Australian Government

Department of Health

National Industrial Chemicals Notification and Assessment Scheme

Applications for certificates under reforms

Reforms consultation

September 2018

This document discusses the types of information that you will be required to provide when applying for an assessment certificate for an unlisted chemical introduction under the proposed new scheme, the Australian Industrial Chemicals Introduction Scheme (AICIS).

Contents

1 Overview of this consultation

We are seeking your feedback on the amount and types of information that you will be required to provide when applying for an assessment certificate for an unlisted chemical introduction under the proposed new scheme, the Australian Industrial Chemicals Introduction Scheme (AICIS).

In this document we describe the information you will need to provide when completing an assessment certificate application. We previously consulted stakeholders on the likely types of information that would be needed for assessment certificate applications in Consultation Paper 5 https://www.nicnas.gov.au/reforms/consultation-paper-5/Part-4-information-requirements-categorisation-and-assessment-of-unlisted-chemical-introductions/assessed-introductions

The information requirements for assessment certificate applications will be set out in the 'approved forms' rather than in the Industrial Chemicals Rules and associated Guidelines. These application forms will be online forms that you must submit to apply for an assessment certificate. We are basing these forms on IUCLID[1]. Once developed, they will be available through the Business Services portal (currently called NICNAS Business Services).

Have your say

Your feedback on the information requirements described in this document is due by **26 October 2018**. In particular, we welcome your comments on:

- the types of information that you need to provide when completing an assessment certificate application
- how the amount and type of information that you need to provide varies depending on certain details of your proposed introduction (such as exposure band or indicative risk)
- the specified information waivers that we have described

[1] IUCLID is a software developed by the European Chemicals Agency (ECHA) and the Organisation for Economic Cooperation and Development (OECD) to record, store, maintain and exchange information on chemicals. IUCLID is used in Europe for information submitted to ECHA under the REACH legislation.

Your feedback on this consultation will help us to develop the final assessment certificate application forms. We might also need to make some practical modifications as we build the forms using IUCLID as the basis.

2 Circumstances resulting in certificate applications

In the new scheme, before you import or manufacture industrial chemicals in Australia, you must first categorise your chemical introduction into one of the following categories:

- Listed
- Exempted
- Reported
- Assessed
- Commercial evaluation
- Exceptional circumstances

Applications for assessment certificates:

- **must** be submitted for introductions categorised as assessed, and
- **may** be submitted for introductions categorised as exempted or reported.

We illustrate this in Figure 1 and discuss in further detail below.

Figure 1

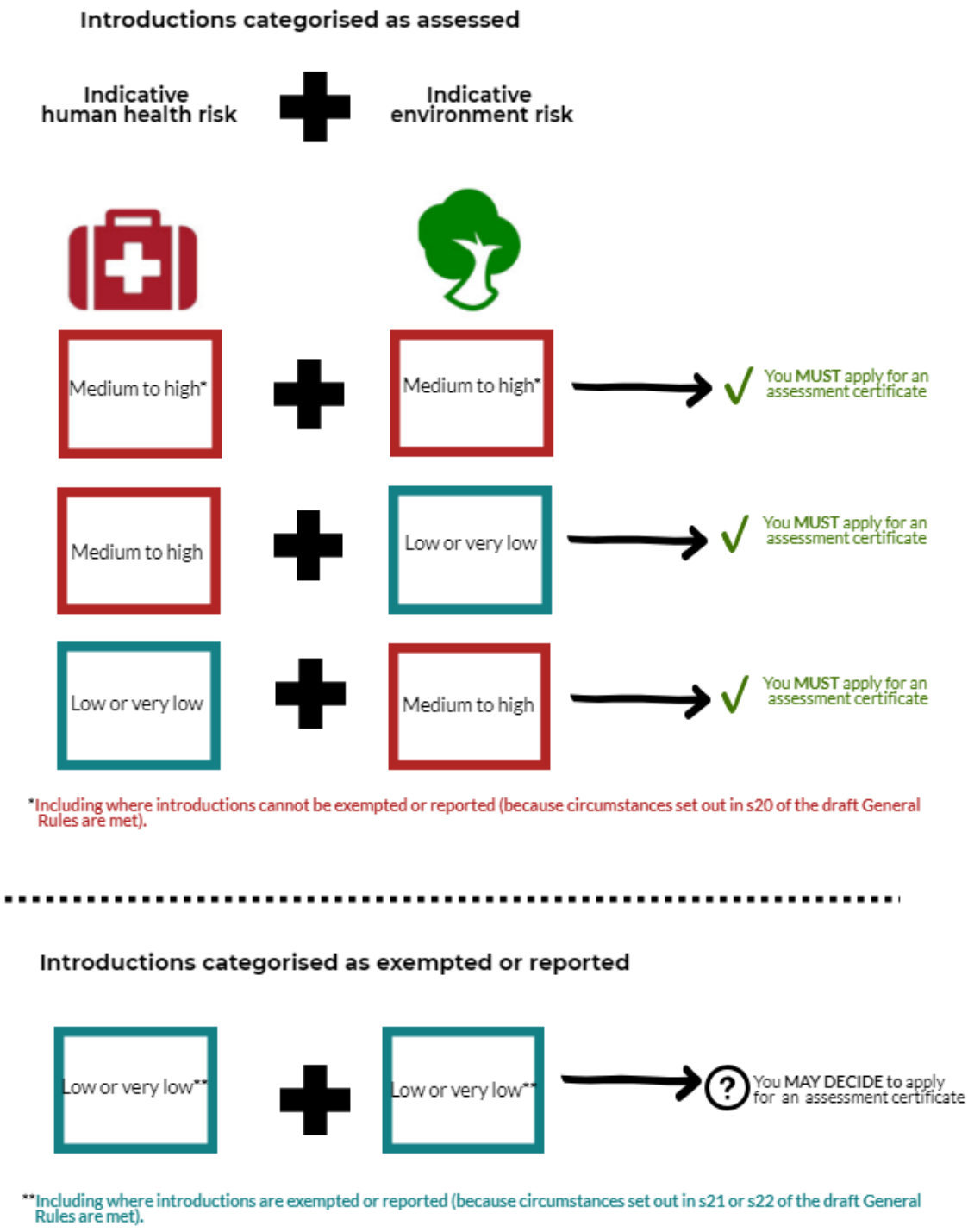

Figure 1 - Categorisation outcomes for your introduction – when you must or may decide to apply for an assessment certificate

2.1 Introductions categorised as assessed

Your introduction will likely be categorised as **assessed** if:

- it can't be exempted or reported according to section 20 of the draft General Rules because it will always be considered to be medium to high risk for human health and the environment (see Attachment A for further information), or
- the highest indicative risk for your introduction is medium to high risk (see the explanatory material for the draft General Rules on determining indicative human health and environment risk - https://www.nicnas.gov.au/reforms/Rules-Guidelines/Draft-General-Rules/Draft-General-Rules-notes/determining-indicative-risk

If your introduction is categorised as **assessed** you:

- must apply for an assessment certificate, and
- will not be able to introduce your chemical until we have completed our risk assessment and given you an assessment certificate.[2]

2.2 Introductions categorised as exempted or reported

Your introduction will be categorised as **exempted** or **reported** if:

- it can be exempted according to section 21 of the draft General Rules because it will always be considered to be very low risk for human health and the environment (see Attachment A for further information), or
- it can be reported according to section 22 of the draft General Rules because it will always be considered to be low risk for human health and the environment (see Attachment A for further information), or
- the highest indicative risk for your introduction is low or very low (see the explanatory material for the draft General Rules on determining indicative human health and environment risk - https://www.nicnas.gov.au/reforms/Rules-Guidelines/Draft-General-Rules/Draft-General-Rules-notes/determining-indicative-risk

[2] There may be circumstances where you could introduce your chemical while we are doing our assessment and before we give you an assessment certificate. For example, you could introduce lower volumes or concentrations of your chemical so that it is categorised as exempted or reported during this time (rather than assessed). You must still continue to meet any categorisation criteria and terms of that introduction category. After we give you a certificate, you can then introduce within the terms of the certificate.

Note. As well as referring to the draft General Rules for information on sections 21 and 22, you can also read our website guidance notes at https://www.nicnas.gov.au/reforms/Rules-Guidelines/Draft-General-Rules/Draft-General-Rules-notes/determining-if-an-introduction-is-exempted-or-reported

If your introduction is categorised as exempted or reported, you may decide to apply for an assessment certificate. This may be, for example, because you want your chemical to be added to the Inventory. For this to occur, we need to do an assessment. You may still introduce under the relevant alternative introduction category (exempted or reported) while we assess the certificate application. You must continue to meet any categorisation criteria and terms of that introduction category.

In the following sections, we provide details of the information requirements for assessment certificate applications.

3 Information required for an assessment certificate application

The information set out in the assessment certificate application form is the information that you will be required to submit as part of a certificate application.

The assessment certificate application form will include the information we need to determine:

- the risks to human health and the environment from the proposed introduction and use of your chemical, and
- whether those risks can be managed.

