SECTION II – New Chemicals

2. Do You Need to Notify?

This chapter aims to help you decide whether a substance you are importing or manufacturing is subject to new chemicals assessment under NICNAS. If it is, you will need to refer to Chapters 2-8 in Section II and Section IV later in the handbook for more information about new chemical assessment. If after reading this chapter, you discover your chemical is not subject to new chemical assessment, no further action is required in most cases. However, annual reporting requirements exist for all chemicals introduced under an exemption category and record keeping requirements and advice prior to introduction is required for certain exempt categories. These categories (and the procedures to follow in order to supply information) are outlined at the end of this chapter. Any forms referred to in this chapter can be downloaded from the NICNAS website at http://www.nicnas.gov.au/Forms.asp

2.1 How to Decide

In general, the chemicals subject to new chemical assessment under NICNAS are those that are not listed on the Australian Inventory of Chemical Substances (AICS) or those whose importation and/or manufacture is subject to a condition of use. See information in Chapter 1 on how to check AICS. Since there are certain exemptions, NICNAS recommends you follow the decision tree below to help you decide if your substance is subject to new chemical assessment. The following pages contain descriptions to help you answer the questions below.

<u>Is the substance a chemical under the NICNAS definition?</u>

- YES
- NO*

<u>Is the substance an industrial chemical?</u>

- YES
- NO*

<u>Is the industrial chemical a new industrial chemical?</u>

- YES
- NO*

<u>Is the new industrial chemical exempt from notification?</u>

- YES[1]

- NO: Your chemical is subject to new chemicals assessment. Refer to Chapter 3 for more information about what to do next.

**No further action required*

[1] Annual reporting obligations may apply, and advice to NICNAS may be required in some cases.

2.2 Is the Substance a Chemical Under the NICNAS Definition?

THE ANSWER IS NO (and the substance does not require notification) if it fits any one of the following descriptions:

a. Articles, being items which, due to their use, have been manufactured into a certain shape or design, and which do not change their chemical composition during use. For example, steel ball bearings, compounded plastic pipe or adhesive films would be considered to be articles (see Appendix 2 – Definitions). For the purposes of NICNAS, articles do not include fluids or substances that may be manufactured or imported in particulate or aggregate form, for example, a polymer in granular form which will be further processed. Further examples of articles are given in Appendix 9 – Description of an article.
b. Radioactive chemicals – chemicals having a specific activity greater than 35 becquerels/g.
c. Mixtures, being physical combinations of chemicals resulting from deliberate mixing or from chemical reactions, but not being UVCB substances. Although a mixture itself is not notifiable, new industrial chemical components in the mixture are notifiable unless exempt (see below).

THE ANSWER IS YES, (and the substance may require notification) if it falls under any of the following definitions:

a. Discrete chemical elements, compounds and complexes of particular molecular identity, either as a pure or technical grade substance, for example:
    i. chemical element: lead (CAS no. 7439-92-1);
    ii. chemical compound: succinic acid (CAS no. 110-15-6), polyvinyl chloride (CAS no. 9002-86-2); and
    iii. chemical complex: ferric ammonium oxalate (CAS no. 14221-47-7).

    Note: the chemical name and the CAS number are the identifying characteristics of the chemical.
b. Chemical elements, compounds and complexes which exist as components in a physical mixture of chemicals, either by chemical reaction or deliberate mixing of the chemicals (the mixture itself is not notifiable). Examples are:
    i. chemical element in a mixture: oxygen (CAS no. 7782-44-7) in a mixture of gases;
    ii. chemical compound in a mixture: the plasticiser dibutyl phthalate (CAS no. 84-74-2) in a poly(vinyl chloride) blend; and

iii. chemical complex in a mixture: ferric ammonium oxalate (CAS no. 14221-47-7) in an aqueous solution

c. chemicals of unknown or variable composition, complex reaction products or biological other than a whole plant or animal (UVCB substances).
These are poorly defined substances that cannot be represented by a complete chemical structure and specific molecular formula, for example:

   i. unknown or variable composition: chlorinated paraffin sodium sulfonate (CAS no. 68910-45-2), where the degree of chlorination varies;

   ii. complex product of a chemical reaction: tall oil, reaction products with diethanolamine (CAS no. 97489-16-2). Where the product of a chemical reaction is in a mixture with its reactants; and

   iii. biological material: geranium oil (CAS no. 8000-46-2)

d. Naturally-occurring chemicals, meaning unprocessed chemicals occurring in nature, or chemicals occurring in nature which have been extracted from the parent material through certain defined processes without chemical change (see Appendix 2 – Definitions), for example:

   i. naturally-occurring biological chemicals;

   ii. inorganic chemicals in the soil; and

   iii. minerals extracted from ore by a physical process such as dissolution or flotation.

2.3 Is the Chemical an Industrial Chemical Under NICNAS Definition?

THE ANSWER IS NO, and the chemical is therefore not subject to notification, if it is used solely as an agricultural or veterinary chemical, a therapeutic good, a food or food additive (so-called ‘excluded uses’ as defined in subsection 7(2) of the Act).

THE ANSWER IS YES, and the chemical may be subject to notification, if it has any industrial use, whether or not it has both an excluded and an industrial use.

Examples of the most common industrial uses for chemicals assessed by NICNAS to date include surface coatings, printing, fuel and oil, textile processing, photography and cosmetics. For information on cosmetics, please refer to latest information on the website www.nicnas.gov.au.

2.4 Is the Industrial Chemical a New Industrial Chemical?

THE ANSWER IS NO (and the industrial chemical does not require notification) if it falls into any of the following categories:

a. Reaction intermediates, due to their transient existence and confinement to their chemical reaction systems (see Appendix 2 – Definitions).
b. Incidentally-produced chemicals, produced as an impurity or by-product from a chemical reaction (see Appendix 2 – Definitions). Incidentally-produced chemicals must have no commercial value. Information on these chemicals would be required if the parent chemical was subject to notification.
c. Naturally-occurring chemicals (which are regarded as being on AICS).
d. Polymers (see Appendix 2 – Definitions) that do not fulfil the criteria for a new synthetic polymer (see (c) under YES answer below for more details). Examples of such chemicals include:
    i. an existing synthetic polymer where only a change in monomer ratios has occurred, for example, if the ethylene-vinyl acetate ratio in an ethylene-vinyl acetate copolymer has change from 70-30% to 40-60%; and
    ii. an existing synthetic polymer containing one or more additional monomer(s) or reactant(s), each at less than 2% weight (see Appendix 2- Definitions).

THE ANSWER IS YES (and the industrial chemical may require notification) if it is any of the following:

a. not listed in AICS; or,
b. listed in AICS with a condition of use and its import and/or manufacture is significantly different to that condition; or,
c. a new synthetic polymer, defined as:
    - a synthetic polymer that includes a combination of monomers and other reactive components, each representing at least 2% by weight, being a combination not listed in AICS, or
    - a synthetic polymer of whose weight at least 2% is attributable to a monomer or other reactive component that is not listed in AICS as a component of a synthetic polymer.

2.5 Is the New Industrial Chemical Exempt from Notification Under NICNAS?

Once AICS has been consulted and it is established that the chemical to be imported or manufactured in Australia is a new industrial chemical, the next step is to determine whether it falls into a category that is exempt from notification.

For most exemption categories no further action is required prior to the introduction of the new chemical. However, in some cases information about exempt category chemicals still needs to be provided to the Director justifying the exemption. The majority of exemption categories have an annual reporting obligation.

The following table summarises the exemptions available. For a more detailed description of these exemptions including the exemption criteria see chapter 2.6.

Exemption	Volume or concentration restriction	Other criteria	Advice required prior to introduction	Other reporting requirements
Research and Development	Not more than 100 kg in a period of12 months	No	No	Annual reporting
Research and Development (manufactured)	N/A	Yes	Yes – Form 6	No
Transhipment	N/A	Yes	No	Annual reporting
Non-Cosmetic (no unreasonable risk)	Not more than100 kg in a period of 12 months	Yes	No (NCE-Form 1)	Annual reporting*
Cosmetic (<1%)	Introduced in a product at 1% or less	Yes	No	Annual reporting*
Cosmetic (no unreasonable risk)	Not more than 10 kg in a period of 12 months	Yes	No	Annual reporting*
Cosmetic (no unreasonable risk)	Greater than 10kg but not more than 100kg in a period of 12 months	Yes	Yes- Form 15	Annual reporting*

* The person who introduces the chemical must keep in writing, for 5 years after the introduction, information available to the person about occupational health and safety, public health and the environmental effects of the chemical (refer to Chapter 15 for information on annual reporting requirements).

2.6 Exemption Categories for New Industrial Chemicals

(a) Research and Development

Notification Requirements

The new chemical is imported or manufactured only for research, development or analytical work in a quantity of not less than 100g and not more than 100kg in any 12 month period.

Obligations

1. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.

(b) Research and Development (Manufactured)

Notification Requirements

The new chemical is:

- manufactured in Australia, solely for the purpose of research, development or analytical work ; and
- is site-limited; and
- manufacture is in an apparatus, which cannot operate effectively to produce smaller quantities.

There is no volume restriction on this category.

Obligations

1. Complete Form 6 and return it to NICNAS prior to manufacture of the new chemical.

(c) Transhipment

Notification Requirements

Introduced by a person at a port or airport in Australia, remains subject to the control of customs at the port or airport at all times and leaves Australia less than 30 days after the day of introduction. There is no volume restriction on this category.

Obligations

1. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.

(d) Non-Cosmetic (No Unreasonable Risk)

Notification Requirements

The new chemical is introduced in quantities not exceeding 100 kg in a period of 12 months, is for non-cosmetic use, and poses no unreasonable risk to occupational health, public health or the environment (to help you decide this, refer to "What is

an unreasonable risk" chapter 2.7). A guidance form for Non-Cosmetic Exemptions (Form NCE-1) is available on the NICNAS website to assist companies in determining No Unreasonable Risk.

Obligations

1. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.
2. Introducers of the chemical must keep in writing, for 5 years after the introduction, all information available to the person about occupational health and safety, public health matters and the environmental effects of the chemical.

(e) Cosmetics (<1%)

Notification Requirements

The new chemical is a non-hazardous chemical introduced in a cosmetic product at a concentration at 1% or less (there is no volume restriction), and meets all of the following criteria:

i. the chemical is not a hazardous chemical according to the *Approved Criteria for Classifying Hazardous Substances*[1];

ii. the chemical is not a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail[2];

iii. the chemical has one of the following characteristics:

- it dissolves in water without dissociation or association and is not surface-active and the partition coefficient (n-octanol/water) at 20^{o}C as log P_{ow} does not exceed 3;
- it's solubility in water is greater than 1 mg/litre;
- the molecular weight or (number-average molecular weight in the case of a polymer) is greater than 1 000; and

iv. the chemical is readily biodegradable;

v. the chemical has a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC50 or EC50 100 mg/L or greater;

vi. the introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment;

vii. the chemical is not used in the cosmetic as a preservative, colouring agent or ultraviolet filter; and

viii. the chemical is not prohibited or restricted for use in cosmetics in the European Union under Council Directive 76/768/EEC (as amended) or in the United States of America under the Food Drugs and Cosmetics Act 1938 (as amended).

[1] [1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

[2] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)

Obligations

1. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.
2. Introducers of the chemical must keep in writing, for 5 years after the introduction, all information available to the person about occupational health and safety, public health matters and the environmental effects of the chemical.

(f) Cosmetic <10 kg/yr (No Unreasonable Risk)

Notification Requirements

The new chemical is introduced in quantities not exceeding 10 kg in a period of 12 months, is for cosmetic use, poses no unreasonable risk to occupational health, public health or the environment (to help you decide this, refer to "What is an unreasonable risk" chapter 2.7) and meets all of the following criteria:

i. the chemical is not used in the cosmetic as a preservative, colouring agent or ultraviolet filter; and

ii. the chemical is not prohibited or restricted for use in cosmetics in the European Union under Council Directive 76/768/EEC (as amended) or in the United States of America under the Food Drugs and Cosmetics Act 1938 (as amended); and

iii. if the chemical is an ingredient in a cosmetic at a concentration of 1% or more, the person who introduces the chemical must have information which indicates that the chemical will be safe for use by potentially high-risk groups, consistent with the anticipated pattern of consumer exposure.

Obligations

1. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.
2. Introducers of the chemical must keep in writing, for 5 years after the introduction, all information available to the person about occupational health and safety, public health matters and the environmental effects of the chemical.

(g) Cosmetic >10 kg/yr but <100 kg/yr (No Unreasonable Risk)

Notification Requirements

The new chemical is introduced in an amount that is greater than 10 kg but not exceeding 100kg in a period of 12 months, is for cosmetic use, poses no unreasonable risk to occupational health, public health or the environment (to help

you decide this, refer to "What is an unreasonable risk" chapter 2.7), and meets all of the following criteria:

i. the chemical is not used in the cosmetic as a preservative, colouring agent or ultraviolet filter; and

ii. the chemical is not prohibited or restricted for use in cosmetics in the European Union under Council Directive 76/768/EEC (as amended) or in the United States of America under the Food Drugs and Cosmetics Act 1938 (as amended); and

iii. if the chemical is an ingredient in a cosmetic at a concentration of 1% or more, the person who introduces the chemical must have information which indicates that the chemical will be safe for use by potentially high-risk groups, consistent with the anticipated pattern of consumer exposure.

Obligations

1. Complete Form 15 and return it to NICNAS, together with the material safety data sheet (MSDS) relevant to the chemical or product containing the chemical, the label to be attached to the packaging of the chemical or product containing the chemical and the letter advising the Director that the chemical is to be introduced.
2. Introducers of chemicals in this category should submit an annual report and return it to NICNAS before or on 28 September of the following registration year.
3. Introducers of the chemical must keep in writing, for 5 years after the introduction, all information available to the person about occupational health and safety, public health matters and the environmental effects of the chemical.

If the New Chemical you wish to import or manufacture does not fall into any of these exemption categories then you will have to notify NICNAS. Refer to Chapter 3 of this handbook to decide the appropriate notification category.

2.7 What is Unreasonable Risk?

In assessing the risk of a chemical, consider both the hazards of the chemical, and the potential exposure of humans and the environment. In assessing whether a risk posed is unreasonable, consider both the potential risk (*i.e.,* the maximum risk a chemical may pose), and how that potential risk might be minimised (through specific handling techniques for instance) as outlined below. If the potential risk is high and/or cannot be minimised, the risk posed may be considered by NICNAS to be unreasonable. If this is the case, you will need to apply for an assessment permit or certificate as outlined in Chapter 3. If you are in doubt, contact the NICNAS Notification and Assessment Team on 1800 638 528 for further guidance.

In estimating risk, the emphasis should be on the risk due to the chemical being introduced, rather than due to the hazards of other components in a product.

Occupational Health & Safety risk

In relation to occupational health, the logical first step in assessing if the risk is unreasonable would be to determine the hazardous nature of the chemical by using the

Approved Criteria for Classifying Hazardous Substances.[1]. If the chemical is imported as part of a formulated product, the hazardous nature of the product should be determined.

If the chemical (or product) is not classified as hazardous according to these criteria, and does not have significant physico-chemical hazards or reactivity, then given the maximum volume of 100 kg per year of chemical introduced, it is likely that the potential risk to occupational health and public health would be low.

Where the chemical (or product) is classified as hazardous, the level of exposure to workers during various processes such as manufacture, formulation, end-use and disposal should be evaluated.

Public Health risk

Public risk can be assessed similarly to occupational risk (as above). In addition, chemicals to be used in cosmetics should be assessed critically for their suitability for deliberate application to the human body. Form 15 lists additional criteria that cosmetic chemicals must meet, to be eligible for the "no unreasonable risk" low volume exemption: (see Ch 2.5 above).

Environmental risk

The environmental fate of the chemical should be considered for each of the possible routes for release (*e.g.*, during manufacture, use, disposal of waste) of the chemical into the environment (air, soil and water). When considering environmental fate, the parameters to evaluate would include volatility, solubility, mobility and the potential for biodegradation and bioaccumulation.

In determining whether an unreasonable risk to the environment might exist, consideration should be given to any known ecotoxicity of the chemical and its behaviour in air, soil and water.

Minimising risk

In the assessment of risk, potential exposure to a chemical should be considered (where appropriate) during manufacture and/or importation, formulation, end use and disposal in relation to the hazards (including toxicity) of the chemical.

Efforts to minimise or eliminate exposure of workplace personnel should be taken into account in determining if an unreasonable risk exists. The risk may be minimised by the use of engineering controls or by the wearing of personal protective equipment such as gloves and safety spectacles.

Similarly, environmental risk is reduced in the first instance through measures to prevent release of the chemical to the environment (*e.g.*, manufacture of the chemical in a closed system). Where environmental release occurs, the environmental risk may

[1] [1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

be minimised through treatment or conversion of the chemical to a less harmful form, for example, on site treatment of production effluent prior to discharge into the sewer.

