

LOW REGULATORY CONCERN CHEMICALS (LRCC)

IMPLEMENTATION OF OUTSTANDING REFORMS

OVERVIEW OF THE PLANNED REFORMS

1. PURPOSE

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) was amended to provide a framework for the introduction of new industrial chemicals under the concept of 'low regulatory concern'. This paper provides a summary of the proposals which will enable a number of LRCC recommendations to be implemented, in particular, those related to low hazard and low risk, and supports a number of focussed Discussion Papers on those items as follows:

- Low-hazardous criteria (for NICNAS notification and assessment only)
- Low risk criteria (for NICNAS notification and assessment only)
- Guidelines for Notification and Assessment of Analogues of Chemical Already Assessed by NICNAS
- Modular Assessment of Chemicals Assessed by Other Australian Authority
- Modular Assessment of Chemicals Assessed under Foreign or International Assessment Scheme
- Low Regulatory Concern Polymers
- Review of Definitions – Naturally-Occurring Chemicals and Essential Oils

Comment is sought on the proposals and implementation strategy.

2. BACKGROUND

The Low Regulatory Concern Chemicals (LRCC) Reform Initiative gave effect to the Government's response to the recommendations of the Chemicals and Plastics Action Agenda. The NICNAS Final Report and Recommendations for LRCC was published in June 2003, with the Implementation Strategy published soon after in July 2003. Some of the proposed reforms were administrative in nature, some required legislative change and others focused on improved consultation.

In the Final Report and Recommendations, it was stated that

'a single definition of LRCC is not possible except in the most generic sense: Chemicals could qualify for reduced regulatory input on the basis of low risk or where regulatory input from elsewhere is sufficient to meet Australian requirements.'

Two of the key concepts critical to the LRCC reforms were low hazard and low risk. Also important was the concept of modular assessment, where NICNAS could streamline its assessment process to take account of information already available.

The *Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Act 2004* (LRCC Amendment Act) 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 provide the legislative framework to implement the majority of LRCC reforms.

A special edition of the Chemical Gazette was issued on 16 August 2004 to identify the elements of the LRCC Amendment Act that were effective immediately. The LRCC Amendment Act put the legislative framework in place to ensure that the majority of LRCC recommendations could be implemented. A number of recommendations required the further development of criteria and guidelines. Among the LRCC reform initiatives requiring further development were the concepts of low hazard and low risk; which required the development of criteria, guidelines and regulatory and administrative measures. A number of the recommendations in the LRCC Final Report concerned low hazard and/or low risk.

The principal outstanding items for implementation are as follows:

- Development of low hazardous criteria (Discussion Paper 1)
- Development of low risk criteria (Discussion Paper 2)
- Introduction of modular assessment fees, incorporating
 - assessments conducted under other assessment schemes, national and international (Discussion Paper 3); and
 - analogues (Discussion Paper 4)
- Review of definition and guidance on naturally-occurring chemicals and essential oils (Discussion Paper 5)
- Assessment of low regulatory concern polymers (Discussion Paper 6)
- Expansion of access to Early Introduction Permit (EIP) system to include low hazardous and/or low risk chemicals

In addition to definitions of the key terms and development of specific criteria, new regulation and development of guidance and administrative processes are also required for implementation.

3. THE CONCEPTS OF LOW HAZARD AND LOW RISK FOR NOTIFICATION AND ASSESSMENT PURPOSES

3.1 Low hazard

The intent of developing low hazard criteria are for the **sole purpose** of allowing the introduction of new chemicals under permit and certificate systems. The aim is to identify a point below which a hazardous (i.e. classifiable) chemical can be considered low-hazardous. Here, it is assumed that the degree of hazard may be on a continuum and that a point on that continuum can be identified as a cut-off below which the chemical is of low hazard. For determining low-hazardous classification criteria, more than one degree of hazard is required, i.e. a continuum (e.g. Very Toxic, Toxic and Harmful for acute toxicity), as if there is only one level of classification it is not possible to consider a continuum of degree of hazard, as the least degree is not distinguished from the highest degree. Furthermore, quantitative classification criteria are required (e.g. LD₅₀/LC₅₀ values for acute toxicity), as qualitative criteria (e.g. carcinogenicity) are based on the strength of the available evidence and do not

give specific consideration to the potency of the chemical for the observed effects (i.e. do not allow a comparison to be made of the same type of toxic effects).