You will also need to provide any other information that you have on the chemical that is relevant to our assessment.

We may request further information during our assessment if we need it to be satisfied that any risks to human health or the environment have been identified and can be managed. We may need this further information even if an information waiver might otherwise apply (refer to later sections of this document for more details about information waivers).

Our assessments of certificate applications will focus on the issues of concern for human health or the environment. The information requirements will be proportionate and risk-based. This means the amount and type of information you need to provide in the assessment certificate application form may vary. Specifically, it may vary depending on certain details of your proposed introduction. For example, the amount of information could be different depending on:

- the human health or environment exposure band relevant for your introduction
- the indicative risk for your introduction for human health or the environment.

We will most likely reflect these circumstances in the defined scope of the resulting assessment.

We have based the information required for an assessment certificate application on the following:

- the information needed for chemicals to be added to the Inventory following assessment

- the information required to undertake risk assessments and make recommendations to risk managers
- the practicality of obtaining the information
- the information that may be available, taking into account information requirements of other jurisdictions
- the need for reduced reliance on information obtained using animal testing
- the level of acceptance and validation of alternatives to animal testing
- feedback obtained on previous Consultation Papers
- the terminology used in other jurisdictions (namely, EU-REACH via IUCLID)
- risk-based and proportionate regulatory impacts and outcomes.

3.1 Information waivers

Information waivers will be available under the new scheme. This means there may be circumstances where you do not have to provide all the information in the assessment certificate application form.

There will be two types of information waivers:

- **Specified information waivers** – these will apply for certain physico-chemical and hazard characteristics. Details of these are included in later sections of this document and will also be set out in the assessment certificate application form and/or guidance material.
- **Case-by-case information waivers** - you may be able to apply for these based on the:
    - characteristics of your chemical; or
    - circumstances of your introduction (e.g. exposure-based waivers).

When applying for case-by-case information waivers, you will need to provide justification to support your application. We will tell you over the course of the assessment if we accept your waiver application or not. Our acceptance will depend on whether we are able to conduct an adequate risk assessment in the absence of the information. If we accept an information waiver due to the circumstances of the introduction (such as an exposure-based waiver), we will most likely reflect these circumstances in the defined scope of the resulting assessment.

3.2 Types of information requirements

- Chemical identity information
- Physico-chemical properties

- Introduction, use and exposure information
- Hazard and fate information
- Other information

We discuss these types of information below.

3.2.1 Chemical identity information we will need

As all chemicals introduced under a certificate will be included on the Inventory, the chemical identity information requirements will be the same for all applications.

We will need the following information from you in your application:

- proper name for the chemical (including the CAS name (preferred) or IUPAC name)
- CAS number (if available)
- proposed AICIS approved chemical name (AACN, if you are applying for the chemical name to be confidential)
- any other names by which the chemical is known
- molecular formula (if defined)
- structural formula (if defined)
- molecular weight or weight range (if defined)
- composition (e.g. purity, identity of impurities, reactants, additives/adjuvants and isomers, identity and concentrations of component chemicals as far as is known if a UVCB substance, and if such composition changes batch-to-batch)
- analytical information (enough information to sufficiently characterise the chemical, such as nuclear magnetic resonance (NMR) spectroscopy, liquid chromatography-mass spectrometry (LC-MS) and Fourier-transform infrared (FT-IR) spectroscopy analytical reports) and
- if the chemical is a UVCB substance, the UVCB substance description (e.g. CAS description and details of the immediate precursors/natural sources)

If your chemical is a polymer, you will also need to provide:

- identity and percentage of all polymer constituents prior to polymerisation
- the percentage residual of each constituent remaining (by weight) following completion of the polymerisation
- A gel permeation chromatography (GPC) analytical report, which provides the:
    - molecular weight distribution of the polymer, including:
        - number average molecular weight (NAMW)

- weight average molecular weight (WAMW), and
- the percentage by mass of molecules with molecular weight that is:
  - <1,000 g/mol, and
  - <500 g/mol.

3.2.2 Physico-chemical properties information we will need

We will need the following information from you in your application:

- the properties set out in the table below (Table 1) for the circumstances of your introduction, and
- any other available physico-chemical property information on your chemical.

If relevant, you'll have to submit test reports to support the information on physico-chemical properties you provide.

Assessments will focus on the issues of concern for human health or the environment. This means that the amount and type of information on physico-chemical properties you need to provide will vary. It will depend on which of the following indicative risk combinations applies to your introduction:

1. **Medium to high indicative risk – human health and the environment**

   Your introduction cannot be exempted or reported (because circumstances set out in s20 of the draft General Rules are met – see Attachment A)

   OR

   Your assessed categorisation is based on the indicative human health and environment risks both being medium to high.

2. **Medium to high indicative risk – human health only**

   Your assessed categorisation is based on the:
   a. indicative human health risk being medium to high and
   b. indicative environment risk being low or very low

3. **Medium to high indicative risk – environment only**

   Your assessed categorisation is based on the:

a. indicative environment risk being medium to high and
b. indicative human health risk being low or very low.

4. **Low or very low indicative risk - human health and the environment**

Your introduction can be exempted or reported (if circumstances of s21 or s22, respectively of the draft General Rules are met – see Attachment A)

OR

Your exempted or reported categorisation is based on the highest indicative risk for human health and the environment being low or very low.

Table 1 – Physico-chemical requirements by the introduction's indicative risk

	Indicative risk combinations[3]			
	Med to high risk for BOTH	Med to high risk for health	Med to high risk for env't	Very low or low risk for BOTH
Appearance / physical state / colour	Yes	Yes	Yes	Yes
Melting point / freezing point	Yes	Yes	Yes	Yes
Boiling point	Yes	Yes	Yes	Yes
Density	Yes	Yes	Yes	Yes
Particle size distribution (granulometry)	Yes	Yes	Yes	Yes
Vapour pressure	Yes	Yes	Yes	Yes
Partition coefficient	Yes	Yes	Yes	Yes
Water solubility	Yes	Yes	Yes	Yes
Flash point	Yes	Yes	No	No
Auto flammability	Yes	Yes	No	No
Flammability	Yes	Yes	No	No
Explosiveness	Yes	Yes	No	No
Oxidising properties	Yes	Yes	No	No
Dissociation constant	Yes	Yes	Yes	Yes
Adsorption/desorption	Yes	Yes	Yes	Yes
Hydrolysis as a function of pH	Yes	Yes	Yes	Yes

[3] See above text for descriptions of these indicative risk combinations.

You may not need to provide the information set out in the above table if an information waiver applies. The specified information waivers for physico-chemical properties are described in Attachment B.

3.2.3 Introduction, use, exposure and release information we will need

We will need the following information from you in your application:

- mode of introduction (import or manufacture)
- introduction volume
- use, exposure, release and disposal information for each relevant life cycle stage in Australia, including:
    - manufacture
    - formulation or re-packing
    - use at industrial site
    - widespread professional use (e.g. use by building and construction tradespeople, small cleaning businesses, hairdressing and beauty salons)
    - consumer use

The amount and type of information you will need to provide will vary. It will depend on which of the following indicative risk combinations applies to your introduction:

1. **Medium to high indicative risk – human health and the environment**

   Your introduction cannot be exempted or reported (because circumstances set out in s20 of the draft General Rules are met – see Attachment A)

   OR

   Your assessed categorisation is based on the indicative human health and environment risks both being medium to high

2. **Medium to high indicative risk – human health only**

   Your assessed categorisation is based on the:
   a. indicative human health risk being medium to high and
   b. indicative environment risk being low or very low

3. **Medium to high indicative risk – environment only**

   Your assessed categorisation is based on the:
   a. indicative environment risk being medium to high and
   b. indicative human health risk being low or very low.

4. **Low or very low indicative risk – human health and the environment**

   Your introduction can be exempted or reported (if circumstances of s21 or s22, respectively of the draft General Rules are met – see Attachment A)

   OR

   Your exempted or reported categorisation is based on the highest indicative risk for human health and the environment being low or very low.

We summarise in Table 2 the use, exposure, release and disposal information you will need to provide to us for the relevant life cycle stages.

The use and exposure terminology we will use in the assessment certificate application form, as well as the structure of the information into lifecycle stages (see the table below – Table 2) is consistent with that used in IUCLID. We are designing the assessment certificate application form based on the OECD harmonised templates implemented in IUCLID, to increase harmonisation with information that industry is required to have in the EU.