How to assess the risks - an example

The following example shows how to assess the risks posed by a chemical. Although it relates to a chemical used in cosmetics (fitting description (f) and (g) in section 2.6), it provides guidance useful for consideration of risks posed by a non-cosmetic (fitting description (d) in section 2.6).

A new chemical is to be imported for use as a component of a skin moisturiser and comprises one per cent of the finished product. The chemical is a liquid under ambient conditions and is not determined to be a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances*[1].

Occupational Health considerations

The chemical is transported in 500 mL bottles packed in impact-resistant containers. It is dispensed directly from the bottle through an open-pour method during manufacture of the cosmetic product. In this case, the potential for worker exposure through scenarios such as spillage or splashing should be evaluated for all facets of the production process - from handling of the concentrate to packaging of the final product.

In this case, the chemical is not a hazardous substance and is present at a relatively low concentration in the final product Therefore the chemical would not be considered of high occupational health risk after formulation, even if some exposure should occur. In general, the risks posed by the final product need to be determined on a case-by-case basis.

In cases where finished products only are imported, occupational health considerations are usually minimal, perhaps restricted to warehousing arrangements.

The occupational health assessment needs to extend to the end use of a cosmetic product if it is used in workplaces such as hairdressing salons and beauty parlours.

Public Health considerations

The potential for public exposure to the cosmetic product would be high. Risk is related in this case to the hazardous nature of the chemical, its concentration in the finished product and its behaviour, for example, mobility, on the surface of the skin. In this case, the chemical is not a hazardous substance and the concentration in the moisturiser is relatively low (1%). For most individuals, the risk even of repeated use would be low.

Environmental considerations

[1] [1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

In this example, possible routes for release include accidental spillage of the chemical or finished product during transport and loss during manufacture, including disposal of waste product. As only a small volume of chemical is involved, risk to the environment may be very low. The ecotoxicity and physico-chemical properties of the chemical, however, would need to be assessed in relation to possible release volumes to determine whether the impact of any local release was unacceptable.

Most of the chemical in consumer products is released to the environment through the normal use of the product. The chemical is highly diluted when it enters the aquatic environment through washing or showering and the pattern of release is highly dispersed. Environmental concern is therefore extremely low in view of the amount of chemical involved (less than 100 kg per year).

Chemicals unsuitable for exemption

Chemicals cannot be considered for exemption if:

- they are likely to be persistent or bioaccumulative, or have breakdown products with these characteristics*;* or
- they are classified as carcinogenic, mutagenic or toxic to reproduction under the *Approved Criteria for Classifying Hazardous Substances*[1].

The following groups of chemicals **might not** be suitable for exemption. If proposed for exemption, a strong case that they do not pose an unreasonable risk in use should be made:

- Chemicals containing <u>other than</u> the following elements:
  - hydrogen, lithium, boron, carbon, nitrogen, oxygen, sodium, magnesium, aluminium, silicon, phosphorus, sulfur, potassium, calcium, titanium, iron, copper, zinc, gallium, germanium, selenium, rubidium, strontium, zirconium, tin, caesium.
  - chlorine, bromine and iodine, only as anions.
- Chemicals containing the following high concern reactive functional groups:
  - pendant acrylates and methacrylates,aziridines, carbodiimides, halosilanes, hydrosilanes, hydrazines, isocyanates, isothiocyanates, alpha or beta lactones,vinyl sulfones or analogous compounds, partially-hydrolysed acrylamides, acid halides, acid anhydrides, aldehydes, epoxides, amines, or other reactive functional groups identified as of high concern
  - alkoxysilanes with C1 or C2 alkoxy groups
- Chemicals having or expected to have high acute or chronic ecotoxicity to any aquatic species. This would include cationic chemicals/polymers and those having LC50 values of less than 1 mg/L (acute) or 0.01 mg/L (chronic). For uses where concentrated discharge is possible, more stringent ecotoxicity limits would apply.
- Chemicals having low biodegradability.
- Chemicals suspected of having carcinogenic, mutagenic or reprotoxic effects.

[1] [1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

An example where exemption might be justified for the groups of chemicals listed above is if the volume is very low (substantially less than 100 kg/yr).

Data requirements

Introducers assessing whether "no unreasonable risk" applies will need data on the hazards of the chemical, or likely hazard based on structure. While no specific requirements are set out for hazard data, it is expected that the determination of hazard will be on an informed basis. In most cases, this information will be available from suppliers.

3. Which Notification Category?

Having established that you wish to import or manufacture a new industrial chemical that needs to be notified (including import of a mixture containing the chemical), reading this chapter will help you determine the most appropriate notification category. It also outlines other kinds of applications allowing you to:

- obtain permission to introduce a chemical already notified even though the assessment is not complete (see Permits in this chapter);
- renew an existing permit (see Renewal of Permits in this chapter)
- have your company name added to an assessment certificate issued to another company importing or manufacturing the same chemical (see Extension of an Original Assessment Certificate in this chapter).
- obtain a fee reduction by providing an acceptable written draft assessment report with your application (see Provision of a Draft Assessment Report in this chapter)
- submit a self assessment for certain categories of chemicals.

For further information about proceeding with any application described in this chapter, refer to Chapter 4 - General Notification Procedures, as well as the relevant sections in Chapter 5 - Certificate Categories and Chapter 6 - Permit Categories.

3.1 Determining the Appropriate Notification Category

There are a number of categories relating to notification for a new chemical assessment, with each category depending on the type of chemical, the amount being introduced, the use of the chemical and the period of use required.

Permit notification categories are suitable for chemicals which meet certain criteria. These notification categories result in the issue of a permit allowing the introduction of fixed quantities of the chemical for the duration of the permit. They also result in the publication of a notice of the permit in the *Chemical Gazette*. The chemical is not added to the AICS. The assessment timeframes for permit categories are shorter and the fees lower than certificate notification categories (see below). An application to renew an existing permit can be made in certain circumstances.

A special type of permit may be applied for in certain circumstances in conjunction with an application for a certificate notification. This allows introduction of the chemical before the certificate assessment is complete.

The certificate notification categories are for chemicals which do not meet the permit criteria or where the introducer prefers a certificate notification to a permit notification. Certificate categories result in an assessment report, the issue of an assessment certificate, publication of a summary report in the *Chemical Gazette* and a full public report on the NICNAS website and the eventual addition of the assessed chemical to the AICS. There are different fees for each category.

The Extension notification category allows for an extension of a current assessment certificate to cover other companies intending to import or manufacture a notified chemical. This results in an amended assessment report, the issue of an assessment certificate and publication of an amended summary report in the *Chemical Gazette* and a full public report on the NICNAS website and the eventual addition of the assessed chemical to the AICS.

In making your decision about which notification category is appropriate for you, read the descriptions below. You may also wish to consult the table in section 3.5, which summarises the categories including the time taken for the assessment and the duration of the certificate or permit issued. Note that chemicals which are polymers and do not meet the criteria for a PLC may be assessed in either the Limited or Standard categories.

3.2 Overview of Permit Categories

This section is intended to give an overview of the different permit categories, the circumstances for which each permit category is intended and the criteria that apply. Information on the notification procedures and the information that is required to demonstrate the criteria is detailed in chapter 6.

Commercial Evaluation Chemical (CEC) permit notifications are for limited volume chemicals to be introduced solely for the purpose of market evaluation where the maximum quantity to be introduced is four tonnes in a maximum period of two years.

Examples of possible uses are:

- to test a new polymer in a surface coating when a large quantity is required to fill paint lines; or
- to evaluate a new process which requires a new industrial chemical.

A CEC may be renewed once only provided certain criteria are met (see chapter 6.7).

Low Volume Chemical (LVC) permit notifications are for small volume chemicals to be introduced at a rate of up to 100 kg per year or 1000 kg per year for a maximum of three years. A LVC permit may be renewed any number of times provided certain criteria are met (see chapter 6.7).

The LVC permit allows the chemical to be introduced at a maximum quantity of 1000 kg per annum where the following low-hazardous criteria are met (otherwise the volume limit is 100 kg):

For chemicals (including polymers with a NAMW <1000), the chemical:

- **is not** a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances*[1] **or is** a hazardous chemical that is

[1] [1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

classified as R36 (irritating to eyes) or R38 (irritating to skin) according to the *Approved Criteria for Classifying Hazardous* Substances (irritation reversible); and

- **is not** a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail[1] (ADG code) **or is** a dangerous good that is a Class 3 flammable liquid as defined in the ADG code; and
- has a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC_{50} or EC_{50} 100 mg/L or greater.

For polymers with NAMW that is 1000 or greater, the polymer must:

- have less than 10% by mass of molecules with molecular weight that is less than 500; and
- have less than 25% by mass of molecules with molecular weight that is less than 1000; and
- have a low charge density i.e. it is not cationic or not likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9 or it is a solid that is not soluble or dispersible in water and is to be used only in its solid phase or for a polymer that includes 1 or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000; and
- not have any of the following hazard classifications as described in *Approved Criteria for Classifying Hazardous Substances*[2] for human health effects:
  (i) carcinogenic effects (R40, R45, R49);
  (ii) mutagenic effects (R46);
  (iii) reproductive effects (R60-64);
  (iv) toxic and very toxic acute lethal effects (R23-28);
  (v) corrosive effects (R34, R35);
  (vi) sensitising effects (R42, R43);
  (vii) non-lethal irreversible effects after a single exposure (R39, R68);
  (viii) severe effects after repeated or prolonged exposure (R48);

Based on their known health and environmental concerns the following chemicals/polymers are not eligible for a low volume chemical permit for volumes exceeding 100 kg per annum:

- chemicals/polymers that are likely to be persistent and/or bioaccumulative, or have breakdown products with these characteristics
- chemicals/polymers that are covered by the NICNAS position paper regarding data requirements for notification of new chemical substances containing a perfluorinated carbon chain
- chemical/polymer classes with an exposure standard e.g. isocyanates, tin compounds

[1] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)
[2] [2] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)].
National Occupational Health and Safety Commission, Canberra, AusInfo.

Controlled Use Permit (CUP) notifications are for the introduction of low risk new chemicals used in highly controlled circumstances for a maximum of three years. There is no volume restriction provided all the following criteria are met:

Industrial chemicals meeting the following criteria will be eligible for the Controlled Use Chemical Permit (CUP):

(a) the chemical does not have any of the following hazard classifications for human health effects (as described in *Approved Criteria for Classifying Hazardous Substances*[1]:

(i) carcinogenic effects (R40, R45, R49;
(ii) mutagenic effects (R46);
(iii) reproductive effects (R60-64);
(iv) toxic and very toxic acute lethal effects (R23-28);
(v) corrosive effects (R34, R35);
(vi) sensitising effects (R42, R43);
(vii) non-lethal irreversible effects after a single exposure (R39, R68);
(viii) severe effects after repeated or prolonged exposure (R48);

AND

(b) the chemical does not have a toxicity:

(i) to fish, expressed as an LC_{50}, that is less than or equal to10 mg/litre, as determined using the Fish Acute Toxicity Test (continuous exposure of fish to a series of concentrations of the chemical in water for 4 days); and
(ii) to aquatic invertebrates, expressed as an EC_{50}, that is less than or equal to 10 mg/litre, as determined using the *Daphnia* sp, Acute Immobilisation Test and Reproduction Test (daphnids exposed to a series of concentrations of the chemical in water); and
(iii) to algae expressed as IC_{50}, that is less than or equal to 10 mg/litre, as determined using the Algal Growth Inhibition Test (algae exposed to a series of concentrations of the chemical in water for at least 3 days);

AND

(c) for human exposure:

(i) there are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance; and
(ii) any worker exposure that is likely to occur will be adequately controlled through use of engineering controls, work practices and personal protective equipment;

AND

(d) for environmental exposure, all routine releases from manufacture, processing and use (including releases associated with cleaning of equipment and from disposal or cleaning of containers and packaging) have been considered and adequate controls are in place to ensure:

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

(i) no ambient release to surface water resulting in concentrations of the chemical above 1 part per billion; and
(ii) no ambient release to air above 1 microgram per cubic metre average annual concentration; and
(iii) no release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Two controlled use exposure scenarios have been developed in consultation with industry. These are for containment and controlled reformulation, and site-limited and closed system manufacture. Typically a chemical being used as described in these scenarios will meet the exposure criteria set out above (exceptions may occur where a chemical has particular physicochemical characteristics, for example where the chemical is highly volatile or persistent). Other use scenarios may meet the criteria set out above. For such other uses it is preferred that Industry work with NICNAS to develop additional exposure scenarios.
For more information on the human and environmental exposure criteria and two controlled use scenarios which have been developed see Appendix 14.

A CUP may be renewed any number of times provided certain criteria are met (see chapter 6.7).

Controlled Use (Export Only) Permit (EOP) notifications are for controlled introduction of a new chemical for export purposes or for its use in controlled formulation of products in Australia for export of the entire quantity for a maximum of three years.

An EOP permit may be renewed any number of times provided certain criteria are met (see chapter 6.7).

Early Introduction Permit (EIP) applications may be made under certain circumstances, in conjunction with a certificate notification. An EIP allows introduction of a chemical into Australia before the assessment certificate is issued.

Section 30A (EIP) Permits are for new industrial chemicals which meet certain hazard or use criteria.

Section 30 Permits are for new chemicals where it can be shown that their immediate introduction is in the public interest.

30A (EIP) Permits Criteria

Chemicals/polymers which may be eligible for an EIP are:

- polymers of low concern (PLC);
- non-hazardous chemicals/polymers;
- chemicals/polymers meeting low-hazardous criteria; or
- low risk highly controlled chemicals/polymers.

The criteria that need to be met are detailed below. In all cases the introduction of the chemical must be consistent with the reasonable protection of occupational health, public health and the environment.

Chemicals/polymers that are likely to be persistent and/or bioaccumulative, or have breakdown products with these characteristics are not eligible for an Early Introduction Permit (persistence and bioaccumulation criteria are set out in Appendix 16).

Polymers of Low Concern (PLC)

In general, a polymer that qualifies for notification and assessment as a PLC under the current PLC criteria would satisfy the criteria for an EIP application. The polymer's largest component must be carbon or silicon.

Non-hazardous chemicals and polymers (other than PLC)

To be considered a non-hazardous chemical or polymer, applicants need to satisfy the Director that:

- the chemical is not a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances*[1];
- the chemical is not a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail[2]; and
- the chemical has one of the following characteristics:
  - (i) it dissolves in water without dissociation or association and is not surface-active and the partition coefficient (n-octanol/water) at 20°C as log P_{ow} does not exceed 3;
  - (ii) it's solubility in water is greater than 1 mg/litre;
  - (iii) the molecular weight or (number-average molecular weight in the case of a polymer) is greater than 1 000; and
- the chemical is readily biodegradable; and
- the chemical has a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC_{50} or EC_{50} 100 mg/L or greater.

The data that is normally required to demonstrate that the criteria are met is detailed in chapter 6.6.1.

C*hemicals and polymers meeting low-hazardous criteria*

To be considered a low-hazardous chemical or polymer, the Director has to be satisfied that the low-hazardous criteria are met. Different criteria exist for chemicals (including polymers with a NAMW <1000) and polymers with NAMW that is 1000 or greater. These criteria are:

For chemicals (including polymers with a NAMW <1000), the chemical:

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

[2] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)

- **is not** a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances*[1] **or is** a hazardous chemical that is classified as R36 (irritating to eyes) or R38 (irritating to skin) according to the NOHSC *Approved Criteria for Classifying Hazardous* Substances[1] (irritation reversible); and
- **is not** a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail[1] (ADG code) **or is** a dangerous good that is a Class 3 flammable liquid as defined in the ADG code; and
- has a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC_{50} or EC_{50} 100 mg/L or greater.

The data that is normally required to demonstrate that the criteria are met is detailed in chapter 6.6.1.

For polymers with NAMW that is 1000 or greater, the polymer must:

- have less than 10% by mass of molecules with molecular weight that is less than 500; and
- have less than 25% by mass of molecules with molecular weight that is less than 1000; and
- have a low charge density i.e. it is not cationic or not likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9 or it is a solid that is not soluble or dispersible in water and is to be used only in its solid phase or for a polymer that includes 1 or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000; and
- not have any of the following hazard classifications as described in *Approved Criteria for Classifying Hazardous Substances*[2] for human health effects:
  (i) carcinogenic effects (R40, R45, R49);
  (ii) mutagenic effects (R46);
  (iii) reproductive effects (R60-64);
  (iv) toxic and very toxic acute lethal effects (R23-28);
  (v) corrosive effects (R34, R35);
  (vi) sensitising effects (R42, R43);
  (vii) non-lethal irreversible effects after a single exposure (R39, R68);
  (viii) severe effects after repeated or prolonged exposure (R48);

The data that is normally required to demonstrate that the criteria are met is detailed in chapter 6.6.1.