Australia has no classification criteria for environmental endpoints, however, for the purposes of setting criteria for chemicals of low hazard to the environment, the intent is to similarly set a hazard level above that normally applied in international hazard classification systems, e.g., the current EU hazard classification system for dangerous substances and preparations.

3.1.1 Proposal

The proposed low-hazardous criteria are detailed in Discussion Paper No. 1, *Low Hazardous Criteria for Notification and Assessment*.

3.1.1.1 Chemicals

In summary the following proposed low hazard criteria cut offs will apply

Criteria	Options
acute oral toxicity (LD ₅₀ values)	<i>option 1</i> LD ₅₀ value > 1500 mg/kg bw <i>option 2</i> LD ₅₀ value > 1100 mg/kg bw
acute dermal toxicity (LD ₅₀ values)	<i>option 1</i> LD ₅₀ value > 1500 mg/kg bw <i>option 2</i> LD ₅₀ value > 1100 mg/kg bw
acute inhalation toxicity (LD ₅₀ values)	LC ₅₀ > 3mg/L/4hr (for aerosols/particulates) or > 11 mg/L/4hr (for gases/vapours)
skin irritation	<i>option 1</i> Cannot be identified <i>option 2</i> R38 irritating to skin <i>option 3</i> R38 irritating to skin and the absence of inflammation in 2 or more animals at the end of the observation period.
eye irritation	R36 irritating to eye.
sensitisation	not hazardous
mutagenicity	not hazardous
carcinogenicity	not hazardous
reproductive toxicity	not hazardous
developmental toxicity	not hazardous
flammability	R10 Flammable
other physical and chemical properties	not a dangerous good
acute aquatic toxicity	R52 Harmful to aquatic organisms or R53 May cause long term adverse effects in the aquatic environment with 55 mg/L > EC ₅₀ /IC ₅₀ /LC ₅₀ ≤ 100 mg/L

Chemicals which are not hazardous chemicals or dangerous goods would also satisfy the requirements for notification and assessment under the proposed low hazardous provisions. Furthermore, chemicals which are persistent and/or bioaccumulative would not be eligible for notification and assessment under the proposed low hazardous provisions.

3.1.1.2 Polymers

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.

3.2 Low risk

Risk can be defined as “the probability of an adverse effect in an organism, or (sub) population caused under specific circumstances by exposure to an agent (OECD, 2003).” Risk is a function of hazard and exposure and as such these parameters offer potential to develop scenarios where risk can be maintained at low or acceptably managed levels.

Fundamentally, when determining the risk posed by a chemical two factors need to be considered; the severity of the hazard of the chemical and the level of exposure to the chemical. This allows a hazard-exposure paradigm to be created which indicates the approximate level of risk.

Low risk applies to lower levels of hazard and/or exposure, with an extension of hazard to ‘moderate’ if there is little exposure and to ‘high’ if there is no exposure. Higher exposures can be tolerated if the chemical’s hazard level is lower.

One of the primary concepts for controlling risk is to control exposure during use to levels that are considered low or where no exposure occurs. Hence the low risk category will be restricted to permits, where conditions of use can be stipulated and where a high degree of compliance can be ensured via auditing and annual reporting.

The low risk criteria are detailed in Discussion Paper No. 2, *Low Risk Criteria for Controlled Use Permits*.

3.2.1 Proposal

3.2.1.1 Low Risk Criteria

3.2.1.1.1 Hazard

A number of limitations on hazard have been made for development of low risk criteria and scenarios; these apply to both low exposure criteria and specific low exposure scenarios.

Firstly, all the relevant hazards of the chemical must be known. Secondly, high hazard chemicals will not be eligible, as indicated below.

It is proposed that chemicals with similar properties to those prohibited or severely restricted under Australia's international obligations would not be considered in this category as they are subject to bans or severe restrictions under different mechanisms. Further, new chemicals with persistent organic pollutant (POPS) characteristics, which include persistence and bioaccumulation, will not be considered a low risk for the purpose of the Controlled Use Permit category. In addition chemicals classified as carcinogenic, mutagenic, or reproductive toxicants (CMR chemicals) would not be considered a low risk for the purpose of the Controlled Use Permit category. This approach is consistent with that taken by other national regulatory schemes, e.g. in the EU and US.

