



Australian Government

Department of Health and Ageing
NICNAS

**A COMPLIANCE GUIDE FOR INTRODUCERS OF
INDUSTRIAL CHEMICALS:**

A CHECKLIST APPROACH

FOREWORD

Industrial Chemicals (Notification and Assessment) Act 1989 (the Act)

NICNAS has prepared this guidance material for the chemical industry to help build its understanding of NICNAS requirements for compliance with the Act and its regulations. This publication will be updated regularly as the need arises to include new and revised aspects of NICNAS requirements.

The checklist guide to compliance is not meant to be comprehensive, but offers guidance on how industry can meet its obligations under the Act.

The Act distinguishes the following compliance elements:

1. New Industrial Chemicals
 - General
 - Exemptions
 - Permits
 - Self assessed chemicals
2. Priority Existing Chemicals
3. Assessed Chemicals
4. Registration of Chemical Introducers
5. Treaties

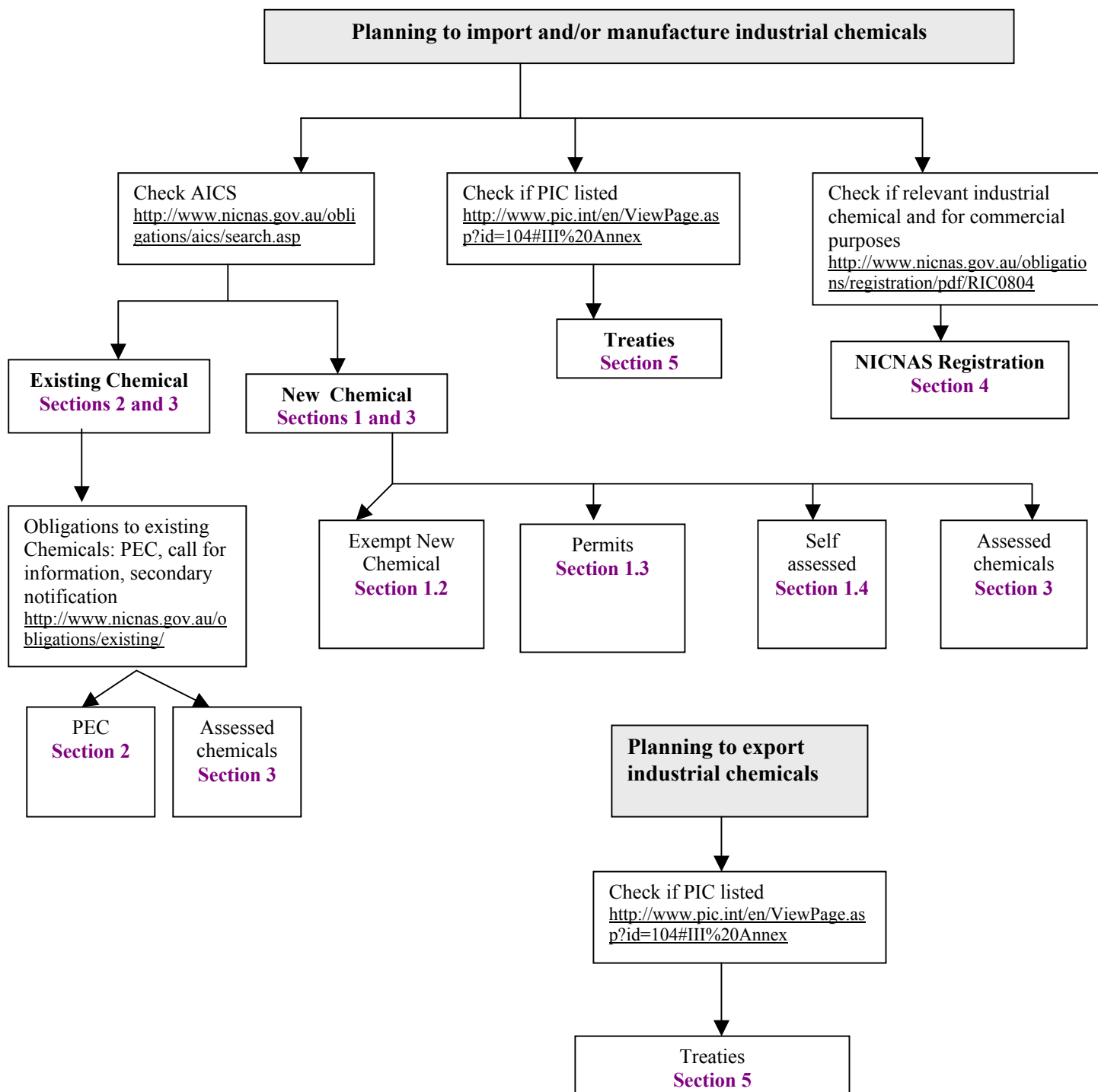
The information contained in this document should be used as a guide only and is not legally binding and non justiciable. Persons should refer to the *Industrial Chemicals (Notification and Assessment) Act 1989* and the Industrial Chemicals (Notification and Assessment) Regulations 1990 which can be accessed via the Comlaw website of the Australia Attorney-General's Department at <http://www.comlaw.gov.au>.

