



Australian Government
Department of Health and Ageing
NICNAS

**National Industrial Chemicals Notification and Assessment
Scheme**

**PROPOSAL ON IMPROVING ACCESS TO
INFORMATION TO SUPPORT INTRODUCERS OF
NICNAS ASSESSED CHEMICALS TO NOTIFY
THE DIRECTOR OF CHANGED
CIRCUMSTANCES**

CLOSING 29 FEBRUARY 2012

1 Purpose

The purpose of this public discussion paper is to seek stakeholder views on how provide introducers of NICNAS assessed chemicals with improved access to information that allows them to fulfil their obligation to notify the Director of NICNAS when a significant change in circumstances occurs relative to the original assessment.

2 Background

When chemicals are added to the AICS (either *via* early listing or after the assessment certificate expires), a notation on the AICS record states they have been assessed by NICNAS. This notation should signify to a potential introducer that secondary notification may be required under certain circumstances. A secondary notification is a new notification that focuses on changed circumstances of introduction and/or use and leads to an amended assessment. It is designed to make the assessment current, particularly if **significant** changes to the original risk have occurred. A significant change may be an increase in the introduction volume or use of the chemical that changes the potential risk to health and/or the environment and warrants a reassessment of the chemical. The meaning of the term significant is discussed at **Attachment 1**.

In order to fulfill their obligations in accordance with the Act, all introducers need to have adequate information about the assessed chemical and the circumstances specified (such as volumes and uses) in the original assessment. This information is necessary in order for the introducer to determine whether to notify the Director when circumstances are significantly different from those for which the chemical was assessed.

This paper examines issues related to how readily introducers can access this information, and puts forward a proposal on how to address these issues.

Legislative basis for Secondary Notification

There is a requirement in the Act that the Director should be notified by introducers of circumstances that have changed since the original assessment that may require secondary notification. This is in keeping with the object of the Act to assess the health and environmental risks of all industrial chemicals and make recommendations for their safe use.

Two sections of the Act specify that the Director should be notified of the changed circumstances. Under section 64(1) of the Act secondary notification circumstances can be specified explicitly whereas under section 64(2) of the Act more general requirements apply. These relate to significant changes in introduction volume, use, whether an imported chemical has begun to be manufactured or whether any new hazard data have become available. The circumstances relating to secondary notification of a chemical are usually highlighted in the Full Public Report by being included in a special section at the end of the report. The wording of the relevant sections of the Act is reproduced at **Attachment 2**.

When a person introducing a chemical becomes aware that the circumstances referred to in section 64(1) or 64(2) of the Act have occurred, the onus is on the person to notify the Director, NICNAS, within 28 days of the circumstances that occurred. Based on the information provided, the Director may determine that a secondary notification, meaning an amended assessment of the chemical, is required.

The Director may, by notice in the *Chemical Gazette* require the secondary notification of a chemical by person/s to whom the notice applies within a period of not less than 28 days. Person/s to whom the notice applies must then provide information about the chemical that is to be given by way of secondary notification within a period of not less than 28 days.

As the information that is considered not only relates to introduction of the chemical, but also relates to use, the utilisation of the chemical by downstream users also impacts on the introducer's obligation to notify the Director of these changed circumstances.

3 Issues involved in raising awareness of secondary notification obligations

3.1 Inconsistency of how advice is presented on the AICS record of a chemical

There is currently a lack of consistency across assessed chemicals in the way in which NICNAS informs introducers that secondary notification conditions are actually present:

- For chemicals that were assessed as **existing chemicals**, a notation on the AICS record **explicitly** alerts introducers to secondary notification requirements under certain circumstances. There is generally also a direct link to the assessment report for the chemical where the secondary notification conditions are clearly specified.
- In contrast, when chemicals that were assessed as **new chemicals** are added to the AICS (either via early listing or after the assessment certificate expires) a notation on the AICS record only indicates that they have been assessed by NICNAS, and it is **implicit** that secondary notification is required under certain circumstances.

It is preferable that the level of information available to potential introducers of chemicals that have been assessed as new chemicals should approach that of existing chemicals where confidentiality constraints are usually not a consideration.

The subsequent issues to be addressed relate specifically to chemicals originally assessed as new chemicals as the new chemical assessment process involves mechanisms designed to protect confidentiality which need to be taken into account when considering how to enable access to information under which the chemical was assessed.