Low-risk highly controlled chemicals and polymers

To be considered a low-risk highly controlled chemical or polymer the Director has to be satisfied that the following criteria are met:

[1] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)
[2] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)].
National Occupational Health and Safety Commission, Canberra, AusInfo.

- the chemical does not have any of the following hazard classifications for human health effects (as described in *Approved Criteria for Classifying Hazardous Substances*[1]:

  (i) carcinogenic effects (R40, R45, R49;
  (ii) mutagenic effects (R46);
  (iii) reproductive effects (R60-64);
  (iv) toxic and very toxic acute lethal effects (R23-28);
  (v) corrosive effects (R34, R35);
  (vi) sensitising effects (R42, R43);
  (vii) non-lethal irreversible effects after a single exposure (R39, R68);
  (viii) severe effects after repeated or prolonged exposure (R48);

AND

- the chemical does not have a toxicity:

  (i) to fish, expressed as an LC_{50}, that is less than or equal to10 mg/litre, as determined using the Fish Acute Toxicity Test (continuous exposure of fish to a series of concentrations of the chemical in water for 4 days); and
  (ii) to aquatic invertebrates, expressed as an EC_{50}, that is less than or equal to 10 mg/litre, as determined using the *Daphnia* sp, Acute Immobilisation Test and Reproduction Test (daphnids exposed to a series of concentrations of the chemical in water); and
  (iii) to algae expressed as IC_{50}, that is less than or equal to 10 mg/litre, as determined using the Algal Growth Inhibition Test (algae exposed to a series of concentrations of the chemical in water for at least 3 days);

AND

- for human exposure:

  (i) there are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance; and
  (ii) any worker exposure that is likely to occur will be adequately controlled through use of engineering controls, work practices and personal protective equipment;

AND

- for environmental exposure, all routine releases from manufacture, processing and use (including releases associated with cleaning of equipment and from disposal or cleaning of containers and packaging) have been considered and adequate controls are in place to ensure:

  (i) no ambient release to surface water resulting in concentrations of the chemical above 1 part per billion; and
  (ii) no ambient release to air above 1 microgram per cubic metre average annual concentration; and
  (iii) no release to land or landfill unless the chemical has negligible potential for migration to groundwater.

The data that is normally required to demonstrate that the hazard criteria are met is detailed in chapter 6.6.1.

Two controlled use exposure scenarios have been developed in consultation with industry. These are for containment and controlled reformulation, and site-limited and closed system manufacture. Typically a chemical being used as described in these scenarios will meet the exposure criteria set out above (exceptions may occur where a chemical has particular physicochemical characteristics, for example where the chemical is highly volatile or persistent). Other use scenarios may meet the criteria set out above. For such other uses it is preferred that Industry work with NICNAS to develop additional exposure scenarios.

Any down-stream user and their practices must be known. Only those users whose details have been provided to NICNAS will be able to use the chemical under the EIP permit (these users will be listed on the permit).

For more information on the human and environmental exposure criteria and two controlled use scenarios which have been developed see Appendix 14.

Section 30 Permit Criteria

Chemicals which do not meet the criteria for a Section 30A Permit, may be eligible for a Section 30 Permit if the Minister is satisfied that:

- the chemical is of special benefit to the public in some way, for example, the import of a chemical may be critical during an environmental emergency;
- it is in the public interest that the chemical be introduced immediately; and
- introduction of the chemical is consistent with the protection of occupational health, public health and the environment.

3.3 Overview of Certificate Categories

Polymers of Low Concern (PLC) notifications are for polymers for which the following applies (refer to Appendix 10 - Polymers of Low Concern Guidance for more detail):

a. *Number-average molecular weight*
   Except for certain polyesters (see below), a PLC must have a number-average molecular weight (NAMW) greater than 1000.
   For polymers with NAMW between 1000 and 10000, the allowable low molecular weight species (MW below 1000 and 500) for these polymers is 25% and 10% respectively provided that the polymer has a limited content of reactive functional groups.
   For polymers with NAMW greater than 10000, the allowable low molecular weight species (MW below 1000 and 500) for these polymers remains at 5% and 2% respectively. There is no restriction on the number of reactive functional groups in the polymer.

b. *Low charge density*
   A polymer has a low charge density if it is not a cationic polymer or is not reasonably anticipated to become a cationic polymer in a natural aquatic

— environment (4 < pH < 9). Certain solid materials and polymers with a low content of cationic groups are allowable as PLCs.

c. *Hazard Classification*
A PLC must not be classified as a hazardous chemical.

d. *Stability*
A polymer is stable under the conditions in which it is used if it does not readily break down by hydrolysis, thermal degradation, photodegradation, depolymerisation or any other means.

e. *Chemical composition*
A PLC must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon and sulfur. There are restrictions on the content of other elements.

f. *Water absorbing polymers*
A water absorbing polymer with NAMW 10000 and greater cannot be a PLC.

g. *Polyesters*
A polyester manufactured solely from one or more allowable reactants may be a PLC, provided that the polymer meets the other criteria.

It should be noted that each batch of a particular new polymer must meet the criteria to be eligible for notification and assessment as a PLC.

A polymer of low concern can be either a synthetic polymer or biopolymer. In addition, the residual monomer content will no longer impact the classification of the polymer as a low concern polymer. However, information regarding the residual monomer content will still need to be provided.

Limited Notifications are for chemicals that fit into the following categories:

a. small volume chemicals, biopolymers and low molecular weight synthetic polymers (NAMW < 1000), i.e. those which are to be imported or manufactured at a rate of up to one tonne per 12 month period (but which do not qualify for a commercial evaluation or low volume chemical permit); or
b. site-limited chemicals, biopolymers and low molecular weight synthetic polymers (NAMW < 1000), i.e. those restricted to their manufacturing site and manufactured at a rate of not more than 10 tonnes per 12 month period; or
c. synthetic polymers with NAMW greater than 1000 and which do not meet the PLC criteria.

Standard Notifications are for chemicals, biopolymers and low molecular weight synthetic polymers imported or manufactured at greater than one tonne per year and which do not fulfil the requirements of any other category.

Self-Assessment

It is possible to submit a self assessment application for the following categories of chemicals:

1. Polymer of Low Concern (PLC) (See Section 5.4 for further information)

2. Non-hazardous chemicals and non-hazardous polymers other than PLC (See Section 5.7 for further information).

Self-Assessments have a shorter assessment timeframe and lower assessment fees than other certificate categories. Third party applications where data is exempt from the notifier or joint notification applications cannot be accepted as Self-Assessments. Annual reporting and record keeping requirements apply. An extension of a Self-Assessment certificate is not allowed.

Extension of an Original Assessment Certificate

The Act allows for an extension of a current assessment certificate (but not a self-assessment certificate) to cover other companies intending to import or manufacture a notified chemical. If one or more companies wish to import or manufacture a notified chemical, their name(s) may be added to the assessment certificate provided that the holder of the original certificate is in agreement and that a certain number of other criteria are met. An extension of a Self-Assessment certificate is not allowed. Refer to Chapter 5 - Certificates for further information.

3.5. Summary of New Chemicals Notification Categories

	Categories								Other kinds of Applications			
	Exemptions-	CEC	LVC	CUP	EOP	PLC	Ltd	Std	Permit renewal	Self Assessment	Early Introduction Permit	Extension of an Original Asst Certificate
Outcome	Letter of consent	Permit	Permit	Permit	Permit	Certificate	Certificate	Certificate	Permit	Certificate	Permit	Certificate
Chemical Amount Introduced	≤100 kg/yr	≤4 tonnes	≤100 kg/yr	Unlimited	Unlimited	Unlimited	≤1 tonne/yr[1] ≤10 tonne/yr[1] for site limited chemicals	>1 tonne/yr	As for previous LVC, CEC, CUP, EOP	As for PLC, Ltd or Std	As for PLC, Ltd or Std	As for PLC, Ltd or Std
Duration of Certificate or Permit	Not applicable	Up to 2 years	36 months	36 months	36 months	5 years	5 years	5 years	36 months (LVC/CUP/EOP) and up to 2 yrs (CEC)	5 years	Until certificate issued, or permit rescinded	5 years from granting of original certificate
Assessment Timeframe	Not applicable	14 days[2]	20 days	28 days[3]	20 days[4]	90 days	90 days	90 days	20 days (LVC/EOP), 28days (CUP) and 14 days[2] (CEC)	28 days	28 days	45 days

For details of current fees see Appendix 4 or the NICNAS website. http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_And_Charges.asp

1 Volume restriction does not apply to synthetic polymers with NAMW > 1000.

2 While there is no legislative time frame for CEC applications, they are usually processed within 14 days.

3 While there is no legislative time frame for CUP applications, they are usually processed within 28 days.

4 While there is no legislative time frame for EOP applications, they are usually processed within 20 days.

4. General Notification Procedures

This chapter outlines the general form and content of applications for new chemical assessments. For additional information about specific application categories and other kinds of application, refer to Chapters 5 & 6. Any forms referred to can be downloaded from theNICNAS website http://www.nicnas.gov.au/Forms.asp

4.1 General Information

4.1.1 Identification of Notifier

The notifier must be the introducer of the chemical. The following information must be provided with each notification statement, using the standard form provided for this information:

- Business name, Australian Business Number (ABN) and address
- Business phone number
- Address for correspondence
- Technical contact details
- Date of submission

For the technical contact, identify a person who can provide the Director with additional information if required. The title or position of the contact, for example, Development Manager or Chief Chemist, should be given. This is normally the primary contact for NICNAS during screening and assessment.

The notifier must also indicate the class of notification or application, that is:

- type of notification, for example, Standard Notification, Low Volume Chemical Permit, extension of an assessment certificate, Secondary Notification;
- whether it is based on an assessment made under a foreign scheme; and
- whether there is application is for an early introduction permit;

4.1.2 Statement and Certification

Each notification must be accompanied by a statement that:

- there is full entitlement to the use of data which has not been produced in laboratories owned or otherwise affiliated with the notifier; and
- all information notified is true and correct.

These declarations are included on the standard forms for each type of application and notification.

Notifiers must also indicate whether:

- the test data have been generated in accordance with the OECD's *Guidelines for the Testing of Chemicals* or other standard test methods recognised by the Director; and
- the laboratory used to generate the test data operated under standards equivalent to those in the OECD's Principles of Good Laboratory Practice.

4.1.3 Submission of Information

All applications and information relating to notifications should be sent to the:

Director of NICNAS
National Industrial Chemicals Notification and Assessment Scheme
GPO Box 58
SYDNEY NSW 2001

If courier is used, it should be sent to:

334-336 Illawarra Road
Marrickville NSW 2004

If information provided is submitted by post, it can be sent to NICNAS street address or PO Box address.

4.1.4 Joint Application

If two or more importers or manufacturers wish to apply for an assessment certificate or a permit, a joint application may be submitted (with only a single fee).

4.1.5 Withdrawal of Notification

A notifier may withdraw an application for an assessment certificate at any time before the assessment report of the chemical is published. The notifier can regain all documents submitted in the notification, including the application for an assessment certificate, by writing to the Director and asking for their return. The notifier may also be eligible for a refund of part of the application fee.

Similarly, a notifier may withdraw an application for a permit.

4.2 Form and Content of Notifications

All applications, notification statements and other documents must be clearly legible and submitted in English. Any translation into English must be accompanied by a signed statement certifying that the translation has been carried out by a competent person or organisation. MSDS must be clearly legible and suitable for publication.

Each notification category has a specific standard form and checklist. These along with additional forms such as an application for any exempt information are located on the NICNAS website.

The specific application forms and notification checklists should be used as far as possible in the submission of data and information required in the notification package. However, most notifications will not be restricted to the completion of these forms and other information will be required, for example, toxicity studies, MSDS and occupational exposure data. The requirements for each notification category are detailed in Chapter 5 and Chapter 6. Notifiers must provide all the information available to them to enable a thorough assessment of the chemical, and they must declare that they are entitled to use and to give the Director all the data in the notification.

Notifiers may seek the professional assistance of consultants in the preparation of submissions. Refer to industry associations or professional associations for guidance in this matter.

Notification packages should be submitted in loose-leaf form rather than be bound.

If known by the notifier, the expected date of commencement of manufacture or importation should be provided in the notification statement.

4.2.1 Number of Copies

For Standard Notifications, Limited Notifications and PLC Notifications, two copies of the complete notification statement, including the technical dossier and other items of information, are required.

For permits, only one copy of all the information required is sufficient, as information submitted for permit applications is not usually sent to other agencies for environmental assessment.

Please refer to NICNAS Matters June 2005 for further details regarding electronic lodgement. Electronic submission of templates in WORD format (not in PDF format) should be provided to NICNAS. Electronic copies in WORD format (not in PDF format) are needed when a template rebate is requested, as well as for self assessment. Even if electronic submission of templates is provided to NICNAS, appropriate number of hard copy should be provided, i.e., two for certificates and one for permits.

4.3 Data Requirements

For most notification categories, the data requirements are described in terms of the Schedule to the Act. For Standard and Limited Notifications, there are different data requirements depending on whether the chemical is a polymer or a non-polymer.

Schedule requirements are divided into Parts A, B, C and D.

Part A

- a statement of which parts of the Schedule are being addressed in the notification;

- a summary of the chemical's occupational health, public health and environmental effects;
- a summary of how the chemical meets the definition of a hazardous substance in accordance with the *Approved Criteria for Classifying Hazardous Substances*[1]; and
- a bibliography of all references used in the notification package.

Part B

- identification, composition and properties of the chemical;
- use and manufacture/import volume;
- exposure data (occupational health, public health and environmental);
- label and MSDS; and
- emergency procedures.

Part C

- results of experimental animal and in vitro toxicological and ecotoxicological studies; and
- biodegradability and bioaccumulation data.

Part D

Specific for polymers and includes:

- molecular weight data;
- residual monomer and impurity data; and
- stability data.

Table 4.3 - Data to be submitted with applications for each notification category

Refer to Appendix 12 - Schedule of data requirements for description of individual paragraphs.

Category	**Data to be Submitted**	
	Non-Polymers	Polymers
PLC	N/A	As per Form 1-PLC
SAPLC	N/A	As per Form 1 - PLC Self Assessment

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

CEC	As per Form CEC-1	
LVC*	As per Form LVC-1	
EOP	As per Form EOP-1	
CUP*	As per Form CUP-1	
LTD	AB	ABD
STD	ABC	ABCD
SANHC	As per Form 1-Self-assessment Non PLC	
SANHP	As per Form 1-Self-assessment Non PLC	

Key:

A. Part A of the Schedule

B. Part B of the Schedule

C. Part C of the Schedule

D. Part D of the Schedule

Polymers include both synthetic polymers and biopolymers.

* certain data may be required to demonstrate criteria

The scheduled items in Table 4.3 above represent a minimum set of data requirements. If additional data is available to the notifier, it should be provided to NICNAS as part of the notification package. Refer to Request for Further Information by Director (chapter 4.8) for more information.

4.3.1 Submission of Test Results

For certificate categories, the technical dossier submitted must include the full reports of all chemical testing. The test methods should be described in sufficient detail to enable the assessor to determine the acceptability of the method. Indicate whether a standard guideline, for example, the OECD Guidelines for the Testing of Chemicals, was used.

Other techniques may be acceptable if they constitute a valid method for determining the required information. This will be determined on a case-by-case basis.

The test method used, and the testing organisation, must be indicated for each data item in the notification statement. For testing carried out in Australia, notifiers must indicate whether the testing has been carried out in accordance with National Association of Testing Authorities' (NATA) standards.

It is preferred that data submitted in support of an application should have been obtained in accordance with currently accepted principles of good laboratory practice, for example, the OECD Principles of Good Laboratory Practice. Tests conducted prior to 1981 may not have been carried out in accordance with good laboratory practice, but recently obtained tests will be expected to conform.

There are specific responsibilities regarding the observance of good laboratory practice on both the manufacturers and importers who require tests to be carried out; and on the managers of the laboratories where the tests are carried out. Therefore, manufacturers and importers who arrange for tests to be carried out in a laboratory not under their control must ensure that the manager of that laboratory is informed of his or her obligations with respect to good laboratory practice before the testing begins.

A quality assurance report should also be provided with each study.

4.3.2 Variation of Data Requirements

NICNAS provides for some flexibility in the provision of data items in the notification statement accompanying applications for an assessment certificate. Variation of data requirements can be gained by written application and subsequent approval from the Director. For example, provision of a data item may be scientifically inappropriate, not technically possible or not economically feasible. Sufficient information must be available to enable the Director to make an adequate assessment of the chemical.

A fee must accompany any application to omit or substitute the data items required by the Schedule. Applications for variation must be made on Form 2 (located on the NICNAS website), which should be part of the notification package when applying for an assessment certificate.

