



LRCC Reform Initiative Implementation Scorecard Report

The LRCC initiative has seen a range of amendments that deliver industry real reform by creating long term, sustainable, competitive advantage for the chemicals and plastics industry. These reforms, developed in partnership with industry, the community and government, offer an innovative approach to introduce flexibility into the regulation of industrial chemicals while improving health, safety and environmental standards and public access to chemical safety information.

The new arrangements under the LRCC reform initiative reflect the Government's commitment to ensure the most efficient regulatory system is in place for industrial chemicals and a system that encourages the introduction of new and safer chemicals. The proposed changes give effect to the Government's response to the recommendations of the Chemicals and Plastics Action Agenda in December 2002. This response indicated the Government's agreement to examine options for flexibility in the assessment processes for industrial chemicals.

The industry has taken the Chemicals and Plastics Action Agenda very seriously and is monitoring government and industry progress in implementing the recommendations through the Chemicals and Plastics Leadership Group.

This Scorecard Report provides an update on the Implementation Strategy for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative – July 2003 including those recommendations which have been completed, those being implemented, or those scheduled for completion during the 2004-05 NICNAS work program. The most significant achievement since the July 2003 report has been the successful passage of the Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Bill 2004 (the Bill) through both Houses of Parliament on 24 June 2004.

The Bill received Royal Assent on 13 July 2004 and is expected to receive Proclamation in mid-August 2004 with the passage of the Industrial Chemicals (Notification and Assessment) Regulations (the LRCC Regs). The Bill provides the legislative framework to implement the majority of recommendations. While the framework is in place, criteria and guidelines for low hazard and/or low risk need to be developed. These changes will require development with industry and the community and once finalised will require amendment to regulations to give effect. However, as can be seen by this report, much of the critical work for LRCC has been completed.

Recommendation

1.1 NICNAS introduces a process of audited self-assessment for LRCC categories.

Completed

Legislation

Completed - The Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Bill 2004 amends Division 2 and Division 3 of Part 3 of the Act to introduce new processes for audited self-assessment of low regulatory concern chemicals.

Sections 33A, 33B and 33C refers to the pre-screening assessment process.

Sections 40K, 40L, 40M and 40N under Division 3B set out the reporting and other obligations for self-assessed assessment certificates.



Regulations

Regulations are required to set a new fee for self-assessment certificates categories as they are developed.



Administrative

Interim arrangements are in place for self-assessment of polymers of low concern. Industry training on the new arrangements has been provided in Sydney and Melbourne in March and April 2004.

NICNAS will develop an annual audit plan for self-assessment certificates in consultation with the Industry Government Consultative Committee (IGCC) and the Community Engagement Forum (CEF), and will publish in its annual report the number of self-assessment reports which:

- followed correct procedures;
- met the criteria; and
- required additional information.



Consultation

NICNAS's Community Engagement Strategy will be used to establish technical working groups in developing criteria and guidelines for self-assessment.



1.2 Introduce an audited self-assessment permit for low hazard chemicals (introduced at low volumes 100-1000kg).**Completed**

Completed – Regulations and administrative arrangements as for 1.1
Development of criteria for low hazard in NICNAS's work program for 2004-05.

**1.3** NICNAS enhance its compliance program to effectively audit the new self-assessment permits and certificates.**Completed****Legislation**

The Bill introduces a range of penalties to support the new provisions for annual reporting and record keeping which will enhance NICNAS's compliance program. New provisions under section 15A have been introduced making it an offence for failing to comply with a condition to which a chemical is subject under the Australian Inventory of Chemical Substances (AICS).

**Regulations**

None required

**Administrative**

NICNAS will undertake an annual plan for self-assessment certificates in consultation with the IGCC and CEF as for 1.1.
Ongoing monitoring and reporting of NICNAS's compliance program is required.

**Consultation**

As for 1.1

**1.4** NICNAS facilitates industry compliance, including with audited self-assessment, by developing electronic tools and templates to assist with assessment, notification and permit applications, tracking information for audited self-assessment processes and standardised application and reporting formats.**Completed****Administrative**

NICNAS has developed a template and guidelines for the interim arrangements for self-assessment of polymers of low concern. Industry training was provided in the use of these templates. As new assessment certificates become available, a similar process will be developed. Monitoring and reporting of industry compliance will be an ongoing NICNAS activity.

**Consultation**

In developing criteria and guidelines for self-assessment NICNAS will develop technical working groups equally represented by industry and the community.

**2.1** NICNAS introduces modular assessment fees for low-hazardous and/or low risk chemicals and targeted assessment for chemicals where controls are in place.**Action planned for NICNAS 2004-05 work program****Legislation**

Legislative provision for rebate based on a modular assessment decision is required. Changes to schedule data requirements (Section 23 of the Act) to allow the notification to be accepted with data substituted by modular inputs. June 2005

**Regulations**

Recognition of Canada as a Foreign Scheme – June 2005

**Administrative**

Development of internal timeframes for modular assessment decisions. Development of modular assessment reporting templates and guidelines required. Development of low hazard, low risk criteria required.

