



Commonwealth
of Australia

Gazette

No. C 8-Special, Monday 16 August 2004
Published by the Commonwealth of Australia

CHEMICAL



Australian Government

Department of Health and Ageing
NICNAS

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) commenced on 17 July 1990. As required by Section 5 of the Act, a Chemical Gazette is published on the first Tuesday in any month or on any days prescribed by the regulations.

INTRODUCTION TO THE LRCC AMENDMENT ACT 2004 AND GUIDANCE FOR IMPLEMENTATION

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.

The purpose of this Special Chemical Gazette is to identify for industry the elements of the LRCC Amendment Act that are effective immediately. The LRCC Amendment Act puts the legislative framework in place to ensure that the majority of LRCC recommendations can be implemented. A number of recommendations require the further development of criteria and guidelines, such as for low hazard and/or low risk. These changes will require development with industry and the community and once finalised will require amendment to regulations. Industry will be advised of progress with these developments.

Noting the Stockholm Convention on Persistent Organic Pollutants and the interest NICNAS has on persistent, bioaccumulative as well as toxic chemicals, it is the policy position of NICNAS that chemicals that are or may be likely to be POPs or persistent and/or bioaccumulative are generally excluded from the provisions of the LRCC including exemptions, <100kg, audited self assessment and <1% cosmetic. Companies should contact NICNAS to discuss any application of LRCC categories concerning such chemicals.

The new arrangements under the LRCC reform initiative reflect the Government's commitment to ensure that the most efficient regulatory system is in place for industrial chemicals, as well as 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.

Listed below are the most significant of these changes. This list is not meant to be exhaustive; rather, it is offered to readers by way of guidance and should not be taken as legal advice. Readers are encouraged to familiarise themselves with the full extent of the changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* by reading the LRCC Amendment Act, accompanying LRCC Regs, and the Explanatory Memorandum at www.aph.gov.au

This Special Chemical Gazette covers changes to the following items:

1. Definitions
2. Exemptions
3. Permits
4. Polymers
5. Self-assessment including information on interim arrangements
6. Annual reporting and record keeping
7. The Australian Inventory of Chemical Substances
8. NICNAS registration requirements
9. Controlled use permits

1. NEW DEFINITIONS TO THE ACT

DEFINITIONS

The LRCC Amendment Act introduces a range of new or amended definitions, including the following:

New definition of ‘chargeable person’

The LRCC Amendment Act amends section 5 of the Act by inserting a new definition of ‘chargeable person’. This definition replaces the previous definition of ‘registrable person’.

chargeable person, in relation to a registration year, means:

- (a) a person who proposes to introduce relevant industrial chemicals in that registration year of a value that equals or exceeds the threshold level if that person:
 - (i) did not introduce relevant industrial chemicals in the previous financial year; or
 - (ii) introduced relevant industrial chemicals in the previous financial year of a value less than the threshold value; or
- (b) a person who proposes to introduce relevant industrial chemicals in that registration year of any value if that person introduced relevant industrial chemicals in the previous financial year of a value that equalled or exceeded the threshold value.

New definition of ‘controlled use permit’

The LRCC Amendment Act provides the legislative framework for the new permit category by inserting a new definition of ‘controlled use permit’ in section 5 of the Act for the purposes of a new division 1C in the Act. Paragraphs 21 (2)(aa) to (b) of the Act have been amended to create a new permit category for the controlled use of chemicals.

NICNAS will introduce targeted assessments for chemicals where controls are in place. Changes to schedule data requirements (Section 23 of the Act) will allow the notification to be accepted with data substituted by modular inputs.

Regulation is required before a new permit category for controlled use chemicals can be put in place; for example, a controlled use permit for Export Only. These new permit categories will have annual reporting and record keeping obligations. New offence and penalty provisions have been introduced to support these measures.

New definition of ‘cosmetic’

This item amends the definition of ‘cosmetic’ in section 5 of the Act to align it with the definition of ‘cosmetic product’ in the Trade Practices (Consumer Product Information Standards) Cosmetics Regulations 1991.

The Trade Practices Consumer Product information Standards (Cosmetics) Regulations (1991) defines a cosmetic product as ‘A substance or preparation intended for placement in contact with any external part of the human body, including: the mucous membranes of the oral cavity and the teeth; with a view to: altering the odours of the body; or changing its appearance; or cleansing it; or maintaining it in good condition; or perfuming it; or protecting it.’

New definition of ‘new industrial chemical’

This item amends the definition of ‘new industrial chemical’ in section 5 of the Act. This is a consequential amendment as a result of the new section 13, which allows the Director, NICNAS to specify conditions of use of an industrial chemical on the Australian Inventory of Chemical Substances (AICS).

new industrial chemical means:

- (a) either:
 - (i) if the chemical is a listed industrial chemical whose introduction is subject to a condition of use under section 13 — but only to the extent that the manufacturer or importer of the chemical introduces, or proposes to introduce, the chemical for any other use; or
 - (ii) otherwise—an industrial chemical that is not a listed industrial chemical; and
- (b) in the case of a synthetic polymer—a chemical that is a new synthetic polymer; but does not include the following:
 - (i) a reaction intermediate;
 - (ii) an incidentally-produced chemical.

