



Australian Government

Department of Health,  
Disability and Ageing

# Submission – Interim Report on *National Competition Policy Analysis 2025*

## Executive Summary

The Department of Health, Disability and Ageing, which includes the Australian Industrial Chemicals Introduction Scheme (AICIS), welcomes the opportunity to respond to the Productivity Commission's Interim Report on National Competition Policy Analysis 2025. The Commission's concern that legislated standards may act as trade barriers is acknowledged. This submission addresses the recommendation to harmonise Australian standards with international and overseas frameworks to reduce trade barriers for industrial chemicals.

While harmonisation with international and overseas standards may offer benefits in some sectors, this submission outlines why careful consideration is required for the regulation of industrial chemicals in Australia. Established under the *Industrial Chemicals Act 2019* (IC Act), AICIS regulates the importation and manufacture of industrial chemicals through a risk-based approach that prioritises protection of both human health and the environment.

The chemicals regulatory environment is complex and at the national level, chemicals are regulated according to their use. The different components of Australia's chemicals regulatory framework, focusing on a particular type of use, are intended to operate in a complementary manner. This ensures that all chemicals are appropriately managed and that human health and the environment are protected. AICIS assesses the risk of industrial chemicals based on their intended use, hazard profile, and exposure potential.

AICIS supports international alignment where appropriate, accepting overseas data, hazard classifications, and frameworks such as International Fragrance Association (IFRA) Standards, Organization for Economic Cooperation and Development (OECD) test guidelines and use of International Nomenclature Cosmetic Ingredient (INCI) names for certain low-risk introductions.

However, full harmonisation is limited by Australia's unique characteristics, including population density and environmental conditions, which differ significantly from those in other countries. Overseas risk assessments of industrial chemicals often fail to reflect

Australia's specific environmental needs. Therefore, AICIS must adopt a risk-based, locally relevant framework rather than directly replicating overseas regulatory models.

AICIS's use of standards is necessary and justified under World Trade Organization (WTO) principles. Recent reforms including the 2024 amendments to the Industrial Chemicals (General) Rules 2019 and the July 2025 updates to Specific Information Requirements (SIRs) demonstrate a commitment to continuous improvement and stakeholder responsiveness.

In conclusion, AICIS's tailored, risk-based model remains essential for safeguarding Australia's public health and environment while supporting proportionate, efficient regulation.

## Introduction

This submission is provided in response to the Productivity Commission's Interim Report on the National Competition Policy Analysis 2025, released on 7 August 2025. The report explores key reform areas aimed at enhancing competition and economic productivity.

In considering the Interim Report, it is noted that a standard refers to a codified specification or rule that sets out how a product, service, or process should be designed, assessed, or delivered. Standards are used to ensure safety, quality, consistency, and interoperability, and may be developed domestically (Australian Standards), adopted from overseas jurisdictions, or aligned with international bodies such as International Organization for Standardization (ISO) or Organization for Economic Cooperation and Development (OECD).

The Interim Report raises concerns that legislated standards, such as those in the Industrial Chemicals General Rules, may act as trade barriers. This view is based on WTO Technical Barriers to Trade (TBT) notifications and legislative reviews.

The department acknowledges the Commission's recommendation to enhance national consistency through greater alignment with international and overseas standards. The department also emphasises the importance of maintaining a fit-for-purpose regulatory framework that reflects Australia's unique environmental, public health, and safety priorities.

The following sections discuss the role of AICIS in chemical regulation, the barriers to harmonisation, and the reasons for the use of certain standards and frameworks available internationally.

## The role of AICIS in Australian chemicals regulation

AICIS was established to assess industrial chemical introductions based on the level of risk they pose to human health and the environment as defined by the IC Act. This approach considers the intended use and hazards of a chemical, and the potential for exposure, rather than relying solely on the volume of chemical introduced. Following the assessment of industrial chemicals AICIS provides information to promote their safe use and makes risk management recommendations to Commonwealth standard setting bodies, and state and territory risk managers. AICIS is designed to make regulatory effort proportionate to the risks posed by industrial chemical introductions. An overview of the key elements of the industrial chemicals framework is provided in the Appendix.