A new chemical in general will not be introduced under this section if NICNAS determines that the chemical, any reasonably anticipated metabolites, environmental transformation products, or by-products of the chemicals, or any reasonably anticipated impurities in the chemical may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical:

- a. Serious acute (lethal or sublethal) effects;
- b. Serious chronic (including carcinogenic and teratogenic) effects; or
- c. Significant environmental effects.

3.2.1.1.2 Exposure

All exposure scenarios for workers, the public and the environment are known and highly controlled for each known use;

- i. Consumers and the general population

For exposure of consumers and the general population to the new chemical during all manufacturing, processing, distribution in commerce, use, and disposal of the chemical:

- a. No dermal exposure;
- b. No potential for oral exposure, i.e. from consumer products; and
- c. No inhalation exposure.

- ii. Workers

For exposure of workers to the new chemical during all manufacturing, processing, distribution in commerce, use and disposal of the chemical:

- a. No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable state and federal guidance); and
- b. No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable state and federal guidance)

- iii. Environment

Ambient surface water

For ambient surface water releases:

- a. No releases resulting in surface water concentrations above 1 part per billion

Atmosphere

For ambient air releases:

- b. No releases of the new chemical above 1 microgram per cubic metre maximum annual average concentration, calculated using the formula: (kg/day of release after treatment) x (number of release days per year) x (9.68 x 10⁻⁶) micrograms per cubic metre.

Land

For releases to land:

- c. No releases to land or to a landfill unless the introducer has demonstrated that the new chemical has negligible groundwater migration potential.

3.2.1.2 Specific low exposure scenarios

To assist in the application of the exposure component of the low risk criteria, two low exposure scenarios have been developed for inclusion in the guidance documents. The low exposure scenarios presented are familiar to NICNAS as a result of experience in assessing a number of new chemicals controlled in this manner. Notifiers may apply to introduce a new industrial chemical under the Controlled Use Permit if it can be demonstrated that the exposure is controlled at every stage of the chemical's lifecycle in accordance with the low exposure elements given in the low exposure scenarios. As low risk criteria contain both exposure and hazard elements, the hazard requirements stated above (in 3.2.1.1.1) will also need to be met. The following low exposure scenarios are given:

- Low Exposure Scenario 1 Containment and Controlled Reformulation
- Low Exposure Scenario 2 Site-Limited and Closed System

It is anticipated that further low risk scenarios will be determined by NICNAS on a case by case basis pending applications. Such precedent setting decisions will be gazetted and added to guidance documents.

4. DEFINITIONS AND CONCEPTS

4.1 Naturally-occurring chemical

Currently a naturally-occurring chemical is defined in section 5 of the Act as:

*“(a) An unprocessed chemical occurring in a natural environment, or
(b) a chemical occurring in a natural environment, being a substance that is extracted by:*

- (i) manual, mechanical, or gravitational means, or*
- (ii) dissolution in water; or*
- (iii) flotation; or*
- (iv) a process of heating for the sole purpose of removing uncombined water,*

without chemical change in the substance”.

This definition is consistent with the US, Canadian and current EU definitions and excludes extraction through steam distillation. However, it differs from the definition proposed in the draft EU REACH legislation, which includes steam distillation as an allowable process. The OECD New Chemicals Task Force currently has a working definition of ‘naturally-occurring chemical’, similar to the NICNAS definition, out for public comment for two years (period ends November 2006). It is noted that once the EU REACH system is established there will be a need to revisit the definition of naturally occurring under harmonisation programs.

More detail is included in Discussion Paper No. 5, *Review of Definitions – Naturally-Occurring Chemicals and Essential Oils*.

4.1.1 Proposal

Recommendation 1

The definition of naturally occurring chemicals in section 5 of the Act is to remain unchanged.

Recommendation 2

In the meantime, it is proposed that NICNAS develop and publish further guidance on the definition of a naturally-occurring chemical. Any guidance information will include steam distillation as an acceptable extraction method only if there is sufficient scientific evidence that the distillation conditions used do not result in chemical transformation of the components. This will allow a level of consistency with EU REACH legislation until there is sufficient scientific rationale for the inclusion of steam distillation in the definition.

