

Consultation on amendments to the Industrial Chemicals (General Rules)

Open 23 August 2021 to 17 September 2021





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Consultation on amendments to the General Rules

Consultation open until 17 September 2021

About this consultation

After the first year of operation of the AICIS, a number of minor operational issues have been identified which require amendments to the details set out in these Ministerial Rules. These issues have been identified both by the regulated industry and by staff within the Office of Chemical Safety (OCS) implementing the scheme.

We are proposing targeted amendments to the Industrial Chemicals (General Rules) 2019 and the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 to clarify the operation of the Ministerial Rules within existing policy. The proposed amendments relate to the following matters:

- industrial chemicals introduced at the nanoscale
- declarations about data ownership
- annual declarations
- record-keeping for listed introductions, specified classes, designated releases to the environment, internationally-assessed
- movement of industrial chemicals into or out of Australia
- transitional provisions

These changes address stakeholder feedback we've received asking for more clarity within the Ministerial Rules. They also fix some minor errors and omissions. They are consistent with decisions made when AICIS was implemented last year, and would assist industry by making compliance requirements clearer.

We explain the proposed amendments below.



Except where indicated otherwise, amendments would take effect when the Minister makes the new Rules.

Part 1 – Requirements for industrial chemicals introduced at the nanoscale

Schedule 1, Clause 1 of the Exposure Draft

Reason for proposed amendment

The proposed amendments are to the definition of specified classes of introductions, in particular to the criteria for introductions at the nanoscale. They would improve clarity for introducers on how these criteria apply in practice. (There is no actual change to criteria proposed.)

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion mean that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.

Proposed amendments are in red under 'Proposed Rule'.

Current Rule	Proposed Rule
7. Specified classes of introduction. (1) An introduction of an industrial chemical is a specified class of introduction if subsection (2), (3) or (4) applies to the introduction. (3) For the purposes of subsection (1), this	7. Specified classes of introduction. (1) An introduction of an industrial chemical is a specified class of introduction if subsection (2), (3) or (4) applies to the introduction. (3) For the purposes of subsection (1), this subsection applies to the following classes of



subsection applies to the following classes of introductions:

- (a) introductions of an industrial chemical that is a biochemical;
- (b) introductions of an industrial chemical that is a GM product;
- (c) introductions of an industrial chemical that:
 - (i) is a solid or is in a dispersion; and
 - (ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale;

introductions:

- (a) introductions of an industrial chemical that is a biochemical;
- (b) introductions of an industrial chemical that is a GM product;
- (c) introductions of an industrial chemical that:
 - (i) is a solid, or is in a dispersion, **at the time of introduction** ; and
 - (ii) consists of 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;

Schedule 1, Clauses 2, 3 and 4 of the Exposure Draft

Reason for proposed amendment

These proposed amendments are for research and development introductions (nanoscale) in the exempted introduction category. They would improve clarity for introducers on how these criteria apply in practice. (There is no actual change to criteria proposed.)

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion mean that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.
3. The lower volume limits for research and development would apply in either of the following circumstances:
 - a. the industrial chemical meets the nanoscale criteria; or
 - b. it has not been determined at the time of introduction if it meets the nanoscale criteria.

This clarifies that an introducer would not need to have carried out tests to see if a chemical meets the nanoscale criteria if they are introducing for research and development purposes at a volume up to 10 kg (exempted introductions).



4. The lower volume limit would apply if any of the industrial chemical introduced in the registration year meets the nanoscale criteria.

Current Rule	Proposed Rule
<p>26 Circumstances in which introductions are exempted introductions</p> <p>(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of sub-sections (2) to (8) of this section apply to the introduction.</p> <p>.....</p> <p>Introduction of industrial chemicals that are solely for use in research and development</p> <p>(3) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the introduction of the industrial chemical is:</p> <p>(i) solely for the industrial chemical to be used in research and development by the person; or</p> <p>(ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely in research and development; and</p> <p>(b) the industrial chemical is not made available to the general public:</p> <p>(i) on its own; or</p> <p>(ii) in combination with one or more other industrial chemicals; or</p> <p>(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and</p> <p>(c) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:</p> <p>(i) persons involved in the research and development for which the industrial</p>	<p>26 Circumstances in which introductions are exempted introductions</p> <p>(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.</p> <p>.....</p> <p>Introduction of industrial chemicals that are solely for use in research and development</p> <p>(3) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the introduction of the industrial chemical is:</p> <p>(i) solely for the industrial chemical to be used in research and development by the person; or</p> <p>(ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely in research and development; and</p> <p>(b) the industrial chemical is not made available to the general public:</p> <p>(i) on its own; or</p> <p>(ii) in combination with one or more other industrial chemicals; or</p> <p>(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and</p> <p>(c) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:</p> <p>(i) persons involved in the research and development for which the industrial chemical is introduced; and</p> <p>(ii) the environment; and</p>



chemical is introduced; and
(ii) the environment; and

- (d) the total volume of the industrial chemical introduced in a registration year by the person does not exceed:
- (i) if the industrial chemical is an industrial chemical that is a solid or is in a dispersion and consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale—10 kg; or
 - (ii) otherwise—250 kg.

(d) the total volume of the industrial chemical introduced in a registration year by the person does not exceed:

- (i) if subsection (3A) applies to the industrial chemical—10 kg; or**
- (ii) otherwise, and subject to subsection (3B)—250 kg.**

(3A) This section applies to an industrial chemical if:

- (a) the industrial chemical is a solid, or is in a dispersion, at the time of introduction and it consists of 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; or**
- (b) it had not been determined, at the time of introduction, whether the industrial chemical meets the description in paragraph (a).**

(3B) Subparagraph (3)(d)(ii) does not apply to the introduction of an industrial chemical by a person in a registration year if an amount of the industrial chemical to which paragraph (3A)(a) applies has been introduced by the person in the registration year.

Schedule 1, Clause 5 of the Exposure Draft

Reason for proposed amendment

These proposed amendments relate to non-functionalised surface treatment of listed chemicals in the exempted introduction category.

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion means that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.



2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.

Current Rule	Proposed Rule
<p>26 Circumstances in which introductions are exempted introductions</p> <p>(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.</p> <p>.....</p> <p><i>Introduction of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals</i></p> <p>(8) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the industrial chemical is the result of a reaction between 2 or more chemicals where the reaction occurs at the surface of one of the chemicals (the substrate chemical); and</p> <p>(b) the substrate chemical and each of the other chemicals that reacts with the substrate chemical is listed on the Inventory; and</p> <p>(c) the industrial chemical is not an industrial chemical that:</p> <p>(i) is a solid or is in a dispersion; and</p> <p>(ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and</p> <p>(d) the industrial chemical does not have any reactive functional groups that were not present on the substrate chemical.</p>	<p>26 Circumstances in which introductions are exempted introductions</p> <p>(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.</p> <p>.....</p> <p><i>Introduction of industrial chemicals resulting from non-functionalised surface treatment of listed industrial chemicals</i></p> <p>(8) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the industrial chemical is the result of a reaction between 2 or more chemicals where the reaction occurs at the surface of one of the chemicals (the substrate chemical); and</p> <p>(b) the substrate chemical and each of the other chemicals that reacts with the substrate chemical is listed on the Inventory; and</p> <p>(c) the industrial chemical is not an industrial chemical that:</p> <p>(i) is a solid, or is in a dispersion, at the time of introduction; and</p> <p>(ii) consists of 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</p> <p>(d) the industrial chemical does not have any reactive functional groups that were not present on the substrate chemical.</p>



Schedule 1, Clauses 6 and 7 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are for industrial chemicals introduced at a low volume solely for research and development in the reported introduction category.

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion means that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.
3. The lower volume limits for research and development would apply in circumstances where:
 - a. the industrial chemical meets the nanoscale criteria; or
 - b. you have not determined at the time of introduction if the chemical meets the nanoscale criteria.

This clarifies that an introducer does not need to have carried out the tests to determine if a chemical meets the nanoscale criteria. This applies if you are making a reported category introduction only for research and development at volumes 100kg or less.

Current Rule	Proposed Rule
<p>27 Circumstances in which introductions are reported introductions</p> <p>(1) For the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p>Introduction of industrial chemicals at the nanoscale that are solely for use in research and development</p>	<p>27 Circumstances in which introductions are reported introductions</p> <p>(1) For the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p><i>Low volume introductions of industrial chemicals that are solely for use in research and development</i></p>



(2) This subsection applies to the introduction of an industrial chemical by a person if:

(a) the introduction of the industrial chemical is:

(i) solely for the industrial chemical to be used in research and development by the person; or

(ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely in research and development; and

(b) the industrial chemical is an industrial chemical that:

(i) is a solid or is in a dispersion; and

(ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and

(c) the industrial chemical is not made available to the general public:

(i) on its own; or

(ii) in combination with one or more other industrial chemicals; or

(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and

(d) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:

(i) persons involved in the research and development for which the industrial chemical is introduced; and

(ii) the environment; and

(e) the total volume of the industrial chemical introduced in a registration year by the person is greater than 10 kg and less than or equal to 100 kg.

(2) This subsection applies to the introduction of an industrial chemical by a person if:

(a) the introduction of the industrial chemical is:

(i) solely for the industrial chemical to be used in research and development by the person; or

(ii) solely for the purposes of making the industrial chemical available to another person for that other person to use solely in research and development; and

(b) either:

(i) the industrial chemical is a solid, or is in a dispersion, **at the time of introduction** and it consists of 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; or

(ii) it had not been determined, at the time of introduction, whether the industrial chemical meets the description in subparagraph (i); and

(c) the industrial chemical is not made available to the general public:

(i) on its own; or

(ii) in combination with one or more other industrial chemicals; or

(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and

(d) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:

(i) persons involved in the research and development for which the industrial chemical is introduced; and

(ii) the environment; and

(e) the total volume of the industrial chemical introduced in a registration year by the person is greater than 10 kg and less than or equal to 100 kg



Schedule 1, Clauses 8, 9 and 10 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are for industrial chemicals introduced for research and development (other than nanoscale) in the reported introduction category.

