1 LOW REGULATORY CONCERN CHEMICALS (LRCC) IMPLEMENTATION OF OUTSTANDING REFORMS FINAL REPORT AND RECOMMENDATIONS OCTOBER 2007

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EXECUTIVE SUMMARY

Additional proposals have been accepted to enable the introduction of more chemicals under the low regulatory concern chemical (LRCC) reform initiative. Specifically, the reforms enable chemicals which meet the relevant criteria to be introduced under the following provisions:

- Increase in volume for low hazardous chemicals introduced under the Low Volume Chemical Permit system;

- Introduction of highly controlled low risk chemicals under the Controlled Use Permit system;

- Extension of the Early Introduction Permit (EIP) system to low hazardous and low risk chemicals;

- Modular assessment of chemicals for which another assessment is available, for example, assessed by another assessment authority or introduction of an analogue of a previously assessed chemical; and

- Free EIP for non-hazardous chemicals and polymers and polymers of low concern.

1. INTRODUCTION

This is the final report of the Low Regulatory Concern Chemicals (LRCC) reform program. The report covers the strategy that will be put in place to implement those outstanding reforms as were detailed in the *Final Report and Recommendations for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative* (June 2003) (the Final Report).

2. BACKGROUND

The LRCC reform program commenced on 19 November 2002, when the then Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth, MP, announced the establishment of a task force to investigate the reform of the regulation of industrial chemicals.

Technical working groups were established by the LRCC Task Force to explore options for LRCC and investigate the feasibility of implementation in Australia.
Following consideration by the working groups and extensive industry, government and community consultation, the Final Report was published in June 2003, with an Implementation Strategy published in July 2003.

A number of the recommendations contained in that report were able to be implemented quickly but others required a longer time frame. Following further technical working groups and consultation, the recommendations which have yet to be implemented were presented in a suite of discussion papers, including the overview paper *Low Regulatory Concern Chemicals (LRCC) Implementation of Outstanding Reforms - Overview of the Planned Reforms* (Outstanding Reforms Discussion Paper), which was published on 16 October 2006. These documents presented proposals for implementation of the outstanding reforms. The discussion papers can be found on the NICNAS website at http://www.nicnas.gov.au/About_NICNAS/Reforms/LRCC.asp.

3. CONSULTATION PROCESS

The consultation process before publication of the Final Report was extensive and is outlined in that report. Subsequently, further technical working groups were established to implement the some of the remaining reforms, e.g. for development of low hazard and low risk criteria.

Following publication of the Outstanding Reforms Discussion Paper, further industry, government and public consultation was undertaken to seek comment on the proposals for implementation.

The overview paper and associated discussion papers were released for public and industry comment for a period of six weeks by:

a) publishing the papers on the NICNAS website;
b) publishing the papers in the NICNAS Chemical Gazette; and
c) sending the papers to key stakeholders, including:
    - States and Territories Memorandum of Understanding group;
    - Community Engagement Forum; and
    - Industry Government Consultative Committee.

A questionnaire was provided on the NICNAS website to facilitate comment on the proposals to NICNAS.

4. SUMMARY OF SUBMISSIONS

Twelve written submissions were received from industry and government.

4.1 General

Overall the reforms were generally supported, with qualifications on some of the proposals. Industry stated that the reforms would allow NICNAS resources to be focused on chemicals of concern, encourage innovation and speed up the time-to-market for low hazardous chemicals. The harmonisation of definitions was also supported.

Government had concerns over terminology, in particular, use of the term 'low hazardous', in that it may cause confusion with the terms used in the current regulatory framework for hazard classification.

One industry submission requested clarification of some of the terms used, e.g. bioaccumulative, persistence and toxic.

Industry commented that more information was required on implementation of the reforms, for example, the impact on timeframes for the various notification categories.

4.2 Low hazardous

The separate proposals in the discussion paper were generally supported, with qualification by submitters in some circumstances. These were as follows.

Proposals I – V (all accepted)

I. That the low hazardous criteria be restricted to those endpoints for which there already exists grading of hazard in the classification system (i.e. more than one degree of hazard), and

II. that 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).

III. That grades of hazard with quantitative criteria, as identified in the Australian classification scheme (the ASCC Approved Criteria), be used for human health effects, and

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

V. As there is no Australian classification scheme for environmental effects, that the EU classification scheme be used to identify low-hazardous criteria for these effects (for notification and assessment) in Australia.

Proposals VI and VII

The most common comment under these proposals was that actual LD_{50} values will not be determined in future acute toxicity testing, mainly for animal welfare reasons. New guidelines will require the Acute Toxicity Class (ATC) method for toxicity testing to be used, which will provide an LD_{50} range rather than an actual dosage. Therefore a median cut-off value for low hazardous with respect to acute toxicity was generally not supported.