4.2 Essential oil

Essential oil is not defined in the Act. It is proposed that the International Organization for Standardization (ISO) definition is adopted by NICNAS. ISO defines essential oils as “products obtained from natural raw materials by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process or by dry distillation. The essential oil is subsequently separated from the aqueous phase by physical means”. NICNAS will also develop guidance on essential oils in relation to their definition and interpretation as naturally occurring.

4.2.1 Proposal

Recommendation 1

NICNAS adopts the ISO definition of essential oil, this would be consistent with the current definition used in SUSPD.

Recommendation 2

Develop guidance on essential oils in relation to their definition and interpretation as naturally-occurring.

Recommendation 3

Establish an expert essential oils working group to work with NICNAS on the guidance material.

4.3 Analogue

In chemistry, an analogue can be defined as a chemical similar in structure to another chemical but differing in some slight structural detail. However, it is important to note that, while the differences in structure may be slight, a chemical with a structure similar to that of another, but differing from it with respect to a certain component, may have a similar or opposite action metabolically. Therefore, for a chemical to be considered an analogue for notification and assessment purposes and to cover set toxicological data requirements, it must bear both a *prima facie* case of obvious structural similarity and demonstrate a similar pattern of activity to another previously assessed chemical (or chemical with an established safety profile based on test data). The criteria for determining whether a new chemical is an acceptable analogue are in the supporting Discussion Paper No. 4, *Modular Assessment of Chemicals for which Appropriate Analogues have been Previously Assessed by NICNAS*.

4.3.1 Proposal

That chemicals that are considered acceptable analogues of chemicals previously assessed by NICNAS will be assessed under the modular assessment concept.

5. MODULAR ASSESSMENT CONCEPT

The intent of modular assessment is to streamline the assessment process where a particular module, or modules, of the assessment are already fulfilled or deemed unnecessary. For example, the hazard assessment of the new chemical may have been completed by another regulatory authority or the chemical being notified may be structurally similar to one already assessed under NICNAS (an analogue) and a full risk assessment of the new chemical may not be necessary.

Similarly, the use and exposure pattern may be well characterised and similar to a chemical already assessed. It is proposed that standard exposure scenarios be generated for situations where exposure is highly controlled. For example, standard low exposure scenarios have been generated for:

- contained and controlled reformulation; and
- site-limited and closed system use.

An analysis of estimates of assessment times for the critical modules of the assessment report indicated that the health and environmental effects components of the assessment report constituted approximately 40% of assessment time (30% health, 10% environment) and the exposure assessment approximately 20%. Based on these estimates, it is proposed that the maximum rebate for modular assessment be 60% (40% hazard assessment, 20% exposure assessment).

It is proposed that modular assessment fees be available for the following:

- Chemicals for which an assessment has been undertaken by another Australian regulatory authority (Discussion Paper No.3);
- Chemicals for which an international assessment has been conducted (Discussion Paper No.3);
- Analogue chemicals (Discussion Paper No.4); and
- Polymers regarded as of low regulatory concern (Discussion Paper No.6).

6. LOW REGULATORY CONCERN POLYMERS

Low regulatory concern polymers (LRCPs) are those polymers where a reduced level of assessment is required, for example, polymers which do not meet the current PLC criteria but for which a full risk assessment under the Limited and Standard assessment certificate categories is not required. LRCPs would include other classes of low hazard polymers, analogues and polymers assessed under other regulatory schemes. Typical LRCPs could therefore include the following:

- Polymers of certain classes which are of low hazard;
- Polymers chemically similar to polymers already assessed by NICNAS;
- Consolidated polymer notification, where more than one polymer can be notified and assessed together; and
- Polymers assessed by other regulatory schemes.

Accordingly, it is proposed that modular assessment fees be available for the following:

- polymers with one monomer less than a polymer already assessed by NICNAS;
- polymers containing a reactant similar (analogue) to that in a polymer already assessed by NICNAS;
- polymers identical to a polymer already assessed by NICNAS but manufactured by a different pathway and, in some cases, using different reactants; and
- polymers assessed by another competent authority, both national and international.

For polymers notified as a family, it is proposed that normal fees would apply to one member of the family and an administrative fee for other members.

The proposals apply to all certificate categories.