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion means that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.
3. This reported introduction type (with higher volume allowed) would not apply if **any** of the industrial chemical introduced in the registration year meets the nanoscale criteria.

Current Rule	Proposed Rule
<p>27 Circumstances in which introductions are reported introductions</p> <p>(1) For the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p>.....</p> <p><i>Introduction of industrial chemicals (other than at the nanoscale) that are solely for use in research and development</i></p> <p>(3) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the introduction of the industrial chemical is solely for the industrial chemical to be used in research and development by the person (the introducer); and</p>	<p>27 Circumstances in which introductions are reported introductions</p> <p>(1) For the purposes of step 3 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p>.....</p> <p><i>Other introductions of industrial chemicals that are solely for use in research and development</i></p> <p>(3) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the introduction of the industrial chemical is solely for the industrial chemical to</p>



(b) the industrial chemical is not an industrial chemical that:

(i) is a solid or is in a dispersion; and

(ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and

(c) the industrial chemical is not made available to the general public:

(i) on its own; or

(ii) in combination with one or more other industrial chemicals; or

(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and

(d) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:

(i) persons involved in the research and development for which the industrial chemical is introduced; and

(ii) the environment; and

(e) the total volume of the industrial chemical introduced in a registration year by the introducer is greater than 250 kg; and

(f) the use of the industrial chemical is subject to the control of the introducer.

be used in research and development by the person (the introducer); and

(b) the industrial chemical is not an industrial chemical that:

(i) is a solid or is in a dispersion **at the time of introduction**; and

(ii) consists of 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

(c) the industrial chemical is not made available to the general public:

(i) on its own; or

(ii) in combination with one or more other industrial chemicals; or

(iii) as part of an article, including where the industrial chemical undergoes a physical or chemical change to produce the article; and

(d) control measures are used to eliminate or minimise the risks from the introduction and use of the industrial chemical to:

(i) persons involved in the research and development for which the industrial chemical is introduced; and

(ii) the environment; and

(e) the total volume of the industrial chemical introduced in a registration year by the introducer is greater than 250 kg **and no amount of the industrial chemical that meets the description in subparagraph (2)(b)(i) has been introduced by the person in the registration year**; and

(f) the use of the industrial chemical is subject to the control of the introducer.



Schedule 1, Clauses 11 and 12 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are to clarify the nanoscale criteria for determining the indicative human health risk of an introduction.

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion means that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.

Current Rule	Proposed Rule
28 Indicative human health risk for introduction of an industrial chemical (1) For the purposes of step 4 of the method statement in section 24, the following table sets out the indicative human health risk for the introduction of an industrial chemical.	28 Indicative human health risk for introduction of an industrial chemical (1) For the purposes of step 4 of the method statement in section 24, the following table sets out the indicative human health risk for the introduction of an industrial chemical.



Indicative human health risk for an introduction

Item	If ...	the indicative human health risk for the introduction is ...
------	--------	--

Medium to high risk

.....
3	(a) the industrial chemical is an industrial chemical that: (i) is a solid or is in a dispersion; and (ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical	medium to high risk

Indicative human health risk for an introduction

Item	If ...	the indicative human health risk for the introduction is ...
------	--------	--

Medium to high risk

.....
3	(a) the industrial chemical is an industrial chemical that: (i) is a solid or is in a dispersion, at the time of introduction ; and (ii) consists of 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 (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical	medium to high risk



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

Low risk

- | Item | Description | Risk Level |
|------|--|------------|
| 7 | (a) the industrial chemical is an industrial chemical that:
(i) is a solid or is in a dispersion; and
(ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and
(b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and
(c) none of table items 1 to 5 apply to the introduction | low risk |

Low risk

- | Item | Description | Risk Level |
|------|--|------------|
| 7 | (a) the industrial chemical is an industrial chemical that:
(i) is a solid or is in a dispersion, at the time of introduction ; and
(ii) consists of 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
(b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and
(c) none of table items 1 to 5 apply to the introduction | low risk |



Schedule 1, Clauses 13 and 14 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are to clarify the nanoscale criteria for determining the indicative environment risk of an introduction.

What the proposed amendments mean

These proposed amendments make it clearer that:

1. The criteria for an industrial chemical being a solid or in dispersion means that it is **introduced** as a solid or in a dispersion. These criteria wouldn't apply if, for example, an industrial chemical exists as a solid in its raw form, but you introduce it dissolved in a liquid.
2. The number size distribution percentage criterion relates to the particles. This would apply regardless of whether they are in an unbound state or as an aggregate or agglomerate.

Current Rule	Proposed Rule
<p>29 Indicative environment risk for introduction of an industrial chemical</p> <p>(1) For the purposes of step 5 of the method statement in section 24, the following table sets out the <i>indicative environment risk</i> for the introduction of an industrial chemical.</p>	<p>29 Indicative environment risk for introduction of an industrial chemical</p> <p>(1) For the purposes of step 5 of the method statement in section 24, the following table sets out the <i>indicative environment risk</i> for the introduction of an industrial chemical.</p>



Indicative environment risk for an introduction			Indicative environment risk for an introduction		
Item	If ...	the indicative environment risk for the introduction is ...	Item	If ...	the indicative environment risk for the introduction is ...
Medium to high risk			Medium to high risk		
.....
3	(a) the industrial chemical is an industrial chemical that: <ul style="list-style-type: none"> (i) is a solid or is in a dispersion; and (ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not incidental to the introduction of the non-nanoscale portion of the industrial chemical	medium to high risk	3	(a) the industrial chemical is an industrial chemical that: <ul style="list-style-type: none"> (i) is a solid or is in a dispersion, at the time of introduction; and (ii) consists of 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 (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) the introduction of the nanoscale portion of the industrial chemical is not	medium to high risk



Australian Government

Department of Health

Australian Industrial Chemicals Introduction Scheme

.....	incidental to the introduction of the non-nanoscale portion of the industrial chemical
Low risk			
....	
10	(a) the industrial chemical is an industrial chemical that: (i) is a solid or is in a dispersion; and (ii) consists of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) none of table items 1 to 5 apply to the introduction	low risk	
.....	
.....	
Low risk			
....	
10	(a) the industrial chemical is an industrial chemical that: (i) is a solid or is in a dispersion, at the time of introduction; and (ii) consists of 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 (b) the industrial chemical is not soluble (within the meaning given by the Guidelines); and (c) none of table items 1 to 5 apply to the introduction	low risk	
.....	
.....	



Schedule 1, Clauses 15 and 16 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are to clarify the record keeping requirements related to the nanoscale criteria for exempted introductions introduced solely for research and development.

What the proposed amendments mean

These proposed amendments complement the proposed changes to the criteria in subsection 26(3) and would align the record keeping requirements in section 48 for exempted introductions that are introduced solely for research and development, with the requirements in section 55 for reported introductions that are introduced solely for research and development.

Current Rule	Proposed Rule
<p>48 Introductions of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(3).</p> <p>Note: Subsection 26(3) deals with introductions of industrial chemicals that are solely for use in research and development.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the person knows the proper name for the industrial chemical, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p> <p>(d) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;</p> <p>(e) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.</p> <p>.....</p>	<p>48 Introductions of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with subsection 26(3).</p> <p>Note: Subsection 26(3) deals with introductions of industrial chemicals that are solely for use in research and development.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the person knows the proper name for the industrial chemical, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p> <p>(d) records to demonstrate that none of subsections 25(2) to (4) of this instrument apply to the introduction;</p> <p>(da) 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 person in a</p>



Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(c) a written undertaking from the chemical identity holder that:

- (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;

(d) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.

registration year is greater than 10 kg—records to demonstrate that the industrial chemical does not consist of 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;

(e) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(c) a written undertaking from the chemical identity holder that:

- (i) none of subsections 25(2) to (4) of this instrument apply to the introduction; and
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;

(ca) 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 person in a registration year is greater than 10 kg—a written undertaking from the chemical identity holder that:

- (i) **the industrial chemical does not consist of 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**
- (ii) **the records to demonstrate this will be provided to the Executive Director if requested;**



(d) records to demonstrate that the requirements of subsection 26(3) of this instrument are being met.

Schedule 1, Clauses 15 and 16 of the Exposure Draft.

Reason for proposed amendment

The proposed amendments are to clarify the record keeping requirements related to the nanoscale criteria for reported introductions introduced solely for research and development.

What the proposed amendments mean

These proposed amendments complement the proposed changes to subsections 27(2) and 27(3) which clarified the nanoscale criteria.

Current Rule	Proposed Rule
<p>55 Introduction of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(2) or (3).</p> <p>Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p> <p>(d) if the industrial chemical is a solid or is in a dispersion and the total volume of the industrial chemical introduced by the person in a registration year is greater than 100 kg—records to demonstrate that the industrial</p>	<p>55 Introduction of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(2) or (3).</p> <p>Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p> <p>(d) 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 person in a registration year is greater than 100 kg—records to</p>



chemical does not consist of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(c) if the industrial chemical is a solid or is in a dispersion and the total volume of the industrial chemical introduced by the person in a registration year is greater than 100 kg—a written undertaking from the chemical identity holder that:

- (i) the industrial chemical does not consist of particles in an unbound state or as an aggregate or agglomerate, at least 50% (by number size distribution) of which have at least one external dimension in the nanoscale; and
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;

.....

demonstrate that the industrial chemical does not consist of 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;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(c) 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 person in a registration year is greater than 100 kg—a written undertaking from the chemical identity holder that:

- (i) the industrial chemical does not consist of 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
- (ii) the records to demonstrate this will be provided to the Executive Director if requested;

.....



Part 2 – Pre-introduction reporting requirements for industrial chemicals introduced at the nanoscale

Schedule 1, Clause 20 of the Exposure Draft

Reason for proposed amendment

The proposed amendments are to clarify the pre-introduction reporting requirements related to the nanoscale criteria for reported introductions introduced solely for research and development.

What the proposed amendments mean

These proposed amendments complement the proposed changes to subsections 27(2) and 27(3) which clarified the nanoscale criteria.