Table 2: Use, exposure and release requirements for each relevant life cycle stage by your introduction's indicative risk

	Indicative risk combinations[4]			
	Med to high risk for BOTH	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH
Description of process(es)/use at each stage	Yes	Yes	Yes	Yes
Percentage (w/w) of substance in mixture at each stage	Yes	Yes	Yes	Yes
Physical form at each stage	Yes	Yes	Yes	Yes
Process category[5] (picklist) for each stage except consumer use	Yes	Yes	Yes	Yes
Product category[5] (picklist) for each stage except manufacture	Yes	Yes	Yes	Yes
Sector of end use[5] (picklist) for use at industrial sites and widespread professional use stages	Yes	Yes	Yes	Yes
Technical function of the chemical[5] (picklist) for each stage except manufacture	Yes	Yes	Yes	Yes
Whether chemical supplied to that use as such or in a mixture for each stage except manufacture	Yes	Yes	Yes	Yes
Tonnage of substance for the use for each stage except manufacture	Yes	Yes	Yes	Yes
Details of amount used, frequency and duration of exposure, including details on duration of activity for manufacture to widespread professional use stages	Yes	Yes	No	No
Details of amount used, frequency and duration of exposure, including details on duration of activity for the consumer use stage	Yes	Yes	Yes	Yes[6]

[4] See above text for descriptions of these indicative risk combinations
[5] Not required for widespread professional use stage
[6] Not required if the chemical is a PLC or low concern biopolymer

Table 2: Use, exposure and release requirements for each relevant life cycle stage by your introduction's indicative risk

	Indicative risk combinations[4]			
	Med to high risk for BOTH	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH
Conditions and measures in place, including technical measures and personal protective equipment (PPE) for each stage except consumer use	Yes	Yes	No	No
Other conditions affecting workers exposure, including use indoors and/or outdoors for each stage except consumer use	Yes	Yes	No	No
Conditions, information and advice for consumers - for consumer use stage only	Yes	Yes	Yes	Yes[6]
Product (article) characteristics for consumer use stage only	Yes	Yes	Yes	Yes
Use amount at a site (tonnes/year) (and details on amount[6]) for each stage except consumer use	Yes	Yes[5]	Yes	Yes[5]
Details on number of emission days and other details related to amounts/frequency/duration for each stage except consumer use	Yes	No	Yes	No
Technologies to minimise emissions for formulation and use at industrial sites stages	Yes	Yes	Yes	Yes[6]
Other conditions of use related to waste treatment for the use at industrial sites stage	Yes	Yes	Yes	Yes[6]
Conditions and measures related to Biological Sewage Treatment Plant for the manufacture stage	Yes	Yes	Yes	Yes[6]
Other conditions affecting environmental exposure, including details on place of use for all stages except consumer use	Yes	No	Yes	No
Where the chemical is released to (picklist) for the consumer use stage	Yes	Yes	Yes	Yes[6]
Release factor to external waste for all stages	Yes	Yes	Yes	Yes[6]

Table 2: Use, exposure and release requirements for each relevant life cycle stage by your introduction's indicative risk

	Indicative risk combinations[4]			
	Med to high risk for BOTH	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH
Details on release to external waste for all stages	Yes	No	Yes	No

3.2.4 Hazard and fate information we will need

We will need the following information from you in your application:

- the information set out below for the circumstances of your introduction, and
- any other available hazard and fate information on your chemical.

Assessments will focus on the issues of concern for human health or the environment. This means that the amount and type of hazard information you need to provide will vary. It will depend on the circumstances of your proposed introduction.

3.2.4.1 Human health information requirements

The amount and type of human health hazard information you need to provide will mostly depend on:

- whether your assessed categorisation is because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- whether your exempted or reported categorisation is because the circumstances in s21 or s22, respectively, of the draft General Rules are met (see Attachment A) but you decide to apply for an assessment certificate, or
- what the relevant human health exposure band for your introduction is.

For all applications, you will need to provide the known hazard classifications for human health and any other hazard information you have on the chemical.

In addition, the assessment certificate application form will set out specific human health hazard information requirements that will apply if:

- your introduction is categorised as assessed because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- the **highest human health exposure band** is relevant for your introduction.

If either of the above applies, you will need to provide information for 1 and 2:

1. Information on your chemical to characterise it against each of the following hazards (see Attachment C for more information):

- acute toxicity
- skin corrosion/irritation
- eye damage/irritation

- skin sensitisation
- specific target organ toxicity after repeated exposure
- genetic toxicity

The assessment certificate application form will set out what the acceptable information is for each of these hazards. This may include the outcomes of:

- in chemico studies on your chemical
- in vitro studies on your chemical or from suitable read-across information
- in vivo studies on your chemical or from suitable read-across information.

Supporting study reports must also be provided (see Attachment C for details).

AND

2. Polymer-specific hazard information if you are introducing a **high molecular weight polymer.** You will need to identify whether it:

- is water absorbing, or
- has lung overloading potential.

Attachment C sets out the circumstances where specified information waivers will apply.

An example of this is specific target organic toxicity after repeated exposure information is **not required** for introductions in the highest human health exposure band if:

- the total introduction volume of the chemical in a registration year is ≤1,000 kg and:
  - an end use for your introduction is in cosmetics or an article with food contact; and
  - you have provided any available read-across information you have that is relevant to specific target organ toxicity after repeated exposure, or
- the total introduction volume of the chemical in a registration year is ≤10,000 kg and all end uses for your introduction are for other than cosmetics, tattoo ink, personal vaporisers, or an article with food contact.

It will also be possible to apply for case-by-case information waivers when submitting a certificate application.

3.2.4.2 Environment information requirements

The amount and type of environment hazard and fate information you need to provide will mostly depend on:

- whether your assessed categorisation is because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- whether your exempted or reported categorisation is because the circumstances in s21 or s22, respectively, of the draft General Rules are met (see Attachment A) but you decide to apply for an assessment certificate, or
- what the relevant environment exposure band for your introduction is, or
- what the indicative environment risk for your introduction is.

For all applications, you will need to provide the known hazard classifications for environment and any other hazard and fate information you have on the chemical.

In addition, the assessment certificate application form will set out specific environment hazard and fate information requirements that will apply if:

- your introduction is categorised as assessed because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- the **highest two environment exposure bands** are relevant for your introduction, or
- the **lowest two environment exposure bands** are relevant for your introduction **and** the indicative environment risk is **medium to high risk**

If any of the above applies, you will need to provide information for 1 and 2:

1. Information on your chemical to characterise it against each of these characteristics:

   - persistence
   - bioaccumulation
   - aquatic toxicity

   The assessment certificate application form will set out the acceptable information for each of these characteristics. This may include the outcomes of:
   - in silico studies on your chemical, or
   - in vivo studies on your chemical or from suitable read-across information.

   Supporting study reports must also be provided (see Attachment D for details).

AND

2. Polymer-specific information if you are introducing a polymer. You will need to provide information on the stability of the polymer, including whether it breaks down into simpler, smaller weight substances as the result of, but not limited to:
    - oxidation
    - hydrolysis
    - heat
    - sunlight
    - attack by solvents or
    - microbial action

Attachment D sets out the circumstances where specified information waivers will apply.

An example of this is where bioaccumulation information is not required if your chemical is a high molecular weight polymer.

It will also be possible to apply for case-by-case information waivers when submitting a certificate application.

3.2.5 Other information we will need

Other information that you need to provide if your introduction is categorised as assessed includes:

- Safety Data Sheet (SDS) on the introduced chemical (as introduced, and for the chemical itself if introduced in a product and the chemical SDS is available)
- Label for the chemical (as introduced)
- Any additional information requirements that apply for:
    - specified classes of introduction (see Attachment E)
    - certain chemicals at the nanoscale (see Attachment F)
    - certain fluorinated organic chemicals (see Attachment G)
    - introductions that involve a designated kind of release into the environment (see Attachment H).

Other information that you need to provide if you decide to apply for an assessment certificate (but your introduction is categorised as exempted or reported) includes:

- Safety Data Sheet (SDS) on the introduced chemical (as introduced, and for the chemical itself if introduced in a product and the chemical SDS is available)
- Label for the chemical (as introduced)
- Any additional information requirements that apply for:
    - specified classes of introduction (see Attachment E)
    - introductions that involve a designated kind of release into the environment (see Attachment H)
- Any additional information to confirm that the circumstances described in s21 or s22 of the draft General Rules have been met (if applicable) (see Attachment A). For example, if you are introducing a polymer of low concern, you will have to provide additional information to support that the criteria outlined in Schedule 1 of the draft General Rules are met, including:
    - the functional group equivalent weight of the polymer (if the polymer contains any moderate or high concern reactive functional groups) and
    - confirmation that the polymer:
        - meets the elemental criteria
        - has a low charge density
        - does not have any known hazard classification, and
        - is not capable of absorbing its own weight in water (if the NAMW for the polymer is ≥10,000 g/mol).

Attachment A: Introductions that are always assessed, always exempted, always reported

Section 20 – always assessed
Section 21 – always exempted
Section 22 – always reported

Read further

Introductions that cannot be exempted or reported (i.e. are always assessed)

Section 20 of the draft General Rules sets out the circumstances where an introduction will always be considered **medium to high risk** for human health and the environment. These introductions must always be assessed by us before you can introduce the chemical.

