LOW REGULATORY CONCERN CHEMICALS (LRCC)

Discussion Paper No. 1

LOW-HAZARDOUS CRITERIA FOR THE PURPOSES OF NOTIFICATION AND ASSESSMENT

1. PURPOSE

The Low Regulatory Concern Chemicals (LRCC) reform initiative resulted in a number of recommendations focused on regulatory efficiency and positive incentives to drive improvements in the safe and sustainable use of new chemicals in Australia. One key reform was to develop notification and assessment categories based on low hazard properties. Before this can be implemented, what constitutes a new industrial chemical to be considered 'low-hazardous' must be defined.

This discussion paper seeks comment on:

- The proposed criteria to be used to classify chemicals as 'low-hazardous'.

2. BACKGROUND

The aim of the Low Regulatory Concern Chemicals (LRCC) reform initiative was to introduce flexibility into the regulation of new industrial chemicals without deregulation. As such the recommendation that came from the LRCC reform initiative focused on regulatory efficiency and positive incentives to drive improvements in the safe and sustainable use of new chemicals in Australia. Recommendations contained within the *Final Report and Recommendations for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative* ('Final Report') (NICNAS, 2003) were developed in partnership with government, industry and community and cumulated in The *Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Act 2004* (LRCC Amendment Act) that received Royal Assent on 13 July 2004 and Proclamation on 9 August 2004 with the passage of the *Industrial Chemicals (Notification and Assessment) Regulations* (the LRCC Regs). The LRCC Amendment Act and the LRCC Regs provided the legislative framework to immediately implement the majority of LRCC reforms. However, it was recognised that a small number of recommendations from the Final Report required further development of criteria and guidelines before they could be implemented.

One such pivotal issue that needs to be finalised before some recommendations from the LRCC reform initiative can be implemented is defining what constitutes a new industrial chemical notification category that is 'low-hazardous'. Such a definition will allow NICNAS to implement the following recommendations:

1) Introduce an audited self-assessment permit for low hazard chemicals (introduced at low volumes 100 – 1000 kg per year) against NICNAS criteria and/or guidelines developed by NICNAS/industry and the community (Recommendation 1.2 in the Final Report).

2) Introduce a low hazard permit for polymers of low volume (1000 kg/yr per introducer) for 3 years. Low hazard criteria appropriate for polymers would need to be developed in consultation with industry and the community (Recommendation 4.2 in the Final Report).
3) Introduce to the standard certificate assessment category of a new low-hazardous chemical sub-category with appropriate criteria and (modular) assessment fee (Recommendation 7.1 in the Final Report).
4) Expand access to the Early Introduction Permit system to include low hazard and low risk chemicals based on appropriately developed criteria (Recommendation 7.2 in the Final Report).
5) Introduce a low hazard permit for chemicals of low volume. These chemicals would be introduced in low volumes, 1000 kg/yr/introducer for three years (Recommendation 7.3 in the Final Report).

This discussion paper will address the definition of criteria for what constitutes a low-hazardous industrial chemical for the purposes of notification and assessment only. This paper also includes criteria for what constitutes a low-hazardous polymer. The application of low-hazardous criteria into the above permit and certificate systems and is addressed in the separate Overview of the Planned Reforms.

3. LOW-HAZARDOUS

3.1. Hazard

Hazard can be defined as the inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub) population is exposed to the agent (OECD, 2003). For industrial chemicals hazard is regulated through classification, and overseas industrial chemicals can be classified for human health and environmental effects and physicochemical properties. In Australia industrial chemicals can be classified for human health effects and physicochemical properties only, as there is presently no classification system for environmental endpoints[1].

Classification systems can be technically highly complex, though essentially such systems are triggered by a defined cut-off value ('hazard trigger') for an intrinsic property that can be quantitative (e.g. an acute oral LD_{50} value of $\leq$ 2000 mg/kg bw/day in the rat under the NOHSC *Approved Criteria for Classifying Hazardous Substances* [NOHSC, 2004]) (the Approved Criteria) or qualitative (eg explosive when mixed with oxidising substances [NOHSC, 2004]). Industrial chemicals that justify classification for human health effects, environmental effects and/or physicochemical properties are referred to as hazardous, and those that do not as non-hazardous.

While all classifications systems have a quantitative or qualitative hazard trigger that defines an industrial chemical as hazardous for human health effects, environmental

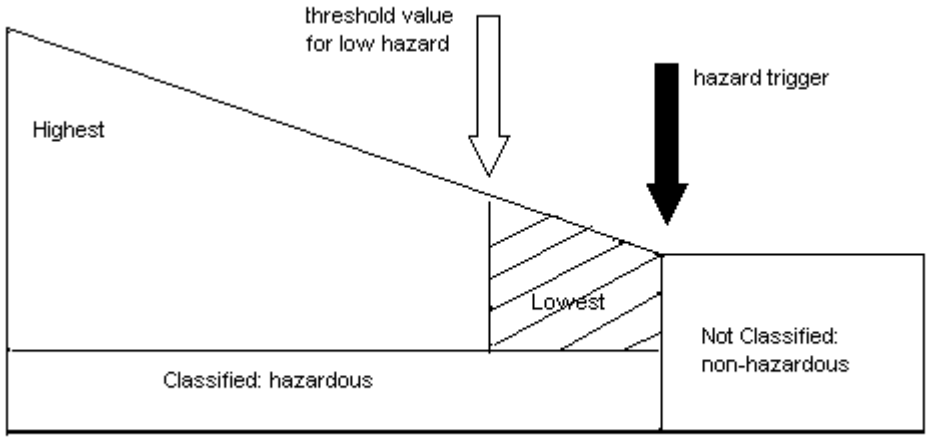
[1] Currently, for new industrial chemicals a provisional classification for environmental effects is made under the Globally Harmonised System for Hazard Classification and Communication (GHS) (OECD, 2002) which will only come into force when GHS is adopted by the Australian Government and promulgated into Commonwealth legislation.

effects and/or physicochemical properties, more than one classification category exists for some endpoints (e.g. there are three classification categories for acute oral toxicity under the Approved Criteria [NOHSC, 2004]). For such endpoints a grading system has clearly been established for industrial chemicals that are hazardous. The use of grading in classification (i.e. more than one degree of hazard) has often been used as a factor to delineate between classes/control of hazardous chemicals in regulatory programs both nationally and internationally:

- Nationally, in the uniform scheduling of drugs and poisons, substances placed in Schedule 5 are considered to have a low toxicity with regard to human health effects and require caution in handling, storage and use, while substance in Schedule 7 have a high to extremely high toxicity and are too hazardous for domestic use or use by untrained persons (NDPSC, 2003).
- Internationally, the EU Commission's White Paper proposing a revision of the EU chemicals policy (EC, 2001) deemed that category 1 and 2 CMRs (substances that are carcinogenic, mutagenic or toxic to reproduction) were to be of 'very high concern' but not category 3 CMRs.

However the intent here, for **the sole purpose**[2] of allowing the introduction of low hazardous chemicals under new permit and certificate systems, is to identify for each intrinsic property where possible a level above that defined by the Act (or the Approved Criteria) as hazardous where the industrial chemical can be considered to be low-hazardous (see Figure 1). This 'low hazardous' status is limited in its application to NICNAS notification and assessment purposes and does not apply to downstream regulatory control frameworks based on hazard determination.

Figure 1 – Diagrammatic view of low hazard in a classification scheme



3.2 Low-hazardous Evaluation

Each national and international classification system has developed its own framework for identifying hazardous industrial chemicals. As a first stage in developing low-hazardous criteria, an overview of national and selected international

[2] In no way do the proposed low-hazardous criteria affect other regulatory requirements, for example, workplace hazardous substances and dangerous goods legislation.

schemes for industrial chemicals and pesticides (as a comparison) has been undertaken to determine whether, for human health effects, environmental effects and physicochemical properties:

- More than one degree of hazard exists in the classification scheme;
- The classification scheme directly identifies what represents low-hazardous; and
- The hazard triggers are quantitative or qualitative[3] in nature.

