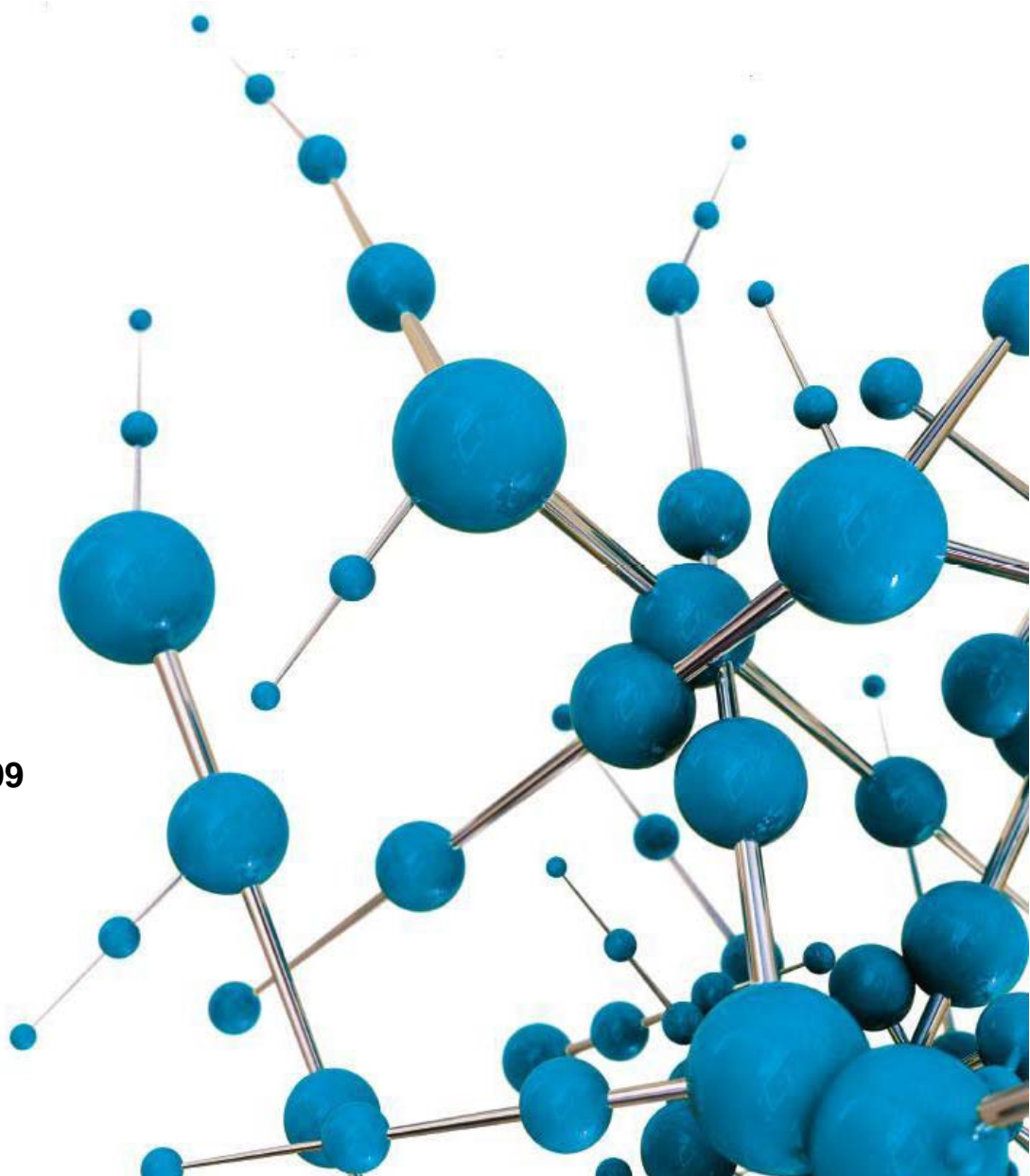




Australian Government
Department of Health and Ageing
NICNAS

A GUIDE TO THE NICNAS COMPLIANCE AND ENFORCEMENT FRAMEWORK

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1 INTRODUCTION

1.1 Overview

The National Industrial Chemicals Notification and Assessment Scheme, or NICNAS, was established in 1990 by the Commonwealth Government to help protect people at work, the public and the environment from the harmful effects of industrial chemicals.

It does so by administering:

- the *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act)
- the *Industrial Chemicals (Notification and Assessment) Regulations 1990*, and
- the *Cosmetics Standard 2007*.