NICNAS Compliance
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FRAMEWORK OF NICNAS's COMPLIANCE CHECK



1. NEW CHEMICALS

1.1 GENERAL REQUIREMENTS

All new industrial chemicals must be notified to NICNAS, and an assessment certificate or permit obtained before they can be imported and/or manufactured in Australia. Certain new industrial chemicals are considered exempt from notifying to NICNAS but are subject to reporting requirements.

A new industrial chemical means an industrial chemical that is not listed on the Australian Inventory of Chemical Substances (AICS). Some chemicals listed on the AICS may be subject to conditions of use under section 13 of the Act. These chemicals are also defined as new industrial chemicals if their use is for other than that stated on AICS.

A chemical that is a reaction intermediate* or an incidentally produced chemical* is not considered a new industrial chemical.

Compliance Criteria

Evidence is required to demonstrate whether the chemical or product imported and/or manufactured is or contains a new industrial chemical. In the case of a new industrial chemical, you must hold a valid assessment certificate or permit for the new chemical.

There are other circumstances where you may introduce an industrial chemical without holding an assessment certificate or permit. For guidance to these cases, see the Exemptions Section.

Checklist

Have you checked that all imported and manufactured industrial chemicals are listed on AICS?

- The imported or manufactured chemical is an industrial chemical or is a constituent of a product having an industrial use
- Industrial chemicals checked against AICS and documentation retained to verify presence on AICS eg. AICS record printout

If the chemical is a new industrial chemical, is it exempt from notification and assessment requirements?

See the Exemptions Section

If the chemical is a new industrial chemical, does the introducer hold a valid assessment certificate or permit?

- New Chemical has a valid assessment certificate or permit
- For permits, does the holder comply with the conditions (refer to Permits)

* See Definitions

1.2 EXEMPTIONS

There are certain circumstances where you may import and/or manufacture a chemical without holding an assessment certificate or permit. In these cases, the chemical may be introduced under a specific exemption category as defined in the Act under section 21.

Compliance Criteria

Relevant data are required to show that the chemical is covered by a specific exemption under the Act.

Where a specific exemption applies (Section 2. to 4. below), you are required to provide a report to the Director on an approved format stating the name of the chemical and the quantity introduced. The report must be provided before or on 28 September of the following registration year. A registration year runs from 1 September to 31 August.

The introducer of the new chemical must provide an annual report detailing:

- the name of the chemical
- the volume of the chemical introduced during the year

Checklist

1. New chemical introduced for research, development or analysis

a- Manufactured in a fixed apparatus in specific location

- Advice of introduction submitted to NICNAS (**Form 6**)
- Procedures related to safe disposal and any hazardous degradation products
- Records showing type and location of the apparatus
- Records showing that it is used for research, development or analysis
- Monitor manufactured volume of the chemical

b- Imported and/or manufactured at a maximum of 100 kg in any 12 months

- Import and/or manufacture volumes are monitored
- Information on the research, development or analysis of the new chemical
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

