

Q&A

Questions and Answers - New Chemicals Notified and Assessed using Overseas Assessments

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| Approved Foreign Scheme – Canada |
| Modular Assessment – Canada |
| Modular Assessment – US |
| Modular Assessment – EU |

1. What is an Approved Foreign Scheme- Canada?

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) provides for the Minister to approve a specified foreign scheme for the purposes of the Act. This means that under certain conditions a new chemical (or polymer) can be notified and assessed under section 44 of the approved foreign scheme provisions.

Canada is now officially an approved foreign scheme, meaning that the provisions of the Act apply to **Standard (STD)**, **Limited (LTD)** and **Polymer of Low Concern (PLC)** notifications in Australia, where the new chemical was previously notified and assessed in Canada **under a comparable schedule**.

Notifiers applying under these provisions should ensure that they are applying using comparable schedules to the Australian assessment category. (See Q9). If unsure it is best to submit an application under the Modular system and NICNAS will determine whether the application fulfils the requirements for an Approved Foreign 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.

2. What are the differences between the Approved Foreign Scheme and the Modular Assessment System?

1. The Approved Foreign Scheme provisions apply only to Canada.
2. Tighter conditions apply to the Approved Foreign Scheme e.g. the notification category must be comparable to the Australian category for an Approved Foreign Scheme application. See also Q5.

3. The fee for an Approved Foreign Scheme application is reduced by 40%. However if your application is considered as unsuitable for this system you may have to pay additional fees and the application reverts to the Modular system. The upfront fee for Modular is the regular fee for the notification category. A rebate of up to 40% is calculated at the end of the assessment.

3. What are the similarities between the Approved Foreign Scheme and the Modular system?

1. The Australian notifier (through the Canadian/US applicant) should arrange release of the overseas review reports to NICNAS. The EU report is supplied by the notifier.
2. The submission must be provided using the NICNAS template.
3. The information accompanying the application is according to the notification category (LTD, STD or PLC).
4. Both systems provide fee incentives. The Modular system is based on issuing rebates (up to 40%) at the end of the assessment. The Approved Foreign system is based on paying an upfront reduced fee [see Q2(3) above].

4. What conditions apply for using overseas assessment reports?

The most important condition is that the overseas assessment must be available to NICNAS for use in the Australian assessment.

5. What does NICNAS look for when screening my application and determining the rebate and eligibility for the Approved Foreign Scheme?

1. If the overseas assessment has been based on information that cannot be released to NICNAS, or cannot be published;
2. If the assessment was based on third party analogue data;
3. If the information used in the overseas assessment does not fulfil the data requirements for the notified category in Australia;
4. If significant additional information has become available since the overseas assessment e.g. additional toxicological or ecotoxicological studies;
5. 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.

6. How do I request release of the Canadian or USA reports to NICNAS?

The following steps are involved:

1) Australian notifier should contact their affiliate in Canada or US to arrange release of the assessment reports. Only the notifier for assessment of the chemical in Canada or US can authorise release of the reports for use in Australia.

Where the chemical was assessed overseas as a foreign supplier notification, authorisation for release of the reports in Australia must be obtained from both the notifier and the foreign supplier;

2) The Canadian or US notifier should request release of the overseas reports.

The link to the pro-forma letter for Canada is [here](#).

Please contact NICNAS to enquire about the arrangements with the US.

3) The pro-forma letter (for Canada) authorising release of the information to NICNAS should be forwarded to Environment Canada **at least 60 calendar days** before the notification to NICNAS is made.

4) A copy of the request letter should be sent to NICNAS, for the attention of the New Chemicals Program, with information about the new chemicals notification that will be made to NICNAS e.g. name of the Australian notifier, category of notification in Australia.

7. What if the review in Canada is not complete at the time of notification in Australia?

The report(s) will be supplied to NICNAS within 60 days of their completion. In these circumstances the notification to NICNAS may be delayed until the Canadian assessment is available, or a normal STD, LTD or PLC notification could be made to NICNAS.

8. What specific matters do I need to consider when submitting an application for a chemical that was previously assessed in Canada or the US?

The Australian notifier should consider:

1. Will the Canadian or US notifier of the chemical be willing to authorise release of the overseas report to NICNAS?
2. What is the Schedule under which the chemical was assessed in Canada under the New Substances Notification Regulations?
3. Was confidential business information (CBI) claimed in Canada or US for any information relating to the chemical? Note that information treated as CBI in Canada or US (for example, chemical identity) will not automatically be considered confidential under the Australian scheme, and an application for Exempt Information will be necessary upon submission of the assessment to NICNAS;
4. For PLC category assessments, whether the polymer meets the PLC criteria in Australia, as there are some differences between the PLC criteria and the Canadian reduced regulatory requirement (RRR, formerly known as low concern polymer) criteria (see below for details). In addition, the polymer should have a similar molecular weight profile and monomer composition to that assessed in Canada. See question 11 for further information.

NOTE: If you are unsure whether your application fulfils all the conditions for the Approved Foreign Scheme, you may submit your notification under the Modular system and NICNAS will consider during screening whether the application is eligible for the full 40% rebate.