Date of effect

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

Current Rule	Proposed Rule
<p>41 Introductions of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(2) or (3).</p> <p>Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>41 Introductions of industrial chemicals that are solely for use in research and development</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is a reported introduction in accordance with subsection 27(2) or (3).</p> <p>Note: Subsections 27(2) and (3) deal with introductions of industrial chemicals that are solely for use in research and development.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>



Pre-introduction reports for reported introductions of industrial chemicals that are solely for use in research and development		Pre-introduction reports for reported introductions of industrial chemicals that are solely for use in research and development	
Item	Prescribed information	Item	Prescribed information
....
5	Whether the industrial chemical is to be introduced as a solid, in a dispersion or neither	5	Whether the industrial chemical is to be introduced as a solid, in a dispersion or neither
....	5A	If the industrial chemical is introduced by the person as a solid or in a dispersion—whether the industrial chemical is known to the person to consist of 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
	

Schedule 1, Clause 21 of the Exposure Draft

Reason for proposed amendment

The proposed amendments are to clarify the pre-introduction reporting requirements related to the nanoscale criteria for reported introductions where the highest indicative risk is low risk.

What the proposed amendments mean

These proposed amendments complement the proposed changes to subsections 28(1) and 29(1) which clarified the nanoscale criteria.

Date of effect

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



Current Rule	Proposed Rule																						
<p>43 Other introductions where the highest indicative risk is low risk</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical is a reported introduction by a person in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>43 Other introductions where the highest indicative risk is low risk</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical is a reported introduction by a person in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>																						
<table><tr><th colspan="2">Pre-introduction reports for reported introductions where the highest indicative risk is low risk</th></tr><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>....</td><td>.....</td></tr><tr><td>6</td><td>Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia</td></tr><tr><td>.....</td><td>.....</td></tr></table>	Pre-introduction reports for reported introductions where the highest indicative risk is low risk		Item	Prescribed information	6	Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia	<table><tr><th colspan="2">Pre-introduction reports for reported introductions where the highest indicative risk is low risk</th></tr><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>....</td><td>.....</td></tr><tr><td>6</td><td>Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia</td></tr><tr><td>6A</td><td>If the industrial chemical is to be introduced as a solid, in a dispersion or neither</td></tr><tr><td>.....</td><td>.....</td></tr></table>	Pre-introduction reports for reported introductions where the highest indicative risk is low risk		Item	Prescribed information	6	Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia	6A	If the industrial chemical is to be introduced as a solid, in a dispersion or neither
Pre-introduction reports for reported introductions where the highest indicative risk is low risk																							
Item	Prescribed information																						
....																						
6	Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia																						
.....																						
Pre-introduction reports for reported introductions where the highest indicative risk is low risk																							
Item	Prescribed information																						
....																						
6	Whether the industrial chemical is: (a) imported; or (b) manufactured in Australia																						
6A	If the industrial chemical is to be introduced as a solid, in a dispersion or neither																						
.....																						



Part 3 – Declaration about data ownership

Schedule 1, Clause 22 of the Exposure Draft

Reason for proposed amendment

Adding clarity about the data permissions an introducer has in place for exempted introductions where the highest indicative risk is very low.

What the proposed amendments mean

Introducers would have to declare they have ownership, or the permission to use, the data when categorising their introduction as exempted. By 'data', we mean what you have used to demonstrate the absence of hazard characteristics. In the legal text this is referred to as 'information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard'.

This new declaration requirement would serve as a checkpoint for introducers to make sure they have appropriate permission to use the data they've relied on.

This proposed change is in response to:

- issues we've found during compliance audits around permissions. This relates to introducers submitting a pre-introduction report for a reported category introduction, when they don't have the appropriate data owner permission. This is likely to also happen with PIDs
- a need to align the declarations for PIDs with those for certificate applications, since all of these involve the use of data for market entry. Certificate applications already include a declaration about data ownership
- a need to fulfil Australia's obligations under the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals.

Date of effect

As these proposed amendments require changes to the online forms they would only apply to post-introduction declarations submitted on or after 10 December 2021.

PIDs for the period 1 July 2020-31 August 2021 will not have this amendment in the declaration.



Current Rule	Proposed Rule																				
<p>36 Post-introduction declarations for exempted introductions</p> <p>(3) This section applies for the purposes of paragraph 96A(2)(b) of the Act.</p> <p><i>Introductions where highest indicative risk is very low risk</i></p> <p>(3) If the introduction is an exempted introduction in accordance with step 6 of the method statement in section 24, the information mentioned in an item of the following table is prescribed.</p>	<p>36 Post-introduction declarations for exempted introductions</p> <p>(3) This section applies for the purposes of paragraph 96A(2)(b) of the Act.</p> <p><i>Introductions where highest indicative risk is very low risk</i></p> <p>(4) If the introduction is an exempted introduction in accordance with step 6 of the method statement in section 24, the information mentioned in an item of the following table is prescribed.</p>																				
<table><tr><th colspan="2">Post-introduction declarations for exempted introductions where highest indicative risk is very low</th></tr><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>.....</td><td>.....</td></tr><tr><td>6</td><td>The maximum concentration of the industrial chemical at end use</td></tr><tr><td>7</td><td>If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction</td></tr></table>	Post-introduction declarations for exempted introductions where highest indicative risk is very low		Item	Prescribed information	6	The maximum concentration of the industrial chemical at end use	7	If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction	<table><tr><th colspan="2">Post-introduction declarations for exempted introductions where highest indicative risk is very low</th></tr><tr><td>6</td><td>The maximum concentration of the industrial chemical at end use</td></tr><tr><td>6A</td><td>A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)</td></tr><tr><td>6B</td><td>In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or (b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information</td></tr><tr><td>7</td><td>If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction</td></tr></table>	Post-introduction declarations for exempted introductions where highest indicative risk is very low		6	The maximum concentration of the industrial chemical at end use	6A	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)	6B	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or (b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information	7	If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction
Post-introduction declarations for exempted introductions where highest indicative risk is very low																					
Item	Prescribed information																				
.....																				
6	The maximum concentration of the industrial chemical at end use																				
7	If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction																				
Post-introduction declarations for exempted introductions where highest indicative risk is very low																					
6	The maximum concentration of the industrial chemical at end use																				
6A	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)																				
6B	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or (b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information																				
7	If the industrial chemical was introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction																				



Schedule 1, Clause 23 of the Exposure Draft

Reason for proposed amendment

Adding clarity about the data permissions an introducer has in place for using international assessment reports for their internationally-assessed reported introductions.

What the proposed amendments mean

Introducers would have to declare they have the permission to use the international assessment report when categorising their introduction as an internationally-assessed reported introduction.

This new declaration would serve as a checkpoint for introducers to make sure they have appropriate permission to use the international assessment report.

The changes are in response to:

- Issues we've found during compliance audits around permissions. This relates to introducers submitting a pre-introduction report for a reported category introduction, when they don't have the appropriate data owner permission.
- A need to align the declarations for PIRs with those for certificate applications, since all of these involve the use of data for market entry. Certificate applications already include a declaration about data ownership.
- A need to fulfil Australia's obligations under the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals.



Date of effect

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

Current Rule	Proposed Rule																
<p>38 Introductions of industrial chemicals that are internationally-assessed for human health and the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>38 Introductions of industrial chemicals that are internationally-assessed for human health and the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>																
<p>Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health and for the environment</p> <table><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>.....</td><td>.....</td></tr><tr><td>14</td><td>A declaration that: (a) the complete international assessment report for the industrial chemical is available; and (b) will be provided to the Executive Director if requested</td></tr><tr><td>.....</td><td>.....</td></tr></table>	Item	Prescribed information	14	A declaration that: (a) the complete international assessment report for the industrial chemical is available; and (b) will be provided to the Executive Director if requested	<p>Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health and for the environment</p> <table><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>.....</td><td>.....</td></tr><tr><td>14</td><td>A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report</td></tr><tr><td>.....</td><td>.....</td></tr></table>	Item	Prescribed information	14	A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report
Item	Prescribed information																
.....																
14	A declaration that: (a) the complete international assessment report for the industrial chemical is available; and (b) will be provided to the Executive Director if requested																
.....																
Item	Prescribed information																
.....																
14	A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report																
.....																



Schedule 1, Clauses 24 and 25 of the Exposure Draft

Reason for proposed amendment

Adding clarity about the data permissions an introducer has in place for using international assessment reports and other data for their reported introductions that are internationally-assessed for human health only.

What the proposed amendments mean

Introducers would have to declare they have the permission to use the international assessment report when categorising their introduction as an internationally-assessed reported introduction. They would also have to declare they have ownership, or the permission to use, the data they have used to demonstrate the absence of hazard characteristics. In the legal text this is referred to as 'information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard'.

This new declaration would serve as a checkpoint for introducers to make sure they have appropriate permission to use the international assessment report and the data they rely on for categorisation.

The changes are in response to:

- Issues we've found during compliance audits around permissions. This relates to introducers submitting a pre-introduction report for a reported category introduction, when they don't have the appropriate data owner permission.
- A need to align the declarations for PIRs with those for certificate applications, since all of these involve the use of data for market entry. Certificate applications already include a declaration about data ownership.
- A need to fulfil Australia's obligations under the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals.

Date of effect

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



Current Rule	Proposed Rule																		
<p>39 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>39 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>																		
<table><tr><th colspan="2">Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment</th></tr><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>11</td><td>A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)</td></tr><tr><td>.....</td><td>.....</td></tr><tr><td>20</td><td>A declaration that: (a) the complete international assessment report for the industrial chemical is available; and</td></tr></table>	Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment		Item	Prescribed information	11	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)	20	A declaration that: (a) the complete international assessment report for the industrial chemical is available; and	<table><tr><th colspan="2">Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment</th></tr><tr><th>Item</th><th>Prescribed information</th></tr><tr><td>11</td><td>A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)</td></tr><tr><td>11A</td><td>In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or</td></tr></table>	Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment		Item	Prescribed information	11	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)	11A	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or
Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for human health but not for the environment																			
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Item	Prescribed information																		
11	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)																		
11A	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or																		



<p>(b) will be provided to the Executive Director if requested</p>	<p>(b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information</p> <hr/> <p>.....</p> <p>20 A declaration that:</p> <p>(a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and</p> <p>(b) the person has permission to use the report</p>
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Schedule 1, Clauses 26 and 27 of the Exposure Draft

Reason for proposed amendment

Adding clarity about the data permissions an introducer has in place for using international assessment reports and other data for their reported introductions that are internationally-assessed for the environment only.

