

AICIS (Australian Industrial Chemical Introduction Scheme)

Speaker

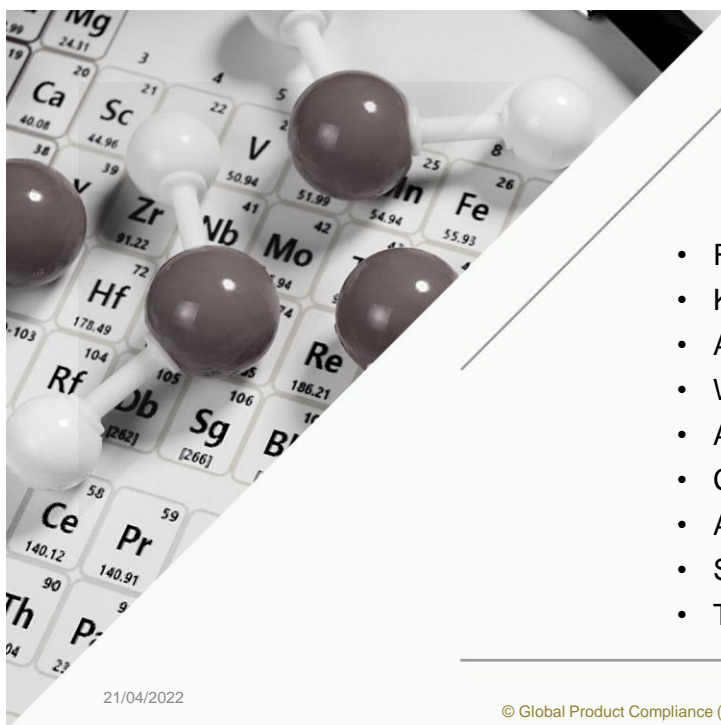
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Summary of Topics

- Regulation overview
- Key terminology
- Australian Chemical Inventory – AICS
- Who can comply or being affected?
- Authorized Representative
- Categorization
- Authority Fee and Charges
- Steps towards Compliance
- Take home message



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Introduction - AICIS

- AICIS - Australian Industrial Chemical Introduction Scheme
- Regulates the introduction of **industrial chemicals** in Australia.
- Protection of human health and the environment through restriction, regulation, assessment, evaluation and by managing risks arising due to introduction.
- Safe use of industrial chemical.
- Maintain a **Register** of Industrial Chemical Introdurers

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Switch from NICNAS to AICIS

The Australia's 30-year-old [National Industrial Chemicals Notification and Assessment Scheme](#) (NICNAS) became the [Australian Industrial Chemical Introduction Scheme](#) (AICIS) from **1st July 2020**.

NICNAS registration will carry over to the AICIS, with same registration id.

Exemptions given under NICNAS registration will carry over to the AICIS, until 31 August 2022

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GHS in Australia

- On **1 January 2021**, Australia began a two-year transition from GHS 3 to GHS 7.
- GHS 3 was adapted by Australia on 1st January 2012.
- During the transition, manufacturers and importers may use either GHS 3 or GHS 7 to prepare classifications, labels and SDS for hazardous chemicals.
- From 1 January 2023, **only GHS 7** shall be used for classification and SDS & Label preparation.

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Key Terms in AICIS

INTRODUCE: means import, or manufacture of an industrial chemical in Australia

INDUSTRIAL CHEMICAL: this covers a broad range of chemicals used in inks, plastics, adhesives, paints, glues, solvents, cosmetics, soaps and many other products.

- ✓ Any chemical element, compounds or complexes of chemical elements, UVCBs with an industrial use
- ✓ Chemicals released by an article, where the article has an industrial use
- ✓ Naturally-occurring chemicals with an industrial use
- ✓ Polymers with industrial use

- **Agricultural chemical product.**
- **Veterinary chemical product.**
- **Therapeutic good.**
- **Use as food for humans or animals.**

Industrial chemicals do not include radioactive chemicals.

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Basic principles of AICIS

- The AICIS regulates chemicals with industrial uses by considering their hazard and risk.
- Business Registration
- No Substance registration
- No direct tonnage/volume criteria
- Annual Reporting for all chemicals

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Australian Inventory of Industrial Chemicals - AICS

- Currently around 40000 chemicals are included
- list of all industrial chemicals in use in Australia between 1 January 1977 to 28 February 1990. In addition, it includes new assessed chemicals and corrections as required.
- Divided into 2 parts – Public Inventory and Confidential Inventory
- It is important to check all the components of product (including impurities) in the inventory

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AICS – Contd.