## Barriers to greater harmonisation

Australia's industrial chemicals regulation framework considers the specific hazards, exposure scenarios, and use patterns relevant to the Australian context. Exposure levels to chemicals in Australia are influenced by unique national factors like population density,

biodiversity, climate, and water systems, which differ significantly from other countries. These national factors necessitate a tailored regulatory approach that cannot be fully addressed by adopting standards used overseas, especially in a sector like industrial chemicals.

Under the IC Act, AICIS is mandated to regulate chemical imports and manufacturing to protect human health and the environment. This requires enforceable standards tailored to national priorities, which legislation best supports.

While legislated standards can sometimes restrict trade, the Commission acknowledges their necessity in safeguarding public health and the environment. AICIS continuously improves its processes, as seen in its July 2025 updates to Specific Information Requirements (SIRs), which simplify compliance based on stakeholder feedback.

There are no globally accepted standards for the risk assessment of industrial chemicals. Regulatory decisions by overseas regulators or risk managers are made in different jurisdictional, geographical and legal contexts to those here in Australia. Overseas risk assessments may not reflect Australia's unique biodiversity, climate, and water systems. AICIS consistently uses international data as a starting point but conducts its own assessments to ensure decisions are locally relevant and protective.

AICIS has a risk-based system that categorises chemical introductions by potential harm and streamlines low-risk cases while ensuring rigorous checks for higher-risk substances. This requires a flexible and enforceable legislative framework.

The risk-based regulatory approach taken by AICIS allows for greater flexibility by enabling larger volumes of low-hazard chemicals to be introduced with fewer regulatory requirements, while maintaining stricter controls on smaller volumes of high-hazard chemicals. This ensures that regulatory effort is focused where it is most needed. Reflecting this principle, the 2024 amendments to the Industrial Chemicals (General) Rules 2019 introduced expanded criteria for categorising low-risk introductions.

## Use of international standards

The Productivity Commission classifies voluntary standards into 3 broad categories: international standards, national standards, and overseas standards. *International standards* are developed by recognised international bodies (e.g. International Standards Organization (ISO)) and are intended to be globally applicable. *National standards* are developed within Australia, typically by Standards Australia or jointly with Standards New Zealand. *Overseas standards* refer to those developed by other countries, regions, or private organisations. Under AICIS's administration of industrial chemical regulation, standards are used to guide chemical hazard classification, the provision of data, and the conduct of regulatory assessments.

A key feature of AICIS is the acceptance of international data formats and regulatory assessments from trusted overseas authorities. AICIS allows businesses to use hazard and risk assessments that have already been completed by trusted overseas or Australian

regulators when applying for an assessment certificate. This includes assessments from authorities in Canada, Europe, and the United States, and data formatted according to OECD test guidelines. These internationally assessed introductions can be submitted under the reported (low risk) category, provided they meet the relevant criteria.

The OECD sets guidelines and standards across diverse areas but leaves their implementation to member and adhering countries. This approach enables countries to adapt the standards to their domestic contexts while upholding shared principles of transparency, accountability, and best practice. AICIS does not require conformity to these guidelines and frameworks but accepts them as valid sources of information for applicants.

The standards referenced in AICIS's regulatory framework, such as the International Fragrance Association (IFRA) Standards, do not fall under the category of internationally recognised standards like ISO. Instead, they are best classified as *overseas standards*. These are developed by industry bodies or national regulators and are not subject to the same multilateral processes or WTO principles that define *international standards*.

Although these alignments do not constitute or include "internationally recognised standards" as defined by the Productivity Commission, this flexibility allows introducers to submit information in a variety of internationally recognised formats. This reduces duplication, lowers costs, and accelerates access to market.