3.2 Guidance on what constitutes significant changes to risk

In **Attachment 1**, guidance is provided on what constitutes significant changes to risk that may warrant secondary notification. These include changes to use, volume, whether a chemical previously imported has begun to be manufactured, a change to the method of manufacture, and new information on potentially hazardous properties of the chemical that may have been identified since the initial assessment. NICNAS seeks views on the clarity of the guidance at **Attachment 1** noting that the guidance is being revised slightly through the current editing of the *Handbook for Notifiers*.

3.3 Access of introducers to original new chemicals assessment report can breach confidentiality

Currently the original notifiers/introducers of a new chemical are aware of their secondary notification obligations as they have direct access to the NICNAS assessment reports for the chemical. In addition, the secondary notification section of the report is specifically highlighted to the notifiers at the time of issuing their assessment certificates (examples of secondary notification sections drawn from public assessment reports are shown in **Attachment 3**).

The issue arises in ensuring that any other potential introducers of the assessed chemical, including downstream users who receive the chemical from the original notifier or another introducer, are also aware of the secondary notification obligations relating to the chemical and can convey information to the introducer which may lead to a secondary notification. This is the responsibility of the introducer and information to this effect can be included in the regulatory information section of MSDS. Currently, such information is not directly accessible through the AICS as the public assessment reports are not directly linked to the inventory listing for a chemical nor is the information included on the AICS. It is noted that while generally the chemical name and CAS

number of a new chemical formerly under a certificate are available on the public AICS, in the majority of cases the associated public assessment report (which details the secondary notification requirements) only contains trade names for the chemical as the chemical name and CAS number in the assessment report are generally treated as exempt information and so are not published.

The absence of a direct link between the chemical identity information and the public assessment report on the chemical helps to maintain confidentiality following listing on the public AICS.

4 A proposal to address these issues

An overall approach is needed to provide, where possible, the same level of advice on the AICS for previously assessed chemicals (whether existing or new chemicals) and to overcome the problems for introducers of chemicals assessed as new chemicals in accessing enough information to enable them to fulfill their secondary notification obligations.

NICNAS proposes to resolve the above issues by using a combination of three measures as follows:

- as an immediate measure, to add a statement in each AICS record of a chemical assessed as a new chemical that secondary notification conditions may apply. This approach is consistent with that used for assessed existing chemicals and can be implemented easily and quickly by updating the record template for assessed chemicals.
- as a medium term measure, in situations where there was no claim for confidentiality in the original assessment, it is proposed to directly link the AICS record of the chemical to its public assessment report or summary report. This would take a moderate amount of effort as individual records would need to be identified and linked to the corresponding assessment report.
- as a longer-term measure, so as to provide access to specific secondary notification information that is currently in the new chemicals assessment report without revealing confidential information, it is proposed to provide an indirect method to access the information, where:
 - the secondary notification information is relatively generic and so cannot be traced to a specific new chemical assessment report, to simply copy that information into the AICS record or refer to the information in a separate document.
 - where the secondary notification information is more specific and so could be traced back to a number of possible new chemical assessment reports, to make the information more generic by converting the specific types of information (volume, use etc) into volume bands and use categories, and placing those bands and categories into the AICS record;
 - where the information is so specific it can be traced back to one or only a few new chemical assessment reports, to place a statement on the AICS record that the introducer will need to contact NICNAS in writing to obtain a determination as to whether secondary notification obligations are triggered.

This longer-term measure will need to be implemented in the longer term as it requires NICNAS to determine the specificity of the secondary notification information in each new chemicals assessment report and ascertain how it should be treated as described above.

The **advantages** of this proposal are that:

- information regarding secondary notification obligations of assessed chemicals is easily accessible to potential introducers while confidentiality is maintained;

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

- potential introducers can more readily determine if circumstances have occurred that could trigger secondary notification, noting the onus is on the introducer to ensure compliance;
- the process will improve the transparency of the NICNAS assessment process and enhance availability of chemical information.

The **disadvantages** of this proposal are that:

- it is resource intensive for NICNAS to initially amend the AICS entries for all chemicals previously assessed as new chemicals;
- it may also be resource intensive for NICNAS to respond to written enquiries relating to secondary notification requirements that are not specified on the AICS record.

This proposal, and the advantages and disadvantages of each of these measures, is discussed in more detail at **Attachment 4**.