These can be introduced (import or manufacture) into Australia without telling the authority about it provided that:

- Business is registered
- Comply with any conditions and obligations (set out in the chemical's terms of listing)
Example - Importation volumes of up to 10 tonnes per year or Use in industrial surface coatings not available for public use, including for coating pipes not intended for potable water sources

(apply for vary the terms of the Inventory listing if conditions can not be met)

Substance not listed in public list:

1. a naturally occurring chemical
2. an alloy or hydrate
3. on comparable chemicals list – (16 substances)

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Australian Inventory of Industrial Chemicals - AICS

	Public Inventory	Confidential Inventory
List	Not downloadable	Not accessible
Substances on Inventory	Listed Introductions	Listed Introductions
Annual Reporting	√	√
Record Keeping	√	√
How to Search	By using <ul style="list-style-type: none"> • CAS Number • Name • Molecular formula 	<ul style="list-style-type: none"> • Apply through AICIS Business Services • Need submit proof of Public Inventory search
Authority Fee	No fee	No fee

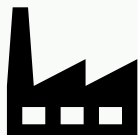
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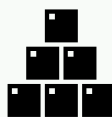


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Who can comply or be affected?



Australian
Manufacturers



Australian
Importers



Non-Australian
Exporters/Authorized
Representatives

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Australian Agent/Authorized Representative

- Foreign companies who directly export to Australia are referred as **Introducers**.
- Business registration is mandatory before any chemical is exported to Australia. Fee is applicable for the same.
- **Australian Registered Business Number (ARBN)** is mandatory to provide for business registration.
- Australian agent or distributor need to be used if any foreign company is unable to obtain ARBN.
- In that case – Australian Agent will be an Introducer and Foreign company will be termed as **Chemical Data provider**.

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Annual Reporting

All importers and manufacturers (introducers) of industrial chemicals must submit an [annual declaration](#) after the end of our registration year regardless of their category.

August 2022 - 30
November 2022

When you must submit your annual declaration

1 July 2021 - 31
August 2022

The period that your annual declaration covers



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New Chemicals - Categorization

Chemicals not on AICS – NEW CHEMICALS – Categorization Required

Categories

1. Listed introductions – substances present in AICS
2. Exempted introductions – very low risk
3. Reported introductions – low risk
4. Assessed introductions – medium to high risk
5. Commercial evaluation introductions
6. Exceptional circumstance's introductions

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1. Listed introductions

- Chemical introduction that is it is available on Inventory
- Must meet any terms of Inventory listing for that chemical.



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2. Exempted introductions

Poses a very low risk to human health and the environment.

- Polymers of Low Concern.
 - Industrial chemicals that are imported and subsequently exported.
 - Industrial chemicals that are solely for use in research and development
 - Non-functionalised surface treatment chemicals
 - Low concern biopolymer
 - Polymers that are comparable with a listed polymer
 - Chemicals that are comparable with listed chemicals
- } Comparable list

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Exempted Introduction contd.

- It is possible to introduce such substance without informing to authority provided business registration is done
- Business registration could be done by Authorized Representative or by Australian importer or by Foreign introducers (having ARBN number)
- Obligations-
 - Record keeping
 - Annual reporting
 - some types of chemicals, **once-off exempted introduction declaration** is required to be submitted before **30 November 2021**

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3. Reported introductions

Low risk to human health and the environment.

- Industrial chemicals at nanoscale that are solely for use in R&D (volume of introduction in registration year is between 10-100kg/year).
- Industrial chemicals (other than at the nanoscale) that are solely for use in R&D (volume of introduction in registration year >250kg).
- Low-risk flavours
- Fragrance blend introductions.
- Introduction of UV filters

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Reported Introductions – Contd.

- **Once-off pre-introduction report** is mandatory to be submitted before introduction
- Details of Australian agent also needs to be submitted if appointed
- Introdurers must keep records about the chemical and its use
- Submit an annual declaration.
- Application for CBI protection can also be made.

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Assessed Introductions – Contd.

- Mandatory to get the introduction assessed by the authority and get the assessment certificate before the chemical (or product containing or releasing the chemical) can be exported, imported or manufactured.
- Fees apply for these applications and must be paid before the start of assessment
- After assessment – Chemical will be listed on the inventory after 5 years of assessment (if not applied for early listing)
- Information on chemical will be published on the website as assessment/evaluation statement

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4. Assessed introductions

Poses medium to high risk to human health and the environment.

- Chemicals that contain a sequence of 4 to 20 fully fluorinated carbon atoms (including per- and poly-fluorinated alkyl substances, known as PFAS)
- Industrial chemical at nanoscale, that are not soluble.
- Polyhalogenated organic chemicals that are persistent or have environmental degradation.
- Polyhalogenated organic chemicals products known to be persistent (greater than 100 kg/year.)
- Persistent gases (greater than 100 kg/year.)
- Organotin chemicals (more than 10kg/year)
- End use as a biocidal active

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5. Commercial Evaluation Introductions

- CEA – Commercial Evaluation Authorization is to evaluate the commercial potential of a chemical.
- This authorization can be granted by the authority for **4 years** for a maximum volume of **10 tonnes** over 4 years
- Application needs to be submitted through online Business Registration service.
- Renewal/extension of CEA is not possible
- Industrial chemical will not be,
 1. available to general public,
 2. release into environment prior treatment,
 3. uncontrolled use at any workplace

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6. Exceptional Circumstances Introductions

Federal Minister of Health may issue an exceptional circumstances authorisation for an introduction of industrial chemical.