**Consultation**

In developing criteria and guidelines for self-assessment NICNAS will develop technical working groups equally represented by industry and the community.



3.1 Introduce a Transshipment Exemption for instances when chemicals are off-loaded at an Australian port of entry and remain in containment unopened for a short period (30 days) before reshipment out of Australia.

Completed

Legislation

Completed - the Bill introduces a new paragraph 21(6) (b) to introduce a transshipment exemption. In addition, the new section 21AA introduces annual reporting requirements under the exemption categories to commence for the registration year 1 September 2004 with the first report required by 28 September 2005. A new section 21AB requires the Director to maintain a list of chemical names and volumes reported under Section 21AA and to publish this in the Gazette.



Regulations

None required



Administrative

Ensure compliance and reporting strategy is in place once legislation takes effect.



3.2 Introduce an exemption for low-hazardous chemicals for volumes up to 100kg.

Completed

Completed - the Bill introduces a new paragraph 21(4) to introduce an exemption for low-hazardous chemicals for volumes up to 100kg. Reporting requirements the same as 3.1.



3.3 Introduce an Exemption "without advice" for imported cosmetic chemicals introduced in mixtures at 1% or less, provided they are not determined to be hazardous.

Completed

Completed - the Bill introduces a new paragraph 21(6) (c) to introduce an Exemption "without advice" for imported cosmetic chemicals introduced in mixtures at 1% or less, provided they are not determined to be hazardous with reporting requirements the same as 3.1, and meet the requirements prescribed by Regulations.



Regulations

Regulations have been drafted and are expected to be in place to give effect to changes in mid-August 2004.



Administrative

Prepare new reporting format for annual reporting to NICNAS.



3.4 Increase the current exemption for Research, Development and Analysis from 50 to 100kg/12months, with new record-keeping requirements for 5 years.

Completed

Completed - the new paragraph 21(6) (a) increases the exemption for R&D. Reporting requirements the same as 3.1.



3.5 Increase the general exemption for low volume non-cosmetic chemicals in line with EU volumes, from 10kg to 100kg/12 months/introducer, maintain existing conditions prescribed by Regulations and introduce new requirements for record keeping for 5 years and an annual report to NICNAS.

Completed

Completed - the Bill introduces a new paragraph 21(4) (b)(ii) to increase the general exemption for low volume non-cosmetic chemicals in line with EU volumes with record keeping and annual reporting to NICNAS.



Regulations

Regulations have been drafted and are expected to be in place to give effect to changes in mid-August 2004.



Administrative

Prepare new reporting format for annual reporting to NICNAS.



4.1 Introduce an audited self-assessment certificate against existing NICNAS guidelines for polymers of low concern.

Completed

Legislation

Completed - The Bill introduces a definition of polymer of low concern.



Regulations

Regulations are required to set a new fee for self-assessment certificates for polymers of low concern. October 2004



Administrative

Interim arrangements are in place for self-assessment of polymers of low concern.

NICNAS will develop an annual audit plan for self-assessment certificates in consultation with the IGCC and CEF as outlined in 1.1.



Consultation

In developing criteria and guidelines for self-assessment NICNAS will develop technical working groups equally represented by industry and the community.



4.2 Introduce a low hazard permit for polymers of low volume (1000kg/yr per introducer) for 3 years. Low hazard criteria appropriate for polymers would need to be developed in consultation with industry and the community.

Action planned for NICNAS 2004-05 work program

Legislation

Completed as for 1.1



Regulations

Low hazard criteria and fees need to be developed prior to the implementation of regulations.

Low hazard – April 2005 Low risk – December 2005



Administrative

Set internal timeframes, processes, fees and reporting format once criteria have been developed and regulations drafted.



Consultation

In developing criteria and guidelines for self-assessment NICNAS will develop technical working groups equally represented by industry and the community.



4.3 Introduce audited self-assessment for low regulatory concern polymers (i.e. polymers which do not meet the existing PLC criteria). New NICNAS criteria will need to be developed with industry and community involvement.

Action planned for NICNAS 2004-05 work program

Legislation

Completed as for 1.1



Regulations

As for 4.2



Administrative

As for 4.2



Consultation

As for 4.2



5.1 Introduce audited self-assessment for all cosmetic ingredients with annual volumes of 10 kg per 12 months or less.

Completed

Legislation

A new paragraph 21(4) (b)(i) introduces an exemption for chemicals introduced in a cosmetic provided that requirements as prescribed by the Regulations are met.



Regulations

Regulations have been drafted and are expected to be in place to give effect to changes in mid-August 2004.



