# Case Study of Australian Industrial Chemicals Introduction Scheme (AICIS)

For the **Inter-Organization Programme for the Sound Management of Chemicals Toolbox** for decision-making in chemicals management

## Industrial Chemicals Management Scheme

# 1 Overview

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) Toolbox for Decision-Making in Chemicals Management's Industrial Chemicals Management Scheme (iomctoolbox.org), hereafter referred to as "the IOMC Toolbox", is an internet-based platform aimed at countries seeking to establish a chemicals management system or to address specific challenges related to chemicals management. The IOMC consists of nine participating organisations that promote the coordination of activities and policies internationally to achieve the sound management of chemicals to minimize their adverse impacts to human health and the environment. The IOMC Toolbox is hosted by the Organisation for Economic Co-operation and Development (OECD).

In 2021, the OECD Chemicals and Biotechnology Committee endorsed a proposal to enhance the utility of the IOMC Toolbox by adding country case studies to the Industrial Chemicals Management Scheme, using Canada's Chemicals Management Plan (CMP) as a pilot. The objective of this initiative is to assist countries developing chemicals management programs by offering real-world examples of technical and functional elements from existing systems.

## Approach

This second case study describes the Australian Industrial Chemicals Introduction Scheme (AICIS). AICIS aids in the protection of the Australian people and the environment from risks associated with the introduction (import or manufacture) and use of industrial chemicals. The case study provides an overview of how key functional and technical elements described in the IOMC Toolbox's Industrial Chemicals Management Scheme are applied in the context of AICIS. The relevant program areas of AICIS are described under one or multiple elements of the Industrial Chemicals Management Scheme (Table 1.1 below). Links to publicly available information are included for further detail.

Table 1.1. Key functional and technical elements described in the IOMC Toolbox's Industrial Chemicals Management Scheme categories

| IOMC TOOLBOX ELEMENT |
|---|
| Legal and Institutional Framework (NEW) |
| Information and Data |
| Industrial Chemicals Inventories (NEW) |
| Hazard Assessment, Exposure Assessment, Risk Characterisation |
| Risk Management |
| Awareness Raising |
| Evaluation of the effectiveness of the system |
| Compliance Monitoring |
| Enforcement of Obligations |

# 2 Legal and Institutional Framework

The Legal and Institutional Framework element of the IOMC Toolbox for Industrial Chemicals Management outlines foundational components of a chemicals management system. It comprises four main sub-elements: (1) Organization of legislation and national administration; (2) Government and industry responsibilities; (3) Financing; and (4) Other aspects/considerations. For more information, refer to the IOMC Toolbox.

## Introduction

Chemicals in Australia are regulated under a number of programs and schemes based on the use of the chemical. If a chemical is not for a therapeutic, agricultural, veterinary or food use, it is considered an industrial chemical.

The *Industrial Chemicals Act 2019* (IC Act) establishes the regulatory scheme, the Australian Industrial Chemicals Introduction Scheme (AICIS), that regulates the importation and manufacture (introduction) of industrial chemicals in Australia. The scheme is administered by the Executive Director supported by staff within the Australian Government Department of Health and Aged Care under a statutory arrangement. Other arrangements govern assistance provided to the Executive Director from the Department of Climate Change, energy, Environment and Water (DCCEEW).

AICIS, which replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on 1 July 2020, is a chemical entity-based scheme that does not regulate products (mixtures of chemicals), but rather, each chemical in a mixture with regulation applying at the point of introduction into Australia.

## Organisation of legal and national administration

### *Chemical regulation in Australia*

Legal and administrative responsibility for the regulation of chemicals in Australia is shared by a number of Government agencies, at the Federal and State and Territory levels. The management of safe chemical use necessitates functions such as risk assessment, risk management and enforcement. These functions are applied across the areas of workplace health and safety, public health, the environment, product safety, and transport.

At the national level, chemicals are regulated according to their use. There are four main national regulatory authorities for chemicals focusing on a particular type of use:

- Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemicals, such as pesticides, animal medicines, insect repellents, garden sprays and some pool chemicals.
- Therapeutic Goods Administration (TGA) regulates medicines and products marketed as having therapeutic effects, such as skin-whitening lotions, complementary medicines, and blood products.

- Food Standards Australia New Zealand (FSANZ) regulates ingredients in food and food additives for human consumption, such as processing aids, colourings, vitamins, and minerals.

- Australian Industrial Chemicals Introduction Scheme (AICIS) regulates chemicals (including polymers) that are introduced into Australia for an industrial use such as in inks, paints, adhesives, solvents, cosmetics and personal care products, cleaning products, as well as in manufacturing, construction and mining applications. Industrial use is defined by exclusion which means that AICIS only regulates uses that are not covered by the other regulatory authorities.

If a chemical has multiple uses, the requirements of each applicable Australian Government and State or Territory regulatory body must be followed.

Apart from AICIS, other agencies/authorities (and applicable legislation) responsible for the management of chemicals in Australia involved in protecting human health and the environment complement activities under the IC Act (Table 2.1 below).

Table 2.1. Complementary bodies responsible for chemicals management in Australia

| Topic | Responsible agencies and authorities and further information |
|---|---|
| Chemicals used in food | Food Standards Australia New Zealand (FSANZ) |
| Chemicals used in medicine, therapeutic goods or classified as poisons | Therapeutic Goods Administration (TGA)<br><br>TGA's Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) |
| Chemicals used in animals and agriculture | Australian Pesticides and Veterinary Medicines Authority (APVMA) |
| Hazardous waste and managing chemicals in the environment | Department of Climate Change, Energy, the Environment and Water |
| Chemicals in drinking water | National Health and Medical Research Council (NHMRC) |
| Consumer protection<br><br>Labelling and safety of chemicals used in consumer products | Australian Competition and Consumer Commission (ACCC) product safety standards<br><br>ACCC's mandatory standard for cosmetics ingredients labelling |
| Chemicals of national security concern | Department of Home Affairs |
| Precursor chemicals-illicit drugs; Imports–prohibited/restricted | Australian Border Force |

| | |
|---|---|
| Transporting dangerous goods (explosives, flammable liquids, gases, corrosives and chemically reactive or highly toxic substances) | National Transport Commission (NTC)<br><br>NTC Australian Dangerous Goods Code<br><br>Civil Aviation Safety Authority (CASA)<br><br>Australian Maritime Safety Authority (AMSA) |
| Workplace safety | Safe Work Australia's Hazardous Chemical Information System<br><br>Safe Work Australia's requirements for hazardous chemical labels<br><br>Safe Work Australia's information on preparing and using SDS<br><br>Safe Work Australia's Model Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace<br><br>Safe Work Australia's WHS regulators' contact information |

***Australian Industrial Chemicals Introduction Scheme (AICIS)***

AICIS authorises the introduction of industrial chemicals in Australia. One of AICIS's core functions is to assess the risks of industrial chemicals (new and existing) to human health and the environment by scientifically interpreting information provided by industry (or obtained from other sources) in the context of the intended use of the chemical.

Most introducers of industrial chemicals must be registered with AICIS. Chemicals listed on the Australian Inventory of Industrial Chemicals (the Inventory) can be introduced as 'listed introductions' by registered businesses, who must comply with any regulatory obligations stipulated in a chemical's terms of listing.

Chemicals not listed on the Inventory (unlisted) generally are not available for industrial use in Australia unless the introducer determines the category of AICIS introduction into which the chemical fits (see Section 5).

***Overview of the IC Act***

AICIS administers the IC Act and its legal framework the objects of which are to:

(a) provide for a national scheme to regulate the introduction of industrial chemicals in Australia; and

(b) aid in the protection of human health and the environment including through:

(i) the regulation of the introduction of industrial chemicals; and

(ii) the assessment and evaluation of the introduction and use of certain industrial chemicals; and

(iii) the provision of information and recommendations about managing the risks arising from the introduction and use of industrial chemicals; and

(c) provide for the collection and publication of information and statistics relating to industrial chemicals; and

(d) give effect to Australia's obligations under international agreements and arrangements relating to the regulation of industrial chemicals.

The IC Act is supported by the Industrial Chemicals (General) Rules 2019 (General Rules) and Industrial Chemicals Categorisation Guidelines, which set out technical and operational details of the scheme and the requirements introducers need to meet to categorise their industrial chemicals.

There are also the *Industrial Chemicals Charges (General) Act 2019,* regulations and rules that authorise the imposition of fees and charges on introducers of industrial chemicals.

The use, storage, disposal, labelling or packaging of industrial chemicals and products containing industrial chemicals is regulated by Australian Government and State or Territory authorities.

## Government and industry responsibilities for industrial chemicals management

### *Key government responsibilities*

In Australia, all levels of government play a part in protecting against risks from industrial chemicals. As a statutory scheme AICIS operates independent of government, however it does operate under government policy settings. At the national level, the key responsibilities of AICIS are:

- conduct of scientific risk assessments on the introduction and intended use of industrial chemicals
- maintenance of the Australian Inventory of Industrial Chemicals (the Inventory). This is a database of chemicals available for industrial use containing chemical identity details and regulatory obligations or conditions attached to the chemical.
- issue of certificates and authorisations for the introduction of industrial chemicals in Australia
- making risk management recommendations to protect human health and the environment for referral to other Australian Government or state, territory risk management agencies under their legislation, regulations and standards
- undertake risk management directly on the basis that the risk management action is necessary to manage the risks to human health and the environment (see Section 6)
- setting and maintenance of the Industrial Chemicals Categorisation Guidelines
- maintenance of the Register of Industrial Chemical Introducers

- updating the Risk Management Recommendations Register
- guidance on compliance expectations with monitoring and investigation of any breaches of relevant laws
- implementation of Australia's obligations under international agreements regarding industrial chemicals
- collaboration with other regulatory authorities involved in chemical regulation in Australia
- working with other countries to harmonise and adopt (where applicable in the Australian context) international standards and risk assessment methods

AICIS does not regulate labelling requirements, safety data sheets (SDS) or packaging requirements. These are set by the government agencies/authorities as summarised in the table 2.1.

