

EXPLANATORY STATEMENT

Issued under the authority of the Assistant Minister for Health and Aged Care

Industrial Chemicals Act 2019

Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022

Authority

The *Industrial Chemicals Act 2019* (IC Act) establishes the Australian Industrial Chemicals Introduction Scheme (AICIS), a risk-based scheme for the Commonwealth regulation of the introduction of industrial chemicals into Australia.

Section 180 of the IC Act provides that the Minister may make rules prescribing matters required or permitted by the Act, or necessary or convenient for carrying out or giving effect to the Act.

Purpose

The *Industrial Chemicals (General) Rules 2019* (General Rules) form part of the legislative framework to establish a risk-based regulatory scheme for the introduction of industrial chemicals in Australia as well as setting out the technical and operational details of the AICIS.

The objectives of the industrial chemicals legislation regarding the protection of human health and the environment remain unchanged. The General Rules made by the Minister allow flexibility to adapt to scientific and regulatory developments within these objectives.

The *Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022* (Amending Rules) make several amendments to the General Rules to ensure the requirements for lower volume chemical introductions are appropriate and risk proportionate. The amendments relate to the following matters:

- circumstances in which introductions of industrial chemicals, where the total volume of a chemical introduced, by a person in a registration year, does not exceed 10 kg, can be reported introductions
- pre-introduction report requirements that can apply to reported introductions of 10 kg or less of an industrial chemical in a registration year
- record keeping requirements that can apply to reported introductions of 10 kg or less of an industrial chemical in a registration year
- record keeping requirements that can apply to listed introductions of 10 kg or less of an industrial chemical in a registration year
- minor updates and corrections relating to wording, referencing within and between provisions, as well as provision numbering, and
- the addition of definitions which are referenced in newly added provisions.

The amendments will assist industry by making the requirements for introductions at volumes of 10 kg or less in a registration year more appropriate and risk proportionate.

The changes are expected to provide a benefit for introducers of chemicals at lower volumes. The amended provisions ensure that:

- appropriate information is known about chemicals being introduced; and
- higher concern chemicals cannot be categorised as low risk (reported) introductions by accessing these amendments.

Instead of holding a written undertaking from the chemical supplier, where the CAS number (if assigned) and CAS name of the chemical is confidential, the introducer would need to know information that is more proportionate to the risk of introduction of a chemical at 10 kg or less.

The exclusions for reported introductions would mean introductions of higher concern chemicals at volumes of 10 kg or less are likely to be categorised as medium to high risk, requiring an application for an assessment certificate to be made and finalised before introduction of these chemicals could be authorised.

Background

At the commencement of AICIS on 1 July 2020, a period of transition commenced, providing time for introducers to ensure their compliance under the IC Act and related legislation.

The Department of Health and Aged Care received feedback from stakeholders in the industrial chemicals industry indicating that a significant number of introducers were unable to get the required information from their chemical suppliers to meet the categorisation and record-keeping requirements under the AICIS before the end of the transition period on 31 August 2022.

The Department was advised that if an industrial chemical introducer is importing lower volumes of chemicals in a registration year, it is more difficult for them to persuade an overseas supplier to provide the information that they need to meet their current obligations under the AICIS, where information about the chemical is confidential or commercially sensitive. This is particularly true if there are multiple stages in the supply chain and/or if Australia's requirements are different to the requirements of comparable international regulatory schemes.

The proposed amendments are the outcome of broader considerations of what is reasonable and appropriate for introducers of chemicals at lower volumes to know and keep as records about their introductions, whilst maintaining protections for human health and the environment.

Introductions of 10 kg or less of chemical in a registration year will generally be lower risk introductions, based on the lower levels of human and environmental exposure. The quality and type of information that introducers would need to know and keep for these lower-volume chemical introductions, under these amendments, is appropriate and risk-proportionate.

Consultation

Public consultation on an exposure draft of these Amending Rules was undertaken between 26 September 2022 and 11 October 2022 through the AICIS website. A total

of 41 submissions were made verbally, via email, and through the web form. Respondents were generally supportive of the proposed changes.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power is construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Regulatory impact assessment

In relation to this assessment, the Office of Best Practice Regulation (OBPR) advised that the proposal is unlikely to have a more than minor regulatory impact and the preparation of a regulatory impact statement is not required (OBPR22-03562).

Commencement

All provisions will commence the day after the Amending Rules are registered on the Federal Register of Legislation.

Details

Details of the Amending Rules are set out in [Attachment A](#).

The Amending Rules are compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in [Attachment B](#).

The Amending Rules are a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022

Section 1 Name of the Instrument

Section 1 states that the name of the instrument is the *Error! Use the Home tab to apply ShortT to the text that you want to appear here.*

Section 2 Commencement

All provisions will commence the day after this instrument is registered on the Federal Register of Legislation.