We must assess the following types of introductions:

Table 3: Introductions that cannot be exempted or reported

Circumstances	Draft General Rules section
Rotterdam and Stockholm Conventions - chemicals listed on one of these conventions and - no action has been taken yet to restrict the chemical in Australia.	s20(2)
Certain chemicals at the nanoscale which: ▪ meet particle size requirements and are introduced as a solid or dispersion. ▪ persist at the nanoscale during intended use and don't rapidly dissolve in water, or have a high dissolution rate. ▪ are not incidental to the introduction of the non-nanoscale portion of the industrial chemical.	s20(3)
Persistent gases introduced in volumes greater than 100 kg/year.	s20(6)
Certain fluorinated organic chemicals.	s20(7)
Persistent polyhalogenated organic chemicals introduced in volumes greater than 100 kg/year.	s20(8)

Introductions that are always exempted

Section 21 of the draft General Rules sets out the circumstances where an introduction will always be considered **low risk** for human health and the environment:

Table 4: Exempted introductions

Circumstances	Draft General Rules section
Chemicals that are imported and subsequently exported	s21(2)
Chemicals that are solely for use in research and development	s21(3)
A polymer that is comparable to a polymer that is listed on the Inventory	s21(4)
A chemical that is comparable to a chemical that is listed on the Inventory	s21(5)
Polymers of low concern	s21(6)
Low concern biopolymers	s21(7)

Introductions that are always reported

Section 22 of the draft General Rules sets out the circumstances where an introduction will always be considered **very low risk** for human health and the environment:

Table 5: Reported introductions

Circumstances	Draft General Rules section
Chemicals that are internationally-assessed for human health and the environment	s22(2)
Chemicals at the nanoscale that are solely for use in research and development	s22(3)

Attachment B: Waivers for physico-chemical properties

For each relevant physico-chemical property, the information **will not be required** if any of the following apply:

- the information waivers described in IUCLID, or
- any of the additional circumstances set out in this table.

Table 6: Additional specified information waivers for physico-chemical properties

Physico-chemical property	**Information will not be required if your chemical:**
Melting point / freezing point	• is a salt that is only stable as an aqueous solution. • has a melting point/freezing point ≤-25 °C or >300 °C. • undergoes a chemical reaction or decomposes. In this case, the temperature of the chemical reaction/decomposition point must be provided. • has a pour point or softening point, which is more applicable to be provided. • is a gas at room temperature and pressure. • the chemical is a PLC or low concern biopolymer.
Boiling point	• is a salt that is only stable as an aqueous solution. • has a sublimation point, which is more applicable to be provided. • the chemical is a PLC or low concern biopolymer.
Density	• if the chemical is a gas. In this case, an estimation based on its molecular weight and the Ideal Gas Laws must be provided. • the chemical is a PLC or low concern biopolymer.
Vapour pressure	• has a melting point between 200 °C and 300 °C. In this case, a limit value based on measurement or a recognised calculation method must be provided. • has a molecular weight >1,000 g/mol. • is an ionic solid. • the chemical is a PLC or low concern biopolymer
Partition coefficient	• is hydrolytically unstable (t½ <12 hours). • is expected to have log Kow >7. • has a water solubility of >5 g/L. • the chemical is a PLC or low concern biopolymer.

Water solubility	• is miscible in water (>1,000 g/L, as per OECD Guideline 105). • is produced in an aqueous solution and is not available in an isolated form. • is surface active and forms a stable emulsion in water, which cannot be separated by filtration or centrifugation methods.
Flash point	• has an estimated flashpoint >200 °C. • has a flashpoint that can be accurately predicted by interpolation from existing characterised materials. • will be introduced at a volume <1,000 kg per year.
Auto flammability	• will be introduced at a volume <1,000 kg per year.
Flammability	• will be introduced at a volume <1,000 kg per year.
Explosiveness	• will be introduced at a volume <1,000 kg per year.
Oxidising properties	• the preliminary test indicates the chemical has oxidising properties (i.e. full test does not need to be conducted). • will be introduced at a volume <1,000 kg per year.
Adsorption/desorption	• is hydrolytically unstable (t½ <12 hours). • has a water solubility of <0.01 mg/L or the water solubility cannot be measured analytically. • is an inorganic compound. • is a gas at room temperature and pressure. • is a high molecular weight polymer. • the chemical is a PLC or low concern biopolymer.
Hydrolysis as a function of pH	• is readily reactive in the presence of water or moisture. • has no readily hydrolysable groups and therefore is not expected to hydrolyse (based on structural formula). • the chemical is a PLC or low concern biopolymer.

Attachment C: Human health hazard characterisation requirements

For all applications, you will need to provide the known hazard classifications for human health and any other hazard information you have on the chemical.

The information described in this attachment is only required if:

- your introduction is categorised as assessed because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- the highest human health exposure band is relevant for your introduction.

You may not have to provide the information in this attachment if:

- specified information waivers (detailed below) apply, or
- you can justify a case-by-case information waiver.

1. Acute toxicity

The information on acute toxicity you will need to submit with your application is ONE or more of the following in vivo studies on your chemical or from suitable read-across information, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available):

- for acute oral toxicity (LD50), conducted following OECD test guideline 420 or 423 or 425 or deleted 401, or
- for acute dermal toxicity (LD50), conducted following OECD test guideline 402 or draft 434, or
- for acute inhalation toxicity (LC50), conducted following OECD test guideline 403 or 436 or draft 433.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is corrosive or severely irritating to the skin (GHS Category 1) or likely to be corrosive to the skin (i.e. the chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5)), together with high buffering capacity (if relevant), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature, or

- your chemical is a **high molecular weight polymer** that has <5% by mass of molecules with molecular weight <1,000 g/mol, or <2% by mass of molecules with molecular weight <500 g/mol, or
- if a NOAEL ≥1,000 mg/kg bw/day was demonstrated in an oral subacute toxicity study on your chemical or from suitable read-across information

2. Skin corrosion/irritation

The information on skin corrosion/irritation you will need to submit with your application is ONE or more of the following:

- one or more in vitro studies on the chemical or from suitable read-across information, which provides sufficient information to determine whether or not the chemical is corrosive or irritating to the skin. This could include one or more studies conducted following OECD test guideline 430, 431, 435 or 439; or
- an in vivo study on the chemical or from suitable read-across information for skin corrosion/irritation, conducted following OECD test guideline 404.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5), together with high buffering capacity (if relevant), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature, or
- your chemical is acutely toxic via the dermal route (GHS Category 1), or
- your chemical is not irritating to the skin in a study conducted following OECD test guidelines 402 or draft 434 results, when tested at 2,000 mg/kg bw.

3. Eye damage/irritation

The information on eye irritation you will need to submit with your application is ONE or more of the following:

- one or more in vitro studies on the chemical or from suitable read-across information, which provides sufficient information to determine whether or not the chemical causes eye damage or eye irritation. This could include one or more studies conducted following OECD test guidelines 437, 438, 460, 491 or 492; or

- an in vivo test result on the chemical or from suitable read-across information for eye damage/irritation, conducted following OECD test guideline 405.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5), together with high buffering capacity (if relevant), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature.

4. Skin sensitisation

The information on skin sensitisation you will need to submit with your application is ONE or more of the following:

- A combination of:
  - An in chemico study on the chemical or from suitable read-across information, conducted following OECD test guideline 442C, and
  - An in vitro test result on the chemical or from suitable read-across information, conducted following OECD test guideline 442D, and
  - An in vitro test result on the chemical or from suitable read-across information, conducted following OECD test guideline 442E, or
- An in vivo test result on the chemical or from suitable read-across information, conducted following OECD test guideline 406, 429, 442A or 442B.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is a high molecular weight polymer that:
  - contains only low concern functional groups, or
  - the only high concern functional groups are unsubstituted positions ortho and para to phenolic hydroxyl groups, or
  - has a combined functional group equivalent weight of ≥ 1000 g/mol, or
- your chemical is corrosive or severely irritating to skin (GHS Category 1), or
- your chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature.

5. Specific target organ toxicity after repeated exposure

The information on specific target organ toxicity after repeated exposure you will need to submit with your application is

- an in vivo study conducted following one of the OECD test guidelines 407, 408, 409, 410, 411, 412, or 413 on your chemical or
- from suitable read-across information, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available).

You will not be required to provide this information if any of the following specified information waivers apply:

- the total introduction volume of the chemical in a registration year is ≤1,000 kg and:
  - an end use for your introduction is in cosmetics or an article with food contact; and
  - you have provided any available read-across information you have that is relevant to specific target organ toxicity after repeated exposure, or
- the total introduction volume of the chemical in a registration year is ≤10,000 kg and all end uses for your introduction are for other than cosmetics, tattoo ink, personal vaporisers, or an article with food contact, or
- your chemical is corrosive or severely irritating to the skin (GHS Category 1) or likely to be corrosive to the skin (i.e. the chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5)), together with high buffering capacity (if relevant)), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature, or
- your chemical is a high molecular weight polymer, or
- your chemical is included in the GRAS for FDA Inventory Notice (GRAS Substances (SCOGS)) Database as a Type 1 Conclusion, unless the GRAS conclusion does not apply to the exposures expected from the industrial use of the chemical.