2. New chemical intended for non cosmetic* use and does not exceed 100 kg in any 12 months

- Evidence that the chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- (Optional) Advice submitted to NICNAS (**Form 21-4a**)
- Import and/or manufacture volumes are monitored
- Records relating to the use of the new chemical
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

3. New Chemical intended for cosmetic* use

A new chemical used in cosmetics as a preservative or colouring agent or an ultraviolet filter is not exempt from notification and should not be introduced under the exemption category.

a- Introduction volume does not exceed 100 kg in any 12 months

i. The chemical is introduced between 10 and 100 kg/annum:

- Evidence that the chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- Advice submitted to NICNAS (**Form15**) including copies of :
 - Material Safety Data Sheet relevant to the chemical or product containing the chemical
 - Label to be attached to the packaging of the chemical or product containing the chemical
- Import and/or manufacture volumes are monitored
- Records relating to the use of the new chemical
- Records must be kept for 5 years after the introduction on all information available to the introducer on occupational health and safety, public health and the environmental effects of the chemical
- If the new chemical is introduced in a cosmetic at 1% or more, you must have information that the chemical will be safe for use by potentially high risk groups (including infants, elderly persons and atopic persons)
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

ii. The chemical is introduced at less than 10 kg/annum:

- The chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- Import and/or manufacture volumes are monitored annually
- Records relating to the use of the new chemical
- Records must be kept for 5 years after the introduction on all information available to the introducer on occupational health and safety, public health and the environmental effects of the chemical
- If the new chemical is introduced in a cosmetic at 1% or more, you must have information that the chemical will be safe for use by potentially high risk groups (including infants, elderly persons and atopic persons)
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

b- Non hazardous and introduced at less than 1%

- The chemical is not a hazardous chemical*, is not a dangerous good and meets the prescribed environmental criteria

- The chemical meets other criteria prescribed in regulation* 6AB
- Records relating to the use of the new chemical and its percentage in the cosmetic
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

4. New chemical introduced under the transshipment category

- The chemical is stored at the port or airport or in a bonded warehouse for not more than 30 days and remains subject to Customs control during this time
- Import and export records relating to the new chemical
- Annual reports using the approved NICNAS format provided at the end of the registration year (first report due by 28 September 2005)

1.3 PERMITS

Commercial Evaluation Chemical (CEC), Low Volume Chemical (LVC) and Early Introduction (EIP) Permits are available for new chemicals introduced under the permit category. Holders of the permit(s) must comply with the stipulated conditions.

Compliance Criteria – all Permits

Evidence is required that the holder(s) of the Permits are complying with the standard Permit conditions, as well as any special conditions.

Holders of permits (CEC and LVC) are required to provide a report to the Director stating the name of the chemical and the quantity introduced. The report must be provided before or on 28 September of the following registration year. A registration year runs from 1 September to 31 August.

Checklist

- Introduction volumes are regularly monitored
- Relevant commercial documents are held supporting import volumes below the specified amount eg Customs records, records of annual import volumes
- Records of import and/or manufacture volumes to show that the amounts and duration did not exceed the permit condition
- For LVC and CEC permits, annual reports to the Director stating the name and introduction volume of the chemical, together with any adverse effects on occupational health and safety, public health or the environment

The report must be provided before or on 28 September of each registration year.

Are the workers handling the new chemical aware that it is being introduced under a Permit system, and what safety measures are in place?

- Workers at all sites are provided with the relevant Material Safety Data Sheets (MSDS), containing a permit statement
- Any other relevant documents, eg worker training manuals, safety guides and labels

How is the chemical disposed of?

- Disposal of the chemical is consistent with Local, State and Federal laws
- Records of disposal procedures

Is there continuous monitoring of the use and health and environmental effects of the chemical?

- Copies of the Permit are kept at each site where the chemical is used
- Documents indicating the identity of sites where the chemical is used, and the quantity of the chemical used at each site
- Use of the chemical is in accordance with all relevant State or Territory occupational health and safety, environmental and poisons legislation.
- Keep records of any adverse occupational health and safety, public health and environmental effects

1.3.1 Commercial Evaluation Chemical Permits

Commercial Evaluation Chemical (CEC) Permits are issued for new industrial chemicals to be introduced solely for the purpose of commercial evaluation where the maximum quantity to be introduced is 4000 kg in a maximum period of two years.

