



Australian Government

Department of Health and Ageing

NICNAS

**Guidelines for Establishing a Case for Confidential Listing
of Chemicals on the Australian Inventory of Chemical
Substances**

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These guidelines are provided to assist in making an application for listing/re-listing of a chemical on the confidential section of the Australian Inventory of Chemical Substances (AICS).

1. Overview

1.1. Chemical Regulation

Assessment and registration of chemicals in Australia takes place at the Commonwealth level, whereas control and use of chemicals is primarily a State and Territory responsibility. The assessment and registration of chemicals occurs under four separate Commonwealth schemes together with supporting legislation, covering agricultural, industrial, therapeutic and food uses of chemicals. Overviews of chemical regulation in Australia are available on the Department of Environment and Heritage (<http://www.deh.gov.au/industry/chemicals/infrastructure.html>) and NICNAS) (<http://www.nicnas.gov.au/about/>) websites.

1.2. NICNAS and the Australian Inventory of Chemical Substances (AICS)

Industrial chemicals are regulated under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), within the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS is a chemical-entity based notification and assessment scheme. Products and mixtures are not assessed. NICNAS maintains the Australian Inventory of Chemical Substances (AICS), which is the legal device that distinguishes new industrial chemicals from existing industrial chemicals in Australia. All chemicals on the AICS are defined as existing industrial chemicals, while industrial chemicals not included are defined as new industrial chemicals and must be notified and/or assessed by NICNAS before they can be introduced (by import or manufacture), unless exempt under the Act.

The AICS consists of a non-confidential section and a confidential section. The current AICS lists approximately 38,000 non-confidential, and fewer than 100 confidential chemicals. Both sections include only the chemical name, Chemical Abstracts Service Registry Number (CAS number) (or an AICS number in certain circumstances), molecular formula and synonyms.

The first edition of the AICS was a listing of industrial chemicals already in commercial use in Australia over the period 1 January 1977 to 28 February 1990. It included approximately 36,000 non-confidential chemicals, and another 1,000 in the confidential section. Additional chemicals (Eligible Chemicals) were added during a two-year amnesty from 1993 to 1995. As all these chemicals were 'grandfathered' onto AICS before the advent of NICNAS, the vast majority have not been assessed in Australia for health and environmental effects.

New chemicals which have been assessed by NICNAS and for which an assessment certificate has been given (that is, Standard, Limited and Polymer of Low Concern notifications) are included on the AICS 5 years after the certificate date. The initial 5-year term is essentially a form of data protection, to protect the rights of the original

provider of the chemical data. At the end of 5 years, the company which is the holder of the confidence (i.e. the assessment certificate) is given the opportunity to request that the chemical be listed in the confidential section. If the company does not apply to have the chemical listed on the confidential section or the application is refused, then the chemical is listed on the non-confidential section.

Chemicals in the confidential section are only permitted to remain there for a certain period of time. At the end of each 5-year term, a new decision is taken as to whether or not they should remain for another term (a process known as re-listing). The original list of 1000 chemicals has declined over time, as many original applicants have decided not to continue confidential listing of certain chemicals, and some applications for confidential listing have been unsuccessful.

1.3 Legislative provision for confidential listing

Under Section 14(3) of the Act, a person (holder of confidence) may apply for listing of a chemical in the confidential section of AICS, five years after an assessment certificate has been given.

A chemical must be transferred from the confidential section to the non-confidential section within 5 years unless the Director decides not to transfer the chemical (section 19). Section 19(4) states that a person (holder of confidence) may request the Director not to transfer the chemical.

The Director must include the chemical in the confidential section, if an application to list/re-list the chemical is made and the Director is satisfied that:

“(a) the publication of some or all of the chemical's particulars could reasonably be expected to prejudice substantially the commercial interests of the applicant; and

(b) the prejudice outweighs the public interest in the publication of those particulars;”

The terms “commercial interest” and “public interest” are not defined in the Act.

1.4. Applying for Confidential Listing

In order to list a chemical in the confidential section, the holder of the certificate must make an application to the Director of NICNAS, addressing certain criteria. There are fees associated with making an application and these can be found on the application form (Form AICS-1).

1.5. Making a decision on confidential listing

The Director makes the decision on whether or not to grant confidential listing. The Director acts on the basis that non-confidential listing on AICS is the precautionary default, with an applicant needing to make a strong case for confidential listing.

The 1997 amendments to the Act permit applicants to seek repeated 5-year terms for confidential listing, under new criteria that enable consideration of the public interest as well the commercial interest (see Section 1.3).

