EXPLANATORY STATEMENT

Issued under the authority of the Minister for Regional Health

Industrial Chemicals Act 2019

Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019

Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021

Authority

The *Industrial Chemicals Act 2019* (the IC Act) establishes the Australian Industrial Chemicals Introduction Scheme (the 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.

Section 50 of the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) provides that the Minister may make rules providing for matters required or permitted by the Transitional Act, or necessary or convenient in order to carry out or give effect to the Transitional Act. The rules may also prescribe matters of a transitional nature (including savings and application provisions).

Purpose

The *Industrial Chemicals (General) Rules 2019* (the General Rules) set out the technical and operational details of the AICIS. The *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules) ensure the effective transition of the Commonwealth regulation of industrial chemicals, from the old scheme (the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)) to the new scheme (AICIS).

The *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021* (Amending Rules) make a number of amendments to the General Rules and the Transitional Rules to clarify the operation of the AICIS within existing policy. The amendments relate to the following matters:

- industrial chemicals introduced at the nanoscale
- declarations about permission to use international assessment reports
- record-keeping for listed introductions, specified classes, designated kinds of releases into the environment, and internationally-assessed introductions

- movement of industrial chemicals into or out of Australia requiring import/export approval under the Rotterdam Convention
- errors and omissions
- transitional provisions

The amendments are consistent with decisions made when AICIS was implemented in July 2020, and would assist industry by making compliance requirements clearer.

Background

After the first year of operation of the AICIS, a number of minor operational issues have been identified which require clarification or corrections to be made to the technical and operational details set out in the General Rules and the Transitional Rules. These issues have been identified both by the regulated industry and by the Office of Chemical Safety (OCS) implementing the scheme.

Consultation

Public consultation on an exposure draft of these Amending Rules was undertaken between 24 August 2021 and 17 September 2021, through the AICIS website. OCS received 7 submissions. The submissions received informed changes to the draft amendments to further clarify the relevant provisions and removal of proposed amendments for which stakeholders indicated regulatory impact would be more than minor.

The stakeholder feedback was used to undertake a preliminary assessment of the regulatory impact of this amending instrument, which concluded that the impact would be minor. In relation to this assessment, the Office of Best Practice Regulation (OBPR) advised that the preliminary assessment was sufficient and a RIS was not required (OBPR ID 44647).

Commencement

The amendments which require changes to the IT system (those amendments related to pre-introduction reports) and those changes requiring additional record keeping requirements will commence on 10 December 2021. All other provisions will commence the day after the instrument is 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.*

ATTACHMENT A

Details of the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*

Section 1 Name of the Instrument
Section 1 states that the name of the instrument is the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021.*

Section 2 Commencement
Section 2 sets out two different commencement dates. Provisions related to pre-introduction reports and those changes in Part 6 requiring additional record keeping requirements will commence on 10 December 2021. All other 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 Act) and the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional 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

Part 1 (Items 1, 5, 9, 11-19) - Amendments to clarify the nanoscale criteria

These amendments do not change the criteria, but clarify that:

1. the criteria related to an industrial chemical being a solid or in dispersion means that it is introduced as a solid or in a dispersion. For example, if an industrial chemical exists as a solid in its raw form but is introduced dissolved in a liquid then the criteria would not apply.
2. The number size distribution percentage criterion relates to the particles, regardless of whether they are in an unbound state or as an aggregate or agglomerate.

Part 1 (Items 2, 3, 4, 6, 7, 8, and 10) – Amendments to clarify the volume requirements for chemicals introduced at the nanoscale for research and development

The amendments in these items clarify two points that have been queried by introducers during the first year of the scheme.

Firstly, the amendments now make it clear that the lower volume limits for research and development apply in circumstances where:

- the industrial chemical meets the nanoscale criteria; or
- it has not been determined at the time of introduction whether the chemical meets the nanoscale criteria.

This clarifies that an introducer would not need to have conducted the tests to determine whether a chemical meets the nanoscale criteria if it is only being introduced for research and development at volume up to 10 kg (for exempted introductions) or 100 kg (for reported introductions).

Secondly, the amendments now make it clear that the lower volume limit applies in respect of both subsection 26(3) and subsection 27(2) if any of the industrial chemical introduced in the registration year meets the nanoscale criteria.