New definition of ‘hazardous chemical’ [s.5 of the Act]

This definition replaces the previous definition of ‘hazardous substance’:

- (a) a chemical that is included in the *List of Designated Substances [NOHSC: 10005]* published in April 1999 by the National Occupational Health and Safety Commission; or
- (b) a chemical that is classified as a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008]* published in April 1999 by the National Occupational Health and Safety Commission.

New definition of ‘holder’ [s.5 of the Act]

In relation to a permit or an assessment certificate, means a person in respect of whom the permit or certificate is issued.

New definition of ‘polymer of low concern’

This item inserts a new definition for ‘polymer of low concern’ in section 5 of the Act. The former definition of “synthetic polymer of low concern” is no longer used within the Act.

polymer of low concern means a polymer that:

- (a) either:
 - (i) has a number average molecular weight, as defined by the regulations, that is greater than 1,000; or
 - (ii) has a number average molecular weight, as defined by the regulations, that is less than or equal to 1,000, and has such other characteristics as are prescribed by the regulations; and
- (b) has a low charge density, as so defined; and
- (c) is not a hazardous chemical; and
- (d) does not dissociate readily, as so defined; and
- (e) under the conditions in which it is used is stable, as so defined; and

- (f) has such other characteristics as are prescribed by the regulations.

The only change to the definition is that residual monomers and other reactants are no longer considered part of the polymer.

New definition of ‘non-hazardous chemical’

For the purposes of the Act, a ‘non-hazardous’ chemical is defined in terms of the conditions previously used for a chemical to be eligible for an Early Introduction Permit.

In this Act, *non-hazardous chemical* means a chemical in respect of which the following conditions are met:

- (a) the chemical is not a hazardous chemical;
- (b) the chemical is not a dangerous good;
- (c) the prescribed criteria relating to the environmental effect of the chemical have been met;
- (d) any other prescribed conditions have been met;
- (e) the introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment.

The Director must take account of the following matters in deciding whether he or she is satisfied that the condition referred to in paragraph (e) of the definition of *non-hazardous chemical* is met:

- (a) the proposed nature of the use of the chemical;
- (b) the extent of the proposed use of the chemical;
- (c) the effect of the chemical on the environment;
- (d) the effect of the chemical on occupational health and safety and public health;
- (e) the structure and activity of the chemical; and
- (f) whether, in Australia or overseas, the chemical is the subject of:
 - (i) investigations initiated by a person because of concerns about a possible adverse effect on occupational health and safety, public health or the environment; or
 - (ii) action taken by a person to control the use of, or access to, the chemical; and
- (g) any other prescribed matter.

2. NEW RANGE OF EXEMPTIONS WHICH TAKE EFFECT IMMEDIATELY

There have been a number of changes to the exemption categories, including the introduction of two new categories, plus changes to volume restrictions and/or reporting requirements in existing categories.

Transshipment exemption (new)

Chemicals off-loaded and unopened at an Australian port or airport for a short period (30 days), and kept in control of Customs before leaving Australia, do not need to be notified to NICNAS prior to introduction [para. 21(6)(b) of the Act]. Annual reporting requirements for this exemption category commence for the registration year 1 September 2004, with the first report required by 28 September 2005. [s.21AA of the Act].

Research and Development (amended)

The volume restriction for the exemption for chemicals introduced solely for the purpose of research, development and analysis has increased from 50 to 100kg/annum [para. 21(6)(a) of the Act]. Annual reporting requirements for this exemption category commence for the registration year 1 September 2004, with the first report required by 28 September 2005. [s.21AA of the Act].

Non-cosmetic chemical (amended)

The volume restriction for the exemption of non-cosmetic chemicals which pose no unreasonable risk to occupational health, public health or environment, has increased from 10 to 100kg/annum [para. 21(4)(bii)]. Introducers of chemicals in this category are asked to fill out Form 21-4a and return it to NICNAS.

There is a new requirement for the introducer to keep records relating to occupational health and safety, public health matters and the environmental effects of the chemical for five years. Annual reporting requirements for this exemption category commence for the registration year 1 September 2004, with the first report required by 28 September 2005. [s.21AA of the Act].

Cosmetic chemical <10kg (amended)

Introducers of cosmetic chemicals which pose no unreasonable risk to occupational health, public health or environment, in quantities of less than 10kg/annum, are no longer required to notify NICNAS prior to introduction.

The criteria for the cosmetic chemical and the five-year record keeping requirement remain unchanged. Annual reporting requirements for this exemption category commence for the registration year 1 September 2004, with the first report required by 28 September 2005. [s.21AA of the Act].

Cosmetic chemical >10kg but <100kg (amended)

The volume restriction for the exemption of non-cosmetic chemicals which pose no unreasonable risk to occupational health, public health or environment, has increased from 10 to 100kg/annum [para. 21(4)(bi)]. Introducers of the chemical must notify the Director, NICNAS of the introduction in writing (Form 15) and provide the material safety data sheet (MSDS) relevant to the chemical or product containing the chemical, with the label attached to the packaging of the chemical or product containing the chemical.