The aim of this document is to increase the transparency of NICNAS's compliance and enforcement approach. It outlines the methods NICNAS uses to maximize voluntary compliance, its approach to identified instances of non-compliance, and the options available to resolve non-compliance.

NICNAS has adopted a cooperative approach to compliance through partnerships with the Australian chemical industry and the community. These concentrate strongly on education and raising awareness. Informing industry participants of NICNAS's approach to monitoring and enforcement will further assist in building these cooperative relationships and to encourage voluntary compliance.

This is not a legal document and should not be relied on as such. Provided for information, it does not limit the discretion of NICNAS to take any action it sees fit under the Act and/or Regulations. It reflects the current policies of NICNAS, which may change from time to time. All changes are notified publicly. Please contact your legal advisor for more information.

1.2 NICNAS's function and powers

NICNAS is the Australian Government's body for regulating the introduction of industrial chemicals.

NICNAS scientifically assesses industrial chemicals for their effects on health and the environment and makes recommendations for safe use. In addition, NICNAS gathers statistics on chemical use in Australia and sets standards for cosmetics imported into or manufactured in Australia.

The ICNA Act sets out regulatory obligations on importers and manufacturers of industrial chemicals, such as the registration of industrial chemical introducers, and chemical-specific obligations associated with new and existing chemicals. The ICNA Act also sets out the regulatory obligations associated with exporting certain chemicals that are subject to international treaties, such as the Rotterdam Convention, to which Australia is a signatory.

All of these obligations are the focus of the compliance program.

Offences committed under the ICNA Act are ultimately punishable by prosecution in a court of competent jurisdiction. The ICNA Act provides NICNAS' Director with information gathering powers, and the ability to revoke permits and certificates. It gives NICNAS inspectors appointed under the Act the power to search premises and seize goods

relating to an offence against the Act either with consent, or with a search warrant approved by a magistrate.

Other enforcement action may include an application for an injunction from the Federal Court of Australia restraining an unregistered company from introducing chemicals, searches and seizures of material used in connection with offences under the Act, and referral to the Commonwealth Director of Public Prosecutions for prosecution of offences under the Act.

1.3 NICNAS's approach to compliance and enforcement

In developing its compliance framework, NICNAS has considered the Organisation for Economic Cooperation and Development's framework¹ which proposes the following criteria for effective compliance:

- A regulated entity must know and understand its obligations – regulations cannot be complied with if they are difficult to understand
- A regulated entity must be willing to comply – voluntary compliance is likely to be low if the costs associated with compliance are too high, if the regulation is overly legalistic, or if the regulation does not mesh with existing market practices or cultural norms, and
- A regulated entity must be able to comply – governments need to ensure that regulated entities have access to necessary information and other support or mechanisms to enable them to comply.

Additionally NICNAS acknowledges its responsibility to provide an assurance to the Australian Public and Industry that the mandated requirements of the ICNA Act are being met. A risk-based compliance monitoring framework is critical to meeting this responsibility and NICNAS has developed, and reviewed its monitoring and enforcement activities in accordance with the principles outlines in the ANAO's Better Practice Guide to Administering Regulation²

NICNAS's approach is to encourage voluntary compliance by industry and supports the adoption by businesses of the *Australian Standard AS3806-2006: Compliance Programs*³. This provides principles for the development, implementation, and maintenance of effective compliance programs within both public and private organisations.

NICNAS is committed to maintaining a cooperative and persuasive enforcement approach. However, it acknowledges that compliance cannot be based solely on encouraging voluntary compliance.

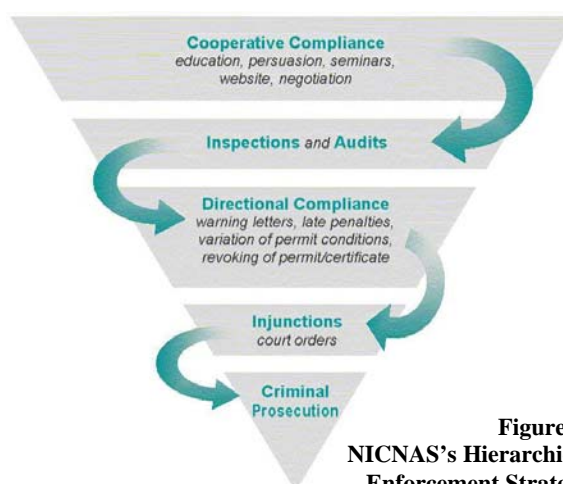


Figure 1:
NICNAS's Hierarchical
Enforcement Strategy

¹ OECD – 2000 – Reducing the risk of policy failure: Challenges for regulatory compliance

² ANAO - Australian National Audit Office – 2007 Best Practice Guide – Administering regulation

³ Standards Australia – AS 3806 – 2006: Compliance Programs

Figure 1 (above) illustrates NICNAS's hierarchical enforcement strategy, which begins with a persuasive approach that employs no sanctions, and gradually progresses through increasingly severe sanctions.