More details are included in the supporting Discussion Paper No.6, *Low Regulatory Concern Polymers* and in Discussion Papers No.1 (*Low Hazardous Criteria*), No.3 (*Modular Assessment of Chemicals Assessed by Another Authority*) and No.4 (*Modular Assessment of Chemicals for which Appropriate Analogues have been Previously Assessed by NICNAS*).

7. IMPACT OF REFORMS ON NEW CHEMICALS NOTIFICATION AND ASSESSMENT CATEGORIES.

Implementation of the above initiatives will translate into the following changes to the notification and assessment categories for new chemicals: It is noted that all changes can be implemented through regulation amendments and/or administrative processes. No amendments to the Act are required.

7.1 Permit Assessments

Category	Chemicals	Polymers	Criteria to be met	Maximum Volume	Data Requirements
Low Volume Chemical Permit (LVC)	✓	✓	low hazard	1000 kg	s 21S(2) and scientific justification of how the chemical meets the low hazard criteria
Controlled Use Permits (CUP)	✓	✓	low risk	Unlimited	s 22C(2) and Reg 6B
Early Introduction Permit (EIP)	✓	✓	low hazard and low risk	Unlimited	s 30A

Low Volume Chemical Permit (LVC)

For low hazardous chemicals and polymers, the introduction volume will be increased to 1000 kg per year.

Controlled Use Permit (CUP)

This permit, which has no maximum introduction volume, will be available for chemicals and polymers which meet the low risk criteria.

Early Introduction Permit (EIP)

The EIP will be extended to chemicals and polymers which meet the low hazardous criteria and/or to those which meet the low risk criteria. It is proposed that EIPs for non-hazardous chemicals and polymers will be free of charge.

The permit system has a number of safeguards that are not available under the certificate system. The chemicals assessed under the permit system are subject to annual reporting, permit conditions, and the Director may revoke a permit or vary the conditions at any time.

7.1.1 Information Required With Permit Applications

Low Volume Chemical Permit (LVC)

The data requirements remain unchanged. However, for permit applications for introduction volumes greater than 100 kg per year, it is proposed that scientific justification of how the chemical meets the low hazardous criteria will be required.

Controlled Use Permit (CUP)

The basic information required by NICNAS with an application for a Controlled Use Permit is listed in subsection 22C(2) of the Act. It is proposed that the other standard

information requirements be consistent with those in Regulation 6B for the recently introduced Controlled Use Permit for Export Only, except that details of export will not be required.

Early Introduction Permit (EIP)

An EIP is submitted with a certificate notification. There are no additional data requirements.

7.2 Certificate Assessments

Category	Chemicals	Polymers	Modular Assessment Available	Maximum Volume	Data Requirements	EIP
Standard	✓		✓ ¹	Unlimited	Parts A, B, and C of Schedule (will vary for modular assessments)	Free (for non-hazardous chemical)
Standard		✓	✓ ²	Unlimited	Parts A, B, C and D of Schedule (will vary for modular assessments)	Free (for non-hazardous polymer)
Limited (chemical)	✓		✓ ¹	Less than one tonne per year	Parts A and B of Schedule	Free (for non-hazardous chemical)
Limited (polymer)		✓	✓ ²	Unlimited	Parts A, B and D of Schedule	Free (for non hazardous polymer)
Polymer of low concern		✓	✓ ³	Unlimited	Section 24A	Free
Low regulatory concern polymer ⁴		✓	✓ ⁵	As per notification category	As per notification category	Free (for a non-hazardous polymer)

¹ Assessment undertaken by another Australian regulatory authority; or Assessment undertaken by a foreign regulatory authority; or Analogues of previously assessed chemicals

² Assessment undertaken by another Australian regulatory authority; or Assessment undertaken by a foreign regulatory authority; or Analogues of previously assessed polymers; or Low Regulatory Concern Polymers

³ Assessment undertaken by another Australian regulatory agency; or Assessment undertaken by a foreign regulatory agency; or Analogue polymers.

⁴ low regulatory concern polymers can be notified under all certificate categories.