The national schemes evaluated are:

- National Occupational Health Safety Commission's *Approved Criteria for the Classifying Hazardous Substances* (NOHSC, 2004**);**
- *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) - Guidelines for the National Drugs and Poisons Schedule Committee (NDPSC, 2003);
- Australian Pesticide and Veterinary Medicine Authority (APVMA) - *Guidelines for Pesticides Used by Householders* (APVMA, 2006**);** and
- *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code) (FORS, 1998).

The international schemes evaluated are:

- United Nations Globally Harmonised System of Classification and Labelling Chemicals (GHS) (GHS, 2005);
- New Zealand's *Hazardous Substance and New Organism (HSNO) Act 1996* in relation to applications for rapid assessment (ERMA, 2001);
- European Communities' Annex 6 General Classification and Labelling Requirements for Dangerous Substances and Preparations (as reported in UK's CHIP Regulations, 2002**);**
- US EPA's 40 CFR Part 152 Pesticide Registration and Classification Procedures Sub Part I – Classification of Pesticides (US EPA, 2004); and
- US EPA Ecotoxicity Categories for Terrestrial and Aquatic Organisms (US EPA, 2006).

It should be noted that the overviews presented in Appendix 1 – 3 are not detailed evaluations of each classification scheme but rather overviews of the hazard classification categories that allow a low-hazardous evaluation to be undertaken (e.g. for acute oral toxicity, only the criteria for classification using LD_{50} values are presented, though criteria exist for the results from other regulatory test guidelines such as the Fixed Dose Procedure; and for acute oral toxicity the avian dietary LD_{50} values are not presented for environmental effects). Additionally, it should be noted that the information presented here for human health effects does not mention effects seen in humans, though it is recognised that practical observations in humans can lead to classification even when results in animal studies do not warrant such.

[3] For this assessment, NICNAS considers that classification of a health effect is qualitative in nature if it does not address the potency of the chemical (see 'Human Health Effects' sub-section for a discussion of this issue).

Summaries of the findings of the evaluation are presented below separately for human health effects, environmental effects and physicochemical properties.

3.3 Human health effects

The national classification schemes that make a low-hazardous comment are:

- The APVMA scheme for household pesticides states that skin and eye irritancy should be low, though no qualitative (i.e. effects seen) and/or quantitative (i.e. severity of effects) information on what would constitute a low-hazardous effect are provided.
- The APVMA scheme for household pesticides states that chemicals are of low hazard from repeated use and should be unlikely to produce irreversible toxicity. However, though limited qualitative information is provided (i.e. which effects) no quantitative information is provided (i.e. severity of the observed effects).
- The SUSDP also states that chemicals placed in Schedule 5 are of low hazard from repeated use and should be unlikely to produce irreversible toxicity but, as for the APVMA scheme, provide no quantitative information.

Furthermore, although the APVMA scheme for household pesticides does not specifically report low-hazardous criteria for acute toxicity, they do delineate hazard with regards to pesticide use. For consumer use of pesticides the hazard the chemical represents in the product is much less than other non-consumer uses with regard to:

- Acute oral and dermal toxicity, for which quantitative criteria are provided (i.e. cut-off LD_{50} values).

Therefore, although in some of these national schemes it is stated that a chemical must be of low-hazard for some human effects, detailed criteria that define such, and which would allow low-hazardous chemicals to be reliably identified, are absent. The APVMA delineation of hazard is presented in Table 1.

The international classification schemes that propose low-hazardous criteria are:

- The GHS classification scheme identifies what constitutes relative low acute oral, dermal and inhalation toxicity providing quantitative information on the dose-range for determined LD_{50}/LC_{50} values;
- The NZ HSNO Act (which adopted the GHS classification scheme) states that the low acute toxicity identified in the GHS scheme represent a low hazard. This distinction of a low hazard is made to allow the rapid assessment of substances within the NZ regulatory scheme[4].

Low hazard is also defined in the NZ rapid risk assessment scheme with quantitative criteria (severity of effects) for skin and eye irritation.

[4] Note: a 'lower' classification to that identified as low-hazardous [i.e. not classified] would still allow rapid risk assessment while a 'higher' classification [i.e. Category 4 for acute toxicity] would prevent such an assessment.

Low hazard is also defined in the NZ rapid risk assessment scheme for skin and respiratory sensitisation and mutagenicity, though only qualitative criteria, not quantitative criteria, are provided for these human health effects.

Low hazard is also defined in the NZ rapid risk assessment scheme for repeat dose toxicity and, though quantitative criteria are provided (i.e. dose ranges for observed effects), the criteria also include a qualitative component (see 'Qualitative classification criteria' below).

Furthermore, though the USA EPA Pesticides Guidelines do not specifically report low-hazardous criteria, they do delineate hazard with regards to pesticide use. For consumer use of pesticides, the hazard the chemical represents in the product is much less than other non-consumer uses with regard to:

- Acute oral, dermal and inhalation toxicity, for which quantitative criteria are provided (i.e. cut-off LD_{50}/LC_{50} values); and
- Skin and eye irritation, for which qualitative criteria are provided that incorporate a time period after which effects should not be seen to persist.

Therefore, in contrast to national classification schemes, the NZ rapid risk assessment scheme provides detailed low-hazardous criteria for a number of human health effects. A summary of the low-hazardous criteria identified in the NZ scheme and the US EPA delineation of hazard are presented in Table 1, while a more detailed evaluation of these and other national and international classification schemes are provided in Appendix 1.

Degrees of hazard

Clearly, from the viewpoint of determining low-hazardous classification criteria, more than one degree of hazard is required i.e. a continuum, as if there is only one classification category there is no possibility of considering a continuum of degree of hazard, as the least degree is not distinguished from the highest degree. In Table 1, the NZ scheme proposes low-hazardous criteria for skin and respiratory sensitisation when only one degree of hazard is available for each health effect and, thus, NICNAS considers these low-hazardous criteria to be inappropriate. Furthermore, the NZ criteria for these health effects are not based solely on the chemical's intrinsic property but also exposure to the chemical (see Appendix 1 Table B), which is not a factor in hazard classification.