What the proposed amendments mean

Introducers would have to declare they have the permission to use the international assessment report when categorising their introduction as an internationally-assessed reported introduction. They would also have to declare they have ownership, or the permission to use, the data they have used to demonstrate the absence of hazard characteristics. In the legal text this is referred to as 'information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard'.

This new declaration would serve as a checkpoint for introducers to make sure they have appropriate permission to use the international assessment report and the data they rely on for categorisation.

The changes are in response to:

- Issues we've found during compliance audits around permissions. This relates to introducers submitting a pre-introduction report for a reported category introduction, when they don't have the appropriate data owner permission.



- A need to align the declarations for PIRs with those for certificate applications, since all of these involve the use of data for market entry. Certificate applications already include a declaration about data ownership.
- A need to fulfil Australia's obligations under the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals.

Date of effect

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

Current Rule	Proposed Rule
<p>40 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.</p> <p>Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>40 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.</p> <p>Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>



Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for the environment but not for human health		Pre-introduction reports for reported introductions of industrial chemicals that are internationally-assessed for the environment but not for human health	
Item	Prescribed information	Item	Prescribed information
10	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)	10	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)
.....	10A	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or (b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information
19	A declaration that: (a) the complete international assessment report for the industrial chemical is available; and (b) will be provided to the Executive Director if requested	19	A declaration that: (a) the complete international assessment report for the industrial chemical is available and will be provided to the Executive Director if requested; and (b) the person has permission to use the report

Schedule 1, Clause 28 of the Exposure Draft

Reason for proposed amendment

Adding clarity about the data permissions an introducer has in place for reported introductions where the highest indicative risk is low.

What the proposed amendments mean

Introducers would have to declare they have ownership, or the permission to use, the data they have used to demonstrate the absence of hazard characteristics. In the legal text this is



referred to as 'information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard'.

This new declaration would serve as a checkpoint for introducers to make sure they have appropriate permission to use the data they rely on for categorisation.

The changes are in response to:

- Issues we've found during compliance audits around permissions. This relates to introducers submitting a pre-introduction report for a reported category introduction, when they don't have the appropriate data owner permission.
- A need to align the declarations for PIRs with those for certificate applications, since all of these involve the use of data for market entry. Certificate applications already include a declaration about data ownership.
- A need to fulfil Australia's obligations under the OECD Recommendation of the Council Concerning Access and Protection of Proprietary Rights to Non-Clinical Health, Safety and Environmental Data and Information on Chemicals.

Date of effect

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

Current Rule	Proposed Rule
<p>43 Other introductions where the highest indicative risk is low risk</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical is a reported introduction by a person in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>	<p>43 Other introductions where the highest indicative risk is low risk</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical is a reported introduction by a person in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>(2) For the purposes of paragraph 97(2)(b) of the Act, the information mentioned in an item of the following table is prescribed.</p>



Pre-introduction reports for other reported introductions where the highest indicative risk is low risk		Pre-introduction reports for other reported introductions where the highest indicative risk is low risk	
Item	Prescribed information	Item	Prescribed information
14	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)	14	A declaration that the person has had regard to the information mentioned in subparagraphs 30(2)(c)(iii) and (iv)
15	If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction	14A	In relation to the information mentioned in subparagraph 30(2)(c)(iv) to which the person has had regard—a declaration that: (a) the person is the owner of the information; or (b) the person has used the information for the purposes of that subparagraph with the permission of the owner of the information
		15	If the industrial chemical is to be introduced for an end use in cosmetics—a statement as to which of the circumstances specified in subsection (3) applies to the introduction

Part 4 – Annual declarations

Schedule 1, Clause 29 of the Exposure Draft

Reason for proposed amendment

This change would allow us to know what types of exempted introductions apply to an introducer. This would allow more targeted monitoring of introducers and minimise unnecessary information requests and follow-ups.

What the proposed amendments mean

This amendment would allow for the annual declaration to include information on the ‘types’ of exempted introductions a person has introduced during the registration year. Only some types of exempted introductions also require a post-introduction declaration under 96A of the IC Act. This change would allow us to know what other types of exempted introductions



apply to an introducer, by having the introducer select from the list of exempted introduction types. The types of exempted introductions are:

- introductions where the highest indicative risk is very low risk
- introductions that are only for use in research and development
- chemicals that are comparable to listed chemicals
- polymers that are comparable to listed polymers
- chemicals resulting from non-functionalised surface treatment of listed chemicals
- chemicals that are imported and subsequently exported
- polymers of low concern
- low-concern biological polymers

Date of effect

As these amendments require changes to the online forms they would only apply to annual declarations submitted on or after 10 December 2021.

Annual declarations for the period 1 July 2020-31 August 2021 will not have this amendment in the declaration.

Current Rule	Proposed Rule
<p>44 Annual declaration for all introduction categories</p> <p>For the purposes of paragraph 99(2)(b) of the Act, the following information for a declaration made by a person for a registration year is prescribed:</p> <p>(a) the registration number for the person;</p> <p>(b) the categories of introduction for the industrial chemicals introduced by the person;</p> <p>(c) a declaration that all introductions made by the person during the registration year were authorised by one of sections 25 to 30 of the Act.</p> <p>Note: This declaration is not required for excluded introductions as section 99 of the Act does not apply to excluded introductions: see subsection 11(1) of the Act.</p>	<p>44 Annual declaration for all introduction categories</p> <p>For the purposes of paragraph 99(2)(b) of the Act, the following information for a declaration made by a person for a registration year is prescribed:</p> <p>(a) the registration number for the person;</p> <p>(b) the categories of introduction for the industrial chemicals introduced by the person;</p> <p>(c) a declaration that all introductions made by the person during the registration year were authorised by one of sections 25 to 30 of the Act.</p> <p>(d) if any of the introductions by the person were exempted introductions—each type of exempted introduction.</p> <p>Note: This declaration is not required for excluded introductions as section 99 of the Act does not apply to excluded introductions: see subsection 11(1) of the Act.</p>



Part 5 – Record keeping for listed introductions

Schedule 1, Clause 30 of the Exposure Draft

Reason for proposed amendment

These changes would improve the record keeping for listed introductions to:

- better reflect the records product importers are able to keep when they do not know the chemical identity, and
- make the written undertakings given by chemical identity holders more effective.

What the proposed amendments mean

This proposed amendment to the record keeping requirements for listed introductions would make 2 changes:

1. Would allow for an extra option for the chemical identity record if the CAS name and number are not known to the introducer. This extra option is 'the names of all products containing the industrial chemical that are imported into Australia by the person'. This reflects the actual information that some product importers are able to record and keep.
2. Would add a time frame in which the CAS name and number (if assigned) would be provided by the chemical identity holder, if we request the information. This time frame (20 working days) is consistent with like information provision and decision-making periods already in the Rules and the IC Act.

The requirement for the written undertakings to include the time frame would only apply to those given on or after this amending instrument commences (that is, it would not apply to written undertakings already given before this date).



Current Rule

46 Listed introductions

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to the listed introduction of an industrial chemical, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the CAS number for the industrial chemical is known to the person	(a) the CAS number for the industrial chemical; and (b) either the CAS name or the INCI name for the industrial chemical
2	a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person	(a) the CAS name for the industrial chemical; or (b) both: (i) the names by which the industrial chemical is known to the person; and (ii) a written undertaking from the chemical identity holder that the CAS name and CAS number (if assigned) for the industrial chemical will be

Proposed Rule

46 Listed introductions

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to the listed introduction of an industrial chemical, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the CAS number for the industrial chemical is known to the person	(a) the CAS number for the industrial chemical; and (b) either the CAS name or the INCI name for the industrial chemical
2	a CAS number for the industrial chemical is not assigned, or the CAS number for the industrial chemical is not known to the person	(a) the CAS name for the industrial chemical; or (b) both: (i) the names by which the industrial chemical is known to the person, or the names of all products containing the industrial chemical that are imported into Australia by the person; and



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provided to the Executive Director if requested	
... ..	
	(ii) a written undertaking from the chemical identity holder that the CAS name and CAS number (if assigned) for the industrial chemical will be provided to the Executive Director, if requested, within 20 working days after the day the request is made

Part 6 – Record keeping for specified classes

Schedule 1, Clause 31 and 32 of the Exposure Draft

Reason for proposed amendment

Adding options for the record keeping of specified classes of introductions for exempted introductions where the highest indicative risk is very low.