Proposals VIII and IX
The proposal that skin irritation directly followed on from corrosivity in classification schemes was generally supported. The favoured option for proposal IX was that the irritation be reversible, i.e. Option 3 in the discussion paper, viz. that the criteria include absence of inflammation in two or more animals at the end of the observation period.

Proposals X and XI
The proposals in the discussion paper for separate criteria for polymers were generally supported. However one comment from industry suggested that further consideration be given to aligning the low hazardous criteria for low-molecular weight polymers (polymers with number-average molecular weight (NAMW) less than 1000) with other polymers rather than the criteria for non-polymers.

4.3 Low risk

Industry suggested that a statutory timeframe for the Controlled Use Permit (CUP) be instituted and suggested 28 days, as for the Early Introduction Permit (EIP). Because there are chemicals on overseas inventories that have been "grandfathered" and have little data available, clarification of what is considered "sufficient data" to satisfy the criterion of no unreasonable risk needs to be provided. It was also noted that the CUP is for chemicals that are highly controlled, so additional data should not be required if quantities greater than 10 tonnes per year are introduced. Comments indicated that a review of a complete data package could not be accomplished by NICNAS in the timeframes allowed for introduction of less than 10 tonnes per year.

In one submission, it was stated that the concept of no unreasonable risk is not practicable as some introducers do not generate the extra data required to prove no unreasonable risk if a chemical is classifiable in the EU.

4.4 Modular assessment

4.4.1 Assessed by another authority

Industry observed that not all data required by NICNAS would be available from other agencies either because an agency might not undertake an OHS assessment or the assessment might not be undertaken to a standard acceptable to NICNAS. Therefore notifiers need to be advised that additional data could be needed. In the submission, it was also suggested that the data requirements were excessive. The concepts of known hazards, known risks and controlled risks require further clarification.

4.4.2 Analogues

Industry did not support the proposals for inseparable analogues on the basis that the same data set would be assessed for both the primary analogue and the other analogues in the inseparable mixture. There was concern that there is no demonstrated benefit to health, safety or the environment by assessing the components of an inseparable mixture.

4.5 Naturally-occurring chemicals

Four submissions were received, with all comments focused on essential oils. There was general support for an expert working group on essential oils and production of guidance material on the definition of a naturally occurring chemical. Comments included acceptance of the ISO definition of an essential oil.

There was general support that steam distillation should be included as an allowable process in the definition of a naturally occurring chemical, however, it was acknowledged, in one submission, that chemical changes can occur during steam distillation.

4.6 Low regulatory concern polymers

No specific comments were received on the proposals in the discussion paper on low regulatory concern polymers.

5. FINDINGS AND RECOMMENDATIONS FOR OUTSTANDING LRCC REFORMS

5.1 Low hazardous criteria

The intent of the low hazardous criteria is to allow new industrial chemicals at the lower end of the hazard spectrum, including chemicals not classified as hazardous substances or dangerous goods, to:

- be eligible for introduction under the Low Volume Chemical (LVC) permit system at up to 1000 kg per year, and
- to extend access to the Early Introduction Permit (EIP) system to chemicals which meet the criteria.

The proposals were generally supported, however, the lack of support for the cut-off concentrations proposed for acute toxicity (mammalian and aquatic) has resulted in an amendment to these cut-off concentrations to align with recognised classification schemes.

The proposals to include chemicals classified as eye irritants (with risk phrase R36) and/or skin irritants (R38) were supported, with Option 3 most favoured for the latter (as in the Approved Criteria, where inflammation of the skin is regarded as significant if it persists in at least two animals at the end of the observation period).

For chemicals classed as dangerous goods, those meeting the low hazardous criteria must either not be dangerous goods or be classified as flammable only.

For environmental criteria, eligible chemicals must not be classified as harmful to the aquatic environment (in accordance with the EU criteria).

The amended criteria are in Table 1 below.

The proposals for polymers were generally supported, although one comment from industry suggested similar criteria for all polymers; this was rejected on the grounds that low molecular weight polymers may contain oligomers with properties similar to those of the parent reactants. The criteria are in Table 2 below.