Table 1: Low-hazardous definitions for human health effects

HUMAN HEALTH EFFECT	LOW-HAZARDOUS CRITERIA
Acute oral toxicity	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 5 Categories each for acute oral, dermal and inhalation (dusts/mists, gases, and vapours) toxicity
Low-hazardous definition	**Yes** – Oral Category 5: 2000< $LD_{50} \leq$ 5000 mg/kg bw, dermal Category 5: 2000< $LD_{50} \leq$ 5000 mg/kg bw, and inhalation Category 5 for dusts/mists, gases, and vapours where the LC_{50} is in the equivalent range of the oral and dermal Category 5 LD_{50} value (i.e. between 2000 and 5000 mg/kg bw)
Qualitative or quantitative	Quantitative for all routes of exposure
	US EPA pesticide guidelines
More than 1 degree of hazard	Only for use, not classification
Low-hazardous definition	**No**, though hazard is delineated through use. For consumers, the pesticide as diluted for use has an oral LD_{50} < 1500 mg/kg bw, dermal LD_{50} < 2000 mg/kg bw, and inhalation LC_{50} < 0.5 mg/L/4hr
Qualitative or quantitative	Quantitative for all routes of exposure
	APVMA scheme for household pesticides
More than 1 degree of hazard	Only for use, not classification
Low-hazardous definition	**No**, though hazard is delineated through use. For consumers pesticide should not be life threatening to a child up to 1500 mg/kg bw if ingested and 1000 mg/kg bw via topical application.
Qualitative or quantitative	Quantitative for all routes of exposure
Skin irritation	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 2 Categories
Low-hazardous definition	**Yes** – Category 3 (Mild irritant): in 2 or more of 3 animals tested erythema/eschar or oedema $\geq$ 1.5 and < 2.3 (and inflammation does not persist to the end of the observation period normally 14 days in 2 animals)
Qualitative or quantitative	Quantitative
	US EPA pesticide guidelines
More than 1 degree of hazard	Only for use, not classification
Low-hazardous definition	**No**, though hazard is delineated through use. For consumers, the pesticide as formulated is not corrosive to the skin or causes severe irritation (severe erythema or oedema) at 72 hrs (after topical exposure)
Qualitative or quantitative	Qualitative
Eye irritation	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 2 Categories, though the lowest category consists of two classes
Low-hazardous definition	**Yes** – Category 2A (reversible effects on the eye) Irritating to eyes: in at least 2 of 3 animals tested corneal opacity $\geq$ 1, iritis $\geq$ 1, conjunctival erythema $\geq$ 2, or conjunctival oedema $\geq$ 2 and fully reverses within the observation period (normally 21 days)
Qualitative or quantitative	Quantitative
	US EPA pesticide guidelines
More than 1 degree of hazard	Only for use, not classification
Low-hazardous definition	**No**, though hazard is delineated through use. For consumers, the pesticide as formulated does not results in corneal involvement or irritation persisting for more than 7 days (after contact with the eyes)
Qualitative or quantitative	Qualitative
Skin sensitisation	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	No
Low-hazardous definition	**Yes –** but is not based solely on the intrinsic hazard: exposure is a condition for consideration as a low hazard (see note 1 in Appendix 1)
Qualitative or quantitative	Qualitative
Respiratory sensitisation	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	No
Low-hazardous definition	**Yes –** but is not based solely on the intrinsic hazard: exposure is a condition for consideration as a low hazard (see note 1 in Appendix 1)
Qualitative or quantitative	Qualitative
Repeat dose toxicity	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 2 Categories each for the oral, dermal and inhalation routes of exposure

Low-hazardous definition	**Yes** – Category 2 (Potential to be harmful to human health): oral > 10 to ≤ 100 mg/kg bw/day, dermal > 20 to ≤ 200 mg/kg bw/day, inhalation > 50 to ≤ 250 ppm, 6hr/day for a gas, > 0.2 to ≤ 1.0 mg/L, 6hr/day for a vapour, and > 0.02 to ≤ 0.2 mg/L, 6hr/day for a dust/mist/fume
Qualitative or quantitative	Quantitative with qualitative component
Mutagenicity	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 2 Categories, though the highest category consists of two classes
Low-hazardous definition	**Yes** – Category 2: cause concern owing to the possibility it may induce inheritable mutation in human germ cells (positive results in somatic cells)
Qualitative or quantitative	Qualitative

Similarly, NICNAS does not consider the US EPA delineation of hazard to be appropriate for identifying low-hazardous criteria, as it has no basis in hazard classification. Additionally, for US EPA skin and eye irritation, the criteria are not quantitative but qualitative in nature, and NICNAS considers this an important issue in developing criteria for identifying low-hazardous chemicals.

Qualitative classification criteria

In the NZ rapid assessment scheme, low-hazardous criteria that are not purely quantitative in nature were proposed for two endpoints that had more than one degree of hazard classification (repeat dose toxicity and mutagenicity). NICNAS considers that, for qualitative criteria, classification is taken according to the strength of the available evidence, and so reflects a level of concern for the seriousness of the health effect (e.g. Category 1, 2 and 3 for mutagenicity), but does not give specific consideration to the potency of the chemical for the observed effects (i.e. does not differentiate between the dose that the adverse effect was observed, or the activity of the chemical). Consequently, NICNAS considers that qualitative criteria are inappropriate for identifying low-hazardous chemicals as they do not address the potency of the chemical. Thus, the NZ proposed low-hazardous criteria for mutagenicity, which is purely qualitative in nature, are not considered appropriate.

The NZ low-hazardous classification proposal for repeat dose toxicity is slightly different in that though it is quantitative by differentiating between doses that adverse effects were observed, it is also qualitative in that it provides guidelines for those effects that warrant classification but does not give consideration to the potency of the chemical for the specified effects (e.g. the range of effects are broad, and classification can be based on death, severe organ damage or major functional changes). Consequently, while it is presently deemed that a low hazard cannot be identified for this health effect as it does not address potency, the quantitative aspect of the classification criteria encourage further discussions on the development of low hazard criteria for this endpoint.

Thus, NICNAS considers that for those health effects where there is more than one degree of hazard whose classification criteria are deemed to have a qualitative aspect,[5] some means of addressing potency in the classification system would first be required if criteria are to be developed that identify low-hazardous chemicals possessing a similar inherent property for that health effect. Furthermore, it is recognised that some human health effects are complex with such a highly diverse set of effects (e.g. carcinogenicity and reproductive toxicity) that comparisons of the

[5] That is, non-lethal irreversible effects, corrosivity, repeat dose toxicity, mutagenicity, carcinogenicity, fertility and developmental toxicity.

same type of toxic effect at a cut-off level for low hazardous (as applied for acute toxicity and irritation) would not be suitable (i.e. potency cannot be reliably addressed).

Low- hazardous criteria – human health effects

Therefore, it is proposed that for human health effects the identification of low-hazardous criteria for classification is restricted to those health effects where:

- There is more than one classification category; and
- The intrinsic property's classification criteria are solely quantitative in nature.

Furthermore, such criteria should allow comparisons to be made for the type of effects seen (i.e. LD_{50}/LC_{50} values for acute toxicity).

Human health effects that meet these criteria in the schemes evaluated are:

- Acute toxicity (oral, dermal and inhalation routes of exposure); and
- Skin and eye irritation.

However, for those human health effects that do not meet the above criteria as the present stage of scientific knowledge and/or classification system do not allow low-hazardous criteria to be identified, a watching brief should be kept and these endpoints revisited when scientific advances and/or amendments to classification systems are made that allow hazard quantification and potency to be addressed. To this end, it should be noted that work is presently ongoing on how consideration could be given to potency for carcinogenicity (e.g. determining the daily dose that induces a tumour incidence of 25 % upon lifetime exposure – the T25 method [EC, 1999]) and skin sensitisation (e.g. use of the local lymph node assay for the estimation of skin sensitisation potency [Basketter et al., 2000]) in classification schemes.

A brief impact analysis on implementing these low-hazardous criteria for skin and eye irritation into the national classification scheme is provided in section 4.1.

3.4 Physicochemical properties

No national classification scheme specifically proposes low-hazardous criteria, though the *Australian Dangerous Goods Code for Road and Rail* (ADG code) states that:

- For explosive properties, chemicals in Class 1.4 present no significant hazard, however, this is based primarily on packaging considerations; and
- For flammability properties, chemicals in Class 2.2 are non-flammable gases.

The only international scheme that proposed low-hazardous criteria is NZ (which adopted the GHS classification scheme) for rapid risk assessment. Criteria were proposed for the following:

- Explosiveness;
- Flammability (see comments below);

- Self-reactivity;
- Organic peroxides; and
- Emission of flammable gases when wet.

A summary of the low-hazardous criteria proposed in the NZ scheme and the above comments from the ADG code are provided in Table 2, together with information on those aspects identified from the human health evaluation as being critical for robust low-hazardous criteria:

- Degrees of hazard; and
- Nature of the classification criteria (i.e. qualitative or quantitative).

A more detailed evaluation of national and international schemes for physicochemical properties can be found in Appendix 2.