When considering an application for variation of data requirements, the Director may allow the omission of certain data items if he or she is satisfied that:

- the introduction of the chemical is not against the public interest;
- the omissions are justified; and
- an adequate assessment of the occupational health, public health and environmental hazards of the chemical can be made without the data items.

In some cases, the Director may allow or recommend the substitution of certain data items with alternatives.

Where the notifier considers that it would not be technically possible to carry out a specified test, or to obtain results for the test, an application for a waiver for the test or relevant data item may be submitted. For example, if the chemical is a gas at room temperature, a feeding study cannot be carried out. Justification for the omission must be included under the appropriate item heading in the notification statement.

The notifier may consider that a specified test or data item is irrelevant, unnecessary or scientifically inappropriate in the evaluation of the potential occupational health, public health and environmental hazards of the chemical. For example, an eye irritation test may be unnecessary for chemicals with a pH above 11.5 or below 2 as irritant effects may be assumed. For another example, if data shows that the chemical is a skin sensitiser in humans, then a skin sensitisation test in animals is not required. However, if the test has been done and is available, it should be submitted. Any

omission on such grounds must be justified, and included under the appropriate item heading.

The notifier may consider that the generation of a particular data item required by the Schedule is not economically feasible, and that the data item is not essential for adequate occupational health, public health and environmental assessment of the chemical. Such omissions on economic grounds must be fully justified by the notifier, who must satisfy the Director that:

- the cost of generating the data may prohibit the introduction of the chemical; and
- the omission will not affect the preparation of an adequate assessment.

Information to be supplied in this case must include the cost of generating each data item that has been omitted and the cost benefit details associated with the introduction of the chemical. For example, income from expected sales, raw material costs and production costs should be provided. Claims for omitting data items that are based solely on the administrative costs associated with preparing a submission will not be considered.

Each notification that has taken advantage of the flexibility provisions of NICNAS by omitting certain data items specified in the Schedule must include a statement which supports the notifier's claim that sufficient data is being submitted to enable an adequate assessment of the occupational health, public health and environmental hazards of the chemical.

Even if a request for variation of schedule data requirement (form and fees) is provided to NICNAS, we still require calculated data/data on similar chemical/scientific justification for the omitted end points.

The only circumstances where the fee may be waived are when it is physically impossible to conduct a particular test or study. In these cases, an omission will be considered on a case-by-case basis.

4.4 New Chemicals Listed on a Recognised Overseas Inventory

Some countries have listings or inventories of chemicals which have been introduced in that country. The listing indicates that the chemical may have been in use at some time in that country, and consequently there may be certain items of information available about the chemical due to that use. The listing does not necessarily mean that the chemical has been assessed in that country.

Unfortunately at present the provisions of information available to the notifier through the chemical's listing on a recognised overseas inventory won’t be adequate for granting an assessment certificate, as the foreign schemes do not contain sufficient information to cover the schedule data requirements for NICNAS.

4.5 Exempt Information

A manufacturer or importer may consider that certain items of information required in a notification may be harmful commercially if disclosed. For all notification categories, including submissions of additional information, notifiers can claim certain items of information to be exempt information. This means that these items would not be published in the publicly available versions of the assessment report of the chemical or in the *Chemical Gazette*.

Notifiers should clearly indicate those pieces of information in the notification statement and other documents that they wish to claim as exempt information, and give reasons to substantiate each claim. Reasons should address why any prejudice to the commercial interests of the applicant resulting from publication would outweigh the public interest. Form 3 should be submitted with these claims. Further guidelines on confidentiality are detailed in Appendix 6 - Confidentiality.

Exemption cannot be granted for certain items of information described in the Act as 'basic information' [subsection 75(2) of the Act]. Publication of these items is deemed to be in the public interest. Information considered to be basic information is listed in Appendix 2 - Definitions.

In applications for exempt information, the Director weighs the public interest in publishing the information against the potential commercial harm to the notifier. If the Director decides that a claim that certain items of information be exempt from publication is justified, then those items will not be published in the full public report or summary report. However, the items are included in the assessment report. On the other hand, if the claim is rejected, then the Director notifies the applicant, who may appeal to the Administrative Appeals Tribunal for a review of the decision. In all cases, the applicant receives written notice from the Director.

4.5.1 Submission of Information by Persons Other Than the Applicant (Third party data).

There are instances where information may be submitted by persons other than the applicant. For instance, an overseas manufacturer of a chemical may not release confidential information to the importer (who requires it for the preparation of a notification or application). Alternatively, an Australian company (or subsidiary company) may not release confidential information to the import agent. In these instances, the company holding the information may supply it directly to NICNAS on behalf of the applicant. NICNAS will endeavour to hold the information in confidence. However, the onus is on the third party to clearly specify in their submission which information is not to be disclosed to the other party.

- Such information must be forwarded to the Director with a completed Form 5 (located on the NICNAS website)

Submitted data should be numbered according to the appropriate notification checklist. Party A (third party) should clearly indicate which information is not to be disclosed to the applicant (party B).

Any attachments should be clearly identified as having been submitted by the third party (party A) in confidence so that an assessor can easily and unequivocally identify its status during assessment.

Information submitted by this means would need to be eligible for exemption (see Appendix 6 - Confidentiality). The party(ies) may seek clarification on this matter when or before the data is submitted. The information will not be included in the publicly available versions of the assessment report or other documentation sent to the applicant.

4.6 Screening of Assessments

In February 2007, NICNAS introduced a pilot Screening framework. The framework set out screening timeframes, the basis for the return of applications and a refund structure. Details of this framework can be found in the February 2007 *Chemical Gazette*.

Currently there is an option to pay the notification fee for Standard Notifications and Limited Notifications in two parts.

- an initial lodgement fee of $500, which must be paid when the notification is first submitted; and
- the remainder of the notification fee, which is payable within seven days after the Director advises that the notification package is complete.

A complete submission is one that meets the Schedule of Data Requirements contained in the Act, detailed in Appendix 12. Also, the notification must be in the approved format, contain all the relevant data (or variations) and meet the required standards in terms of level of detail.

If the submission is not complete, the applicant will be advised of the outstanding data items required for the assessment, and also that the assessment has not commenced. If the submission is grossly deficient, it will be returned to the notifier with an explanation of the deficiencies. In any event, the assessment will not commence until the notification is considered complete.

The Submit Once - Review Once system does not prevent the Director from requesting additional information at a later time. However, SORO aims to increase efficiency by limiting the need to request additional information during the assessment process.

4.7 Method of payment of assessment fees

Payment Options

1. **CHEQUE PAYMENTS**

Cheques are to be made payable to National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in $AUD. Payments marked **Attn New Chemicals Admin** are to be mailed to:

NICNAS
GPO Box 58
SYDNEY NSW 2001
AUSTRALIA

2. ELECTRONIC FUNDS TRANSFER

Electronic Funds Transfers can only be made if you have an invoice number and or a notification number. Please contact New Chemicals Admin on 02 8577 8800 if you require an invoice number.

If payment is being made from a foreign bank, all bank charges/fees in getting the exact $AUD to NICNAS is payable by the payee.

The details for EFT payments are as follows:

Reserve Bank of Australia	BSB Number:	092-009
London Circuit	Account Number:	11608-5
Canberra ACT 2600	Account Name:	Dept of Health and Ageing Official Departmental NICNAS Special Account

Please quote your Invoice Number and/or Notification number when making the payment.

Please Fax Remittance Confirmation from your bank to NICNAS on: 02 8577 8888

3. CREDIT CARD PAYMENTS

Invoice or Notification number:

☐ MasterCard ☐ Visa

Expiry Date: Amount:

__ __ / __ __ / __ __ $ _____

Credit Card number:

Authorised Signature: Print Name:

- **For further information, please contact New Chemicals Admin on:**
  - Free call: 1800 638 528
  - Phone: (02) 8577 8800
  - Fax: (02) 8577 8888
  - Email: info@nicnas.gov.au
  - or visit our website at **www.nicnas.gov.au**

4.8 Request for Further Information by Director

In certain cases, it may become apparent that the notification statement does not contain all the information required by the Schedule. There may also be a need to obtain clarification about certain pieces of information submitted in the initial notification. For example, ambiguities or inconsistencies in data may need to be resolved, or interpretation of unqualified test data may need to be carried out. In these cases, the Director can ask the notifier to provide more information.

Secondly, the Director might consider that certain information additional to that required under the Schedule is necessary for the proper assessment of the chemical. In these cases, the Director will ask the notifier to provide specific additional test data or information. For example, where long-term exposure to the chemical is likely and short-term or screening toxicity tests indicate possible longer- term effects, chronic toxicity test results may be requested. Another example is the case of CFC replacements, where ozone depleting potential and global warming potential data are normally required.

Also, for chemicals which may be persistent in the environment or bioaccumulate, additional information may be requested. This is to satisfy the requirements of the Stockholm Convention on Persistent Organic Pollutants (POPS), which Australia ratified and came into force on 18th August 2004 (refer to January 2004 *Chemical Gazette).*

The written request by the Director for further information will specify a time period of not less than 28 days for compliance. In cases where further information is to be submitted, the timeframe to complete the assessment begins from the receipt of the complete notification statement.

In order to minimise delays and requests for further information by the Director, it is in the best interest of notifiers to ensure that a complete notification statement is submitted and that the statement is unambiguous. Checklists are provided for each notification category on the NICNAS website to assist notifiers in this matter.

4.9 Provision of New Information During Assessment

During the assessment process, the notifier might become aware of new information relevant to the assessment of the chemical. Such information could include:

- references to the chemical in the scientific literature;
- results of further testing carried out in Australia or in a foreign country;
- new information on occupational, public or environmental exposure;
- new uses of the chemical;
- information available from within the company or from the parent company or supplier;
- information presented at conferences; and
- information from patent specifications.

Any new assessment information, in the form of a separate technical dossier, must be submitted to the Director as soon as practicable. The dossier should make reference to the relevant parts of the Schedule and conform to the general requirements for notification statements as far as possible.

The requirement to provide new information puts the onus on notifiers to regularly monitor the scientific literature and other known information sources with respect to the notified chemical.

The provision of new information as described in this subsection is dependent on the notifier's skills, experience and resources, and any other factors which might affect the notifier's awareness of new information. For example, the notifier's links with parent or associated companies, years in the business and information systems may be taken into account in deciding whether a notifier should have known about the new information.

Failure to provide additional new information on a chemical during its assessment can lead to the suspension of the assessment process until the information is received.

5. Certificate Categories

This chapter provides specific information aimed at helping you to compile the necessary forms and additional documents for each of the certificate assessment categories namely: (PLC, Limited or Standard) and other types of applications (Extension of an Original Certificate and Provision of a Draft Assessment Report) outlined in Chapter 3. Joint applications may be submitted with the fee shared between the applicants.

Information on the assessment process e.g. timeframes and the outcomes e.g. reports and certificates is included in chapter 5.10.

Information on post-assessment obligations is included in chapter 7.

Any forms and checklists referred to can be downloaded from the NICNAS website (http://www.nicnas.gov.au/Forms.asp)

. Current fees and charges can also be found on the NICNAS website.

5.1 Confidentiality

Exemption provisions apply to all certificate notification categories

The notifier can claim for certain items of information to be exempt from publication (see chapter 4.5).

An application for exempt information can be made by filling out Form 3 and paying the fee. Notifiers should also indicate the relevant data items on the appropriate Checklist. Further guidelines on confidentiality are detailed in Appendix 6 - Confidentiality.

5.2 Variation of Data Requirements

NICNAS provides for flexibility of data requirements in a notification. However, the Director needs to be satisfied that the chemical can be adequately assessed without the specific data or by substituting with other data, for example, read across data (analogue).

An application to vary data requirements can be made by filling out Form 2 and paying the fee. Notifiers should also indicate the relevant data items on the appropriate Checklist. Further guidelines on Variation of Data Requirements are detailed in Chapter 4.

5.3 Polymer of Low Concern (PLC) Notification

Notification Requirements

Each notification for a PLC (non self assessed) must consist of:

- the application for an assessment certificate, using Form 1-PLC
- the information about the polymer, comprising the data items listed on Form 1-PLC
- any other information available to the notifier which may assist in the proper assessment of the polymer, for example, additional information on its use
- any application for variation of Schedule requirements (Form 2), with the appropriate fee
- any application for exempt information (Form 3), with the appropriate fee.
- any application for third party information (Form 5)
- the PLC Notification checklist, indicating which items on the form have been completed and items for which an application for exempt information has been made
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form 1-PLC)
- a declaration that all available information has been submitted (included on Form 1-PLC); and
- the appropriate fee

Two copies of each technical dossier are required.

Assessment process and outcomes

In normal circumstances, an assessment of a PLC notification is completed within 90 days of the date of acceptance of a complete application. The certificate is issued within a set time from the completion of the assessment (See 5.10 for more details)

A completed PLC notification results in an assessment report, the issue of an assessment certificate, publication of a summary report in the *Chemical Gazette*, publication of a full public report on the NICNAS website and eventual listing of the chemical on AICS (See 5.10 and chapter 7 for more details).

5.4. Self Assessment: Polymer of Low Concern (PLC)

Notification procedure

The self-assessment submission need consist only of an electronic copy of the signed notification form with attached self-assessment report (Form 1-PLC Self Assessment (WORD 460Kb) Large file warning), the relevant fee, and a copy of the MSDS for the notified polymer. Other than the MSDS, no supporting data such as physicochemical and toxicological studies should be sent with the application. If supporting data is submitted with the application then this application would not be considered a self-assessed application (see Chemical Gazette 5th July 2005 – Audited Self-Assessment - Frequently Asked Questions). Supporting data must be retained for 5 years from the date the certificate is issued and may be subject to audit. In addition, there may be requirements for information to be held confidential, in which case Form 3 - Exempt Information (WORD 72Kb) and the relevant fee should also be submitted

Third party applications where data is exempt from the notifier cannot be accepted as self-assessment. In addition, joint notification applications are not accepted as self-assessments.

To assist in filling out the self-assessment template, there is guidance material within the template in the form of highlighted headings, and a separate Guidance Document (WORD 450Kb) Large file warning which includes suggestions on how to report on the risk posed by the polymer at the appropriate level of detail. The suggested text may be used where appropriate, or more relevant text may be devised by the notifier on a case by case basis. An Example Notification (WORD 460Kb) Large file warning (not a real case) has been prepared by NICNAS and is also available to illustrate the use of the template.

On receipt of a self-assessment submission, NICNAS will screen the notification for three issues:

1. Correct application of the PLC criteria
2. Whether the polymer poses any residual concern; and
3. Completeness of the self-assessment

If the PLC criteria have been found to have been incorrectly applied in determining the status of the polymer, based on the information in the self-assessment report, the notification will be rejected and the notifier advised to re-notify in the correct category.

There may be cases where a polymer fully meets the PLC criteria, but some residual concern remains, primarily in cases where exposure is high such as where polymers with significant water solubility are released directly to the environment (eg cosmetic or water treatment applications) or where polymers are constituents of products deliberately applied to the body (eg cosmetics) or in food contact applications. In addition, if effects are observed during toxicological or ecotoxicological studies and these are relevant to exposure conditions, residual concern may be invoked. NICNAS may request some additional information to enable assessment of the specific concern. The notifier will be informed of the circumstances, including any intent to request additional information, at 14 days after receipt of the notification. If a significant health or environmental concern is identified by NICNAS during the screening period, the self-assessment process will lapse, with the assessment reverting to the normal 90-day timeframe.

The self-assessment report will be the only document received by NICNAS and as such is required to be a complete record of risk assessment for the polymer. If there are gaps or inconsistencies in the risk assessment document, the notifier will be requested to revise the document and re-submit it. The assessment clock will not be started until NICNAS has accepted that the report is complete.

Assessment process and outcomes

NICNAS will prepare the Self-Assessment Report, Full Public Report, Summary Report and certificate for the notifier and will forward these by Day 28 of the assessment clock. The report may contain information prepared by NICNAS on other matters where these have been flagged in a request for additional information. On receipt of the report, the notifier will have the opportunity to advise NICNAS of confidentiality concerns within 14 days, after which time, the Full Public Report and Summary Report of the assessment will be published on the NICNAS website. (See 5.10 and Chapter 7 for more details).

Annual Reporting and Record keeping

Under the Act, a person who is issued a self-assessed assessment certificate must keep records to support any statement made in or in connection with the application for the certificate for 5 years from the date the certificate is issued and also must provide a report to the Director before or on 28 September of the following registration year. This report must state the following:

(a) the name of the chemical in respect of which the permit or certificate is issued; and

(b) the volume of the chemical that was introduced during the year; and

(c) any adverse effect of the chemical on occupational health and safety, public health or the environment of which the person has become aware during the year.

5.5 Limited Notifications

Notification requirements

A Limited Notification occurs when a full assessment of the occupational health, public health and environmental effects of the chemical is not required. In this case, data items for Part C of the Schedule (toxicological and ecotoxicological data) are not required. However data items for Part C should be provided if available.

