according to Stages 2 and 3.
Figure 2: Stage 1. Deriving a TWA value for a non-threshold based genotoxic carcinogen
Stage 2: Deriving a TWA value for other chemicals

Stage 2 of the evaluation process involves deriving a TWA value for chemicals that are not confirmed or assumed non-threshold based genotoxic carcinogens. A detailed flowsheet of Stage 2 is shown in Figure 3.

If neither SWA nor any primary agency has a TWA value, Stage 2 of the evaluation will be skipped and the evaluation will proceed to Stage 3.

If all primary agencies have the same TWA value, this value will be recommended. If the TWA values or WES parameters from the primary sources are not all the same, a weight of evidence approach will be taken to decide the WES parameter and value for SWA that best reflects the data. A justification for the choice of WES parameter and TWA value will be provided in the evaluation report.

Recommendations

Possible recommendations regarding the TWA value include:

- withdraw or not assign a TWA value
- assign an interim TWA value
- retain the existing TWA value, or
- adopt a new TWA value.

The basis for the recommendation will be clearly articulated in the evaluation report. Any of the above TWA recommendations can be accompanied by a recommendation for further assessment. A further assessment will only be recommended if:

- it can be reasonably expected that data to resolve any residual uncertainty or any outstanding data may be found in literature not cited in either the primary or secondary sources, or
- data in secondary sources suggest the available primary source WES values for a chemical may not be sufficiently protective.

Next steps

After assigning a TWA value, if neither SWA nor any primary agency has assigned a short term or acute limit, the evaluation will proceed to Stage 5 (assessment for advisory notations), else the evaluation will proceed to Stage 3.
Figure 3: Stage 2. Deriving a TWA value for other chemicals (Part 1)
**Figure 3**: Stage 2. Deriving a TWA value for other chemicals (Part 2)
Stage 2 – Part 3

- More than one primary source assigns a TWA value.
- At least one TWA value has been reviewed since the SWA value was last reviewed.
- Not all values are the same as the SWA TWA value.

**Are all primary source TWA values the same?**

- **Y** Recommend adoption of TWA value from primary sources.
- **N** Consult secondary data sources.

**Consult secondary data sources**

**Does SWA or any primary agency assign a STEL or a Peak limitation?**

- **Y** Recommend TWA value that best reflects the data.
- **N** Based on weight of evidence, can a TWA value be recommended with good confidence?

**Based on weight of evidence, can a TWA value be recommended with good confidence?**

- **Y** Recommend TWA value that best reflects the data.
- **N** Recommend interim TWA value that best reflects the data.

**Recommend interim TWA value that best reflects the data.** Recommend further assessment.

**Recommend further assessment.**

**Go to Stage 3**
Stage 3: Recommending a short term or acute limit

The overall flowsheet for the determination of a short term or acute limit (STEL and Peak limitation) is shown in Figure 4.

The process for assigning a short term limit involves two steps:

- evaluating whether there is a need for a short term limit, and
- if there is a need, evaluating whether the short term limit should be a STEL or a Peak limitation.

Evaluating whether some form of short term or acute limit is required

The need to evaluate whether a short term should be assigned will normally be triggered by SWA or one of the primary source agencies having a STEL or Peak limitation for that particular chemical.

Evaluating whether to assign a STEL or a Peak limitation

A peak limitation will generally be assigned if:

- the acute effect is severe (e.g. irreversible or intolerable) and the effect is immediate or occurs rapidly (e.g. occurs within 15 min)
- the initial acute effect subsequently leads to a severe chronic health effect (e.g. chronic irritation leading to tumour formation), or
- there is a steep response-concentration relationship (i.e. there is a narrow margin between a no effect concentration and a concentration that causes a severe adverse effect)

If there appears to be a need for a short term limit but the acute effects are not sufficiently severe or immediate to warrant a Peak limitation, a STEL may be assigned.

As both a STEL and a peak limitation are assigned to be protective for short term or acute effects, only one of these parameters will be assigned if there is a need to be protective for short term/acute effects. The value for the short term or acute limit will be determined based on a weight of evidence approach.