Section 3 Authority

Section 3 states that the instrument is made under the *Industrial Chemicals Act 2019* (the IC Act).

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to this instrument will be amended or repealed as set out in the applicable items in the Schedule, and any other item in the Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendment of the Industrial Chemicals (General) Rules 2019

Item 1 – Insert new definitions into section 5

This item inserts definitions of two terms into section 5 (Definitions) and directly relate to the new subsection 27(6), which references the terms.

There is a defined term for the *GHS* (Globally Harmonized System of Classification and Labelling of Chemicals), which has the same meaning as in the *Work Health and Safety Regulations 2011*. There is also a defined term for *hazard class*, which relates to the nature of a physical, health or environmental hazard under the GHS. The authority for this manner of incorporation is subsection 180(3) of the IC Act.

The GHS is a publicly available document published by the United Nations at <https://unece.org/ghs-rev7-2017>.

Items 2-3 – Amendment to add a new circumstance in which introductions are reported introductions

Item 2 amends subsection 27(1) to omit “or (4)” and substitute “, (4) or (6)” so that for the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is also covered by section 27 if new subsection 27(6) of this section applies to the introduction.

Item 3 adds new subsections 27(6) and (7) at the end of section 27 of the General Rules. The new subsections 27(6) and (7) relate to introductions of 10 kg or less of an

industrial chemical, as a new type of industrial chemical introduction that can be a reported introduction.

New subsection 27(6) provides that introduction of an industrial chemical by a person will be a reported introduction if the following criteria are met:

- (a) the total volume of the chemical introduced in a registration year by a person must not be more than 10 kg
- (b) the chemical is not known by the person to be classified as having carcinogenicity, germ cell mutagenicity or reproductive toxicity, in accordance with the criteria set out under the GHS
- (c) if the chemical has a cosmetic end use, it must not be prohibited or restricted in the European Union or the United States for use as a cosmetic, or in a cosmetic. This means that the chemical is not identified in any of:
 - Annexes II and III of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as in force from time to time (publicly available at eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009R1223). The Annexes are also published by the European Chemicals Agency and are publicly available at:
 - Annex II (prohibited substances) – echa.europa.eu/cosmetics-prohibited-substances
 - Annex III (restricted substances) – echa.europa.eu/cosmetics-restricted-substances
 - the Federal Food, Drug, and Cosmetic Act (prohibited and restricted ingredients in cosmetics), as in force from time to time (publicly available at www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics)

The authority for this manner of incorporation is subsection 180(3) of the IC Act.

- (d) the chemical is not, to the person's knowledge, to be introduced as a solid or in a dispersion, or is not known to meet certain nanoscale criteria
- (e) the chemical must either:
 - not be known by the person to contain fluorine; or
 - is known by the person to be an inorganic salt
- (f) the chemical must not be known to the person to be persistent, bioaccumulative and toxic to the environment (as described in the Industrial Chemicals Categorisation Guidelines, which are publicly available at www.industrialchemicals.gov.au/about-us/industrial-chemicals-law-australia), and
- (g) neither of the following applies:
 - an assessment certificate for the chemical has been cancelled under section 52 of the IC Act, or
 - the chemical has been removed from the Australian Inventory of Industrial Chemicals (the Inventory, established under section 80 of the IC Act) under section 95 of the IC Act,

because the Executive Director of the AICIS concluded as part of an evaluation that the risks to human health or the environment from the introduction or use of the chemical could not be managed.

New subsection 27(7) clarifies for subparagraph 27(6)(g)(i) that in the situation when the Executive Director has cancelled an assessment certificate, it does not matter who held the assessment certificate or who was covered by the same certificate.

Item 4 – amendment to wording in subsection 41(2) (table item 6) for pre-introduction reports for industrial chemicals that are solely for use in research and development-

Item 4 amends table item 6 in the table to subsection 41(2) to omit the words “have been” and substitute “are being”. This amendment changes the wording to the present tense to clarify that the requirement can only be met at the time of introduction, rather than at the time when the pre-introduction report is submitted. This complements a similar provision in item 5 below (specifically table item 8 in the table set out in new subsection 42A(2)).

Item 5 – Amendment to add the prescribed information for pre-introduction reports for reported introductions of 10 kg or less of an industrial chemical

Item 5 inserts new section 42A after section 42 of the General Rules. This amendment complements the changes made in item 3 and sets out the pre-introduction reporting requirements for reported introductions of 10 kg or less.

New section 42A prescribes the information that must be included in the pre-introduction report for a reported introduction of 10 kg or less of an industrial chemical (under new subsection 27(6) to be inserted by item 2 above).