Table 2: Low-hazardous definitions for physicochemical properties

PHYSICOCHEMICAL PROPERTY	LOW-HAZARDOUS CRITERIA[1]
Explosive	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 6 Divisions
Low-hazardous definition	**Yes** – Division 1.4: Substances, mixtures and articles which present no significant hazard
Qualitative or quantitative	Qualitative
	ADG code
More than 1 degree of hazard	Yes – 6 Classes
Low-hazardous definition	**No** – but the NZ definition that the mixture or article presents no hazard is also made in the ADG scheme – Class 1.4.
Qualitative or quantitative	Qualitative
Flammable	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 4 Categories for liquids, 2 categories for gases, 2 categories for aerosols and 2 categories for solids
Low-hazardous definition	**Yes** - Flammable Liquid Cat. 4: Flash point > 60 °C and ≤ 93 °C **Yes** - Flammable Gases Cat. 2: at 20 °C and a standard pressure of 101.3 kPa, have a flammable range while mixed in air Yes - Flammable Aerosol Cat. 1: on the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test, for foam aerosols, and the ignition distance test and enclosed space test, for spray aerosols. **Yes** - Flammable Solid Cat. 2: Burning rate test for solids other than metal powders: wetted zone stops the fire for at least 4 min and the burning time < 45 seconds or burning rate > 2.2 mm/second. Burning rate test for metal powders: burning time > 5 minutes and ≤10 minutes.
Qualitative or quantitative	Quantitative for liquids, and essentially quantitative for gases, aerosols and solids
	ADG code
More than 1 degree of hazard	Yes – 2 Classes
Low-hazardous definition	**No**, there is no low-hazardous criteria, furthermore, chemicals in Class 2.2 stated to be "Non-flammable (non-toxic) gases' are not considered to be hazardous, while those in Class 2.1 stated to be 'Flammable gases' are considered to be hazardous (i.e. considered to be only 1 degree of hazard)
Qualitative or quantitative	Quantitative
Self-reactive substances	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 7 Types
Low-hazardous definition	**Yes** - Self-reactive substances Type G
Qualitative or quantitative	Qualitative
Organic peroxides	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 7 Types

Low-hazardous definition	**Yes** - Organic peroxides Type G
Qualitative or quantitative	Essentially Qualitative
In contact with water emit flammable gases	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 3 Categories
Low-hazardous definition	**Yes** – Category 3
Qualitative or quantitative	Essentially Qualitative

[1] Low-hazardous criteria are only provided for those properties whose classification is quantitative or essentially quantitative in nature.

For the flammability of aerosols the proposed low-hazardous criteria is actually the highest classification of hazard in the NZ scheme and, consequently, NICNAS does not consider this proposal to be appropriate.

Low- hazardous criteria – physicochemical properties

Therefore, with the exception of the comments on flammability provided above and in Table 2, low-hazardous criteria were consistently proposed when there is more than one degree of hazard, though the intrinsic property's classification criteria were generally qualitative in nature. However, the findings of the human health effect evaluation are also considered to be appropriate here for physicochemical properties, that is, the identification of low-hazardous criteria for classification is restricted to those physicochemical properties where:

- There is more than one classification category; and
- The intrinsic property's classification criteria are solely quantitative in nature.

Furthermore, such criteria should allow comparisons to be made for the type of effects seen.

The only physicochemical property that met these criteria in the schemes evaluated was:

- Flammability (liquids, gases and solids)

As for human health effects a watching brief will be kept on those physicochemical properties that do not meet the above criteria, and these endpoints revisited when hazard quantification and potency can be addressed.

A brief impact analysis on implementing the low-hazardous criteria for flammability into the national classification scheme is provided in section 4.2.

3.5 Environmental effects

As stated previously, there is presently no Australian classification system for environmental effects.

The only international scheme that proposed low-hazardous criteria was NZ (which adopted the GHS classification scheme for aquatic toxicity and terrestrial toxicity derived from the US EPA scheme) for rapid risk assessment. Criteria were proposed for the following:

- The aquatic environment;
- The soil environment;
- Terrestrial vertebrates; and
- Terrestrial invertebrates.

Furthermore, though the US EPA scheme does not directly propose low-hazardous criteria, potential criteria have been identified in the classification scheme for:

- Avian toxicity; and
- Toxicity to wild mammals.

A summary of the low-hazardous criteria proposed in the NZ scheme and identified in the US EPA scheme are provided in Table 3, together with information on those aspects identified from the human health evaluation as being critical for robust low-hazardous criteria:

- Degrees of hazard; and
- Nature of the classification criteria (i.e. qualitative or quantitative).

Table 3: Low-hazardous definitions for environmental effects

ENVIRONMENTAL EFFECT	LOW-HAZARDOUS CRITERIA
AQUATIC ENVIRONMENT	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 4 Categories
Low-hazardous definition	**Yes** - Category D: 96 hr LC_{50} (for fish) > 1 - ≤ 100 mg/L, or 48 hr EC_{50} (for crustacea) > 1 - ≤ 100 mg/L g/L, or 72 or 96 hr ErC_{50} (for algae) > 1 - ≤ 100 mg/L and not classified in Category A, B or C, or no acute toxicity and lack of rapid degradability and bioaccumulative and not classified in Category A, B or C
Qualitative or quantitative	Quantitative
	US EPA ecotoxicity categories
More than 1 degree of hazard	Yes – 5 Categories
Low-hazardous definition	**No** – though the category of 'Slightly Toxic' (EC50 or LC50 values >10 and ≤ 100 ppm) between the 'Moderately Toxic' and 'Practically Non-Toxic' categories could be considered to be low-hazardous criteria
Qualitative or quantitative	Quantitative
NON-AQUATIC ENVIRONMENT	
Soil environment	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 4 Categories
Low-hazardous definition	**Yes** - Category D: 10 < soil ecotoxicity value ≤ 100 mg/kg and Soil DT_{50} ≤ 30 days
Qualitative or quantitative	Quantitative
Terrestrial vertebrates	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 3 Categories
Low-hazardous definition	**Yes** – Category C: 500 < LD_{50} ≤ 2000 mg/kg bw, or 1000 < LC_{50} (diet) ≤ 5000 mg/kg food, or a chronic MATC < 100 ppm in the diet but which does not meet the criteria for Category A or B
Qualitative or quantitative	Quantitative
Avian	**US EPA ecotoxicity categories**
More than 1 degree of hazard	Yes – 5 Categories
Low-hazardous definition	**No** – though the category of 'Slightly Toxic' (500 < LD_{50} ≤ 2000 mg/kg bw) between the 'Moderately Toxic' and 'Practically Non-Toxic' categories could be considered to be low-hazardous criteria
Qualitative or quantitative	Quantitative
Wild mammals	**US EPA ecotoxicity categories**
More than 1 degree of hazard	Yes – 5 Categories

Low-hazardous definition	**No** – though the category of 'Slightly Toxic' ($500 < LD_{50} \leq 2000$ mg/kg bw) between the 'Moderately Toxic' and 'Practically Non-Toxic' categories could be considered to be low-hazardous criteria
Qualitative or quantitative	Quantitative
Terrestrial invertebrates	**NZ rapid risk assessment scheme**
More than 1 degree of hazard	Yes – 3 Categories
Low-hazardous definition	**Yes** - Category C: Invertebrate ecotoxicity value $\geq$11 and < 25 µg/bee
Qualitative or quantitative	Quantitative
Insects	**US EPA ecotoxicity categories**
More than 1 degree of hazard	Yes – 3 Categories
Low-hazardous definition	**No** – it is considered that low-hazardous criteria cannot be identified from the 3 categories of 'Highly Toxic', 'Moderately Toxic' and 'Practically Non-Toxic'.
Qualitative or quantitative	Quantitative

A more detailed evaluation of the international schemes for environmental effects can be found in Appendix 3.

Low-hazardous criteria – environmental effects

The findings of the environmental effects evaluation support those of the human health evaluation, as the identification of low-hazardous criteria for classification was restricted to those environmental effects where:

- There is more than one classification category; and
- The intrinsic property's classification criteria are solely quantitative in nature.