Table 1 – Low hazardous criteria for chemicals

Hazard property	**Low Hazardous Value**
acute oral toxicity (LD_{50} value)	not hazardous (LD_{50} value > 2000 mg/kg bw)
acute dermal toxicity (LD_{50} value)	not hazardous (LD_{50} value > 2000 mg/kg bw)
acute inhalation toxicity (LD_{50} values)	not hazardous (LC_{50} > 5 mg/L/4hr (for aerosols and particulates) or LC_{50} > 20 mg/L/4hr (for gases and vapours))
skin irritation	not hazardous or meeting R38 (Irritating to skin) criteria
eye irritation	not hazardous or meeting R36 (Irritating to eyes) criteria
acute aquatic toxicity	Not harmful to aquatic organisms and will not cause long term adverse effects in the aquatic environment (EC_{50}/IC_{50}/LC_{50} > 100 mg/L)
Sensitisation	not hazardous
Mutagenicity	not hazardous
Carcinogenicity	not hazardous
Reproductive toxicity	not hazardous
Developmental toxicity	not hazardous
Flammability	Not a dangerous good or meeting R10 (flammable) criteria
Other physical and chemical properties	not a dangerous good

Table 2 – Low hazardous criteria for polymers

For low-hazardous polymers with number-average molecular-weight of 1000 or less, the criteria in Table 1 apply.

For low-hazardous polymers with number-average molecular-weight greater than 1000, eligible polymers must have:

- 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
- low charge density, as defined in Regulation 4C.

Note: Regulation 4C states that a polymer has a low charge density if:

(a) it is both:

(i) not cationic; and

(ii) not likely to become cationic in an aquatic environment that has a pH value greater that 4 and less than 9; or

(b) it is a solid that is:

(i) not soluble or dispersible in water; and

(ii) to be used only in its solid phase; or

(c) for a polymer that includes 1 or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000.

Polymers classified as OASCC Type 1 ingredients or which are persistent or bioaccumulative are not eligible for consideration as low hazardous polymers.

5.2 Low risk criteria

The intent of the low risk criteria is to enable new industrial chemicals which are of low risk to occupational health and safety, public health and the environment, including chemicals not classified as hazardous substances or dangerous goods, to:

- be eligible for introduction under the Controlled Use Permit (CUP) system, and
- extend access to the Early Introduction Permit (EIP) system to chemicals which meet the criteria.

The proposals were generally supported, however, it was suggested that the hazard criteria be consistent with current chemical regulatory criteria rather than introducing a new set of criteria. Accordingly it is recommended that, for human health effects, chemicals which are classified as carcinogenic (R40, R45, R49), mutagenic (R46), reproductive toxicants (R60-64), very toxic (R26-28), corrosive (R34, R35, R41), sensitising (R42, R43) and chemicals which may cause irreversible effects after a single exposure (R39, R68) or severe effects after repeated or prolonged exposure (R48) not be eligible for introduction under the CUP and EIP systems.

Similarly it is recommended that, for environmental effects, chemicals which are very toxic or toxic to aquatic organisms (R50, R51) also not be eligible for introduction under the CUP and EIP systems. Further, as proposed in the discussion paper, new chemicals with persistent organic pollutant (POPS) characteristics, which include persistence and bioaccumulation, will not be eligible. Currently Australia defers to the POPS criteria listed in the Stockholm Convention.

The amended criteria are summarised in Table 3 below.

Table 3 – Low risk criteria for chemicals and polymers – hazard criteria

Human health effects

Chemicals and polymers with the following hazard classifications are not eligible:

carcinogenic (R40, R45, R49), or
mutagenic (R46), or
reproductive toxicants (R60-64), or
very toxic (R26-28), or
corrosive (R34, R35, R41), or
sensitising (R42, R43) or
may cause irreversible effects after a single exposure (R39, R68) or
may cause severe effects after repeated or prolonged exposure (R48)

Environmental effects

Chemicals and polymers with the following EU hazard classifications are not eligible:

very toxic to aquatic organisms (R50 and R53), or
toxic to aquatic organisms (R51 and R53).

Chemicals and polymers with persistent organic pollutant (POPS) characteristics, which include persistence and bioaccumulation, are not eligible.

Minor comments only were submitted on the low risk proposals for exposure in the discussion paper and therefore these proposals are adopted for the purposes of the low risk criteria. In summary, there are two approaches, viz.:

- specific low risk scenarios; and
- restrictions on exposure to the public, workers and the environment.

Currently two specific low risk scenarios have been developed in consultation with stakeholders, viz.:

- containment and controlled reformulation; and
- site-limited and closed system manufacture.

It is proposed to work with industry in the development of additional standard exposure scenarios which will meet the statutory requirement of 'highly controlled'.

The specific exposure criteria are in Table 4 below.