What the proposed amendments mean

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



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

Current Rule	Proposed Rule												
<p>51 Other introductions where the highest indicative risk is very low risk</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with step 6 of the method statement in section 24.</p> <p>Note: An introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 24 if the highest indicative risk for the introduction is very low.</p> <p>.....</p> <p><i>Additional record keeping requirements for specified classes of introduction</i></p> <p>(4) For the purposes of item 22 of the table in subsections (2) and (3), the following table has effect.</p>	<p>51 Other introductions where the highest indicative risk is very low risk</p> <p>(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with step 6 of the method statement in section 24.</p> <p>Note: An introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 24 if the highest indicative risk for the introduction is very low.</p> <p>.....</p> <p><i>Additional record keeping requirements for specified classes of introduction</i></p> <p>(4) For the purposes of item 22 of the table in subsections (2) and (3) and subject to subsection (5), the following table has effect.</p>												
<table><tr><th colspan="3">Additional record keeping requirements for specified classes of introductions</th></tr><tr><th></th><th>Column 1</th><th>Column 2</th></tr><tr><th>Item</th><th>If ...</th><th>the kinds of records that must be kept are ...</th></tr><tr><td>1</td><td>the introduction is of a kind mentioned in paragraph 7(2)(d)</td><td>information about the release into the environment, including:</td></tr></table>		Additional record keeping requirements for specified classes of introductions				Column 1	Column 2	Item	If ...	the kinds of records that must be kept are ...	1	the introduction is of a kind mentioned in paragraph 7(2)(d)	information about the release into the environment, including:
Additional record keeping requirements for specified classes of introductions													
	Column 1	Column 2											
Item	If ...	the kinds of records that must be kept are ...											
1	the introduction is of a kind mentioned in paragraph 7(2)(d)	information about the release into the environment, including:											



	(involves a designated kind of release into the environment)	(a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment	Additional record keeping requirements for specified classes of introductions		
			Column 1		Column 2
			Item	If ...	the kinds of records that must be kept are ...
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical	1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment
3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	(a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity	2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for end use in an			



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		<p>article with food contact in another country by an agency or authority of that country—records to demonstrate that the industrial chemical has been so approved; and</p> <p>(b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)</p>	3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	<p>(a) the name of the genetically modified organism from which the GM product was derived or produced; and</p> <p>(b) information on any genetically modified organism that remains in the GM product as an impurity</p>
5	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)	<p>(a) whether the article can be placed in the mouth; and</p> <p>(b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)</p>	4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	<p>(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact in another country by an agency or authority of that country—records to demonstrate that the industrial chemical has been so approved; and</p> <p>(b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)</p>

Note 1: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of **children's care product** and **end use in an article with food contact**, see section 5.



5	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)	(a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)
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Note 1: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of **children's care product** and **end use in an article with food contact**, see section 5.

(5) If:

(a) the person is required to keep records of the information (the relevant information) mentioned in column 2 of item 2, 3 or 4 of the table in subsection (4), or paragraph (b) of column 2 of item 5 of that table; and

(b) the person does not know the relevant information;

the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.



Schedule 1, Clause 33 and 34 of the Exposure Draft

Reason for proposed amendment

Adding record keeping options for specified classes of introductions for reported introductions that are internationally-assessed for human health only.

What the proposed amendments mean

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

- Biochemicals
- GM products

Current Rule	Proposed Rule
<p>53 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p>	<p>53 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p>



Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

(4) For the purposes of paragraphs (2)(l) and (3)(k), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment.
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

(4) For the purposes of paragraphs (2)(l) and (3)(k) **and subject to subsection (5)**, the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment.
2	the introduction is of a kind mentioned in	(a) the concentration of any remaining viable cell or cellular components of



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		remaining viable cell or cellular components of the organisms used to produce the biochemical	paragraph 7(3)(a) (biochemical)	the organisms used to produce the biochemical; and
3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	(a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity		(b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
			3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product) (a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity

Note: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

Note: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

(5) If:
(a) the person is required to keep records of the information (the relevant information) mentioned in column 2 of item 2 or 3 of the table in subsection (4); and
(b) the person does not know the relevant information;



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the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

Schedule 1, Clause 35 and 36 of the Exposure Draft

Reason for proposed amendment

Adding options for the record keeping of specified classes of introductions for reported introductions that are internationally-assessed for the environment only.

What the proposed amendments mean

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

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



Current Rule

54 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health

(1) This section applies if:

- (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and
- (b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.

Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.

.....

(4) For the purposes of paragraphs (2)(m) and (3)(l), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the

Proposed Rule

54 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health

(1) This section applies if:

- (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and
- (b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.

Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.

.....

(4) For the purposes of paragraphs (2)(m) and (3)(l) **and subject to subsection (5)**, the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in	(a) the concentration of any remaining viable cell or



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		organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical	paragraph 7(3)(a) (biochemical)	cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
2	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	(a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity	2	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product) (a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity
3	(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and (b) the human health exposure band for the introduction is 4	(a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and (b) photostability information (within the meaning given by the Guidelines) about the industrial chemical	3	(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and (b) the human health exposure band for the introduction is 4 (a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and (b) photostability information (within the meaning given by the
4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact in		



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		another country by an agency or authority of that country—records to demonstrate that the industrial chemical has been so approved; and			Guidelines) about the industrial chemical
		(b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)		4	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)
5	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)	(a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)			(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact in another country by an agency or authority of that country—records to demonstrate that the industrial chemical has been so approved; and (b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)
Note: For the definitions of children's care product and end use in an article with food contact , see section 5.					
				5	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)
					(a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)



Note: For the definitions of **children's care product** and **end use in an article with food contact**, see section 5.

(5) If:

(a) the person is required to keep records of the information (the relevant information) mentioned in column 2 of item 1, 2, 3 or 4 of the table in subsection (4), or paragraph (b) of column 2 of item 5 of that table; and

(b) the person does not know the relevant information; the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

Schedule 1, Clause 37 and 38 of the Exposure Draft

Reason for proposed amendment

Adding options for the record keeping of specified classes of introductions for reported introductions where the highest indicative risk is low.

What the proposed amendments mean

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

- Biochemicals
- GM products



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

Current Role

57 Other introductions where highest indicative risk is low risk

(1) This section applies if:

(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and

(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

.....

(5) For the purposes of paragraph (2)(n), the following table has effect.

Additional record keeping obligations for certain kinds of introductions

	Column 1	Column 2
Item	If ...	the records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d)	information about the release into the environment, including:

Proposed Rule

57 Other introductions where highest indicative risk is low risk

(1) This section applies if:

(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and

(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

.....

(6) For the purposes of paragraph (2)(n) **and subject to subsection (4)**, the following table has effect.



	(involves a designated kind of release into the environment)	(a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical
3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	(a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity
4	(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and	(a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and

Additional record keeping obligations for certain kinds of introductions		
Column 1		Column 2
Item	If ...	the records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment
2	the introduction is of a kind mentioned in paragraph 7(3)(a) (biochemical)	(a) the concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical; and (b) information on any known adverse effects of any remaining viable cell or cellular components of the organisms used to produce the biochemical



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	(b) the human health exposure band for the introduction is 4	(b) photostability information (within the meaning given by the Guidelines) about the industrial chemical	3	the introduction is of a kind mentioned in paragraph 7(3)(b) (GM product)	(a) the name of the genetically modified organism from which the GM product was derived or produced; and (b) information on any genetically modified organism that remains in the GM product as an impurity
5	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact in another country by an agency or authority of that country—records to demonstrate that the industrial chemical has been so approved; and (b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)	4	(a) the introduction is of a kind mentioned in paragraph 7(4)(a) (UV filter); and (b) the human health exposure band for the introduction is 4	(a) toxicokinetics information (within the meaning given by the Guidelines) about the industrial chemical; and (b) photostability information (within the meaning given by the Guidelines) about the industrial chemical
6	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)	(a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)	5	the introduction is of a kind mentioned in paragraph 7(4)(b) (end use in an article with food contact)	(a) if the person knows that the industrial chemical has been approved (however described) for end use in an article with food contact in another country by an agency or authority of that country—records to demonstrate that the



Note 1: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of **children's care product** and **end use in an article with food contact**, see section 5.

		industrial chemical has been so approved; and (b) the potential for the industrial chemical to migrate to food (within the meaning given by the Guidelines)
6	the introduction is of a kind mentioned in paragraph 7(4)(e) (end use in an article that is a children's toy or a children's care product)	(a) whether the article can be placed in the mouth; and (b) if so, the potential for the industrial chemical to be released into the mouth during end use or mouthing (within the meaning given by the Guidelines)

Note 1: For when the introduction of an industrial chemical involves a **designated kind of release into the environment**, see subclause 3(2) of Schedule 1.

Note 2: For the definitions of **children's care product** and **end use in an article with food contact**, see section 5.

(4) If:

(a) the person is required to keep records of the information (the relevant information) mentioned in column 2 of item 2, 3, 4 or 5 of the table in subsection (3), or paragraph (b) of column 2 of item 6 of that table; and

(b) the person does not know the relevant information;



the person must keep a written undertaking from the person who has the relevant information stating that the relevant information will be provided to the Executive Director if requested.

Part 7 – Record keeping for designated releases to the environment

Schedule 1, Clause 39 of the Exposure Draft

Reason for proposed amendment

Clarifying requirements for the record keeping of exempted introductions that involve a designated kind of release into the environment.

What the proposed amendments mean

These proposed amendments would make 2 changes to the record keeping requirements for introductions with a designated release to the environment:

1. The addition of 'if practicable'. This proposed change is to best support introducers to comply with the requirements in practice, since the current rules could present issues in practice for certain types of releases. To support industry's understanding of what it is and is not practicable to record, we would create guidance to explain the instances in which it is practicable to keep records and we would therefore expect records to be kept.
2. Addition of the requirement to record the quantity of the chemical released into the environment, which is an important piece of information for considering the risk of these introductions where the chemical is released directly to the environment.



Current Rule

51 Other introductions where the highest indicative risk is very low risk

(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with step 6 of the method statement in section 24.

Note: An introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 24 if the highest indicative risk for the introduction is very low.

.....

Additional record keeping requirements for specified classes of introduction

(4) For the purposes of item 22 of the table in subsections (2) and (3), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and

Proposed Rule

51 Other introductions where the highest indicative risk is very low risk

(1) This section applies if an introduction of an industrial chemical by a person is an exempted introduction in accordance with step 6 of the method statement in section 24.

Note: An introduction of an industrial chemical is an exempted introduction in accordance with step 6 of the method statement in section 24 if the highest indicative risk for the introduction is very low.

.....

Additional record keeping requirements for specified classes of introduction

(4) For the purposes of item 22 of the table in subsections (2) and (3) and subject to subsection (5), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	if practicable , information about the release into the environment, including:



(b) the frequency of the release into the environment	(a) the location of the release into the environment (including all receiving water bodies); and
...	(b) the frequency of the release into the environment; and
.....	(c) the quantity of the industrial chemical released to the environment
.....