Furthermore, such criteria should allow comparisons to be made for the type of effects seen.

Environmental effects that meet these criteria in the schemes evaluated are for:

- The aquatic environment;
- The soil environment;
- Terrestrial vertebrates (with the US scheme providing specific criteria for birds and wild mammals); and
- Terrestrial invertebrates.

As for human health effects, a watching brief will be kept on those environmental effects that do not meet the above criteria, and these endpoints revisited when hazard quantification and potency can be addressed.

A brief impact analysis on implementing these low-hazardous criteria for the aquatic and soil environment together with terrestrial vertebrates and invertebrates into the national classification scheme is provided in section 4.3.

4. COMPARISON OF THE IDENTIFIED LOW-HAZARDOUS CRITERIA AGAINST THE AUSTRALIAN CLASSIFICATION SYSTEMS FOR INDUSTRIAL CHEMICALS

Low-hazardous criteria have been proposed or identified in international but not national classification schemes when there is more than one degree of hazard and the criteria are quantitative in nature. A summary of all the human health effects, physicochemical properties and environmental effects that meet these low-hazardous criteria are presented in Tables 4, 5 and 6 respectively.

The next step now that low-hazardous criteria have been identified from international schemes is a brief 'impact analysis' of these criteria on the existing national classification scheme for industrial chemicals (i.e. NOHSC Approved Criteria). Consequently, for comparative purposes the corresponding lowest degree of hazard in the NOHSC Approved Criteria is presented for human health effects (Table 4) where low-hazardous criteria have been identified.

For physicochemical properties, the Australian classification system viz ADG code is unsuitable for use in setting low hazardous criteria. However, the current EU classification system as described in the NOHSC Approved Criteria is widely used in Australia and therefore it is proposed that this approach be applied for setting low hazardous criteria for physicochemical properties (Table 5).

For environmental effects there is presently no Australian classification scheme, and while a provisional classification for such is generated for new industrial chemicals using the GHS scheme, this classification scheme (which only covers the aquatic environment) is a voluntary non-regulatory activity. Consequently, until an agreed 'version' of GHS has been implemented in Australia, it is proposed that, on the basis that the NOHSC Approved Criteria for human health effects are adopted from the European Community's legislation[6] for classifying dangerous substances, the same approach is used for environmental effects. Therefore, as for human health effects and physicochemical properties, the lowest degree of hazard in the EU scheme is also presented (Table 6).

Comparisons are presented below separately for human health effects, physicochemical properties and environmental effects.

4.1 Human health effects

It can be seen from Table 4 (see below) that the identified international definitions of hazardous (i.e. the hazard trigger) for acute oral, dermal, and inhalation toxicity and skin and eye irritation are more conservative than the Australian definition, as the quantitative low-hazardous criteria for all these effects are below the level defined as hazardous in Australia. Consequently, implementation of the identified overseas low-hazardous criteria is impracticable as:

- It is incompatible with the present Australian classification scheme; and

[6] No low-hazardous criteria were proposed or identified for environmental effects in the EU classification scheme.

- If the national classification scheme was adjusted to take account of these low-hazardous criteria, implementation would lead to an increase in the incidence of notified industrial chemicals classified as hazardous and, thus, would be counter productive as it will restrict the number of chemicals that would potentially meet low-hazardous criteria.

Consequently, it is considered that low-hazardous criteria for human health effects have to be defined using the present Australian classification scheme. Furthermore, the comparison indicates that the only human health effects with more than one degree of hazard and quantitative classification criteria in the national scheme are:

- Acute toxicity (oral, dermal and inhalation); and
- Eye irritation.

However, for acute oral, dermal and inhalation toxicity it is noted that the value range for the identified hazard grade in the Australian classification system is broad, i.e. 200 < LD50 < 2000 mg/kg bw for acute oral toxicity. It is considered that the higher values in these ranges are beyond the upper end of a hazard scale that would constitute a low hazard, thus requiring identification of a low-hazardous cut-off value within the lowest degree of hazard range.

Of the national and international schemes evaluated both the APVMA house hold pesticides and US EPA pesticide guidelines delineate hazard through pesticide use by identifying a cut-off values that must be exceeded if the pesticide is to be used for residential and institutional purposes and not restricted. The following cut-off values were identified for acute toxicity:

Acute oral: The APVMA states that the pesticide should not be life threatening to a child up to 1500 mg/kg bw, while the US EPA states that the pesticide as diluted for use has a LD_{50} > 1500 mg/kg bw.

Acute dermal: The APVMA states that the pesticide should not be life threatening to a child up to 1000 mg/kg bw, while the US EPA states that the pesticide as formulated has a LD_{50} > 2000 mg/kg bw.

Acute inhalation: The US EPA states that the pesticide as formulated has a LC_{50} > 0.5 mg/L/4hr. The APVMA household pesticide guidelines do not address inhalation.

What constitutes a life threatening event in the APVMA scheme is not defined, however, for the basis of this assessment in identifying a cut-off value for low-hazardous within the hazard grade the reported values are taken as LD_{50} values. Thus for acute oral toxicity a cut-off value LD_{50} value > 1500 mg/kg bw is identified by both the APVMA and US EPA. For acute dermal toxicity a cut-off LD_{50} value of > 1000 mg/kg bw is identified by the APVMA. While the cut-off LD_{50} value of > 2000 mg/kg bw identified by the US EPA is not appropriate, as in the Australian classification scheme industrial chemicals with dermal LD_{50} values > 2000 mg/kg are considered non-hazardous. Alternatively for acute inhalation toxicity the cut-off LC_{50} value of > 0.5 mg/L/4hr identified by the US EPA is not appropriate as this could capture chemicals considered toxic, since the lower cut-off LC_{50} value for such is $\leq$ 1

mg/L/4hr for aerosols and particulates and ≤ 2 mg/L/4hr for gases and vapours in the Australian classification scheme.

It should be noted that the basis for the above APVMA and US EPA cut-off values could not be determined. Consequently, additional cut-off values have been proposed for acute oral, dermal and inhalation toxicity that simply represent the median value within the range of the identified hazard grade in the Australian classification scheme. The alternative cut-off values are ≥ 1100 mg/kg bw for acute oral toxicity, ≥ 1200 mg/kg bw for acute dermal toxicity and for acute inhalation toxicity ≥ 3 mg/L/4hr for aerosols and particulates and ≥ 11 mg/L/4hr for gases and vapours.

Thus, Table 7 includes 2 options for acute oral toxicity are:

- Option 1 – The chemical meets the criteria for classification with R22 but has a LD_{50} value > 1500 mg/kg bw as identified by APVMA and US EPA for household pesticides;
- Option 2 – The chemical meets the criteria for classification with R22 but has a LD_{50} value equivalent to or greater than the median point of this classification grade i.e. ≥ 1100 mg/kg bw.

The available options for acute dermal toxicity are:

- Option 1 – The chemical meets the criteria for classification with R21 but has a LD_{50} value > 1000 mg/kg bw as identified by APVMA for house hold pesticides;
- Option 2 – The chemical meets the criteria for classification with R21 but has a LD_{50} value equivalent to or greater than the median point of this classification grade i.e. ≥ 1200 mg/kg bw.

In contrast, for acute inhalation toxicity, a cut-off value was not proposed by the APVMA while the value from the US EPA is not appropriate. Consequently, the only proposal for identification of a low-hazardous cut-off value is the median value: LC_{50} ≥ 3 mg/L/4hr for aerosols or particulates and ≥ 11 mg/L/4hr for gases or vapours.