***Industry/Business responsibilities***

Industry/business operating at different stages of a chemical's lifecycle are responsible for:

- compliance with requirements for introduction and export of industrial chemicals
- being informed about the industrial chemicals they are managing
- incorporating risk management practices into daily operations
- considering industrial chemical risks in the design of products
- ensuring that their products containing industrial chemicals meet the labelling, SDS and packaging obligations
- identifying appropriate mechanisms for handling and disposing of industrial chemicals
- providing information on risk management requirements and permitted uses to others
- preventing and reporting potential environmental harm.

***Specific obligations***

The specific obligations of introducers are as below and described in other sections of this case study:

- introducers of industrial chemicals (or products that contain industrial chemicals) into Australia for commercial, research or any business-related purposes are required to categorise their introductions (see Section 5)
- obligations related to registration, authorisation, record keeping, reporting and international agreements (see Section 9)

## Financing

***Sources of funding***

Consistent with Australian government policy, the full cost of AICIS regulatory activities is recovered from regulated entities (introducers of industrial chemicals). The cost of administering the scheme is recovered through:

- fees for services and

- registration charges (levies).

The proposed fees and charges are outlined in a draft Cost Recovery Implementation Statement (CRIS) [link] which provides information on how AICIS will implement cost recovery for regulatory activities in the upcoming year. Public consultation is undertaken on the draft CRIS and stakeholder views are taken into account in finalising AICIS charging arrangements.

Fees for services apply to regulatory activities attributable to a service provided to a specific introducer. These are activities such as pre-market assessments and authorisations of unlisted (new) chemicals, listing chemicals on the Inventory or amending Inventory listings, applications to protect confidential business information and authorisations to import/export industrial chemicals subject to international agreements.

All registrants pay an annual application fee to be listed (or re-listed) on the Register of Industrial Chemical Introducers.

Most of AICIS's operational costs are met from the annual registration charge levied on introducers of relevant industrial chemicals. This charge relates to the regulation of the market as a whole and funds regulatory activities that are not attributable to a service provided to a specific introducer. Where an introducer introduces relevant industrial chemicals above a certain threshold, an annual registration charge is payable. The applicable levy depends on the introduction value of relevant industrial chemicals introduced in the previous financial year and is calculated based on a statutory formula. Activities supported by the annual registration charge include evaluation of industrial chemicals, post-market compliance monitoring and enforcement, provision of information and recommendations about managing risks from the introduction and use of industrial chemicals, collection and publication of information and statistics, and corporate activities to support the efficient operation of the scheme.

### *Staffing structure*

AICIS is led by the Executive Director, who is an independent statutory office holder with specific powers and functions under the IC Act. The Executive Director is assisted by staff in the Australian Government Department of Health and Aged Care. Scientific staff from DCCEEW assist AICIS in the assessment of the environmental risks of industrial chemicals. Specific sections in AICIS undertake chemical assessment, compliance, scientific integrity and capability, regulatory and corporate functions.

## Other aspects/considerations

### *Planning and reporting*

The Department of Health and Aged Care publishes annual Portfolio Budget Statements that outline the key activities and performance measures for delivery of the objective to protect human health and the environment through regulatory oversight of industrial chemicals. The activities and performance measures are also described in more detail in a Department of Health and Aged Care Corporate Plan with a four year projection. The performance measures include data source and methodology, measure type and alignment against principles outlined in the 'Regulator Performance and Best Practice Principles'.

Annual reports published every financial year by the Department of Health and Aged Care provide a transparent account to the public and Parliament of the activities undertaken to deliver services and programs and report against the performance targets identified in the

Portfolio Budget Statements. An Appendix reports on the operation of AICIS. The annual report also provides information about reforms, operations, finances and governance.

***Coordination mechanisms that enable the participation of stakeholders and partners in decision-making processes or implementation***

Active engagement with government entities, the chemical industry, community groups, and academia is conducted through a range of mechanisms which are addressed under the 'Awareness Raising' element of this document.

The AICIS Strategic Engagement Committee (SEC), with representatives drawn from peak industry and civil society groups, is an important stakeholder consultation mechanism.

Publication of monthly editions of a stakeholder newsletter containing information on new online forms, guidance materials and consultation opportunities.

Engagement with stakeholders on our assessments informs our risk assessment outcomes and assists national, state and territory governments implement risk management controls and facilitates safe use of industrial chemicals by workers and the public.

***Key terms and principles***

Part 1, section 9 of the IC Act presents definitions that have a particular meaning in this Act. AICIS also maintains an online glossary of terms related to its work on industrial chemicals.

In addition, AICIS publishes a service charter which sets out the standard of service that stakeholders can expect from staff and outlines what is expected from people who engage and transact with AICIS.

# 3 Information/Data

A key technical element of the IOMC Toolbox for Industrial Chemicals Management Scheme, the Information/data element, describes information management activities that support risk assessments and risk management actions. It contains three sub-elements: (1) Data collection, (2) Data storage, and (3) Data dissemination. For more information, refer to the generic description of Information/data on the IOMC Toolbox webpage.

Information is one of the most valuable assets that AICIS holds. It supports AICIS in performing regulatory activities and evidence-based approaches to risk assessments and compliance activities. Data and information gathered by AICIS also informs policy development and enables monitoring of services provided to stakeholders. Efficient and effective management of data under AICIS is supported by an Information Technology (IT) System that provides mature technologies using Australian Government supported solutions. AICIS follows the Department of Health and Aged Care Data Strategy 2022 – 2025 to collect, manage and analyse data effectively.

## Data collection

Business, technical and scientific data and information are collected as part of administering the IC Act. Technical and scientific data are collected from many sources, including application submissions, studies commissioned by industry, voluntary or mandatory information requests for information and public scientific literature. Business data are collected via AICIS Business Services portal, enquiries and stakeholder engagement.

### *Approach to management of Confidential Business Information*

Any person or company submitting information to AICIS can request that Confidential Business Information (CBI) be treated as protected. Businesses can apply for an AICIS approved chemical name (AACN) to protect the chemical name as protected information. They can also apply to use a generalised end use (GEU) instead of a specific end use to protect details of the end use. Businesses can also 'flag' (identify) commercially sensitive or confidential information for protection at the time it is submitted to AICIS. If AICIS determines that the flagged information should be published, the business is contacted and they can formally apply to protect the information as confidential business information.

AICIS staff apply a statutory test to decide on applications for protection of information. When applying the test staff consider whether publication or disclosure of protected information could reasonably be expected to substantially prejudice the commercial interests of an applicant and whether the prejudice outweighs the public interest. If an application for protection of information is approved, that information is not published.

### *Information gathering for unlisted and listed chemicals*

*Mandatory mechanisms*
Under the IC Act the Executive Director may by written notice require a person, importer, manufacturer or prescribed body to provide information for the purposes of risk assessment.

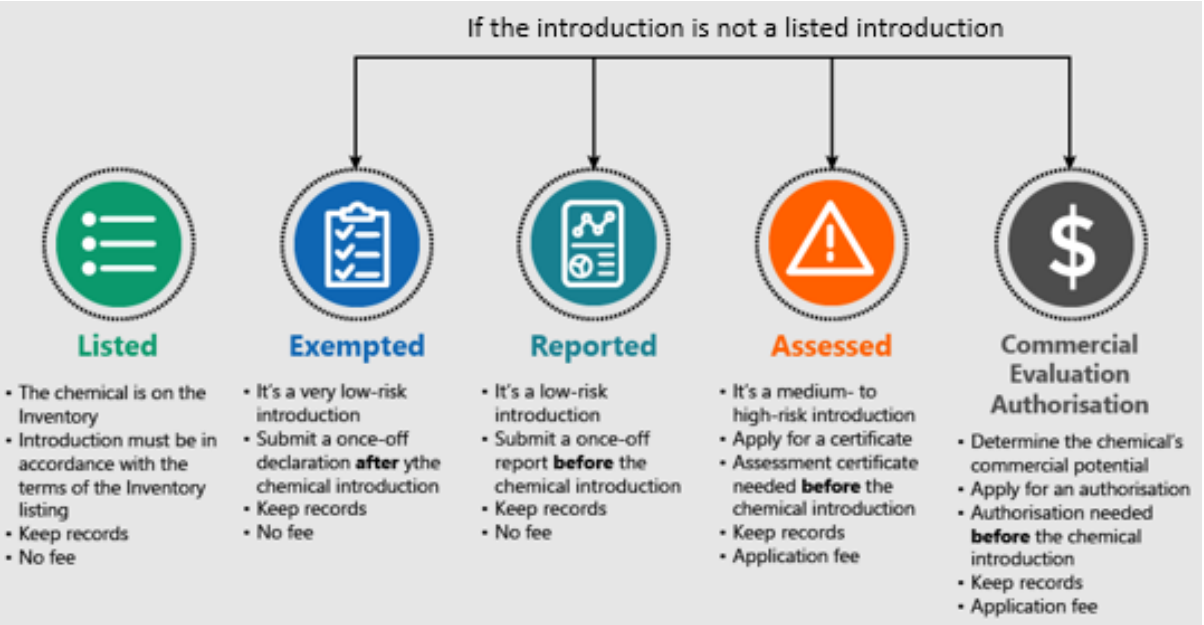
For chemicals listed on the Inventory (listed), introducers must comply with any regulatory

obligations stipulated in a chemical's terms of listing. Terms of a listing may include, for example, specific information requirements, for which there is a legal obligation under section 101 of the IC Act, for introducers to provide certain information about the introduction of the chemical into Australia.