Examples of the information that may be included on the AICS record for chemicals under this proposal are provided in **Attachment 3** although the exact details will need further consideration and comments are invited.

5 Points for discussion

NICNAS is seeking views on a number of issues:

5.1 *Access to information*

- issues associated with improving access by introducers to information on secondary notification as described above
- the proposal at **Attachment 4** which is designed to address these issues, including specific comment on the various measures to improve access and their advantages and disadvantages;

5.2 *Guidance on the meaning of significant changes in circumstances*

In addition, separate to the question of improving access to information to assist in determining if secondary notification obligations would be triggered, NICNAS would appreciate any comments on the clarity of constitutes significant changes in circumstances since the original assessment (**Attachment 1**):

- are the examples in **Attachment 3** sufficiently clear to enable an introducer to judge whether their proposed use of a chemical would constitute a significant change, and therefore whether secondary notification obligations would be triggered? The guidance will be improved over time as feedback is received from introducers, original notifiers and down stream users.
- should NICNAS provide a proforma so that requests for guidance in specific circumstances can be systematic and used to improve the guidance provided?
- how should introducers of a chemical take steps to make customers aware of circumstances under which secondary notification may be triggered? What can NICNAS do in this regard to make users of chemicals aware that secondary notification conditions could be triggered by circumstances surrounding the use of the chemical?

5.3 Confidentiality considerations

Finally, in the examples given in **Attachment 3**, is it possible to link the original assessment report to the AICS record? When the information is to be appended to the AICS record, should the original notifier have an opportunity to suggest amendment if they feel that the confidentiality of their assessment report may be compromised?

Guidance on the meaning of the word “significant” in relation to changed circumstances regarding an introduced chemical

The NICNAS Handbook for Notifiers contains guidance surrounding the interpretation of ‘significantly’ as relevant to section 64(2) of the Act:

“The Introducer Becomes Aware of a Significant Change in Circumstances

When there is a change of circumstances associated with a chemical that has been previously assessed, the onus is on the importer or manufacturer to inform the Director of Chemicals Notification and Assessment (the Director) within 28 days of becoming aware that circumstances have changed.

Relevant circumstances requiring a secondary notification are those which may result in an increased occupational health and safety, public health or environmental risk, as follows:

- A significant new use of the chemical which may:
 - i. increase the potential for human exposure,
 - ii. increase the environmental exposure, or
 - iii. change the type of exposure, for example, from dermal exposure to inhalation.

For example, a chemical initially used as a catalyst in a chemical reaction may later be used as a metal cleaning agent.

- A significant increase in the quantity of chemical imported or manufactured.

For example, a tonnage increase from 1 to 10 tonnes per year or from 50 to 500 tonnes per year. Apart from the potentially increased exposure, a significant increase in quantity may lead to a change in the type of exposure; for example, the means of disposing of large quantities may be different from the methods used to dispose of small quantities.

- Production in Australia may have begun for a chemical initially assessed as an imported chemical.
- A change from less than 1 tonne to more than 1 tonne for a chemical originally notified as Limited Notification Polymer of Low Concern.
- A change in the method of manufacture which may lead to an increased risk by:
 - i. changing from a closed process to an open system,
 - ii. using different raw materials,
 - iii. using different processing conditions,
 - iv. increasing the number of workers required,
 - v. changing the type of exposure,
 - vi. changing the method of waste disposal, or
 - vii. increasing the environmental exposure.

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

New information on potentially hazardous properties of the chemical may have been identified since the initial assessment. For example, it may become known at a later stage that the chemical is carcinogenic.

**EXTRACT FROM THE ICNA ACT RELATED TO SECONDARY NOTIFICATION
PROVISIONS**

Division 6—Secondary Notification after Assessment

64 Introducer to notify Director of certain matters

(1) Where:

- (a) either or both of the following recommends the secondary notification of the chemical in particular circumstances:
 - (i) an assessment report about a chemical;
 - (ii) particulars included in respect of a chemical in the Inventory; and
- (b) the circumstances occur in relation to the introduction of the chemical by a person;

the person must, within 28 days of the occurrence, notify the Director in writing that the circumstances have occurred.

Penalty: 120 penalty units.