6. Genetic toxicity

The information on genetic toxicity you will need to submit with your application is BOTH of the following:

1. a study on the chemical or from suitable read-across information that addresses point mutations in microbial systems. This could be in vitro

(conducted following OECD test guideline 471 or 476) or in vivo (conducted following OECD test guideline 486, 488 or 489), and

2. a study on the chemical or from suitable read-across information that addresses chromosome damage in mammalian cells. This could be in vitro (conducted following OECD test guideline 473, 487 or 490) or in vivo (conducted following OECD test guideline 474 or 475).

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is included in the GRAS for FDA Inventory Notice (GRAS Substances (SCOGS)) Database as a Type 1 Conclusion, or
- the chemical is a high molecular weight polymer
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature.

Attachment D: Environment hazard characterisation requirements

For all applications, you will need to provide all hazard information you have on the chemical.

The information described in this attachment is only required if:

- your introduction is categorised as assessed because the circumstances set out in s20 of the draft General Rules are met (see Attachment A), or
- the highest two environment exposure bands are relevant for your introduction, or
- the lowest two environment exposure bands are relevant for your introduction and the indicative environment risk is medium to high risk.

You may not have to provide the information in this attachment if:

- specified information waivers (detailed below) apply, or
- you can justify a case-by-case information waiver.

1. Persistence

The information on persistence that you will need to submit with your application is measured ready biodegradability (conducted following OECD test guideline 301) for the chemical or from suitable read-across information.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is inorganic, or
- your chemical is a biochemical or a biological substance.

2. Bioaccumulation

The information on bioaccumulation that you will need to submit with your application is ONE or more of the following:

- Measured bioconcentration factor (BCF; following OECD TG 305) for the chemical or from suitable read-across information, or
- Measured bioaccumulation factor (BAF; following OECD TG 315 or 317) for the chemical or from suitable read-across information, or

- Measured partition coefficient (log Kow; conducted following OECD TG 107, 117, or 123) for the chemical or from suitable read-across information, or
- An in-domain in silico prediction (using KOWWIN) for the partition coefficient (log Kow) of the chemical.

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical has a molecular weight > 1,000g/mol, or
- your chemical is a high molecular weight polymer, or
- your chemical is an inorganic chemical, or
- your chemical is a gas that is not expected to partition to the aquatic compartment.

3. Aquatic toxicity

The information on aquatic toxicity that you will need to submit with your application is ONE or more of the following:

- In-domain in silico predictions (using ECOSAR) for the toxicity of your chemical to :
  - Fish (96 hours LC50)
  - Invertebrates (48 hours EC50), and
  - Algae (96 hours ErC50)
- In vivo studies on your chemical or from suitable read-across information for its toxicity to:
  - Fish (LC50 or NOEC conducted following OECD test guideline 203 or 210)
  - Invertebrates (EC50 or NOEC conducted following OECD test guideline 202 or 211), and
  - Algae (ErC50 or NOEC conducted following OECD test guideline 201)
- A combination of in-domain in silico predictions for the chemical and in vivo test result(s) on the chemical or from suitable read-across information (using the above programs/test guidelines) for:
  - fish,
  - invertebrates, and
  - algae

You will not be required to provide this information if any of the following specified information waivers apply:

- Your chemical has a molecular weight > 1,000g/mol and does not have an overall cationic charge, or
- Your chemical is a high molecular weight polymer that does not have an overall cationic charge, or
- Your chemical is a gas that is not expected to partition to the aquatic compartment.

Attachment E: Specified classes of introduction

If your introduction is a specified class of introduction (see section 7 of the draft General Rules) your assessment certificate application will need to include the information set out in the:

- relevant earlier sections of this document, and
- table below.

If relevant, you'll have to submit test reports to support the information you provide.

The amount and type of information you will need to provide will depend on which of the following indicative risk combinations applies to your introduction:

1. **Medium to high indicative risk - human health and the environment**

   Your introduction cannot be exempted or reported (because circumstances set out in s20 of the draft General Rules are met – see Attachment A)

   OR

   Your assessed categorisation is based on the indicative human health and environment risks both being medium to high.

2. **Medium to high indicative risk - human health only**

   Your assessed categorisation is based on the:
   a. indicative human health risk being medium to high, and
   b. indicative environment risk being low or very low

3. **Medium to high indicative risk - environment only**

   Your assessed categorisation is based on the:
   a. indicative environment risk being medium to high and
   b. the indicative human health risk being low or very low.

4. **Low or very low indicative risk - human health and the environment**

   Your introduction can be exempted or reported (if circumstances of s21 or s22,

respectively of the draft General Rules are met – see Attachment A)

OR

Your exempted or reported categorisation is based on the highest indicative risk for human health and the environment being low or very low.

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
UV filter with a molar extinction coefficient >1000Lmol^{-1}cm^{-1} at wavelengths 290-700 nm	UV-vis absorption spectra	Yes	Yes	Yes	Yes
	Photostability information	Yes	Yes	Yes	Yes
	Toxicokinetics information	Yes	Yes	Yes	Yes
	Potential for interaction with other UV filters	Yes	Yes	Yes	Yes
	Photocarcinogenicity - if introduction volume is greater than 100kg/year	Yes	Yes	Yes	Yes
	Photomutagenicity/photogenotoxicity – if introduction volume is greater than 100kg/year	Yes	Yes	Yes	Yes
	Photosensitisation - if introduction volume is greater than 100kg/year	Yes	Yes	Yes	Yes
Tattoo inks with a molar extinction coefficient >1000Lmol^{-1}cm^{-1} at wavelengths 290-700 nm	UV-vis absorption spectra	Yes	Yes	Yes	Yes
	Photosensitisation – if end use concentration is ≥ 0.1%	Yes	Yes	Yes	Yes
	Photoirritation (skin) – if end use concentration is ≥ 0.1%	Yes	Yes	Yes	Yes
GM products	The genetically modified organism from which the	Yes	Yes	Yes	Yes

[7] See above text for descriptions of these indicative risk combinations.
[8] This includes introductions that cannot be exempted or reported, according to section 20 of the draft General Rules
[9] This includes introductions that are exempted or reported, according to section 21 and 22 respectively of the draft General Rules

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	GM product was derived or produced				
	Information on any genetically modified organism that remains in the GM product as an impurity	Yes	Yes	Yes	Yes
Personal vaporisers	Information on acute toxicity or specific target organ toxicity after repeated exposure required according to Attachment C must include information on toxicity via the inhalation route	Yes	Yes	Yes	Yes
Biochemicals	The concentration of any remaining viable cell or cellular components of the organisms used to produce the biochemical (the production organism)	Yes	Yes	Yes	Yes
	Information on any known adverse effects of any remaining production organism	Yes	Yes	Yes	Yes
	Any genetically modified organisms used for producing the biochemical	Yes	Yes	Yes	No
	The species/strain of the production organism	Yes	Yes	Yes	No
	The methods used to purify or extract the biochemical from the production organism	Yes	Yes	Yes	No
	Any by products that are present in the biochemical and have known hazard classifications	Yes	Yes	Yes	No

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	Whether the biochemical is an enzyme	Yes	Yes	Yes	Yes
Chemical with end use in an article with food contact	Whether the chemical has been approved (however described) elsewhere for end use in an article with food contact, and if so information on this approval	Yes	Yes	Yes	Yes
	Whether the chemical is of low concern following migration to food (within the meaning given by the Guidelines), and if so information to demonstrate this	Yes	Yes	Yes	Yes
	Quantitative information on the extent of the chemical's transfer from the article to food (unless the chemical is of low concern following migration to food)	Yes	Yes	Yes	Yes
	Specific target organ toxicity after repeated exposure: An in vivo study via the oral route conducted following OECD test guideline 407-409 on your chemical or from suitable read-across	Yes	Yes	Yes	Yes

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	information – if introduction volume is greater than 1,000 kg/year[10]				
Gas	Flammability	Yes	Yes	Yes	Yes
	Explosivity	Yes	Yes	Yes	Yes
	Information on acute toxicity or specific target organ toxicity after repeated exposure required according to Attachment C must include information on toxicity via the inhalation route	Yes	Yes	Yes	Yes
	Information on the persistence of your gas - if introduction volume is greater than 100 kg/year. This must be one of the following: • An in silico model of the chemical conducted	Yes	Yes	Yes	Yes

[10] Not required if one or more of the following applies:
- your chemical is corrosive or severely irritating to the skin (GHS Category 1) or likely to be corrosive to the skin (i.e. the chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5)), together with high buffering capacity (if relevant)), or
- your chemical is spontaneously flammable in air or in contact with water or moisture at room temperature, or
- your chemical is a high molecular weight polymer, or
- your chemical is a PLC or a low concern biopolymer, or
- your chemical is included in the GRAS for FDA Inventory Notice (GRAS Substances (SCOGS))Database as a Type 1 Conclusion, unless the GRAS conclusion does not apply to the exposures expected from the industrial use of the chemical.