Part 1 (Items 15 and 16) – Record keeping requirements related to requirements for chemicals introduced at the nanoscale

The amendments in these items complement the other changes made in Part 1 and align the record keeping requirements in section 48 for exempted introductions that are introduced solely for research and development, with the requirements in section 55 for reported introductions that are introduced solely for research and development.

Part 2 (Item 20) - Pre introduction report information related to requirements for chemicals introduced at the nanoscale

The amendment in this part complements the changes made in Part 1 and allows for more effective monitoring and targeting of audit effort related to the nanoscale criteria.

Item 20 amends the information required for reported introductions solely for research and development by making it clearer whether the industrial chemical is known to meet the nanoscale criteria.

As this amendment requires changes to the online pre-introduction report forms, it will only apply to those submitted on or after 10 December 2021.

Part 3 (Items 21-23) – Declaration of permission to use international assessment reports

These amendments add a requirement to declare that an introducer has the permission to use the complete international assessment report for introductions of industrial chemicals that are internationally-assessed.

This is a checkpoint for introducers who would have already considered this when categorising their introduction. This declaration will streamline the audit process for these types of introductions.

As these amendments require changes to the online forms, they will only apply to pre-introduction reports submitted on or after 10 December 2021.

Part 4 (Item 24) –Record keeping requirements for listed introductions

This amendment to the record keeping requirements for listed introductions makes 2 changes:

1. Allows for an additional option for the chemical identity record if the CAS name and number are not known to the introducer. This additional option is 'the names of all products containing the industrial chemical that are imported into Australia by the person'. This reflects the actual information that some product importers are able to record and keep.
2. Inserts a timeframe in which the CAS name and number (if assigned) will be provided by the chemical identity holder, if a request for this information is made. This timeframe (40 working days) is longer than other information provision timeframes in the IC Act to allow for the additional time that may be needed to liaise with chemicals identity holders that are often overseas entities.

The requirement for the written undertakings to include the timeframe will only apply to those given on or after this amending instrument commences (i.e. it will not apply to written undertakings already given before this date).

Part 5 (Items 25- 32) – Amending record keeping requirements for specified classes of introduction

The amendments in this part allow for flexibility in the records that must be kept for certain specified classes when the introducer does not have access to the relevant information (e.g. because the chemical identity is not known to the introducer, only to a chemical identity holder). Instead, an introducer can hold a written undertaking from the person who does know the relevant information. The specified classes these amendments apply to are:

- Biochemical
- GM product
- End use in an article with food contact
- End use in an article that is a children's toy or a children's care product
- UV filter

Part 6 (Items 33- 35) - Record keeping requirements for introductions with a designated kind of release into the environment

These amendments make 2 changes to the record keeping requirements for introductions with a designated kind of release into the environment:

1. The insertion of 'if practicable'. The intent of this change is to best support introducers to comply with the requirements in practice (where the current requirement could present issues in practice in respect of certain types of releases). To support introducers' understanding of what it is and is not practicable to record, guidance will be published to explain the instances in which it is practicable to keep records and therefore introducers would be expected to keep these records.
2. Inclusion of the requirement to record the quantity of the chemical released into the environment, which is an important piece of information for considering the risk of these introductions where the chemical is released

directly to the environment. Requesting this information to be generated retrospectively would be difficult and so it is appropriate that an introducer keep this information.

Part 7 (Items 36-39) –Record keeping requirements for internationally-assessed introductions.

The amendments in this part correct an omission regarding the type of volume records that will need to be kept by an introducer for these type of reported introductions. In order to demonstrate both continued compliance with the internationally-assessed introduction criteria, as well as the terms of the pre-introduction report both types of volume records need to be kept.

Part 8 (Items 40-50) – Amendments to the restrictions on movement of industrial chemicals into or out of Australia

The amendments in this part make changes to better align the Rules with the scope of the Rotterdam Convention and the process undertaken when deciding on an application for approval to import or export restricted industrial chemicals.

Items 42 to 47 amend the introductions that are subject to the requirements of sections 71, 72 and 73. This is to align with the scope of the Rotterdam Convention, which does not apply to chemicals used for research or analysis in low volumes.