The criteria for the cosmetic chemical and the five-year record keeping requirement remain unchanged. Annual reporting requirements for this exemption category commence for the registration year 1 September 2004, with the first report required by 28 September 2005. [s.21AA of the Act].

Non-hazardous cosmetic chemical <1% (new)

Non-hazardous chemicals introduced in cosmetics at a concentration at 1% or less do not need to be notified to NICNAS prior to introduction [para. 21(6)(c) of the Act]. The chemical must meet the criteria of a non-hazardous chemical as defined in the Act [s.5 of the Act]. The chemical is not exempt if it is used in the cosmetic as a preservative, colouring agent or ultraviolet filter, or if it is prohibited or restricted for use in cosmetics overseas.

3. NEW RANGE OF PERMITS WHICH TAKE EFFECT IMMEDIATELY

Renewal of CEC and LVC Permits [subs. 21B(2) and 21R(1A) of the Act]

Once a fee has been finalised, existing CEC permits and LVC permits will be able to be renewed under the following circumstances:

- the existing permit must still be current;
- the function or use of the chemical has not changed, and is not likely to change significantly;
- the amount of the chemical being introduced has not increased, and is not likely to increase significantly;
- in the case of a chemical that was not manufactured, or proposed to be manufactured, in Australia at the time the permit was issued, and it continues not to be manufactured in Australia;
- the method of manufacture of the chemical in Australia has not changed, and is not likely to change in a way that may result in an increased risk of an adverse effect on occupational health and safety, public health or the environment;
- no additional information has become available to the manufacturer or importer as to any adverse effects of the chemical on occupational health and safety, public health or the environment;
- all conditions of the current permit were complied with during the period of the current permit; and
- no changes are required to any conditions of the permit.

Although an LVC permit can be renewed any number of times a CEC permit may be renewed only once.

Removal of Global Restriction for LVC Permits

The nationwide volume restriction for chemicals introduced under a LVC permit has been removed [s. 21Q of the Act]. Therefore, more than one company can hold an LVC permit for the same chemical allowing the introduction of 100kg per year. However, if two or more companies submit a joint application, the maximum quantity would be shared among the applicants.

Subsection 21W(1) also draws attention to the need for holders of low volume permits to comply with obligations in Division 3B of Part 3 of the Act. These new obligations relate to record keeping, effective immediately, and to annual reporting, effective September 2005.

4. NEW ARRANGEMENTS FOR POLYMERS WHICH TAKE EFFECT IMMEDIATELY

Part D

Notification statements for all polymers, including biopolymers but excluding polymers of low concern, must contain the matters specified in part D [subs. 23(6), (7), (8) of the Act]. Schedule data requirements are as follows:

- PLC - As per form 1-PLC
- LTD - A B and D
- STD - A, B, C and D

Changes to PLC Criteria

There have been two changes to the PLC criteria:

1. Polymers of low concern can now be either a synthetic polymer or biopolymer.
2. The residual monomer content will no longer impact the classification of the polymer as a low concern polymer. These criteria have been replaced by the criteria that the polymer is not a hazardous chemical (see definition section). Notifiers will still be required to provide details regarding the residual monomer content.

5. NEW ARRANGMENTS FOR SELF-ASSESSMENT SYSTEM FOR LOW REGULATORY CONCERN CHEMICALS

The new processes for audited self-assessment of low regulatory concern chemicals are contained in Division 2 and Division 3 of Part 3 of the Act. The new audited self-assessment system allows introducers, under the Act, to self-assess a chemical against criteria and guidelines issued by NICNAS and/or prescribed by the regulations. This change will introduce flexibility into the current assessment process for industrial chemicals and enable the fast tracking of low regulatory concern chemicals while maintaining existing levels of worker safety, public health and environmental standards.

Audited self-assessment is initially limited to certificate assessments for polymers of low concern, non-hazardous chemicals and non-hazardous polymers. The existing polymers of low concern criteria serve as the framework for audited self-assessment. For non-hazardous chemicals and non-hazardous polymers the criteria defining non-hazardous has been introduced in the definitions of the Act. Further guidance for these categories is also provided by NICNAS.

The increased flexibility of the self-assessment system is balanced with record keeping and annual reporting requirements for introducers who hold self-assessment certificates, which are outlined in new Division 3B of the Act. Holders of self-assessment certificates will also be subject to audits by NICNAS inspectors, under Part 4 of the Act, to ensure compliance with the self-assessment requirements.

Sections 33A, 33B, and 33C of the Act refer to the pre-screen process, and Sections 40K, 40L, 40M and 40N under Division 3B set out reporting and other obligations for self-assessed assessment certificates. The LRCC Amendment Act provides the legislative framework to introduce the new concept of self-assessment against established criteria. Criteria will be developed for low hazard and low risk categories in full consultation with the industry and the community.