- Introduction of the industrial chemical **is in the public interest to address significant risks to human health or the environment.**

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Authority Fee and Charges

Particular	Fee \$(AUD)
Inventory – Early Listing	1,490
Apply for an assessment certificate - health and environment focus	34,965
Apply for an assessment certificate - health focus	23,375
Apply for an assessment certificate - environment focus	23,375
Apply for an assessment certificate - very low to low risk	7,435
Apply for an assessment certificate (consolidated application) - additional chemical that has the same end use as the first chemical and meets the similarity criteria	7,015
Apply for a commercial evaluation authorization	6,490

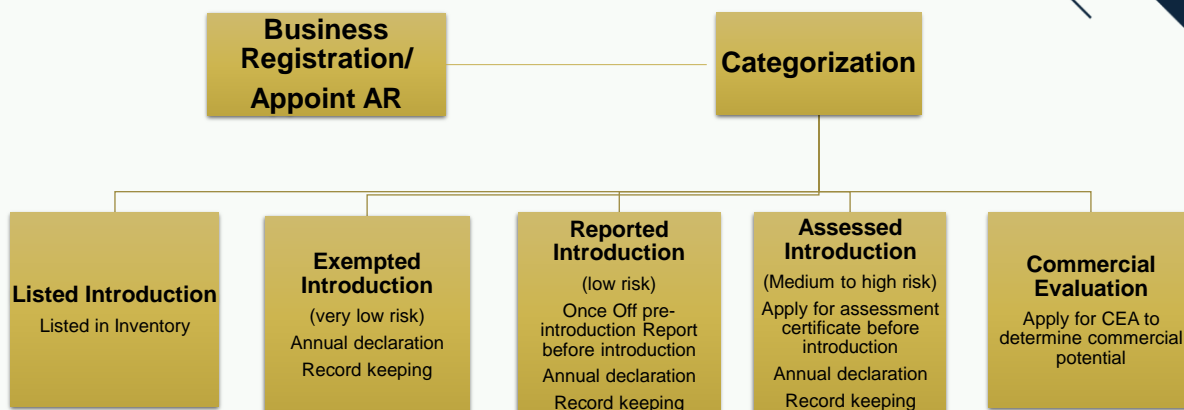
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Steps towards Compliance



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The Industrial Chemicals Environmental Management Standard (IChEMS)

- Managing chemical use, storage, handling and disposal
- It will deliver more consistent environmental regulation and make it easier for industry to choose less harmful chemicals.
- Mid 2022.
- This will help government, industry, and the community make informed choices about chemicals.
- A draft of the IChEMS Principles is now available for public consultation. (23 March 2022 - 24 May 2022)

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	Description	Controls
1	Schedule 1 Very low or no hazard to the environment	General responsibilities to protect the environment, no additional controls.
2	Schedule 2 Hazardous, low risk	Proportional controls and requirements.
3	Schedule 3 Hazardous, moderate risk	Proportional controls and requirements.
4	Schedule 4 Hazardous, higher risk e.g. bioavailable metals, bioaccumulative substances, and endocrine disruptors.	Proportional controls and requirements.
5	Schedule 5 Potentially significant and long-lasting impact e.g. chemicals that are likely to cause environmental harm, or that demonstrate a combination of persistence, bioaccumulation, and toxicity.	Proportional controls for assessed uses. Controls may be enforced through additional requirements, such as licences, permits or regulations.
6	Schedule 6 Significant risk of serious or irreversible harm to the environment as per Schedule 7, but: the chemical has an essential use, there are no viable alternatives, and there are no exceptional circumstances making Schedule 7 more appropriate.	Severe restriction, with rigorous standards for any remaining uses. Controls will be enforced through additional requirements, such as licences, permits or regulations.
7	Schedule 7 Significant risk and highly hazardous to the environment e.g. chemicals that are persistent, bioaccumulative and toxic, such as chemicals under the Stockholm Convention.	Prohibited from import, manufacture, and use.

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Take Home Message

- Identify the substances expected to export to Australia
- Check the status of the inventory
- Identify the competent person within the organization/consultant
- Perform substance assessment for identifying hazard nature to categorize
- Plan your activities in advance
- Keep up to date information available for any further requirements from the authority

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How GPC can help

GPC has a legal entity in Australia

- Authorized Representative services
- Review and Interpret Regulatory applicability – AICS
- Prepare and submit application for confidential inventory check
- Annual Reporting
- Substance assessment
- Categorization of new chemicals
- Application preparation & submission for relevant introductions



Write to us for AICIS related services:
compliance@au.gpcregulatory.com

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Thank You.

Contact us for global regulatory services



<https://gpcgateway.com/>



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