In making a decision, the Director considers information provided by the applicant and draws on the advice of the Technical Advisory Group (TAG). Members of the TAG are selected so as to provide the broad expertise in commercial and public interest and may seek additional advice or information from other sources as needed. They are bound not to disclose confidential information.

The Director makes the decisions on a case-by-case basis, using criteria that include the following:

- Previous disclosures/protection of confidentiality known to applicant
- Applicants efforts to protect disclosure of information
- Actual intellectual property protection status
- Demonstration of substantial prejudice to the commercial interests of the applicant
- Ease of analysis and reverse engineering of chemical
- Confirmation of NICNAS assessment
- Level of impact on people and environment
- Closer scrutiny of dispersed / public use chemicals
- Additional data provided, for example on use, toxicity, monitoring and controls
- Ultimate fate and effect of the chemical

These criteria are described in more detail in Section 3.

The Director may seek further clarification or information from the applicant and the applicant is given a specific time to comply. To ensure that there is sufficient time for consultation with the applicant and the TAG, NICNAS calls for applications for 5-year listing or re-listing on AICS at least 3 months before the AICS listing date.

When seeking advice concerning the application, the Director ensures that confidential information is protected.

The Director is required under the Act to advise applicants in writing of the decision. If, after the Director has considered any additional information provided by the applicant and does not agree to confidential listing, the applicant may request that the decision be reviewed by the Administrative Appeals Tribunal (AAT). Further information on the AAT can be found at <http://www.aat.gov.au/>. An application to the AAT must be within 28 days of the decision being made. The chemical cannot be listed in the non-confidential section before the appeal decision is finalised.

1.6. Technical Advisory Group

The Director established the Technical Advisory Group (TAG) in August 1998. The Group has acted as an independent advisory panel to the Director in developing and revising the criteria and guidelines, to help ensure consistency in the decision making

process for confidential listing on the AICS. Members of the TAG serve as independent experts and are not representative of any organisation or industry group. Members are selected for their recognised knowledge of chemicals and regulation issues, particularly concerning confidentiality, commercial matters and public right to know considerations. Members are engaged for 2-year terms that may be repeated. Membership of the TAG may change over time, but it is envisaged such a group will remain in an ongoing advisory role to the Director.

The TAG developed the original guidelines in 2000 to assist the community and industry in understanding how criteria on commercial and public interest are applied in their decision-making process. The guidelines have been revised following extensive peer review and public consultations and adopted in 2004. The TAG considered a range of documents in developing and revising these guidelines. The guidelines will be reviewed periodically so as to assess their continuing appropriateness and effectiveness.

As well as assisting persons making an application, the guidelines will also help them to decide whether or not to seek confidential listing on AICS. Only those chemicals where the commercial interest of the chemical can be demonstrated to the Director to outweigh the public interest, can be listed in the confidential section.

2. Interests in Chemical Substances

2.1. Commercial

An innovative and progressive chemical industry makes important contributions to the continued growth of the Australian economy. The development within Australia of new industrial chemicals and the introduction of overseas-developed chemicals, subject to assessment through NICNAS, is an essential feature of industry activity.

Some detailed aspects of this commercial focus are:

- (a) The discovery, production and use of new chemical substances which improve the sustainable use of resources and human lifestyles or replace substances which have unfavorable human health and environmental impacts, is to be encouraged.
- (b) Significant costs are likely to be incurred by developers of new chemicals. Disclosure may hinder cost recovery through sales or reduce competitive advantage or market exclusivity.
- (c) Industry groups recognise a responsibility to manage, use and dispose of chemical substances, as the chemical industry does through voluntary programs such as:
 - The Plastics and Chemicals Industries Association (PACIA) Responsible Care
(<http://www.pacia.org.au/indexSectionLinks.html?name=Environment/environment5.html>)

- ‘Product Stewardship’ programs (<http://www.pacia.org.au/Environment/RCCRG-PS5.PDF>).
 - The Australian Paint Manufacturers’ Federation Coatings Care™ program (http://www.apmf.asn.au/html/coatings_care.html).
- (d) Companies use trade secrets to protect commercial positions. This involves withholding information such as the identity of a chemical (for example, chemical name, CAS number, molecular and structural formula, constituents and impurities) and specific import volumes from competitors and therefore from the public. Under the Act, companies must not withhold health and environment information. Also, Occupational Health and Safety (OHS) regulation requires disclosure of certain information on MSDS and product labels.
- (e) It is in the interest of both the public and the chemical industry to achieve a balance between the commercial benefits of secrecy and the benefits of wider disclosure, by means such as community-industry dialogue and hazard avoidance through community monitoring.