(2) Where a person who introduces an industrial chemical that has been assessed under this Act becomes aware of any of the following circumstances, namely, that since the assessment:

- (a) the function or use of the chemical has changed, or is likely to change, significantly;
- (b) the amount of the chemical being introduced has increased, or is likely to increase, significantly;
- (c) in the case of a chemical not manufactured, or proposed to be manufactured, in Australia at the time of the assessment—it has begun to be manufactured in Australia;
- (d) the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the chemical on occupational health and safety, public health or the environment;
- (e) additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health or the environment;
- (f) a prescribed event has happened;

the person must, within 28 days of becoming aware, notify the Director in writing of the circumstances of which the person has become aware.

Penalty: 120 penalty units.

(2A) To avoid doubt, the reference in subsection (2) to an industrial chemical that has been assessed under this Act includes a reference to:

- (a) a chemical that has been assessed under section 33A (self-assessment); and
- (b) a chemical that has been assessed but that is now included in the Inventory.

(3) For the purposes of subsection (2), a person is to be taken to have become aware of circumstances if, having regard to:

- (a) the person's abilities, experience, qualifications and other attributes; and
- (b) the nature of the circumstances;

the person ought reasonably to have become aware of the circumstances.

(4) 2 or more persons on whom are imposed obligations under this section in relation to an industrial chemical may comply with those obligations by jointly notifying the Director under this section.

EXAMPLES OF PROPOSED ADDITIONS TO AICS RECORDS DERIVED FROM THE SECONDARY NOTIFICATION SECTIONS OF PUBLIC ASSESSMENT REPORTS

In this attachment examples of the sections of assessment reports outlining the conditions under which secondary notification may be required are given. All categories of new chemicals assessment are covered. Following each example a possible addition of information to the AICS record of the notified chemical is appended. The precise wording is yet to be decided upon and is provided for illustrative purposes. These are not annotations under the Section 13 power of the Act.

Note: highlighted text has been added to draw attention to key points.

Example 1 – Polymer of Low Concern (PLC) assessment

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from an additive in lubricants, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 100 tonnes, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record in the 'Information field' of the record only

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for

which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the notified polymer is introduced in a chemical form that does not meet the PLC criteria;
- (ii) If the function or use of the chemical has changed from use in fuel and oil products, or is likely to change significantly;
- (iii) The amount of chemical being introduced has increased from 100 tonnes, or is likely to increase, significantly;
- (iv) If the polymer has begun to be manufactured in Australia;
- (v) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

Example 2 – Polymer of Low Concern (PLC) assessment

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
 - the notified polymer is introduced in the powdered form.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from component of printer ink for use in inkjet printers, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record in the 'Information field' of the record only

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the notified polymer is introduced in a chemical form that does not meet the PLC criteria;
- (ii) If the function or use of the chemical has changed from use in officer supplies, or is likely to change significantly;
- (iii) The amount of chemical being introduced has increased from [assessed volume to be inserted], or is likely to increase, significantly;
- (iv) If the polymer has begun to be manufactured in Australia;
- (v) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

IMPORTANT NOTE: Additional secondary notification requirements apply to this chemical. Please contact NICNAS to enquire about these obligations before introducing this chemical.

Example 3 – Limited (LTD) assessment (Synthetic polymer with Mn ≥ 1000 Da)

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

- (1) Under Section 64(1) of the Act; if
- the polymer has a number-average molecular weight of less than 1000;
 - the polymer is imported in a mixture that can be aerosolised;
- or
- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from hotmelt adhesive for book-binding, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 30 tonnes, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record under the proposed option ('Information field' of the record only)

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the notified polymer has a number-average molecular weight of less than 1000;
- (ii) If the amount of polymer being introduced has increased from 30 tonnes, or is likely to increase, significantly;
- (iii) If the polymer has begun to be manufactured in Australia;
- (iv) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

IMPORTANT NOTE: Additional secondary notification requirements apply to this chemical. Please contact NICNAS to enquire about these obligations before introducing this chemical.

Example 4 – Limited (LTD) (Chemical other than polymer (1 tonne or less per year)).

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the importation volume exceeds one tonne per annum notified chemical;
 - the notified chemical is introduced with a particle size of 100 nm or less.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component in toner cartridges at a concentration of 1%, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record in the ‘Information field’ of the record only

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the importation volume exceeds one tonne per annum notified chemical;
- (ii) If the function or use of the chemical has changed from use in officer supplies at concentrations exceeding 1%, or is likely to change significantly;
- (iii) If the polymer has begun to be manufactured in Australia;
- (iv) If additional information has become available to the person as to an adverse

effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

IMPORTANT NOTE: Additional secondary notification requirements apply to this chemical. Please contact NICNAS to enquire about these obligations before introducing this chemical.