Item 40 amends the circumstances in which introductions of chemicals listed in the Rotterdam Convention are not exempted or reported. This is to align with the changes in items 42-47. The outcome of the proposed amended 25(2)(b) is that if a chemical is listed on one of the prescribed international convention lists, and the chemical is not being introduced for research and analysis in low volumes, then it cannot be exempted or reported. It must be authorised under a different introduction category (such as listed or assessed).

Item 41 amends the way the record keeping requirements for these introductions are worded to reflect the changes in items 42-47.

Item 48 amends the description of what a person may apply for, to align with the changes in items 42-47.

Item 49 amends subsection 75(2) to include a new matter to which the Executive Director must have regard in considering an application. While ‘Australia's obligations under relevant prescribed international agreements or arrangements’ should come under 75(2)(c) (any other information the Executive Director considers relevant), the intent of this change is to ensure the law expressly requires such consideration.

Item 50 adds an additional subsection to section 75 to make it clear that an approval notice under subsection 75(4) will also include certain terms. This better reflects the actual outcome of this approval process, including that the Executive Director needs to apply certain standard terms in order for Australia to meet its obligations under the Rotterdam Convention.

Part 9 – Other amendments

The amendments in this part are to address miscellaneous errors and omissions that have been identified during the first year of the scheme.

Item 51 - Amendment of the table of international assessment bodies (Subsection 6(3) (table item 5, columns 1 and 2)

This amendment corrects an error in the name of the European Commission Scientific Committee on Consumer Safety.

Items 52 and 53 – Amendment of the list of chemicals comparable to listed chemicals (Subsection 26(5) (table item 15))

These amendments remove item 15 from the table of industrial chemicals that are comparable to listed industrial chemicals (thereby making them exempted introductions) and then renumber the remaining final table item.

The chemical in column 3 of table item 15 (Tylosin, (2R, 3R)-2,3-dihydroxybutanedioate (salt)) was removed from the Inventory during the transition from the old to the new scheme (under section 76 of the Transitional Rules) as it is not an industrial chemical. Therefore the chemical in column 1 (Tylosin, (2R, 3R)-2,3-dihydroxybutanedioate (1:1)) is no longer comparable to a listed industrial chemical.

Item 54 – Correcting an omission in the list of circumstances for when an AICIS Approved Chemical Name (AACN) or generalised end use must be used

This amendment corrects an omission by adding circumstances to the list prescribed for when an AACN or generalised end use must be used. The circumstances added are:

- When making the Inventory publicly available on the AICIS website.
- When listing an industrial chemical on the Inventory 5 years after an assessment certificate was issued.

Item 55 – Excluding the time taken for making a CBI application from the consideration period of the related application

This amendment adds a new item in the table at section 79 of the General Rules to enable the consideration period to be ‘paused’ (i.e. the specified period to be excluded) if the Executive Director gives a notice of intention to publish information under subsection 113(1) of the IC Act. This allows time for an applicant to make an application for information flagged under section 112 of the IC Act to be treated as confidential business information (and therefore not published).

Item 56 – Amending the criteria for a designated kind of release into the environment

This amendment excludes all introductions where the end use is in an air freshener, from being considered as an 'intentional release to air during use', and therefore excludes them from being an introduction that involves a designated kind of release into the environment. This amendment has been made to address an issue raised by introducers where introductions for an end use in air fresheners in commercial settings such as hospitality and aged care facilities were being considered as involving a designated kind of release into the environment, with the increased information, reporting and record keeping requirements. It was never the intention that these commercial air fresheners would need these additional requirements.

Part 10 (Items 57 and 58) - Transitional Provisions

The amendments in this part add provisions that allow for certain provisions within this amending instrument to only apply in certain circumstances. These are:

- In relation to record keeping for listed introductions the amendments only apply to an undertaking that is given after commencement of this amending instrument (e.g. written undertakings already given before this instrument commences will not have to be modified).
- In relation to pre-introduction reports the amendments only apply to reports given or varied on or after 10 December 2021.