2.2. Public

Members of the public are interested in the nature of chemical substances used in industry, in particular those chemicals or products they use themselves or which they are likely to encounter in their everyday lives because of manufacture, transport, storage, use or disposal of chemicals in their vicinity. This interest is primarily concerned with the properties of a substance and its intended use but also extends to the identity of the particular chemical substance.

The following points help to delineate this interest.

- (a) Public interest in chemical substances is well documented and concern is generally focussed on matters of industrial waste, environmental pollution and short and long-term health effects (for example contact dermatitis, asthma, cancer and endocrine disruption). There is public interest also as to any benefits flowing from introduction of new and safer chemicals.
- (b) The public has a formal right to information as recognised in the Commonwealth Freedom of Information legislation.
- (c) In Australia, the public ‘right to know’ is most developed in respect of the workplace, and workers’ right to know about hazardous substances in the workplace (such as, employer’s duty of care, MSDSs, labels and other requirements of the workplace hazardous substances regulatory package).
- (d) It is in the public interest for the community to be informed, to exercise their right to understand, to make informed choices, and to participate in informed decision-making. (Bahia Declaration on Chemical Safety, 2000, UNEP, 1992)

While public interest has to be balanced against commercial interest, it is important to recognise that the greater the hazard and broader the potential exposure, the greater is the justification to release commercially sensitive information.

3. Guidelines for Applicants

3.1. Scope

These guidelines apply to information submitted as applications for confidential listing and re-listing on the AICS under relevant sections [14(3) and 19(6)] of the Act.

It is the responsibility of the applicant to convince the Director that commercial considerations outweigh public interests, in order for a chemical substance to be listed or remain in the confidential section of the AICS. If the Director makes the decision not to grant confidential listing, the applicant may seek a review of the decision by the Administrative Appeals Tribunal (see Section 1.5). All applications are treated as commercial-in-confidence.

3.2. What Information is Required from the Applicant?

The applicant needs to provide information that addresses **commercial** and **public interest** in order for the Director to consider confidential listing on AICS for the chemical substance. Applicants may need to obtain some of this information from their parent companies or suppliers.

Technical information required for consideration of **commercial interest** may be outside the scope of data normally required by NICNAS for a new chemical notification. For example, patents relevant to the use of the chemical in Australia and details of public disclosure in other country inventories should be provided.

Applicants need to be aware of the matters of most concern to the public. These include how much is known of the toxicity and ecotoxicity of the chemical, whether or not there is wide consumer use and hence potential exposure to the chemical and/or its degradation products, whether or not the chemical is taken up by living organisms (persistent and bioaccumulative), and the means used to dispose of waste chemical. The public interest criteria are designed to determine when a clear public benefit exists in knowing the identity of the chemical and therefore its hazard and potential risks.

Some information to enable consideration of the **public interest** may be also outside the scope of data normally required for a new chemicals notification. Applicants will need to provide all the relevant information accessible to them. Applicants do not need to undertake additional chemical testing or provide test reports but if requested, need to be prepared to address gaps in relevant information. Where a substance has been identified as hazardous, provision of monitoring data by the applicant will assist in consideration of the application. Chemicals in this category would include those of international concern, for example potential endocrine disrupters. Occasionally where NICNAS has assessed the chemical, the assessment report may indicate that future monitoring or testing is to be done. Applicants subsequently seeking confidential

listing need to check if this work has been done, and include the outcomes in the application.

Applicants are encouraged to provide information items that have become available since the NICNAS assessment was completed. This enables checking that the conclusions and recommendations of the original assessment still apply for the chemical and to assure the public that independent information is available.

Applicants are reminded that information that relates to secondary notification requirements should have been provided to NICNAS within 28 days of becoming aware of the information. Further information on secondary notification is provided in the NICNAS Handbook for Notifiers (www.nicnas.gov.au/publications/handbook/).

Chemicals that are the subject of international conventions (for example, ozone depleters) are unlikely to be granted confidential listing.

3.2.1. Commercial Interest Criteria

The applicant needs to explain why confidential listing is being sought. This means an assessment of the significant detrimental effect that could be done to the applicant's business if the identity of the substance was disclosed, for example, recognising the need to protect the company's investment in research and development, and the international consequences of confidential listing in Australia. Analysis should describe the pathway to commercial loss of competitive advantage, intellectual property and/or corporate viability and quantify the loss if possible. It would be useful to quantify the threat to Australian and global business, and to development of next generation technology.

NICNAS considers that the following criteria are relevant to confidential listing, and applicants should provide the relevant information to support the claim for confidential listing.

Criteria (a) - (d) seek to define if disclosure would result in commercial harm to the applicant. Criteria (e) - (h) seek to define the measures taken to prevent disclosure of the chemical identity.