1.4 Regulatory principles

The following principles apply to NICNAS's approach to compliance:

- Provide constructive advice to stakeholders about compliance issues.
- Decision-making will be consistent with Government policy, justifiable and subject to public scrutiny.
- All its decisions and decision-making processes will be clearly communicated to stakeholders.
- Use of legislative powers will be fair and consistent but also firm enough to discourage non-compliance.
- NICNAS staff will undertake their duties in accordance with the Australian Public Service Code of Conduct and the NICNAS Service Charter and will act within the powers of the ICNA Act.

2 INDUSTRY ENGAGEMENT

Engagement with industry and other stakeholders is the cornerstone of the NICNAS compliance framework. By doing so, NICNAS can better target education and compliance activities.

2.1 *Industry stakeholders*

Section 80B of the Act requires all introducers to be registered with NICNAS. Then, by using the *Register of Industrial Chemical Introducers*, NICNAS can readily identify introducers of industrial chemicals, monitor the legitimate trade in chemicals, and respond to incidents arising from the harmful effects of chemicals. Through this registration, the Australian Government is able to provide the industry with information about their legal obligations and the safe use of industrial chemicals. Information contained in the register is publicly available and used by NICNAS to disseminate important chemical-related health and safety information.

2.2 *Education and awareness raising*

NICNAS publishes extensive guidance on the Internet, in its monthly *Chemical Gazette* and in regular newsletters. This provides assistance in complying with the obligations of the ICNA Act and informs industry of changes to those obligations.

In addition, NICNAS provides regular training and awareness-raising sessions in all major Australian capital cities. Registrants are regularly invited to attend training sessions that provide an overview of NICNAS's role and of their obligations under the ICNA Act. Specific workshops and information sessions are provided on demand to advise stakeholders of important developments and changes in the regulation of industrial chemicals.

2.3 *Consultation and cooperation*

NICNAS works with stakeholders affected by changes or developments in legislation, not only to increase industry awareness, but also to seek feedback throughout the development and implementation of new regulatory activities.

Industry participants are encouraged to meet NICNAS representatives to discuss compliance issues and for guidance about their legal obligations.

3 MONITORING COMPLIANCE

Several avenues are available to NICNAS to monitor compliance with the ICNA Act, the regulations, and the Cosmetics Standard. The Act requires strict reporting conditions that are used to monitor the obligations of introducers and to identify potential breaches of the legislation.

3.1 *Inter-agency cooperation*

In keeping with the Australian Government's commitment to streamline regulation, NICNAS uses information already provided to other government agencies to help it monitor compliance with the ICNA Act.

For example, information available to NICNAS through its Memorandum of Understanding with the Australian Customs and Border Protection Service identifies importers of relevant industrial chemicals as well as specific stakeholder groups of interest. Data from the Australian Taxation Office also provide details of potential industrial chemical introducers and assists NICNAS in contacting them. NICNAS also liaises regularly with its State and Territory partner agencies and may exchange information on industrial chemical regulation.

NICNAS may also undertake joint investigations with other agencies such as the Australian Federal Police, State and Territory Police, the Australian Customs Service, the Therapeutic Goods Administration or the Australian Competition and Consumer Commission.

3.2 *Compliance audits and reporting obligations*

NICNAS may undertake audits regarding the various obligations under the ICNA Act. They range from desktop auditing to site inspections, and may vary in technical nature depending on the particular aspect of the legislation being audited. NICNAS may require introducers of industrial chemicals to produce documentation to support information provided, or to demonstrate compliance with the legislation. Auditing may be random in order to assess general compliance, may be in response to particular concerns such as failure to meet a reporting obligation, or directed towards a particular industry.

In identifying potential audit recipients, NICNAS will take into account an organisation's compliance history. Companies that have demonstrated a consistently high level of voluntary compliance will be audited less frequently than those with a poor record. This is an incentive to organisations that manage their regulatory responsibilities well.

The ICNA Act also imposes regular reporting obligations on the importers of industrial chemicals introduced under certain circumstances. It also imposes them on introducers/exporters of specific chemicals that are subject to an International Treaty, such as the previously mentioned Rotterdam Convention, to which Australia is a party.