In addition, when an evaluation of a listed chemical is initiated by the Executive Director, the Executive Director may in a notice specify the information to be provided by a specified person (Section 76 of the IC Act).

Chemicals not listed on the Inventory (unlisted) can be introduced into Australia for industrial use under one of the following introduction categories: exempted, reported, assessed, and commercial evaluation authorisation (see Figure 3.1 below). Introducers are required to categorise their chemical prior to introduction into one of these categories.

Figure 3.1. Risk-based introduction categories




A chemical introduction that is categorised as 'exempted' means it meets a very strict set of criteria that is considered very low risk to both human health and the environment. A 'reported' introduction means it meets criteria to be considered low risk to human health and the environment. Under the exempted and reported categories, mandatory information gathering approaches include: submission of a post-introduction declaration (PID) for exempted category introductions (section 96A of the IC Act) and submission of a pre-introduction report (PIR) for reported category introductions (section 97 of the IC Act).

Under the 'assessed' category (assessment certificate application process) there are mandatory requirements for applicants to provide information and data necessary to conduct a risk assessment and determine if an introduction of an unlisted chemical poses a risk to the environment or human health. For more information on assessments see Section 5.

A commercial evaluation authorisation allows an introducer to test an industrial chemical's commercial potential in Australia and has strict eligibility criteria. The authorisation may contain conditions needed to manage any risks, and/or requirements to provide specific information in relation to the introduction.

Where further information is required to demonstrate that an introduction has been categorised correctly, the Executive Director may request a person to provide this information under sections 102 and 104 of the IC Act.

Additional requirements relating to hazard information, reporting or record keeping apply to specified classes of introductions, defined under section 7 of the General Rules. These vary depending on whether the introduction has been categorised as exempted, reported or assessed. The reason for the additional information requirements is due to an increased level of concern for these introductions because of greater potential for particular hazards or high levels of human or environmental exposure.

If a trusted overseas body listed in section 6 of the General Rules has assessed an unlisted chemical, and assessment information is available internationally and meets the criteria described in the guide, an introducer of the industrial chemical can use the internationally assessed pathway to submit a PIR. This is a streamlined way to utilise the international information to categorise introductions of industrial chemicals that have been assessed overseas. Specific information about such chemicals needs to be provided to AICIS prior to these types of chemicals being introduced in Australia.

*Penalties*
Penalties may be applied when the Executive Director has requested information from an introducer of an industrial chemical and it is not supplied (see Section 9).

*Voluntary Mechanisms*
AICIS relies on voluntary information gathering mechanisms to collect information from introducers. Data obtained voluntarily may also provide the basis for a mandatory call for information.

Information that was not available to AICIS at the time of conducting an evaluation may be provided during the two-month public consultation processes undertaken when draft Evaluation Statements are published on the AICIS website. The new information may inform the risk management recommendations when the publication of an Evaluation Statement is finalised.

### *Information gathering for unlisted and listed chemicals online*

AICIS Business Services portal is an online data reporting system that enables reporting of data for various areas. It can be used to provide both mandatory and voluntary data. The portal's online form allows users to add notes and upload documents as well as supporting information.

Information collected through both mandatory and voluntary information gathering initiatives is reviewed by AICIS staff and assessed for quality, completeness, and relevance within the Australian chemicals management context.

### *Other information gathering*

The AICIS staff review publicly available information (e.g., studies published in peer reviewed scientific journals) and draw on information from other programs within the Government of Australia (e.g., DCCEEW) as well as from state or territory governments. Chemicals agencies in other jurisdictions, notably the United States Environmental Protection Agency, the European Chemicals Agency, Health Canada and Environment and Climate Change Canada, are also valuable sources of information. Information may also be gathered when working in collaboration with interested parties (e.g., academics) during various stages of risk assessment and risk management activities.

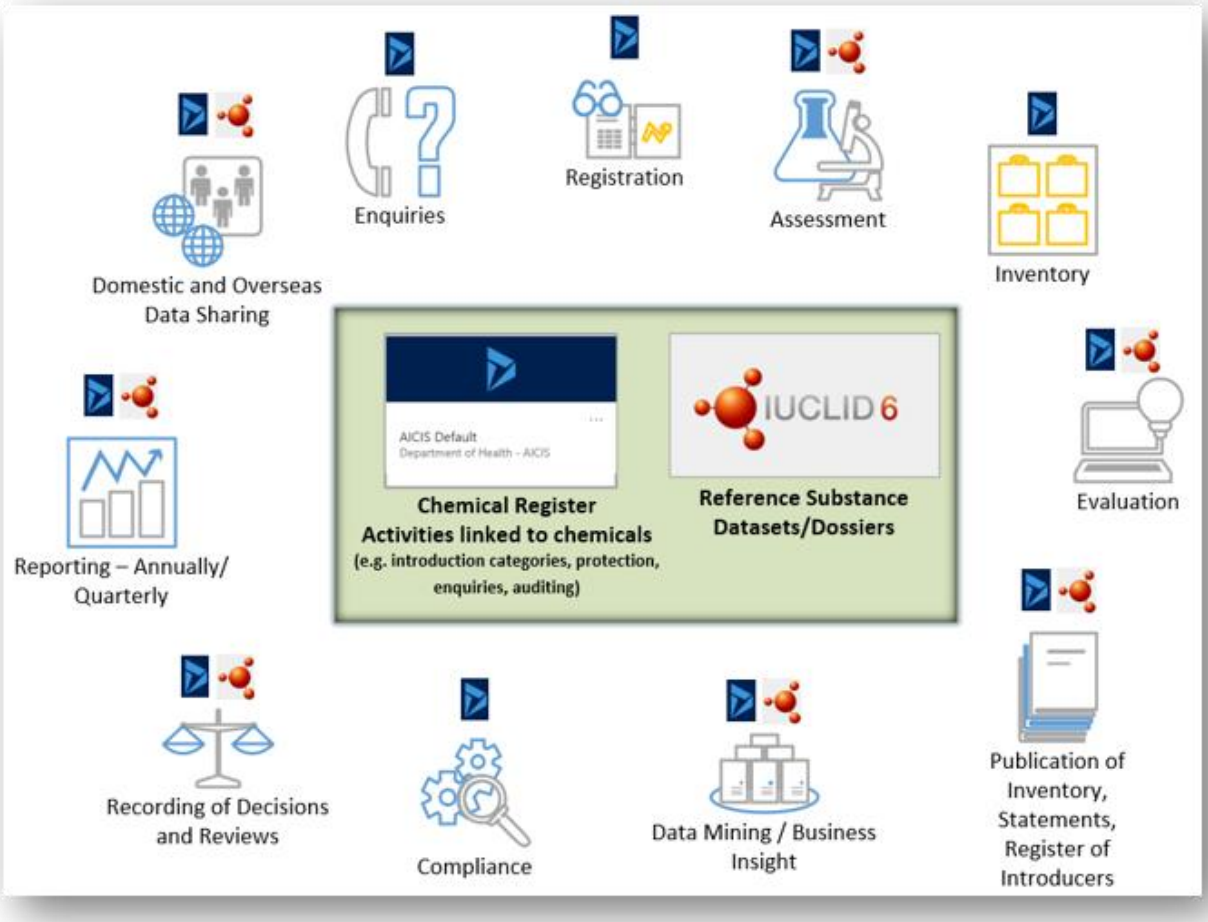
## Data storage

Information received via AICIS Business Services online portal is stored in Microsoft Dynamics 365 Online Customer Relationship Management (CRM) and International Uniform Chemical Information Database (IUCLID). CRM primarily stores business, financial and application information along with the Inventory and stakeholder communications. IUCLID primarily stores data on introduction and use information, physical, chemical and hazard properties of chemical substances. The two central databases are integrated to enable the tracking of key information and decisions (refer to Figure 3.1). These two databases can only be accessed by AICIS staff within a protected Departmental IT network. In addition to these two databases, information is stored in TRIM which is an Electronic Document and Records Management System (EDRMS) and is the central repository of information for the Department of Health and Aged Care.

### *Chemical information management*

The chemical information management software used by AICIS is customised and is integral to the centralised tracking of information. As shown in the diagram below, the chemical information management software tracks and links different pieces of work related to chemicals, along with information about that work, enabling full tracking of risk assessment and risk management processes. Work tracked includes links to chemical data used in certain risk assessment and risk management documents.

Figure 3.1. AICIS Chemical Information Management Tracking and Linkages



### *Storing Confidential Business Information*

Confidential business information collected by AICIS staff or submitted via AICIS Business Services Portal is stored in CRM, IUCLID and TRIM. Information is classified with protective markings. AICIS staff are responsible for maintaining proper marking, storage, transmission, and authorised disclosure of any protected information that comes into their possession.

### *Chemical data management*

A variety of chemical databases or information repositories are used by AICIS staff, including the IUCLID and the AICIS Evaluation Prioritisation Tool (EPT). IUCLID is used to store chemical identity/property information and key endpoint data. The EPT is used for screening collected information and to assist with prioritising chemical evaluations and data verification activities. For more information on the EPT, refer to Section 5.