Schedule 2 - Amendment of the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019

Item 1 – Transitional provision for listing on Inventory of conditions on transitioned assessment certificates

This amendment adds a new transitional rule in the Transitional Rules such that when a transitioned assessment certificate is included on the Inventory in accordance with section 82 (listing on Inventory after 5 years) or section 83 (listing on Inventory before 5 years) of the IC Act, the conditions on the transitioned assessment certificate can be included on the listing on the Inventory (i.e. subsection 81(2) of the new law does not apply).

This amendment is to address an issue that was identified where the Transitional Act allows for conditions to be put on these certificates that are not limited to volume, site or duration (refer section 15 of the Transitional Act), but when the industrial chemical comes up for listing on the Inventory (in accordance with sections 82 or 83 of the IC Act), subsection 81(2) of the IC Act places limitations on what conditions can be included on the Inventory – and the Transitional legislation does not currently modify this.

Item 2 – Repealing certain transitioned conditions of use

This amendment repeals the transition of conditions of use for the following chemicals:

- Table item 1 - Hexanoic acid, 2 ethyl , 1,1' (2,2 dimethyl 1,3 propanediyl) ester
- Table item 9 - L-Ascorbic acid, tetrakis(2-hexyldecanoate)

- Table item 39 - 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, 1,2,3-tris(2-octyldodecyl) ester
- Table item 64 - Hexanoic acid, 2-ethyl-, C16-18-alkyl esters

These conditions of use should not have been transitioned as defined scopes of assessment as there were subsequent assessments after the conditions of use were applied. These assessments had broader scopes of use and either the recommended risk management changes from these assessments had already been implemented (table items 1 and 64), or the specific information requirements arising from these assessments cover the broader scope (table items 9 and 39).

ATTACHMENT B

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

Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021

This Disallowable 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 Disallowable Legislative Instrument

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

The Industrial Chemicals (General) Rules 2019 (the General Rules) set out the technical and operational details of the AICIS. The Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules) ensure the effective transition of the Commonwealth regulation of industrial chemicals, from the old scheme (the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)) to the new scheme (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 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 Amending Rules make a number of amendments to the General Rules and the Transitional Rules to clarify the operation of the AICIS within existing policy. The amendments relate to the following matters:

- industrial chemicals introduced at the nanoscale
- declarations about permission to use international assessment reports
- record-keeping for listed introductions, specified classes, designated kinds of releases into the environment, and internationally-assessed introductions
- movement of industrial chemicals into or out of Australia requiring import/export approval under the Rotterdam Convention

- errors and omissions, including to provisions related to applying for information to be protected information, and when confidential information will be protected through partially masked chemical names and/or a generalised end use
- transitional provisions

Human rights implications

This instrument engages the following rights:

- Right to health – Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), and
- Right to privacy and reputation – Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR).

Right to health

This instrument engages the right to health as set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights 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 amend the criteria for categorising industrial chemical introductions according to indicative human health risk and indicative environment risk promotes protection of public health, and improvement of environmental and industrial hygiene. These amendments make the criteria clearer and easier to comply with. Having clear criteria for streamlined introduction pathways (reported and exempted introductions) encourages the introduction of newer and safer chemical products for consumers.

Right to privacy and reputation

Lawful interference with the right to privacy is permitted under Article 17 of the ICCPR, provided it is not arbitrary. In order for an interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the particular circumstances. The United Nations Human Rights Committee has interpreted the requirement of 'reasonableness' to imply that any interference with privacy must be proportional to the end sought and be necessary in the circumstances.

The scheme engages the right to protection against arbitrary and unlawful interferences with privacy by describing an approach that assumes protection of protected information (with penalties for inappropriate disclosure by entrusted persons) while also enabling disclosure in limited circumstances where this is reasonable and warranted.

Item 54 of this instrument corrects an error in the circumstances in which certain information (such as proper chemical name and end use) will be protected. Item 55 allows additional time for an applicant to make an application for information flagged under section 112 of the IC Act to be treated as confidential business information (and therefore not published).

These provisions will predominantly apply to business entities, while a small proportion of chemical introducers will conduct business as individuals. This instrument will operate to ensure that, for such individuals, privacy is only interfered with to the extent necessary to protect occupational health and safety, public health and the environment by the publication of information about risks associated with introduction and use of industrial chemicals, i.e. consistent with the right to health of all Australians.

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 Dr David Gillespie MP

Minister for Regional Health