Administrative

Prepare new reporting format for annual reporting to NICNAS.



5.2 Require advice of introduction for low hazardous chemicals for cosmetic use of more than 10 kg and up to 100 kg per 12 months; similar to the current less than 10 kg exemption notice.

Completed

Legislation

A new paragraph 21(4) (b)(i) introduces an exemption for chemicals introduced in a cosmetic provided that requirements as prescribed by the Regulations are met.



Regulations

Regulations have been drafted and are expected to be in place to give effect to changes in mid-August 2004.



Administrative

Revise format for case-by-case reporting.



5.3 To amend the definition of cosmetics currently used in the Act to that used in the Trade Practices Act 1974, thus improving consistency in the Government's regulatory approach to cosmetics.

Completed

Legislation

Definition in Section 5 of the Act was revised.



5.4 Recognising that negotiations are ongoing between industry and the Therapeutic Goods Administration (TGA), the LRCC Task Force recommends that the Parliamentary Secretary asks NICNAS and TGA to examine the reform options for addressing the interface issues dealing with:

- antiperspirants,
- mass market anti-dandruff shampoos,
- moisturisers with SPF,
- antibacterial skin washes; and
- anti-acne skin cleansers.

A report on options should be provided to the Parliamentary Secretary by December 2003.

Being implemented

Administrative

NICNAS and the Therapeutic Goods Administration (TGA) have taken the initiative to establish a Working Group comprising nominated senior staff from the TGA, NICNAS and the Australian Competition and Consumer Commission (ACCC, responsible for enforcing the mandatory labelling standard for cosmetic products). The Working Group will clarify the demarcation between cosmetics and therapeutic goods, consider policy implications of regulating products at the interface, and develop criteria for the regulation of cosmetic products which may contain certain medicines. The scope of the work has been extended to take into account the regulation of therapeutics under the new Trans Tasman agency due to commence operations on 1 July 2005.

The indicative timeframe identified in the Implementation Strategy for examining the options relating to the interface was December 2003. Given the magnitude of the task and the extent of consultation required, an options paper for management of the cosmetic/drug interface is now expected to be provided to the Parliamentary Secretary by end August 2004.



Consultation

It is expected that there will be a public consultation process with final proposals put to Ms Worth in October 2004.



6.1 Examine the introduction of a controlled use/specified use assessment (permit and/or certificate) category based on history of use, limited exposure and/or use in controlled environments.

Action - completed

Legislation

The Bill inserts new sections 22A –220 under a new Division 1C in Part 3 of the Act to introduce controlled use permits.



Regulations

Guidelines may be prescribed in regulations. Fees will need to be prescribed in regulations.



Administrative

Internal arrangements, procedures and reporting templates will need to be developed. Guidelines will need to be developed.



Consultation

In developing criteria and guidelines NICNAS will develop technical working groups equally represented by industry and the community.



6.2 Examine the introduction of an Export Only Permit.**Action - completed as for 6.1**

The Export Only Permit will be issued as a controlled use permit and is a first priority for NICNAS. December 2004

**7.1** Introduce to the standard certificate assessment category a new low-hazardous chemical sub-category with appropriate criteria and modular assessment fee.**Action planned for NICNAS 2004-05 work program****7.2** Expand access to the Early Introduction Permit (EIP) system to include low hazard and/or low risk chemicals based on appropriately developed criteria.**Completed***Legislation*

The Bill amends section 30A to redefine the categories of chemicals that may be the subject of an application for an EIP.

*Regulations*

As for 1.1.

*Administrative*

Internal procedures and reporting templates will need to be developed.

*Consultation*

In developing criteria and guidelines NICNAS will develop technical working groups equally represented by industry and the community.

**7.3** Introduce a low hazard permit for chemicals of low volume. These chemicals would be introduced in low volumes, 1000kg/yr per introducer for 3 years.**Completed***Legislation*

The Bill amends subsection 21U(2) to increase the quantity of chemicals introduced under a low volume permit from 100kgs to 1000kgs in certain cases.

*Regulations*

As for 1.1.

*Administrative*

Guidelines will need to be developed.

*Consultation*

In developing criteria and guidelines NICNAS will develop technical working groups equally represented by industry and the community.

**8.1** That industry and NICNAS further cooperate to identify and pursue agreement with countries of similar regulatory standards where bilateral arrangements may present opportunities for cost-effective progress with bilateral agreements.**Action planned for NICNAS 2004-05 work program***Administrative*

NICNAS staff have commenced discussions with the USA Environmental Protection Agency on bilateral arrangements.

Development of Work Plan – March 2005



9.1 Permit renewals for the current CEC, LVC permits to be administrative rather than assessment processes (unless new data is available or the conditions of introduction have significantly changed).

Completed

Legislation

Completed – the Bill introduces a new subsection 21U(2A) to renew an application if the conditions set out in subsection 21R(1A) have been met and the approved form has been complied with under section 21S.