There are 9 areas where AICIS accepts standards, depending on the purpose for which they may be used. These are as follows:

### International hazard assessments

AICIS allows businesses to use hazard assessments that have already been completed by trusted overseas or Australian regulators when applying for an assessment certificate, as prescribed by the Industrial Chemicals (General) Rules 2019. This means that instead of repeating scientific studies, applicants can rely on existing assessments of a chemical's potential health or environmental hazards.

When AICIS receives such an application, it uses the overseas hazard assessment and then considers how the chemical would be used in Australia to determine any local risks. Only assessments from recognised (mainly international) bodies can be accepted under this pathway.

Because much of the scientific work has already been done, this type of application has a lower fee than most others through reduced AICIS assessment fees. It also reduces the costs for businesses to generate new data.

### International risk assessments

The risk assessment of a chemical that was conducted by a trusted international body can be used by an introducer as the basis for their chemical introduction to be 'low risk' to

human health or the environment, if the criteria are met. In many circumstances, this will mean the introduction can be in the 'reported' category. This can be the case even if the chemical introduction may have otherwise been in the 'assessed' category and required a full assessment by AICIS prior to its introduction into Australia, due to its risk being medium to high.

The outcomes of the international risk assessment are trusted by AICIS. This means that AICIS does not conduct its own risk assessment of the chemical because the criteria ensure that the risks of introducing the chemical in Australia are similar to what was assessed overseas.

There are neither fees nor waiting time to market for reported introductions. This reduces the costs involved in AICIS assessment fees, the generation of information about the hazards of a chemical, and reduces time to market delay (as no assessment by AICIS is required before the chemical is introduced).

### Guidelines for the testing of chemicals (OECD and equivalent)

The OECD *Guidelines for the Testing of Chemicals* are accepted internationally as standard methods for safety testing of chemicals. Study results generated using OECD Test Guidelines are accepted by AICIS for the categorisation of chemical introductions and Assessment Certificate applications. Acceptance of studies conducted overseas using OECD Test Guidelines means that introducers do not need to repeat the studies for the Australian regulatory requirements, reducing costs and time for the pre-market assessment.

### Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

The GHS is an internationally recognised framework to standardise the classification and labelling of chemicals. AICIS uses the GHS system for the categorisation of chemical introductions and for Assessment Certificate applications.

### International Uniform Chemical Information Database (IUCLID)

IUCLID is a software application for recording, storing, maintaining and exchanging data on chemicals in the format of the OECD Harmonised Templates. Most templates are built around the OECD Test Guidelines, as these are accepted internationally. It is used by many OECD member countries such as EU, Canada, USA, and New Zealand. It can be used for the submission of an assessment certificate application to AICIS. This means an applicant can reuse information submitted to another regulator in their submission to AICIS for an application for an assessment certificate and vice versa. This streamlines processes for applicants by reducing duplication of effort and making the exchange of information more efficient.

## List of chemicals with high hazards for categorisation

The AICIS list of *chemicals with high hazards for categorisation* is a compilation of chemicals that trusted national and international sources consider to be highly hazardous to human health or the environment. It must be used in certain circumstances when categorising chemical introductions. This means that AICIS accepts the conclusions of these trusted bodies and in many circumstances does not require new toxicity information to be generated for high concern hazard characteristics, e.g. carcinogenicity.

## In silico predictions

In silico predictions involve the use of computer-based models and simulations to predict effects in complex systems, such as biological systems. There are several in silico models that are designed to predict physico-chemical, toxicological and ecotoxicological properties of chemicals. For example, the OECD QSAR Toolbox is a software application intended for the use of governments, chemical industry and other stakeholders in filling gaps in (eco)toxicity data needed for assessing the hazards of chemicals. It was developed in close collaboration with the European Chemicals Agency.

AICIS accepts information from certain in silico predictions for the categorisation of chemical introductions and Assessment Certificate applications. This can reduce the need to conduct chemical testing.