Each Limited Notification must consist of:

- the application for an assessment certificate, using Form 1-LTD
- the technical dossier of information about the chemical, comprising Parts A and B of the Schedule, and Part D for a synthetic polymer or biopolymer (see Chapter 4 and Appendix 12 for further information)
- any other information available to the notifier which may assist in the proper assessment of the chemical, for example, additional occupational, toxicological or environmental exposure data
- any application for variation of Schedule requirements (Form 2), with the appropriate fee
- any application for exempt information (Form 3), with the appropriate fee.

- any application for third party information (Form 5)
- the Limited Notification checklist, indicating which items in the Schedule have been submitted, items for which an application for variation has been made, and items for which an application for exempt information has been made
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form 1-LTD)
- a declaration that all available information has been submitted (included on Form 1-LTD); and
- the appropriate fee

For all Limited Notifications, the technical dossier of information submitted must include the full reports of all testing, for example, for the physico-chemical properties. Methods should be fully described to enable the assessor to identify the methods used and the protocols followed.

Toxicity results must include the observations and results obtained for individual animals. Summaries and summary tables of mean score observations alone are not acceptable. A statement should be included specifying whether the laboratory practices followed in obtaining data were in accordance with the currently accepted principles of good laboratory practice.

Two copies of the technical dossier are required.

Assessment process and outcomes

In normal circumstances, an assessment of a Limited notification is completed within 90 days of the date of acceptance of a complete application. The certificate is issued within a set time from the completion of the assessment (See 5.10 for more details)

A completed Limited notification results in an assessment report, the issue of an assessment certificate, publication of a summary report in the *Chemical Gazette*, publication of a full public report on the NICNAS website and eventual listing of the chemical on AICS (See 5.10 and chapter 7 for more details).

5.6 Standard Notifications

Notification Requirements

Each Standard Notification must consist of:

- the application for an assessment certificate, using Form 1-STD
- the technical dossier of information about the chemical, comprising Parts A, B and C of the Schedule, and Part D for synthetic polymer or biopolymer (see Chapter 4 and Appendix 12 for further information)

- any other information available to the notifier which may assist in the proper assessment of the chemical, for example, additional toxicity data
- any application for variation of Schedule requirements (Form 2), with the appropriate fee
- any application for exempt information (Form 3), with the appropriate fee
- any application for third party information (Form 5)
- the Standard Notification checklist, indicating which items in the Schedule have been submitted, items for which an application for variation has been made, and items for which an application for exempt information has been made
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form 1-STD)
- a declaration that all available information has been submitted (included on Form 1-STD); and
- the appropriate fee.

For all Standard Notifications, the technical dossier of information submitted must include the full reports of all testing, for example, for the physico-chemical properties. Methods should be fully described to enable the assessor to identify the methods used and the protocols followed.

Toxicity results must include the observations and results obtained for individual animals. Summaries and summary tables of mean score observations alone are not acceptable. A statement should be included specifying whether the laboratory practices followed in obtaining data were in accordance with the currently accepted principles of good laboratory practice.

Two copies of the technical dossier are required.

Assessment process and outcomes

In normal circumstances, an assessment of a Standard notification is completed within 90 days of the date of acceptance of a complete application. The certificate is issued within a set time from the completion of the assessment (See 5.10 for more details)

A completed Standard notification results in an assessment report, the issue of an assessment certificate, publication of a summary report in the *Chemical Gazette*, publication of a full public report on the NICNAS website and eventual listing of the chemical on AICS (See 5.10 and chapter 7 for more details).

5.7 Self assessment: non-hazardous chemicals and non-hazardous polymers

To establish that a chemical or polymer is non-hazardous, certain data is required to be held by the notifier. The data needed is detailed below.

Health Criteria

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 *Approved Criteria for Classifying Hazardous Substances*[1]. 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.

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 and Maximisation tests) OECD TG 429 (LLNA)
7. Rat, repeat dose toxicity *		
	Oral NOAEL >50 mg/kg bw/day	OECD TG 407 – 409, 422
	Dermal NOAEL > 100 mg/kg bw/day	OECD TG 410 – 411
	Inhalation NOAEL > 0.25 mg/L, 6h/day	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

Table 1. Data requirements for non-polymers under the self-assessment scheme
* Data from only one repeated-dose mammalian toxicity test required.

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 self assessment scheme as case by case NICNAS assessment is

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

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.

For a polymer, the above requirements hold for biopolymers and low molecular weight synthetic polymers (NAMW < 1000). For synthetic 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

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 physico-chemical data are also required to be presented in the self-assessment report.

Notification procedure

The self-assessment submission need consist only of an electronic copy of the signed notification form with attached self-assessment report (Form 1-Self Assessment non PLC (word document)) the relevant fee, and a copy of the MSDS for the notified chemical/polymer. Other than the MSDS, no supporting data such as physicochemical and toxicological studies should be sent with the application. If supporting data is submitted with the application then this application would not be considered a self-assessed application (see Chemical Gazette 5th July 2005 – Audited Self-Assessment - Frequently Asked Questions). Supporting data must be retained for 5 years from the date the certificate is issued and may be subject to audit. In addition, there may be requirements for information to be held confidential, in which case Form 3 - Exempt Information (WORD 72Kb) and the relevant fee should also be submitted. Third party applications where data is exempt from the notifier cannot be accepted as self-assessment. In addition, joint notification applications are not accepted as self-assessments.

To assist in filling out the self-assessment template, there is guidance material within the template in the form of highlighted headings. A separate guidance document which includes suggestions as to how to report on the risk posed by the chemical at the appropriate level of detail is also available.

On receipt of a self-assessment submission, NICNAS will screen the notification for three issues:

1. Correct application of the non-hazardous criteria
2. Whether the chemical/polymer poses any residual concern; and
3. Completeness of the self-assessment

If the non-hazardous criteria have been found to have been incorrectly applied in determining the status of the chemical/polymer, based on the information in the self-assessment report, the notification will be rejected and the notifier advised to re-notify in the correct category.

There may be cases where a chemical/polymer fully meets the non-hazardous criteria, but some residual concern remains. In these cases, NICNAS may request additional information to enable assessment of the specific concern. The notifier will be informed of the circumstances, including any intent to request additional information, at 14 days after receipt of the notification. If a significant health or environmental concern is identified by NICNAS during the screening period, the self-assessment process will lapse, with the assessment reverting to the normal 90-day timeframe.

The self-assessment report will be the only document received by NICNAS and as such is required to be a complete record of risk assessment for the chemical/polymer. If there are gaps or inconsistencies in the risk assessment document, the notifier will be requested to revise the document and re-submit it. The assessment clock will not be started until NICNAS have accepted that the report is complete.

NICNAS will prepare the Self-Assessment Report, Full Public Report, Summary Report and certificate for the notifier and will forward these by Day 28 of the assessment clock. The report may contain information prepared by NICNAS on other matters where these have been flagged in a request for additional information. On receipt of the report, the notifier will have the opportunity to advise NICNAS of confidentiality concerns within 14 days, after which time, the Full Public Report and Summary Report of the assessment will be published on the NICNAS website.

Annual Reporting and Record Keeping

Under the Act, a person who is issued a self-assessed assessment certificate must keep records to support any statement made in or in connection with the application for the certificate for 5 years from the date the certificate is issued and also must provide a report to the Director before or on 28 September of the following registration year. This report must state the following:

(a) the name of the chemical in respect of which the permit or certificate is issued; and

(b) the volume of the chemical that was introduced during the year; and

(c) any adverse effect of the chemical on occupational health and safety, public health or the environment of which the person has become aware during the year.

5.8 Extension of Assessment Certificate

Each application should consist of:

- the application for an extension of the original assessment certificate, using Form 1-EXT;
- the technical dossier of information (see Chapter 4 and Appendix 12), comprising:
    - for a PLC, the data items listed on Form 1-PLC ; or
    - for any other chemical or polymer other than PLC, paragraphs 1, 2, 3, 5, 11 and 12 of Part B of the Schedule, that is, the identity and composition of the chemical, its use and volume of use, and a label and MSDS;
- supplementary information on matters affecting occupational, public and environmental exposure if the application contains any significant differences from the original application;
- any new health and environmental effects information that is available about the notified chemical;
- confirmation that the applicant has access to the full public assessment report for the notified chemical;
- the written agreement of the holder of the original assessment certificate to the application for extension, using Form 14;
- any application for exempt information (Form 3), with the appropriate fee
- a statement that the applicant is entitled to use and give the Director all the data in the notification (included on Form 1-EXT);
- a declaration that all available information has been submitted (included on Form 1-EXT); and
- the appropriate fee

Note: Information provided in an application for extension for which the extension applicant claims confidentiality is not provided to the original notifier.

Assessment Process And Outcomes

Under the Extension of an Original Assessment Certificate Notification, the original assessment report is modified within 45 days after application or after additional information was submitted.

The modified report acts as a consolidated source of information. It contains all the information from the original assessment plus new information from the extension notification. Therefore the modified report will provide a link between the original notifier's use and name by which the chemical will be known in Australia and the extension applicant's use and name by which the chemical will be known in Australia.The following reports are prepared:

- a list of the modifications to the assessment report, which may contain exempt information;
- a list of the modifications to the assessment report without the exempt information;
- a modified assessment report (the version containing exempt information);
- a modified full public report (modified assessment report without the exempt information);
- a list of modifications to the summary report; and
- modified summary report.

Following the assessment of information and preparation of reports, a copy of the modified assessment report is sent to the holder of the original assessment certificate and the applicant for extension. The copy of the report sent to the holder of the original assessment certificate will not contain exempt information.

5.9 Electronic Draft Assessment Report Using NICNAS Template

A rebate of up to 15% of the assessment fee for Standard Notifications, Limited Notifications and Polymer of Low Concern Notifications is available to applicants who submit an acceptable written draft assessment report with their notification statements. In practice, this applies principally to the electronic lodgement of notification, for limited and standard notifications only, using the template on the website.

Applicants for the rebate must pay the full notification fee when lodging their notification. The rebate will be returned by NICNAS if the draft report meets the criteria outlined below.

The criteria defining an acceptable written draft assessment report fall into three broad areas:

- approved format;
- level of detail required for each section; and
- completeness of the submission.

For further information see Rebates in Chapter 8 of this handbook.

Approved Format

The format must be consistent with the current requirements under the Schedule. The certificate notification template has been designed to provide information about the chemical in a standardised format and also to comply with the notification requirements of the Act. The permit notification template is also available and use of the template generally simplifies the permit application process. However, there are no rebates associated with their use. Templates are available electronically from the NICNAS website

Level of Detail

Sufficient information is required to enable an assessment of the occupational health, public health and environmental effects and exposure. The report should include details of tests performed and a summary of any toxicity and ecotoxicity data, together with copies of the full supporting study reports.

Completeness

Notifiers should provide a detailed explanation of the manufacturing and/or import process. Notifiers should also describe the likely occupational health, public health and environmental hazards of the notified chemical and the potential for occupational, public and environmental exposure. In considering this information, the notifier must determine the risk of any adverse occupational health, public health or environmental effects and consider the practical options to control such risks. The draft assessment report must include recommendations for the safe use, handling and disposal of the chemical.

Notifiers applying for the rebate in assessment fees should provide the following:

- the normal application for an assessment certificate, using Form 1-STD for a Standard Notification and Form 1-LTD for a Limited Notification;
- an application for the rebate on Form 13;
- the draft assessment report (word document) , preferably on CD, according to the criteria outlined above;
- any other information available to the notifier which may assist in the comprehensive assessment of the chemical, for example, additional occupational exposure data;
- any application for variation of Schedule requirements (Form 2), with the appropriate fee
- any application for exempt information (Form 3), with the appropriate fee
- the appropriate notification checklist, indicating which items in the Schedule have been submitted, items for which an application for variation has been made, and items for which an application for exempt information has been made; and
- the appropriate fee for the type of notification.

5.10 Assessment Process and Reports

In normal circumstances, an assessment for a new industrial chemical is completed within 90 days from the date of acceptance of an application for an assessment certificate, that is, the date of receipt of the complete notification package. Following provision of the assessment report to the applicant, there is a two-week period for the applicant to apply for variation to the report. The assessment certificate for a new chemical is given to the notifier, within 7 days of consent to publish, or at some time after 28 days if no consent is provided.

In certain circumstances, the time for an assessment will exceed 90 days, that is:

- when additional information has been requested by the Director, the period of 90 days will begin from the date of receipt of the additional information; or
- when an unusually detailed or complex assessment is necessary, an additional 90 days may be granted, with the applicant being advised as soon as practicable.

Following the assessment of a notified chemical under the Standard Notification, Limited Notification and PLC notification categories, the following reports will be written and sent to the notifier:

- assessment report (composed of the full public report and any exempt information); and
- full public report (which does not include exempt information); and
- summary report (condensed version of the full public report for publication in the *Chemical Gazette*).

If information has been supplied by a third party on behalf of the notifier, then this confidential information will be deleted from the assessment report before it is sent to the notifier, provided that the information is justifiably exempt from publication. Further guidelines on confidentiality are detailed in Appendix 6 - Confidentiality.

When the reports are sent to the notifier, advice will be given regarding publication of the reports and possible variation of the assessment report before publication (see sections below).

5.10.1 Requests for Variation of Assessment Reports

Within 14 days of receipt of an assessment report (non self assessed), the notifier may ask the Director to make changes to it, stating the reasons for the request. For example, the notifier may disagree with the conclusions and/or recommendations on scientific grounds and request a change (or variation) to the report.

To request a variation of the assessment report, notifiers should complete Form 4 and attach the appropriate fee. Notifiers should ensure that the reasons for the request to vary the report are clearly stated. Supporting documentation may be necessary.

The Director may either agree to the changes or refuse to change (vary) the report. Whichever way the Director decides, the notifier will be given notice in writing of the decision.

The notifier may then:

- give written consent for the publication of the reports;
- appeal against the decision (see Appendix 8 - Appeals); or
- withdraw the notification.

Applications to vary assessment reports after publication can also be made (see below).

5.10.2 Publication of Assessment Reports

If the Director has not received any request for changes to an assessment report from the notifier within 28 days of first forwarding the report, then it may be published.

Under the Act, the assessment report is published by:

a. publishing the summary report of the notified chemical in the *Chemical Gazette*;
b. giving a copy of the assessment report to Department of the Environment, Water, Heritage and the Arts, and
c. giving a copy of the full public report to any person that the Minister directs.

A copy of the full public report is published on the NICNAS website.

5.10.3 Variation of Assessment Reports after publication

Notifiers may apply to the Director for variation of the full public report within 28 days after the summary report has been published in the *Chemical Gazette*. As for applications for variation before publication, notifiers should complete Form 4 and attach the appropriate fee. The Director must publish a notice in the *Chemical* Gazette setting out each proposed variation. Under this provision of the Act, third parties, such as members of the public, can similarly apply to the Director for variation of the report after publication.

5.10.4 Assessment Certificates

The assessment certificate for a new chemical is given to the notifier, within 7 days of consent to publish, or at some time after 28 days if no consent is provided. The chemical will be added to the AICS five years after the assessment certificate is given, unless an application for early AICS listing is made.

Assessment certificates can be transferred only in special circumstances [section 73 of the Act], that is:

- upon the death of the holder of the assessment certificate;
- upon bankruptcy;
- upon liquidation; or
- upon disposal of the business.

Any new holder of an assessment certificate must advise the Director as soon as possible. A form (Form 73) can be located on the NICNAS website.

6. Permit Categories

This chapter provides further information including how to compile the necessary forms and additional documents for each of the permit assessment categories (CEC LVC, CUP and EOP) and other types of applications (Early Introduction Permits and renewal of existing permits) outlined in Chapter 3.

Any forms and checklists referred to can be downloaded from the NICNAS website (http://www.nicnas.gov.au/Forms.asp).

6.1 Exempt Information

Exemption provisions apply to all permit notification categories.

In these cases, no assessment reports are published. A notice is placed in the *Chemical Gazette* (see Appendix 5). If the applicant does not want the chemical identity or specific use published, an application for this information to be exempt from publication in the *Chemical Gazette* can be made, with reasons to substantiate each claim. Reasons should address why any prejudice to the commercial interests of the applicant resulting from publication would outweigh the public interest.

Further guidelines on confidentiality are detailed in chapter 4.5 and Appendix 6 - Confidentiality.

6.2 Commercial Evaluation Chemical (CEC) Permits

The Commercial Evaluation Permit allows the introduction of a chemical without a detailed notification package, or full assessment, to provide a cost effective way for industry to extend existing markets or create new markets. It allows the manufacture or import of up to four tonnes of a chemical for a period of up to two years for the purposes of commercial evaluation of that chemical.

