

GUIDANCE
Use of overseas assessments in the notification of new chemicals

Currently there are four avenues for using overseas assessments conducted elsewhere:

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| Approved Foreign Scheme - Canada |
| Modular Assessment (Comparable Agency) - Canada |
| Modular Assessment (Comparable Agency) - US |
| Modular Assessment (Comparable Agency) - EU |

Under these arrangements, if a new chemical is notified to NICNAS and had been previously assessed in Canada, the US or the EU, **and if access to the overseas health and environmental hazard assessment can be provided to NICNAS**, the hazard assessment can be considered and, where appropriate, used in the NICNAS assessment report. The other elements of the risk assessment and recommendations on safe use of the chemical in Australia will still be carried out by NICNAS.

Approved Foreign Scheme - Canada

Applications under the Approved Foreign Scheme Provisions can be made for a chemical that was notified and assessed in Canada as a new chemical under an **equivalent schedule (refer to table below)** to a Standard (STD), Limited (LTD) or Polymer of Low Concern (PLC) notification in Australia.

The following table summarises the equivalent notification categories in Australia and Canada:

| NICNAS CATEGORY | CANADA CATEGORY (current regulations - 2005) | CANADA CATEGORY (older regulations - 1994) |
|------------------------|---|---|
| Limited | 5 or 10 | II or VII |
| Standard | 6 or 11 | III or VIII |
| PLC* | 9 (only RRR) | VI or VII (only low concern polymers) |

*Polymers must meet Australian PLC criteria in order to be considered under the Approved Scheme.

Circumstances under which an application under the Approved Foreign Scheme provision does not apply, however will be considered as a modular assessment category include, but are not limited to, the following:

- If the Canadian assessment has been based on information that cannot be released to NICNAS, or cannot be published;
- If the assessment was based on third party analogue data;
- If the information used in the Canadian assessment does not fulfil the data requirements for the notified category in Australia;
- If significant additional information has become available since the Canadian assessment e.g. additional toxicological or ecotoxicological studies;

- For the PLC category, if additional data is required due to significant potential releases to the environment or intended wide dispersive use by the public, eg. cosmetics.

If unsure whether your application fulfils the requirements of an approved foreign scheme it is best to make the application under the Modular assessment (Comparable Agency) – Canada category. Please contact NICNAS if unsure which category is appropriate.

After receipt of the notification and screening, NICNAS will advise you if the application is considered as an approved foreign scheme or modular category.

Modular Assessment- US and Modular Assessment - Canada (Comparable Agencies)

This assessment type covers applications (STD, LTD or PLC) of new chemicals that were previously notified and assessed in Canada OR the US.

Note that an application under the Approved Foreign Scheme is only applicable for Canada and for chemicals that were assessed under equivalent notification categories. If unsure, it is strongly recommended to make the application under the Modular (Comparable Agency) Assessment type, in order to avoid delays in the assessment process. Under some circumstances (see above), the Director may consider the application not to be suitable under the approved foreign scheme.

Modular Assessment – EU (Comparable Agency)

This assessment type covers LTD and STD applications where the chemical was previously assessed in the European Union (EU) and the notifier can provide NICNAS with the EU assessment report to be used in the Australian notification. A validation letter from the EU authority is also needed. Please contact NICNAS if you wish to use this system. The arrangements apply to new chemicals assessed pre-REACH, and we understand that similar reports may not be available under REACH.

Outline of the Process:

Notification category

(a) Applications under the Modular (Comparable Agency) or Approved Foreign Scheme system can be made for the STD, LTD and PLC categories. An application for a self-assessed assessment certificate cannot be made under these provisions.

Assessment

A key requirement is that the notifier must be able to arrange for Agreement to release information from Canada or US to Australia (see below). Release of the information or overseas report(s) should be requested from Environment Canada (if the chemical was assessed in Canada) or the United States Environmental Agency (US EPA) (if the chemical was assessed in the US).

For Canada, the request to release information should be arranged **at least sixty days** prior to submission of the notification to NICNAS. Information on the process for obtaining these assessment reports can be found under Q6 of the Q&A document. EU reports should be provided with the NICNAS notification. Contact NICNAS if you are considering using the arrangements with the US.

Notification forms

The relevant notification form for a STD, LTD or PLC notification should be completed.

The information required to accompany the template notification includes:

(a) A copy of all information provided to US, Canada or EU, and available to the notifier, including:

- (i) all test data;
- (ii) all other information submitted in the technical dossier; and
- (iii) any information that was provided in response to a request for further information.

(b) A copy of any other available information about the chemical, for example, toxicity test data, environmental test data and information not provided for notification to Canada/US, or information or data generated since the overseas assessment. All NICNAS schedule data requirements should be addressed for the relevant assessment category. An application for variation of the data requirements can also be made.