Currently, full implementation of the audited self-assessment process will require the establishment of new fees through regulation. Activity based costing will be used to determine the fee structure for the new range of audited self-assessment certificates. Interim arrangements for the following classes of audited self-assessment certificates are currently in place.

Industry should note, a chemical or polymer will not be accepted as low concern, either for purposes of self-assessment, or for consideration as a polymer of low concern, if the chemical or polymer can be predicted to be persistent and bioaccumulative or to have breakdown products which can be predicted to be persistent and bioaccumulative.

Interim arrangements for polymers of low concern, non-hazardous chemicals and non-hazardous polymers

Interim arrangements for self-assessment for polymers of low concern (PLC), non-hazardous chemicals and non-hazardous polymers other than PLC have been established and are currently available. The arrangements will be on interim basis until a fee structure can be put into place. Audited self-assessment for standard certificates are now available for non-hazardous chemicals, non-hazardous polymers and polymers of low concern. Currently, audited self-assessment limited certificate categories are not available unless data under schedule C is available. All audited self-assessment certificates automatically attract a 15% reduction in fees because of the electronic lodgement requirements and in general are processed within 28 days upon acceptance of the assessment.

The following audited self-assessment certificates are available from NICNAS.

- ***Audited self-assessment certificates for polymers of low concern (PLC)***

Interim arrangements are in place for self-assessment of polymers of low concern, effective immediately. Regulations are required to set a new fee for self-assessment certificates for polymers of low concern. Electronic lodgement templates (Form 1-PLC), the PLC criteria themselves and guidance material are available from NICNAS's website www.nicnas.gov.au/forms/

- ***Audited self-assessment certificates for non-hazardous chemicals***

For non-hazardous chemicals, Section 23A of the Act provides an option for introducers of non-hazardous chemicals to make an application for a self-assessed assessment certificate.

Subsection 5(2) contains a new definition of 'non-hazardous chemicals' and stipulates a number of conditions that must be met for a chemical to be defined as a non-hazardous chemical under the Act.

This subsection of the Act also includes a provision for additional conditions to be prescribed by the regulations under new paragraph 5(2)(d).

One of the conditions prescribed by paragraph 5(2)(e) is that the introduction of a chemical must be consistent with the reasonable protection of occupational health and safety, public health and the environment.

Subsection 5(3) outlines a number of matters that the Director must take into account when assessing whether this condition has been met. Paragraph 5(3)(g) allows additional matters to be prescribed by the regulations.

- ***Guidance for audited self-assessment certificates for standard notifications and limited notifications for non-hazardous chemicals***

To establish that a chemical other than a polymer is a non-hazardous chemical with respect to mammalian toxicity for purposes of self-assessment, the data listed in Table 1 must be available to the notifier (**regardless of import volume**). This means that whilst full toxicological data may not be required for current limited category notifications, these data are required for audited self-assessment purposes for the limited assessment category.

For each test, the result must lead to the chemical not being classified as hazardous in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances.

Indicative results are listed in Table 1. For genotoxicity testing, the results of the two genotoxicity tests should both independently be negative. The relevant Test Guidelines (normally OECD) are also provided for information.

If data beyond that specified in Table 1 is available, this must also be reported, and any classification as a hazardous substance based on this additional data will also preclude the chemical being accepted for purposes of self-assessment.

Waivers of test requirements or substitution of analogue or product results are not possible for the interim self assessment scheme as case by case NICNAS assessment is required for any variations to these requirements. However Acute Inhalation Toxicity results are not required if:

- a) The chemical has a vapour pressure less than 1.5 kPa; and
- b) The chemical as introduced has less than 25% of particles having less than 10 μm diameter; and
- c) The chemical is not purposely aerosolised during use (except where this constitutes a “controlled use”).

The results of the toxicity testing must be listed in the report template, along with discussion of any observed results below classification thresholds. NICNAS may ask that the notification be changed to a non-self assessed category if the information indicates that there are any concerns requiring further assessment. ‘Slightly irritating’ refers to irritation test results where effects are observed but these are below classification thresholds. ‘Non mutagenic’ and ‘non genotoxic’ refer to negative results as defined for the individual test guidelines.

Table 1. Data requirements (Part C of Schedule) for non-hazardous chemicals under the interim self-assessment scheme

Endpoint	Indicative Result	Test Guideline
1. Rat, acute oral	LD50 > 2000 mg/kg bw	OECD TG 401 OECD TG 423
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	OECD TG 402
3. Rat, acute inhalation (aerosols or particulates) (gases or vapours)	LC50 > 5 mg/L/4 hour LC50 > 20 mg/L/4 hour	OECD TG 403
4. Rabbit, skin irritation	slightly to non-irritating	OECD TG 404
5. Rabbit, eye irritation	slightly to non-irritating	OECD TG 405
6. Skin sensitisation	no evidence of sensitisation.	OECD TG 406 (Buehler) OECD TG 406 (Maximisation) OECD TG 429 (LLNA)
7. Rat, repeat dose toxicity – ≥ 10 days	(oral) NOAEL > 50 mg/kg bw/day (dermal) NOAEL > 100 mg/kg bw/day (inhalation) NOAEL > 0.25 mg/l, 6h/day	OECD TG 407 – 409, 422 OECD TG 410 – 411 OECD TG 412 – 413
8. Genotoxicity - bacterial reverse mutation	non mutagenic	OECD TG 471 – 472
9. Genotoxicity – in vitro	non genotoxic	OECD TG 473, 476. 479 – 482

• ***Interim arrangements for self-assessment for non-hazardous polymers other than PLC***

Interim arrangements for self-assessment for non-hazardous polymers other than PLC are being established immediately, under interim arrangements. To establish that a polymer is non-hazardous, certain data is required to be held by the notifier.