Table 4 – Low risk criteria for chemicals and polymers – exposure criteria

1. There must be no dermal, oral or inhalation exposure to consumers and the general population;
2. There must be no dermal or inhalation exposure to workers (this criterion is met if adequate controls are in place);
3. There must be no ambient release to surface water resulting in concentrations of the chemical above 1 part per billion;
4. There must be no ambient release to air above 1 microgram per cubic metre average annual concentration and;
5. There must be no release to land or landfill unless the chemical has negligible potential for migration to groundwater.

5.3 Modular assessment

The proposals for introduction of the modular assessment concept were generally supported. One comment suggested that one group of chemicals listed as suitable for modular assessment in the LRCC Final Report, namely, *'Substances of known hazard for which risks are specified and controlled'* was not addressed in the reforms. These substances will be covered in these reforms by:

(a) the modular assessment approach if a hazard assessment is available, for example, from another assessment authority or by use of the analogue provisions, and for which exposure is well-characterised; or

(b) use of the controlled use permit system, where health and environmental effects information is provided and exposure is highly controlled.

In summary, chemicals assessed by another recognised assessment authority, national or international, will be eligible for a streamlined assessment under NICNAS, together with chemicals for which appropriate analogues have been previously assessed by NICNAS.

In response to comment received during the public comment period, the assessment of inseparable analogues as separate notifications is justified on the grounds that the identity information and some properties of the individual chemicals will be different and may present different risks to health, safety and the environment. Except for UVCB substances (as defined in the Act), the notification and assessment of mixtures is outside the scope of the Act. A reduced assessment and fee will apply for the secondary chemicals in, for example, a mixture of inseparable isomers.

5.4 Naturally-occurring chemicals

Maintenance of the current definition of 'a naturally-occurring chemical' was not supported in four submissions on the grounds that steam distillation is not included in the definition as an acceptable extraction method. However NICNAS policy dictates that its definitions be consistent with other international definitions and therefore, at this stage, amendment of the NICNAS definition is not warranted.

The proposal to establish an expert essential oils working group was supported. The group will assist NICNAS in providing guidance on the definition of a naturally-occurring chemical and its interpretation.

5.5 Low regulatory concern polymers

The proposals in the discussion paper were supported and will be incorporated into the legislative reforms for modular assessment.

6. IMPLEMENTATION OF OUTSTANDING LRCC REFORMS

6.1 Low volume chemical permit

Regulatory

Regulations pursuant to paragraph 21Q(a) and subparagraph 21U(2)(c)(i) of the Act will be introduced to enable the introduction of new industrial chemicals meeting the low hazardous criteria at volumes up to 1000 kg per year. The information requirements will remain as detailed in subsection 21S(2) of the Act.

Administrative

Guidelines will be published in the Chemical Gazette and the NICNAS Handbook for Notifiers. Applicants will need to demonstrate how the notified chemical meets the criteria.

6.2 Controlled use permit

Regulatory

Regulations pursuant to subparagraph 22F(1)(b)(ii) of the Act will be introduced to enable the introduction of new industrial chemicals which meet the low risk criteria. The information requirements will remain as detailed in regulation 6B. These requirements currently apply for the Export Only Permit.

Administrative

Guidelines detailing the low risk criteria will be published in the Chemical Gazette and the NICNAS Handbook for Notifiers. Applicants will need to demonstrate how the notified chemical meets the criteria.

6.3 Early introduction permit

Regulatory

Regulations pursuant to paragraphs 30A(1A)(c) of the Act will be introduced to allow the early introduction of new industrial chemicals meeting the low hazardous criteria. The regulation will also state that chemicals which meet the low risk criteria will be eligible for introduction under an early introduction permit. The information requirements remain as stipulated for the relevant notification category.

Administrative

Guidelines detailing the extension of the early introduction permit to chemicals and polymers which meet the low hazardous and low risk criteria will be published in the Chemical Gazette and NICNAS Handbook for Notifiers.

It is proposed that an application for an early introduction permit for non-hazardous chemicals, non-hazardous polymers and polymers of low concern will be free of charge.

6.4 Modular assessment

Regulatory

The modular assessment option will be available for Standard, Limited and Polymer of Low Concern notification categories. At this stage, modular assessment will not be available for self-assessment applications. To implement the modular assessment of these chemicals, NICNAS intends to introduce a new regulation to enable the Director to set lower fees for applications which use the new modular assessment options, viz.:

- a remission of up to 40% of the fee for the hazard assessment; and
- a remission of up to 20% of the fee for the exposure assessment.

That is, a maximum rebate of 60% of the normal fee will be available to applicants. It is proposed that the fee be set during the 14-day screening phase immediately after notification, when NICNAS will advise the applicant of the fee and timeframe for assessment. The notified chemical will be assessed under the normal notification and assessment process if the data package supplied is insufficient to allow a modular assessment.