Schedule 1, Clause 40 of the Exposure Draft

Reason for proposed amendment

Clarifying requirements for the record keeping of reported introductions that are internationally-assessed for human health only and involve a designated kind of release into the environment.

What the proposed amendments mean

These proposed amendments would make 2 changes to the record keeping requirements for introductions with a designated release to the environment:



1. The addition of 'if practicable'. This proposed change is to best support introducers to comply with the requirements in practice, since the current rules could present issues in practice for certain types of releases. To support industry's understanding of what it is and is not practicable to record, we would create guidance to explain the instances in which it is practicable to keep records and we would therefore expect records to be kept.
2. Addition of the requirement to record the quantity of the chemical released into the environment, which is an important piece of information for considering the risk of these introductions where the chemical is released directly to the environment.

Current Rule	Proposed Rule
<p>53 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>.....</p> <p>(7) For the purposes of paragraphs (2)(l) and (3)(k), the following table has effect.</p>	<p>53 Introductions of industrial chemicals that are internationally-assessed for human health but not internationally-assessed for the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) applies to the introduction but item 9 of the table in subsection 29(1) does not apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p>.....</p> <p>(4) For the purposes of paragraphs (2)(l) and (3)(k) and subject to subsection (5), the following table has effect.</p>



Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment
...

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	if practicable, information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment; and (c) the quantity of the industrial chemical released to the environment
...



Schedule 1, Clause 41 of the Exposure Draft

Reason for proposed amendment

Clarifying requirements for the record keeping of reported introductions where the highest indicative risk is low risk.

What the proposed amendments mean

These proposed amendments would make 2 changes to the record keeping requirements for introductions with a designated release to the environment:

1. The addition of 'if practicable'. This proposed change is to best support introducers to comply with the requirements in practice, since the current rules could present issues in practice for certain types of releases. To support industry's understanding of what it is and is not practicable to record, we would create guidance to explain the instances in which it is practicable to keep records and we would therefore expect records to be kept.
2. Addition of the requirement to record the quantity of the chemical released into the environment, which is an important piece of information for considering the risk of these introductions where the chemical is released directly to the environment.

Current Rule	Proposed Rule
57 Other introductions where highest indicative risk is low risk (1) This section applies if: (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and	57 Other introductions where highest indicative risk is low risk (1) This section applies if: (a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and



(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

.....

(3) For the purposes of paragraph (2)(n), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and (b) the frequency of the release into the environment

... ..

.....

(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) do not apply to the introduction.

Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.

.....

(3) For the purposes of paragraph (2)(n) and subject to subsection (4), the following table has effect.

Additional record keeping requirements for specified classes of introductions

Column 1		Column 2
Item	If ...	the kinds of records that must be kept are
...		
1	the introduction is of a kind mentioned in paragraph 7(2)(d) (involves a designated kind of release into the environment)	if practicable, information about the release into the environment, including: (a) the location of the release into the environment (including all receiving water bodies); and



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(b) the frequency of the
release into the
environment; and

**(c) the quantity of the
industrial chemical
released to the
environment**

....

....

....



Part 8 – Record keeping for internationally-assessed introductions

Schedule 1, Clauses 42 and 43 of the Exposure Draft

Reason for proposed amendment

Correcting requirements for the record keeping of volumes for reported introductions that are internationally-assessed for human health and the environment.

What the proposed amendments mean

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

Current Rule	Proposed Rule
<p>52 Introductions of industrial chemicals that are internationally-assessed for human health and the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act,</p>	<p>52 Introductions of industrial chemicals that are internationally-assessed for human health and the environment</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 6 of the table in subsection 28(1) and item 9 of the table in subsection 29(1) apply to the introduction.</p> <p>Note: Item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health, and item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p>



the following kinds of records are prescribed:

.....

(e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum total volume of the industrial chemical the person intends to introduce in a registration year;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(d) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum total volume of the industrial chemical the person intends to introduce in a registration year;

.....

.....

(e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed either of the following:

(i) the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year;

(ii) the volume of the industrial chemical assessed in the international assessment or evaluation;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(d) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed either of the following:

(i) the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year;

(ii) the volume of the industrial chemical assessed in the international assessment or evaluation;



Schedule 1, Clauses 44 and 45 of the Exposure Draft

Reason for proposed amendment

Correcting requirements for the record keeping of volumes for reported introductions that are internationally-assessed for the environment only.

What the proposed amendments mean

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

Current Rule	Proposed Rule
<p>54 Introductions of industrial chemicals that are internationally assessed for the environment but not internationally assessed for human health</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.</p> <p>Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p> <p>(f) records to demonstrate that the total volume of the industrial chemical introduced by the</p>	<p>54 Introductions of industrial chemicals that are internationally-assessed for the environment but not internationally-assessed for human health</p> <p>(1) This section applies if:</p> <p>(a) an introduction of an industrial chemical by a person is a reported introduction in accordance with step 6 of the method statement in section 24; and</p> <p>(b) item 9 of the table in subsection 29(1) applies to the introduction but item 6 of the table in subsection 28(1) does not apply to the introduction.</p> <p>Note: Item 9 of the table in subsection 29(1) deals with industrial chemicals that are internationally-assessed for the environment, and item 6 of the table in subsection 28(1) deals with industrial chemicals that are internationally-assessed for human health.</p> <p><i>Proper name for industrial chemical known to person</i></p> <p>(2) If the proper name for the industrial chemical is known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:</p> <p>.....</p>



person in a registration year does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum total volume of the industrial chemical the person intends to introduce in a registration year;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed the volume specified in the pre-introduction report for the industrial chemical as the maximum total volume of the industrial chemical the person intends to introduce in a registration year;

.....

(f) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed either of the following:

(i) the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year;

(ii) the volume of the industrial chemical assessed in the international assessment or evaluation;

.....

Proper name for industrial chemical not known to person

(3) If the proper name for the industrial chemical is not known to the person, for the purposes of paragraph 104(2)(b) of the Act, the following kinds of records are prescribed:

.....

(e) records to demonstrate that the total volume of the industrial chemical introduced by the person in a registration year does not exceed either of the following:

(i) the volume specified in the pre-introduction report for the industrial chemical as the maximum volume of the industrial chemical the person intends to introduce in a registration year;

(ii) the volume of the industrial chemical assessed in the international assessment or evaluation;

.....

Part 9 – Movement of industrial chemicals into or out of Australia

Schedule 1, Clause 46 of the Exposure Draft

Reason for proposed amendment



This proposed amendment would change the circumstances in which introductions of chemicals on international convention lists are not exempted or reported.

What the proposed amendments mean

This proposed amendment would complement the proposed changes in clauses 48-53, which are to better align the Rules with the scope of the Rotterdam Convention. The Rotterdam Convention and Stockholm Convention do not apply to industrial chemicals used for research or analysis in low volumes.

The outcome of the proposed amended 25(2)(b) would be that if a chemical is listed on one of the prescribed international convention lists, and the chemical is not being introduced for research and analysis in low volumes, then it cannot be exempted or reported. It must be authorised under a different introduction category (such as listed or assessed).

Current Rule	Proposed Rule
<p>25 Circumstances in which introductions are not exempted or reported</p> <p>(1) For the purposes of step 1 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p><i>Introduction of industrial chemical subject to an international agreement or arrangement</i></p> <p>(2) This subsection applies to the introduction of an industrial chemical by a person if:</p> <p>(a) the industrial chemical is listed in:</p> <p>(i) Annex III to the Rotterdam Convention; or</p> <p>(ii) Part 1 of Annex A, B or C to the Stockholm Convention; and</p> <p>(b) the industrial chemical is not listed in section 71, 72 or 73 of this instrument.</p> <p>Note: Sections 71, 72 and 73 set out rules prohibiting the introduction or export of certain industrial chemicals and imposing conditions to which the introduction or export of certain industrial chemicals are subject.</p>	<p>25 Circumstances in which introductions are not exempted or reported</p> <p>(1) For the purposes of step 1 of the method statement in section 24, the introduction of an industrial chemical is covered by this section if subsection (2), (3) or (4) of this section applies to the introduction.</p> <p><i>Introduction of industrial chemical subject to an international agreement or arrangement</i></p> <p>(2) This subsection applies to the introduction of an industrial chemical by a person if the industrial chemical is listed in:</p> <p>(a) Annex III to the Rotterdam Convention; or</p> <p>(b) Part 1 of Annex A, B or C to the Stockholm Convention;</p> <p>unless:</p> <p>(c) the industrial chemical is to be introduced solely for use in research or analysis; and</p> <p>(d) the total volume of the industrial chemical introduced by the person in a registration year does not exceed 100 kg.</p>



Schedule 1, Clause 47 of the Exposure Draft

Reason for proposed amendment

This proposed amendment would change the way the record keeping requirements are expressed for introductions or exports that have been approved under Chapter 6 of the Rules.

What the proposed amendments mean

This proposed amendment would complement the proposed changes in clauses 48-53, which are to better align the Rules with the scope of the Rotterdam Convention. The Rotterdam Convention does not apply to industrial chemicals used for research or analysis in low volumes.

Current Rule

61 Introductions under section 163 of the Act

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an introduction or export of an industrial chemical that is authorised under section 163 of the Act, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
	Column 1	Column 2
Item	If ...	the kinds of records that must be kept are ...
1	the introduction is of an industrial chemical to which section 71 or 72 applies	the name of the industrial chemical
2	the export is of an industrial chemical to which section 73 applies	the name of the industrial chemical

Proposed Rule

61 Introductions under section 163 of the Act

For the purposes of paragraph 104(2)(b) of the Act, if a circumstance mentioned in column 1 of an item in the following table applies in relation to an introduction or export of an industrial chemical that is authorised under section 163 of the Act, records of the kind mentioned in column 2 of the item are prescribed in relation to the introduction of the industrial chemical.