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	using EPI Suite™ , or • A study or estimation conducted on the chemical according to a method described in the OECD 1993 monograph[11]				
Polyhalogenated organic chemicals[12]	Reproductive toxicity: An in vivo study conducted following OECD test guideline 408, 409, 411, 413, 414, 415, 416, 421, 422, 443, 451, 452 or 453 on your chemical or suitable read-across information – if the highest human health exposure band is relevant for your introduction[13]	Yes	Yes	Yes	Yes
	Developmental toxicity: An in vivo study conducted following OECD test guideline 414, 415, 416, 421, 422, 426 or 443 on your chemical or suitable read-	Yes	Yes	Yes	Yes

[11] The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions. Environment Monograph No 61, OECD/GD(92)172, Paris 1993

[12] This class of introduction includes polyfluorinated chemicals that do not meet the circumstances set out for certain fluorinated organic chemicals (section 20(7) of the draft General Rules.

[13] Not required if your chemical is a PLC or a low concern biopolymer

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	across information – if the highest human health exposure band is relevant for your introduction[13]				
	Information on persistence and identity of persistent degradants (as described in Attachment D) – if the introduction volume is greater than 100 kg/year	Yes	Yes	Yes	Yes
	Information on bioaccumulation (as described in Attachment D) – if the introduction volume is greater than 100 kg/year	Yes	Yes	Yes	Yes
	Information on aquatic toxicity (as described in Attachment D) – if the introduction volume is greater than 100 kg/year	Yes	Yes	Yes	Yes
	Multi-generation fish tests conducted following OECD test guideline 240 – if the introduction volume is greater than 100 kg/year	Yes	Yes	Yes	Yes
Biocides	Any aquatic toxicity information required according to Attachment D needs to be in vivo test results for chronic toxicity to aquatic life – if the introduction volume is greater than 10 kg/year. This means you must have in vivo test results on the	Yes	Yes	Yes	Yes

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	chemical or from suitable read-across information for: • Fish (conducted following OECD test guideline 210), • Invertebrates (conducted following OECD test guideline 211), and • Algae (conducted following OECD test guidelines 201)				
Highly branched organic chemical	Any persistence information required according to Attachment D needs to be measured information on the chemical itself	Yes	Yes	Yes	Yes
	In vivo test results for chronic toxicity to aquatic life if the chemical is persistent and the introduction volume is greater than 100 kg/year. You must have in vivo test results on the chemical or from suitable read-across information for: • Fish (conducted following OECD test guideline 210), • Invertebrates (conducted following OECD	Yes	Yes	Yes	Yes

Table 7: Additional information requirements for specified classes of introduction

Specified class of introduction	Additional information requirements	Indicative risk combinations[7]			
		Med to high risk for BOTH[8]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[9]
	test guideline 211), and • Algae (conducted following test guideline 201)				

Attachment F: Certain chemicals at the nanoscale

Section 20(3) of the draft General Rules deals with certain industrial chemicals at the nanoscale.

You need to provide the information below (at a minimum) if your introduction meets the circumstances set out in section 20(3).

This includes introductions of those chemicals which:

1. meet particle size requirements and are introduced as a solid or dispersion
2. persist at the nanoscale during intended use and don't rapidly dissolve or don't have a high dissolution rate, and
3. are not incidental to the introduction of the non-nanoscale portion of the industrial chemical.

Refer to the draft General Rules for further details on the above circumstances.

In addition to any requirements outlined in earlier sections of this document, we will require the following information:

- Particle size (addressing size distribution and agglomeration/aggregation state, as introduced and as used)
- Surface area (including specific surface area (SSA) and volume specific surface area (VSSA))
- Shape (including aspect ratio for fibres and other relevant information to describe the morphology, such as crystallinity)
- Particle concentration
- Surface chemistry (such as a description of any chemical coating or surface treatments applied and information on surface charge)
- Dissolution rate
- Hydrophobicity
- Zeta potential (may be measured indirectly based on iso-electric point and/or electrophoretic mobility)
- Dispersibility (measured data on van der Waals energy and/or zeta potential may be provided)
- Dustiness (unless inhalation can be shown to not be a relevant route of exposure)
- Toxicokinetics (study should address the potential to cross biological barriers)

- Acute inhalation toxicity (unless inhalation can be shown to not be a relevant route of exposure)
- Specific target organ toxicity after repeated inhalation exposure (unless inhalation can be shown to not be a relevant route of exposure)
- Activated sludge inhibition
- Chemical deposition, attachment and other relevant environmental fate information, depending on the chemical you are introducing and how it is used (including disposal) - further information will be provided in guidance material.

As for other information requirements, it will be possible to apply for case-by-case information waivers. Read about information waivers in section 3.1.

If needed during the assessment, we may request further information than that identified above. Any information requests will depend on the circumstances of the introduction. For example, we may request additional information related to:

- the degradation of your chemical if it will have an end use in an article with food contact, or
- sediment toxicity, if your chemical is expected to partition to sediment following release.

Attachment G: Certain fluorinated organic chemicals

You will need to provide the additional information described in this attachment if your chemical contains a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms. That is, your introduction is categorised as assessed because the circumstances set out for certain fluorinated organic chemicals (section 20(7) of the draft General Rules) are met.

Your assessment certificate application will need to include the information set out in the relevant earlier sections of this document, as well as additional information on:

- Impurities
- Certain human health hazards
- Identity and hazards of degradation products – unless you accept that we will make certain conservative assumptions about these.

Information on impurities

You will need to provide the identity and level of all impurities and residual monomers that contain fully fluorinated carbon atoms where these are present above certain defined levels. These levels are not yet defined but will not be higher than what is currently needed for an assessment certificate application (and may be lower)[14]. Particular regard should be given to perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS) and longer-chain congeners or their precursors.

Information on human health hazards

Specific target organ toxicity after repeated exposure

If the total introduction volume of the chemical in a registration year is >1,000 kg you will need to provide information on specific target organ toxicity after repeated exposure that addresses the potential for adverse hepatotoxic effects. This will need to be an in vivo study conducted following OECD test guideline 407-413 on your chemical or from suitable read-across information, with the administration route dependent on the most relevant route of exposure (or the oral route if information on the most relevant route is not available).

[14] The current levels are ≥ 0.0001% for food contact end uses, and ≥ 0.01% for other end uses

You will not be required to provide this information if any of the following specified information waivers apply:

- your chemical is corrosive or severely irritating to the skin (GHS Category 1) or likely to be corrosive to the skin (i.e. the chemical is a strong acid (pH ≤ 2.0) or base (pH ≥ 11.5)), together with high buffering capacity (if relevant)), or
- your chemical is a high molecular weight polymer.

Acute inhalation toxicity

You will need to provide information on the acute inhalation toxicity of your chemical. This will need to be an in vivo study on your chemical or from suitable read-across information conducted following OECD test guideline 403, 436 or draft 433.

You will not be required to provide this information if:

- You can show that inhalation will not be a relevant route of exposure

Information on degradation products

Information on identity of fluorinated degradation products

We will assume that your chemical degrades in one of these ways:

- If the fully fluorinated carbon chain in your chemical is terminated with a sulfonyl group (e.g. sulphonamide) it will degrade to a perfluoroalkyl sulfonate with the same fully fluorinated carbon chain length as your chemical, or
- If the fully fluorinated carbon chain in your chemical is terminated with a hydrolysable group (e.g. iodide or silane) it will degrade to a perfluoroalkyl carboxylic acid containing a fully fluorinated carbon chain length that is one carbon shorter than your chemical, or
- If the fully fluorinated carbon chain in your chemical is terminated with an alkyl or aryl group it will degrade to a perfluoroalkyl carboxylic acid with the same fully fluorinated carbon chain length as your chemical, or
- If the fully fluorinated carbon chain in your chemical is terminated with any other group it will degrade to a perfluoroalkyl carboxylic acid with the same fully fluorinated carbon chain length as your chemical.

If you disagree with our default degradation assumptions, you will need to provide:

- Detailed information on the biodegradation of your chemical. This must include characterisation of the degradation products and their rate of

formation. The tests that you will need to provide should be decided in consultation with us.

- Information on whether your chemical degrades by other pathways, including hydrolysis and polymer degradation via side chain cleavage (if relevant).

Information on hazard and fate of fluorinated degradation products

We will assume that the ultimate fully fluorinated degradant of your chemical will have the same hazards and fate as the relevant default fluorinated chemical and we will use the hazard and fate information from the relevant IMAP assessment in our risk assessment (see table below).