AICIS also participates in the OECD Chemicals and Biotechnology Committee subsidiary groups in activities related to data generation. These include contributing to and using the OECD QSAR Toolbox and eChemPortal for analysis and information gathering.

### *Business intelligence*

The AICIS IT system integrates data stored in Dynamics 365 and IUCLID. To enhance chemical and business intelligence, AICIS has built a data structure in a standardised and uniform format using Dynamics 365 and Microsoft technologies. Power BI is connected to the data structure to enable generation of standard reports and business insights.

## Data dissemination

AICIS uses PowerApps portal solution for publishing assessment and evaluation statements on the AICIS website. Assessment and evaluation statements may be searched on our website.

In addition, AICIS also publishes information online including:

- Inventory updates
- business register
- the AICIS risk management recommendations register
- regulatory notices
- news and updates.

# 4 Industrial Chemicals Inventory

The Industrial Chemicals Inventories element of the IOMC Toolbox for Industrial Chemicals Management contains five sub-elements: (1) Aim of inventory; (2) Timeline; (3) Information; (4) Maintenance; and (5) Accessibility. For more information, refer to the generic description of Industrial Chemicals Inventories on the IOMC toolbox webpage.

Australian Inventory of Industrial Chemicals (the Inventory) is a list of industrial chemicals manufactured in or imported into Australia on a commercial scale. The Inventory is an integral part of decision making under AICIS to regulate the introduction (manufacture and Import) of industrial chemicals.

## Purpose of the Inventory

The Inventory is a central and critical feature of the regulatory framework, as it defines the regulatory treatment for industrial chemical introductions based on its listings. It is a database of chemicals available for industrial use in Australia and has a legal purpose. It contains chemical identity details and regulatory obligations or conditions relating to the importation and manufacture of industrial chemicals in Australia. The relevant information for protecting human health and the environment from chemical risks is published by linking it to the chemical listed on the Inventory, while at the same time protecting commercial information.

## Timeline

The first edition of the Inventory was compiled from nominations received from manufacturing and importing companies in Australia over four reporting phases between 1 January 1977 and 28 February 1990. Chemicals that were granted confidential status at that time were not included in the published version of the Inventory.

On 18 July 1990, the former National Industrial Chemicals Notification and Assessment Scheme (NICNAS) came into effect. Any new industrial chemical intended for import or manufacture in Australia was added to the Inventory after being assessed. The Inventory was an integral part of the scheme as a means of distinguishing between new chemicals and existing chemicals in the operation of the scheme. NICNAS maintained two Inventories side by side: one with the listings fully visible to the public, and the other with the listings fully hidden from the public (Confidential Inventory). Listings on the Confidential Inventory often followed from assessments that included what was called ‘Exempt Information’, which was masked when the public assessment reports were published.

From 1 July 2020, NICNAS transitioned to AICIS. Section 80 of the IC Act requires that the Executive Director must establish and keep an inventory of industrial chemicals. The Inventory is explicitly limited to industrial chemicals, so the non-industrial chemicals that were on the NICNAS’s Inventory did not transition across to the AICIS’s Inventory. ‘Existing chemicals’ (being chemicals on NICNAS’s Inventory), under AICIS are called ‘listed introductions’, and ‘new chemicals’ are referred to as ‘unlisted introductions”.

A new approach to protecting confidential business information (refer to Section above) was also introduced, replacing the concept of ‘Exempt information’ with ‘protected CBI’. AICIS

has one Inventory, with all listings available to the public. The aim is to make information about risks associated with industrial chemical introduction and use accessible, while using other means to protect CBI that is not necessary to disclose for the purpose of managing chemical risks. NICNAS's Confidentially Listed Inventory transitioned into 'Transitional Confidential Listing' on the new Inventory. The word 'confidential' now replaces each term of the listing on the Inventory for those chemicals that transitioned.

## Information

### *Contents of the Inventory*

The Inventory contains around 40,000 industrial chemicals which are available for use in Australia.

For a chemical listed on the Inventory, the listing contains chemical identity details and regulatory obligations or conditions (the terms of the Inventory listing) relating to the importation and manufacture of industrial chemicals in Australia.

As defined under section 81 of the IC Act, the Inventory must include the following (the ***terms*** of the Inventory listing) for each industrial chemical that is included on the Inventory:

- CAS name and CAS number
- the molecular formula (if defined)
- any defined scope of assessment
- any conditions relating to the introduction or use
- any specific requirements to provide information to the Executive Director about the introduction
- any other information that is prescribed by the rules for the purposes of this paragraph.

If an application to treat the proper name for the industrial chemical as confidential business information has been approved, the Executive Director must publish an AICIS approved chemical name (AACN) instead of the CAS name, CAS number and molecular formula (see Section 3).

The Inventory listing for an industrial chemical also includes the website address where each assessment statement (if any) or evaluation statement (if any) that has been published for the industrial chemical can be accessed.

A defined scope of assessment describes the parameters of any previous assessment of a chemical, such as how the chemical is used, volume or quantity and concentration in products.

Conditions of introduction or use restrictions that are imposed on the importation or manufacture of a chemical - how much (volume) can be imported or manufactured (introduced), where the chemical is permitted to be introduced or used, the period for which the industrial chemical is permitted to be introduced.

An Inventory listing for a chemical may include a 'specific information requirement'. This means that AICIS has assessed this chemical, and introducers are obligated to tell AICIS about their introduction in certain situations. The information introducers provide helps us determine if the chemical needs to be reassessed (see Section 3).

## Maintenance

***Inventory updates***

Maintenance of the Inventory is one of the key activities of AICIS. Chemicals categorised as assessed introductions under the IC Act are assessed by AICIS and are listed on the Inventory five years after a certificate is granted. Certificate holders have the option to apply for an ‘early listing’ of the chemical so that it can be added to the Inventory before the end of those five years.

During the five-year pre-listing period, the chemical can only be imported or manufactured by the certificate holder(s). Once the chemical is listed on the Inventory, anyone who wishes to introduce is authorised to import or manufacture the chemical as a 'listed introduction'. The introducer must also be registered with AICIS before they introduce the chemical and be able to meet any obligations relating to the terms of the listing. They also need to keep records about the chemical and submit an annual declaration at the end of the registration year.

Chemicals introduced under the exempted or reported introduction categories, or that have been authorised for commercial evaluation or exceptional circumstances introduction, are not listed on the Inventory.

The primary means of protecting CBI so that it is not placed on the Inventory is by partially masking chemical names and specific end use details with AACNs and GEUs (see Section 3).

If a chemical was granted an AACN at the time of the assessment, it will be subject to review of CBI protection after five years to decide whether the chemical will be listed on the Inventory with an AACN, or with the full chemical name. Ongoing CBI protection of a chemical name will be periodically reviewed every five years from the date of first approval of the CBI (including for chemicals early listed on the Inventory).

Under the IC Act, the Executive Director can initiate an evaluation (with public consultation) for a chemical listed on the Inventory. If the evaluation concludes that a variation to the listing is necessary to manage the risks to human health or the environment from the introduction of the industrial chemical, the Inventory listing record will be revised (i.e. updated or removed based on the evaluation).

Inventory activities that may trigger an evaluation can be chemicals on the Inventory that were previously regulated by another agency, or the identification of wrongly added or misidentified chemicals on the Inventory (see Section 5).

When a chemical is listed on the Inventory or a listing is varied, the Executive Director must publish a website notice within 20 working days after the industrial chemical is listed or the listing varied.

The Executive Director can make administrative changes to the Inventory at any time (without undertaking consultation) where those changes have no regulatory impact and the identity of the chemical is not changed (e.g., correction of typographical errors, updating chemical names as per the Chemical Abstract Services, etc.)

AICIS fees for Inventory services apply to activities such early listing chemicals on the Inventory or varying Inventory listings, applications for continued protection of confidential business information.

## Accessibility

***Inventory chemicals search tool***

Subject to certain confidentiality provisions, section 80 of the IC Act requires the terms of the Inventory listing for each industrial chemical that is listed on the Inventory must be made publicly available on the AICIS website. This requirement is fulfilled by having the chemical Inventory database searchable via the AICIS website to find chemicals with the most up to date information including any regulatory obligations associated with importing or manufacturing those chemicals. The database is also available in Excel spreadsheet format for user convenience only and is not the official version of the Inventory. The downloadable list, while administratively useful to industry, should not be relied upon as it provides a snapshot of chemicals on the Inventory at a point in time. The list is updated every six months.

Any business with a genuine intention to introduce (manufacture or import) the chemical into Australia can apply online through AICIS Business Services to search for confidentially listed chemicals on the Inventory if they cannot find their industrial chemical on the Inventory.

# 5 Scientific evaluation

The IOMC Toolbox for Industrial Chemicals Management outlines the process of scientific evaluation to determine the risk posed by chemicals to human health and the environment including the technical elements of hazard assessment and exposure assessment. “Evaluation” has legal meaning under the IC Act, and so in this section we refer to “risk assessment”.

## Risk Assessment Overview

Risk assessments of industrial chemicals are conducted by AICIS staff to determine the level of risk to people and the environment associated with the introduction and use of industrial chemicals, whether risks need to be managed, and the recommendations that should be made to manage the identified risks  Details of AICIS risk assessment of industrial chemicals are available here.

A standard set of human health and environmental hazard endpoints, along with the characteristics of exposures, are used to determine the potential human health and environmental risks associated with a use of the industrial chemical.