For a non-hazardous polymer other than a PLC, the requirements for audited self-assessment category for non-hazardous systems hold for polymers with Number Average Molecular Weight (NAMW) < 1000. For polymers with NAMW ≥ 1000, only data items 1, 4 and 8 (in Table 1) are normally required to be available to the notifier. However, where the polymer contains one or more High Concern Reactive Functional Groups with FGEW < 5000, as defined in the PLC criteria (except unsubstituted positions ortho and para to phenolic hydroxyl or partially-hydrolysed acrylamides), item 6 is also required to be available.

Environmental criteria are identical to those required to obtain an Early Introduction Permit for a chemical or polymer in the relevant category. Chemicals meeting criteria for persistence and/or bioaccumulation will not be accepted for purposes of self-assessment. All relevant environmental data and a full set of physical and chemical data are also required to be presented in the self-assessment report. Please note that new record keeping and data holding requirements now apply for audited self-assessment as described below.

Table 2 Summary of currently available audited self-assessment certificate categories and their data requirements compared with existing assessment categories.

Standard certificate		Limited certificate		PLC Certificate	
Assessment	Audited Self Assessment	Assessment	Audited Self Assessment	Assessment	Audited Self Assessment
All chemicals Schedule A,B,C	Non haz chemicals Schedule A,B,C	All chemicals Schedule A,B	Non haz chemicals Schedule A,B,C	Both assessment types open to PLCs Form 1-PLC defines the data requirements	
All polymers Schedule A, B, C, D	Non haz polymers Schedule A,B,C,D	All polymers Schedule A,B, D	Non Haz Polymers Schedule A,B,C*,D		

* indicated some or all elements of Part C data are required for audited self-assessment.

6. NEW ANNUAL REPORTING REQUIREMENTS FOR EXEMPTIONS AND SELF-ASSESSMENT CERTIFICATES WHICH TAKE EFFECT IMMEDIATELY

New annual reporting and record keeping obligations for exemption categories in subsections 21(4) and 21(6)

The LRCC Amendment Act also establishes annual reporting and record keeping obligations for importers and/or manufacturers to support the new audited self-assessment and permit categories. These obligations are effective immediately.

New Section 21AA introduces annual reporting obligations for introducers under the exemption categories in subsections 21(4) and 21(6). Introducers are required to provide an annual report to the Director, NICNAS, stating the name and volume of chemical introduced during the year.

The annual report must be provided in an approved form by 28 September each year. Introducers have 28 days from the end of the company registration year on 31 August to provide their annual report. (A registration year is defined in section 5 of the Act as a period of 12 months beginning on 1 September).

This means that a person who introduced chemicals under the exemption categories in subsections 21(4) and (6) will be required to make an annual report for chemicals introduced in the 12-month period from 1 September – 31 August.

An introducer who fails to provide an annual report commits an offence. This is a continuing offence under new subsection 21AA(4), which means that in accordance with subsection 4K(2) of the *Crimes Act 1914*, a person who fails to provide an annual report by the final date required will be guilty of a separate offence for each day of non-compliance and will incur 10

penalty units per day up to a maximum of 120 penalty units, which would be reached in 12 days.

Record keeping requirements are effective immediately, and annual reporting is required for the period 1 September 2004 to 31 August 2005 with the report due on 28 September 2005.

New annual reporting and record keeping obligations for low volume permits, controlled use permits and self-assessment certificates

This item inserts new sections 40K, 40L, 40M, and 40N under a new Division 3B in the Act, which sets out the obligations relating to commercial evaluation permits, low volume permits, controlled use permits and self-assessed assessment certificates.

New section 40K requires all holders of these permits and certificates to keep records for 5 years for audit purposes. If a person fails to keep these records a penalty of 120 units is applicable to this offence.

New section 40L gives the Director the power to require all holders of these particular permits and certificates to provide information in or in connection with their application for, or application for renewal of, the permit or certificate that they hold, to the Director on request. The Director's request must be made in writing and give the person at least 14 days to respond.

New section 40M makes the provision of information subject to the privilege of self-incrimination. The offence for failing to provide this information is 60 penalty units. This is consistent with similar offences under the Act and corresponding penalties involving the failure of a person to provide information to the Director on request under s48(7), s58(8) and s69(4) of the Act.

New section 40N requires all holders of these permits and certificates to make an annual report to the Director stating the name and volume of the chemical, together with any adverse effect of the chemical on occupational health and safety, public health or the environment. The annual report must be provided on or by 28 September of each year, with first report required under these new arrangements due on 28 September 2005. This gives introducers 28 days from the end of the company registration year on 31 August to provide the annual report.

