

EXPLANATORY STATEMENT

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

Industrial Chemicals Act 2019

Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024

Purpose and operation

The purpose of this instrument is to make amendments to the Australian Industrial Chemicals Introduction Scheme (AICIS) by amending technical and operational details set out in the *Industrial Chemicals (General) Rules 2019* (General Rules).

The *Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024* (Amending Rules) amend the General Rules to:

- replace written undertaking record keeping requirements for listed, exempted and reported introductions to create more flexibility for introducers in meeting requirements and clarify and expand on the particular chemical names that introducers can use to meet reporting and record keeping requirements.
- amend certain record keeping requirements to be based on the circumstances of the introduction (i.e. which exposure band the introduction is in rather than the name by which the chemical is known to the introducer).
- amend existing requirements and include new provisions for certain industry sectors to address industry concerns and ensure risk proportionate requirements (e.g. small-scale soap manufacturers, hazardous chemicals used in controlled circumstances, and chemicals introduced in flavour/fragrance blends).
- ensure that introductions of industrial chemicals determined to have persistent organic pollutants characteristics cannot be categorised as reported or exempted.
- provide a new definition and term for ‘designated fluorinated chemical’ and clarify the existing definition for ‘biological chemical’ to avoid ambiguity.
- clarify that industrial chemicals containing certain chemical elements are in the highest human health hazard band, human health hazard band C.
- require introducers of exempted introductions to identify in their annual declarations the type of exempted introduction, to assist AICIS monitoring of introductions.
- make minor changes to clarify the intent of existing definitions (e.g. ‘particles’).
- refer to domestic thresholds of persistence, bioaccumulation and toxicity rather than the existing criteria in the Industrial Chemicals Categorisation Guidelines (Guidelines) in certain circumstances.

Background

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

The General Rules are made under the IC Act and form part of the legislative framework that establishes the risk-based regulatory scheme by setting out the technical and operational details of the AICIS.

The IC Act takes a risk-based approach to the regulation of industrial chemicals, where regulatory effort is proportionate to the indicative level of risk to human health and safety and the environment from the introduction and use of industrial chemicals.

Under the AICIS:

- Introducers are required to categorise introductions based on objective risk-based criteria set out in the General Rules made under the IC Act. The General Rules establish the technical and operational details of the AICIS and allow flexibility to adapt to scientific and regulatory developments within these objectives.
- Introducers are required to keep records about their introductions and meet any specific obligations based on the introduction category.

When AICIS commenced on 1 July 2020, replacing the former NICNAS, a transition period began, providing time for introducers to ensure compliance with the IC Act and delegated legislation. The transition period ended on 31 August 2022.

The amendments address industry feedback provided prior to the end of the transition period, that certain regulatory requirements are challenging to comply with, including obtaining written undertakings from the chemical identity holders, when chemical identity is confidential business information. The amendments also strengthen certain aspects of the Rules to ensure appropriate protection of human health and the environment and/or clarify the intent of certain requirements.

Authority

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.

In addition to the power to make this instrument under section 180 of the IC Act, subsection 33(3) of the Acts Interpretation Act 1901 provides that 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.

The Amending Rules are a legislative instrument for the purposes of the *Legislation Act 2003* and subject to disallowance under section 42 of that Act.

Consultation

These Amending Rules were the subject of significant consultation, including through explanatory webinars and published materials. During a public consultation period on an exposure draft of the Amending Rules, from 15 September 2023 to 9 November

2023, formal submissions were received from 44 stakeholders, including small-scale businesses, large companies, industry representatives and individuals.

The submissions informed refinement to the technical details of the proposals, as now set out in the Amending Rules.

Documents incorporated by reference

These Amending Rules incorporate the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (*Australian PBT Criteria*), as existing from time to time. The *Australian PBT Criteria* is a document published by the Department of Climate Change, Energy, the Environment and Water. The authority for this manner of incorporation is subsection 180(3) of the IC Act.

The meaning of technical terms (persistent, bioaccumulative and toxic) proposed to be used in the General Rules are described in the *Australian PBT Criteria*. This means that an introducer of industrial chemicals may need to refer to the *Australian PBT Criteria* when categorising particular industrial chemical introductions in order to understand the meanings of the relevant terms for categorisation.

The *Australian PBT Criteria* can be publicly and freely accessed at <https://www.dcceew.gov.au/>

These Amending Rules incorporate the International Fragrance Association (IFRA) Standards, as existing from time to time. The IFRA Standards ban, limit or set criteria for the use of certain fragrance ingredients. They are used within the rules as part of the criteria for a specific low risk introduction.

The IFRA Standards can be publicly and freely accessed at <https://ifrafragrance.org/>

Regulatory impact assessment

In relation to this assessment, the Office of Impact Analysis (OIA) determined that a detailed Impact Analysis is not required as the proposal is unlikely to result in more than minor impacts on individuals, businesses or community organisations (OIA24-06678).

Commencement

All provisions will commence on 24 April 2024.

Details

Details of the Amending Rules are set out in Attachment A.

Statement of Compatibility with Human Rights

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.

Details of the *Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024*

Section 1 Name of the Instrument

Section 1 states that the name of the instrument is the *Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024*.

Section 2 Commencement

All provisions will commence on 24 April 2024.

Section 3 Authority

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

Section 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Part 1 – Record keeping for listed introductions

Industrial Chemicals (General) Rules 2019

Item 1 – Section 5

Item 1 inserts a new definition in section 5 of the General Rules: *eligible INCI plant extract name*.

Eligible INCI plant extract names are a sub-set of INCI names. The term eligible INCI plant extract name is inserted in the General Rules to enable the eligible INCI plant extract name for an industrial chemical to be reported or kept as part of recording keeping requirements in certain circumstances. These circumstances are further described in the amendments below.

The inclusion of this new definition is consequential to broader changes being made across the General Rules to provide more options for record keeping for listed introductions and to replace most instances of the term ‘proper name of the industrial chemical’. These latter changes, further detailed at Part 2 (Reporting and record keeping for exempted and reported introductions), refine the legislative scheme to provide greater clarity and certainty for introducers in meeting reporting and record keeping requirements about the identity of industrial chemicals.

Item 2 – Subsection 46(1)

Item 2 repeals and substitutes a new subsection 46(1). Subsection 46(1) of the General Rules is made for the purposes of paragraph 104(2)(b) of the IC Act to prescribe the kinds of records that a person must keep in respect of listed introductions.

The changes to the requirements set out in new subsection 46(1):

- Expand the kinds of records that must be kept in the prescribed circumstances to provide more flexibility for chemical identity information for introducers. It includes:
 - the IUPAC name for the industrial chemical (refer items 1 and 2 of the table)
 - an eligible INCI plant extract name for the industrial chemical (refer item 3 of the table)
 - an AICIS approved chemical name (AACN) (refer item 4). This provides an option for an introducer who was the holder of (or covered by) an assessment certificate for an industrial chemical, where the identity of the chemical is confidential business information held by a third party, to keep the AACN of the industrial chemical as a record, rather than needing to obtain the CAS number and name of the chemical after it has been listed on the Inventory.
- Specify the kinds of records that must be kept in the circumstance where none of table items 1 to 4 apply to the introduction (i.e. the person does not know the chemical names included in tables items 1 to 4). In this circumstance (item 5) the person (introducer) must keep the records described in column 2 of the table. This includes:
 - (a) records that indicate the chemical is on the Inventory
 - (b) one of the matters set out in subitem (b) (i.e. the names by which the chemical is known to the introducer, the names of any products containing the industrial chemical that are imported into Australia by the introducer, or the name of the flavour blend or fragrance blend that the industrial chemical is to be introduced as part of)
 - (c) the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give to the Executive Director the CAS number (if assigned) for the industrial chemical and the CAS name or IUPAC name for the industrial chemical
 - (d) records of the basis on which the introducer holds that belief (i.e. why the introducer believes, on reasonable grounds, that the person named would give the required information if asked to do so).
- Improve consistency across like provisions to improve readability and interpretation of the requirements.
- Re-number existing table items 3, 4 and 5 to be new items 6, 7 and 8 to accommodate additions to the table.

New table item 5 provides a variation on current table item 2, which requires a written undertaking from the chemical identity holder that the CAS name and number (if assigned) for the industrial chemical will be given to the Executive Director if requested. The changes at items 1-5 provide more flexibility for introducers and addresses the challenges that have been experienced by introducers in obtaining written undertakings,

whilst ensuring that AICIS has access to adequate information to accurately identify the Inventory listing for a chemical.

New table item 5 thereby removes the need for a written undertaking but still requires the introducer to keep records of the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the required information. The introducer is also required to record the basis on which they hold that belief. For example:

- the introducer may record the name of the person who has emailed them stating that they hold the chemical identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.
- the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the chemical identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.

This change in approach to requirements in the General Rules that currently specify the need for a written undertaking are made consistently across the General Rules in respect of relevant record keeping requirements.

Consistent with similar provisions in the General Rules (e.g. see current subsection 46(4)), new subsection 46(1A) states that for the purposes of subsection 46(1) a person will be taken to know the CAS number or relevant chemical name if it would be reasonable for the person to find out that information. This ensures that introducers are proactive in ascertaining information that it would be reasonable for them to find out about the chemical introductions they intend to make. The Amending Rules insert this type of provision in relevant reporting and record keeping requirements across the General Rules to ensure a consistent standard of expectation.

Item 3 – Subsection 46(3) (table item 3, column 2, paragraph (b))

For the purposes of paragraph 104(2)(b) of the IC Act, subsection 46(3) of the General Rules prescribes alternative record keeping requirements for listed introductions of 10 kg or less of an industrial chemical. That is, if the total volume of the industrial chemical introduced by the person in the registration year does not exceed 10 kg, then the record keeping requirements in subsection 46(3) can apply (rather than those described in subsection 46(1)).

Column 1 of table item 3 specifies the circumstances in which the kinds of records that must be kept for listed introductions of 10 kg or less of an industrial chemical apply, i.e. if:

- (a) a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person (the introducer); and
- (b) neither the CAS name, IUPAC name nor INCI name for the industrial chemical is known to the introducer.

Column 2 specifies the kinds of records that must be kept in those circumstances.

Item 3 of the Amending Rules amends column 2 of table item 3 to replace paragraph (b) with a new paragraph (b) and to include a new paragraph (ba).