The approach to our risk assessments considers hazards and exposure scenarios in line with international best practice. Risk assessments involve evaluating:

- how chemicals are used, which then defines the scope of our risk assessment
- relevant hazards for the chemical
- characterisation of hazards, which determines how hazards and their severity vary with different levels of exposure
- exposure scenarios and levels of exposure
- characterisation of risks based on the information above.

Several common key principles underline a consistent approach of AICIS to chemicals risk assessment that ensures our approach is:

- proportionate to the risk
- aligned with best regulatory and scientific practice
- transparent
- targeted, practical and implementable when referring risk management recommendations.

### *International harmonisation of risk assessment*

Under the IC Act one of the functions of the Executive Director is to promote the international harmonisation of risk assessment approaches through engagement and collaboration with international organisations. AICIS builds and maintains strong relationships with comparable national and international regulators to benchmark our regulatory and assessment approaches and methodologies (where appropriate) and minimise regulatory burden.

### *Hazard*

To assess hazards, specific responses or effects for various hazard human health and environmental endpoints are considered.  Standardised endpoints that are internationally

accepted as adequately exploring a range of possible adverse effects are used. As hazard endpoints are standardised, results can be shared with and accepted from other comparable regulators.

When there are no data on a specific chemical, 'read across' data from other chemicals that are structurally or functionally similar are used. Relying on chemical analogue data for read across always requires robust scientific justification.

Data about physicochemical and environmental fate properties are also collected. This data enables predictions for certain hazards. For example, a highly acidic chemical would likely cause skin irritation, while chemicals that naturally partition to water in the environment would be a concern for aquatic organisms.

Hazardous chemicals are classified according to the criteria relevant to worker health and safety and the environment under the 'Globally Harmonised System of Classification and Labelling of Chemicals' (GHS), Seventh revised edition, published by the United Nations.

### *Exposure*

Several distinctions are made when considering exposure:

- worker (occupational) exposure versus public (consumer) exposure
- intentional versus unintentional exposure
- direct versus indirect exposure.
- environmental exposure

Worker and public exposure are considered separately because the exposure routes (ingestion, inhalation, skin, eye or mucous membrane contact) can be very different. Public exposure also considers infants and young children, who are not part of the workforce.

The quality of available data and any assumptions made due to uncertainty always limit risk characterisation. To manage uncertainty, realistic conservative assumptions are used to protect human health and the environment.

Information for a risk assessment sometimes is contradictory or of varying quality. In such cases, the information is assessed and decisions are made using expert judgement and a weight of evidence approach. This approach examines both the quality and consistency of data.

### *Peer Review*

All risk assessments undergo internal peer review to ensure that the work is technically defensible, competently performed, properly documented and consistent with quality and legislative requirements. A detailed review is undertaken of the relevance and reliability of information, assumptions, completeness, conclusions and recommendations pertaining to the scientific or technical work and supporting documentation. In some instances, an external peer review may be undertaken by another trusted international regulator.

Under the IC Act, any chemical that meets the definition of an industrial chemical (or class of industrial chemicals) may be subject to risk assessment (evaluation or assessment).

### *Evaluations*

Evaluations are conducted of chemicals that are already available for use in Australia (existing chemicals). These are proportionate to risks associated with their industrial use.

Evaluations can be conducted on chemicals that are:

- listed on the Inventory
- introduced under a current assessment certificate
- introduced under reported or exempted categories
- excluded from other parts of the IC Act (for example, naturally occurring chemicals).

An evaluation can cover:

- a single chemical
- a class or group of chemicals
- a specific use
- a specific hazard
- a specific exposure
- specific circumstances of a chemical introduction

An evaluation may be triggered due to:

- a new or changed use of a chemical that may lead to increased or different human exposure, or increased release to the environment, such as changes in chemical volume, concentration, formulation method, use pattern or product types
- new hazard information that may include toxicological or ecotoxicological data
- new information or requests from risk managers − for example, the identification of nanoforms of a chemical, for which hazards or behaviour are not well characterised, health effects from consumer products that can be linked to a common chemical ingredient, or environmental contamination
- new information from international regulators, such as bans or restrictions on the use of chemicals
- post market monitoring activities indicating the need to evaluate a potential risk relating to chemical introductions
- prioritisation activity – Evaluation Screening Analysis (ESA) indicates the need for more detailed evaluation.

The Rolling Action Plan (RAP) is the AICIS work plan for chemicals prioritised for evaluation. The RAP is an important part of a larger strategic approach to protecting the Australian public and the environment via the evaluation of industrial chemicals, outlined by the AICIS Evaluation Roadmap 2020-24.

Chemicals are listed on the RAP following a formalised two stage prioritisation process commencing with an ESA followed by the Evaluation Candidate (EvC) process. A notice on the AICIS website is published for each update of the RAP. This notice directs users to the RAP webpage where further details about the subject, reason and time period for a chemical evaluation is provided.

*Evaluation Selection Analysis (ESA)*

To identify candidates for evaluation (the Evaluation Candidates), an ESA must be conducted as this validates the chemicals selected as a priority for evaluation. An ESA may be triggered as a result of prioritisation activity, a post-market audit, Inventory activities or information provided as part of post assessment information obligations. The ESA is a three-step process which is described in the link provided above.

*The Evaluation Prioritisation Tool*

The Evaluation Prioritisation Tool (EPT) is an innovative prototype using R programming drawing on hazard and use data.  It assists in prioritising the remaining unassessed

industrial chemicals on the Inventory for risk assessment. This tool enables efficient analysis of large volumes of chemical data and facilitates screening to determine both high and low concern chemicals. Weighting scores and modifiers are applied to the data to determine preliminary risk profile for industrial chemicals.

*Grouping*

Selection of chemicals for specified chemical groups is an important step of the ESA process. Where possible, chemicals are grouped using scientific and technical guidance. This promotes efficiency and consistent decision making about similar chemicals based on:

- chemical structure
- common toxic species (for example, esters, salts)
- mode of action
- functional use
- physico-chemical properties.

*Evaluation outcomes*

Evaluations can lead to any one of the following outcomes:

- no regulatory action required
- recommendations to prescribed bodies
- recommendation for risk management under the IC Act.

*Inventory listings – variation or removal*

An Inventory listing for a chemical may include a ‘specific information requirement’. This means that a chemical has been assessed, and introducers are obligated to inform AICIS about the introduction of the chemical in certain situations. The information provided is used to determine if an evaluation needs to be initiated to reassess the chemical (refer to Section 3).

An evaluation conclusion may support a recommendation that the Executive Director vary a term of an Inventory listing if necessary to manage the risks of a chemical which could include variation to the:

- defined scope of assessment
- conditions of introduction or use
- specific requirement(s) to provide information to AICIS.

Alternatively, an evaluation conclusion may support a recommendation that the chemical be removed from the Inventory where it is determined that the risk to human health and/or the environment cannot be managed through existing frameworks.

*Evaluation Statements*

The Evaluation Statement is a structured summary of the information considered when conducting the evaluation, and the evaluation outcomes. The purpose of an Evaluation Statement is to provide introducers and the public with concise information about identified risks and the means for managing those risks. An Evaluation Statement must be in writing and contain the following:

- subject of the evaluation
- parameters of the evaluation
- a summary of the evaluation and any identified risks to human health or environment

identified during the evaluation
- the proposed means for managing any risks
- any other information the Executive Director considers relevant relating to the safe introduction and use of an industrial chemical that was considered as part of the evaluation
- the conclusion of the evaluation.

The Evaluation statement must be published on the AICIS website.

***Assessments***

An industrial chemical introduction that is categorised as 'assessed' means that the chemical has an indicative risk to human health or the environment, of medium to high risk, according to legal definitions (see Section 3). If the chemical is not on the Inventory, then the introduction must be assessed and an Assessment Certificate issued before the chemical can be imported or manufactured in Australia. The chemical will be listed on the Inventory five years after a certificate is issued or be early listed upon the certificate holder's application (refer to Section 4).

There are four types of assessment certificates that applicants can apply for based on how they categorised their introductions:
- health and environment focus
- health focus
- environment focus
- very low to low risk.

Although a 'very low to low risk' type is only for introductions that are categorised in exempted or reported categories, introducers may still apply for assessment certificates so that these industrial chemicals can be listed on the Inventory.

Applicants can only select one type for each application and each application type has different information requirements. Additional requirements may apply to specified classes of introductions. For fee saving purposes, there are:
- consolidated applications for multiple chemicals that meet similarity criteria.
- comparable hazard assessments for chemicals already assessed by another competent regulator
- multicomponent applications for inseparable chemicals introduced in a mixture.

The consideration period for an application of an assessment certificate is generally 70 working days however this may vary if, for example, additional information has been requested from the applicant during the assessment process.

When an industrial chemical introduction is assessed and an assessment certificate issued, a 'defined scope of assessment' must be included as one of the terms of the assessment certificate. It is a legal obligation for certificate holders to introduce a chemical within the defined scope of assessment and other terms on the certificate. The defined scope of assessment is published as part of the assessment statement that is available on our website when the assessment is complete.

Applicants can apply online for an assessment certificate through AICIS Business Services Portal. There is guidance designed to help prepare and submit an online certificate application. There is extra guidance for chemicals at the nanoscale.