If the product to be evaluated is a mixture of chemicals, then each new chemical constituent of the mixture requires an individual permit.

Commercial Evaluation

The commercial evaluation permit allows the chemical to be used only for the specified purpose of commercial evaluation, for example, to test a new polymer in a surface coating when a large quantity is required to fill paint lines, or to evaluate a new process that requires a new industrial chemical. The use of the chemical is specified in the permit, together with the period of introduction and the maximum quantity permitted.

Applications for Commercial Evaluation Permits will be refused if there is insufficient evidence that the chemical is for commercial evaluation only. It is unlikely that a company could obtain a series of Commercial Evaluation Permits to cover importation over a period of years.

Volume

Although the maximum introduction volume allowed is four tonnes, notifiers should only apply for quantities that reasonably reflect the needs for commercial evaluation of the chemical. Notifiers will need to provide sufficient justification for their claims.

Duration

The maximum duration introduction of a permit is 2 years. Use of the chemical under the permit may continue beyond the period of introduction, providing the chemical is used for the purposes of commercial evaluation.

If the period of a commercial evaluation will exceed the period of introduction under the Permit, the applicant can request permission from the Director for extra use time beyond the allowed period of introduction before the Permit expires and explain why the extended use period is needed.

User Agreements

To ensure adequate safeguards, under subsection 21D(2) of the Act, User Agreements between the applicant and all users conducting the evaluation of the chemical need to be provided to NICNAS. Only those proposed users who have completed a User Agreement can use the chemical. Under the agreement, users agree to be bound by the conditions of the permit until the end of the evaluation and to provide NICNAS with a final report on permit expiry. The report must include any health or environmental effects observed during use. User Agreements (Form 8) can be submitted to NICNAS after the initial application.

In some instances, applicants may wish to have permits issued before agreements are made. These applications will be considered on a case-by-case basis. However, a likely scenario is that the Director may need to impose a further permit condition, for example, that the chemical could not be passed on to, or used by, another person without an agreement being first forwarded to NICNAS. If no agreement is submitted with an application for a Commercial Evaluation Permit, applicants need to explain their customer arrangements.

The commercial evaluation permit system is not available without a User Agreement. That is, a CEC permit cannot be issued for chemicals to be evaluated through retail sale where a user agreement cannot be obtained, for example, end-use consumer products such as cosmetics and domestic cleaners.

Application requirements

Each notification for a CEC permit must consist of:

- the application for a CEC permit, using Form 1-CEC;
- the total quantity of chemical to be introduced, including a written explanation justifying the quantity (this should relate to the chemical entity);
- the total time period for introduction;

- the use of the chemical, clearly indicating the purpose for which the chemical is being evaluated. Description of distribution arrangements should be included and all users, including end-users, clearly identified;
- details of any previous or current permits (if the applicant has knowledge of any permits which have been previously issued in Australia for the chemical under any legislation, including this Act, particulars should be provided);
- User Agreements .The applicant and each proposed user of the chemical must sign an agreement to comply with the conditions of the permit. This agreement must be included with the application.
- a summary of the chemical's occupational health, public health and environmental effects (as in Paragraph 2 of Part A of the Schedule);
- information about the chemical, comprising the data items listed in paragraphs 6(a)(i) to 6(iv), 7, 8, 11 and 12 of Part B of the Schedule (see Appendix 12);
- any application for exempt information [Form 3], with the appropriate fee
- the CEC checklist, indicating which items on Form 1-CEC have been completed and items for which an application for exempt information have been made;
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form 1-CEC);
- a declaration that all available information has been submitted (included on Form 1-CEC); and
- the appropriate fee

The necessary standard forms for a CEC Notification including the "Template for preparation of CEC submission with guidance material", are included on the NICNAS website.

Assessment Process and Permit Conditions

There is no statutory deadline for issuing Commercial Evaluation Permits. The process is usually completed within 14 days.

Commercial Evaluation Permits include the following standard conditions plus any additional chemical-specific recommendations:

- The maximum quantity of chemical that can be introduced and the introduction period for the purpose of commercial evaluation;
- The applicant must advise NICNAS in writing before the permit expires, if the period of commercial evaluation is to extend beyond the duration of the permit;
- The Applicant must forward any outstanding User Agreement forms to the Director, prior to the chemical being distributed to or used by the user;

- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls;
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- The MSDS for the chemical and products containing it must carry advice that the chemical is being manufactured or imported under a Commercial Evaluation Permit granted under section 21G of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Suggested wording is: '…….. is being introduced under a Commercial Evaluation Permit granted under section 21G of the *Industrial Chemicals (Notification and Assessment) Act 1989*.' ;
- Disposal of waste should be in accordance with Local, State and federal government regulations;
- Records are to be kept at the site(s) of use of the quantity used, any adverse occupational health and safety, public health and environmental effects resulting from use;
- Holders of the Permit are to report any adverse occupational health and safety, public health and environmental effects to the Director as soon as possible; and
- At the end of the evaluation, the notifier must advise the Director of:
    1. quantities used,
    2. means of disposal of any excess quantity,
    3. any adverse occupational health and safety, public health and environmental effects during permit use, and
    4. the outcome of this commercial evaluation.

The Director may by written notice impose further conditions or revoke or vary any condition, after the permit has been issued.

Under the Act, there is a penalty if the holder of a CEC permit contravenes any permit condition without a good reason. The Director may also by written notice cancel a permit. Chemicals that are the subject of a CEC permit are not eligible for listing on the AICS.

If a Commercial Evaluation Permit is in force, a second permit for the chemical cannot be issued to the same notifier or customer (proposed user of the chemical).

If the commercial evaluation of the chemical proves satisfactory and the notifier wishes to continue importing the chemical for full-scale commercial use, the notifier

should allow sufficient time to obtain an assessment certificate. Joint applications may be submitted with the fee shared between the applicants.

Chemicals that are the subject of a CEC Permit, are not eligible for listing in the AICS.

Publication

Notice of the granting of a Commercial Evaluation Permit will be published in the *Chemical Gazette*. Details published are as follows:

- name of the chemical or trade name;
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued;
- volume of chemical which may be introduced;
- duration of the permit (maximum two years); and
- general use of the chemical.

Final Report

At the end of the commercial evaluation process each Permit holder must provide a Final Report to the Director.

Annual reporting and record keeping

A person who is issued a commercial evaluation permit must also 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.

Renewal of CEC permit

Existing CEC permits can be renewed provided certain criteria are met (see section 6.7 for further information). A CEC permit can be renewed only once (NEW CHEMICALS-RENEWAL OF PERMITS-FAQ).

6.3 Low Volume Chemical (LVC) Permits

A LVC permit allows a chemical to be introduced at a maximum quantity of 100 kg per year, or 1000 kg where certain criteria are met, for a maximum period of three years.

There is no longer a limit on the maximum total amount of a chemical that can be introduced by all companies nationwide i.e. more than one company can hold a LVC permit allowing the introduction of the maximum quantity per year for the same chemical. However, if two or more companies submit a joint application the maximum quantity would be shared among the applicants.

Volume

The LVC permit allows the chemical to be introduced at a maximum quantity of 1000 kg per annum where the following low-hazardous criteria are met (otherwise the volume limit is 100 kg):

Chemicals including polymers with a NAMW <1000

Endpoint	*Criteria*
Acute oral toxicity	Not classified as hazardous*
Acute dermal toxicity	Not classified as hazardous*
Acute inhalation toxicity	Not classified as hazardous*
Skin irritation	Not classified as hazardous* or classified* with the risk phrase R38 (Irritating to skin). Irritation must be reversible.
Eye irritation	Not classified as hazardous* or classified* with the risk phrase R36 (Irritating to eyes).
Sensitisation	Not classified as hazardous*
Repeat dose toxicity	Not classified as hazardous*
Mutagenicity	Not classified as hazardous*
Carcinogenicity	Not classified as hazardous*
Developmental and reproductive toxicity	Not classified as hazardous*
Other toxicological endpoints	Not classified as hazardous*
Aquatic toxicity	Toxicity to fish (ie LC_{50}), as determined using the Fish Acute Toxicity Test, is > 100 mg/L
	Toxicity to aquatic invertebrates (ie EC_{50}), as determined using the *Daphnia* sp, Acute Immobilisation Test, is > 100 mg/L
	Toxicity to algae (ie EC_{50}), as determined using the Algal Growth Inhibition Test, is > 100 mg/L
Flammability	Not a dangerous good** **OR** classified as class 3 flammable liquid only
Other physical and chemical properties	Not a dangerous good

* In accordance with the *Approved Criteria for Classifying Hazardous Substances*[1]
** In accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail[2]

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

[2] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)

Based on their known health and environmental concerns the following chemicals are not eligible for a low volume chemical permit for volumes exceeding 100 kg per annum:

- chemicals that are likely to be persistent and/or bioaccumulative, or have breakdown products with these characteristics (persistence and bioaccumulation criteria are set out in Appendix 16)
- chemicals that are covered by the NICNAS position paper regarding data requirements for notification of new chemical substances containing a perfluorinated carbon chain
- chemical classes with an exposure standard e.g. isocyanates, tin compounds

Polymers with a NAMW that is 1000 or greater

The polymer must:

- have less than 10% by mass of molecules with molecular weight that is less than 500; and
- have less than 25% by mass of molecules with molecular weight that is less than 1000; and
- have a low charge density i.e. it is not cationic or not likely to become cationic in an aquatic environment that has a pH value greater that 4 and less than 9 or it is a solid that is not soluble or dispersible in water and is to be used only in its solid phase or for a polymer that includes 1 or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000; and
- not have any of the following hazard classifications as described in *Approved Criteria for Classifying Hazardous Substances*[1] for human health effects:
  (i) carcinogenic effects (R40, R45, R49);
  (ii) mutagenic effects (R46);
  (iii) reproductive effects (R60-64);
  (iv) toxic and very toxic acute lethal effects (R23-28);
  (v) corrosive effects (R34, R35);
  (vi) sensitising effects (R42, R43);
  (vii) non-lethal irreversible effects after a single exposure (R39, R68); and
  (viii) severe effects after repeated or prolonged exposure (R48).

Based on their known health and environmental concerns the following polymers are not eligible for a low volume chemical permit for volumes exceeding 100 kg per annum:

- polymers that are likely to be persistent and/or bioaccumulative, or have breakdown products with these characteristics (persistence and bioaccumulation criteria are set out in Appendix 16)

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

- polymers that are covered by the NICNAS position paper regarding data requirements for notification of new chemical substances containing a perfluorinated carbon chain
- polymer classes with an exposure standard e.g. isocyanates, tin compounds

Application requirements

An electronic template is available on the website for applications (Form LVC-1). It must be submitted to NICNAS with the fee and the required information for assessment.

Joint applications can be made by manufacturers and/or importers of a new industrial chemical for a LVC permit.

An application claiming certain information to be treated as exempt from publication can be made as part of Form LVC. It is not necessary to complete a separate Form 3. Only certain information is published in the chemical gazette. A request for exempt information is not required for data items not published.

The necessary forms for a Low Volume Chemical Permit Notification are included on the NICNAS website.

All available information should be detailed in Form LVC-1. The applicant should consider the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) effects when providing a summary of the health effects. Where the chemical or polymer contains a structural alert for a certain human health endpoint, for example, sensitisation, then data would need to be provided for this endpoint to support applications for > 100 kg per annum. However for polymers, data for an endpoint where there is a structural alert may not need to be provided where the % by mass of molecules with molecular weight that is less than 1000 is less than the concentration cut-offs (used to determine whether or not a mixture is hazardous on the basis of its ingredients) for that end point. The concentration cut-offs are detailed in Chapter 6 of the Approved Criteria for Classifying Hazardous Substances[1]. A list of structural alerts is included in Appendix 15.

For applications for >100 kg per annum the notifier must provide evidence to demonstrate that each environmental hazard criterion are satisfied.

The following types of evidence will be considered acceptable to address the hazard criteria:

- (Eco)toxicity Test Report for the chemical;
- Published literature data for the chemical;
- (Eco)toxicity Test Report for an accepted close analogue;
- Published literature data for an accepted close analogue;

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

- QSAR data generated for the chemical by an appropriate, validated QSAR model.

A copy of all available ecotoxicological data should be provided to NICNAS. Where a repeat dose study has been conducted, a copy of the study summary (not the full study report) should be provided to NICNAS. For all other endpoints, the original data should only be provided to NICNAS where a structural alert exists for this endpoint. NICNAS may request copies of original data where deemed necessary to determine no unreasonable risk.

Data sourced from published literature should be accompanied by a copy of the journal article or document from which it was sourced, in English, as an attachment to the Permit Application.

Evidence supplied for close analogues should include sound scientific argument as to why the analogue should be considered acceptable, including discussion of comparability of the physico-chemical properties of the chemical and proposed analogue.

For data generated by QSAR (including ecotoxicity data) to be considered, notifiers must supply full details of the QSAR model used (including version), as well as all input values used by the model including the SMILES string. These requirements would be satisfied, for example, if an electronic copy of the Full Report generated by the US EPA's EPISuite[1] is provided.

Special Requirements for azo colourants

Azo colourants are a class of concern for their potential induction of mutagenicity and carcinogenicity, and several azo dyes have been demonstrated to be skin sensitisers in humans using clinical patch tests. In addition to genotoxicity and sensitisation data proving the chemical meets the low hazardous criteria, the chemical should contain negligible aromatic amine content (impurities).Information on the identity and genotoxicity profile of the potential metabolic breakdown products, i.e. the component amines, should also be provided to demonstrate that the chemical meets the low-hazardous criteria.

Assessment Process and Permit Conditions

LVC Permits are issued within 20 days of receipt of a complete notification, provided the Director is satisfied that the requirements of the Act are fulfilled.

A permit is granted on the condition that the holder of the permit notify the Director if:

- the function or use of the chemical has changed, or is likely to change, significantly;

[1] US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v3.20. United States Environmental Protection Agency, Washington, DC, USA.

- the amount of the chemical being manufactured or imported has exceeded, or is likely to exceed, the volume limit per year;
- a chemical subject to a LVC Permit for import only has begun to be manufactured in Australia;
- the method of manufacture has changed, or will be changed, resulting in a possible increased risk of adverse occupational health, public health or environmental effects; or
- the holder of the permit has become aware of additional information relating to adverse occupational health, public health or environmental effects of the chemical.

The holder of the permit must notify the Director within 28 days of becoming aware of any of these changes or circumstances.

LVC Permits include the following standard conditions in addition to recommendations specific to individual chemicals:

- The total quantity of chemical that can be introduced per annum;
- The length of time the permit will remain in force;
- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls;
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- The MSDS for the chemical and products containing it must carry advice that the chemical is being manufactured or imported under a Low Volume Chemical Permit granted under section 21U of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Suggested wording is: '…… is being introduced under a Low Volume Chemical Permit granted under section 21U(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989*.' ; and
- Disposal of waste should be in accordance with Local, State and Federal government regulations.

The Director may by written notice impose further conditions or revoke or vary any condition, after the permit has been issued.Under the Act, there is a penalty if the holder of a LVC permit contravenes any permit condition without a good reason. The Director may also by written notice cancel a permit.

Chemicals that are the subject of a LVC Permit, are not eligible for listing in the AICS.

Publication

Notice of the granting of a LVC Permit is published in the *Chemical Gazette*. Details published include:

- name of the chemical or trade name;
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued;
- duration of the permit (maximum three years); and
- general use of the chemical.

Annual reporting and record keeping

Holders of a low volume permit must keep records to support any statement made in or in connection with their application for the permit, or any application for a renewal of the permit, for 5 years from the date the permit is issued. Holders must also 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.

Renewal of LVC permit

Existing LVC permits can be renewed provided certain criteria are met (see chapter 6.7 for further information). A manufacturer or importer may apply for a LVC permit to be renewed any number of times.

6.4 Controlled Use (Export Only) Permit (EOP)

Industrial chemicals introduced under the following scenarios will be eligible for the Controlled Use (Export Only) Permit, known as EOP:

- importation of a new chemical into Australia for export of entire quantity;
- importation of a new chemical into Australia for use in formulation of products for export of entire quantity;
- manufacture of a new chemical in Australia for export of entire quantity; and
- manufacture of a new chemical in Australia for use in formulation of products for export of entire quantity.

The EOP will be available for chemicals where low risk can be demonstrated. In particular, sufficient control measures must be in place to satisfy the criterion of ‘highly controlled’. Sufficient control measures must be in place to prevent exposure to workers and the public and release to the environment.

The duration of the EOP will be a maximum of three years. Renewal of the permit may be allowed provided there is no significant change in circumstances.

Chemicals prohibited or severely restricted under Australia's international obligations will not be eligible for an EOP. For example, new chemicals with persistent organic pollutant (POPS) characteristics, which include persistence and bioaccumulation, will not be eligible.

Application Requirements

An electronic template is available on the website for applications (Form 1-EOP). It must be submitted to NICNAS with the fee and the required information for assessment.