The effect of this change is to include an additional optional record keeping requirement that is specific to flavour or fragrance blend introductions, to create further flexibility for introducers and allow the name of the flavour blend or fragrance blend that the industrial chemical is to be introduced as part of to be kept (rather than the names by which the industrial chemical is known to the introducer, as is currently required).

Part 2 – Reporting and record keeping for exempted and reported introductions

Industrial Chemicals (General) Rules 2019

Part 2 of Schedule 1 to the Amending Rules makes various amendments to the General Rules to enable the current reference to ‘proper name for the industrial chemical’ to be replaced with more specific references to the:

- CAS name
- IUPAC name
- INCI name or eligible INCI plant extract name, as appropriate to the introduction type and circumstances of the introduction.

While ‘proper name’ is not a defined term in the industrial chemicals legislation, ‘CAS name’, ‘IUPAC name’ and ‘INCI name’ are, and the definition of ‘eligible INCI plant extract name’ is inserted by item 1 of the Amending Rules.

Various amendments to the General Rules are also made to replace written undertakings with other information, depending on the circumstance.

The changes refine the legislative scheme to provide greater clarity and certainty for introducers in meeting reporting and record keeping requirements under the General Rules. The added flexibility for introducers addresses the challenges that have been experienced by introducers in obtaining written undertakings and is more practical and reasonable for an introducer to obtain.

The changes to replace reference to ‘proper name’ are made in relation to reporting and record keeping for most exempted and reported introductions, except for internationally-assessed introductions, where the ‘proper name’ (or AACN) is published on the AICIS website (section 97(5) of the IC Act). The CAS name or IUPAC name for a chemical is generally provided in the specified kinds of assessments and evaluations conducted by international bodies.

Item 4 – Subsection 36(2) (table items 1 to 3)

Item 4 repeals and replaces table items 1 to 3 of subsection 36(2), which specifies the requirements for post-introduction declarations for exempted introductions where the highest indicative risk is very low risk.

Changes to subsection 36(2) achieved by the inclusion of new table items 1, 1A, 1B, 2 and 3 include:

- replacing references to the ‘proper name for the industrial chemical’ with the specific name that must be provided as part of the prescribed information (e.g. new table item 1 specifies that it is the CAS name or IUPAC name for the industrial chemical that must be provided in the post-introduction declaration if known to the person)
- providing that if neither the CAS name nor the IUPAC name for the industrial chemical is known to the person then new table items 1A or 1B could apply depending on the human health and environment exposure bands for the introduction – in these circumstances the person may instead be able to give the INCI name or the eligible INCI plant extract name where it is known to the person
- specifying in new table items 2 and 3 the information that must be provided in the post-introduction declaration if none of the names for the industrial chemical, as specified in table items 1 to 1B, are known to the person. While the reporting requirements for these items remain largely consistent with current table items 2 and 3, the items are redrafted to enable reference to the expanded list of chemical names that are included by new table items 1 to 1B. As per the current arrangements, the items apply based on whether the total volume of the industrial chemical introduced by the person during the registration year is 10 kg or less, or greater than 10 kg. That is:
 - Consistent with existing table item 2 and changes to replace references to ‘the proper name for the industrial chemical’ with more specific descriptions of the chemical name, if the total volume of the industrial chemical introduced by the person during the registration year is 10 kg or less, then the person must submit:
 - the names by which the industrial chemical is known to the introducer
 - the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give to the Executive Director the CAS number (if assigned) for the industrial chemical and the CAS name, IUPAC name or INCI name for the industrial chemical, and
 - the reasons why the introducer holds that belief (i.e. that the person named would give the required information – the introducer would draw this information from the records that they must hold about their introduction).
 - Consistent with existing table item 3 and changes to replace the proper name for the industrial chemical, if the total volume of the industrial chemical introduced by the person during the registration year is greater than 10 kg, then the person must submit:
 - the names by which the industrial chemical is known to the person, and
 - the name of the chemical identity holder who has provided to the Executive Director: the CAS number (if assigned) for the industrial chemical; and the CAS name, the IUPAC name or an eligible INCI plant extract name for the industrial chemical.

These changes ensure proportionate and risk-based regulation by balancing what is necessary information to be given to the Executive Director in the circumstances of the

introduction with a practical consideration of what is reasonable information for the introducer to know or to obtain.

Item 5 – Subsections 38(2), 39(2) and 40(2) (table)

Item 5 amends each of subsections 38(2), 39(2) and 40(2) regarding pre-introduction reports for reported introductions that are internationally-assessed for human health and/or the environment to replace all current references to the CAS name or the IUPAC name for the industrial chemical in the context of its proper name with an expanded reference that also includes an eligible INCI plant extract name. For example, the reference to the proper name for the industrial chemical as it currently appears in table item 1 will be amended to instead read “the proper name for the industrial chemical (including the CAS name, the IUPAC name or an eligible INCI plant extract name)”.

This change provides greater certainty for stakeholders as to the information to be provided as part of a pre-introduction report by clarifying that the eligible INCI plant extract name will be acceptable in the prescribed circumstances.

Item 6 – Subsection 41(2) (table items 1 and 2)

Item 6 repeals and replaces table items 1 and 2 in subsection 41(2), which describes, for the purposes of paragraph 97(2)(b) of the IC Act, information to be included in a pre-introduction report for a reported introduction of industrial chemicals used solely in research and development.

Consistent with other changes made by the Amending Rules, new table items 1, 1A and 2 replace references to ‘proper name’ to be more specific, enable the INCI name for the industrial chemical to be provided in certain circumstances, and maintain the current requirement in table item 2 (in the scenario that the introducer does not know the CAS name, IUPAC name, nor the INCI name for the chemical).

Item 7 – Subsection 42A(2) (table item 4, column headed “Prescribed information”, paragraph (d))

Item 7 amends table item 4 in subsection 42A(2) which describes, for the purposes of paragraph 97(2)(b) of the IC Act, information to be included in a pre-introduction report for a reported introduction of 10 kg or less of an industrial chemical.

The amendment aligns similar reporting and record keeping requirements across the General Rules to require introducers who do not know the specified chemical name for the industrial chemical they are proposing to introduce to record the name of the person who they believe on reasonable grounds could provide the required information if requested to do so, and the basis on which that belief is formed.

Item 8 – Subsection 43(2) (table items 1 to 4)

Item 8 repeals and replaces table items 1 to 4 in subsection 43(2) to align pre-introduction reporting requirements in the circumstances described in section 43 (for ‘other’ reported introductions where the highest indicative risk is low risk) with similar changes made to

other reporting provisions. This enables specification of information to be reported based on whether the person:

- knows the CAS name, IUPAC name or INCI name for the chemical (see new table items 1 and 1A)
- does not know any of those names for the chemical
 - in which case, the person must submit the names by which the industrial chemical is known to the person and the name of the chemical identity holder who has provided to the Executive Director: the CAS number (if assigned) for the industrial chemical; and the CAS name, the IUPAC name or - INCI name for the industrial chemical (see new table item 2 which has consistent requirements as existing table item 2 with greater specification of the chemical name).
- knows the CAS name or IUPAC name for the chemical (see new table item 3) or does not know the CAS name, IUPAC name or INCI name for the chemical (see new table item 4), and the chemical is a UVCB substance, and the relevant human health and environment exposure bands for the introduction are as described (i.e. either the human health exposure band for the introduction is 4 or the environment exposure band for the introduction is 3 or 4).

Consistent with other changes made by the Amending Rules, new table items 1, 1A, 2, 3 and 4 replace references to ‘proper name’ to be more specific. Notably, the changes enable the INCI name for the industrial chemical to be provided in certain circumstances.

Item 9 – Subsection 43(2) (table item 16)

Item 10 – At the end of section 43

Item 9 makes a minor change to table item 16 in subsection 43(2) to clarify that the requirement to report information about whether the information is a specified class of introduction to which subsection 7(2), (3) or (4) applied, and, if so, which such class applies if that information is known to the person.

Item 10 of the Amending Rules makes a related amendment to ensure that, for the purpose of table item 16, where it would be reasonably practicable for the person to find out that the introduction is such a class, the person is taken to know that the introduction is that class (see new subsection 43(4)).

Item 11 – Section 47

Item 11 repeals and replaces section 47 regarding record keeping for certain exempted introductions. This section is made for the purposes of paragraph 104(2)(b) of the Act.

New section 47 is about exempted introductions that are in accordance with subsection 26(2) – introductions that are imported and subsequently exported. In accordance with this section, records to be kept are specified depending on whether the CAS name, IUPAC name or INCI name for the industrial chemical is known to the person.

There are no changes to records relating to the categorisation of the chemical introduction, but rather to align with broader changes made across the General Rules in relation to information about the chemical identity. Changes made by the new section 47:

- replace references to ‘proper name for the industrial chemical’ with references to the specific name (i.e. CAS name, IUPAC name or INCI name)
- specify that where the introducer does not know the CAS number, CAS name, IUPAC name or INCI name for the industrial chemical but it would be reasonably practicable for the introducer to find out that information, the introducer is taken to know that number or name (see new subsection 47(3))
- provide that, if neither the CAS name, nor the IUPAC name, nor the INCI name, for the industrial chemical is known to the introducer, then records to be kept include the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give to the Executive Director the CAS number (if assigned) for the industrial chemical and the CAS name or IUPAC name for the industrial chemical; and the basis on which the introducer holds that reasonable belief. This replaces the current written undertaking requirement. For example: i) the introducer may record the name of the person who has emailed them stating that they hold the chemical identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email; or ii) the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the chemical identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.

Note that record keeping requirements for exempted introductions in accordance with subsection 26(5), (6) or (7) are included in a new section 49A (see item 27 of the Amending Rules).

Item 12 – Subsection 48(2) (heading)

Item 12 repeals and substitutes the subheading of subsection 48(2) to replace the current reference to ‘proper name’ with ‘certain names’, to guide the reader that matters in that subsection apply if certain names for industrial chemical are known to person.

Item 13 – Subsection 48(2)

Item 14 – Paragraph 48(2)(b)

Item 15 – Paragraph 48(2)(c)

Changes made to subsection 48(2) by items 13, 14 and 15 replace references to the ‘proper name’ for the industrial chemical with specific references to CAS name, IUPAC name or INCI name for the industrial chemical. This change is consistent with broader changes across the General Rules.