Example 5 – Standard (STD) assessment

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from use as a stabiliser for polymer dispersion in coatings and adhesives, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 20 tonnes, or is likely to increase, significantly;
 - the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

How this may appear on the AICS record in the 'Information field' of the record only

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

importer or manufacturer if *any* of the below circumstances occur:

- (i) If the function or use of the chemical has changed from **use in surface coating products and engineering products**, or is likely to change significantly;
- (ii) If the amount of chemical being introduced has increased **from 20 tonnes**, or is likely to increase, significantly;
- (iii) If the polymer has begun to be **manufactured in Australia**;
- (iv) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

Example 6 – Standard (STD) assessment

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - adverse incidents involving the notified chemical occur;
 - regulatory action on the notified chemical is undertaken by other jurisdictions;
 - details of the operation description are altered such that exposure to workers or the environment may be increased;
 - additional data become available on the genotoxicity or carcinogenicity of the notified chemical;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from **production of composite aerospace components**, or is likely to change significantly;
 - the amount of chemical being introduced has increased from **40 tonnes per annum**, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record in the ‘Information field’ of the record only

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the amount of chemical being introduced has increased from 40 tonnes, or is likely to increase, significantly;
- (ii) If the chemical has begun to be manufactured in Australia;
- (iii) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

IMPORTANT NOTE: Additional secondary notification requirements apply to this chemical. Please contact NICNAS to enquire about these obligations before introducing this chemical.

HAZARD INFORMATION

The NICNAS assessment of this chemical has assessed it as follows, according to the *Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004)*:

R48/22: Harmful – danger of serious damage to health by prolonged exposure if swallowed.

Example 7 – Standard (STD) assessment

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the function or use of the chemical has changed from an ingredient in cosmetics and domestic products at $\leq 0.05\%$.

or

- (2) Under Section 64(2) of the Act; if

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

- the amount of chemical being introduced has increased from 2 tonnes, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

How this may appear on the AICS record in the 'Information field' of the record only

NOTE: the precise wording has not been confirmed and the below is only provided for example purposes.

NICNAS conducted a risk assessment on this chemical based on the information available at the time of notification. Under Section 64 of the Industrial Chemicals (Notification and Assessment) Act (1989) any importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when there are changes to any of the circumstances for which it was assessed. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

The Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer if *any* of the below circumstances occur:

- (i) If the function or use of the chemical has changed from use in cosmetic/personal products or domestic/cleaning products at concentrations exceeding 0.05%, or is likely to change significantly;
- (ii) If the amount of chemical being introduced has increased from 2 tonnes, or is likely to increase, significantly;
- (iii) If the chemical has begun to be manufactured in Australia;
- (iv) If additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (ie. a secondary notification and assessment) is required.

NICNAS PROPOSAL FOR IMPROVING ACCESS TO INFORMATION ON SECONDARY NOTIFICATION CONDITIONS FOR ASSESSED CHEMICALS

1 The Proposal

To improve access to information on secondary notification conditions for assessed chemicals, NICNAS proposes to implement a combination of three measures. These were outlined in the main body of the proposal and are presented in more detail here.

1.1 Measure One - short term implementation

For each chemical assessed as a new chemical that is listed on the AICS, a statement will be added as part of the AICS record as follows:

Secondary Notification Conditions

Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act 1989*, the secondary notification of a chemical that has been assessed under the Act may be required where change of any circumstances that may warrant a reassessment of its hazards and risks occurs.

The Director of NICNAS must be notified within 28 days of the introducer becoming aware of any circumstances prescribed under Section 64 of the Act. It is an offence under section 64 of the Act if the Director is not notified of the change in circumstances.

This will provide consistency with the current wording used for existing chemicals that have been assessed by NICNAS.

1.2 Measure Two - medium term implementation

As a medium term measure, in situations where there was no claim for confidentiality in the original assessment by way of data being exempt from publication, it is proposed to directly link the AICS record of the chemical to its public assessment report or summary report.

1.3 Measure Three – longer term implementation

To ensure effective implementation of the sections of the Act relating to secondary notification and improved access to information about secondary notification obligations regarding chemicals assessed as new chemicals, and remaining cognisant of confidentiality considerations, it is proposed that different approaches be taken depending on whether the information is generic, somewhat specific or highly specific to one or a few new chemical assessment reports. This will determine what, if any, information is placed on the AICS record.