Records that must be kept		
	Column 1	Column 2
Item	If ...	the kinds of records that must be kept are ...
1	subsection 71(1) or 72(1) applies to the introduction of the industrial chemical	the name of the industrial chemical
2	subsection 73(1) applies to the export of the industrial chemical	the name of the industrial chemical



3	the approval includes conditions relating to the introduction or use of the industrial chemical	records to demonstrate that those conditions are being complied with	3	the approval includes conditions relating to the introduction or use of the industrial chemical	records to demonstrate that those conditions are being complied with
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Schedule 1, Clauses 48 and 49 of the Exposure Draft

Reason for proposed amendment

These proposed amendments would change the introductions that are subject to the conditions in sections 71 of the Rules.

What the proposed amendments mean

These proposed amendments would align with the scope of the Rotterdam Convention, which does not apply to chemicals used for research or analysis in low volumes.

Current Rule	Proposed Rule
<p>71 Introduction of certain industrial chemicals subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act, introduction of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:</p> <p>(a) that the introduction has been approved by the Executive Director, in writing, before the industrial chemical is introduced;</p> <p>(b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p>	<p>71 Introduction of certain industrial chemicals subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, introduction of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:</p> <p>(a) that the introduction has been approved by the Executive Director, in writing, before the industrial chemical is introduced;</p> <p>(b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p> <p>(1A) Subsection (1) does not apply to the introduction of an industrial chemical specified in subsection (2) by a person in a registration year if:</p>



(a)the industrial chemical is to be introduced solely for use in research or analysis; and
(b)the total volume of the industrial chemical introduced by the person in the registration year does not exceed 100 kg.

Schedule 1, Clauses 50 and 51 of the Exposure Draft

Reason for proposed amendment

These proposed amendments would change the introductions of tetraethyl lead that are subject to the conditions in sections 72 of the Rules.

What the proposed amendments mean

These proposed amendments would align with the scope of the Rotterdam Convention, which does not apply to chemicals used for research or analysis in low volumes.

Current Rule	Proposed Rule
<p>72 Introduction of tetraethyl lead subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act, introduction of tetraethyl lead by a person is subject to the following conditions:</p> <p>(a)that the introduction comply with one or more of the following:</p> <p>(i)the introduction has been approved by the Executive Director, in writing, before the tetraethyl lead is introduced;</p> <p>(ii)the tetraethyl lead may only be introduced in aviation gasoline, or for use in the production of aviation gasoline;</p> <p>(iii)the tetraethyl lead may only be introduced by a person in the circumstances set out in subsection (2);</p> <p>(b)that the person keep the records relating to the introduction of the tetraethyl lead that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p>	<p>72 Introduction of tetraethyl lead subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, introduction of tetraethyl lead by a person is subject to the following conditions:</p> <p>(a)that the introduction comply with one or more of the following:</p> <p>(i)the introduction has been approved by the Executive Director, in writing, before the tetraethyl lead is introduced;</p> <p>(ii)the tetraethyl lead may only be introduced in aviation gasoline, or for use in the production of aviation gasoline;</p> <p>(iii)the tetraethyl lead may only be introduced by a person in the circumstances set out in subsection (2);</p> <p>(b)that the person keep the records relating to the introduction of the tetraethyl lead that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p>



(1A) Subsection (1) does not apply to the introduction of tetraethyl lead by a person in a registration year if:

(a) the tetraethyl lead is to be introduced solely for use in research or analysis; and

(b) the total volume of the tetraethyl lead introduced by the person in the registration year does not exceed 100 kg.

Schedule 1, Clauses 52 and 53 of the Exposure Draft

Reason for proposed amendment

These proposed amendments would change the exports that are subject to the conditions in sections 73 of the Rules.

What the proposed amendments mean

These proposed amendments would align with the scope of the Rotterdam Convention, which does not apply to chemicals used for research or analysis in low volumes.

Current Rule	Proposed Rule
<p>73 Export of certain industrial chemicals subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act, export of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:</p> <p>(a) that the export has been approved by the Executive Director, in writing, before the industrial chemical is exported;</p> <p>(b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p>	<p>73 Export of certain industrial chemicals subject to conditions</p> <p>(1) For the purposes of paragraph 163(1)(b) of the Act and subject to subsection (1A) of this section, export of an industrial chemical specified in subsection (2) of this section by a person is subject to the following conditions:</p> <p>(a) that the export has been approved by the Executive Director, in writing, before the industrial chemical is exported;</p> <p>(b) that the person keep the records relating to the introduction of the industrial chemical that are required by Part 8 of Chapter 4 of this instrument.</p> <p>Note: Applications for approval must be made to the Executive Director in writing: see section 74.</p> <p>(1A) Subsection (1) does not apply to the export of an industrial chemical specified in subsection (2) by a person in a registration year if:</p>



- (a) the industrial chemical is to be exported solely for use in research or analysis; and
- (b) the total volume of the industrial chemical exported by the person in the registration year does not exceed 100 kg.

Schedule 1, Clause 54 of the Exposure Draft

Reason for proposed amendment

This proposed amendment would change the description of what a person may apply for under section 74 of the Rules.

What the proposed amendments mean

This proposed amendment would complement the proposed changes in clauses 48-53, which are to better align the Rules with the scope of the Rotterdam Convention.

Current Rule	Proposed Rule
<p>74 Applying for approval to introduce or export restricted industrial chemicals</p> <p>(1) A person may apply, in writing, to the Executive Director for approval to introduce an industrial chemical mentioned in section 71 or 72, or to export an industrial chemical mentioned in section 73.</p> <p>Note 1: For general requirements relating to applications, see section 167 of the Act.</p> <p>Note 2: Application fees are prescribed by the <i>Industrial Chemicals (Fees and Charges) Rules 2019</i>: see section 5 of that instrument.</p>	<p>74 Applying for approval to introduce or export restricted industrial chemicals</p> <p>(1) A person may apply, in writing, to the Executive Director for approval:</p> <ul style="list-style-type: none">(a) to introduce an industrial chemical to which subsection 71(1) or 72(1) applies; or(b) to export an industrial chemical to which subsection 73(1) applies. <p>Note 1: For general requirements relating to applications, see section 167 of the Act.</p> <p>Note 2: Application fees are prescribed by the <i>Industrial Chemicals (Fees and Charges) Rules 2019</i>: see section 5 of that instrument.</p>



Schedule 1, Clause 55 of the Exposure Draft

Reason for proposed amendment

This proposed amendment would add a new matter to which the Executive Director must have regard in considering an application. This would better align the Rules with the current process undertaken when deciding on an application for approval to import or export restricted industrial chemicals.

What the proposed amendments mean

While 'Australia's obligations under relevant prescribed international agreements or arrangements' should come under 75(2)(c) (any other information the Executive Director considers relevant), this amendment would ensure the law expressly requires the Executive Director to consider this.

Current Rule

75 Decision on application

.....

(2) In considering the application, the Executive Director must have regard to:

- (a) any further information provided by the applicant under subsection 74(4); and
- (b) if the applicant has held a previous approval to introduce or export the industrial chemical—the applicant's compliance with the terms of the previous approval; and
- (c) any other information the Executive Director considers relevant.

.....

Proposed Rule

75 Decision on application

.....

(2) In considering the application, the Executive Director must have regard to:

- (a) any further information provided by the applicant under subsection 74(4); and
- (b) if the applicant has held a previous approval to introduce or export the industrial chemical—the applicant's compliance with the terms of the previous approval; and
- (ba) Australia's obligations under relevant prescribed international agreements or prescribed international arrangements; and**
- (c) any other information the Executive Director considers relevant.

.....



Schedule 1, Clause 56 of the Exposure Draft

Reason for proposed amendment

This proposed amendment adds an additional subsection to section 75 to make it clear that an approval notice under subsection 75(4) would also include certain terms.

What the proposed amendments mean

This proposed amendment would better reflect the actual outcome of this approval process, including because in order to meet Australia's obligations under the Rotterdam Convention the Executive Director needs to apply certain standard terms.

Current Rule

75 Decision on application

.....

(4) The Executive Director must give the applicant written notice of:

- (a) the decision; and
- (b) if the decision is to refuse the application—the reasons for the decision.

.....

Proposed Rule

75 Decision on application

.....

(4) The Executive Director must give the applicant written notice of:

- (a) the decision; and
- (b) if the decision is to refuse the application—the reasons for the decision.

(4A) If the decision is to approve the introduction or export of the industrial chemical, the notice under subsection (4):
(a) must also include the following terms of the approval:

- (i) the proper name for the industrial chemical;**
- (ii) the period for which the approval is in force;**
- (iii) any conditions relating to the introduction or export of the industrial chemical that are necessary to manage risks to human health or the environment from the introduction or export of the industrial chemical; and**
- (b) may include any other terms the Executive Director considers appropriate.**

.....



Part 10 – Other amendments

Schedule 1, Clause 57 of the Exposure Draft

Reason for proposed amendment

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

What the proposed amendments mean

This proposed amendment would not change the prescribed international assessment body that is acceptable for the internationally-assessed reported category. It would correct an error that had left out part of the name.

Current Rule

6 Internationally-assessed industrial chemicals

.....

(3) For the purposes of paragraphs (1)(a) and (2)(a), the following table sets out the kinds of assessments or evaluations, and the bodies that conduct the assessments or evaluations.

Assessments and evaluations conducted by international bodies		
	Column 1	Column 2
Item	Type of assessment or evaluation	International assessment body
....

Proposed Rule

6 Internationally-assessed industrial chemicals

.....

(3) For the purposes of paragraphs (1)(a) and (2)(a), the following table sets out the kinds of assessments or evaluations, and the bodies that conduct the assessments or evaluations.

Assessments and evaluations conducted by international bodies		
	Column 1	Column 2
Item	Type of assessment or evaluation	International assessment body
....



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- 5 Opinions from the European Scientific Committee on Consumer Safety that:
- (a) have been finalised and adopted by that Committee; and
 - (b) have terms of reference that include a question about the safety of a chemical in a cosmetic product; and
 - (c) have a conclusion of safety with respect to the question about the safety of the chemical in a cosmetic product

....