Item 16 – After subsection 48(2)

Item 16 inserts a new subsection 48(2A) to state, consistent with like provisions in the General Rules, that, for the purposes of subsection 48(2), if the person does not know the CAS number, CAS name, IUPAC name or INCI name for the industrial chemical but it

would be reasonably practicable for the person to find out that information, the person is taken to know that number or name.

Item 17 – Subsection 48(3)

Item 17 repeals and replaces subsection 48(3) to set out the record keeping requirements for exempted introductions that are introductions of industrial chemicals that are solely for research and development where certain names for the industrial chemical are not known to the introducer.

Changes made by the inclusions of a new subsection 48(3) include:

- replacing references to ‘proper name for the industrial chemical’ with references to the specific name (i.e. CAS name, IUPAC name or INCI name)
- replace written undertakings (as currently required by paragraphs (b), (c) and (ca))
- providing that, if the total volume of the industrial chemical introduced by the introducer in a registration year is greater than 10 kg, records to be kept include the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give to the Executive Director the CAS number (if assigned) for the industrial chemical and the CAS name or IUPAC name for the industrial chemical, and the basis on which the introducer holds that reasonable belief
- providing that, if the industrial chemical is a solid, or is in a dispersion, at the time of introduction and the total volume of the industrial chemical introduced by the introducer in a registration year is greater than 10 kg, records to be kept include:
 - the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give to the Executive Director records to demonstrate that the industrial chemical does not consist of solid particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale, and
 - records of the basis on which the introducer believes that the industrial chemical does not consist of solid particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale, and
 - records of the basis on which the introducer holds the belief that the person would give the Executive Director the records described.

For the purposes of paragraphs (b) and (d) - for example, i) the introducer may record the name of the person who has emailed them stating that they hold the required information, the type of information that they hold (such as a relevant study conducted on the industrial chemical) and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email; or ii) the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the information required, the type of information that they hold (such as a relevant study conducted on the industrial chemical) and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.

New subsection 48(3) does not include the legislative note directing the reader to the definition of ‘chemical identity holder’ in section 5 of the General Rules as this term is no longer used in subsection 48(3) as amended.

Item 18 – Paragraph 49(2)(a)

Item 18 replaces paragraph 49(2)(a) to ensure that if the person first introduces the industrial chemical before 1 July 2020, then the records to be kept are those specified in new subsection (2B) (as described in item 22 of the Amending Rules).

Item 19 – Paragraph 49(2)(b)

Item 20 – Paragraph 49(2)(c)

Changes made to subsection 49(2) by items 19 and 20 replace references to the ‘proper name’ for the industrial chemical with specific references to CAS number, CAS name, or IUPAC name for the industrial chemical. This change clarifies the record keeping requirements and is consistent with broader changes to the ‘proper name for the industrial chemical’ made across the General Rules.

Item 21 – Subsection 49(2) (note)

Item 21 repeals the note under subsection 49(2) which directs the reader to the definition of ‘chemical identity holder’ in section 5 of the General Rules, as this term is no longer used in subsection 49(2) as amended.

Item 22 – After subsection 49(2)

Item 22 inserts new subsections 49(2A), (2B) and (2C).

For the purposes of paragraph 49(2)(a) (as amended to reference new subsection 49(2B)), subsection (2B) specifies that the kinds of records for industrial chemicals first introduced before 1 July 2020 (that are exempted introductions of polymers that are comparable to listed polymers) are:

- the CAS name and CAS number for the listed polymer (within the meaning of subsection 26(4)), or
- if the introducer does not know the CAS name and CAS number for the listed polymer (within the meaning of subsection 26(4)):
 - the name by which the listed polymer is known to the introducer, and
 - the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give to the Executive Director the CAS name and CAS number (if assigned), and
 - the basis on which the introducer holds that reasonable belief. Consistent with like provisions, for example: i) the introducer may record the name of the person who has emailed them stating that they hold the chemical identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email; or ii) the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the chemical

identity and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.

Consistent with like provisions, new subsections 49(2A) (for the purposes of paragraphs 49(2)(b)) and 49(2C) (for the purposes of paragraph 49(2B)(a)) provide that if the person does not know the relevant chemical identity specified, but it would be reasonably practicable for the person to find out that information, the person is taken to know that information.

Item 23 – Subsection 49(3) (heading)

Item 27 repeals the current heading of subsection 49(3) and replaces it with ‘Industrial chemicals first introduced on or after 1 July 2020’.

This change sets up the new structure of the section, where the kinds of records prescribed for ‘industrial chemicals first introduced before 1 July 2020’ are set out in subsection 49(2B) and the kinds of records prescribed for ‘industrial chemicals first introduced on or after 1 July 2020’ are set out in subsection 49(3).

Item 24 – Subparagraph 49(3)(a)(ii)

Item 25 – Paragraph 49(3)(b)

Changes made to subsection 49(3) by items 24 and 25 clarify the record keeping requirements regarding chemical identity and specify the relevant chemical name for the industrial chemical consistent with broader changes to clarify and remove references to the ‘proper name for the industrial chemical’.

Item 26 – Subsection 49(4)

Item 26 replaces subsection 49(4) to specify, for the purposes of paragraph 49(2)(c), that the kinds of records to be kept (if the person first introduces the chemical on or after 1 July 2020 and neither the CAS number, nor the CAS name, nor the IUPAC name, for the industrial chemical is known to the person) are

- the names by which the industrial chemical is known to the introducer
- records to demonstrate that none of subsections 25(2) to (4) apply to the introduction
- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the following to the Executive Director:
 - records to demonstrate that the requirements of subsection 26(4) are being met
 - the CAS name or IUPAC name for the industrial chemical
 - the CAS number (if assigned) for the industrial chemicaland records of the basis on which the introducer holds this belief
- records of the basis on which the introducer believes that the requirements of subsection 26(4) are being met.
- records of the basis on which the introducer holds the belief mentioned in paragraph (c). For example, i) the introducer may record the name of the person who has emailed them stating that they hold the required information, the type of information

that they hold and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email; or ii) the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the information required, the type of information that they hold and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.

Item 27 – After section 49

Item 27 inserts, for purposes of paragraph 104(2)(b) of the Act, a new section 49A in the General Rules that sets out record keeping requirements if the exempted introduction is in accordance with subsection 26(5), (6) or (7).

Record keeping requirements for these types of exempted introductions are currently included in section 47 of the General Rules, however, item 11 of the Amending Rules replaces section 47 of the General Rules so that it now only deals with record keeping requirements if the exempted introduction is in accordance with subsection 26(2). Changes to split these requirements into two provisions improve readability of the General Rules.

Consistent with how other record keeping provisions are now structured, new section 49A sets out record keeping requirements if certain names for the industrial chemical are known to the person, and requirements to apply if certain names are not known to the person.

Clarifying or consequential changes are made to the existing requirements to and/or changes that are consistent with other provisions of the Amending Rules, for example:

- replace references to proper name with the certain chemical name (e.g. the CAS name, IUPAC name or eligible INCI plant extract name for the industrial chemical)
- update cross-references within the provision so that it applies to exempted introductions in accordance with subsection 26(5), (6) or (7), and not subsection (2) (as this is provided for in section 47 as amended)
- replace the need for written undertakings from the chemical identity holder to instead require records of the name of a person whom the introducer believes on reasonable grounds would give the relevant information (specified in new paragraphs (b) and (f)) to the Executive Director (if requested), and the basis on which the introducer holds that belief. For example, i) the introducer may record the name of the person who has emailed them stating that they hold the required information, the type of information that they hold and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email; or ii) the introducer may record the name of the person whom they have had a meeting with, where at that meeting, the person stated that they hold the information required, the type of information that they hold and that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the minutes from that meeting.
- consistent with like provisions, new subsection 49A(3) (for the purpose of subsection 49A(2)) provide that if the person does not know the relevant chemical identity

specified, but it would be reasonably practicable for the person to find out that information, the person is taken to know that information.

Item 28 – Subsection 50(2) (heading)

Item 28 aligns the heading of subsection 50(2) with other changes to the General Rules to instead read ‘certain names for industrial chemical known to person’.

Item 29 – Subsection 50(2)

Item 29 makes changes to clarify and prescribe the specific chemical name (i.e. the CAS name or IUPAC name) that the chapeau for subsection 50(2) refers to.

Item 30 – Paragraphs 50(2)(a) and (b)

Item 30 makes changes consistent with the change made by item 29, to remove the reference to ‘proper name’ and to include specific references to the chemical name in paragraphs 50(2)(a) and (b) (ensuring that the IUPAC name is also expressly referenced in subparagraph (a)(ii), where the CAS number is known to the person).

Item 31 – After subsection 50(2)

Item 31 inserts a new subsection 50(2A) consistent with similar provisions to provide that, for the purposes of paragraph 50(2)(a), a person will be taken to know the CAS number or relevant chemical name if it would be reasonable for the person to find out that information.

Item 32 – Subsection 50(3)

Item 32 repeals and replaces subsection 50(3) to prescribe, for the purposes of paragraph 104(2)(b) of the Act, the kinds of records that must be kept by an introducer if the introduction is an exempted introduction in accordance with subsection 26(8) of the General Rules, and they do not know either the CAS name or the IUPAC name for the industrial chemical.

The changes maintain the substance of the existing requirement but reframe it to apply changes being made consistently across the General Rules to, for example, remove and replace reference to ‘proper name’ with the relevant specific chemical name, and to replace written undertakings to instead require records of particular matters to be kept, including the basis on which the introducer believes the matters that are the subject of those records.

Item 33 – Subsections 51(2) and (3)

Item 33 repeals existing subsections 51(2) and (3), and replaces these with new subsections 51(2), (2A), (3), (3A) and (3B). These provisions set out, for the purposes of paragraph 104(2)(b) of the Act, record keeping requirements for exempted introductions where, in accordance with step 6 of the method statement in section 24, the highest indicative risk for the introduction is very low.

The changes made by item 33 reframe the record keeping requirements to focus on the exposure band of the introduction and not whether the person knows the ‘proper name’ for the industrial chemical.