New chemicals which are introduced under certain certificate or permit categories, as well as those which are exempt from notification must be reported to NICNAS annually. This requires reporting of details such as the quantity of chemical introduced – as well as any additional information about known adverse effects of the chemical on occupational health and safety, public health or the environment which may have come to the introducer's attention.

Importers and exporters of specific chemicals subject to the requirements of the Rotterdam Convention are required not only to seek permission from the Director prior to import/export but to report the details of each consignment to NICNAS within a set timeframe. These reports are acquitted against transaction details received from the Australian Customs Service, ensuring that Australia fulfils its obligation under the treaty.

These reporting arrangements allow NICNAS to monitor compliance with the specific legislative requirements associated with the introduction and/or export of these chemicals.

3.3 Targeted campaigns

NICNAS undertakes targeted compliance activities in response to community or industry concerns, or to assist specific industry sectors understand their obligations under the ICNA Act. These campaigns complement routine monitoring activities. The results of such activities are reported to external governance committees and may be published in the NICNAS annual report or other publications.

3.4 Investigations

When NICNAS monitoring identifies potential breaches of the ICNA Act, regulations, or the Cosmetic Standard, it will initiate an investigation to establish the existence, nature and extent of any breach.

Initially it will request the cooperation of the company or individuals, seeking information required for the investigation. If this is not produced voluntarily, NICNAS may exercise the information gathering powers of *section 80W* of the Act which allows its Director to obtain information relating to the alleged offence. NICNAS inspectors, under *section 86*, may enter any premise with consent of the occupier in order to search for and gather information relating to a suspected breach of the legislation. The Act also provides for, under *sub-section 87(2)*, obtaining a warrant to search and seize without the consent of the occupier.

In cases of a serious nature an investigation may culminate in a brief being provided to the Office of the Commonwealth Director of Public Prosecutions (DPP) for prosecution.

4 ENFORCEMENT

The ICNA Act allows NICNAS to act against industry participants found in breach of the legislation. However NICNAS exercises discretion in the ways it applies enforcement action and the type of enforcement action taken. NICNAS will use its powers in a way that is – and is seen to be – firm, fair and consistent. If enforcement action is considered necessary, NICNAS will ensure that the principles of procedural fairness are applied.

4.1 Appointment of inspectors

The Act provides for the Director of NICNAS to appoint Inspectors. They are trained to meet the Public Service Education and Training Australia standards outlined in the Commonwealth Fraud Control Guidelines⁴. NICNAS investigations follow Australian Government Investigations Standards⁵.

4.2 Impartiality, consistency and fairness

Enforcement decisions made by NICNAS should be impartial and be seen to be impartial. The decision made and action taken should be capable of being justified in terms of the overall Compliance Framework. The decision to take enforcement action will not be influenced by:

- the race, sex, national origin or political association, activities or beliefs of the non-compliant person
- personal views of NICNAS inspectors concerning the non-compliant person or any other individual who has been affected by that person's acts
- possible political advantage or disadvantage to the Government or any political group or party
- public perception or the possibility of public, industry or political criticism, or
- the possible effect of the decision on the personal or professional circumstances of those responsible for the decision.

4.3 Determination of enforcement action

NICNAS inspectors may identify non-compliance through their own monitoring and audits. Information about alleged instances of non-compliance may also come from industry, the community, or by referral from other Government agencies. All such allegations are checked to determine whether a contravention of the Act has occurred.

Instances of non-compliance may be identified through the following:

⁴ Attorney General Department - 2002 Commonwealth Fraud Control Guidelines

⁵ Heads of Commonwealth Law Enforcement Agencies (HOCLEA) - 2003. Australian Government Investigations Standards

4.3.1. Self-reported breaches

Introducers may identify non-compliance with the Act through internal auditing or quality control procedures. In these cases importers and/or manufacturers or exporters are advised to formally advise NICNAS of non-compliance with the legislation. Such notification would normally include information that demonstrated, or otherwise makes a claim, that non-compliance was inadvertent.

4.3.2. Third-party allegations

NICNAS encourages the community, industry, industry associations and other government agencies to provide information about any breaches of the industrial chemicals legislation. As a matter of policy all formal third party reports are investigated. Complete confidentiality is assured in all cases.

4.3.3. Detection by NICNAS

Breaches of the legislation may be identified by NICNAS inspectors when monitoring or auditing activities.

NICNAS may choose to terminate a preliminary inquiry or an investigation with a recommendation that no further action be taken. This may occur if, for example, the identity of the alleged offender cannot be confirmed, or if there is insufficient evidence to establish that a breach of the legislation has occurred.

The aim of any enforcement action is to change the behaviour of the offender. It must also be proportionate to the impact of the breach, the circumstances surrounding the breach, and the compliance history and attitude of the offender.