For skin irritation, although there is only one degree of hazard in the NOHSC Approved Criteria, alternative evaluations of the criteria have been proposed (options 2 and 3 below) as a low-hazardous criteria has been proposed for eye irritation and identification of such would allow the endpoint of irritation to be dealt with completely.[8] The options proposed are:

- Option 1 - As there is only one degree of hazard for irritation low-hazardous criteria cannot be identified;
- Option 2 - If it is accepted that skin irritation directly follows on from corrosivity and represents a lesser (third) degree of hazard for damage to the skin, then the skin irritation criteria can be considered to be low-hazardous;

[8] Excluding respiratory irritation (for which no international low-hazardous criteria were identified), as not only is classification for this endpoint qualitative but the absence of a regulatory test guideline for this health effect prevents a reliable comparison of potency between chemicals for effects observed.

- Option 3 - Alternatively, if the approach outlined in option 2 is adopted, then, for consistency with the low-hazardous eye irritation criteria, the persistence of irritation may need to be considered, i.e. additionally, inflammation should not persist in 2 or more animals at the end of the observation period.

Opinions are sought on the preferred option for acute toxicity and skin irritation presented in Table 4.

How these low-hazardous criteria would be applied for the purposes of notification and assessment categories in Australia is provided in Section 5.

Table 4: Comparison of identified low-hazardous criteria for human health effects with the Australian classification scheme

HUMAN HEALTH EFFECT	International scheme	Australia[1]
Acute oral toxicity	Low-hazardous definition: 2000< LD_{50} ≤ 5000 mg/kg bw	Lowest degree of hazard: 200< LD_{50} ≤ 2000 mg/kg bw, however, it is proposed that within this range low hazardous chemicals have a: **Option 1:** LD_{50} > 1500 mg/kg bw; or **Option 2:** LD_{50} ≥ 1100 mg/kg bw
Acute dermal toxicity	Low-hazardous definition: 2000< LD_{50} ≤ 5000 mg/kg bw	Lowest degree of hazard: 400< LD_{50} ≤ 2000 mg/kg bw, however, it is proposed that within this range low hazardous chemicals have a: **Option 1:** LD_{50} > 1000 mg/kg bw; or **Option 2:** LD_{50} ≥ 1200 mg/kg bw
Acute inhalation toxicity	Low-hazardous definition: for dusts/mists, gases and vapours the LC_{50} in the equivalent range of the oral and dermal Category 5 LD_{50} (i.e. between 2000 and 5000 mg/kg bw).	Lowest degree of hazard: 1< LC_{50} ≤ 5 mg/L/4 hr (aerosols and particulates) 2< LD_{50} ≤ 20 mg/L/4 hr (gases and vapours), however, it is proposed that within this range low hazardous chemicals have a LC_{50} ≥ 3 mg/L/4hr for aerosols/particulates or ≥ 11 mg/L/4hr for gases/vapours
Skin irritation[2]	Low-hazardous definition: in 2 or more of 3 animals tested erythema/eschar or oedema ≥ 1.5 and < 2.3 (and inflammation does not persist to the end of the observation period normally 14 days in 2 animals)	Lowest degree of hazard: only one degree of hazard for skin irritation - in 2 or more animals tested erythema/eschar or oedema ≥ 2 or inflammation persists in at least 2 animals at the end of the observation time (normally 14 days). Therefore, it is proposed that: **Option 1:** low hazardous criteria can not be identified; **Option 2:** the criteria for skin irritation are considered low-hazardous criteria; or **Option 3:** the criteria for skin irritation together with the absence of inflammation in 2 or more animals at the end of the observation period are considered low-hazardous criteria.

Eye irritation[2]	Low-hazardous definition: in at least 2 of 3 animals tested corneal opacity ≥ 1 (and < 3), iritis ≥ 1 (and ≤ 1.5), conjunctival erythema ≥ 2, or conjunctival oedema ≥ 2 and fully reverses within the observation period (normally 21 days)	Lowest degree of hazard: in at least 2 of 3 animals tested corneal opacity ≥ 2 and < 3, iritis ≥ 1 and ≤ 2, conjunctival erythema ≥ 2.5), or conjunctival oedema ≥ 2 and fully reverses within the observation period (normally 21 days)

[1] All these human health effects listed in the national scheme have quantitative classification criteria
[2] The classification criteria for the next 'higher' degree of hazard are provided in brackets for the NZ scheme.

4.2. Physicochemical properties

It can be seen from Table 5 (see below) that the identified international definitions of hazardous (i.e. the hazard trigger) for flammability is more conservative for liquids than the EU definition, while low-hazardous criteria cannot be identified for gases and solids as only one degree of hazard is available and the classification criteria are qualitative in nature. Consequently, the finding that quantitative low-hazardous criteria be defined using the current EU classification scheme, is considered to be applicable for physicochemical properties. The only low-hazardous criteria meeting this requirement is for:

- Flammability (liquids only).

How the low-hazardous criteria for flammability would be applied for the purposes of notification and assessment categories in Australia is provided in Section 5.

Table 5: Comparison of identified low-hazardous criteria for physicochemical properties with the EU classification scheme

	International scheme	**EU**[1]
Flammable	Low-hazardous definition: Liquid - flash point > 60 °C and ≤ 93 °C Gas - at 20 °C and a standard pressure of 101.3 kPa, have a flammable range while mixed in air (and at 20 °C and a standard pressure of 101.3 kPa are not ignitable when in a mixture of 13% or less by volume in air or have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit). Solid - Burning rate test for solids other than metal powders: wetted zone stops the fire for at least 4 min and the burning time < 45 seconds or burning rate > 2.2 mm/second. Burning rate test for metal powders: burning time > 5 minutes and ≤10 minutes.	Lowest degree of hazard: Liquid - Flash point ≥ 21 °C and ≤ 55 °C Gas[2] – no, only 1 degree of hazard Solid[2] – no, only 1 degree of hazard

[1] It should be noted that though a low-hazardous criteria was proposed for aerosols in the international scheme the classification of aerosols are not addressed in the EU Criteria.
[2] Classification criteria are qualitative in nature

4.3. Environmental effects

It can be seen from Table 6 (see below) that the identified international definitions of hazardous (i.e. the hazard trigger) for the aquatic environment are similar to the EU

definition, while low-hazardous criteria cannot be identified for the soil environment, terrestrial vertebrates and invertebrates as only one degree of hazard is available. However, in an approach similar to that proposed for human health effects, additional cut offs values have been proposed for acute aquatic toxicity that simply represent the median value within the range of the international scheme.

Table 6: Comparison of identified low-hazardous criteria for environmental effects with the EU classification scheme

ENVIRONMENTAL ENDPOINT	International scheme	EU
Aquatic environment	Low-hazardous definition: Category D: 96 hr LC_{50} (for fish) > 1 - ≤ 100 mg/L, or 48 hr EC_{50} (for crustacea) > 1 - ≤ 100 mg/L g/L, or 72 or 96 hr ErC_{50} (for algae) > 1 - ≤ 100 mg/L and not classified in Category A, B or C, or no acute toxicity and lack of rapid degradability and bioaccumulative and not classified in Category A, B or C	Lowest degree of hazard: 96 hr LC_{50} >10 - ≤ 100 mg/L for fish, or 48 hr EC_{50} >10 - ≤ 100 mg/L for daphnia, or 72 hr IC_{50} >10 - ≤ 100 mg/L for algae and is not readily degradable. This applies unless there is sufficient additional scientific evidence concerning degradation and/or toxicity to provide adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment. Such additional information could include: a proven potential to degrade rapidly in the aquatic environment, or an absence of chronic toxicity effects at a concentration of 1.0 mg/L. However, it is proposed that an additional low hazardous cut off value for acute toxicity that represents the median value of the harmful hazard grade in the EU classification system ie. >55 mg/L
Soil environment	Low-hazardous definition: Category D: 10 < [1]soil ecotoxicity value ≤ 100 mg/kg and [2]Soil DT_{50} ≤ 30 days	Lowest degree of hazard: No, only 1 degree of hazard
Terrestrial vertebrates	Low-hazardous definition: Category C: 500 < LD_{50} ≤ 2000 mg/kg bw, or 1000 < LC_{50} (diet) ≤ 5000 mg/kg food, or a chronic [3]MATC < 100 ppm in the diet but which does not meet the criteria for Category A or B	Lowest degree of hazard: no, only 1 degree of hazard
Terrestrial invertebrates	Low-hazardous definition: Category C: [4]Invertebrate ecotoxicity value ≥11 and < 25 µg/bee	Lowest degree of hazard: no, only 1 degree of hazard