- New subsection 51(2) sets out general record keeping requirements for all exempted introductions of this type and new subsection 51(3) sets out alternative requirements for introductions where the human health exposure band is 1 or 2 and the environment exposure band is 1. This replaces the current approach whereby subsection 51(2) describes records keeping requirements if the ‘proper name’ for the industrial chemical is known to the person and subsection 51(3) describes records keeping requirements if the ‘proper name’ for the industrial chemical is not known to the person. Table items in new subsection 51(2) and 51(3) provide for circumstances in which certain chemical identification information is or is not known to the introducer.
- A notable difference between table item 3 in new subsection 51(2) and 51(3) relates to holding of an eligible INCI plant extract name or INCI name (i.e. it depends on the exposure band for the introduction).

Other changes to subsections 51(2) and (3) are consistent with like changes across the record keeping requirements in the General Rules. For example, the changes made by item 33:

- replace references to ‘proper name for the industrial chemical’ with specific references to the relevant name for the industrial chemical (see new table items 1-3 in subsection 51(2) and 51(3))
- replace written undertakings (as currently required by subsection 51(3)) to instead require records of the name of a person whom the introducer believes on reasonable grounds would give the relevant information to the Executive Director (if requested), and the basis on which the introducer holds that belief (e.g. new table item 4 in subsections 51(2) and 51(3) regarding the name and CAS number of the chemical and new table item 6 in subsection 51(2) regarding the UVCB substance description of the industrial chemical). For new items 7, 10 and 24 in subsection 51(2), the introducer also needs to hold records of the basis on which the introducer believes specified elements related to the chemical introduction or categorisation of the chemical introduction to be true (such as based on information from the person who holds the information in an email or that is recorded in minutes of a meeting), e.g.
 - for item 7, the introducer may record the name of the person who has emailed them stating that the chemical meets the AICIS definition of a high molecular weight polymer and that they could give the AICIS Director records to demonstrate the polymer molecular weight details, if requested. As part of their records, the introducer should keep a copy of the email.
 - for item 24, the introducer may record the name of the person who has emailed them stating i) the outcomes of the information specified in the Guidelines to demonstrate the absence of any relevant hazard characteristics; ii) details of the type of information used to demonstrate the absence of hazard characteristics (such as OECD test guideline numbers, in silico models used); and iii) that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.
- set consistent expectations regarding information about the introduction that it would be reasonably practicable for the introducer to find out, such that the introducer is

taken to know that information in the circumstances described (see new subsections 51(2A), (3A) and (3B))

- include consequential amendments to ensure accurate cross-referencing of provisions as amended and to remove notes that reference defined terms no longer used in these subsections.

Item 34 – Subsection 51(4)

Item 34 makes a consequential amendment to the chapeau of subsection 51(4) to update cross-references to provisions of the General Rules amended by the Amending Rules. That is, the amendment removes the reference to the subsection being for the purposes of “item 22 of the table in subsections (2) and (3)...” and substitutes this with “item 25 of the table in subsection (2) and item 20 of the table in subsection (3).”.

Item 35 – Subsection 51(5)

Item 35 substitutes subsection 51(5) to align with like provisions in the Amending Rules. The change removes the existing requirement to keep a written undertaking and instead, where the introducer does not know the relevant information required to be kept under paragraph (5)(a), the introducer must keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the relevant information to the Executive Director; and
- the basis on which the introducer holds that belief.

Item 36 – Subparagraph 52(2)(a)(ii)

Item 37 – Paragraph 52(2)(b)

Item 38 – Paragraph 52(3)(c)

Item 39 – Subsection 52(3) (note)

Items 36 to 39 amend section 52 of the General Rules regarding record keeping for reported introductions of industrial chemicals that are internationally-assessed for human health and the environment.

Changes to remove references to ‘proper name’ (or to restructure record keeping on the basis that the introducer does or does not know the proper name for the chemical) are not made in relation to sections 52, 53 or 54 of the General Rules regarding record keeping in respect of internationally-assessed introductions. This is because, in the circumstance of internationally-assessed introductions, the ‘proper name’ (or AACN) is published on the AICIS website (section 97(5) of the IC Act). The CAS name or IUPAC name for a chemical is generally provided in the specified kinds of assessments and evaluations conducted by international bodies. Changes to these sections are therefore focused on increasing clarity by expanding the types of proper names that are expressly referenced in the General Rules for this purpose.

Item 36 makes minor changes to subparagraph 52(2)(a)(ii) to express that the proper name for the chemical in these circumstances includes not only the CAS name or INCI name but also the IUPAC name for the industrial chemical.

Item 37 makes minor changes to paragraph 52(2)(b) to replace the current reference to the CAS name or the IUPAC name for the industrial chemical in the context of its proper name, with an expanded reference that also includes an eligible INCI plant extract name.

Item 38 amends subsection 53(2) regarding internationally-assessed introductions where the proper name for the industrial chemical is not known to the introducer to replace paragraph (c). This change is consistent with others in the Amending Rules. The purpose of this change is to remove the requirement for a written undertaking from the chemical identity holder and to instead require records of:

- the name of another person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give to the Executive Director records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of the General Rules, and records of the basis on which the introducer holds that belief
- the basis on which the introducer believes that the introduction is not covered by any of those provisions.

Item 39 repeals the legislative note under subsection 52(3) directing the reader to the definition of ‘chemical identity holder’ in section 5 of the General Rules as this term is no longer used in subsection 52(3) as amended.

Item 40 – Subparagraph 53(2)(a)(ii)

Item 41 – Paragraph 53(2)(b)

Items 40 and 41 amend section 53 of the General Rules regarding record keeping for reported introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment.

Item 40 makes minor changes to subparagraph 53(2)(a)(ii) to express that the proper name for the chemical in these circumstances includes not only the CAS name or INCI name but also the IUPAC name for the industrial chemical.

Item 41 makes minor changes to paragraph 53(2)(b) to replace the current reference to the CAS name or the IUPAC name for the industrial chemical in the context of its proper name, with an expanded reference that also includes an eligible INCI plant extract name.

Item 42 – Paragraph 53(2)(i)

Item 43 – Paragraph 53(3)(c)

Item 44 – Paragraph 53(3)(h)

Item 45 – Subsection 53(5)

Consistent with other changes in the Amending Rules, the changes at items 42-45 replace written undertakings with other information requirements.

Item 42 repeals and replaces paragraph 53(2)(i) and item 44 repeals and replaces paragraph 53(3)(h). Subparagraphs (i) to (iii) mirror the current provisions. Changes to insert new subparagraphs (iv) to (vi) replace the existing requirement to keep a written

undertaking to instead require, in the circumstances described for the introduction, that the introducer keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give to the Executive Director detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics, and
- the basis on which the introducer holds the belief that the person recorded has that detailed information, and
- the basis on which the introducer holds the belief that the person recorded would, if requested to do so, give that detailed information to the Executive Director.

For example, the introducer may record the name of the person who has emailed them stating i) the outcomes of the information specified in the Guidelines to demonstrate the absence of any relevant hazard characteristics; ii) details of the type of information used to demonstrate the absence of hazard characteristics (such as OECD test guideline numbers, in silico models used); and iii) that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.

Item 43 replaces paragraph 53(3)(c) to replace the current requirement for a written undertaking to instead require records of a kind that are consistent with like provisions where the relevant name for the industrial chemical is not known to the person. That is, in the circumstances described for the introduction, records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give the Executive Director records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of the General Rules, and the basis on which the introducer holds that belief
- the basis on which the introducer believes that the introduction is not covered by any of those provisions described in the above point.

Item 45 replaces subsection 53(5) to replace the current requirement for a written undertaking and to instead require that if the introducer does not know the relevant information (referred to in paragraph 53(5)(a)), they must keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the relevant information to the Executive Director, and
- the basis on which the introducer holds that belief.

Item 46 – Subparagraph 54(2)(a)(ii)

Item 47 – Paragraph 54(2)(b)

Items 46 and 47 amend section 54 of the General Rules regarding record keeping for reported introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health. These are consistent with

the changes made by items 36 and 37, and also changes made by items 40 and 41 to include express reference to the IUPAC name for the industrial chemical in subparagraph 54(2)(a)(ii) and to the eligible INCI plant extract name for the industrial chemical in paragraph 54(2)(b).

Item 48 – Paragraph 54(2)(g)

Item 48 makes a consequential change to paragraph 54(2)(g) to include reference to ‘Item 1A’ of the table in subclause 1(1) of Schedule 1 to the General Rules (inserted by item 74, discussed below).

Item 49 – Paragraph 54(2)(j)

Item 49 replaces paragraph 54(2)(j) consistent with the changes to 53(2)(i) made by item 42 and to paragraph 53(3)(h) made by item 44.

Subparagraphs 54(2)(j)(i) to (iii) mirror the current provisions. Changes to insert new subparagraphs (iv) to (vi) replace the existing requirement to keep a written undertaking to instead require, in the circumstances described for the introduction, that the introducer keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give to the Executive Director detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics, and
- the basis on which the introducer holds the belief that the person recorded has that detailed information, and
- the basis on which the introducer holds the belief that the person recorded would, if requested to do so, give that detailed information to the Executive Director.

For example, the introducer may record the name of the person who has emailed them stating i) the outcomes of the information specified in the Guidelines to demonstrate the absence of any relevant hazard characteristics; ii) details of the type of information used to demonstrate the absence of hazard characteristics (such as OECD test guideline numbers, in silico models used); and iii) that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.

Item 50 – Paragraphs 54(3)(c) and (d)

Consistent with other changes in the Amending Rules, item 50 replaces paragraph 54(3)(c) to remove the current requirement for a written undertaking and to instead require that if the introducer does not know the proper name for the industrial chemical, they must keep a record of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give the Executive Director records to demonstrate that the introduction is not covered by any of the provisions of section 25, items 1 to 3 of the table in

subsection 28(1), or items 1 to 5 of the table in subsection 29(1) of the General Rules, and the basis on which the introducer holds that belief, and

- records of the basis on which the introducer believes that the introduction is not covered by any of those provisions described in the above point.

New paragraph 54(3)(d) is inserted to similarly replace the existing requirement for a written undertaking (in current paragraph 54(3)(d)) and to instead require that if the industrial chemical is a high molecular weight polymer and the human health exposure band for the introduction is 4, the introducer must keep records to demonstrate the polymer molecular weight details of the industrial chemical, or all of the following:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give the Executive Director records to demonstrate the polymer molecular weight details of the industrial chemical, and the basis on which the introducer holds that belief, and
- records of the basis on which the introducer believes that the industrial chemical is a high molecular weight polymer.