Compliance Criteria - CEC Permits

Evidence is required that the holder(s) of the Commercial Evaluation Permit are complying with the Permit conditions.

Evidence is required that the annual report was submitted to NICNAS.

Checklist

Was the chemical used only for commercial evaluation, and what were the results?

- ❑ Have records showing that the chemical was only used for commercial evaluation such as evaluation reports
- ❑ Annual reports and a Final Evaluation Report are submitted to the Director, NICNAS, containing information on any occupational health and safety, public health or environmental effects observed, the amount of the chemical used and the means of disposal of any surplus

The annual report is required by the end of the registration year; however, the Final Evaluation Report is required at the end of the permit period.

Do all users of the chemical have signed user agreements in place?

- ❑ A user agreement has been signed and submitted to NICNAS by all users prior to commencement of the chemical's use (**NICNAS Form 8**)
- ❑ Copies of the signed user agreements are available at each site

1.3.2 Low Volume Chemical Permits

Low Volume Chemical Permits (LVC) are issued for new industrial chemicals to be introduced at a maximum volume of 100 kg/year (1000 kg/year in certain cases) for a period of 3 years.

Compliance Criteria – LVC Permits

Evidence is required that the holder(s) of the Low Volume Chemical Permit are complying with the Permit conditions.

Evidence is required that the permit holder keeps records for up to 5 years and an annual report is submitted to NICNAS.

Checklist

- ❑ Records to indicate that, if the use or introduction methods of the chemical changed significantly throughout the duration of the permit, NICNAS was informed within 28 days of the permit holder(s) becoming aware of the change
- ❑ Records must be kept for five years after the issue of the permit, to support any statement made in connection with the application for the permit

1.3.3 Early Introduction Permits

Application for an Early Introduction Permit (EIP) can be made in conjunction with a Limited (LTD), Standard (STD) or Polymer of Low Concern (PLC) Notification. The holder of an EIP may commence introduction of the chemical before the assessment is completed.

Compliance Criteria – Early Introduction Permits

Evidence is required that the holder(s) of the Early Introduction Permit are complying with the Permit conditions.

Checklist

Were the volume and period of introduction within the limits specified in the permit conditions?

- ❑ Relevant commercial documents supporting import/manufacture volumes below the specified amount e.g. Customs records, records of annual import volumes
- ❑ If stated as a condition on the permit, at the end of the permit period, the holder(s) of the Permit must report to the Director any adverse occupational health as safety, public health or environmental effects reported from the use of this chemical

1.4 SELF ASSESSED ASSESSMENT CERTIFICATE

A manufacturer and/or importer may apply for a self-assessed assessment certificate for a polymer of low concern; or any other chemical or class of chemical for which the criteria are prescribed in the regulations.

Compliance Criteria

A person issued a self-assessed assessment certificate must keep records to support any statement made in or in connection with the application for the certificate.

Records must be kept for 5 years.

The holder of the certificate must provide an annual report annual report detailing:

- the name of the chemical
- the volume of the chemical introduced during the year; and
- any adverse effect of the chemical on OHS, public health or the environment of which the holder has become aware during the year

The report must be provided before or on 28 September of the following registration year.

Checklist

Keeping of records relating to application for self-assessed certificate

- Relevant documents supporting information in the application are available
- Relevant records to support the assessment report are kept for 5 years

Annual reporting requirements

- Annual reports submitted on or before 28 September of each following registration year while the certificate remains current

2. EXISTING CHEMICALS

An existing chemical is an industrial chemical other than a new industrial chemical. NICNAS requires importers and/or manufacturers to provide information on existing chemicals of interest

The Director may place a notice in the *Chemical Gazette* calling for information about an existing chemical that is being considered for declaration as a priority existing chemical (PEC). The *Chemical Gazette* notice will include details of the person/s required to provide the information and the period in which the information is to be provided (the time frame specified must be at least 28 days).