If the ultimate fully fluorinated degradant is a:	And has a carbon chain length of:	We will use the hazard and fate information from the IMAP assessment of:
perfluoroalkyl sulfonate	4	Perfluorobutanesulfonate (PFBS) and its direct precursors • human health assessment • environment assessment
perfluoroalkyl sulfonate	5-7	Perfluoroalkane sulfonates (PFSA) (C5-C7) and their direct precursors • human health assessment • environment assessment
perfluoroalkyl sulfonate	8	Perfluorooctane sulfonate (PFOS) and its direct precursors • human health assessment • environment assessment
perfluoroalkyl sulfonate	> 8	Perfluoroalkyl sulfonates (PFSA) (> C8) and their direct precursors • human health assessment • environment assessment

perfluoroalkyl carboxylic acid	≤ 6	Short chain perfluorocarboxylic acids and their direct precursors • human health assessment • environment assessment
perfluoroalkyl carboxylic acid	7	Perfluoroheptanoic acid and its direct precursors • human health assessment • environment assessment
perfluoroalkyl carboxylic acid	8	Perfluorooctanoic acid (PFOA) and its direct precursors • human health assessment • environment assessment
perfluoroalkyl carboxylic acid	> 8	Indirect precursors of long-chain perfluorocarboxylic acids (PFCAs) • human health assessment • environment assessment

If you disagree with our default assumptions, you will need to provide information to characterise the toxicity of the ultimate fluorinated degradation product for your chemical, unless the degradation information you provided shows that your chemical is fully mineralised. This will need to include all of the following:

Human Health

- long-term repeated dose studies (> 28 days) (OECD TG 407, 408 or 409) addressing hepatotoxicity; and
- reproductive/developmental studies (OECD TG 407 and 421 or OECD TG 422); and
- carcinogenicity studies (OECD TG 451, 452 or 453); and

Environment

- information on the bioaccumulation potential.
- information to characterise the chronic toxicity to aquatic species, including multi-generation fish toxicity studies (OECD test guideline 240) and a daphnia reproduction study (OECD TG 211).

- If the chemical and/or its ultimate degradation products will be exposed to soil, then we may also require information to characterise the acute and chronic toxicity to soil dwelling species (e.g. OECD TG 222).

Attachment H: Designated kind of release into the environment

If your introduction involves a designated kind of release into the environment (see section 28(2) of the draft General Rules) your assessment certificate application will need to include the information set out in the:

- relevant earlier sections of this document, and
- table below.

If relevant, you'll have to submit test reports to support the information you provide.

The amount and type of information you will need to provide will depend on which of the following indicative risk combinations applies to your introduction:

1. **Medium to high indicative risk – human health and the environment**

   Your introduction cannot be exempted or reported (because circumstances set out in s20 of the draft General Rules are met – see Attachment A)

   OR

   Your assessed categorisation is based on the indicative human health and environment risks both being medium to high.

2. **Medium to high indicative risk – human health only**

   Your assessed categorisation is based on the:
   a. indicative human health risk being medium to high, and
   b. indicative environment risk being low or very low

3. **Medium to high indicative risk – environment only**

   Your assessed categorisation is based on the:
   a. indicative environment risk being medium to high and
   b. the indicative human health risk being low or very low.

4. **Low or very low indicative risk – human health and the environment**

Your introduction can be exempted or reported (if circumstances of s21 or s22, respectively of the draft General Rules are met – see Attachment A)

OR

Your exempted or reported categorisation is based on the highest indicative risk for human health and the environment being low or very low.

Table 8: Additional information requirements for introductions that involve a designated kind of release to the environment

Additional information requirements	Indicative risk combinations[15]			
	Med to high risk for BOTH[16]	Med to high risk for health	Med to high risk for env't	Very low or Low risk for BOTH[17]
If the chemical will be released to water - Any aquatic toxicity information required according to Attachment D needs to be acute and chronic in vivo test results for the most relevant aquatic compartment – i.e. freshwater or marine.	Yes	Yes	Yes	Yes
If the chemical will be released to soil - acute toxicity tests on soil organisms, earthworms or microorganisms, conducted following OECD test guideline 207 (earthworms) or 209 microbial activity).	Yes	Yes	Yes	Yes
The persistence information required according to Attachment D needs to be measured test results for the relevant compartment (water, soil or air). Acceptable Test Guidelines: ready biodegradability OECD TG 301, water and water/sediment OECD TG 308, soil OECD TG 307 and air US EPA 2011.	Yes	Yes	Yes	Yes
If the chemical will be released to water - additional information on all receiving waterbodies, including geographic location, existing endangered species in the waterbodies, water quality, population and human activities of the waterbodies.	Yes	Yes	Yes	Yes

[15] See above text for descriptions of these indicative risk combinations.
[16] This includes introductions that cannot be exempted or reported, according to section 20 of the draft General Rules
[17] This includes introductions that are exempted or reported, according to section 21 and 22 respectively of the draft General Rules)

4 Abbreviated terms

Acronym	Full name
AACN	AICIS approved chemical name
AICIS	Australian Industrial Chemicals Introduction Scheme
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service
EC50	Median effect concentration
ErC50	Median effect concentration for growth rate
ECOSAR	Ecological Structure Activity Relationships Predictive Model
EU	European Union
EU-REACH	European Union's regulation for Registration, Evaluation, Authorisation and Restriction of Chemical substances
FDA	United States Food & Drug Administration
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GRAS	Generally recognised as safe
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
Kow	Octanol/water partition coefficient
LC50	Median lethal concentration
NAMW	Number average molecular weight
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PLC	Polymer of low concern
SCOGS	Select Committee on GRAS Substances
UVCB	Unknown variable composition or biological substance
UV-vis	Ultraviolet-visible
WAMW	Weight average molecular weight

5 Defined terms

The sources of each of the definitions below include:

1. The Industrial Chemicals Bill 2017
2. The draft Industrial Chemicals (General) Rules 2018
3. Other sources, including adapting text used in:
    a. The Industrial Chemicals Bill 2017 Explanatory Memorandum
    b. The draft Industrial Chemicals Categorisation Guidelines

Term	Definition	Source
AACN	(AICIS approved chemical name) means a name for an industrial chemical determined by the Executive Director under paragraph 108(3)(a).	1
Approved form	A form that is approved, in writing, by the Executive Director	1
Assessed introduction	An introduction of an industrial chemical is generally an assessed introduction if it does not fall within the definition of an exempted or reported introduction and is not a listed industrial introduction. These introductions require pre-introduction assessment by AICIS and are authorised if the introducer holds, or is covered by, an assessment certificate issued by the Executive Director and the introduction is in accordance with the terms of the assessment certificate. Assessed introductions are generally of industrial chemicals that pose a medium to high risk to human health or the environment.	3
Bioaccumulation factor	The concentration of test substance in/on the test organism divided by the concentration of the substance in the surrounding medium.	3

Term	Definition	Source
Biochemical	An industrial chemical that: (a) is directly produced by living, or once-living, cells or cellular components; or (b) is a derivative or modification of such an industrial chemical, in which the original industrial chemical remains substantially intact.	2
Biocide	An industrial chemical that is an active constituent in a product that is for an end use to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by chemical means.	2
Bioconcentration factor	The concentration of test substance in/on the fish or other tissue divided by the concentration of the chemical in the surrounding medium.	3
Biopolymer	A polymer that is a biochemical.	2
CAS name	The Chemical Abstracts Index Name for the industrial chemical.	1
CAS number	The Chemical Abstracts Service Registry Number for the industrial chemical	1
Commercial evaluation introductions	An introduction of an industrial chemical authorised by the person holding a commercial evaluation authorisation and the introduction being in accordance with the terms of that commercial evaluation authorisation.	3
Cosmetic	(a) A substance or preparation intended for placement in contact with any external part of the human body, including: (i) the mucous membranes of the oral cavity; and (ii) the teeth; with a view to: (iii) altering the odours of the body; or (iv) changing its appearance; or (v) cleansing it; or (vi) maintaining it in good condition; or (vii) perfuming it; or (viii) protecting it; or	1

Term	Definition	Source
	(b) a substance or preparation prescribed by the rules for the purposes of this paragraph. but does not include: (c) a therapeutic good within the meaning of the Therapeutic Goods Act 1989, or (d) a substance or preparation prescribed by the rules for the purposes of this paragraph. Note: An ingredient or component of a cosmetic could be an industrial chemical	
Defined scope of assessment	A description of the parameters of the assessment undertaken by the Executive Director, and therefore the scope of introduction and use for which any subsequent recommendations on risk management arising from the assessment will be relevant. It will be informed by the scope of the application made by the applicant.	3
Designated kind of release into the environment	The meaning given by subsection 28(2) of the draft Industrial Chemicals (General) Rules 2018, which includes: (2) For the purposes of the table in subsection (1), each of the following is a kind of release into the environment (a designated kind of release into the environment): (a) intentional release during use to land, biota, natural waterways or municipal water supplies; (b) intentional release to air during use (other than solely domestic or personal use); (c) if the industrial chemical is introduced for an end use in fire-fighting—release (intentional or otherwise) into the environment; (d) if the industrial chemical is introduced for an end use in offshore drilling—release (intentional or otherwise) into the ocean.	2
End use	A purpose to which the industrial chemical can be applied.	1
End use in an article with food contact	An industrial chemical has an end use in an article with food contact where the industrial chemical becomes part of an article that will come into contact with food, other than: (a) where the end use of the industrial chemical is at the non-food contact surface of a glass or metal article; or (b) if the food that the article will come into contact with is	2