9. Which assessment categories in Australia and Canada are similar?

| 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 (RRR only) | VI or VII (only low concern polymers) |

*Must meet Australian PLC criteria in order to be considered under the Approved Foreign Scheme.

10. What is the procedure for using the Modular – EU option?

This category can apply to notifications to NICNAS in the Standard (STD) and Limited (LTD) categories if the chemical has been previously assessed in the European Union (EU), and the notifier can provide NICNAS with the EU risk assessment report. A validation letter

from the EU national authority should also be provided, stating that the report is the full and final version issued for the chemical.

These arrangements apply to chemicals assessed in the EU pre-REACH. Similar reports are not expected to be available under REACH.

11. What if my polymer was notified under the low concern or RRR polymer category in Canada but does not meet the NICNAS PLC criteria?

There are some differences between the Australian PLC criteria and the Canadian RRR criteria. If the notified polymer is found to have met the RRR criteria, but does not meet *all* of the PLC criteria, particularly related to the aspects outlined below, it will not be eligible for a PLC notification under the approved foreign scheme or modular provisions. In such circumstances, an alternative notification category, such as STD or LTD, should be considered. Further information on the PLC criteria can be found in Appendix 10 of the [NICNAS Handbook for Notifiers](#).

The Australian PLC criteria differ from the Canadian RRR criteria in the following aspects:

- The PLC criteria include requirements for the notified polymer not to be classified as a hazardous chemical or dangerous good.
- A polymer that is capable of absorbing its own weight in water and has a number average molecular weight greater than 10,000 Dalton does not meet the PLC criteria.
- The PLC criteria requires that the reactive functional groups present within the notified polymer that are listed as being of *high* concern must have a combined functional group equivalent weight (FGEW) of at least **5000**. Note that, according to the Canadian RRR or low concern polymer criteria, a number of these same functional groups must have a combined FGEW of only **1000** or more (see below for list of these groups).

Reactive functional groups for which the FGEW cut off is 1000 under the Canadian RRR criteria, but 5000 under the NICNAS PLC criteria:

| | |
|-----------------|---|
| Acid halides | Alkoxysilanes with alkoxy greater than C ₂ - |
| Acid anhydrides | Allyl ethers |
| Aldehydes | Conjugated olefins |
| Hemiacetals | Cyanates |
| Methylol-amides | Epoxides |
| Methylol-amines | Imines |
| Methylol-ureas | Unsubstituted positions ortho and para to phenolic hydroxyl |

***NOTE:** If you are unsure whether the polymer meets the PLC criteria, please contact the New Chemicals Program at NICNAS.*

12. Do I have to submit the usual data to NICNAS for assessment, for Approved Foreign Scheme or Modular notifications?

Yes, all schedule data requirements for the NICNAS assessment must be addressed. However, an application for variation of the data requirements can be made, as for other assessments. Further, any other relevant data held must be submitted. Please note that the data requirements are not identical between countries and that the data submitted to the overseas country may not meet all NICNAS data requirements. During screening NICNAS will consider to the extent possible whether the information submitted to the overseas country can

fulfil the requirements for the assessment in Australia. The Director may also request further information if required to enable an adequate assessment of the chemical.

The following table summarises the comparable 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.

13. What should I do if I have additional data on the chemical that was not assessed by the overseas country?

This data should be submitted as part of the data package to NICNAS, and will be assessed by NICNAS.

14. Can third party data be submitted for a new chemicals application under the approved foreign scheme provisions?

Yes. Data from a third party can be submitted directly to NICNAS for the Australian assessment. Please contact the New Chemicals Program if unsure.

15. What is the timeframe for assessment of applications made under the approved foreign scheme or modular provisions?

The 90-day statutory assessment timeframe applies for the STD, LTD and PLC applications. The clock starts when the overseas reports, assessment fees and all information have been received.

16. Under the Approved Foreign Scheme, how will NICNAS use the Canadian assessment in the NICNAS report?

NICNAS will incorporate elements of the Canadian assessment, including physico-chemical properties, toxicity and ecotoxicity, into the NICNAS assessment. The Canadian assessment reports will also be used to confirm chemical identity information, molecular weight distribution (for polymers) and justification of the PLC criteria (where appropriate). Any additional hazard data will be assessed by NICNAS. Other elements of the risk assessment and recommendations on safe use of the chemical in Australia will be carried out by NICNAS.

17. My company wishes to notify a new chemical in more than one country in the near future. Are there any co-operative arrangements for doing this?

Yes, the chemical could be notified and assessed under the OECD Mutual Acceptance of Notifications (MAN) pilot Parallel Process, which also offers fee reductions. Participating countries include Canada and Australia, as well as other OECD countries. Contact NICNAS if you are interested in these arrangements.

18. How can I find further information on making new chemical applications under the Bilateral or Multilateral arrangements?

Please [contact NICNAS](#) and ask to have your query directed to the New Chemicals Program.

You may also wish to request a pre-notification consultation with NICNAS staff to obtain advice relating to your submission.