

Regulatory Alert

Australian Industrial Chemicals Introduction Scheme (AICIS) under the Industrial Chemicals Act 2019 Enter into Force 1 July 2020

Country: Australia

INTENDED AUDIENCE

This Regulatory Alert is intended for those who introduce in Australia for commercial purposes industrial chemicals (import or manufacture) or products that release industrial chemicals.

EXECUTIVE SUMMARY

Background on Regulation:

On 15th March 2019, the Australian Government published the Industrial Chemicals Act 2019 (the Act). This reforms the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and establishes a new regulatory scheme known as the Australian Industrial Chemicals Introduction Scheme (AICIS). The new scheme came into force on 1 July 2020. NICNAS was the administrator of industrial chemical regulations by the Australian Government. "It provided a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effect of industrial chemicals." Manufacturers and importers were previously required to register with NICNAS beginning 1 September 2004.

AICIS now regulates the introduction (manufacture and import) of chemicals or the manufacture and import of products that release chemicals. According to the Australian government, "...The regulation will apply only to industrial chemicals, which are chemicals with an industrial use. Industrial chemicals cover a broad range of chemicals used in inks, dyes, plastics, adhesives, paints, glues, solvents and many other products. It does not apply to agricultural, veterinary/ therapeutic chemicals, chemicals used in food/ feed or radioactive substances..."

AICIS aims to make the level of substance assessment better reflect the risks posed by industrial chemicals, to make regulatory effort more proportionate to risk. The benefit of re-directing regulatory effort toward higher-risk chemicals is in reduced costs to businesses and consumers that use lower-risk chemicals. The faster regulatory pathway for lower-risk chemicals is intended to incentivize the introduction of new, safer industrial chemicals and the replacement of more hazardous existing chemicals. The reforms will improve protection from higher-risk chemicals by allowing conditions to be imposed on their introduction. If an identified risk cannot be managed, the introduction of chemicals can be refused or stopped.

The Australian Inventory of Chemical Substances: The current Australian Inventory of Chemical Substances (AICS) was replaced by the Australian Inventory of Industrial Chemicals (AIIC). The Australian Government released a request for information from industry in November 2019, to confirm the industrial use of several thousand chemicals listed on the inventory. Chemicals with no industrial use in Australia were removed from the inventory under the new scheme.

APPLICABILITY

- This regulation applies to all companies who introduce (manufacture or import) any chemical with an industrial use, and any chemical released from an article where the article has an industrial use.
- The following exemption categories (these will be categorized as exempted introductions) under NICNAS, which may be of relevance to the aerospace and defense industries, can continue to be used until 31 August 2022:
 - i) Research and development or analysis - manufactured in a fixed apparatus in a specific location;
 - ii) Research and development or analysis - importation only (Not more than 100kg in a 12-month period);
 - iii) Non-cosmetic use (no unreasonable risk);
- Further exempted introductions are:
 - i) Polymers of low concern
 - ii) Chemicals imported for the purpose of re-export
 - iii) Polymers and Industrial chemicals that are like those already listed, following the criteria in Sections 26(4) and 26(5) of the Industrial Chemicals (General) Rules 2019 (the General Rules).
 - iv) Industrial chemicals resulting from non-functionalized surface treatment of listed industrial chemicals, following the criteria in Section 26(8) of the General Rules.
- Registration, categorization, reporting and record-keeping requirements do not apply to excluded introductions; these are:
 - i) Naturally occurring chemicals;
 - ii) Non-isolated intermediates;
 - iii) Incidentally introduced chemicals;
 - iv) Any industrial chemical released from an article that was not designed to release it;
 - v) Chemicals introduced solely for an individual's personal use;
 - vi) Chemicals imported for the purpose of re-export within 25 days (subject to the conditions of Part 1 Subsection 11(3) of the Act).