A person who fails to provide an annual report by the date required will be committing an offence. This is a continuing offence under new section 40N, which means that in accordance with subsection 4K(2) of the *Crimes Act 1914* a person who fails to provide an annual report by the final date required will be guilty of a separate offence for each day of non-compliance and will incur 10 penalty unit per day up to a maximum of 120 penalty units, which would be reached in 12 days. This will provide a strong incentive for compliance with the continuing obligations under section 40N.

7. NEW CONDITIONS FOR THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES

Industry may now nominate an assessed chemical for immediate inclusion on the Australian Inventory of Chemical Substances (AICS)

Under section 13B of the Act, certificate holders have the option to request that an assessed chemical be included on the non-confidential section of the AICS before the five-year period following the assessment of the chemical has ended.

This amendment provides an optional alternative to the current system where chemicals are not listed on the AICS until five years after they are assessed. A certificate holder may make this request at any time between being given an assessment certificate and expiry of the five-year period following the assessment of the chemical, but there is an incentive for certificate holders to make the request within 28 days of being given an assessment certificate as the early listing of the chemical in these cases will not attract a fee. Certificate holders who make an application for early listing after 28 days of being given the certificate will be required to pay a fee. Holders of existing certificates will not be required to pay for immediate AICS listing.

Where there are two or more assessment certificates in force for the same chemical and one certificate holder has requested that the chemical be listed on the AICS before the five year period following assessment expires, the Director must write to each certificate holder to give them the opportunity to object to the proposed early listing.

Should any certificate holder object to the proposed early listing of the chemical on the AICS, the listing cannot proceed. The Director must then inform the applicant/s that this has happened and any fees paid must be returned.

If an application for early listing is rejected under this section 13B of the Act, the chemical will still be automatically listed on the AICS at the end of 5-year certificate period under section 14 of the Act.

Annotation of the Australian Inventory of Chemical Substances (AICS)

The Director, NICNAS may now put the particulars of a chemical, including any conditions to which it is subject, on the AICS. Under new section 13 of the Act, the Director, NICNAS may now annotate the AICS to include additional particulars. These include details of the assessment of the industrial chemical, details of use, if applicable, and any other conditions, such as conditions that may give rise to secondary notification requirements. Annotation may contain conditions of use as discussed under the definition of 'new industrial chemical'.

This change will give industry and the community better access to information about industrial chemicals. In addition, introducers will no longer need to envisage what uses their chemicals might be put to in the future because a particular chemical may only be introduced for the particular use or uses that are specified for that chemical in the AICS.

This amendment will also prevent chemicals that have been assessed for a particular use from being imported or manufactured for a different use that has not been assessed, and which could be more harmful to health, safety and the environment.

New subsection 13(2) also gives the Director the power to include particulars, either at the time the chemical is included in the AICS or at a later time, and to vary or remove such details from the AICS, where applicable.

New section 13A of the Act imposes a requirement on the Director to publish a notice in the Chemical Gazette where the Director proposes to include or vary the particulars of a chemical on the AICS. It also requires the Director to send a copy of the notice to a person who is introducing or proposing to introduce the chemical if the person's name and address are known to the Director.

This will mean that in circumstances where the Director proposes to include particulars, such as conditions, at the same time as adding a chemical to the AICS, then the Director will be required to publish a notice in the Chemical Gazette before the chemical is added to the AICS.

New section 13A provides the details that must be included in the notice and requires the Director to reconsider the proposed inclusion or variation of the particulars if a person writes to the Director giving reasons why the particulars should not be included or varied. This section also gives the Director the power to accept or reject these reasons and to make a decision about whether or not to include or vary the particulars in light of these reasons.

New subsection 102(1)(1A) provides that the Director's decisions made under new section 13A may be appealable to the Administrative Appeals Tribunal. New paragraph 13A(6)(b) prevents the Director from including or varying the particulars (where the Director has rejected the reasons why they should not be included or varied) until 28 days after the date of giving the notice, or until any Administrative Appeals Tribunal review of the decision has been finalised.

8. NEW NICNAS REGISTRATION REQUIREMENTS WHICH TAKE EFFECT 1 SEPTEMBER 2004

Mandatory company registration for all chemical introducers

Mandatory company registration for all chemical introducers is effective immediately. Company registration will be replaced with NICNAS registration: Tiers 1, 2 and 3.

Part 3A of the Act establishes mandatory registration of all persons who introduce – that is, import and/or manufacture – or propose to introduce relevant industrial chemicals, as defined in section 7A of the Act.

In extending NICNAS registration provisions to cover all introducers, those who introduce relevant industrial chemicals below the threshold value (currently \$500,000) per company per registration year, which runs from 1 September to 31 August in the following year, will continue to be exempt from NICNAS registration charges.

However, as NICNAS is a fully cost recovered scheme a small annual registration fee (currently \$353) will be required from all those who register.