If the information is generic it can be placed on the AICS record or provided in a document linked to the record.

If the information can be made more generic so that the original assessment report cannot be traced or can be generalised as, for example, volume bands or general use categories, those bands and categories can be placed on the AICS record.

If the information is highly specific a statement should be made on the AICS record stating that the introducer will need to contact NICNAS in writing to obtain a determination as to whether secondary notification obligations are triggered.

1.3.1 Addition of information to the AICS record

It is proposed that, whenever possible, information regarding the secondary notification conditions relevant to an assessed chemical be added to the 'Information' field of the AICS record for the chemical. The content of the information placed on the AICS record for a particular chemical will be dependent upon the level of unique detail present in the secondary notification conditions for the chemical and the confidentiality requested by the original notifier and agreed to by NICNAS. The overall approach is discussed below with a generic example, and specific examples of how text would appear in the AICS records of various types of chemicals are given in **Attachment 3**.

The following secondary notification information proposed to be included in the AICS record for an assessed chemical *where there has been a claim for exempt information in the original assessment*:

Section 64(1) conditions (where specified)

The following is the proposed information to be available on the AICS record for such a chemical:

- Explicit s. 64(1) conditions unique to a particular risk assessment would **not** be included. Instead, introducers would be instructed to contact NICNAS in writing to obtain more complete information pertaining to the secondary notification obligations.
- Standard s. 64(1) conditions as follows (see Examples 1, 3 and 4 in **Attachment 3**):
 - for PLC assessments: *for example*
the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
 - for Limited (LTD) assessments: *for example*
the importation volume exceeds one tonne per annum notified chemical;
the notified chemical is introduced with a particle size of 100 nm or less.
 - for Limited assessments (synthetic polymers with number-average molecular weight ≥ 1000) *for example*
the polymer has a number-average molecular weight of less than 1000;
the polymer is imported in a mixture that can be aerosolised.

Note: In all cases where s. 64(1) conditions are present, the information outlined below for the relevant s. 64(2) conditions should also be included in the AICS record.

Section 64(2) conditions (present in all reports)

The following is the proposed information to be available on the AICS record for all such chemicals, and employs the use of categories to minimize the tracing of specific information back to the original new chemicals assessment report:

Use of the chemical:

- In most cases, **general use categories** may be included. Such categories may correspond to the general use categories by which recent public assessment reports are categorised on the NICNAS website (**see list of general use categories at the end of this Proposal**).

A PROPOSAL TO IMPROVE ACCESS TO INFORMATION ON ASSESSED CHEMICALS TO BETTER
INFORM SECONDARY NOTIFICATION OBLIGATIONS

- In some cases, the AICS record is proposed to instruct potential introducers to contact NICNAS in writing for further information. This will be used in cases such as those where the assessed use is not appropriately covered by the general use categories, or those falling under the ‘Other’ use category.

Introduction volume:

An appropriate indication of the introduction volume will be used. This may include information regarding the maximum assessed introduction volume or a volume range.

Import/manufacture:

- Specify whether the chemical has been assessed for import or manufacture.
- In cases where the original assessment was for manufacture, it is proposed to instruct potential introducers to contact NICNAS in writing for further information (given that the requirement under s. 64(2)(d) relates to changes in the method of manufacture from that which was assessed).

Text taken directly from s. 64(2)(e) relating to additional information as to adverse effects of the chemical.

This text should be included in the AICS record of all assessed chemicals. Additionally, it is proposed that, in order to assist in the determination of potential introducers relating to this item, that any **hazard classifications** for the assessed chemicals also be included in the AICS record (see Example 6, **Attachment 3**).

Examples of the information that may be included on the AICS record for chemicals under this proposal are provided in **Attachment 3**.

1.3.2 Contacting NICNAS directly

When potential introducers are directed to contact NICNAS, they would need to provide NICNAS with information in writing detailing their proposed introduction and use of the chemical in Australia. NICNAS would then advise if their proposed circumstances were covered by the original assessment of the chemical and whether secondary notification was necessary. Each time the introducer amends the details of their introduction or use of the chemical in Australia (in aspects not specified on the AICS record), it would be necessary for NICNAS to be contacted in order to confirm the acceptability of these details.