For example, the introducer may record the name of the person who has emailed them stating that the chemical meets the AICIS definition of a high molecular weight polymer and that they could give the AICIS Director records to demonstrate the polymer molecular weight details, if requested. As part of their records, the introducer should keep a copy of the email.

Item 51 – Paragraph 54(3)(f)

Item 51 makes a consequential change to paragraph 54(3)(f) to include reference to ‘Item 1A’ of the table in subclause 1(1) of Schedule 1 to the General Rules (inserted by item 74, discussed below).

Item 52 – Paragraph 54(3)(i)

Item 52 replaces paragraph 54(3)(i) consistent with the changes made by items 42, 44 and 49 (as described above).

Subparagraphs 54(3)(i)(i) to (iii) mirror the current provisions. Changes to insert new subparagraphs (iv) to (vi) replace the existing requirement to keep a written undertaking to instead require, in the circumstances described for the introduction, that the introducer keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request from the Executive Director, give to the Executive Director detailed information, including full study reports, of the kind specified in the Guidelines to demonstrate the absence of the hazard characteristics
- the basis on which the introducer holds the belief that the person recorded has that detailed information, and
- the basis on which the introducer holds the belief that the person recorded would, if requested to do so, give that detailed information to the Executive Director.

For example, the introducer may record the name of the person who has emailed them stating: i) the outcomes of the information specified in the Guidelines to demonstrate the absence of any relevant hazard characteristics; ii) details of the type of information used to demonstrate the absence of hazard characteristics (such as OECD test guideline numbers, in silico models used); and iii) that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.

Item 53 – Subsection 54(3) (note)

Item 53 repeals the legislative note under subsection 54(3) directing the reader to the definition of ‘chemical identity holder’ in section 5 of the General Rules as this term is no longer used in subsection 54(3) as amended.

Item 54 – Subsection 54(5)

Consistent with item 45, item 54 replaces subsection 54(5) to replace the current requirement for a written undertaking and to instead require that if the introducer does not know the relevant information (referred to in paragraph 54(5)(a)), they must keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the relevant information to the Executive Director, and
- the basis on which the introducer holds that belief.

Item 55 – Subsections 55(2) and (3)

Item 55 repeals subsection 55(2) and (3) and replaces with a new subsection (2).

Section 55 sets out record keeping requirements for the purposes of paragraph 104(2)(b) of the Act. If the reported introduction is in accordance with subsection 27(2) or (3) of the General Rules (introductions of industrial chemicals that are solely for use in research and development), then the records to be kept are as prescribed in the table in new subsection (2).

The new approach to including the records in a table enables consolidation of the current provisions (currently separated by whether or not the proper name is known to the person) and makes changes consistent to similar provisions across the General Rules to:

- replace references to proper name with the certain chemical names (the CAS name, IUPAC name or INCI name for the industrial chemical), while still enabling the name by which the industrial chemical is known to the person as per the pre-introduction report.
- update cross-references within the provision (to reflect the removal of subsection 55(3)).
- replace the need for written undertakings from the chemical identity holder to instead require records of the name of a person whom the introducer believes on reasonable grounds would give the relevant information (specified in new paragraphs (b)) to the Executive Director (if requested), and the basis on which the introducer holds that

belief. For example, i) the introducer may record the name of the person who has emailed them stating that they hold the required information, the type of information that they hold and that they could give the required information to AICIS, if requested.

- clarify that the nanoscale provisions in table item 4(b)(i) and (ii) of new subsection 55(2) apply to solid particles.

Item 56 – Subsection 57(2)

Item 56 repeals and replaces subsection 57(2) which, for the purposes of paragraph 104(2)(b) of the Act, sets out record keeping requirements for ‘other’ reported introductions where the highest indicative risk is low risk.

The new subsection replaces the current list approach with a table format consistent with like provisions (and to simplify reading of the legislation).

Item 56 largely retains the current record keeping requirements for this type of introduction but incorporates changes that are made consistently across like provisions in the General Rules.

For example, the changes made by item 56:

- replace the reference to ‘proper name for the industrial chemical’ with specific references to the relevant names for the industrial chemical
- replace written undertakings (as currently required in paragraphs 57(2)(d), (e) and (m)) to instead (new table items 4, 5 and 13) require records of the name of a person whom the introducer believes on reasonable grounds would give the relevant information to the Executive Director (if requested), and the basis on which the introducer holds that belief, plus records of the basis on which the introducer believes specified elements related to the chemical introduction or categorisation of the chemical introduction to be true (such as based on information from the person who holds the information in an email or that is recorded in minutes of a meeting), e.g.
 - for item 5, the introducer may record the name of the person who has emailed them stating that the chemical meets the AICIS definition of a high molecular weight polymer and that they could give the AICIS Director records to demonstrate the polymer molecular weight details, if requested. As part of their records, the introducer should keep a copy of the email.
 - for item 13, the introducer may record the name of the person who has emailed them stating i) the outcomes of the information specified in the Guidelines to demonstrate the absence of any relevant hazard characteristics; ii) details of the type of information used to demonstrate the absence of hazard characteristics (such as OECD test guideline numbers, in silico models used); and iii) that they could give the required information to AICIS, if requested. As part of their records, the introducer should keep a copy of the email.
- include consequential amendments to ensure accurate cross-referencing of provisions as amended and to remove notes that reference defined terms no longer used in subsection 57(2) (e.g. ‘chemical identity holder’).

Item 57 – Subsection 57(3)

Item 57 makes a consequential change to the chapeau in subsection 57(3) to update the current cross-reference to “paragraph (2)(n)” to instead reference “item 14 of the table in subsection (2)” (i.e. where item 56 as described above inserts a new subsection 57(2)).

Item 58 – Subsection 57(4)

Consistent with other amendments (such as items 45 and 54), item 58 replaces subsection 57(4) to replace the current requirement for a written undertaking and to instead require that if the introducer does not know the relevant information (referred to in paragraph 57(4)(a)), they must keep records of:

- the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give the relevant information to the Executive Director, and
- the basis on which the introducer holds that belief.

Part 3 – Manufactured soaps

Industrial Chemicals (General) Rules 2019

The changes in Part 3 apply a risk proportionate response to stakeholder feedback and operational experience of the regulation, to better enable small-scale soap makers to understand and meet their categorisation and associated obligations under the AICIS (by making the requirements specific to the introduction type and based on information that the introducer reasonably knows (or should have access to)) and by excluding some introductions under section 11 of the IC Act.

Item 59 – Section 14 (after the heading)

Subsection 11(4) of the IC Act enables the General Rules to specify that an introduction is an excluded introduction in the circumstances prescribed by the rules. Item 59 inserts a new subsection 14(1) in the General Rules that states the introduction will be an excluded introduction if the circumstances prescribed in either subsection 14(2) or (3) apply.

The effect of this change is to include a new circumstance in which the introduction of an industrial chemical will be an excluded introduction. The circumstance currently described in section 14 of the General Rules is maintained (in a new subsection (2) as per item 60) and a new circumstance relating to the introduction of manufactured soap is included as per new subsection (3) (as per item 61).

Item 60 – Section 14

Item 60 makes a minor technical and consequential change to enable the inclusion of subsections within existing section 14. It does not change the existing circumstance in which an introduction will be an excluded introduction as already described in that section. It simply amends the existing content to be a new subsection (2).

Item 61 – At the end of section 14

Item 61 amends current categorisation criteria to include a new circumstance, for the purpose of subsection 11(4) of the IC Act, in which an introduction of an industrial chemical will be an excluded introduction. The effect of this change is to enable the introduction of a manufactured soap chemical to be an excluded introduction in certain circumstances.

That is, new subsection 14(3) will apply to an introduction by a person if:

- (a) the introduction of the industrial chemical by the person occurs only by manufacture; and
- (b) the industrial chemical is manufactured by the person in a saponification reaction using:
 - (i) a fat or an oil; and
 - (ii) aqueous sodium hydroxide or aqueous potassium hydroxide; and
- (c) the fat or oil is listed on the Inventory; and
- (d) the total volume of the fat or oil used by the person to manufacture the industrial chemical in a registration year does not exceed 10 kg.

Item 62 – Subsection 26(1)

Item 63 – At the end of section 26

Items 62 and 63 provide for changes that include a new circumstance in which introductions are exempted introductions (i.e. the introduction of manufactured soaps).

Item 62 makes a consequential amendment to subsection 26(1) to ensure that section 26 covers the new circumstances in subsection (9). Item 69 sets out the new circumstance in a new subsection 26(9).

Item 63 amends current categorisation criteria to include a new circumstance, for the purposes of step 2 of the method statement in section 24 of the General Rules, in which an introduction of an industrial chemical will be an exempted introduction. The effect of this change is to enable the introduction of a manufactured soap chemical to be an exempted introduction in certain circumstances.

That is, new subsection 26(9) of the General Rules will apply to an introduction by a person if:

- (a) the introduction of the industrial chemical by the person occurs only by manufacture; and
- (b) the industrial chemical is manufactured by the person in a saponification reaction using:
 - (i) a fat or an oil; and
 - (ii) aqueous sodium hydroxide or aqueous potassium hydroxide; and
- (c) the total volume of the fat or oil used by the person to manufacture the industrial chemical in a registration year does not exceed 100 kg.

Item 64 – At the end of section 37

Section 37 of the General Rules provides, for the purposes of subsection 96A(3) of the Act, the circumstances in which a post-introduction declaration for an exempted introduction is not required.

Changes to section 37 are consequential to the inclusion of the new circumstance in section 26 of the General Rules (in which the introduction of a manufactured soap chemical in the circumstances prescribed will be an exempted introduction).

Item 64 inserts new paragraph 37(f) to specify that an introduction covered by subsection 26(9) of the Rules (i.e. regarding manufactured soap) is included in the list of excluded introductions for which a post-introduction declaration is not required.

Item 65 – After section 50

Item 65 inserts a new section 50A into Part 3 of Chapter 4 of the General Rules regarding record keeping for exempted introductions.

This change relates to the new circumstance in subsection 26(9) (see item 63) and prescribes, for the purposes of paragraph 104(2)(b) of the IC Act, the records relating to that exempted introduction in that registration year that must be kept by a person.