RELEVANT DATES

- ❖ **The Industrial Chemicals Act 2019/ AICIS published:** 15 March 2019
- ❖ **The Industrial Chemicals Act 2019/ AICIS in force:** 1 July 2020
- ❖ **Renew Registration with AICIS:** If you continue to introduce industrial chemicals after 31 August 2020, you must renew your registration by 1 September 2020.
- ❖ **First Annual declaration under AICIS due:** 30 November 2021
- ❖ **Exemptions under NICNAS valid until:** 31 August 2022
- ❖ **Permits held under NICNAS valid until:** 30 June 2022 or until the permit expires

REGULATORY OBLIGATIONS

Registration:

An introducer of an industrial chemical must be registered on the Register of Industrial Chemical Introducers at least a year before introducing an industrial chemical for the registered year. Introducers must register for each year they intend to introduce the chemical (a registration fee or charge is payable for each year). If a company was already registered under NICNAS, no action was required. Registration was automatically transferred to AICIS on 1 July 2020, with the same registration ID. If you continued to introduce industrial chemicals after 31 August 2020, the registration had to be renewed by 1 September 2020. The below graphic prepared by the Australian authority

provides an illustration of some of the AICIS process. It also highlights reasons for chemicals not being included on the Australian Inventory of Industrial Chemicals (AIIC).



Categorization:

Under AICIS, those introducing chemicals into Australia are required to categorize each introduced chemical using the detailed information provided under Chapter 2 of the General Rules. To categorize chemicals, the introducer must first evaluate the risk of the chemical based on the criteria provided in Chapter 3 Part 2 of the General Rules. There are 6 categories of introductions under the Industrial Chemicals Act 2019, these are:

1. **Listed Introductions:** An industrial chemical is classed as a listed introduction if it is currently listed on the AIIC. In this case, the introducer and user must meet the terms of Inventory listing for that chemical. Listed introductions are subject to annual declaration and record-keeping requirements.
2. **Exempted introductions:** An industrial chemical is classed as an exempted introduction if it falls under any of the exemption categories described in the 'Applicability' section of this document. These are classed as very low-risk chemicals. However, the General Rules state that an introduction may still be exempted if it does not fall under these categories, depending on the level of risk to human health and the environment from the introduction.

3. Reported Introductions: These are low-risk introductions based on consideration of the proposed exposure scenario for the chemical and its intrinsic hazards. The following qualify for reported introduction: industrial chemicals and nanoscale industrial chemicals used solely in research and development; industrial chemicals that have been internationally assessed for human health and the environment (the introducer must be proposing to introduce the chemical for the same use, in the same or lower volume, and is able to comply with any conditions imposed by the international regulator). Chemicals may also qualify for reported introduction if the highest indicative risk, based on health and environmental exposure and hazards, is low.

4. Assessed introductions: A chemical is classed as an Assessed Introduction if it is medium-to-high risk to human health and the environment. A chemical assessment is required for this category. The Australian authority must assess the introduction of a chemical and issue an assessment certificate before it can be manufactured or imported. Assessments should be applied for before the chemical is introduced; they will take up to 90 days and may lead to different regulatory outcomes. Those outcomes include granting of an assessment certificate; granting of an assessment certificate with or without recommendations to risk managers and/or conditions of introduction; refusal of assessment certificate.

Conditions of introduction are imposed when risk needs to be managed, with controls being limited to annual introduction volume, sites of use or duration of the assessment certificate. When conditions of introduction or existing risk management frameworks are not adequate to manage the human health and/or environmental risks, an assessment certificate is refused. Chemicals covered by an assessment certificate are listed on the inventory after 5 years; however, applications can be made for early listing.

5. Commercial evaluation introductions: Commercial evaluation authorization can be made by any organization proposing to test a chemical with a view to ascertaining its potential for commercial application. Commercial evaluation introductions are medium-risk introductions. To be eligible for a commercial evaluation authorization, the evaluation must not involve: the chemical being made available to the general public at any time on its own, in a mixture or in an article; untreated release of the chemical to the environment; or uncontrolled exposure to workers.

Introducers will be required to apply for an authorization that would be subject to conditions concerning how the chemical can be used, the time period and location within which the evaluation can occur, and who can introduce the chemical. These chemicals will not be entered on the AICC unless they are fully assessed.