Next steps

If both a TWA and a short term or acute limit appears to be warranted based on the available data, the evaluation will proceed to Stage 4 to decide the most appropriate combination of WES parameters.

If a short term or acute limit alone has been recommended (i.e. no TWA value), the evaluation will proceed to Stage 5 (assessment for advisory notations).

Stage 4: Recommending the best combination of WES parameters

If the data suggest a need to protect for both long term and short term/acute effects, a TWA value and a STEL or Peak limitation value may be recommended. Generally, a Peak limitation or STEL value will be higher than the TWA value.

If, during the evaluation, it appears chronic effects occur at airborne concentrations greater than those causing short term/acute effects, there may be no need to assign a TWA value; a STEL or Peak limitation alone should be sufficiently protective for long term effects as well as short term effects.

If the derived short term/acute limit value is only marginally different from the TWA value, from a practical perspective, there may be no need for both a TWA and a short term limit value; assigning a short term/acute limit at the lower of the two values may be sufficiently protective.

The most appropriate combination of WES parameters will be dependent on the available data for a chemical and thus will be considered on a case-by-case basis using expert judgement. A justification for the choice of the WES combination will be provided in the evaluation report.

Next steps

After recommending the most appropriate combination of WES parameters and values, the evaluation will proceed to Stage 5 (assessment for advisory notations).
Stage 3

Is there indication of an immediate or acutely severe adverse health effect?

**Yes** Recommend STEL value based on weight of evidence

**No**

Is the adverse effect both immediate and severe?

**Yes**
Recommend Peak limitation

**No**

Was a TWA value recommended during Stage 2?

**Yes**
Recommend STEL value based on weight of evidence

**No**
Consult secondary data sources (if not performed previously)

Figure 4: Stage 3. Recommending a short term or acute limit; Stage 4. Recommending the best combination of WES parameters
Stage 5: Recommending advisory notations

Having decided on the WES recommendation(s) for a chemical, the next step is to evaluate what advisory notations should be assigned together with the WES. As described earlier, there are four possible advisory notations:

- carcinogen
- sensitiser (dermal or respiratory)
- skin, and
- IDLH.

All of these notations are independent, providing different advisory information to PCBUs. As such, there are no restrictions to the combination of notations.

**Carcinogen and sensitiser notations**

The primary source for the carcinogen (Carc. Cat. 1A, Carc. Cat. 1B or Carc. Cat. 2) and sensitiser (DSEN and RSEN) notations is the HCIS database. The data assessed during the WES evaluation will be examined for consistency with the carcinogenicity and sensitisation classifications for that hazardous chemical in the HCIS database. The flowsheet for recommending carcinogenicity and/or sensitiser notations is shown in Figure 5.

If the sensitiser or carcinogen classification listed in HCIS is consistent with data obtained during the WES evaluation, the appropriate notation or notations will be assigned.

If there are no sensitiser or carcinogenicity classifications in HCIS and there was no evidence during evaluation indicating that either of these hazard classifications is needed, the recommendation will be not to assign a carcinogen or sensitiser notation.

If the classification regarding carcinogenicity or sensitisation in HCIS is not consistent with data obtained during the WES evaluation, then notation sources will be checked for classifications.

If the notation sources have classified the chemical, and the classifications differ from those in the HCIS database, then the following may be recommended:

- assign a notation or notations based on the recent classifications, and
- amend the classification in the HCIS database to reflect the classifications reported in the more recent review.

If the notation sources have not classified the chemical or notation source data are inconsistent with data examined during the WES evaluation, then the following may be recommended:

- request a review of the classification of the chemical by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), and
- not assign a notation until the classification has been reviewed by NICNAS

**‘Skin’ notation**

See [Criteria for assignment of skin notation](#).

**IDLH notation**

See [New advisory notation proposal Immediately Dangerous to Life or Health](#).

...
Figure 5: Stage 5. Recommending advisory notations
References

American Conference of Governmental Industrial Hygienists (ACGIH®) (2016). Threshold limit values for chemical substances and physical agents.