As specified in new subsection 50A(2), the records are:

- the names by which the fat or oil (mentioned in new subparagraph 26(9)(b)(i)) are known to the person, and
- records to demonstrate that the requirements specified in new subsection 26(9) are being met.

Part 4 – Low-risk flavour or fragrance blend introductions

Industrial Chemicals (General) Rules 2019

Item 66 – Subsection 27(1)

Item 66 inserts a consequential cross-reference to new subsection 27(4A) which is inserted by item 67 of the Amending Rules.

Section 27 sets out the circumstances in which an introduction is a reported introduction. This change means that, for the purpose of step 3 of the method statement in section 24 of the General Rules, the introduction of an industrial chemical is covered by section 27 if subsection (2), (3), (4), new subsection (4A) or subsection (6) of section 27 applies to the introduction.

Item 67 – After subsection 27(4)

Item 67 inserts a new subsection 27(4A) that builds on the circumstances in which an introduction of a low-risk flavour or fragrance blend is a reported introduction (i.e. the

existing circumstances in subsection 27(4) are retained and expanded on by the additional circumstances in new subsection 27(4A)).

New subsection (4A) states that the subsection will apply to the introduction of an industrial chemical if the introduction is either a flavour blend or a fragrance blend introduction, and if the matters in paragraphs (b) to (g) are true.

The new introduction circumstances as described in paragraphs (b) to (g) include:

- either:
 - the concentration of the industrial chemical at introduction and at end use is 1% or less and the total volume of the industrial chemical introduced by the person in a registration year does not exceed 1,000 kg, or
 - the total volume of the industrial chemical introduced by the person in a registration year does not exceed 10 kg
- the introduction is not for an end use in a personal vaporiser
- the industrial chemical is not known by the person to satisfy the criteria for any of the following hazard classes in the GHS:
 - germ cell mutagenicity
 - carcinogenicity
 - reproductive toxicity, and
- the industrial chemical is not known by the person to be a persistent, bioaccumulative and toxic (within the meaning set out in new subsection 27(8) – item 87 of the Amending Rules), and
- the industrial chemical is not known by the person to cause adverse effects mediated by an endocrine mode of action, and
- either:
 - when the pre-introduction report for the industrial chemical is given to the Executive Director by the person, the industrial chemical is included on the IFRA Transparency List, or
 - before the industrial chemical is first introduced by the person, the Executive Director is given written notice of the information specified in subsection (5) (as amended by items 68 and 69 of the Amending Rules), and
- the use of the industrial chemical is in accordance with any applicable IFRA Standards published by the International Fragrance Association (also known as the IFRA), as existing from time to time.

The information in paragraph (g) is consistent with the information in paragraph (e) of current subsection 27(4). The 'IFRA Transparency List' is defined in the General Rules. The note below subsection 27(4A) directs the reader to where the IFRA Standards can be freely accessed and viewed.

Item 68 – Subsection 27(5)

Item 68 makes a consequential change to ensure the matters set out in subsection 27(5) apply for the purposes of both subparagraph (4)(e)(ii) and (4A)(g)(ii) regarding low-risk flavour or fragrance blend introductions that are reported introductions.

Item 69 – Paragraph 27(5)(a)

Item 69 replaces paragraph 27(5)(a) regarding information to be provided for certain low-risk flavour or fragrance blend introductions, to remove the reference to ‘proper name’ and to instead specify the name for the chemical is the CAS name, the IUPAC name or an eligible INCI plant extract name for the industrial chemical. It also specifies ‘the CAS number (if assigned) for the industrial chemical’ in a separate paragraph for clarity and consistency in drafting.

Item 70 – Section 42

Item 70 repeals and replaces section 42 which, for the purposes of paragraph 97(2)(b) of the Act, sets out the information to be included in a pre-introduction report. Replacing section 42 in this way enables the section to prescribe reporting requirements in relation to introductions that are in accordance with either subsection 27(4) or (4A).

While retaining a number of the existing requirements, substituting section 42 enables changes to be made that ensure consistency across reporting and record-keeping provisions to, for example:

- replace references to ‘proper name for the industrial chemical’ with references to the specific names, and to specify what information must be reported depending on the chemical identity information that is known to the introducer (e.g. see new table items 2, 3 and 4)
- provide that if neither the CAS name, nor the IUPAC name nor the eligible INCI plant name extract for the industrial chemical is known to the introducer, then the report must include the name of a person whom the introducer believes on reasonable grounds would, if requested to do so by the introducer following a request by the Executive Director, give to the Executive Director that information; and the basis on which the introducer holds that reasonable belief (see new table item 4), such as based on information from the person who holds the information in an email or that is recorded in minutes of a meeting, e.g. the introducer may indicate in their pre-introduction report the name of the person who has emailed them stating that they hold the identity of the chemicals in the blend and that they could give the AICIS Director this information, if requested. As part of their report, the introducer should indicate that they hold an email from the person who holds the identity of the chemical.
- specify that where the introducer does not know the CAS number, CAS name, IUPAC name or eligible INCI plant extract name for the industrial chemical but it would be reasonably practicable for the introducer to find out that information, the introducer is taken to know that number or name (see new subsection 42(3))

As a consequence of combining the prescribed pre-introduction reporting requirements for introductions made under subsections 27(4) and (4A), table item 5 requires a statement as to which subsection applied to the introduction. Table item 6 requires a declaration that the requirements of whichever subsection the introduction is being made under are being met.

The amended section 42 also removes the existing requirement for the pre-introduction report to include a statement as to which of the circumstances regarding use of animal test

data (as described in current subsection 42(3)) applies to the introduction of an industrial chemical that is to be introduced for an end use in cosmetics. This current requirement does not provide AICIS with meaningful information for the purposes of a pre-introduction report for the introduction of a chemical meeting the low-risk flavour or fragrance blend introduction criteria, as test data is not required to determine that an introduction can be a low-risk flavour or fragrance blend introduction.

Subsection 42(4) continues to clarify that a person may prepare a single pre-introduction report for all the industrial chemicals in a flavour blend or a fragrance blend that are to be introduced in accordance with subsection 27(4) or (4A).

Item 71 – Section 56

Item 71 repeals and substitutes section 56 to set out the record keeping requirements for low-risk flavour or fragrance blend introductions that are in accordance with subsection 27(4) or (4A).

New subsection 56(2) sets out requirements for introductions in accordance with subsection 27(4) and new subsection 56(3) sets out requirements for introductions in accordance with subsection 27(4A).

The changes to record keeping requirements in section 56 are made consistent with the changes to reporting requirements described at item 70 for reported introductions of this type.

Substituting section 56 enables changes made to reporting and record keeping provisions across the General Rules to be applied here also (e.g. to replace references to ‘proper name’ and to remove written undertakings in favour of records about the basis on which an introducer holds a belief about a particular matter etc.).

Paragraph (e) of subsection 56(2) requires the introducer to keep a record of why they believe the requirements of subsection 27(4) have been met, the name of a person whom the introducer believes on reasonable grounds would give the relevant information to the Executive Director (if requested) to demonstrate that requirements have been met, and the basis on which the introducer holds that belief (such as based on information from the person who holds the information in an email or that is recorded in minutes of a meeting), e.g. the introducer may record the name of the person who has emailed them stating that they hold the relevant information about the chemicals in the blend, the relevant criteria that are met in subsection 27(4) (including that the industrial chemical does not have any of the human health hazard characteristics in human health hazard band C or any of the hazard characteristics in environment hazard band D, clause 2 and clause 4 of Schedule 1 of the General Rules), and that they could give the AICIS Director the information to demonstrate that the requirements have been met, if requested. As part of their records, the introducer should indicate that they hold an email from the person who holds the identity of the chemical.

Part 5 – Controlled use circumstances

Industrial Chemicals (General) Rules 2019

Item 72 – Section 5 (definition of consumer end use)

Item 72 repeals the current definition of consumer end use in section 5 of the General Rules as the meaning of this term will now be included in Schedule 1 (regarding exposure bands and hazard bands that enable categorisation of an industrial chemical introduction) – refer item 78.

Item 73 – Subsection 43(2) (after table item 9)

Item 73 inserts a new table item 9A to provide that if item 1A of the table in subclause 1(1) of Schedule 1 to the General Rules applies to the introduction, then the pre-introduction report for that reported introduction must include details of the control measures referred to in paragraphs 1A(d), (e) and (f).

Item 74 – Subclause 1(1) of Schedule 1 (after table item 1)

Item 74 inserts a new item 1A in the table in subclause 1(1) of Schedule 1 to the General Rules setting out the human health exposure bands for the introduction of an industrial chemical.

This change responds to industry feedback regarding introductions of industrial chemicals with hazard characteristics in the highest hazard bands for human health or the environment that are currently categorised as an assessed introduction, regardless of whether exposure is controlled or not.

The intent of this change is for some further consideration of controlled use circumstances by amending the human health exposure bands for the introduction of an industrial chemical in Part 1 of Schedule 1 to the Rules to add an additional circumstance. Controlled exposure to the environment is not a part of this consideration.

New item 1A provides a series of requirements relating to exposure (use, volume and control measures), including that the introduction does not involve a designated kind of human exposure (as defined in subclause (2)) and is not for any consumer end use (as defined in new subclauses (3) and (4) (refer item 78)).

The concept of control measures as described in new paragraph 1A(d) involves eliminating or minimising exposure of persons to the industrial chemical during introduction and use (either via isolation of the chemical or through engineering controls (including a mechanical device or process)).

The effect of this change is to shift the introduction of certain non-consumer end use chemicals with known human health hazard band C characteristics from human health exposure band 2 to human health exposure band 1. This change enables categorisation of the introduction as reported rather than as assessed, provided the indicative environment risk is low or very low.

Item 75 – Subclause 1(1) of Schedule 1 (table item 2, column headed “If...”, paragraph (c))

Item 76 – Subclause 1(1) of Schedule 1 (table items 4 to 6, column headed “If...”, paragraph (c))

Items 75 and 76 make consequential changes to table items 2, 4, 5 and 6 in subclause 1(1) of Schedule 1 to include references to new item 1A. These table items establish the relevant human health exposure band for relevant introductions, and inserting cross-references to item 1A maintains the exclusivity of the introductions described in the table.