*Assessment Statements*

Based on the IC Act, the Executive Director must be satisfied that any risks to human health or the environment can be managed before deciding to issue an assessment certificate. Following the process of a certificate application, an assessment statement will be generated and published on the AICIS website. The assessment statement must be a written statement issued by the Executive Director in relation to an assessment of an industrial chemical that includes the following information:

- the proper name for the industrial chemical
- the end use for the industrial chemical
- the defined scope of assessment
- a summary of the assessment and any risks to human health or the environment from the introduction or use of the industrial chemical
- the means for managing any risks identified in the course of conducting the assessment, including the following:
  - recommendations relating to the introduction or use of the industrial chemical
  - any conditions relating to the introduction or use of the industrial chemical
  - any specific requirements to provide information to the Executive Director
- any other information relating to the safe introduction and use of the industrial chemical that the Executive Director considers relevant.

The Executive Director may vary the terms of an assessment certificate (see section 50 of the IC Act) if necessary to manage the risks including:

- conditions relating to the introduction or use of the industrial chemical (introduction volume, where the chemical is permitted to be introduced or used, and the period for which the chemical is permitted to be introduced)
- specific requirement(s) to provide information in relation to the introduction
- other information prescribed by the General) Rules

Where it is determined that the risk to human health and/or the environment cannot be managed through existing risk management frameworks the Executive Director will consider cancelling the assessment certificate (see section 52 of the IC Act).

# 6 Risk Management

The risk management element of the IOMC Toolbox for Industrial Chemicals Management describes the process for selecting and developing appropriate regulatory actions to control and prevent risks to human health and the environment posed by a substance. It includes the following sub-elements: (1) Risk evaluation (consideration) and (2) Exposure control. For more information, refer to the IOMC toolbox.

In the Australian context, based on the potential human health and/or the environment risk associated with the use, import or manufacture of industrial chemicals an assessment may be conducted to determine whether risk mitigation is required and what risk management recommendations are necessary to mitigate the risks. The goal is to effectively manage the risks associated with the use of an assessed chemical by controlling conditions that might cause harm.

## Risk assessment

AICIS assessments and evaluations examine the potential risks to human health and environment associated with the introduction and use of industrial chemicals. They can include recommendations on the proposed means for managing any identified risks to human health or the environment. These risk management recommendations are referred to relevant Australian standard setting bodies or state and territory agencies (also known as prescribed bodies under the IC Act) such as:

- Safe Work Australia (workplace chemicals)
- Department of Health and Aged Care Advisory Committee on Chemicals Scheduling (consumer chemicals)
- ACCC (consumer chemicals and product safety)
- Department of Climate Change, Energy, the Environment and Water (scheduling under the Industrial Chemicals Environmental Management Standard [IChEMS])
- State/Territory bodies (the environment, public health, work health and safety)

The complete list of prescribed bodies is specified in section 15 of the General Rules. AICIS consults with these risk management agencies to ensure that any risk management recommendations are targeted, practical and easily implemented. The agencies consider the recommendations and ultimately determine the regulatory standards that are appropriate for management of the identified risks.

AICIS also directly conducts risk management activities in certain circumstances as specified in Part 3 and Part 5 of the IC Act. An evaluation conclusion may support a recommendation that the Executive Director either varies the term of an Inventory listing (section 86), or the chemical be removed from the Inventory, if necessary to manage a chemical's risks (section 95). The Executive Director may also refuse to issue (section 37), vary the terms of (section 50), or consider cancelling (section 52), an assessment certificate if necessary to manage the risks (see Section 5).

***Engagement and communication***

Under the IC Act, AICIS is obligated to seek advice from the relevant prescribed body if the Executive Director is considering any of the following risk management action on the basis that action is necessary to manage the risks to human health or environment:

- including, removing or varying a condition relating to the introduction or use of an industrial chemical on the assessment certificate
- refusing to issue a certificate
- cancelling a certificate

AICIS may seek advice in other circumstances if there is a need to inform an assessment or evaluation.

AICIS consults during the course of an evaluation, or after publication of the draft evaluation statement and its preliminary conclusion. Feedback from stakeholders is considered for incorporation into the final evaluation statement.

Publication of completed assessments and evaluations on the AICIS website assists national, state and territory governments with implementing risk management controls, and facilitates their safe use by workers and the public.

AICIS maintains a Risk Management Recommendations Register which lists risk management recommendations for industrial chemicals that have been assessed or evaluated and referred to the relevant prescribed bodies. The register is part of a commitment to give industry, workers, the community and all stakeholders timely and accessible information about recommendations made, to whom they were referred to and the status of actions taken on the recommendations. AICIS works closely with these risk management agencies to make sure that the register is updated as soon as they advise that there is a change to the risk management recommendations status. AICIS also engages with the agencies and the public to make sure the register continues to be fit-for-purpose. For the purpose of transparency AICIS also reports on the risk assessments and recommendations in the Department of Health and Aged Care's annual report.

# 7 Awareness Raising

This element of the IOMC Toolbox for Industrial Chemicals Management describes the mechanisms for gaining public, political, and industry interest and support for the implementation of a chemicals management system. It contains two sub-elements: (1) Public awareness raising and (2) Raising awareness among decision makers. For more information, refer to the IOMC Toolbox.

## Introduction

AICIS works with a diverse range of stakeholders (including industry, workers, government, community groups and the public) to share information and promote the use of our published scientific risk assessments to help protect people and the environment. Raising awareness and engaging stakeholders in the regulation and management of industrial chemicals is one of AICIS's key functions. AICIS offers a range of resources and educational activities to inform the public and to aid industry in understanding and compliance with their obligations. These are publicised through various engagement channels and accessed through the AICIS website. AICIS assessments and evaluations include information about hazards and risks to the health of Australians and the environment from the introduction and use of industrial chemicals. AICIS also collaborates with international regulatory bodies to contribute to the development of and utilising best practice for the regulation and assessment of industrial chemicals (see Section 5).

## Public awareness raising

***Information and communication***

AICIS raises awareness of our activities and decisions by publishing through various communications channels. These include:

- publishing on a 'News and notices hub' on the AICIS website which includes:
    - 'News and updates', for example, new and updated guidance and tools
    - 'Inventory notices' including legal notices for chemicals added to/removed from the Inventory and variations to listings.
    - 'Regulatory notices' including listing published new chemical assessment statements and in progress/completed evaluations of listed chemicals.
    - Supported by posts on a Facebook page
- sending targeted emails
- articles in a monthly, subscriber-based e-newsletter
- AICIS chemical risk assessment and evaluation reports that are searchable by the public
- AICIS Evaluations Roadmap and Rolling Action Plan
- The 'Risk Management Recommendations Register' which is a searchable database of regulatory recommendations that AICIS has made to risk management authorities in Australia.

- A 'Consultation hub' on the website to seek public feedback on regulatory proposals and amendments to legislation.
- Webinars to help inform interested parties about proposed regulatory changes.
- Online presentations aimed at industry and businesses to understand their compliance obligations.

## Awareness raising of decision makers, including the regulated industry

Active engagement with the chemical industry is maintained through a range of mechanisms including the communication channels described above.

A Help and guides page on the AICIS website assists introducers with their obligations and includes videos on a range of key topics. The videos include detailed guidance on the categorisation process (including worked examples), reporting and record-keeping obligations, assessed chemical introductions and evaluations of chemicals already available for an industrial use in Australia (existing chemicals).

Regular meetings of the AICIS Strategic Engagement Committee (SEC), with representatives drawn from peak industry and civil society groups, are the primary stakeholder consultation mechanism. The role and functions of the SEC are to:

- facilitate active engagement and input of relevant sectors affected by the functions of AICIS;
- provide strategic advice on mechanisms to more efficiently and effectively achieve the objects of the IC Act;
- enable transparent on-going communication and information sharing on strategic issues between different stakeholder groups engaging with AICIS.

AICIS participates in regular activities of a Regulatory Science Network (RSN), a network of Australian government regulatory science agencies including the prescribed bodies. The RSN aims to help improve the performance of regulatory agencies by strengthening evidence-based decision-making by improving the quality and consistency of regulatory science and fostering interagency collaboration and knowledge sharing.

AICIS staff frequently attend meetings with prospective and registered introducers and industry associations in an effort to help with compliance and understanding of the regulatory landscape. These may be targeted at specific sectors, client groups or regional areas.

Other engagement channels include:

- site visits and company briefings
- focus groups and industry user acceptance testing on process (guidelines, e-business tools)
- technical and scientific working groups of experts on evolving issues

## International engagement and collaboration

AICIS's international engagement directly supports the objective of helping protect the health of Australians and the environment from the risks associated with the use of industrial chemicals through contributing to the development of and utilising best practice for their regulation and assessment. Through participation in various major international chemical forums and cultivation of relationships with likeminded organisations, AICIS stays aligned with the international chemicals regulatory landscape and maintains currency of international efforts for the benefit of AICIS and our stakeholders.

An essential consideration in the adoption of internationally developed practices is that they are consistent with domestic laws and applicable to Australian circumstances. The importance of international engagement is recognised in AICIS legislation, which provides,

for example, a pathway for AICIS to accept assessments conducted by trusted overseas bodies to support the introduction of industrial chemicals into Australia (section 27 of the IC Act and section 38 of the General Rules). Section 142 of the IC Act specifies that one of the functions of the Executive Director is to promote the international harmonisation of regulatory controls or standards for industrial chemicals.

***Multilateral engagement***

AICIS collaborates with international counterparts on regulatory and scientific matters via participation in multilateral fora and conferences. Where appropriate AICIS participates collaboratively with other areas of the Australian government that have overlapping interests for these multilateral fora. This may include AICIS providing technical policy advice to other areas of the Australian government on matters related to a particular forum.