(c) Information relevant to occupational health and safety in Australia.

(d) Information about the use, volume, manufacture and disposal of the chemical, including exposure information in Australia.

(e) Confirmation that the chemical notified to NICNAS is the same as the chemical assessed in the overseas assessment. For PLC notifications, the polymer must meet the NICNAS PLC criteria and have a similar molecular weight profile and monomer composition to the polymer assessed overseas.

(f) An application for exempt information where the applicant claims certain information to be treated as exempt from publication. Please note that information that was treated as confidential business information overseas is not automatically treated as confidential (exempt) information in Australia.

The Director may request further information if required to enable an adequate assessment of the chemical.

Fees

A specific reduced fee (either Approved Foreign Scheme or Comparable Agency) will apply. If during screening it is determined that an Approved Foreign Scheme application is not eligible for this category, the application may be considered under the Modular (Comparable Agency) category. If unsure, it is best to make the application under the Modular assessment - Canada.

Additional guidance about these arrangements is provided under the Q&A document.

OECD Parallel Process under the OECD Clearing House on New Chemicals

The Organization for Economic Cooperation and Development (OECD), through its New Chemicals Task Force, has encouraged efforts to maximise work sharing arrangements in the notification and assessment of new chemicals, with a goal of Mutual Acceptance of Notifications (MAN). Accordingly, the Parallel Process has been developed to facilitate the notification and assessment of new industrial chemicals under multi-lateral arrangements.

The Parallel Process will reduce the time associated with notification to multiple jurisdictions. In addition, this work sharing process is intended to improve decision making by sharing knowledge and expertise in the area of new chemical assessments, increasing work efficiencies among OECD member countries, and building upon the efforts of all countries involved. Procedures are in place to preserve confidentiality.

The Parallel Process

In the Parallel Process a company notifies a new chemical to multiple jurisdictions (of their choice), providing an agreed set of data to all participating countries, namely, a lead country and secondary countries. In principle, the lead country conducts the hazard assessment, secondary countries provide input into this process, and then, once the hazard assessment is accepted by the notifier, each participating country uses the hazard assessment in conducting its own risk assessment.

Phases of the Parallel Process

The Parallel Process consists of three phases, namely, the Pre-notification Phase, the Notification Phase and the Assessment Phase. These are described below.

(a) Pre-notification Phase

The notifier identifies and contacts the potential lead authority and requests their agreement to participate and to be the lead authority. The company contacts the other selected authorities and requests their agreement to participate as secondary countries. If any authority declines to participate, the company revises its plans accordingly. The company may identify countries where it would be beneficial to engage as observers. Observer status allows the country to receive information and monitor how assessments are conducted and provide informal input on the hazard assessment, without affecting the timing or content of the process.

In preparation for a Pre-Notification Consultation (PNC), the company gathers a draft Predetermined Set of Information (PSI) for the substance, which is structured around the OECD Minimum Pre-marketing Dataset, similar to the standard NICNAS notification package. Contents of the PSI should address, as appropriate, physical and chemical properties, environmental fate parameters (including biodegradation and bioaccumulation), ecotoxicity and health effects information relevant to the notified substance, and any additional information in the company's possession. The PSI may be revised accordingly as a consequence of the PNC discussions.

The company provides the draft PSI package to the lead authority and to the other participating authorities prior to the PNC in order to enable a preliminary review of the notification package. The lead country chairs the PNC meeting(s), or teleconference(s), the intent being to discuss the PSI with all parties and seek agreement on its content. The decision on the acceptability of any proposed testing, including approaches used to address the PSI and how these approaches satisfy the needs of participating jurisdictions, may require more than one meeting before final acceptance by all participants. The participants are expected to work promptly to complete this process, within a timeframe agreed at the start of the PNC process.

(b) Notification Phase

The company submits the notification package to the lead country, including any specific notification form as required and payment of any required fees. The lead country assesses the

notified substance as per its legally required assessment time clock, following their national regulatory assessment procedures.

(c) Assessment Phase

The lead country prepares a draft hazard assessment report and sends it to the participating countries for comment. The lead authority will develop the final collective draft hazard assessment considering comments received from the secondary countries. This will be issued to the notifier for comments, and subsequently, finalised by the lead country.

After receipt of the final hazard assessment, the notifier supplies national notification forms and the completed collective hazard assessment to the other participating countries, with any fees as required by those countries (although commonly notification forms and secondary country specific information such as environmental release and occupational exposure data are submitted to the secondary countries at an earlier stage).

Fees

Normal fees apply if Australia is the lead country. Otherwise a reduced fee applies (contact NICNAS). No fee applies if Australia is an observer only.

Further Information

Further information on the Parallel Process can be obtained from the New Chemicals Program at NICNAS.