6. Exceptional circumstances introductions: These are granted by the Minister under exceptional circumstances, an authorization will be received from the Minister in writing.

The fees for each type of introduction can be found on the [AICIS fees and charges](#) page.

Reporting and record-keeping:

All registered introducers of chemicals into Australia are subject to reporting requirements under the Act, and the level of reporting is proportional to the risk level of the chemical being introduced. All introducers will need to submit an [Annual declaration](#) to confirm compliance. Declarations are required for all AICIS introduction categories and must

be submitted every year that a registration is renewed. The first annual declaration under AICIS is due by 30 November 2021 and will cover the period from 1 July 2020 to 31 August 2021 (after this the usual registration year applies : 1 September – 31 August). An annual report is not required to be submitted in September 2020. The annual declaration is submitted by the person who introduced the chemical(s) and must be submitted via AICIS Business Services.

For the following types of Exempted Introduction, a one-off '[Exempted introduction declaration](#)' must be submitted on top of the usual annual declaration: polymers of low concern, low-concern biopolymers, and chemicals that you have categorized as very low risk for human health and the environment.

Reported introductions require a one-time '[Pre-introduction report](#)' to be submitted to the Executive Director of the Australian Department of Health in accordance with Section 97 of the Act, on top of the usual annual declaration.

Under section 104 of the Act, a person who introduces an industrial chemical (other than an excluded introduction) during a registration year is subject to [Record-keeping requirements](#). These requirements depend on the type of introduction. The record-keeping requirements for individual categories are detailed under Chapter 4 Part 2 of the Act, and must demonstrate the following:

- (i) each industrial chemical that the person introduced during the year;
- (ii) the category of each of those introductions;
- (iii) the basis on which the person determined the category of the introduction;
- (iv) the amount of registration charges payable by the person

Records must be kept for a minimum of 5 years in all cases.

Transitional measures:

NICNAS permits: Commercial evaluation permits held under NICNAS will transition into the commercial evaluation introductions category under the AICIS. The terms and conditions of the permit will remain the same up until the NICNAS permit is due to expire. All other NICNAS permits in force on 30 June 2020 will automatically become AICIS assessment certificates on 1 July 2020. They will have the same terms and conditions as under NICNAS. These certificates will be of a limited duration - either the time left on the original permit, or until 30 June 2022, whichever is the later date. This means that there will be a transition period of at least 2 years to re-categorize any introductions to ensure continued compliance with AICIS.

NICNAS exemptions: As previously discussed, these will be valid until 31 August 2022, after which introductions must be categorized in line with the new scheme.

NICNAS annual declarations: An annual report under NICNAS does not need to be submitted in September 2020.

RISKS TO AEROSPACE AND DEFENSE

- Significant time and resources required to fulfill obligations, especially related to categorization
- High penalties for non-compliance – penalties for a single offense can exceed AUD \$100000 under the Crimes Act 1914

IAEG ACTIONS RELATED TO THIS RISK

Australian chemical regulations are within the scope of the development of the IAEG Aerospace and Defense Declarable Substances List, AD-DSL, and are subject to substance declarations in the A&D industry supply chain. IAEG is tracking regulatory developments in Australia for possible future additions to the AD-DSL.

USEFUL LINKS

Industrial Chemicals Act 2019: <https://www.legislation.gov.au/Details/C2019A00012>

Industrial Chemicals (General) Rules 2019: <https://www.legislation.gov.au/Details/F2019L01543>

Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019:

<https://www.legislation.gov.au/Details/F2019L01548>

AICIS Fact Sheet: https://www.nicnas.gov.au/data/assets/pdf_file/0011/94781/AICIS-Fact-Sheet.pdf

Guidance on reporting: <https://www.nicnas.gov.au/New-scheme-1-July-2020/aicis-topics/compliance,-reporting-and-record-keeping>

Guidance on categorization: <https://www.nicnas.gov.au/New-scheme-1-July-2020/aicis-topics/categorise-your-chemical-introduction>

Transitioning from NICNAS to AICIS: <https://www.nicnas.gov.au/New-scheme-1-July-2020/Transitioning-from-NICNAS-to-AICIS>

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