The OECD Chemicals and Biotechnology Committee and its subsidiary groups related to industrial chemicals are key bodies for engagement by AICIS. Participation by AICIS and other Australian government entities allows for the Australian perspective to be considered in areas relevant to the regulation of industrial chemicals, avoids duplication of effort, and allows for Australia to contribute to the harmonisation of assessment methods.

AICIS also provides input to the Asia-Pacific Economic Cooperation's Chemical Dialogue, which includes Australia's key regional trading partners and other international associations. This forum assists government and industry in countries in the Asia-Pacific region to manage the risks from chemicals. Engagement by AICIS has included, providing input on documentation related to industrial chemicals management, providing advice on developing chemical inventories and participating in risk assessment workshops.

In addition, AICIS provides input to other multilateral programs relevant to the management of industrial chemicals. This includes the Global Perfluorinated Chemicals (PFAS) Group supported by the OECD and the United Nations Environment Programme (UNEP), United Nations (UN) – Globally Harmonized System of Classification and Labelling of Chemicals (GHS) through the UN Sub-Committee of Experts on GHS (UNSCEGHS) and the International Organization for Standardization (ISO) Technical Committee 229 on Nanotechnology (ISO/TC 229).

***Bilateral engagement***

AICIS has bilateral relationships with comparable international regulators aimed at international harmonisation and information sharing. Efficiencies are gained across various areas of assessment work through opportunities to directly share knowledge and expertise. Formal bilateral cooperative arrangements/memoranda of understanding are in place with counterparts in the European Union, United States of America, Canada, Republic of Korea, and New Zealand. Regular dialogue is maintained with these agencies on topics of mutual interest, such as the use of new methods for the assessment of chemicals and the sharing of information on chemicals and their management.

***International conventions***

AICIS implements relevant regulation the following international conventions ratified by Australia by providing expert technical advice on industrial chemicals for: Rotterdam Convention on Prior Informed Consent; Stockholm Convention on Persistent Organic Pollutants; and the Minamata Convention on Mercury. AICIS also assists in managing Australia's obligations under these conventions which is discussed further in Section 9.

# 8 Evaluation of the effectiveness of the system

The Evaluation of the Effectiveness of the System element of the IOMC Toolbox for Industrial Chemicals Management describes the processes for ensuring that risk management actions are having the intended effect. It comprises two sub-elements: (1) health monitoring and (2) environmental monitoring. For more information on the Evaluation of the Effectiveness of the System element refer to the IOMC toolbox.

## Introduction

Following a chemical risk assessment, and where appropriate, AICIS may make recommendations to risk management agencies to control any identified risks. AICIS itself does not, however, have powers to monitor chemical exposure.

National standard-setting bodies and state and territory risk managers may monitor exposure to hazardous chemicals to provide information on their effects. Monitoring both human and environmental exposure to these chemicals is done by gathering data through their measurement in air, water, soil, sediment, biota and humans.

This information can inform risk assessment and risk management activities and serve to assess whether risk management measures are meeting their objective to reduce the risk of hazardous chemicals to human health and the environment. To monitor the effectiveness of our risk assessments and ensure that we provide relevant information to risk management agencies and the public, we track the status of recommendations using the Risk Management Recommendations Register (see Section 6).

## Evaluation of the Effectiveness of the System – Health (Biomonitoring)

AICIS is not empowered undertake human health monitoring of industrial chemicals. Some prescribed bodies who implement the risk management measures recommended by AICIS do administer legislation that serves to assess whether these measures have proved effective. For example, the Safe Work Australia Model Health Work and Safety Regulations and guidance related to hazardous chemicals requiring health monitoring under the Work Health and Safety (WHS) Regulations specifies health monitoring. As mandated, a person conducting a business must ensure that health monitoring is provided to a worker using, handling, generating or storing certain hazardous chemicals and there is a significant risk to the worker's health because of exposure to those chemicals (subject to specific conditions).

## Evaluation of the Effectiveness of the System – Environment (Environmental monitoring)

AICIS does not undertake environmental monitoring of industrial chemicals.

However, the DCCEEW maintains the National Pollutant Inventory (NPI) which tracks pollution across Australia by collecting data on 93 substances emitted into the environment. The substances were chosen because of the problems they can potentially cause for human health and the environment. The data comes from facilities like mines, power stations and factories, and from other sources such as households and transport. Facility operators are required to monitor, measure and report their own emissions and transfers, and diffuse

emissions from households and other sources like motor vehicles are estimated by government agencies.

State and territory based regulatory authorities also administer extensive environmental legislative mechanisms and are responsible for monitoring emissions and compliance, conducting audits and investigating reports of pollution including transport and factory spills.

# 9 Compliance Monitoring

In the IOMC Toolbox for Industrial Chemicals Management, the Compliance Monitoring element outlines effective strategies for regulatory authorities to verify industry compliance with legislative and regulatory requirements. It contains two sub-elements: (1) Local control and (2) Customs control. The Compliance Monitoring element is closely related to the "Enforcement of Obligations" element and some of the information may overlap. For more information, refer to the IOMC Toolbox.

## Introduction

Compliance monitoring activities are undertaken to promote awareness of obligations under the IC Act and identify non-compliance. Compliance officers use a range of activities such as desktop monitoring, customs data, targeted audits, and site visits to detect non-compliance under the IC Act. A large proportion of the work carried out by AICIS is providing education to industry stakeholders on their obligations under the IC Act.

The AICIS website is a valuable source of information for stakeholders which provides text-based resources, training videos and the option to submit enquiries. AICIS also regularly runs monitoring campaigns to raise awareness and determine the level of industry compliance with their obligations. These range from desktop activities using information available to AICIS, site inspections and using monitoring powers available to AICIS under the *Regulatory Powers (Standard Provisions) Act 2014* (the RP Act) (see Section 10). Refer to the link for more information on compliance monitoring activities under the IC Act.

## Local Control

### *Management of non-compliance*

AICIS investigates reports of non-compliance with the IC Act from multiple sources such as third-party allegations, self-reported breaches, monitoring activities and referrals from other government agencies. All instances of non-compliance identified are screened and prioritised for response.

### *Compliance Monitoring*

In relation to compliance monitoring activities, AICIS uses a risk-based approach and focuses on introducers at higher risk of non-compliance as well as introductions that pose a higher risk to human health and the environment. Monitoring activities are also modified to accommodate emerging risks.

### *Types of monitoring activities*

*Registration Obligations*

All introducers (importers and manufacturers) of industrial chemicals are required to be registered with AICIS and registered at the correct level. Registration is done online by completing a form and paying a fee. Refer to the link for more information on registration.

*Authorisation Obligations*

It is the responsibility of the Introducer (importer or manufacturer) to ensure that all industrial chemical introductions are authorised under section 24 of the IC Act and to comply with all relevant reporting and record keeping obligations. The introduction of an industrial chemical which is not authorised under section 24 of the Act may incur penalties. Industrial chemicals are required to be authorised by one of sections 25 – 30 of the IC Act which means that industrial chemicals that do not meet the listed introduction category are required to meet the categorisation requirements of another introduction category. It is the responsibility of the introducer to categorise all chemical introductions prior to introduction.

*Record Keeping Obligations*

Introducers must keep certain records about their industrial chemical introductions to confirm their introductions are authorised. It also ensures the introducer is aware of any changes that could impact the categorisation. There are different record keeping obligations for each category of introduction and the introducer must keep these records for 5 years, even after they have stopped introducing the chemical. Refer to the link for more information on record keeping obligations for each category.

*Reporting Obligations*

All introducers are required to submit an annual declaration to AICIS. This can be done online using the AICIS business services portal. The information provided in the declaration includes the introduction categories for the industrial chemicals that were imported or manufactured during the previous registration year. It also includes a declaration that all introductions were authorised under sections 25 to 30 of the IC Act.

Reporting obligations differ depending on the category of chemicals introduced. Refer to the link to learn more about reporting obligations for the different introduction categories (see Section 5).

*Obligations Relating to International Agreements*

Australia is a party to several international agreements and treaties such as the Rotterdam and Stockholm Conventions to regulate the trade of certain hazardous chemicals. Annex III to the Rotterdam Convention is a list of pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons. Entities wishing to trade certain Annex III-listed industrial chemicals, must receive prior authorisation from AICIS. Introduction of chemicals listed on Annex III of the Rotterdam Convention is subject to section 25 of the General Rules and is monitored under the Exempted and Reported categories. Refer to the link to find out more.

AICIS also regulates the import and export of mercury for industrial use under the Minamata Convention. Obligations under the IC Act regarding mercury are supported by Customs Prohibited Import/Export Regulations which create an offence for the import/export without approval from AICIS. Anyone seeking to export mercury from Australia to a party or non-party to the Convention must apply and receive authorisation from AICIS. Anyone seeking to import mercury from a non-party to the Convention must apply and receive authorisation from AICIS. Refer to the link to find out more.

### *Risk Assessment of Introducers*

To help inform monitoring activities, a regulated entity's compliance risk against obligations under the IC Act is assessed. All regulated entities undergo some level of risk profiling and assessment by AICIS which considers the introducer's level of introduction, compliance history, and type/range of industrial chemicals introduced. Monitoring activities focus on the regulated entities assessed as being a higher relative risk of non-compliance. These entities will be subject to more regular and detailed monitoring to encourage compliance. This risk-based approach to compliance monitoring ensures AICIS's limited compliance resources are directed towards areas/entities considered to be at higher risk of non-compliance.

### *Desktop monitoring*

Most stakeholder obligations can be determined via desktop monitoring using data provided by other Australian Government Departments, information routinely reported to AICIS by regulated entities, or information and records provided in response to requests for information by AICIS.