- 5 Opinions from the European **Commission** Scientific Committee on Consumer Safety that:
- (a) have been finalised and adopted by that Committee; and
 - (b) have terms of reference that include a question about the safety of a chemical in a cosmetic product; and
 - (c) have a conclusion of safety with respect to the question about the safety of the chemical in a cosmetic product

....



Schedule 1, Clauses 58 and 59 of the Exposure Draft

Reason for proposed amendment

The proposed amendment would correct an error in the table of industrial chemicals that are comparable to listed industrial chemicals. Chemicals on this list can be exempted introductions.

What the proposed amendments mean

This proposed amendment would remove Tylosin, (2R, 3R)-2,3-dihydroxybutanedioate (salt) from the comparable chemicals table (item 15 (column 3)) as it is no longer listed on the Inventory – we removed it at the time we transitioned to AICIS - because it has no industrial use. This means the chemical shown as 'comparable' - (Tylosin, (2R, 3R)-2,3-dihydroxybutanedioate (1:1)) - can no longer be included in the table.

In relation to the removal of the chemical from the Inventory – we did this under s76 of the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 following stakeholder consultation.

We would also renumber items in the adjusted table.

Current Rule

26 Circumstances in which introductions are exempted introductions

(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.

.....

(5) This subsection applies to the introduction of an industrial chemical by a person if:
(a) the introduction is of an industrial chemical mentioned in column 1 of an item in the following table; and

.....

Proposed Rule

26 Circumstances in which introductions are exempted introductions

(1) For the purposes of step 2 of the method statement in section 24, the introduction of an industrial chemical by a person is covered by this section if any of subsections (2) to (8) of this section apply to the introduction.

.....



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Industrial chemicals comparable to listed industrial chemicals				
	Column 1	Column 2	Column 3	Column 4
Item	Industrial chemical to be introduced	CAS no. of industrial chemical to be introduced	Listed industrial chemical	CAS no. of listed industrial chemical
...
15	Tylosin, (2R,3R)-2,3-dihydroxybutane dioate (1:1)	74610-55-2	Tylosin, (2R,3R)-2,3-dihydroxybutane dioate (salt)	1405-54-5
16	Wheat germ oil	313258-61-6	Oils, wheat	68917-73-7

(5) This subsection applies to the introduction of an industrial chemical by a person if:

(a) the introduction is of an industrial chemical mentioned in column 1 of an item in the following table; and

.....

Industrial chemicals comparable to listed industrial chemicals				
	Column 1	Column 2	Column 3	Column 4
Item	Industrial chemical to be introduced	CAS no. of industrial chemical to be introduced	Listed industrial chemical	CAS no. of listed industrial chemical
...
15	Wheat germ oil	313258-61-6	Oils, wheat	68917-73-7



Schedule 1, Clause 60 of the Exposure Draft

Reason for proposed amendment

The proposed amendment would correct an omission by adding circumstances to the list for when an AICIS Approved Chemical Name (AACN) or generalised end use must be used.

What the proposed amendments mean

The proposed amendment would add these circumstances:

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

Current Rule	Proposed Rule
66 When an AACN or a generalised end use must be used (1) For the purposes of paragraphs 109(1)(b) and (2)(b) of the Act, the circumstances mentioned in subsection (2) of this section are prescribed in relation to an application made under subsection 105(1) or (2) of the Act for the proper name or end use for an industrial chemical to be treated as confidential business information. (2) For the purposes of subsection (1), the circumstances are that the Executive Director is publishing information (including by giving it to a person) under any of the following provisions of the Act in relation to the industrial chemical: (g) subsection 78(3) (which deals with publishing evaluation statements of other introductions or matters); (h) section 83 (which deals with listing on the Inventory before 5 years);	66 When an AACN or a generalised end use must be used (1) For the purposes of paragraphs 109(1)(b) and (2)(b) of the Act, the circumstances mentioned in subsection (2) of this section are prescribed in relation to an application made under subsection 105(1) or (2) of the Act for the proper name or end use for an industrial chemical to be treated as confidential business information. (2) For the purposes of subsection (1), the circumstances are that the Executive Director is publishing information (including by giving it to a person) under any of the following provisions of the Act in relation to the industrial chemical: (g) subsection 78(3) (which deals with publishing evaluation statements of other introductions or matters); (ga) subsection 80(2) (which deals with making the Inventory publicly available); (gb) subsection 82(1) (which deals with listing on the Inventory after 5 years); (h) section 83 (which deals with listing on the Inventory before 5 years);



Schedule 1, Clause 61 of the Exposure Draft

Reason for proposed amendment

The proposed amendment would add a new item in the table at section 79 of the Rules to allow the consideration period to be 'paused' (that is, the specified period to be excluded) if the Executive Director gives a notice of intention to publish information under subsection 113(1) of the IC Act.

What the proposed amendments mean

This would allow time for an applicant to apply for information flagged under 112 to be treated as confidential business information (and therefore not published).

Current Rule

79 Calculating the consideration period for an application

For the purposes of item 12 of the table in subsection 169(1) of the Act:

- (a) the circumstances mentioned in column 1 of an item in the following table are prescribed; and
- (b) the days mentioned in columns 2 and 3 of an item in the following table are prescribed in relation to the circumstance mentioned in column 1 of the item.

Proposed Rule

79 Calculating the consideration period for an application

For the purposes of item 12 of the table in subsection 169(1) of the Act:

- (a) the circumstances mentioned in column 1 of an item in the following table are prescribed; and
- (b) the days mentioned in columns 2 and 3 of an item in the following table are prescribed in relation to the circumstance mentioned in column 1 of the item.



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Calculating excluded periods

	Column 1	Column 2	Column 3
Item	If this circumstance applies:	exclude the period beginning on this day:	and ending on this day:
...
2	Advice is sought from the Gene Technology Regulator under section 92 of the Act	The day notice of the request is given	The earlier of: (a) the day a complete response is given to the Executive Director; and (b) the last day of the period specified in the notice in accordance with subsection 92(3) of the Act

Calculating excluded periods

	Column 1	Column 2	Column 3
Item	If this circumstance applies:	exclude the period beginning on this day:	and ending on this day:
...
2	Advice is sought from the Gene Technology Regulator under section 92 of the Act	The day notice of the request is given	The earlier of: (a) the day a complete response is given to the Executive Director; and (b) the last day of the period specified in the notice in accordance with subsection 92(3) of the Act
3	A notice is given to a person under subsection 113(1) of the Act in relation to information	The day the notice is given	The earlier of: (a) the day a complete application in response to the notice is made under



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**included in an
application under
section 31, 43,
53, 62 or 88 of
the Act**

**subsection 113(2)
of the Act; and
(b) the last day of
the period specified
in the notice in
accordance with
subsection 113(3) of
the Act**



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Part 11 – Transitional provisions

Schedule 1, Clause 62 of the Exposure Draft

Reason for proposed amendment

This proposed amendment would add provisions that allow for certain changes within this amending instrument to only apply after certain dates.

What the proposed amendments mean

Record keeping for listed introductions - the proposed amendments would apply to any undertakings given after commencement of this amending instrument. For example, written undertakings given before this commencement would not have to be modified.

Proposed amendments to the following declarations and reports would **apply on or after 10 December 2021**.

- post-introduction declarations
- pre-introduction reports (including varied reports)
- annual declarations



No
current
Rule

Proposed Rule

Chapter 8—Application, saving and transitional provisions

Part 1—Application provisions relating to the Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021
80 Record keeping for listed introductions

Item 2 of the table in section 46, as amended by Part 5 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, applies in relation to an undertaking mentioned in that item that is given on or after the commencement of that Part.

63 At the end of Part 1 of Chapter 8

Add:

81 Post-introduction declarations for exempted introductions

Subsection 36(2), as amended by Part 3 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, applies in relation to a declaration made under section 96A of the Act on or after the commencement of that Part.

82 Pre-introduction reports for reported introductions

(1) Subsections 41(2) and 43(2), as amended by Part 2 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, apply in relation to a report given under subsection 97(1) of the Act, or varied under section 98 of the Act, on or after the commencement of that Part.

(2) Subsections 38(2), 39(2), 40(2) and 43(2), as amended by Part 3 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, apply in relation to a report given under subsection 97(1) of the Act, or varied under section 98 of the Act, on or after the commencement of that Part.

83 Annual declarations for all introduction categories

Section 44, as amended by Part 4 of Schedule 1 to the *Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021*, applies in relation to a declaration made under section 99 of the Act on or after the commencement of that Part.



Schedule 2 – Amendments to the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019

Schedule 2, Clause 1 of the Exposure Draft

Reason for proposed amendment

The proposed amendment would add a new transitional rule so that when a transitioned assessment certificate is included on the Inventory under sections 82 (listing after 5 years) or 83 (listing before 5 years) of the IC Act, the conditions on the transitioned assessment certificate could be included on the Inventory listing.

What the proposed amendments mean

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

No current Rule	Proposed Rule
	20A Listing on Inventory of conditions on transitioned assessment certificates
	(1) This section applies in relation to an industrial chemical for which an assessment certificate:
	(a) was taken to have been issued under the new law in accordance with item 11 of Schedule 2 to the transitional Act; or
	(b) was issued under the new law in accordance with item 13 of Schedule 2 to the transitional Act.
	(2) Subsection 81(2) of the new law does not apply in relation to the listing of the industrial chemical on the Inventory under section 82 or 83 of the new law.



Schedule 2 – Amendments to the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019

Schedule 2, Clause 2 of the Exposure Draft

Reason for proposed amendment

The proposed amendment would remove the following chemicals from the table of conditions of use transitioned to defined scopes of assessment:

- Table item 1 - Hexanoic acid, 2 ethyl , 1,1' (2,2 dimethyl 1,3 propanediyl) ester
- Table item 9 - L-Ascorbic acid, tetrakis(2-hexyldecanoate)
- Table item 39 - 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, 1,2,3-tris(2-octyldodecyl) ester
- Table item 64 - Hexanoic acid, 2-ethyl-, C16-18-alkyl esters

What the proposed amendments mean

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