Once a chemical is declared a PEC, importers and/or manufacturers must within 28 days, submit an application for assessment of the chemical with NICNAS. For the purpose of assessing a PEC, the Director may, by notice in the *Chemical Gazette*, require a person to provide information about the chemical. All persons specified in the Gazette notice must provide the required information to the Director within the timeframe specified.

Compliance Criteria

Priority Existing Chemicals:

Evidence is required that a Priority Existing Chemical (PEC) has not been introduced unless the person has applied for assessment of the declared chemical.

Call for information (Section 48):

Evidence is required that the person(s) specified in the Director's call for information has submitted the required information as listed in the *Chemical Gazette* within the specified timeframe.

Checklist

Is the Chemical a Priority Existing Chemical?

- If you are introducing a PEC, you must submit an application to NICNAS within 28 days; or
- Stop importation of the declared chemical

Are the information requirements about a chemical that has been declared/being considered for declaration as a priority existing chemical relevant to the introducer/user?

- Chemical Gazette* is regularly checked for Notices about chemicals; the notice specifies the persons, information requirements and timeframe

Are the information requirements about a chemical that has been declared/being declared a priority existing chemical relevant to the introducer/user?

- Chemical Gazette* is regularly checked for Notices about chemicals; the notice specifies the persons, information requirements and timeframe
- If the Notice is relevant to the introducer, the required information is submitted within the specified timeframe

3. ASSESSED CHEMICALS

All notified and assessed new and existing chemicals are subject to secondary notification obligations when certain circumstances set out in the original assessment report occur, namely:

- the function or use of the chemical has or is likely to change
- the amount of the chemical introduced has or is likely to increase
- in the case of an imported chemical, it has begun to be manufactured
- the method of manufacture has or is likely to change
- additional information is available on the adverse health or environmental effects of the chemical; and/or
- other circumstances recommended on the assessment report for the chemical have occurred

The introducer of the assessed chemical must report to the Director within 28 days of becoming aware of any of the above circumstances.

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 provide information about the chemical that is to be given by way of secondary notification within a period of not less than 28 days.

Compliance Criteria

Evidence is required that known significant changes in circumstances to assessed chemicals are reported to the Director within 28 days of introducers becoming aware of them.

Evidence is required that the person(s) specified in the Director's call for information has submitted the required information as listed in the *Chemical Gazette* within the specified timeframe.

Checklist

Is there continuous monitoring of the use and health and environmental effects of the chemical?

- Relevant commercial documents showing the amount of the chemical introduced and used
- Observations of adverse health and environmental effects are recorded
- The introducers checks full public reports of assessed chemicals to monitor increases in introduction volumes and changes in use
- For a chemical proposed to be introduced through import at the time of the assessment, has it, or is it likely to be manufactured?
- Has the method of manufacture changed, or is likely to change?
- Will the changes increase the risk of adverse health effects, or adverse environmental effects?
- Has any additional information become available on the health or environmental effects of the chemical?
- Are measures being taken to ensure any health or environmental effects are being recorded?
- Have any other changes occurred?
- Other specific issues stated in the original report are checked

4. REGISTRATION OF CHEMICAL INTRODUCERS

Registration of chemical introducers applies to those who import and/or manufacture relevant industrial chemicals at any value in a registration year for commercial purposes.

Compliance Criteria

Evidence is required that the introducer holds relevant commercial documents to show the total value of relevant industrial chemicals* and where applicable a NICNAS Registration certificate. If the chemicals are not considered relevant industrial chemicals, the introducer should provide supporting statements.

- Registration year* starts from 1 Sept to 31 Aug the following year
- Renewals are due by 31 August before the start of the next registration year
- For Tier 2 registrants, the final statement of introduction is due by 31 October for the past registration year. See '[Your simple guide to the NICNAS Registration cycle](#)'

Checklist

Are the chemicals introduced relevant industrial chemicals?

- Supporting statements specifying whether the introduced chemicals are considered relevant industrial chemicals, and if not, evidence is required that the chemicals do not fit the description eg excluded use, naturally occurring See NICNAS fact sheet '[Which chemicals are within the scope of NICNAS Registration](#)'
- A current registration certificate in force in relation to the registration year at the time of introduction

What is the total value of introduced relevant industrial chemicals?