A negotiated enforcement outcome is appropriate when the following factors are present:

- the non-compliance was inadvertent
- the non-compliant person has a constructive attitude to complying with the regulatory obligations
- the non-compliant person has not previously been involved in similar instances of non-compliance, and/or
- it is determined that informal enforcement action will provide an adequate deterrent.

A negotiated enforcement outcome is generally not an appropriate response to serious contraventions of the Act when the following factors are present:

- the contravention is deliberate or demonstrates reckless disregard for the legislation
- the contravention is part of a pattern of contraventions committed by the person, and/or
- the contravention seriously endangers human health or the environment.

4.4 Enforcement options

NICNAS takes enforcement action when it detects non-compliance with obligations imposed by the Act. The tools available to it when taking enforcement action are:

1. Initial action:

- advice
- warning
- requiring a person to provide information
- inspection

2. Formal action:

- revoking permits
- seizure of goods/chemicals
- injunctions
- prosecution

NICNAS will investigate, with a view to referring the matter to the Commonwealth Director of Public Prosecutions (DPP), any contraventions that:

- are deliberate and serious or demonstrate a reckless disregard of the Act
- form part of a pattern of similar contraventions, and/or
- seriously endanger human health or the environment.

In any matter where an investigation results in findings of admissible, reliable and substantial evidence of a contravention of the type referred to above, the matter will be referred to the DPP for prosecution. The decision to prosecute rests with the DPP and section 2 of Prosecution Policy of the Commonwealth⁶ explains the rationale and considerations that are taken into account in a decision to prosecute.

Where non-compliance with the ICNA Act is detected by NICNAS inspectors, the inspectors will provide advice to the duty holder regarding the most appropriate action to rectify an alleged breach. Where the alleged breach is addressed by the duty holder at the time of its detection by the inspector (that is, immediate and satisfactory remedial action is taken) then the inspector may decide to take no further enforcement action.

4.5 Complaints management and appeal processes

The NICNAS Service Charter outlines the standards of service that the users of the Scheme and the public can expect. The Charter also outlines the avenues available should these standards not be met and how complaints are managed.

In addition, section 102 of the ICNA Act contains review provisions. These include the making of an application to the Administrative Appeals Tribunal (AAT) for a review of certain actions taken by NICNAS.

Where compliance and enforcement action involves a decision made by the Director or by the Minister for Health and Ageing which is subject to these provisions, the affected party may apply to the Tribunal for an independent review of the decision.

⁶ CDPP. 1990. Prosecution Policy of the Commonwealth

5 OPERATIONAL PRIORITIES

Compliance and enforcement related operational priorities are determined each year and are published in the [NICNAS Business Plan](#). These annual yearly activities contribute to ongoing operational priorities for the next five years that include:

- A scoping study of the enforcement provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989*
- A review of compliance and enforcement practices within Australia and establishment of best practice within NICNAS
- An ongoing program of auditing which cycles through industry sectors, notification categories, and chemical specific issues, as required.

Operational priorities are established in consultation with industry and the community. Progress on these activities and the results of auditing programs are published each year in the [NICNAS Annual Report](#).

GLOSSARY

Australian Inventory of Chemical Substances (AICS)

The Australian Inventory of Chemical Substances (AICS) is the legal device that distinguishes new from existing chemicals. AICS is a listing of all industrial chemicals available for use in Australia between 1 January 1977 and 28 February 1990. It includes newly assessed chemicals and corrections, as required.

Commonwealth Director of Public Prosecutions

The Office of the Commonwealth Director of Public Prosecutions (CDPP) is an independent prosecuting service that was established by Parliament to prosecute alleged offences against Commonwealth law, and to deprive offenders of the proceeds and benefits of criminal activity.

Existing Chemicals

Existing chemicals are those industrial chemicals available for use in Australia. They include all the chemicals that are listed on the Australian Inventory of Chemical Substances (AICS).

Industrial Chemical

A chemical which is not a therapeutic good, veterinary medicine, pesticide, agricultural chemical, food or food additive. Industrial chemicals are subject to the requirements of *the Industrial Chemicals (Notification and Assessment) Act 1989*.

Memorandum of Understanding (MoU)

An agreement between parties that details mutual obligations in relation to services and/or the exchange of information (relating to industrial chemicals).

New Industrial Chemical

A new industrial chemical is a chemical that is being introduced into Australia for the first time. It is defined as an industrial chemical that is not listed on the Australian Inventory of Chemical Substances (AICS), or is a listed chemical subject to a condition of use.

NOTES