- (a) How will disclosure of the chemical identity lead to commercial loss for your business? Quantify the loss if possible. Both immediate and longer term implications should be considered, as well as potential for commercial loss locally and internationally. The potential impact on innovation in Australia should be considered.
- (b) Has the chemical substance been publicly identified in a chemical inventory of another country, as revealed for example in the SciFinder database produced by Chemical Abstracts Services? If so, in which country(ies) and in what way will confidential listing in Australia protect the commercial interest.

- (c) Has the substance already been granted (based on commercial interest) confidential status in a chemical inventory of another country? If so, these countries should be identified.
- (d) Has confidential listing in any jurisdiction has been sought and denied? If so the reasons should be disclosed, if available.
- (e) What measures have been taken by the owner to protect the confidential nature of the information including manufacture and importation of the substance?
- (f) How feasible is it (including cost and simplicity) for competitors to obtain a sample and to identify, duplicate and market the substance in a competitive environment? An assessment of feasibility should be provided.
- (g) Has the substance been identified by other than trade or generic names in journals, books or other public sources? If so, information should be provided on why granting of confidential status in Australia is required to protect commercial interest.
- (h) Has the substance and/or its use been patented? Applicants should provide copies of patent(s) relevant to the use of the chemical in Australia and comment as to how the failure to grant confidential status will harm their commercial interest. Patent coverage may not necessarily involve transparent disclosure of the substance, the manufacturing process or the use application.

Provided that the application has adequate justification for confidential listing, patents do not mitigate against confidential listing when they are broad, vague, do not specifically reveal the chemical name (or it cannot be gleaned from the patent), and are difficult to defend. However, the case for confidential listing is weakened when patents disclose the chemical in sufficient detail to bring the chemical identity into the public domain.

3.2.2. Public Interest Criteria

Applicants seeking confidential listing are requested to refer to the original NICNAS assessment and provide information on the matters listed below. If information is not available, an explanation is required. Any new information should be provided. In general, the more data provided, the stronger the case. The case is strengthened, particularly for hazardous substances, by the provision of monitoring data on the fate and on the human health and environmental effects of the chemical.

- (a) The likelihood of beneficial impacts flowing from the use of this chemical. Examples could include benefits to society from use, replacement of old for new technology, replacement of chemicals or processes dangerous to human health and the environment with less harmful ones.

- (b) The public availability of data, including data from other countries, concerning the properties, fate or effects of the chemical substance. Chemical information may be available in literature reports, media reports and other published sources including the Internet.
- (c) Exposure patterns for workers, the public and the environment, both short and long term, in manufacture, use, transport and disposal. Applicants need to describe new exposure scenarios that may not have been assessed by NICNAS in the initial assessment. Information on special or new technology controls to reduce exposure, for example use of special containment facilities, special training for workers, or special packaging needs to be included. Similarly, situations likely to increase exposure, such as the use of casual or contract workers need to be mentioned with an explanation of how risk controls for these workers (transfer of information on chemical hazards, exposure controls and worker training) are being implemented to minimise exposure. Exposure patterns will be used to consider the risks posed by hazardous substances.
- (d) Information on adverse incident reporting mechanisms for workers, including contract workers, to alert employers to problems with chemicals.
- (e) Information on the potential of the chemical substance or degradation products or by-products or wastes from its manufacture or formulation:
- to cause adverse short term or long term impacts directly or synergistically on human health; and
 - to cause adverse short term or long term impacts directly or synergistically in the environment
- (f) Results from monitoring studies for the chemical, by-products, degradation products, or wastes; and on the level of compliance with State and Territory standards and licences.
- (g) Whether disclosure of chemical identity is required under other Australian Commonwealth State or Territory legislation. For example, under hazardous substances regulations, poisons scheduling, environmental regulations, the National Pollutant Inventory or other.
- (h) Substantiate how environment, public and workers health and safety would not be compromised by the inclusion of the chemical on the confidential section of AICS.
- (i) Whether the applicant has available sufficient information to enable tracking of the substance, including residues, metabolites and/or degradation products, in the environment.
- (j) Indicate availability of MSDS to workers and others. [Note: A current MSDS is required with the application.]

- (k) Describe the type of information available to the public (in Australia) on the chemical, for example product sheets and brochures for the chemical and its products, or on the operations of the chemical industry sites that handle the chemical substance.

State and Territory Governments may be asked to provide independent information on applications for confidential listing. This information may cover compliance and other investigations or monitoring activities of the chemical.

4. References

Bahia Declaration on Chemical Safety,
Intergovernmental Forum on Chemical Safety,
Forum III Final Report of Intergovernmental Forum on
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