⁵ for polymer already assessed by NICNAS and one monomer less than a polymer already assessed; or one monomer substituted for a polymer already assessed; or if new polymer identical to polymer already assessed by with different CAS number

Standard Notification

It is proposed that:

- (i) modular assessment fees be available for
 - Chemicals and polymers for which an assessment has been undertaken by another Australian regulatory authority;
 - Chemicals and polymers for which an international assessment has been conducted;
 - Analogue chemicals and polymers; and
 - Low regulatory concern polymers; and
- (ii) the EIP system be extended to low-hazardous chemicals, with a free EIP proposed for non-hazardous chemicals.

Limited Notification

It is proposed that similar options be available for chemicals and polymers notified under the Standard and Limited Notification categories. It is noted that the volume of introduction of polymers under this category is unlimited.

Polymers of Low Concern (PLC)

It is proposed that modular assessment fees also be available for PLCs, namely:

- polymers for which an assessment has been undertaken by another Australian regulatory authority;
- polymers for which an international assessment has been conducted; and
- analogue polymers.

It is also proposed that a free EIP be available for PLCs.

Low Regulatory Concern Polymers

It is proposed that modular assessment fees be available, for all assessment certificate categories, for polymers chemically similar to polymers already assessed by NICNAS, namely:

- if one monomer less than a polymer already assessed;
- if one monomer substituted for a polymer already assessed; and
- if new polymer identical to a polymer already assessed but with a different CAS number, e.g. due to different reactants.

It is also proposed that reduced notification requirements, with reduced fees, be available for the consolidated notification of a group of polymers (the 'family approach'). It is proposed that normal notification requirements and fees apply for the first member of the group and an administrative fee for other members of the group.

7.2.1 Information Required With Certificate Applications

Standard Notification

No amendments are proposed for the normal Standard notification, namely, Parts A, B and C for chemicals and Parts A, B, C and D for polymers.

For modular assessment applications, those information requirements deemed unnecessary need not be provided. For example, Part C items would not be required if an acceptable hazard assessment was provided for a chemical assessed under another regulatory authority. Similarly, for chemicals subject to standard exposure controls, the detailed exposure items in Part B would not be required.

Limited Notification

No amendments are proposed for the normal Limited notification, namely, Parts A and B for chemicals and Parts A, B and D for polymers.

Polymers of Low Concern (PLC)

No amendments are proposed for the normal PLC notification.

Low Regulatory Concern Polymers

The data requirements will be in accordance with the relevant certificate category applicable, that is, Standard Notification, Limited Notification or Polymer of Low Concern, with variations for information previously assessed or already available. Where the hazard assessment is already available, e.g. from an overseas scheme, then separate data need not be submitted.

7.3 Safeguards

The Act provides for a number of safeguards in the notification and assessment of new chemicals. These will also apply for the proposals outlined above.

For permits, the following safeguards apply:

- the Director has the power to reject any permit application, e.g. if insufficient data for assessment, or use of the chemical does not satisfy the criterion of ‘no unreasonable risk to occupational health and safety, public health and the environment’;
- all permits are subject to conditions enforceable by the Director, and can be withdrawn if any condition is breached;
- all permits and self-assessment certificates are subject to audit by the NICNAS compliance team and annual reporting; and
- the Controlled Use Permit is available only for new industrial chemicals that are low risk to occupational health and safety, public health and environment.

For all applications dependent on the low hazardous and/or low risk criteria, scientific justification of how the chemical meets the criteria must be demonstrated by the applicant, otherwise the application is rejected.

For all modular assessment applications, scientific justification of how certain elements of the risk assessment may not be necessary must be demonstrated by the applicant, otherwise the application is rejected.

8. EFFECTIVE ENGAGEMENT

NICNAS has consulted widely with key stakeholders throughout the LRCC process, with progress reports regularly provided to NICNAS's industry, government and community committees. For this suite of remaining reforms, NICNAS is now seeking engagement with interested stakeholders within its Community Engagement Charter.

It is intended to release this overarching paper and its associated discussion papers for public comment for a period of six weeks by:

- Publishing the papers on the NICNAS website;
- Publishing the papers in the NICNAS Chemical Gazette; and
- Sending the papers to key stakeholders.

Comments may be provided to NICNAS by mail, e-mail or by completing a questionnaire on the NICNAS website.

For information regarding this notice or matters regarding the LRCC reforms, please contact Bob Graf on 02 8577 8850 or 1800 638 528 (e-mail bob.graf@nicnas.gov.au).