## International Fragrance Association (IFRA) Transparency List and IFRA Standards

The International Fragrance Association (IFRA), a private, industry-led body, represents a significant portion of the global fragrance industry. IFRA Standards are a set of voluntary guidelines developed by the IFRA to ensure the safe use of fragrance ingredients in consumer products. These standards are based on scientific assessments by the Research Institute for Fragrance Materials (RIFM) and are periodically updated through IFRA Amendments.

IFRA maintains the IFRA Transparency List, a periodically updated snapshot of ingredients used by its members. While this list provides valuable insight into materials commonly used in fragrance formulations, it is not exhaustive and does not reflect real-time changes. Additionally, not all ingredients listed have corresponding IFRA Standards, and the list includes substances used only in specific regions or in minimal quantities.

In 2024, AICIS introduced expanded criteria allowing chemicals listed on the IFRA Transparency List to be categorised as Reported introductions provided they are used in accordance with IFRA Standards and meet additional safeguards. These additional safeguards, such as limits on the concentration and the known hazards of the chemical, were embedded in these criteria to ensure that public health and environmental protection remain paramount. This supports low-risk classification and comes with minimal reporting

and record-keeping obligations, reducing the administrative burden on industry while upholding the scheme's core objective of proportionate, risk-based regulation.

### International Nomenclature Cosmetic Ingredient (INCI) names

INCI names are systematic names used to identify cosmetic ingredients. These names are used globally to identify ingredients in cosmetic products, especially on product labels. INCI names are developed by the International Nomenclature Committee (INC), which operates under the Personal Care Products Council (PCPC) in the USA. The INC is a private, industry-led body composed of scientists from academia, industry, and government. It is not a government or treaty-based international standards organisation, such as the ISO.

INCI names do not constitute formal *international standards* in the sense defined by the Productivity Commission which typically refers to standards developed by treaty-based or intergovernmental organisations. The absence of international standardisation highlights the need for jurisdiction-specific regulatory approaches when using INCI names.

The INCI naming system conveys less precise information about chemicals than the legislated chemical naming systems used by AICIS, the Chemical Abstracts Index name (CAS), or the naming system of the International Union of Pure and Applied Chemistry (IUPAC). INCI names are primarily used to convey information to consumers about ingredients in a cosmetic product (on the product label). INCI names allow introducers to identify chemicals while simultaneously protecting proprietary information.

Since the level of detail that INCI names convey about a chemical often lack the specificity provided by CAS or IUPAC names, they may not contain sufficient detail about the chemical's identity to ensure regulatory certainty, such as AICIS being able to identify if a chemical is or is not listed on the AICIS Inventory.

Industrial chemicals identified only by INCI names can still be introduced into Australia under the appropriate introduction category. The primary use of INCI names in Australia is for the labelling of consumer products under the Consumer Goods (Cosmetics) Information Standard 2020, which is the responsibility of the Australian Competition and Consumer Commission.

An INCI name can always be used by an Australian importer to identify a chemical, however, they may also need to know (or be able to provide) other information to enable AICIS to confirm that an introduction is authorised and allow the objects of the IC Act to be met (including considering risks that may arise from the introduction and use of the chemical).

The amendments to the Industrial Chemicals (General) Rules 2019 introduced in 2024 provide expanded options for the provision of INCI names for Reported and Exempted Introductions (low to very low indicative risk), and INCI plant extract names for Listed Introductions.



## Conclusion

The department supports the Productivity Commission's goal of improving regulatory consistency and reducing unnecessary duplication. However, the regulation of industrial chemicals primarily relies on *overseas standards* rather than *international* or *national standards*.

Therefore, adoption of standards from other jurisdictions, where localised risk assessment is essential, requires consideration of the relevance and compatibility with the Australian regulatory framework. The department supports a balanced and risk-based regulatory approach that fosters efficiency and innovation, preserves Australia's high standards for health and environmental protection, and ensures that standards remain current, relevant, and responsive to national priorities.