A person who introduces or proposes to introduce relevant industrial chemicals above the threshold value in the registration year is defined as a 'chargeable person'. (The term 'chargeable person' replaces the term 'registrable person' throughout the new Act.)

While all introducers will be registered persons, only those who introduce or propose to introduce chemicals above the threshold value will be chargeable persons who must pay a registration charge as well as the registration fee. This is explained in the amended section 80A of the Act.

Those who are registered for between \$500,000 and \$5,000,000 and currently provide the Director with a final statement will be entitled to a refund of the registration charge if they do not introduce more than the threshold in a registration year. The Director also has the power, under the amended subsection 80W(1), to request a written statement from any person who he or she reasonably believes may have introduced a relevant industrial chemical during the particular registration year, indicating the value of the industrial chemicals that the person introduced in that year. This change enables the Director to identify situations where an unregistered person is required to be registered and, in some cases, where an unregistered person is also required to pay the company registration charge.

Under section 80QD, registered persons at the threshold values of \$500,000 and \$5,000,000 must retain records for five years after the end of the registration year in order to ascertain whether the registration charge is payable, plus the amount of registration charge payable by the person.

NICNAS will be providing new registrants with training in understanding NICNAS registration requirements and compliance obligations. The aim of NICNAS registration is to improve industry compliance and awareness of their legal obligations when importing and/or manufacturing industrial chemicals leading to safer use of chemicals in Australia.

9. INTRODUCTION OF NEW CONTROLLED USE PERMIT SYSTEM

Division 1C—Controlled use permit system

22A. Object of controlled use permit system

The object of the controlled use permit system is:

- (a) to provide an alternative to the assessment certificate system in respect of a new industrial chemical that is a low risk to occupational health and safety, public health and the environment, because its use, handling and disposal are highly controlled; and
- (b) to ensure that this alternative is subject to adequate safeguards.

22B. Who may apply for permit or renewal of permit

- (1) A manufacturer or importer of a new industrial chemical may apply for a controlled use permit in respect of the chemical.
- (2) A manufacturer or importer whose controlled use permit in respect of a new industrial chemical is still in force may apply for the permit to be renewed if the following conditions are met:
 - (a) the function or use of the chemical has not changed, and is not likely to change, significantly;
 - (b) the amount of the chemical being introduced has not increased, and is not likely to increase, significantly;

- (c) in the case of a chemical that was not manufactured, or proposed to be manufactured, in Australia at the time the permit was last issued—it continues not to be manufactured in Australia;
 - (d) the method of manufacture of the chemical in Australia has not changed, and is not likely to change, in a way that may result in an increased risk of an adverse effect on occupational health and safety, public health or the environment;
 - (e) no additional information has become available to the manufacturer or importer as to any adverse effects of the chemical on occupational health and safety, public health or the environment;
 - (f) no event prescribed for the purposes of section 64 has happened;
 - (g) any conditions of the permit imposed by or under section 22H were complied with during the period of the current permit; and
 - (h) no changes are required to any conditions of the permit.
- (3) A manufacturer or importer may apply for a controlled use permit to be renewed any number of times.
 - (4) 2 or more persons, each of whom is a manufacturer or importer of a new industrial chemical, may make a joint application under subsection (1) or (2).
 - (5) If a joint application is made, then, unless the contrary intention appears, a reference in this Division to the applicant is a reference to the joint applicants.

22C. How an application is to be made

- (1) An application for a controlled use permit, or a renewal of a controlled use permit, must:
 - (a) be in writing;
 - (b) be in an approved form; and
 - (c) be given to the Director.
- (2) An application for a controlled use permit is taken not to be duly made unless the applicant has provided a written statement about the chemical that:
 - (a) states the use for which the chemical is to be introduced; and
 - (b) contains a summary of the chemical's effects on occupational health and safety, public health and the environment; and
 - (c) states the quantity of the chemical proposed to be introduced by the applicant in the period beginning on the date on which the application is made and ending at the end of the calendar year in which that date occurs; and
 - (d) states the quantity of the chemical proposed to be introduced by the applicant in each of the next 3 calendar years; and
 - (e) contains such other information as is prescribed in the regulations.
- (3) An application for a controlled use permit, or a renewal of a controlled use permit, is taken not to be duly made unless the applicant has paid the prescribed fee.

22D. Director may request further information about application

- (1) The Director may give an applicant a written notice requiring the applicant to give the Director further information about a matter referred to in subsection 22C(2), or a

matter referred to in the application for the renewal of the controlled use permit, within the period specified in the notice.

- (2) The notice must specify a period of at least 14 days.

22E. Applicant may withdraw or amend application

An applicant may, at any time before the application has been determined, by written notice to the Director, withdraw the application or amend the application or any document that accompanied the application.