[1] The lowest value (in mg substance/kg dry weight of soil) from: (i) plant or soil invertebrate 14 day exposure EC_{50} data; or (ii) data demonstrating a 25 % reduction in soil micro-organism respiration or nitrification at completion of 28 day exposure to the substance

[2] Time to reduce original substance soil concentration by 50 %

[3] The maximum acceptable toxicant concentration, being the geometric mean of the NOEC and LOEC where the NOEC and LOEC are derived from the same study

[4] Lowest value (in µg substance/terrestrial invertebrate) from contact or oral LD_{50} data 48 hours after exposure

Consequently, the findings of the human health evaluation, that quantitative low-hazardous criteria be defined using the surrogate EU classification scheme, are also considered to be applicable for environmental effects. The only low-hazardous criteria meeting this requirement is for:

- Aquatic environment.

How the low-hazardous criteria for the aquatic environment identified in the surrogate EU classification scheme would be applied for the purposes of notification and assessment categories in Australia is provided in Section 5.

5. IDENTIFIED LOW-HAZARDOUS CRITERIA FOR THE PURPOSES OF NOTIFICATION AND ASSESSMENT CATEGORIES IN AUSTRALIA

5.1 Chemicals

For notification and assessment categories in Australia the principles of low-hazardous criteria identified in this paper (i.e. more than one degree of hazard with quantitative criteria) should be applied to the NOHSC Approved Criteria for human health effects and the surrogate EU classification scheme for physiochemical and environmental effects. In applying this proposed scheme, it should be noted that:

- An inherently low-hazardous chemical may have one or more properties classified as a low-hazardous property;
- If a chemical exceeds the low-hazardous cut offs or triggers a classification for which low-hazardous criteria have not been identified, it can no longer be considered to be an inherently low-hazardous chemical; and
- If a chemical is not classified for any endpoint, it is non-hazardous, not low-hazardous.

Summaries of the classification endpoints that meet the criteria are presented in Tables 7, 8 and 9 for human health effects, physicochemical properties and environmental effects, respectively. These tables also indicate those endpoints for which low-hazardous criteria could not be identified, as there was only one degree of hazard and/or the classification criteria were not quantitative in nature (i.e. do not allow potency to be reliably addressed). The data is presented in these tables as the appropriate risk phrase within the classification system that represents the lowest degree of quantitative hazard (i.e. R36 for eye irritation).

Furthermore, for acute oral toxicity, acute dermal toxicity and skin irritation more than one option is proposed for the identification of low-hazardous criteria (see section 4.1 for the rationale for each of these different options).

Table 7: Human health effects for which low-hazard criteria are proposed

ENDPOINT	LOW-HAZARDOUS	NOT LOW-HAZARDOUS
Acute oral toxicity option 1	R22 Harmful if swallowed **with** a $LD_{50} \geq 1100$ mg/kg bw	R22 Harmful if swallowed **with** a $LD_{50} < 1100$ mg/kg bw; R28 Very toxic if swallowed; or R25 Toxic if swallowed
Acute oral toxicity option 2	R22 Harmful if swallowed **with** a $LD_{50} > 1500$ mg/kg bw	R22 Harmful if swallowed **with** a $LD_{50} \leq 1500$ mg/kg bw; R28 Very toxic if swallowed; or R25 Toxic if swallowed
Acute dermal toxicity option 1	R21 Harmful in contact with skin **with** a $LD_{50} \geq 1200$ mg/kg bw	R21 Harmful in contact with skin **with** a $LD_{50} < 1200$ mg/kg bw; R27 Very toxic in contact with skin; or R24 Toxic in contact with skin
Acute dermal toxicity option 2	R21 Harmful in contact with skin **with** a $LD_{50} > 1000$ mg/kg bw	R21 Harmful in contact with skin **with** a $LD_{50} \leq 1000$ mg/kg bw; R27 Very toxic in contact with skin; or R24 Toxic in contact with skin
Acute inhalation toxicity	R20 Harmful by inhalation **with** a LC_{50}: $\geq$ 3 mg/L/4hr mg/kg bw for aerosols/particulates; or $\geq$ 11 mg/L/4hr mg/kg bw for gases/vapours	R20 Harmful by inhalation **with** a LC_{50}: < 3 mg/L/4hr mg/kg bw for aerosols/particulates; or < 11 mg/L/4hr mg/kg bw for gases/vapours; R26 Very toxic by inhalation; or R23 Toxic by inhalation
Non-lethal irreversible effects after a single exposure	Not proposed	R39 Danger of very serious irreversible effects[1]
Aspiration hazard	Not proposed	R65 Harmful: may cause lung damage if swallowed
Corrosive	Not proposed	R35 Causes severe burns; or R34 Causes burns
Skin irritation option 1	Cannot be identified	R38 Irritating to skin

Skin irritation option 2	R38 Irritating to skin	R35 Causes sever burns; or R34 Causes burns
Skin irritation option 3	R38 Irritating to skin	R35 Causes sever burns; R34 Causes burns; or If inflammation of the skin persists in at least two animals at the end of the observation time.
Eye irritation	R36 Irritating to eyes	R41 Risk of serious eye damage
Respiratory irritation	Not proposed	R37 Irritating to the respiratory system
Skin sensitisation	Not proposed	R43 May cause sensitisation by skin contact
Respiratory sensitisation	Not proposed	R42 May cause sensitisation by inhalation
Repeat dose toxicity	Not proposed	Toxic - R48 Danger of serious damage to health by prolonged exposure Harmful – R48 Danger of serious damage to health by prolonged exposure
Mutagenicity	Not proposed	Category 1: R46 May cause heritable genetic damage; Category 2: R46 May cause heritable genetic damage; or Category 3: R68 Possible risk of irreversible effects
Carcinogenicity	Not proposed	[2]Category 1: R45 May cause cancer; [2]Category 2: R45 May cause cancer; or Category 3: R40 Limited evidence of a carcinogenic effect
Effects on fertility	Not proposed	Category 1: R60 May impair fertility; Category 2: R60 May impair fertility; or Category 3: R62 Possible risk of impaired fertility
Developmental toxicity	Not proposed	Category 1: R61 May cause harm to the unborn child Category 2: R61 May cause harm to the unborn child Category 3: R63 Possible risk of harm to the unborn child
Other health effects for substances which have already been classified[3]		
	Not proposed	R33 Danger of cumulative effects
	Not proposed	R64 May cause harm to breastfed babies
	Not proposed	R66 Repeated exposure may cause skin dryness or cracking
	Not proposed	R67 Vapours may cause drowsiness and dizziness

[1] R39 assigned and determined to be very toxic or toxic when effects are seen in the dose ranges (all routes of exposure) assigned for R26/27/28 and R23/24/25 respectively.
[2] This category also includes classification with the risk phrase R49 May cause cancer by inhalation.
[3] Already classified for physicochemical properties, human health or environmental effects. See Approved Criteria (NOHSC, 2004) for a more detailed explanation of the assignment of these additional risk phrases.

For effects where no separate criterion is proposed, eg sensitisation, mutagenicity, carcinogenicity, the cut off for "low hazardous" equates to the cut off for non hazardous. That is, a chemical classified as hazardous on the basis of mutagenicity will not meet the 'low-hazardous' requirements for notification and assessment.