### *Authorised Inspectors*

The Executive Director of AICIS appoints AICIS inspectors in writing for the purpose of undertaking monitoring activities in accordance with the IC Act and the RP Act. AICIS inspectors are authorised to enter any premises (either with consent or under a monitoring warrant) to determine whether an entity is complying with a provision under the IC Act (or related offences) or have provided information that is correct. AICIS inspectors may exercise several powers under the IC Act and the RP Act, including:

- searching a premises
- taking still or moving images
- inspecting and copying documents
- taking and keeping samples of any substance at the premises

### *Monitoring warrants*

AICIS officers may apply for a monitoring warrant under the RP Act. Under the warrant, AICIS officers may enter a premises to determine compliance with a provision subject to monitoring, or to determine whether information subject to monitoring is correct. The warrant also allows various information-gathering powers and creates an obligation for the occupier of the premises to answer any questions or produce documents relating to their obligations under the IC Act. Obstruction of an AICIS Officer executing a monitoring warrant is an offence under section 147 of the *Criminal Code Act 1995*.

### *Inspections*

Authority for inspections is provided under section 128 of the IC Act and is also subject to the RP Act. AICIS inspectors may enter any premises (either with consent or under a monitoring warrant) for the purposes of obtaining evidential material relating to a provision of the IC Act (or related offences under the *Crimes Act 1914* or the Criminal Code). AICIS inspectors may exercise powers under the RP Act and the IC Act including the searching of premises, seizing evidential material, operating and seizing electronic equipment and securing electronic equipment.

***Laboratory analysis***

In a small number of cases, analytical testing may be undertaken as part of AICIS's monitoring activities. Authorised inspectors are permitted to take samples during site visits and inspections to verify compliance with the IC Act. Samples collected may be tested to determine the presence or absence of a particular chemical. Samples can be taken under warrant or by consent.

***Case Management & Investigations***

When monitoring activities identify non-compliance, it is referred to a team of compliance officers for case management. When a case of non-compliance is accepted under the IC Act, it is prioritised based on criteria set out in the AICIS case prioritisation standard operating procedure (see Section 10). AICIS also investigates cases in collaboration with other government agencies in matters relating to industrial chemicals and their use.

AICIS investigations consist of formal evidence-gathering and information-collation activities where serious non-compliance is suspected or identified and formal enforcement is the likely outcome. Our investigations can also result in preventative action or referral to other government agencies.

Investigations focus on contraventions of the IC Act and related offences against the Criminal Code that relate to the IC Act. Refer to the link to learn more about the AICIS investigations.

## Customs Control

As mentioned above, Australia is a party to several international agreements and treaties such as the Rotterdam Convention to regulate the trade of certain hazardous chemicals and the Minamata Convention which regulates the import and export of mercury for industrial use. Customs data informs AICIS of the import and export of these prohibited and restricted chemicals which is part of monitoring activities. Refer to the link for more information.

***Responsible Authorities and Partners***

**Australian Border Force (ABF)**

AICIS has a memorandum of understanding with the ABF which allows the exchange of information between AICIS and ABF relating to industrial chemicals. For example, the ABF supplies AICIS with import data relating to industrial chemicals on a regular basis. The data received, informs AICIS registration monitoring activities, and is used in many other compliance monitoring activities and investigations but is limited by the amount of detail provided.
The import data is also used for monitoring compliance obligations under the IC Act relating to prescribed international agreements such as the Minamata and Rotterdam Convention as approvals are required for the import and export of chemicals which are subject to these Conventions.

**Department of Climate Change, Energy, the Environment and Water (DCCEEW)**

DCCEEW is the designated national authority for Minamata and Rotterdam Conventions. AICIS consults with DCCEEW on the relevant aspects of these monitoring activities.

When importing mercury from a party to the Convention, the exporting country must seek written consent from DCCEEW.

# 10 Enforcement of Obligations

The Enforcement of Obligations element of the IOMC Toolbox for Industrial Chemicals Management outlines the process for ensuring consistent enforcement in the event of non-compliance with legislative and regulatory requirements. It includes two sub-elements: (1) Sanctions and (2) Liability. For more information, refer to the IOMC toolbox.

## Introduction

AICIS monitors compliance with the IC Act. AICIS assesses all referred instances of non-compliance to determine the most appropriate response. For more information on our powers and enforcement measures, refer to the following link.

## Response to Contraventions of the IC Act

Contraventions of the IC Act may range from relatively minor, inadvertent non-compliance through to more serious deliberate or negligent contraventions. Response to non-compliance is determined on a case-by-case basis in accordance with the AICIS Case Prioritisation Model. This model assigns higher priority to those small number of cases involving repeated or deliberate non-compliance.

In most cases, a suitable resolution will involve assisting the entity in resolving any non-compliance and preventing future non-compliance. This administrative approach to non-compliance may be appropriate for self-reported breaches where the contravention is unintentional and there is a low risk of harm to human health or the environment.

Formal investigation activities are normally reserved for high-priority cases that seriously contravene the IC Act. These investigations are carried out in accordance with the Australian Government Investigation Standards (AGIS).

## Legislation and Policies Governing Enforcement Activities

### *Industrial Chemicals Act 2019*

The IC Act places a range of regulatory obligations on the introducers (and in some cases, exporters) of industrial chemicals. The IC Act also contains provisions for monitoring and enforcement.

### *The Australian Government Investigations Standard (AGIS)*

The Australian Government Investigations Standard (AGIS) articulates Australian Government policy and is the foundational standard, framing accountability and security for entities conducting investigations relating to the government programs and legislation they administer. More information on the AGIS is available here.

### *Regulatory Powers (Standard Provisions) Act 2014*

AICIS has access to the standard suite of regulatory enforcement powers available to Australian Government Regulators under the RP Act. These powers include:

- Civil Penalties
- Criminal Penalties
- Infringement Notices
- Enforceable Undertakings
- Injunctions.

The RP Act commenced on 1 October 2014, but only has effect where Commonwealth Acts are drafted or amended to trigger its provisions. The standard provisions of the RP Act are an accepted baseline of powers required for an effective monitoring, investigation or enforcement regulatory regime, whilst providing adequate safeguards and protecting important common law privileges. More information on the RP Act is available here.

Formal enforcement (and monitoring powers) available under the RP Act are assigned to:

- The Executive Director of AICIS; and
- AICIS authorised inspectors

Authorised inspectors are appointed under section 137 of the IC Act. Under the RP Act each AICIS authorised inspector is an authorised applicant, authorised person, and an infringement officer for the purposes of the RP Act.

### *The Criminal Code Act 1995*

The Criminal Code Act 1995 (Criminal Code) also includes a range of sanctions which apply to dealings with Commonwealth Officials which are relevant to the administration of the IC Act. For example, the giving of false or misleading information/documents and causing harm to or obstructing Commonwealth public officials are offences under the Criminal Code. More information on the Criminal Code Act is available here.

### *Memoranda of Understanding*

AICIS has formalised (Memoranda of Understanding) with certain regulators and enforcement agencies which outlines information sharing arrangements and cooperative arrangements. Informal arrangements also exist with other jurisdictions which results in the sharing of information and regulatory intelligence and the documented referral of non-compliance. Joint investigations or projects are undertaken in response to issues of mutual interest.

### *Case Screening and Prioritisation – Standard Operating Procedure (SOP)*

Internal AICIS Case Screening Categorisation and Prioritisation SOP assists AICIS officers in screening referred instances of non-compliance and assigning a relative priority to accepted referrals of non-compliance. The SOP is designed to ensure a consistent approach to the case management of non-compliance with the IC Act.

## Sanctions

### *Offences*

There are a range of offences under the IC Act which incur penalties. These offences are detailed in sections 13, 24, 70, 77, 96A, 99, 100, 101,102, 104, 162 and 164 of the Act.

### *Infringement Notices*

Infringement notices are used to address certain contraventions of the IC Act without resorting to prosecution or civil litigation. The RP Act creates an administrative framework for AICIS infringement officers to issue infringement notices where there is reasonable belief that a person has contravened the IC Act. Infringement notices are used to manage strict liability offences under the IC Act that are less serious and where the contravention is such that AICIS can easily assess the offence.

### *Civil penalties*

In cases of serious non-compliance, AICIS may apply to the court for a civil penalty order. A civil penalty is a pecuniary penalty imposed by courts exercising a civil rather than criminal jurisdiction.

### *Criminal prosecution*

Criminal prosecution is reserved for the most serious contraventions of the IC Act. Where non-compliance is deliberate, repeated or poses serious risk to human health and the environment, a brief of evidence may be prepared for consideration by the Commonwealth Director of Public Prosecutions (CDPP).

### *Cancellation of registration*

An introducer's registration may be cancelled if they have been convicted of an offence or subject to a civil penalty under the IC Act. Additionally, if a person gives information relating to an AICIS registration that is false or misleading this can also be grounds for a decision to cancel a registration.

More information on infringement notices, civil penalties, criminal prosecution, and cancellation of registration is available here.

### *Mechanisms to prevent risk to human health and the environment*

AICIS powers and enforcement tools are designed to support its role in industrial chemical risk assessment. The management of risks posed by industrial chemicals is performed by national, state and territory risk management agencies.

AICIS supports these agencies through the provision of information as a result of assessment and evaluation activities or through regulatory intelligence and referral of non-compliance (see Section 5).

### *Cost recovery*

AICIS is a fully cost-recovered scheme with registration charges funding most activities including compliance activities.