22F. Determination of application

- (1) The Director must grant an application for a controlled use permit in respect of a chemical and issue the permit to the applicant if the Director is satisfied of the following:
- (a) section 22C has been complied with in respect of the application; and
 - (b) the intended use of the chemical does not pose an unreasonable risk to occupational health and safety, public health or the environment, having regard to the following:
 - (i) the inherent nature of the chemical;
 - (ii) any guidelines prescribed for the purposes of this section; and
 - (iii) any other matters that the Director considers relevant.
- (2) The Director must grant an application for a renewal of a controlled use permit in respect of a chemical and issue the permit to the applicant if the Director is satisfied of the following:
- (a) section 22C has been complied with in respect of the application; and
 - (b) the conditions referred to in subsection 22B(2) have been met.
- (3) If any further information required by the Director under section 22D is not given to the Director within the period specified in the notice requiring that further information, the application is taken to have been withdrawn.
- (4) If the Director is not satisfied under subsection (1) or (2), the Director must refuse the application.

22G. Duration of permit

A controlled use permit:

- (a) comes into force at the beginning of the period of not more than 36 months that is stated in the permit; and
- (b) remains in force until the end of that period.

22H. Permit may be subject to conditions

- (1) A controlled use permit is granted subject to a condition that the chemical in respect of which the permit is issued is only imported or manufactured for the use stated in the permit.

Note: A person who holds a controlled use permit must also comply with the obligations in Division 3B of this Part.

- (2) A controlled use permit is granted subject to a condition that, if the holder of the permit becomes aware of any of the circumstances referred to in subsection (3) happening since the permit was last issued the holder will, within 28 days, give written notice to the Director of the circumstances.
- (3) These are the circumstances:
- (a) the function or use of the chemical has changed, or is likely to change, significantly; or
 - (b) in the case of a chemical not manufactured, or proposed to be manufactured, in Australia when the permit was last issued—it has begun to be manufactured in Australia; or
 - (c) the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect on occupational health and safety, public health or the environment; or
 - (d) additional information has become available to the holder as to an adverse effect of the chemical on occupational health and safety, public health or the environment; or
 - (e) a prescribed circumstance has happened.
- (4) For the purposes of subsection (2), the holder of a permit is taken to have become aware of circumstances if the holder ought reasonably to have become aware of the circumstances, having regard to:
- (a) the holder's abilities, experience, qualifications and other attributes;
 - (b) the nature of the circumstances.
- (5) A controlled use permit may be expressed to be granted subject to such other conditions as the Director considers necessary or desirable to ensure that use of the chemical will not constitute an unreasonable risk to occupational health and safety, public health or the environment.
- (6) If the Director considers it necessary or desirable to ensure that use of a chemical will not constitute an unreasonable risk to occupational health and safety, public health or the environment, the Director may, by written notice given to the holder of a controlled use permit issued in respect of the chemical:
- (a) impose one or more further conditions to which the permit is to be subject; or
 - (b) revoke or vary a condition:
 - (i) imposed under paragraph (a); or
 - (ii) stated in the permit.
- (7) The notice under subsection (6) must specify a day on which the permit:
- (a) becomes subject to the condition imposed, or the condition as varied, under that subsection; or
 - (b) ceases to be subject to the condition revoked under that subsection.

The day must be at least 28 days after the giving of the notice.

22I. Offence for contravention of permit

A person commits an offence if:

- (a) the person is or was the holder, or any of the holders, of a controlled use permit; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission breaches a condition to which the permit is subject.

Penalty: 300 penalty units.

22J. Cancellation of permit

The Director may, by written notice given to the holder of a controlled use permit, cancel the permit if:

- (a) a condition to which the permit is subject has been breached; or
- (b) a written statement provided or any information given:
 - (i) in or in connection with the application for the permit or any application or a renewal of the permit; or
 - (ii) in accordance with a condition to which the permit was subject;
 - (iii) was false or misleading in a material particular.

22K. Form of permit

A controlled use permit must be in an approved form.

22L. Notice of permit to be published in Chemical Gazette

As soon as practicable after a controlled use permit is issued, the Director must cause to be published in the Chemical Gazette a notice stating that the permit has been issued and setting out:

- (a) the name of the holder of the permit;
- (b) the trade name of the chemical; and
- (c) the use for which the chemical may be imported or manufactured; and
- (d) the period of the permit.

22M. Notice of refusal of application

If the Director decides to refuse an application, he or she must, as soon as practicable, give to the applicant a written notice of the decision that sets out:

- (a) the findings on material questions of fact; and
- (b) the evidence or other material on which those findings were based;
- (c) the reasons for the decision.

22N. List of controlled use chemicals

- (1) The Director must maintain a list of the following:
 - (a) the chemicals in respect of which controlled use permits are in force;
 - (b) the conditions of use to which those permits are subject.
- (2) At least once a year, the Director must publish the list in the Chemical Gazette.

22O. Exempt information

- (1) An application for a controlled use permit, or an application for a renewal of a controlled use permit, may include an application that certain information given in accordance with section 22D be treated as exempt information under section 75.
- (2) The giving of information about a chemical in accordance with a condition of a kind referred to in subsection 22H(2) may be accompanied by an application in the approved form that some or all of the information be treated as exempt information under section 75.

Importers and manufacturers of industrial chemicals who have queries about registration obligations or any other matter regarding the new low regulatory concern chemicals reform initiatives should contact NICNAS on 1800 638 528.