Joint applications can be made by manufacturers and/or importers of a new industrial chemical for EOP.

An application can be accompanied by an application (Form 3) with the fee claiming certain information to be treated as exempt from publication (see Section 6.1).

For introduction volumes exceeding 10 tonnes per year, all available toxicological and ecotoxicological data must be provided with the application. Toxicological and ecotoxicological information may be requested in other cases.

Assessment process and permit conditions

There is no statutory deadline for issuing an EOP. However, the process is expected to be completed within 20 days of receipt of a complete notification, provided the Director is satisfied that the requirements of the Act are fulfilled.

The holder of the permit is bound by the permit conditions – a permit is granted on the condition that the holder of the permit notify the Director if:

- the function or use of the chemical has changed, or is likely to change, significantly; or
- a chemical subject to an EOP permit for import has begun to be manufactured; or
- the method of manufacture has changed, or will be changed, resulting in a possible increased risk of adverse occupational health, public health or environmental effects; or
- the holder of the permits become aware of additional information relating to adverse occupational health, public health or environmental effects of the chemical.

The holder of the permit must notify the Director within 28 days of becoming aware of any these changes or circumstances.

Export Only Permits include the following standard conditions in addition to recommendations specific to individual chemicals:

- The total quantity of chemical that can be introduced per annum;
- The entire quantity of the notified chemical introduced into Australia must be exported.
- The length of time the permit will remain in force;
- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Use of the chemical under this permit should be in accordance with the controls specified in the application.
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls;
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- The MSDS for the chemical and products containing it must carry advice that the chemical is being manufactured or imported under a Low Volume Chemical Permit granted under section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Suggested wording is: '…… is being introduced under a Controlled Use (Export Only) Permit granted under section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989*.' ; and
- Disposal of waste should be in accordance with Local, State and Federal government regulations.

The Director may by written notice impose further conditions or revoke or vary any condition, after the permit has been issued.

Under the Act, there is a penalty if the holder of a EOP permit contravenes any permit condition without a good reason. The Director may also by written notice cancel a permit. Chemicals that are the subject of a EOP Permit are not eligible for listing in the AICS.

Publication

Notice of granting of an EOP Permit will be published in the *Chemical Gazette*. Details of the notice include:

- name of the chemical or trade name;

- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued;
- volume of chemical which may be introduced;

- duration of the permit (maximum three years); and
- general use of the chemical.

Annual reporting and record keeping

Holders of an EOP must keep records to support any statement made in or in connection with their application for the permit, or any application for a renewal of the permit, for 5 years from the date the permit is issued. Holders must also 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.

Renewal of EOP permit

Existing EOP permits can be renewed provided certain criteria are met (see section 6.7 for further information). A manufacturer or importer may apply for a EOP permit to be renewed any number of times.

6.5 Controlled Use Chemical Permit (CUP)

Industrial chemicals meeting the following criteria will be eligible for the Controlled Use Chemical Permit (CUP):

(a) the chemical does not have any of the following hazard classifications for human health effects (as described in *Approved Criteria for Classifying Hazardous Substances*[1]*)*:

(i) carcinogenic effects (R40, R45, R49);
(ii) mutagenic effects (R46);
(iii) reproductive effects (R60-64);
(iv) toxic and very toxic acute lethal effects (R23-28);
(v) corrosive effects (R34, R35);
(vi) sensitising effects (R42, R43);
(vii) non-lethal irreversible effects after a single exposure (R39, R68);
(viii) severe effects after repeated or prolonged exposure (R48);

AND

(b) the chemical does not have a toxicity:

(i) to fish, expressed as an LC_{50}, that is less than or equal to10 mg/litre, as determined using the Fish Acute Toxicity Test (continuous exposure of fish to a series of concentrations of the chemical in water for 4 days); and

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

(ii) to aquatic invertebrates, expressed as an EC_{50}, that is less than or equal to 10 mg/litre, as determined using the *Daphnia* sp, Acute Immobilisation Test (daphnids exposed to a series of concentrations of the chemical in water over 2 days); and
(iii) to algae expressed as IC_{50}, that is less than or equal to 10 mg/litre, as determined using the Algal Growth Inhibition Test (algae exposed to a series of concentrations of the chemical in water for at least 3 days);

AND

(c) for human exposure:

(i) there are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance; and
(ii) any worker exposure that is likely to occur will be adequately controlled through use of engineering controls, work practices and personal protective equipment;

AND

(d) for environmental exposure, all routine releases from manufacture, processing and use (including releases associated with cleaning of equipment and from disposal or cleaning of containers and packaging) have been considered and adequate controls are in place to ensure:

(i) no ambient release to surface water resulting in concentrations of the chemical above 1 part per billion; and
(ii) no ambient release to air above 1 microgram per cubic metre average annual concentration; and
(iii) no release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Two controlled use exposure scenarios have been developed in consultation with industry. These are for containment and controlled reformulation, and site-limited and closed system manufacture. Typically a chemical being used as described in these scenarios will meet the exposure criteria set out above (exceptions may occur where a chemical has particular physicochemical characteristics, for example where the chemical is highly volatile or persistent). Other use scenarios may meet the criteria set out above. For such other uses it is preferred that Industry work with NICNAS to develop additional exposure scenarios.

For more information on the human and environmental exposure criteria and two controlled use scenarios which have been developed see Appendix 14.

The duration of the CUP will be a maximum of three years. Renewal of the permit may be allowed provided there is no significant change in circumstances

Chemicals prohibited or severely restricted under Australia's international obligations will not be eligible for an CUP. For example, new chemicals with persistent organic pollutant (POPS) characteristics (see Appendix 16), which include persistence and bioaccumulation, will not be eligible.

Down-stream users

A chemical introduced under a CUP will be able to be supplied to down-stream users. However, the down-stream user and their practices must be known. The application

should provide a description of the operations at the proposed user's site. The notifier is responsible for ensuring that this description is accurate.

Only those users whose details have been provided to NICNAS will be able to use the chemical (these users will be listed on the permit). NICNAS must be satisfied that the user of the chemical is aware of the conditions of the permit i.e. that the use is highly controlled.

The conditions of the permit (see below) place obligations on both the holder of the permit and the down-stream user.

Application Requirements

An electronic template is available on the website for applications (Form ~~1 CUP~~CUP-1). It must be submitted to NICNAS with the fee and the required information for assessment.

Joint applications can be made by manufacturers and/or importers of a new industrial chemical for a CUP.

An application claiming certain information to be treated as exempt from publication can be made as part of Form LVC. It is not necessary to complete a separate Form 3. Only certain information is published in the chemical gazette. A request for exempt information is not required for data items not published.

The necessary forms for a Controlled Use Chemical Permit Notification are located on the NICNAS website.

All available information should be detailed in Form ~~1 CUP~~CUP-1. The applicant should consider the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) effects when providing a summary of the health effects. Where the chemical or polymer contains a structural alert for a certain endpoint e.g. sensitisation then data would need to be available for this endpoint to support applications. However for polymers, data for an endpoint where there is a structural alert may not need to be provided where the % by mass of molecules with molecular weight that is less than 1000 is less than the concentration cut-offs (used to determine whether or not a mixture is hazardous on the basis of its ingredients) for that end point. The concentration cut-offs are detailed in Chapter 6 of the Approved Criteria for Classifying Hazardous Substances[1]..

A list of structural alerts is included in Appendix 15. In addition the notifier must provide evidence to demonstrate that each environmental hazard criterion are satisfied.

The following types of evidence will be considered acceptable to address the hazard criteria:

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

- (Eco)toxicity Test Report for the chemical;
- Published literature data for the chemical;
- (Eco)toxicity Test Report for an accepted close analogue;
- Published literature data for an accepted close analogue;
- QSAR data generated for the chemical by an appropriate, validated QSAR model.

For introduction volumes exceeding 10 tonnes per year, all available toxicological and ecotoxicological data must be provided with the application. Otherwise, original data should only be provided to NICNAS where a structural alert exists for this endpoint. Toxicological and ecotoxicological information may be requested in other cases.

Data sourced from published literature should be accompanied by a copy of the journal article or document from which it was sourced, in English, as an attachment to the Permit Application for consideration.

Evidence supplied for close analogues should include sound scientific argument as to why the analogue should be considered acceptable, including discussion of comparability of the physico-chemical properties of the chemical and proposed analogue.

For data generated by QSAR (including ecotoxicity data) to be considered, notifiers must supply full details of the QSAR model used (including version), as well as all input values used by the model including the SMILES string. These requirements would be satisfied, for example if an electronic copy of the Full Report generated by the US EPA's EPISuite[1] is provided.

Assessment process and permit conditions

There is no statutory deadline for issuing a CUP. However, the process is expected to be completed within 28 days of receipt of a complete notification, provided the Director is satisfied that the requirements of the Act are fulfilled.

The holder of the permit is bound by the permit conditions – a permit is granted on the condition that the holder of the permit notify the Director if:

- the function or use of the chemical has changed, or is likely to change, significantly; or
- a chemical subject to a CUP for import has begun to be manufactured; or
- the method of manufacture has changed, or will be changed, resulting in a possible increased risk of adverse occupational health, public health or environmental effects; or
- the holder of the permit become aware of additional information relating to adverse occupational health, public health or environmental effects of the chemical.

1 US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v3.20. United States Environmental Protection Agency, Washington, DC, USA.

The holder of the permit must notify the Director within 28 days of becoming aware of any of these changes or circumstances. The holder of the permit should have mechanisms in place to ensure that they become aware of changes in circumstances as a result of operations at a down-stream user site.

Controlled Use Chemical Permits include the following standard conditions in addition to recommendations specific to individual chemicals:

- The total quantity of chemical that can be introduced per annum;
- The length of time the permit will remain in force;
- The chemical can only be supplied to companies listed in the attached permit Schedule.
- A copy of this permit must be provided to and retained by all companies listed in the attached permit Schedule.
- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Use of the chemical under this permit should be in accordance with the controls specified in the application.
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary in addition to those specified in the application, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls;
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- The MSDS for the chemical and products containing it must carry advice that the chemical is being manufactured or imported under a Controlled Use Chemical Permit granted under section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Suggested wording is: '…… is being introduced under a Controlled Use Permit granted under section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989*.' ; and
- Disposal of waste should be in accordance with Local, State and Federal government regulations.

The Director may by written notice impose further conditions or revoke or vary any condition, after the permit has been issued. Under the Act, there is a penalty if the holder of a CUP contravenes any permit condition without a good reason. The Director may also by written notice cancel a permit.

Chemicals that are the subject of a CUP are not eligible for listing in the AICS.

Publication

Notice of granting of an CUP will be published in the *Chemical Gazette*. Details of the notice include:

- name of the chemical or trade name;
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued;
- volume of chemical which may be introduced;
- duration of the permit (maximum three years); and
- general use of the chemical.

Additional down-stream users

The holder of the permit can only supply the chemical to down-stream users listed on the permit. Therefore the holder of the permit would be required to advise NICNAS of any additional down-stream users identified after a permit has been issued. Where it is demonstrated that the new site is applying the same risk management controls as that described in the initial permit application, NICNAS would normally revise the permit to include a new down-stream user. A new controlled use permit application would be required for new uses and circumstances where an additional down-stream user is not employing the same risk management controls.

Annual reporting and record keeping

Holders of a CUP must keep records to support any statement made in or in connection with their application for the permit (including information of operations at down-stream user sites), or any application for a renewal of the permit, for 5 years from the date the permit is issued. Holders must also 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.

Renewal of CUP

Existing CUPs can be renewed provided certain criteria are met (see chapter 6.7 for further information). A manufacturer or importer may apply for a CUP to be renewed any number of times.

6.6 Early Introduction Permits

6.6.1 Section 30A Permits

Early Introduction Permit (EIP) applications are available under certain circumstances, in conjunction with a certificate notification. An EIP allows introduction of a chemical into Australia before its certificate assessment is complete. Chemicals which may be eligible for an EIP are:

- polymers of low concern (PLC);

- non-hazardous chemicals/polymers;
- chemicals and polymers meeting low-hazardous criteria; or
- low risk highly controlled chemicals/polymers.

The criteria that need to be met are detailed in section 3.2. In all cases the introduction of the chemical is consistent with the reasonable protection of occupational health, public health and the environment.

Application Requirements

An application for an EIP can be made at the same time as a Standard Notification, Limited Notification or PLC Notification, or it can be made later, but before the assessment is completed. An application can be made by filling out Form EIP-1 with the appropriate fee. This amount is additional to the normal notification and assessment fee. Joint applications may be submitted (in which case one fee is charged). EIPs for PLCs and chemicals which are demonstrated to meet the definition of a non-hazardous chemical are free of charge..

Supporting information for the application for an EIP should be provided as part of the certificate notification (see below).

Assessment Process

In deciding whether to grant the EIP, the Director needs to be satisfied that the chemical is either a polymer of low concern (PLC), a non-hazardous chemical/polymer, a chemical/polymer meeting low-hazardous criteria or a low risk highly controlled chemical/polymer. In all cases the introduction of the chemical must be consistent with the reasonable protection of occupational health, public health and the environment.

Chemicals (including polymers with a NAMW < 1000)
To be satisfied that the chemical (including polymers with a NAMW < 1000) meets the human health hazard criteria for a non-hazardous chemical, test data for the notified chemical or an accepted close analogue, should normally be available for at least the following endpoints:

acute oral toxicity,
acute dermal toxicity,
skin irritation,
eye irritation,
sensitisation,
repeat dose toxicity,
genotoxicity – bacterial reverse mutation and
genotoxicity in vitro.

For genotoxicity testing, the results of the two genotoxicity tests should both independently be negative.

In addition acute inhalation toxicity test data is normally required unless:

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").

To be satisfied that a chemical (including polymers with a NAMW < 1000) meets the human health hazard criteria for a low hazardous chemical and low risk highly controlled chemical, data would normally be required where there is a structural alert for a certain endpoint (A list of structural alerts are included in Appendix 15). (Note: Data addressing part C of the schedule of data requirements a requirement for a STD notification).

To be satisfied that a chemical meets the environmental hazard criteria data would normally be required for all three trophic levels. Where data is not available i.e. for Limited notifications, the chemical/polymer may be eligible for an EIP if certain release criteria are met (see matters taken into account below).

Polymers with a NAMW $\geq$ 1000 (other than a PLC)
To be satisfied that a polymer with a NAMW $\geq$ 1000 (other than a PLC) is non-hazardous, test data for the notified polymer or an accepted close analogue, should normally be available for at least the following endpoints:

acute oral toxicity,
skin irritation and
genotoxicity – bacterial reverse mutation

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), data on skin sensitisation should also be available.

To be satisfied that a polymer meets the human health hazard criteria for low-hazardous polymers and low risk highly controlled polymers, test data for the notified chemical or an accepted close analogue, should normally be available where there is a structural alert for a certain endpoint. (A list of structural alerts are included in Appendix 15). Data for an endpoint where there is a structural alert may not need to be available where the % by mass of molecules with molecular weight that is less than 1000 is less than the concentration cut-offs (used to determine whether or not a mixture is hazardous on the basis of its ingredients) for that end point. The concentration cut-offs are detailed in the Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)].

To be satisfied that a polymer (other than a PLC or polymer meeting the low-hazard criteria) meets the environmental hazard criteria data would normally be required for all three trophic levels. Where data is not available i.e. for Limited notifications, the chemical/polymer may be eligible for an EIP if certain release criteria are met (see matters taken into account below).

Additional matters taken into account

In deciding whether to grant the EIP, the Director will take into account a number of matters, including the proposed use of the chemical and information about its occupational health, public health and environmental effects.

The Director must also take into account the likelihood of release of the chemical to the aquatic environment. For Standard and Limited Notifications, direct release into a natural waterway must be considered. For Limited notifications where there is no ecotoxicity or ready biodegradability data to support the application, the Director must also take into account release into a water treatment works at a rate more than 10 kg per year from an individual source or 50 kg in total.

In taking into account the likelihood of the chemical being released to water, the Director will only consider releases that result from normal use practices rather than from spills, etc. Qualitative or semi-quantitative estimates of release to water rather than detailed calculations will normally be sufficient.

Under normal circumstances, an application for an EIP will be decided within 28 days.

Permit Conditions

EIPs for polymers of low concern, non hazardous chemicals/polymers and chemicals/polymers meeting the low hazardous criteria, include the following standard conditions in addition to recommendations specific to individual chemicals:

- The EIP is in force only until the assessment certificate is issued
- If the application for an assessment certificate is withdrawn, the permit lapses;
- If full assessment of the chemical cannot commence or is stopped due to outstanding data for a specified period, the permit lapses*;*
- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls;
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- Disposal of waste should be in accordance with Local, State and Federal government regulations;
- records are to be kept at the site(s) of use; and
- At the end of the period for which this permit is issued, the applicant must report to the Director any adverse occupational health and safety, public health and environmental effects, reported from the use of this chemical.