Item 77 – Subclause 1(1) of Schedule 1 (note)

Item 77 amends the note under the table in subclause 1(1) to remove the reference to there being a definition of consumer end use in section 5 of the General Rules. This is subsequent to the repeal of the definition in section 5 where the meaning of the term will now be included in new subsections in clause 1 itself (refer item 78).

Item 78 – At the end of clause 1 of Schedule 1

Item 78 inserts new subclauses (3) and (4) in clause 1 of Schedule 1 to the General Rules that provide a meaning of consumer end use for the purposes of the human health hazard bands in subclause 1(1).

New subclause (3) provides that consumer end use, for an industrial chemical, means an end use for the industrial chemical that involves making the industrial chemical available to the general public:

- (a) on its own; or
- (b) in combination with one or more other industrial chemicals; or
- (c) as part of an article (other than where the industrial chemical undergoes a chemical change to produce the article).

New subclause (4) inserts an avoidance of doubt provision to clarify that the following end uses involve making the industrial chemical available to the general public:

- (a) an end use that involves using the industrial chemical in an inhabited residential building;
- (b) an end use that involves using the industrial chemical (either on its own or in combination with one or more other industrial chemicals) in an area that is accessible to the general public before the chemical has been rendered unavailable for human exposure.

Part 6 – Persistent organic pollutants

Industrial Chemicals (General) Rules 2019

Item 79 – Subsection 25(2)

Item 79 repeals existing subsection 25(2) of the General Rules and replaces it with new subsections (2) and (2A) regarding the introduction of industrial chemicals that are subject to an international agreement or arrangement etc.

The method statement at section 24 of the General Rules enables a person to determine if an introduction is exempted or reported. These provisions specify circumstances in which introductions are covered by section 25 and are therefore not exempted or reported (for the purpose of step 1 of the method statement in section 24).

Subject to subsection (2A) (described below), new paragraph (2)(a) continues to provide that section 25 applies to introductions of industrial chemicals that are listed in:

- Annex III to the Rotterdam Convention, or
- Part 1 of Annex A, B or C to the Stockholm Convention.

The introduction described in existing subsection 25(2) (which will be new paragraph 25(2)(a)) is of chemicals that have been listed in the Rotterdam or Stockholm Conventions and for which action has not yet been taken to restrict the chemicals in Australia. Note that once a decision has been made to restrict these chemicals (for example, through a ratification process) these chemicals will be listed in section 71, 72 or 73 of the General Rules, and be subject to the requirements under Part 9 of the Act.

New paragraphs (2)(b) and (c) expand on these Conventions to also include introductions of industrial chemicals that:

- (b) the Persistent Organic Pollutants Review Committee (within the meaning of the Stockholm Convention) has decided that it is satisfied that the screening criteria specified in Annex D of that Convention have been fulfilled in relation to the industrial chemical; or
- (c) the Executive Director is satisfied:
 - (iii) as a result of deciding whether or not to issue an assessment certificate for the industrial chemical; or
 - (iv) based on an evaluation under Part 4 of the Act relating to the introduction of the industrial chemical;that the screening criteria specified in Annex D of the Stockholm Convention have been fulfilled in relation to the industrial chemical.

The intent of these amendments is to address potential gaps in the categorisation of introductions that could currently enable introductions of chemicals with Persistent Organic Pollutants (POPs) characteristics to be categorised as exempted or reported.

This recognises that the process of listing chemicals with POPs characteristics in Annexes A to C to the Stockholm Convention consists of several steps subsequent to the Persistent Organic Pollutants Review Committee being satisfied that the chemical fulfills the screening criteria in Annex D to the Stockholm Convention, and that these steps can be lengthy. It also enables decisions of the Executive Director in relation to assessment certificates or evaluations to interact with the screening criteria specified in Annex D of the Stockholm Convention in a way that is consistent with the international response to certain chemicals.

The effect of this, subject to new subsection (2A), is that the introduction of such chemicals would not be categorised as exempted or reported and instead typically be assessed.

New subsection (2A) specifies that subsection (2) does not apply to the introduction of an industrial chemical introduced solely for use in research or analysis purposes, provided that the total volume introduced by the person in a registration year does not exceed 100 kg. This subsection maintains the current position in existing paragraphs (2)(c) and (d) to acknowledge the distinct nature and limited scale of research or analysis activities involving smaller quantities of chemicals.

Part 7 – Designated fluorinated chemicals

Industrial Chemicals (General) Rules 2019

Item 80 – Section 5

Item 80 inserts new definitions in the General Rules for the terms designated fluorinated chemical and fluorinated carbon atom.

A designated fluorinated chemical will be defined in the General Rules to mean an industrial chemical that contains a sequence of atoms (whether linear, branched or cyclic) to which all of the following paragraphs apply:

- (a) subject to paragraph (b), the sequence consists only of at least 4, but no more than 20, fluorinated carbon atoms, none of which are fluorinated carbon atoms that are part of conjugated double bonds;
- (b) if the sequence is broken in any place, the break consists only of a single atom or single substituted atom;
- (c) the sequence includes at least one perfluorinated methyl group (CF₃) or perfluorinated methylene group (CF₂).

As the term fluorinated carbon atom is used in the definition of designated fluorinated chemical, a definition of fluorinated carbon atom is also inserted into the General Rules. The new definition provides that a fluorinated carbon atom means a carbon atom attached to at least one fluorine atom.

The term designated fluorinated chemical will be used to replace three current references in the General Rules to “an industrial chemical that contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms” (refer to changes made by items 81-83).

Including the definition of designated fluorinated chemical in the General Rules clarifies the types of fluorinated chemicals that would warrant an AICIS assessment and approval before being introduced into Australia, to maintain protection of humans and the environment. The types of fluorinated chemicals that would be captured by the definition is more closely aligned with regulatory approaches on fluorinated chemicals by overseas jurisdictions.

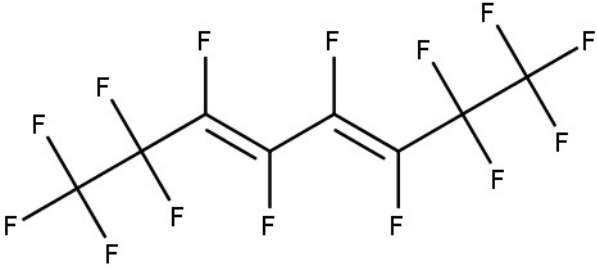
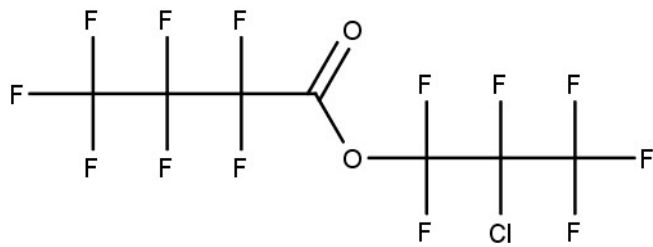
For the avoidance of doubt, the following images describe chemical structures that are or are not designated fluorinated chemicals for the purpose of the General Rules.

Examples of chemicals that meet the definition of designated fluorinated chemical

Chemical	Reasons why the chemical meets the definition
<p style="text-align: center;">CAS RN 2106-55-0</p>	<ul style="list-style-type: none"> • Chemical contains a cyclic sequence of 6 fluorinated carbon atoms
<p style="text-align: center;">CAS RN 13846-22-5</p>	<ul style="list-style-type: none"> • Chemical contains a sequence of 7 fluorinated carbon atoms • The fluorinated carbon atoms on the double bonds are part of the sequence of fluorinated carbon atoms because the double bonds are not conjugated • Both ether linkages are single atom breaks in the sequence, so the fluorinated carbon atoms on either side of these breaks are counted as part of the sequence
<p style="text-align: center;">CAS RN 958445-44-8</p>	<ul style="list-style-type: none"> • Chemical contains a sequence of 6 fluorinated carbon atoms • The “CFH” carbon atom is part of the sequence of fluorinated carbon atoms • Both ether linkages are single atom breaks in the sequence, so the fluorinated carbon atoms on either side of

	these breaks are counted as part of the sequence
--	--

Examples of chemicals that do not meet the definition of designated fluorinated chemical

Chemical	Comments
 <p>CAS RN 105311-63-5</p>	<ul style="list-style-type: none"> • Chemical contains a sequence of 2 fluorinated carbon atoms • Sequence is broken by fluorinated carbon atoms that are part of conjugated double bonds
 <p>CAS RN 67135-90-4</p>	<ul style="list-style-type: none"> • Chemical contains a sequence of 3 fluorinated carbon atoms • Sequence is broken by more than a single atom or single substituted atom

Item 81 – Paragraph 7(3)(e)

Item 82 – Subsection 28(1) (table item 1, column headed “If...”)

Item 83 – Subsection 29(1) (table item 1, column headed “If...”)

Items 81, 82 and 83 make a consistent amendment to various provision across the General Rules to remove the current description of an industrial chemical that “contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms” to instead refer to an industrial chemical that “is a designated fluorinated chemical” in line with the new definition inserted by item 80 of the Amending Rules.

Part 8 – Human health hazard band C

Industrial Chemicals (General) Rules 2019

Item 84 – Clause 2 of Schedule 1 (before table item 1)

Item 84 inserts new table item 1AA in Clause 2 of Schedule 1 to the General Rules to provide that if the industrial chemical has the following human health hazard characteristic, then the human health hazard band that applies to the hazard characteristic is C:

- is an inorganic arsenic compound; or
- contains beryllium, cadmium, chromium (VI), lead or nickel.

Chemicals described by item 84 are well established to be of high concern for human health toxicity. Their insertion into human health hazard band C will provide improved clarity for introducers and assist with the categorisation of industrial chemical introductions.

Part 9 – Annual declarations

Industrial Chemicals (General) Rules 2019

Item 85 – After paragraph 44(c)

Item 85 inserts a new paragraph (d) in section 44 regarding the annual declaration that introducers make regarding their introductions for the registration year.

The amendment expands on the current requirement in paragraph 44(b), which requires information more generally about the categories of introduction for the industrial chemicals introduced by the person during a registration year, to also require information about the type of exempted introductions made by the person (if any exempted introductions were made).

This change provides AICIS with more specific information about the types of exempted introductions made by an introducer, which enables improved compliance monitoring and more appropriate targeting of audits.