Regulations

To be amended to introduce a renewal fee. October 2004

Administrative

New procedures and forms will need to be put in place to process repeat permit applications.

9.2 Introduce an option for industry to nominate an assessed chemical for immediate inclusion on the AICS (rather than a five year certificate period).

Completed

Legislation

The Bill introduces a new section 13B which gives certificate holders the option to request that an assessed chemical be included in the non-confidential section.

Regulations

A fee needs to be prescribed in regulations. October 2004

Administrative

Internal procedures need to be established.

9.3 Review the definition of naturally occurring substances particularly in relation to steam distillation extraction for essential oils.

Action planned for NICNAS 2004-05 work program

10.1 NICNAS introduces mandatory company registration of all chemical introducers currently below the current \$500,000 threshold. An administrative fee only should apply.

Completed

Legislation

The Bill amends Part 3A of the Act to introduce mandatory registration of all persons who introduced or propose to introduce relevant industrial chemicals. A new definition of 'chargeable person' differentiates between all persons required to register with NICNAS and those to whom the threshold applies and are required to register for Tier 2 or Tier 3.

Regulations

Completed – a NICNAS registration fee of \$353 for the 2004-05 registration year has been set.

Administrative

A range of initiatives such as the establishment of a call centre and small business training to assist compliance with the new registration requirements are underway. New NICNAS registration requirements will be implemented for the registration year commencing 1 September 2004.

Consultation

Industry associations and NICNAS's IGCC have been involved in the development of the implementation strategy.

10.2 The costs, benefits and practicality of a mandatory registration number for chemical introducers be further investigated.

Being implemented

Administrative

NICNAS has obtained funding under the National Strategy for the Prevention of the Diversion of Precursor Chemicals to improve knowledge of the licit movement of precursor chemicals throughout Australia and to improve the controls on industrial chemicals used as chemical precursors through the electronic tracking of the movement of industrial chemicals. NICNAS's proposal to the National Strategy includes feasibility for the registration and tracking of certain chemicals using NICNAS's existing databases. The feasibility study into the movement of precursor chemicals will provide NICNAS with valuable information on the practicality of requiring the use of a mandatory registration number in the control and supply of industrial chemicals throughout the supply chain. Final feasibility analysis expected to be available in December 2004.

Consultation

Following the results of the study, industry, government and the community will be involved in recommending the next steps.

10.3 NICNAS, industry and the community investigate opportunities and the feasibility of introducing effective co-regulatory approaches where appropriate in relation to industrial chemicals regulation.

Being implemented

Administrative

The range of NICNAS exemptions and notifications provide a mechanism for a co-regulatory approach to industrial chemicals between NICNAS and introducers, based on risk assessment. The LRCC reforms will provide further scope for co-regulatory approaches with a greater number of exemptions and notifications balanced by increased annual reporting and record keeping requirements.



11.1 NICNAS consolidates its on-line information to improve public and industry access to industrial chemicals information.

Being implemented

Legislation

A new section 13 gives the Director the ability to annotate the AICS to include details of assessment, details of use and other conditions which may apply. This will provide industry with information that will help prevent chemicals being used for a purpose different to that for which they were assessed.



Regulations

Regulations may be required from time to time which prescribe certain conditions on industrial chemicals.



Administrative

The AICS was made publicly available online in January 2004. NICNAS ran training sessions in Melbourne and Sydney to assist industry in the proper uptake of AICS on-line. Further enhancements are proposed to the AICS to improve its useability. Action planned in the 2004-05 work plan with first project identified as the addition of synonyms on the AICS.



Consultation

NICNAS's IGCC and CEF will be involved in providing advice on enhancements to NICNAS's on-line information to improve access to chemical safety information.



12.1 NICNAS improve community participation in NICNAS's decision making processes through the establishment of a community based Consultative Forum.

Completed

Administrative

The Parliamentary Secretary, Ms Worth, appointed members to NICNAS's Community Engagement Forum (CEF) and the first meeting was held on 10 November 2003.



12.2 NICNAS and the IGCC, in consultation with the newly established community Consultative Forum, explore options to expand NICNAS's public inquiry service to address aspects of community right to know.

Being implemented

Administrative

The Terms of Reference for the Community Engagement Forum ensure that it will provide advice on:

- strategies to improve public access to chemical health and safety and environmental standards;
- community right to know issues including the development of a community right to know charter;
- the development of NICNAS's stakeholder engagement policies;
- all NICNAS reform programs and participate where practicable; and
- other issues, as required.



12.3 That the open and inclusive consultation model adopted for LRCC reform processes be used by NICNAS in future reform processes.

Being implemented

NICNAS will formally adopt upon completion, the Community Engagement Forum Community Engagement Strategy as the process for consultation. September 2004.

