

LOW REGULATORY CONCERN CHEMICALS (LRCC)

Discussion Paper No. 3

MODULAR ASSESSMENT OF CHEMICALS THAT HAVE BEEN ASSESSED BY ANOTHER AUTHORITY

1. PURPOSE

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) was amended to provide a framework for, among other things, the issue of certificates for the introduction of new industrial chemicals following modular assessment. This discussion paper proposes a strategy for implementing the modular assessment of chemicals that have been assessed by another Australian or overseas authority; through the development of regulations, criteria, guidance documents and other administration requirements.

2. BACKGROUND

Among the LRCC reform initiatives provided for in the LRCC Amendment Act, and requiring further development is modular assessment; which includes the criteria, timeframe and the regulatory and administrative measures. Recommendation 2.1 of the LRCC Final Report recommends that:

NICNAS introduce modular assessment fees for low hazard and or low risk chemicals and targeted assessment for chemicals where controls are in place such as:

Item A

- *Situations where an assessment has been undertaken by another Australian regulatory authority;*

Item B

- *Substances of known hazard for which risks are specified and controlled;*

Item C

- *Analogue chemicals;*

Item D

- *Substances for which an international assessment has been conducted; and/or*

Item E

- *Polymers of low regulatory concern for which a potential risk is determined during screening (i.e. from the audited self assessment process).*

The modular assessment criteria presented here are for:

Item A

- situations where an assessment of a chemical has been undertaken by another Australian regulatory authority such as the Therapeutic Goods Administration (under the Therapeutic Goods Act 1989), the Australian Pesticides and Veterinary Medicines Authority (under the Agricultural and Veterinary Chemicals Code Act 1994), and Food Standards Australia New Zealand (under the Food Standards Australia New Zealand Act 1991); and

Item D

- chemicals for which an international assessment has been conducted – chemicals which have been assessed by regulatory agencies overseas (such as an OECD member country such as any European Union member state or Canada) for which full assessment reports are available.

Under the current regulatory arrangements, NICNAS is required to complete a full assessment for chemicals that have been previously assessed by another competent Australian regulatory authority. This usually occurs when the chemical use changes and it is considered an industrial chemical. NICNAS recognises that this may result in commercial delays and additional costs to industry. By introducing modular assessment, NICNAS will streamline its assessment of these chemicals. NICNAS will reduce assessment timeframes and costs by considering assessments reports for the chemical prepared by other authorities that are available to the notifier.

Due to the global nature of the chemical industry and trade, many new chemicals notified to NICNAS may have been notified and assessed by other overseas. Presently NICNAS is required to complete a full assessment for these chemicals. This requires industry to duplicate efforts in preparing notifications for each country and NICNAS duplicates efforts in re - assessing the chemical.

There are important difference in the data requirements and assessment process between NICNAS and other Australian regulatory agencies and foreign regulatory agencies. For example, NICNAS and APMVA assess the risk to the worker, the public, and the environment while the other Australian agencies focus on public health. Table One compares various aspects of federal Australian regulatory agencies and their activities. While when compared to foreign agencies, NICNAS publishes its assessment reports, while many foreign regulatory agencies do not. Moreover, many regulatory agencies rely on third party data, i.e. information provided by another source, such as notification data provided by another company to fill data gaps that exist for notified chemical. The administrative policy and procedure developed for modular assessment will need to ensure the proprietary rights are maintained.

Table 1

AGENCY	National Industrial Chemicals Notification & Assessment Scheme (NICNAS)	Australian Pesticides & Veterinary Medicines Authority (APVMA)	Therapeutic Goods Administration (TGA)	Food Standards Australia New Zealand (FSANZ)
RELEVANT LEGISLATION	Industrial Chemicals (Notification & Assessment) Act 1989, as amended	Agricultural & Veterinary Chemicals (Code) Act 1994 & Agricultural & Veterinary Chemicals Administration Act 1994	Therapeutic Goods Act 1989	Food Standards Australia New Zealand Act 1991 & Australia New Zealand Food Standards Code
MINISTRY	Health & Ageing	Agriculture, Fisheries and Forestry	Health & Ageing	Health & Ageing
SCOPE	Assessment only, not registration based	Assessment & Product Registration	Assessment & Product Registration	Assessment & Product Registration
RISK	Assessment of the	Assessment of the	Assessment of the	Assessment of the