## APPENDIX

### Background

AICIS is led by the Executive Director, who is an independent statutory office holder appointed by the Governor-General with specific powers and functions under the IC Act. The Executive Director is assisted by staff in the Australian Government Department of Health, Disability and Ageing, and scientific staff from the Department of Climate Change, Energy, the Environment and Water (DCCEEW) who assess the environmental risks of industrial chemicals on behalf of AICIS.

### Registration framework

Introducers (importers and manufacturers) of industrial chemicals into Australia must be registered on the AICIS Register of Industrial Chemical Introducers (Register) before introducing a chemical into Australia. To register, introducers pay a low, flat fee (all registrants) and an annual charge (levy) based on the value of relevant industrial chemicals introduced in the previous financial year. The revenue from registration funds post-market evaluations of industrial chemicals, compliance monitoring and management of contraventions of relevant laws, and provides scheme support and communication activities.

There are 8 levels of registration. In 2023-24, 7,341 introducers were registered with AICIS compared to 7,323 in the previous financial year. A total of 1,347 introducers that registered in 2023-24 were new registrants. The number of new registrants each year reflects the dynamism of Australia's chemical industry with businesses seeking to commence introduction of industrial chemicals, as well as businesses identified by AICIS compliance activities as needing to become registered.

### Risk-proportionate introduction categories

Introducers of industrial chemicals into Australia must also comply with the requirements of a category of introduction, which are based on the level of risk to human health and the environment from the introduced chemical. Industrial chemicals listed on the Australian Inventory of Industrial Chemicals (Inventory) can be introduced as 'listed introductions' by registered introducers.

**Listed Introductions** are introductions of chemicals already listed on the Inventory, and must comply with any regulatory obligations and restrictions stipulated in the terms of listing. Terms of a listing may include a defined scope of assessment, conditions of introduction or use, specific information requirements (SIRs) or any other legal obligations. Chemicals may become listed once 5 years has passed from the issuing of an assessment certificate for that chemical, or upon application by an introducer. During 2023-24, 99 industrial chemicals were added to the Inventory.

Chemicals not listed on the Inventory are not available for industrial use in Australia unless their introduction is authorised under one of the following introduction categories: exempted, reported, assessed or commercial evaluation.

**Exempted Introductions** are considered to be 'very low risk' to human health and the environment according to criteria in the IC Rules and on the AICIS website. This includes chemicals that are imported and subsequently exported, chemicals used purely in research, and chemicals comparable to Listed Chemicals. This category encourages innovation by providing a no-cost, fast option to introduce very low indicative risk industrial chemicals. Introducers using this pathway maintain records and in prescribed circumstances submit a once-off post-introduction declaration (PID) after the industrial chemical's introduction.

**Reported Introductions** are considered to be 'low risk' to human health and the environment. Similar to Exempted Introductions, this category provides a no-cost option to introduce low risk chemicals. Introducers using this introduction pathway maintain records and provide a once-off pre-introduction report (PIR) prior to the industrial chemical's introduction. Once a PIR is submitted, an introducer can commence importing or manufacturing their industrial chemical. Submitted PIRs undergo rapid, pre-screening to select reports for further analysis.

**Assessed Introductions** are industrial chemical introductions that pose a medium to high risk to human health or the environment. If an introduction of an industrial chemical does not fall within the definition of an exempted or reported introduction and is not listed on the Inventory, it is generally an assessed introduction. These introductions mean that AICIS has assessed the chemical and granted an Assessment Certificate. Introducers in other categories may voluntarily request an Assessment Certificate.

In addition to the 4 introduction categories above, AICIS also supports a **Commercial Evaluation Authorisation** option for commercial introductions. This pathway is a quick-turnaround, cost-effective way to introduce an industrial chemical. This option contains restrictions to allow businesses to meet immediate commercial needs while introducing chemicals whose commercial potential may not be known. AICIS must be satisfied that risks to human health or the environment can be managed.