EIPs for low risk highly controlled chemicals/polymers, include the following standard conditions in addition to recommendations specific to individual chemicals:

- The EIP is in force only until the assessment certificate is issued;
- If the application for an assessment certificate is withdrawn, the permit lapses;
- If full assessment of the chemical cannot commence or is stopped due to outstanding data for a specified period, the permit lapses*;*
- The chemical can only be supplied to companies listed in the attached permit Schedule.
- A copy of this permit must be provided to and retained by all companies listed in the attached permit Schedule.
- Use of the chemical under this permit must be in accordance with all relevant State or Territory OHS, environmental and poisons legislation;
- Use of the chemical under this permit should be in accordance with the controls specified in the application.
- Where a suitable and sufficient workplace risk assessment indicates that control measures are necessary in addition to those specified in the application, these should be implemented to prevent, or where this is not practicable, minimise the risks to human health. Adequate control of exposure to workers should be in accordance with the hierarchy of controls
- Workers exposed to the chemical and products containing it must be informed that it is being introduced into Australia under a permit;
- The MSDS is to be made available at all sites where the chemical is used;
- Disposal of waste should be in accordance with Local, State and Federal government regulations;
- records are to be kept at the site(s) of use; and
- At the end of the period for which this permit is issued, the applicant must report to the Director any adverse occupational health and safety, public health and environmental effects, reported from the use of this chemical.

Publication

Under the Act, the Director must decide an application for an EIP within 28 days of receipt of the application. A list of EIPs granted are published in the *Chemical Gazette*.

Details published include:

- name of the chemical or trade name;
- name of the company to which the permit is issued; and
- general use of the chemical

6.6.2 Section 30 Permit

Application requirements

A Section 30 Permit application must accompany or follow an application for an assessment certificate. Joint applications may be submitted with the fee shared between the applicants. Section 30 permits are issued only under exceptional circumstances.

The notifier must write to the Minister outlining the reasons for the application, in particular:

- the reasons why the introduction of the chemical is in the public interest;
- why the introduction must be without delay; and
- how introduction of the chemical will impact on occupational health, public health and the environment.

The amount required for introduction should be justified in the application. All other supporting information must be submitted. The appropriate fee should be sent with the application.

Assessment Process and Permit Conditions

In deciding whether to grant a Section 30 Permit, the Minister would usually seek advice from the Director, taking into account a number of matters, including the proposed use of the chemical, information about its health and environmental effects and the volume of chemical required.

Section 30 Permits are subject to conditions stated in the permit. There is no set limit on the amount of chemical for which a Section 30 Permit may be granted, however, the permit will specify limits on amount and time. Conditions specified in the permit must be consistent with the reasonable protection of occupational health, public health and the environment.

If the application for an assessment certificate is withdrawn, the permit lapses.

Publication

In granting a permit, the Minister will give notice in the *Chemical Gazette* as early as possible. The notice will contain the following items of information unless the Minister is satisfied that any items should be withheld in the public interest:

- name of the applicant;
- name(s) of the chemical, as shown to the public; and
- terms of the permit, including period in force.

Applicants may appeal to the Administrative Appeals Tribunal against a decision to publish information against their wishes.

6.7 Renewal of permits

Existing permits (except EIPs) can be renewed provided certain criteria are met. Although an LVC, EOP and CUP permit can be renewed any number of times, a CEC permit maybe renewed only once.

CEC permit renewal

Each application for a renewal of a CEC Permit must consist of:

- the application for a CEC permit renewal, using Form CEC-1R including evidence that the criteria listed below have been met;
- a copy of the current permit including conditions;
- new user agreements forms. [Form 8] The applicant and each proposed user of the chemical must sign an agreement to comply with the conditions of the permit. This agreement must be included with the application;
- any application for exempt information (Form 3), with the appropriate fee for information that was not claimed as exempt in the original application. Form 3 – Exempt Information needs not to be resubmitted if it was in the original permit submission;
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form CEC-1R);
- a declaration that all available information has been submitted (included on Form CEC-1R); and the appropriate fee.

Criteria for CEC renewal

- the existing permit must still be current. Applications for renewal of a permit must be lodged no earlier than three months and no later than two weeks before the current permit expires.

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- the permit has not previously be renewed
- 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, 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;
- no changes are required to any conditions of the permit.

LVC/CUP/EOP Permit Renewal

Each application for a renewal of a LVC/CUP/EOP Permit must consist of:

- the application for a Permit renewal, using Form LVC-1R, Form EOP-1R, Form CUP-1R including evidence that the criteria listed below have been met;
- a copy of the current permit including conditions;
- any application for exempt information (Form 3), with the appropriate fee for information that was not claimed as exempt in the original application. Form 3 – Exempt Information needs not to be resubmitted if it was in the original permit submission;
- a statement that the notifier is entitled to use and to give the Director all the data in the notification statement (included on Form 1);
- a declaration that all available information has been submitted (included on Form 1) and the appropriate fee.

Criteria for LVC/CUP/EOP renewal

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- the existing permit must still be current. Applications for renewal of a permit must be lodged no earlier than three months and no later than two weeks before the current permit expires.
- 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 last issued—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;
- no changes are required to any conditions of the permit.

7. Continuing Obligations

This chapter provides information on your obligations to NICNAS when relevant changes occur in circumstances associated with a chemical that has been previously assessed. It also outlines the processes of listing a new chemical on the confidential section of the Australian Inventory of Chemical Substances (AICS).

7.1 Secondary Notification

A secondary notification may be required when circumstances arise that were set out in the initial assessment report as requiring secondary notification, or when an introducer (which may or may not be the original applicant) of an assessed chemical, or the Director, becomes aware of a significant change in circumstances.

For further information on Secondary Notifications, including how to apply, see Section IV - Continuing Notifications and Assessment Methodologies.

7.2 AICS (this might combine with AICS section in the overview)

7.2.1 Applying to Have a Chemical Listed in the Confidential Section of AICS

The director is obliged by law to give a holder of an assessment certificate at least 28 days written notice of an intention to add the chemical to the non-confidential section of the AICS. The holder of the certificate may then apply to the Director for the chemical to be included in the confidential section of the AICS. A fee applies.

Applicants must use Form AICS-1, which lists the criteria to be addressed in the claim. The Director will give the applicant written notice of the decision.

If the Director is satisfied that publication of some or all of the chemical's particulars could reasonably be expected to prejudice the commercial interests of the applicant, and the prejudice outweighs the public interest in the publication of those particulars, then the Director must include the chemical in the confidential section of the AICS. Otherwise the chemical must be listed in the non-confidential section of the AICS.

7.2.2 Holder of a Confidence

A person who applies to have a chemical listed in the confidential section of the AICS will be treated as the 'holder of a confidence' in relation to that listing. The holder of a confidence will be advised of any intention to remove the chemical from the confidential section of the AICS. He or she may then give the Director reasons why the chemical should not be transferred and appeal against any such decision to transfer the chemical.

Those who buy a business that has had a chemical in the confidential section of the AICS may apply to become the holder of a confidence in relation to this chemical. Applications must be made by use of Form AICS-3. A fee applies.

7.2.3 Transfer From the Confidential Section to the Non-Confidential Section

A new chemical, which has been listed in the confidential section of the AICS following assessment, will be transferred to the non-confidential section of the AICS five years after the confidential listing unless:

- an application against the transfer is made by the holder of a confidence using Form AICS-1, with full justification for retaining the confidential listing (a fee applies); and
- the Director is satisfied that the reasons given by the holder of a confidence warrant the retention of the chemical in the confidential section of the AICS.

Where such an application is successful, the chemical will remain in the confidential section of the AICS for a further five years before the next review for transfer to non-confidential section of the AICS.

The holder of a confidence will receive advice of any proposal to transfer a chemical at least three months before the fifth anniversary of the relevant inclusion or re-inclusion date of the chemical.

7.2.4 Appeals Relating to Listing on the Confidential Section of the AICS

If the request for reconsideration of the decision by the Director not to list the new chemical in the confidential section of the AICS or to transfer the chemical to the non-confidential section is rejected, an appeal can be made to the Administrative Appeals Tribunal.

8. Rebate

You may be granted a reduction in the fee for a notification assessment if you submit an electronic copy of the notification submission prepared using the approved NICNAS electronic Template for a Standard or Limited notification category. A reduction in the fee may also be granted for a Standard or Limited notification category if you submit an assessment report of a chemical assessed under an assessment scheme from any OECD country.

This chapter outlines the procedures to follow to make an electronic lodgement of notification, the factors you should consider in submitting a foreign assessment report and the process to follow should you wish to nominate a foreign scheme for approval by NICNAS. Any forms referred to can be downloaded from the NICNAS website (http://www.nicnas.gov.au/Forms.asp)

8.1 Electronic Lodgement of Notification

In an effort to reduce the cost and time of assessment of new chemicals, NICNAS aims to streamline the assessment process by providing a Template to enable applicants to submit information about a chemical in a standardised format and also to comply with the notification requirements of the Act. The information provided in the Template must be comprehensive to enable NICNAS to conduct its assessment of the chemical.

Eligibility for the 15% Rebate in Notification Fee

Applicants for the rebate must pay the full notification fee when lodging their notification. The rebate will be sent by NICNAS if the notification meets the criteria outlined below. A rebate of up to 15% of the assessment fee for Standard and Limited notifications may be provided to applicants who submit an acceptable electronic notification (word document) with their notification statement.

The criteria defining an acceptable notification fall into 3 broad areas:

- approved format.
- level of detail required for each section.
- completeness of the submission.

Approved Format

The Approved Format comprises the required Schedule Attachments. The Template comprises six documents: (i) the notification form for electronic submission (ii) Schedule Part A - Summary of Notification (iii) Schedule Part B - Identity, Properties and Uses (iv) Schedule Part C1 - Toxicology Information (v) Schedule Part C2 - Environment (vi) Schedule Part D - Polymer Information. If data which is outside the

required Schedule parts for the notification category is available to you, the appropriate Schedule Attachment should also be completed to the extent required to cover this data; for example, if mammalian toxicology or genotoxicity data is available for a notification submitted as a Limited notification, the appropriate sections of Schedule Attachment C1 should be completed. For toxicology, ecotoxicology and physico-chemical properties data, there are additional sections that correspond to test data, which is not on the schedule but may be available to you. These additional tests sections should be filled out to the extent required to cover all of the data available to you.

Level of Detail

Sufficient information is required to enable the assessment to be made from an occupational, public health and environmental perspective. This includes details of tests performed and where toxicity data are available a summary of the data is required with supporting study reports. Although provision of toxicity data is not a scheduled requirement for Limited notifications, the Act does stipulate that if these data are available to the applicant they should be provided with the submission.

Completeness

The schedule in the table below indicates the information required for an acceptable submission.

Assessment Report Template Section Number	Assessment Report Template Section Title	Applicant to Complete	Applicant to Complete for 15% Rebate
1	APPLICANT & NOTIFICATION DETAILS	Yes	Yes
2	IDENTITY OF CHEMICAL	Yes	Yes
3	COMPOSITION	Yes	Yes
4	INTRODUCTION & USE INFORMATION	Yes	Yes
5	PROCESS AND RELEASE INFORMATION	Yes	Yes
6	PHYSICOCHEMICAL PROPERTIES	optional	Yes
7	TOXICOLOGICAL INVESTIGATIONS	optional	Yes
8	ENVIRONMENT	optional	Yes
13	BIBLIOGRAPHY	Yes	Yes

Attach completed copies of Schedule Attachments Parts A and B, and Parts C1, C2 and D as required.

Guidance for applicants covering content and completeness required to further define the criteria for an acceptable submission can be found in Chapter 5 - Certificate Category.

8.2 Foreign Schemes

The Transitional Arrangements Towards Recognition of Approved Foreign Schemes (Transitional Arrangements) were first published in the *Chemical Gazette* No. C 4, 7 April 1998. Updated arrangements were later published in the November 2001 issue of the *Chemical Gazette* (No. C11).

Rebates are available to applicants for assessment certificates if assessment reports can be obtained from approved foreign schemes. In practice, assessment reports can be obtained from European Union member states and Canada. In particular, Australia and Canada signed a Bilateral Arrangement in 2002, which facilitates the exchange of reports and information between the two countries.

In addition, Canada and Australia share similar criteria for defining a Polymer of Low Concern (PLC), so NICNAS can introduce resource savings for both industry and NICNAS where the applicant provides evidence to NICNAS that a polymer has been notified and assessed in Canada under the Canadian Environment Protection Act (CEPA) as a Low Concern Polymer. In this circumstance, NICNAS can waive the application fee for an Early Introduction Permit (EIP).

The following options are available to applicants notifying new industrial chemicals to NICNAS in the standard, Limited or PLC categories.

Option 1 For Standard or Limited categories

Up to 40% Rebate in Notification Fee for Provision of an Acceptable Assessment Report issued by a National Authority

Option 1 applies to chemicals or polymers for notification under subsections 23(4) to 23(9) of the Act, that is, notification under the Standard or Limited Notification category.

Criteria for an Acceptable Assessment Report

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.

Conditions

In all instances, acceptance of an assessment report is subject to approval by the Director.

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 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 scheme.

NICNAS statutory timeframes for assessment remain unchanged.

Rebate

NICNAS will decide the level of rebate on a case-by-case basis. The maximum rebate is 40% of the notification fee, however the fee rebate will be less than 40% if data on toxicological and environmental effects are absent or incomplete. Delays in provision of the overseas assessment report, while possibly outside the control of the applicant, will also affect the level of rebate.

Method of Application and Fees

Applications for Assessment Certificates under the New Transitional Arrangements are to be made on the usual Form 1-STD or Form 1-LTD. Notification fees must be paid in full. The rebate is determined at the end of the assessment period.

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. This will expedite the process of obtaining the Canadian assessment report and reduce the likelihood of a reduced rebate due to late arrival of the Canadian report. It is advisable to start this process as early as possible, and preferably before the notification is made to NICNAS.

Option 2: For polymers of Low Concern

A Free Early Introduction Permit (EIP) for Polymers of Low Concern (PLC) Assessed as Low Concern Polymers in Canada

Option 2 applies to polymers notified and assessed as a Low Concern Polymer under CEPA. This option is not necessary for the self-assessment of PLCs as these are processed within 28 days of an accepted self-assessment report.

Eligibility Criteria

The polymer has been assessed as a Low Concern Polymer under CEPA. The PLC notification statement and EIP application to NICNAS includes a Validation Letter from Environment Canada to this effect.

The PLC notified to NICNAS meets the requisite criteria for early introduction described under section 30A of the Act.

Conditions

In all instances, recognition of the Validation Letter from Environment Canada is subject to the approval of the Director. NICNAS and Environment Canada will assume that the presence of a copy of the letter indicates that the applicant is entitled to use it.

In all instances, the granting of an EIP is subject to the approval of the Director.

Polymers which have had conditions or restrictions imposed by CEPA are ineligible for this option.

NICNAS statutory timeframes for both assessment of the EIP application and PLC assessment certificate remain unchanged.

Method of Application and Fees

An application for an EIP under the Transitional Arrangements is to be made on Form EIP-1. The fee need not be provided, as long as the Eligibility Criteria and Conditions are met.

Accessing the CEPA 'No Suspicion of Toxic' Validation Letter

Applicants need to contact the Canadian company applicant to obtain a copy of the Environment Canada Validation Letter. This letter states that:

- the Schedule VI information on the polymer completes the applicant's obligations under the CEPA New Substances Notification Regulations (that is, meets Low Concern Polymer criteria);
- the assessment outcome is 'Not suspected to be Toxic'; and

- depending on trigger threshold volumes, the polymer is eligible for addition to the Domestic Substances List.

It should be noted that, as a general rule, assessment reports prepared under a foreign notification and assessment scheme should be of at least the same standard as the reports produced by NICNAS.

For further details on the Transitional Arrangements please contact NICNAS New Chemicals on freecall 1800 638 528.

8.2.1 Nomination of Foreign Schemes

Approved State and Territory Notification Procedures

Some States and Territories may introduce their own legislation regarding the notification of new chemicals to be manufactured in Australia. For the purposes of NICNAS, the Minister may approve, by notice in the *Chemical Gazette*, a notification law in a State and Territory if:

- the notification requirements under the State and Territory law are at least equal to that required under the Commonwealth Act; and
- there are arrangements in place between the State and Territory and the Commonwealth which would enable a copy of the notification statement to be sent to the Director promptly [section 41 of the Act].

At the time of publishing this Handbook for Notifiers, there was no intention by any of the States or Territories to introduce their own notification laws.

8.2.2 Further Information

For a notification based on an assessment under an approved foreign scheme, the Director may request further information relating to the use, volume or method of manufacture of the chemical. The Director may also request the clarification of certain data items submitted in the notification.