Table 8: Physicochemical properties for which low-hazard criteria are proposed

Note that in the table below the risk phases as applicable in the EU classification system are used. These are used in Australia, eg in the HSIS, and are described in the NOHSC Approved Criteria.

ENDPOINT	LOW-HAZARDOUS	NOT LOW-HAZARDOUS
Explosive	Not proposed	R2 Extreme risk of explosion by shock, friction, fire or other sources of ignition; or R3 Risk of explosion by shock, friction, fire or other sources of ignition
Oxidising	Not proposed	R7 May cause fire; R8 Contact with combustible material may cause fire; or R9 Explosive when mixed with combustible material
Flammable	R10 Flammable	R12 Extremely flammable; or R11 Highly flammable[1]

[1] Substances classified "Highly Flammable' also include those that are assigned risk phrase R15 (Contact with water liberates extremely flammable gas) and R17 (Spontaneously flammable in air).

As for human health effects, the criterion for 'low hazardous' will equate with non-hazardous where no separate criterion is proposed. That is, except for a chemical meeting R10, any chemical classified as dangerous good on the basis of its physicochemical properties will not meet the 'low hazardous' requirements for notification and assessment.

Table 9: Environmental effects for which low-hazard criteria are proposed

Note that in the table below the risk phases as applicable in the EU classification system are used. These are used in Australia, eg in the HSIS, and are described in the NOHSC Approved Criteria.

ENDPOINT	LOW-HAZARDOUS	NOT LOW-HAZARDOUS
Aquatic environment	R52 Harmful to aquatic organisms; or R53 May cause long-term adverse effects in the aquatic environment **with** 55 mg/L $<EC_{50}/LC_{50}/IC_{50} \leq$100mg/L	R50 Very toxic to aquatic organisms; and R53 May cause long-term adverse effects in the aquatic environment or R51 Toxic to aquatic organisms; and R53 May cause long-term adverse effects in the aquatic environment or R52 Harmful to aquatic organisms; and R53 May cause long-term adverse effects in the aquatic environment **with** 10 mg/L $<EC_{50}/LC_{50}/IC_{50} \leq$55mg/L)
Non-aquatic environment		
- Flora	Not proposed	R54 Toxic to flora
- Fauna	Not proposed	R55 Toxic to fauna
- Soil organisms	Not proposed	R56 Toxic to soil organisms
- Terrestrial	Not proposed	R57 Toxic to bees
	Not proposed	R58 May cause long-term adverse effects in the environment[1]
- Ozone layer	Not proposed	R59 Dangerous for the ozone layer

[1] Substances which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted or observed environmental fate and behaviour, may present a danger, immediate or long term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered for the aquatic environment.

Safeguard – chemicals with POPs characteristics are not eligible for consideration as 'low hazardous'

5.2 Polymers

NICNAS currently has low concern criteria for polymers, namely, the criteria for notifying new chemicals as 'polymers of low concern (PLC)'. The criteria are stipulated in regulation 4 of the regulations to the Act. However, as outlined above, the intent of this reform has been to set a hazard level above that defined by the definition of 'a hazardous chemical' in the Act (or 'hazardous substance' in the NOHSC *Approved Criteria for Classifying Hazardous Substances*). The PLC criteria are more conservative than the definition of 'a hazardous chemical' and are therefore unsuitable for this reform.

In developing low hazardous criteria for polymers, it is necessary to recognise that the range of effects data usually generated for polymers is less than that generated for chemicals, particularly for the higher molecular-weight polymers. Therefore, it is proposed to take a simpler approach for polymers.

For low-hazardous polymers with number-average molecular-weight of 1000 or less, it is proposed that the criteria developed and proposed for chemicals be adopted.

For low-hazardous polymers with number-average molecular-weight greater than 1000, it is proposed that the polymer has:

- less than 10% by mass of molecules with molecular weight that is less than 500; and
- less than 25% by mass of molecules with molecular weight that is less than 1000; and
- has low charge density, as defined in Regulation 4C.

In both situations, polymers shown to not meet the definition of 'a hazardous chemical' would also be accepted under this proposal.

As a safeguard, polymers classified as a NOHSC Type I ingredient (i.e. carcinogenic, mutagenic, a skin or respiratory sensitiser, very corrosive, corrosive, toxic or very toxic, a harmful substance which can cause irreversible effect after acute exposure or a harmful substance which can cause serious to health after repeated prolonged exposure) or a reproductive toxicant are excluded from consideration as low hazardous polymers. New polymers with persistent organic pollutant (POPS) characteristics, in accordance with Annex D of Stockholm Convention, are also excluded from consideration as low hazardous. Similarly, polymers would not qualify as low hazardous if they readily break down to degradation products that may be persistent and bioaccumulative.

6. NICNAS PROPOSAL

To summarise, while all classifiable properties have a 'hazard trigger' that defines an industrial chemical as hazardous, grading of hazard already occurs in classification schemes for some intrinsic properties, e.g. hazardous chemicals can be classified as Very Toxic, Toxic or Harmful for acute toxicity in Australia. However, the intent undertaken here is to identify a point in the 'hazard spectrum' below which a

hazardous (i.e. classifiable) chemical can be considered as "low-hazardous". Thus, comments are sought on the NICNAS proposal that low-hazardous criteria for the purposes of notification and assessment categories be restricted to:

I. **Those endpoints for which there already exists grading of hazard in the classification system (i.e. more than one degree of hazard), and**

II. **The grading of hazard for the endpoint is quantitative in nature (i.e. provides cut-off values), therefore allowing a comparison to be made of the same type of toxic effects (i.e. the criteria allow consideration of the potency of the chemical).**

Furthermore, comments are sought on the proposal that:

III. **Grades of hazard with quantitative criteria are identified in the Australian classification scheme (the NOHSC Approved Criteria) for human health effects, and**

IV. **As there is no quantitative Australian classification scheme with grades of hazard for physicochemical properties, the EU classification scheme is used to identify low-hazardous criteria for notification and assessment in Australia; and**

V. **As there is no Australian classification scheme for environmental effects of new industrial chemicals, the EU classification scheme is used to identify low-hazardous criteria (that correspond to points I and II) for notification and assessment in Australia.**

Comments are also sought on the proposal that, in applying the criteria for acute toxicity (points I, II and III):

VI. **The higher LD_{50}/LC_{50} values contained within the identified lowest degree of hazard range for acute oral, dermal and inhalation toxicity require that a low-hazardous cut-off value be identified, and**

VII. **If point VI is supported, preference is stated for the identification of a cut-off value for acute oral and dermal toxicity based on the median value within the LD_{50} range, or adoption of a cut-off value based on the delineation of pesticide use in Australia (the basis for which is unclear), i.e. an LD50 value that determines whether pesticides can be used residentially or are restricted in their use.**

Additionally, comments are sought on the proposal that:

VIII. **As skin irritation directly 'follows on' from corrosivity in classification schemes, it can be considered to represent a lesser degree of hazard for damage to the skin, thus allowing points I, II and III to be met, and**

IX. **If point VIII is supported, preference is stated for whether the low-hazardous criteria for skin irritation does (as for the low-hazardous criteria for eye irritation) or does not address persistence of irritation.**

Finally, comments are sought on the proposal that:

X. **There be separate 'low-hazardous' criteria for polymers with NAMW > 1000; and**

XI. **The criteria proposed for polymers are appropriate.**

In conclusion, it should be re-iterated that if the above approach is adopted (as defined in points I - V), then for those human health, physicochemical properties and environmental effects for which low-hazardous criteria have not been identified (e.g. skin sensitisation), a watching brief will be kept by NICNAS and a re-evaluation of low-hazardous criteria for notification and assessment categories undertaken if any significant advances in scientific knowledge and/or amendments to classification systems occur, e.g. introduction of the GHS system in Australia.

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