DFG, Deutsche Forschungsgemeinschaft (2016). Maximum Concentrations at the Workplace
WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim.


Health Council of the Netherlands (2008) Prevention of work-related airway allergies:
Recommended occupational exposure limits and periodic screening.


United States National Institute for Occupational Safety and Health (NIOSH) (2013). Derivation of Immediately Dangerous to Life or Health (IDLH) Values. DHHS (NIOSH) Publication No. 2014–100
## Appendix A — Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH®</td>
<td>American Conference of Governmental Industrial Hygienist</td>
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<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
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<tr>
<td>BMD</td>
<td>Benchmark dose</td>
</tr>
<tr>
<td>BMDL</td>
<td>Lower 95% confidence bound on the benchmark dose</td>
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<tr>
<td>Carc Cat 1A</td>
<td>Category 1A carcinogen notation</td>
</tr>
<tr>
<td>Carc Cat 1B</td>
<td>Category 1B carcinogen notation</td>
</tr>
<tr>
<td>Carc Cat 2</td>
<td>Category 2 carcinogen notation</td>
</tr>
<tr>
<td>DECOS</td>
<td>Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands</td>
</tr>
<tr>
<td>DFG</td>
<td>Deutsche Forschungsgemeinschaft (German Research Foundation)</td>
</tr>
<tr>
<td>DSEN</td>
<td>Dermal sensitiser notation</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification and Labelling of Chemicals</td>
</tr>
<tr>
<td>HCIS</td>
<td>Hazardous Chemical Information System</td>
</tr>
<tr>
<td>HMW</td>
<td>High molecular weight</td>
</tr>
<tr>
<td>IDLH</td>
<td>Immediately Dangerous to Life or Health</td>
</tr>
<tr>
<td>LMW</td>
<td>Low molecular weight</td>
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<tr>
<td>LOAEC</td>
<td>Lowest observed adverse effect concentration</td>
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<tr>
<td>LOAEL</td>
<td>Lowest observed adverse effect level</td>
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<tr>
<td>MAK value</td>
<td>Maximum Concentration in the Workplace Air value (DFG)</td>
</tr>
<tr>
<td>mg/m³</td>
<td>Milligrams per cubic metre</td>
</tr>
<tr>
<td>NICNAS</td>
<td>National Industrial Chemicals Notification and Assessment Scheme</td>
</tr>
<tr>
<td>NOAEC</td>
<td>No observed adverse effect concentration</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No observed adverse effect level</td>
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<tr>
<td>OARS</td>
<td>Occupational Alliance for Risk Science</td>
</tr>
<tr>
<td>PCBU</td>
<td>Person Conducting a Business or Undertaking</td>
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<tr>
<td>PoD</td>
<td>Point of Departure</td>
</tr>
<tr>
<td>ppm</td>
<td>parts per million</td>
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<tr>
<td>RSEN</td>
<td>Respiratory sensitiser notation</td>
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<tr>
<td>SCOEL</td>
<td>Scientific Committee on Occupational Exposure Limits of the European Commission</td>
</tr>
<tr>
<td>Abbreviations</td>
<td>Description</td>
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<tr>
<td>---------------</td>
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<tr>
<td>STEL</td>
<td>Short Term Exposure Limit</td>
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<td>SWA</td>
<td>Safe Work Australia</td>
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<tr>
<td>TLV-C</td>
<td>Threshold Limit Value-Ceiling</td>
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<tr>
<td>TLV-STEL</td>
<td>Threshold Limit Value-Short-Term Exposure Limit</td>
</tr>
<tr>
<td>TLV-TWA</td>
<td>Threshold Limit Value-Time-Weighted Average</td>
</tr>
<tr>
<td>TWA</td>
<td>Time-weighted average</td>
</tr>
<tr>
<td>WES</td>
<td>Workplace Exposure Standard</td>
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<tr>
<td>WHS</td>
<td>Work Health and Safety</td>
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</table>
Appendix B — Key to Figures

- Start
- Process
- Decision
- On-page reference
- Off-page reference