- Relevant commercial documents relating to industrial chemicals are kept for at least 5 years after the end of the registration year such as commercial invoices, order/confirmation, bill of lading / airway bill, insurance certificate
- Receipt for purchase of goods, and other records provided to Customs
- If the chemical is manufactured, then the factory cost is calculated. (i.e. Cost of labour + cost of materials + factory overhead expenses)
- For imports it is the Customs Value + Customs duty + insurance and freight

Renewal of registration

- Have you checked the last financial year introductions?
- What is the plan for the next registration year?
- Exceeded \$500,000 total value of relevant industrial chemicals last financial year then renew at Tier 2/3 if intending to import next year
- Did not exceed \$500,000 total value of relevant industrial chemicals last financial year then register at Tier 2/3 if planning to exceed \$500,000 next year or Tier 1 if estimated value is below \$500,000
- Renewals due by 31 August before the start of the next registration year ([Form NR-1A.](#))
- Not required to renew if not planning to introduce

Final Statement of Introduction

For Tier 2 registrants, final statement submitted by 31 October indicating the total value of relevant industrial chemicals actually imported and/or introduced over the past registration year (See Final Statement guidance Note)

- * See Definitions

5. TREATIES

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (referred to as the Rotterdam Convention; also commonly known as PIC), puts obligations on the import and export of certain hazardous chemicals. This means that countries that are signatories of the Rotterdam Convention can make informed decisions on which chemicals they want to receive and to exclude those they cannot manage safely.

Compliance Criteria

Evidence is required to demonstrate that any imported or exported industrial chemical complies with obligations under the Rotterdam Convention.

Checklist

Are PIC listed chemicals being exported?

- Is the chemical PIC listed (Check the Rotterdam Convention website www.pic.int)
- export authorisations have been obtained for any of the PIC listed chemicals (**Form Export**)
- systems are in place for checking exports against signatory countries response

Are chemicals excluded from the Rotterdam Convention

- evidentiary documentation is available to support the purported exemption

DEFINITIONS

Introduce	Act of importing and/or manufacturing industrial chemicals
Introducer	Person(s) who import and/or manufacture industrial chemicals
Incidentally produced chemical	<p>A chemical that is produced as a result of:</p> <ol style="list-style-type: none">the exposure of another chemical to light, heat or other environmental conditions in the course of handling or storage; orthe occurrence of a chemical reaction during the manufacture or use of another chemical, <p>but not a chemical whose production has commercial value for a person manufacturing, handling, storing or using that other chemical.</p>
Reaction intermediate	<p>A substance that:</p> <ol style="list-style-type: none">is produced in the course of a chemical reaction; andhas a transient existence; anddoes not become a major component of the reaction mixture; andis not removed from the reaction system
Site Limited Chemical	A chemical which is confined to its site of manufacture solely for the purposes of further manufacture.
Non hazardous chemical	<p>A chemical in respect of which the following conditions are met:</p> <ol style="list-style-type: none">the chemical is not a hazardous chemicalthe chemical is not a dangerous goodthe prescribed criteria relating to the environmental effect of the chemical have been metany other prescribed conditions have been metthe introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment.
Commercial Evaluation	Commercial evaluation means testing the chemical with a view to ascertaining its potential for commercial application prior to commercial release
The Act	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i>
Regulations	Industrial Chemicals (Notification and Assessment) Regulation 1990
Priority Existing Chemical	A Priority Existing Chemical (PEC) is an industrial chemical which has been selected for assessment because there are reasonable grounds to believe that the manufacture, handling, storage, use or disposal of the chemical gives rise, or may give rise, to a risk of adverse health and/or environmental effects

Registration year 1 Sept to 31 Aug the following year

Relevant industrial Chemical Relevant industrial chemical means an industrial chemical that is NOT intended solely for excluded use, a naturally occurring chemical, biological material, an incidentally produced chemical, a reaction intermediate, a radioactive chemical or an article