The table to new section 42A prescribes the following information:

- the chemical identity of the industrial chemical. The nature of the chemical identity information needed is dependent upon whether the proper name or any other names by which the industrial chemical is known (including the CAS name, INCI name or the IUPAC name) is known to the person.
 - The **CAS name** refers to the Chemical Abstracts Index Name and the **CAS number** refers to the Chemical Abstracts Service Registry Number for the industrial chemical. These terms are defined under the IC Act.
 - The **IUPAC name**, means the International Union of Pure and Applied Chemistry name for the industrial chemical and the **INCI name**, means the International Nomenclature of Cosmetic Ingredients name for the industrial chemical and are defined under the General Rules.
 - If the CAS number for the industrial chemical is known to the introducer, it must be provided in the report, together with the CAS name, IUPAC name or INCI name and any other names by which the chemical is known to the person.
 - If a CAS number for the industrial chemical is not assigned or is not known to the person, but the CAS name or IUPAC name for the industrial chemical is known to the person, then the CAS name or IUPAC name for the industrial chemical and any other names by which the industrial chemical is known to the person must be provided in the report.

- If a CAS number for the industrial chemical is not assigned or is not known to the person (or is not assigned), and neither the CAS name nor the IUPAC name is known to the person, but the INCI name is known to the person, then the INCI name must be provided in the report.
- If a CAS number for the industrial chemical is not assigned or is not known to the person (the introducer) and the introducer does not know the CAS name, IUPAC name or INCI name for the industrial chemical then they must provide:
 - the names by which the industrial chemical is known to the introducer, and;
 - the name of the person whom the introducer believes on reasonable grounds would provide the CAS number (if assigned), and CAS name, IUPAC name or INCI name of the industrial chemical to the Executive Director, if requested.
- information about introduction of the industrial chemical as a solid, in dispersion or neither, based on the knowledge of the person:
 - whether the industrial chemical will be introduced as a solid or in dispersion (if the person knows this), or
 - that the industrial chemical is to be introduced neither as a solid nor in dispersion (if the person knows this), or
 - that the person does not know whether the industrial chemical is to be introduced as a solid, in dispersion or neither.
- the end uses for the industrial chemical.
- any known hazard classification for the industrial chemical, and
- a declaration that the requirements of subsection 27(6), for industrial chemicals introductions of 10 kg or less, are being met for the introduction.

New subsection 42A(3) provides that, for the purposes of the table in subsection 42A(2), if a person does not know the CAS number, CAS name, IUPAC name or INCI name for an industrial chemical being introduced, but it would be reasonably practicable for the person to find out the relevant number or name, then the person is taken to the number or name.

Items 6-9 – Amendment to section 46 to add new subsections 46(2), (3) and (4) - Record keeping for listed introductions

Items 6-8 make minor amendments to section 46. For instance, item 6 inserts a “(1)” before “For the purposes of” in section 46 so that the legislative provisions currently under section 46 become new subsection 46(1). The amendments in items 6-8 will assist to differentiate between general record keeping requirements for listed introductions and alternate record keeping requirements for listed introductions of 10 kg or less of an industrial chemical.

Item 9 adds new subsections 46(2), (3) and (4) at the end of section 46 of the General Rules to set out alternative record keeping requirements for listed introductions of 10 kg or less of an industrial chemical.

New subsection 46(2) provides that new subsection 46(3) (described below) applies to the introduction of an industrial chemical by a person in a registration year if the total

volume of the industrial chemical introduced by the person in the registration year does not exceed 10 kg.

The new subsection 46(3) prescribes the kinds of records that must be kept for listed introductions of 10 kg or less of an industrial chemical. For all listed introductions, a person must keep records of the kind prescribed by subsection 46(1) of the General Rules (as formed by item 6). Alternatively, the person must keep records of all the following:

- the names of any products containing the industrial chemical that are imported into Australia by the person
- records to demonstrate that the total volume of the industrial chemical introduced by the person in the registration year does not exceed 10 kg
- any known hazard classification for the industrial chemical
- if a circumstance mentioned in column 1 of an item in the table to subsection 46(3) applies, then the records of the kind mentioned in column 2 of the item.

The table provides three circumstances which may apply to the introduction of an industrial chemical and the corresponding kind of record that must be kept in each circumstance.