In addition, under this proposal, having accessed the information (from the AICS record) against which the person introducing the chemical can compare their intended uses and introduction information for the chemical, the person would still need to determine whether they should then notify the Director as to a possible secondary notification under sections 64(1) or (2) of the Act.

The following must also be noted regarding this consideration:

- The resource intensiveness of NICNAS manually deciding on the appropriate general use categories and volume ranges/limits to be included on the AICS record; and
- That the information on the AICS record needs to be reliable enough to allow an introducer to make an informed decision regarding their secondary notification obligations.

2 Advantages and disadvantages of the proposal

The combination of the three proposed measures –short term , medium term and longer term – has the following advantages and disadvantages, which need to be jointly considered to determine the practicality of applying this proposal.

2.1 *Advantages of the proposed approach*

- (i) Information regarding secondary notification obligations of assessed chemicals is easily accessible to potential introducers. Introducers can alert downstream users to these obligations and request to be notified if use patterns are proposed to be modified. Ultimately this will also provide NICNAS with a better idea of how chemical use patterns change over time.
- (ii) Confidentiality is largely maintained. Where confidentiality is no longer required, the information on the AICS record can be expanded. It is common for chemicals for which exempt information has been claimed for identity in the original notification to be listed on the public AICS when the Assessment Certificate expires. This indicates that confidentiality considerations change over time. It is of interest to NICNAS to obtain more information on the life cycle of chemicals as this improves the ability of NICNAS to assess chemical risks.
- (iii) Allows potential introducers to make their own determination, on several aspects of the secondary notification conditions, as to whether secondary notification of a chemical is necessary. Currently potential introducers would need to obtain information from the original notifier to make the determination.
- (iv) Maintains the onus largely on introducers, as required under legislation, to ensure compliance with the secondary notification obligations under the Act. This is consistent with section 64 of the Act where the obligation is placed on the introducer to notify the Director of certain circumstances. However, the intent is to provide introducers with easy access to information to fulfill their obligations under the Act.
- (v) Improves the transparency of the NICNAS assessment process and enhances availability of chemical information. This is consistent with the AICS being more than just a list of chemical particulars and is consistent with the expected increase in chemical information derived from the NICNAS IMAP process in which AICS chemicals are intended to be ranked in order of concern.

2.2 *Disadvantages of the proposed approach*

- (i) The longer term measure is resource intensive for NICNAS to initially amend the AICS entries for all chemicals previously assessed as new chemicals. This is not a trivial exercise and will need to be allowed for in forward planning.
- (ii) Under the longer term measure, it may be resource intensive for NICNAS to deal with written enquiries relating to secondary notification requirements that are not specified on the AICS record. This will also need to be allowed for in forward planning although it is difficult to predict the number of enquiries that can be expected.

GENERAL USE CATEGORIES

The use categories shown in the table below are currently the basis upon which public assessment reports on the NICNAS website are categorised. The first column shows the use category, as appearing on the website, whilst the second column shows examples of the specific uses that may be covered by each category.

| General use category | Examples |
|--------------------------------|--|
| Engineering | adhesives/sealants, concrete, other |
| Cosmetics/Personal | hair, nail, lip, skin, cleaners-hand/body, eye, oral cavity, perfume, deodorant, personal products |
| Domestic/Cleaning | air freshener/deodoriser, cleaners-surface, dishwashing/laundry |
| Education | - |
| Research & Development | - |
| Electrical/Electronic | - |
| Explosives | - |
| Fuel and Oil | fuel and fuel additives, oil-general, oil-other, hydraulic fluid |
| Leather Processing | colouring, preservative |
| Manufacture of Other Chemicals | - |
| Mining and Metal Extraction | flotation agent, other |
| Office Supplies | photocopying/laser printing, inkjet printing, other office supplies |
| Packaging | - |
| Paper & Pulp | surface chemicals, other additives |
| Photographic | film and paper manufacture, developing chemicals |
| Plastics | monomers, catalysts, base resins, additives-flame retardants, additive-antimicrobial, additives-other |
| Printing Industry | acrylates/plate making, inks, other lithographic applications |
| Refrigeration | - |
| Surface Coatings | auto-refinishing, auto-original equipment manufacture, architectural-solvent based, architectural-water based, industrial coatings |
| Textile Processing | dyes, softeners, other |
| Water Treatment | - |
| Other | - |