The new regulation will also enable the Director remit fees paid for an application where an acceptable hazard assessment report is available from another assessment authority, including assessments conducted under the following Australian Acts:

Therapeutic Goods Act 1989
Agricultural & Veterinary Chemicals (Code) Act 1994
Agricultural & Veterinary Chemicals Administration Act 1994
Food Standards Australia New Zealand Act 1991
Australia New Zealand Food Standards Code

An assessment report from an OECD member country such as any European Union member state or Canada, may allow the modular assessment of chemical.

Administrative

The criteria for an acceptable assessment report and the arrangements for obtaining the report will be published in the Chemical Gazette and NICNAS Handbook for Notifiers.

Similarly, the guidelines for an acceptable analogue will be published in the Chemical Gazette and NICNAS Handbook for Notifiers.

The justification for assessment of the chemical under the new modular assessment provisions must be provided by the applicant, e.g. scientific reasons why the previous NICNAS assessment of an analogue can be used.

The process for determining the appropriate remission of fees will be detailed in the NICNAS Handbook for Notifiers.

6.5 Naturally-occurring chemicals

Regulatory

No regulatory change is required at this stage.

Administrative

An expert essential oils working group will be established to assist NICNAS in providing guidance on the definition of a naturally-occurring chemical and its interpretation for notifiers. Guidance will then be published in the Chemical Gazette and NICNAS Handbook for Notifiers.

6.6 Form of Applications

Electronic templates are available on the NICNAS website for all types of permit and assessment applications. The completed template must be submitted to NICNAS with the prescribed fee and the required information for assessment.

For applications for assessment certificates under the new modular assessment concept, a new form will be available on the website. At this stage, the 40% rebate for use of the electronic template will not be available for modular assessment applications.

Joint applications may be made by manufacturers and importers of a new industrial chemical for all notification categories.

An application may be accompanied by an application that some of the information provided be treated as exempt information under section 75 of the Act.

6.7 Fees

The fees for applications for all notification categories are prescribed in the regulations.

6.8 Safeguards

Under the Act, the Director may reject an application for a Low Volume Chemical permit or a Controlled Use Permit if not satisfied that (a) sufficient data have been provided for assessment and (b) use of the chemical satisfies the criterion of 'no unreasonable risk to occupational health and safety, public health and the environment'. Upgraded guidance for 'no unreasonable risk' is currently included in the NICNAS Handbook for Notifiers.

Under the permit system in NICNAS, conditions may be applied to the permit to ensure that use of the chemical will not result in any unreasonable risk to workers, the public or the environment. The conditions may refer to any aspect of the chemical's manufacture, handling, storage, use or disposal. The conditions may also specify special packaging and labelling requirements and procedures relating to potential release of the chemical or its waste products into the environment. Standard conditions currently applied to permits acknowledge the role of States and Territory legislation in enforcing workplace, consumer and environmental controls.

Under the permit system, the conditions on the permit are binding, not only on the applicant, but any user of the chemical. The conditions on the permit can also be varied by the Director at any time. If any condition on a permit is breached, the permit may be withdrawn by the Director and/or a penalty imposed.

As with other permits issued by NICNAS, Controlled Use Permits will be subject to audit by NICNAS. Penalties apply for failure to meet conditions on the permit, for example, exceeding the maximum volume of introduction specified on the permit.

Under the new annual reporting requirements in the Act (Division 3B), holders of permits are required to keep records of any application for 5 years after issue of the permit. Holders of the permit must also submit an annual report to NICNAS including details of the chemical's name and volume and any information about adverse effects of the chemical on occupational health and safety, public health and the environment.

Applications for an assessment certificate under the new modular assessment provisions will be subject to acceptance by the Director of the justification provided by the applicant.

6.9 Further Information

This Final Report on Implementation of the Outstanding LRCC Reforms will be posted on the NICNAS website www.nicnas.gov.au. For information regarding the notice or matters regarding the new options, please contact Hana Hamdan on 02 8577 8855 (e-mail hana.hamdan@nicnas.gov.au) or Bob Graf on 02 8577 8850 (e-mail bob.graf@nicnas.gov.au).

APPENDIX – List of Submitters

Australian Botanical Products Pty Ltd

Essential Oil Producer's Association of Australia

Haztech Environmental

Larkman Nurseries

NSW Department of Environment and Conservation

Office of the Australian Safety and Compensation Council, Department of Employment and Workplace Relations

PACIA

SafeWork South Australia

The Australian Society of Cosmetic Chemists

The Shell Company of Australia Ltd

Uniqema

Wacker Chemicals Australia Pty Ltd