Part 10 – Persistent, bioaccumulative and toxic chemicals

Industrial Chemicals (General) Rules 2019

Item 86 – Paragraph 27(6)(f)

Item 86 makes a consequential amendment to paragraph 27(6)(f) of the General Rules to provide that “the industrial chemical is not known by the person to be persistent, bioaccumulative and toxic” with the meaning of new subsection 27(8) rather than within the meaning given by the Guidelines (refer item 87).

Item 87 – At the end of section 27

Item 87 adds a new subsection (8) at the end of section 27 (regarding reported introductions of 10 kg or less of an industrial chemical). This amendment inserts a new meaning for the term ‘persistent, bioaccumulative and toxic’ into the General Rules (rather than the current reference to the meaning given by the Guidelines).

The new meaning is drawn from a document called the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (Australian PBT Criteria), which provides the meaning for each of the terms persistent, bioaccumulative and toxic. The incorporation of these definitions simplifies the requirements and ensures the use of consistent domestic thresholds.

The document is published by the Department of Climate Change, Energy, the Environment and Water and can be readily and freely accessed on their website at: <https://www.dcceew.gov.au/>

The Australian PBT Criteria may be updated from time to time and the General Rules (as amended) provide for any future amendment to, or version of, the document to be automatically incorporated so as to reference the most current meaning of the Australian PBT Criteria.

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

Part 11 – Particles

Industrial Chemicals (General) Rules 2019

Item 88 – Subparagraph 27(6)(d)(ii)

Item 88 of Schedule 1 to the Amending Rules amends subparagraph 27(6)(d)(ii) of the General Rules to make a minor clarifying amendment for consistency with like provisions to replace the words “any of which” with the words “where any of the particles”. It also replaces the first instance of the word “particles” with “solid particles” for the same reasons described for item 89.

Item 89 – Amendments of listed provisions—particles

Item 89 makes changes to a series of provisions that use the term particle to instead read solid particle. These changes clarify that these provisions only apply to solid particles. The following provisions will be amended:

- subparagraph 7(3)(c)(ii);
- paragraph 26(3A)(a);
- subparagraph 26(8)(c)(ii);
- subparagraph 27(2)(b)(i);
- subparagraph 27(3)(b)(ii);
- subsection 28(1) (table items 3 and 7, column headed “If...”, subparagraph (a)(ii));
- subsection 29(1) (table items 3 and 10, column headed “If...”, subparagraph (a)(ii));
- subsection 41(2) (table item 5A, column headed “Prescribed information”);
- paragraph 48(2)(da).

The equivalent amendment has also been made in section 55 of the General Rules (refer to item 55 of the Amending Rules).

Part 12 – Biological chemicals

Industrial Chemicals (General) Rules 2019

Item 90 – Section 5 (definition of biological chemical)

Item 90 repeals the existing definition of biological chemical and inserts a new definition that provides that a biological chemical means an industrial chemical that is:

- (a) derived from a living or once-living organism, without further modification; or
- (b) produced by a living or once-living organism, without further modification.

While the existing definition of biological chemical is consistent with the policy intent, the new definition further clarifies that intent and reduces any ambiguity or potential misinterpretation that a chemical produced by a living organism that is then chemically modified could meet the existing definition.

Part 13 – Application provisions

Industrial Chemicals (General) Rules 2019

Item 91 – In the appropriate position in Chapter 8

Item 91 inserts a new Part 2 in Chapter 8 of the General Rules to provide for the application of the changes made by the Amending Rules.

The new part is called ‘Application provisions relating to the Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024’.

New section 82 sets out definitions to support interpretation of Part 2, including the meaning of the ‘amending instrument’ (as per the title of the Part) and that the commencement day means “the day the amending instrument commences”.

New section in General Rules	Provisions of General Rules amended	Application of the change
83 – Record keeping for listed introductions	Subsection 46(1) (as made by Part 1 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
84 – Reporting and record keeping for exempted and reported introductions	Amendments to Chapter 3 (as made by Part 2 of Schedule 1 to the Amending Rules)	Changes apply in relation to a declaration made under section 96A of the Act, a report given under section 97 of the Act, or a report varied under section 98 of the Act on or after the commencement day.
84 – Reporting and record keeping for exempted and reported introductions	Amendments to Chapter 4 (as made by Part 2 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.

85 – Manufactured soaps	Sections 14 and 26 (as made by Part 3 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
86 – Low-risk flavour or fragrance blend introductions	Sections 27, 42 and 56 (as made by Part 4 of Schedule 1 to the Amending Rules)	Changes to subsection 27(4A) and section 56 apply in relation to an introduction of an industrial chemical on or after the commencement day. Changes to section 42 apply in relation to a report given under section 97 of the Act, or varied under section 98 of the Act, on or after the commencement day.
87 – Controlled use circumstance	Provisions amended by Part 5 of Schedule 1 to the Amending Rules	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
88 – Persistent organic pollutants	Subsection 25(2) (as made by Part 6 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
89 – Designated fluorinated chemicals	Section 5 (as made by Part 7 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
90 – Human health hazard band C	Item 1AA of the table in clause 2 of Schedule 1 (as made by Part 8 of Schedule 1 to the Amending Rules)	Changes apply in relation to an introduction of an industrial chemical on or after the commencement day.
91 – Annual declarations	Section 44 (as made by Part 9 of Schedule 1 to the Amending Rules)	Changes apply in relation to a declaration made under section 99 of the Act on or after the commencement day.

Statement of Compatibility with Human Rights

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

Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024

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 *Industrial Chemicals (General) Amendment (2024 Measures No. 1) Rules 2024* (Amending Rules) make amendments to the General Rules to:

- replace written undertaking record keeping requirements for listed, exempted and reported introductions to create more flexibility for introducers in meeting requirements and clarify and expand on the particular chemical names that introducers can use to meet reporting and record keeping requirements.
- amend certain record keeping requirements to be based on the circumstances of the introduction (i.e. which exposure band the introduction is in rather than the name by which the chemical is known to the introducer).
- amend existing requirements and include new provisions for certain industry sectors to address industry concerns and ensure risk proportionate requirements (e.g. small-scale soap manufacturers, hazardous chemicals used in controlled circumstances, and chemicals introduced in flavour/fragrance blends).
- ensure that introductions of industrial chemicals determined to have persistent organic pollutants characteristics cannot be categorised as reported or exempted.
- provide a new definition and term for ‘designated fluorinated chemical’ and clarify the existing definition for ‘biological chemical’ to avoid ambiguity.
- clarify that industrial chemicals containing certain chemical elements are in the highest human health hazard band, human health hazard band C.
- require introducers of exempted introductions to identify in their annual declarations the type of exempted introduction, to assist AICIS monitoring of introductions.
- make minor changes to clarify the intent of existing definitions (e.g. ‘particles’).

- refer to domestic thresholds of persistence, bioaccumulation and toxicity rather than the existing criteria in the Industrial Chemicals Categorisation Guidelines (Guidelines) in certain circumstances.

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. Article 12(1) of the ICESCR makes provision in relation to the right to health, specifically the right to the enjoyment of the highest attainable standard of physical and mental health. Article 12(2)(b) includes the improvement of all aspects of environmental hygiene as a step to be taken to achieve the full realisation of the right to health. In its *General Comment No 14 (August 2000)*, the United Nations Committee on Economic Social and Cultural Rights states that this encompasses the prevention and reduction of the population's exposure to harmful substances such as harmful chemicals or other detrimental environmental conditions that directly or indirectly impact upon human health (at [15]).

The Amending Rules amend the General Rules to make a range of risk-based regulatory changes that continue to improve the operation of the Scheme. For example, the changes increase certainty and provide clarity for introducers regarding the information they are required to report or keep records of regarding the chemical identity of the industrial chemicals they introduce. These changes respond to stakeholder feedback regarding information that it is reasonable for introducers of industrial chemicals to know and keep as records about whilst ensuring the regulation maintains appropriate risk-based protections for human health and the environment.

Changes are made consistently across the General Rules in respect of very low and low risk introductions to ensure that where a person (introducer or proposed introducer) does not know the required type of chemical name for the industrial chemical they must instead provide, or keep records of, the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give the relevant information to the Executive Director, and the basis on which the introducer holds that belief.

The Amending Rules also amend the General Rules to ensure appropriate risk-based categorisation of chemical introductions and proportionate regulation in the related requirements for reporting and record keeping. The amendments make the criteria clearer and easier to comply with. Having clear criteria for streamlined introduction pathways (reported and exempted introductions) could encourage the introduction of newer and safer chemical products for consumers.

Further changes made by the Amending Rules increase protections for human health and the environment by addressing potential gaps, for example, changes that are designed to

ensure that introductions of chemicals determined to have persistent organic pollutant characteristics cannot be categorised as reported or exempted in most circumstances.

The combine effect of these changes is to improve the operation of the Scheme and promote the continued protection of human health and the environment. For these reasons, the Amending Rules are consistent with the right to health in Article 12(1) of the ICESCR.

Right to Privacy

Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home or correspondence, and protects a person's honour and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. 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 circumstances. The United Nations Human Rights Committee has interpreted the requirement of 'reasonableness' as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances. While the United Nations Human Rights Committee has not defined 'privacy', the term is generally understood to comprise freedom from unwarranted and unreasonable intrusions into activities that society recognises as falling within the sphere of individual autonomy.

The Amending Rules amend the General Rules to require a person to keep records or provide certain information to the Executive Director in compliance with the regulation of industrial chemical introductions. In certain circumstances, where a person (introducer or proposed introducer) does not know the required type of chemical name for the industrial chemical they must instead provide, or keep records of, the name of a person whom the introducer believes on reasonable grounds would, if requested to do so, give the relevant information to the Executive Director, and the basis on which the introducer holds that belief. Requiring persons to keep records and/or to provide certain information or documents may incidentally require the provision of personal information. The collection, use, storage, and disclosure of personal information may engage the right to freedom from arbitrary or unlawful interference with privacy.

The collection of this information in the specific circumstances described in the General Rules (as amended) is necessary for the legitimate objective of regulating the introduction of industrial chemicals.

For these reasons, this limitation to the right to privacy is reasonable, necessary and proportionate to achieve legitimate objectives and is consistent with the right to privacy in Article 17 of the ICCPR.

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