- If the CAS number for the industrial chemical is known to the person, then the kind of records that must be kept are the CAS number for the industrial chemical and the CAS name, IUPAC name or INCI name for the industrial chemical.
- If a CAS number for the industrial chemical is not assigned or is not known to the person and the CAS name, IUPAC name or INCI name for the industrial chemical is known to the person, the kind of records that must be kept are the records that indicate that the industrial chemical is listed on the Inventory and the CAS name, IUPAC name or INCI name for the industrial chemical.
- If a CAS number for the industrial chemical is not assigned or is not known to the person (the introducer) and neither the CAS name, IUPAC name or INCI name for the industrial chemical is known to the introducer, then the kinds of records that must be kept are records that indicate that the industrial chemical is listed on the Inventory, the names by which the industrial chemical is known to the introducer and the name of the person whom the introducer believes on reasonable grounds would provide the CAS number (if assigned), and CAS name, IUPAC name or INCI name to the Executive Director.

New subsection 46(4) provides that, for the purposes of new subsection 46(3), if a person does not know the CAS number, or CAS name, IUPAC name or INCI name for an industrial chemical being introduced, but it would be reasonably practicable for the person to find out the relevant number or name, then the person is taken to know the number or name.

Item 10 – Amendment to add new record keeping for reported introductions of 10 kg or less of an industrial chemical

Item 10 adds new section 56A after section 56 of the General Rules. This amendment complements the other changes made in item 3 to set out recording keeping requirements for reported introductions of 10 kg or less of an industrial chemical.

If an introduction of an industrial chemical, by an introducer, is a reported introduction in accordance with subsection 27(6) (as per item 3) then the records that must be kept include:

- any names by which the industrial chemical is known to the person which must include the name included in the pre-introduction report for the industrial chemical
- the names of any products containing the industrial chemical that are imported into Australia by the person, and
- records demonstrating the requirements of subsection 27(6) are being met.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The *Industrial Chemicals Act 2019* (IC Act) establishes the Australian Industrial Chemicals Introduction Scheme (AICIS), a risk-based regulatory scheme for the Commonwealth regulation of the introduction of industrial chemicals in Australia.

The *Industrial Chemicals (General) Rules 2019* (General Rules) form part of the legislative framework for AICIS, as well as setting out the technical and operational details of the AICIS.

The scheme is designed to be proportionate to risk, and to promote safer innovation by encouraging the introduction of lower risk chemicals. It also encourages greater harmonisation with international approaches to the regulation of industrial chemicals and provides for the use of assessments of comparable international regulators.

The scheme also improves transparency, striking an appropriate balance between confidentiality and publicly available information, as the Executive Director of the AICIS will publish information that is more meaningful for industry and the public about chemical assessments, while allowing for appropriate confidentiality for business information through partially masked names and/or end use when in the public interest.

The *Industrial Chemicals (General) Amendment (Introductions of 10 kg or Less) Rules 2022* (Amending Rules) make several amendments to the General Rules to ensure the requirements for lower volume chemical introductions are appropriate and risk proportionate. The amendments relate to the following matters:

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- pre-introduction report requirements that can apply to reported introductions of 10 kg or less of an industrial chemical in a registration year
- record keeping requirements that can apply to reported introductions of 10 kg or less of an industrial chemical in a registration year
- record keeping requirements that can apply to listed introductions of 10 kg or less of an industrial chemical in a registration year
- minor updates and corrections relating to wording, referencing within and between provisions, as well as provision numbering, and

- the addition of definitions which are referenced in newly added provisions.

The amendments will assist industry by making the requirements for introductions at volumes of 10 kg or less in a registration year more appropriate and risk proportionate. The changes are expected to provide a benefit for introducers of chemicals at lower volumes. The amended provisions ensure that:

- appropriate information is known about chemicals being introduced; and
- higher concern chemicals cannot be categorised as low risk (reported) introductions by accessing these amendments.

Instead of holding a written undertaking from the chemical supplier, where the CAS number (if assigned) and CAS name of the chemical is confidential, the introducer would need to know information that is more proportionate to the risk of introduction of a chemical at 10 kg or less.

The exclusions for reported introductions would mean introductions of higher concern chemicals at volumes of 10 kg or less are likely to be categorised as medium to high risk, requiring an application for an assessment certificate to be made and finalised before introduction of these chemicals could be authorised.

Human rights implications

The Amending Rules engage the human rights contained in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), which sets out the right to the enjoyment of the highest attainable standard of physical and mental health.

Right to health

This instrument engages the right to health as set out in Article 12 of the ICESCR by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The requirements in this instrument to categorise industrial chemical introductions according to low volumes (introduction volumes of 10 kg or less) promotes continued protection of public health, and improvement of environmental and industrial hygiene. Having criteria for streamlined introduction pathways (reported introductions) will also encourage the introduction of newer and safer chemical products for consumers.

Conclusion

The legislative instrument is compatible with human rights because to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate for the protection of human health and the environment.

The Hon Ged Kearney MP

Assistant Minister for Health and Aged Care