ASSESSMENT	risk to public, worker and the environment	risk to the public, worker and the environment	risk to the public only	risk to the public only
ABOUT THE CHEMICALS	Industrial chemicals are varied and cover, for example, dyes, solvents, adhesives, plastics, laboratory chemicals, paints, as well as chemicals used in cleaning products and toiletries.	Agricultural products include chemicals which generally destroy/repel pests or plants. Veterinary products are used to prevent, diagnose or treat diseases in animals.	Therapeutic goods include prescription and non-prescription (including over-the-counter and complementary medicines), as well as medical devices (including some sterilants and disinfectants).	Chemicals are added to food to assist in food processing or to achieve a technological purpose in the food, for example, colouring or flavouring. Other chemicals may occur naturally in food or be present as a result of contamination

3. PROPOSAL FOR MODULAR ASSESSMENT

To implement the modular assessment of these chemicals, NICNAS intends to amend the Regulations of Industrial Chemicals (Notification and Assessment) Regulations 1990 (which allows the Director to remit fees paid for application) to include the following 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.

3.1 Criteria for an Acceptable Assessment Report

The following factors will be considered when the reports from overseas or local agencies are reviewed:

The reports should provide sufficient information to determine:

- the identity of the notified chemical and where analogue data have been utilised;
- the extent to which the risk to the public, the worker and environment have been addressed;
- the methodology used to conduct the risk assessment and the relevance of these to the Australian exposure or use scenario (in the case of local assessment report); and
- the transparency of the assessment process or evidence of agreed standard or recognised status of the authority through access to the original data submitted for foreign or local assessment.

A letter of validation from the respective authority should accompany the assessment report stating that that the report is the full and final report issued for the chemical.

The local or foreign assessment report provided should allow NICNAS to publish a complete and transparent assessment report while maintaining the confidentiality requirements of the original notifier and the foreign or local authority.

The assessment report must be for an equivalent assessment category. That is, the chemical should have been assessed at the same or higher notification level by the original assessing agency; this will ensure that the data requirements are met and that the level of detail in the assessment reports is adequate.

The following specific factors will be considered for local and foreign assessment reports.

3.1.1 Item B – for local assessment report

- date from post-1994. Electronic reports are also acceptable;
- originate from the Australian regulatory authority given in the Regulations;
- include confidential information, for example, chemical identity. Sanitised documents are not acceptable;
- include a summary and assessment of physicochemical properties;
- include a summary and assessment of toxicological and environmental effects data, as appropriate;
- include a health and environmental risk assessment; and
- be accompanied by a letter of validation from the Australian authority that the report is the full and final report issued for that chemical.

3.1.2 Item D – for international assessment reports

The assessment report must:

- date from post-1994. Preferably, the report should be in English, however, authorised translations are acceptable. Electronic reports are also acceptable;
- originate from the national authority of an OECD Member country, preferably Canada or any European Union Member State;
- include confidential information, for example, chemical identity. Sanitised documents are not acceptable;
- include a summary and assessment of physicochemical properties;
- include a summary and assessment of toxicological and environmental effects data, as appropriate;
- include a health and environmental risk assessment; and
- be accompanied by a letter of validation from the overseas authority that the report is the full and final report issued for that chemical.

In all instances, acceptance of an assessment report is subject to approval by the Director. Applicants are strongly advised to contact NICNAS their application prior to submission.

Applicants are still required to follow the notification procedures as described in Section 23 of the Act and submit a notification statement about the chemical or polymer that contains the information required as per the Schedule. Where not already covered by the notification requirements of Section 23, the following information should also be submitted to the Director.

- Details of the overseas authority, that is, when and where notified;
- A copy of all the particulars about the chemical that were given under the foreign or Australian scheme and are available to the applicant; and
- Any other information about the chemical available to the applicant, that is, assessment information or information given under another foreign or Australian scheme.

If not all schedule requirements are met, applicants will need to apply for a Variation of Schedule Requirements and provide the appropriate scientific argument and fees.

3.1.2.1 Obtaining Assessment Reports from the Canadian Authority

Applicants should first contact NICNAS to obtain a proforma authorising Environment Canada to transmit the Canadian assessment report to NICNAS. It is planned to recognise Canada as an approved foreign scheme under Section 43 of the Act in late 2006.

4. METHOD OF APPLICATION AND FEES

It is proposed that applications for an assessment certificate under the modular assessment provisions will be made on the usual forms. The complete notification including the assessment report from the foreign or local authority must be submitted with the appropriate fee. The notification will be screened and assessed against the criteria given above within 14 days of receipt of the submission and fee. NICNAS will advise the applicant if the chemical has been accepted for modular assessment and the fees and timeframes for the 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.

It is anticipated a new part (similar to that for draft assessment reports) will be added to Regulation 15 to allow introduction the modular assessment fees.

4.1 Form of Application

It is proposed that an electronic template will be available on the website for applications.