Term	Definition	Source
	rainwater–where the contact with the rainwater is transient.	
Environment exposure band	For the introduction of an industrial chemical, has the meaning given by section 28 of the draft Industrial Chemicals (General) Rules 2018, which sets out the criteria relevant to each environment exposure band.	2
Exceptional circumstances introduction	An introduction of an industrial chemical authorised by the person holding an exceptional circumstances authorisation from the Minister and the introduction being in accordance with the terms of the exceptional circumstances authorisation.	3
Exempted introduction	An introduction meeting the rules made under subsection 26(2) of the Industrial Chemicals Bill 2017. An exempted introduction is an industrial chemical introduction that poses a very low risk to human health and the environment.	1
Food	The same meaning as in the Food Standards Australia New Zealand Act 1991.	2
GM product	The same meaning as in the Gene Technology Act 2000	1
the Guidelines	The draft Industrial Chemicals Categorisation Guidelines	3
Highest indicative risk	In relation to the introduction of an industrial chemical, has the meaning given by step 6 of the method statement in section 19 of the draft Industrial Chemicals (General) Rules 2018. It is the highest of the indicative risks determined for human health and environment. It could be very low, low or medium to high.	2
Highly branched organic chemical	An industrial chemical that is branched at: (a) more than one tertiary carbon; (b) more than one quaternary carbon; or (c) a combination of tertiary and quaternary carbons.	2
High molecular weight polymer	A polymer that has a number average molecular weight that is greater than or equal to 1,000 g/mol.	2
Human health exposure band	For the introduction of an industrial chemical, has the meaning given by section 24 of the draft Industrial Chemicals (General) Rules 2018, which sets out the criteria relevant to each human health exposure band.	2
Import an industrial chemical	To do an act that constitutes importation of the industrial chemical for the purposes of the Customs Act 1901, or would constitute such importation if that Act extended to the external Territories.	1

Term	Definition	Source
In chemico	Abiotic (i.e. non-biological) assay that measures chemical reactivity.	3
In-domain	The chemical is within the applicability domain of the in silico model (i.e. the chemical's properties fall within those the model is known to produce reliable predictions for).	3
Indicative environment risk	In relation to the introduction of an industrial chemical, has the meaning given by section 30 of the draft Industrial Chemicals (General) Rules 2018, which sets out how to determine this based on the environment exposure band and the hazard characteristics from the environment hazard bands.	2
Indicative human health risk	In relation to the introduction of an industrial chemical, has the meaning given by section 26 of the draft Industrial Chemicals (General) Rules 2018, which sets out how to determine this based on the human health exposure band and the hazard characteristics from the human health hazard bands..	2
Industrial chemical	See section 10. This section from the Industrial Chemicals Bill 2017 includes: (1) For the purposes of this Act, industrial chemical means any of the following: (a) a chemical element that has an industrial use; (b) a compound or complex of a chemical element that has an industrial use; (c) a UVCB substance that has an industrial use; (d) a chemical released from an article where the article has an industrial use; (e) a naturally-occurring chemical that has an industrial use; (f) any other chemical or substance prescribed by the rules for the purposes of this paragraph that has an industrial use. (2) Despite subsection (1), industrial chemical does not include a chemical or substance prescribed by the rules for the purposes of this subsection. (3) To avoid doubt, this Act only applies in relation to an industrial chemical to the extent that the industrial chemical is used, or proposed to be used, for an industrial use. Notes:	1

Term	Definition	Source
	- For the purposes of subsection 10(1), the draft (General) Rules do not prescribe any other chemical or substance. - From section 12 of the draft (General) Rules: • For the purposes of subsection 10(2) of the Act, radioactive chemicals are prescribed.	
In silico	Information derived from (or produced by) computer software or simulation.	3
Introduce an industrial chemical	Import, or manufacture in Australia, the industrial chemical.	1
Inventory	The Australian Inventory of Industrial Chemicals established under section 80.	1
In vitro	Conducted in a controlled environment outside of a living organism (e.g. isolated organs, tissues, cells).	3
In vivo	Conducted within a whole living organism.	3
Known hazard classification	Known hazard classification, for an industrial chemical, means hazard information that the introducer is aware of in the form of one of the following: • A hazard class and category arising from classification under the 'Globally Harmonized System of Classification and Labelling of Chemicals' (the GHS) published by the United Nations. • A hazard class and category found in the Safe Work Australia Hazardous Chemical Information System (HCIS)(previously known as Hazardous Substances Information System), or • A non-GHS hazard statement, assigned under the classification criteria in 'Guidance on the Classification of Hazardous Chemicals under the WHS Regulations' published by Safe Work Australia. Except that it does not include any of the following hazard classes: • flammable gases, category 2 • acute toxicity-oral, category 5 • acute toxicity-dermal, category 5 • acute toxicity-inhalation, category 5	2/3

Term	Definition	Source
	• skin corrosion/irritation, category 3 • serious eye damage/eye irritation, category 2B • aspiration hazard, category 2	
KOWWIN	KOWWIN estimates octanol-water partition coefficient, log Kow	3
Listed introduction	The introduction of an industrial chemical in accordance with the terms of its listing on the Inventory.	3
Low concern biopolymer	Has the meaning given by section 21(7) of the draft Industrial Chemicals (General) Rules 2018, which includes that the industrial chemical is: (a) a biopolymer; and (b) would be a polymer of low concern if the definition of polymer of low concern in Schedule 1 did not include a requirement that the polymer is stable (within the meaning given by the (Guidelines).	2
Low concern following migration to food	Low concern following migration to food, in relation to the introduction of an industrial chemical that has an end use in an article with food contact, means: • The industrial chemical has an estimated dietary exposure value less than the threshold of toxicological concern (TTC) for the industrial chemical based on its structural class categorisation according to Cramer (Cramer GM, Ford RA, Hall RL, Estimation of toxic hazard--a decision tree approach. Food Cosmet Toxicol. 1978 Jun; 16(3):255-76), or • The end use of the industrial chemical, concentration at the end use and dietary concentration associated with the end use, as applicable, are consistent with one of the following: o The listing of the industrial chemical under Annexes I or II to Regulation (EC) No 10/2011 or Annex I to Regulation (EC) No 1935/2004 and any applicable restrictions. o An adopted opinion on the industrial chemical by the European Food Safety Authority.	

Term	Definition	Source
	o Use of the industrial chemical authorised under the United States Food and Drug Administration (US FDA) regulations, 21 CFR.170-199, or	
Low concern following migration to food	• The industrial chemical is a permitted flavouring substance as defined by Standard 1.1.2 of the Food Standards Australia New Zealand Act 1991, with the dietary concentration associated with the end use of the industrial chemical less than that associated with use as a flavouring substance, or • The extent of migration was below the level of detection in a migration study conducted under conditions that simulated: o The food types that will be contacted at end use. o The food contact conditions that are relevant for the end use, or • The No Observed Adverse Effect Level (NOAEL) in an in vivo study on the industrial chemical or from suitable read-across information conducted following The Organisation for Economic Co-operation and Development (OECD) test guidelines: o OECD test guideline 407 was ≥1000 mg/kg bw/day o OECD test guideline 408 or 409 was ≥300 mg/kg bw/day	2/3
Lung overloading potential	A high molecular weight polymer has lung overloading potential if it is a polymer that: • has a number average molecular weight that is >70,000 g/mol, and • has a solubility in water of <0.1 mg/L, and • becomes aerosolised during end use.	3
Manufacture an industrial chemical	Do any of the following: (a) produce the industrial chemical in the course of a chemical reaction;	1

Term	Definition	Source
	(b) extract the industrial chemical from a natural environment, with or without chemical change; (c) extract the industrial chemical from a UVCB substance; (d) produce or extract the industrial chemical in circumstances prescribed by the rules for the purposes of this paragraph; but does not include producing or extracting the industrial chemical as described in paragraphs (a), (b) or (c) in circumstances prescribed by the rules for the purposes of this definition. Note: The draft (General) Rules do not currently prescribe any circumstances.	
Nanoscale	The particle size range of 1 to 100 nm.	2
Personal vaporiser	A device that produces a vapour or aerosol that is intended to be inhaled into the lungs, including the following devices: (a) e-cigarettes; (b) e-cigars; (c) e-hookah pens; (d) e-pens; (e) e-pipes; (f) vape pens.	2
Polyhalogenated organic chemical	A chemical that: (a) is carbon based, and (b) contains more than one covalently bonded bromine, chlorine, fluorine or iodine substituent.	2
Polymer	A chemical that consists of molecules that: (a) are characterised by the sequence of one or more types of monomer units; and (b) are distributed over a range of molecular weights where the difference in molecular weights is primarily attributable to differences in the number of monomer units, and (c) are greater than 50% by weight of which have a sequence of at least 3 monomer units covalently bound to at least one other: (i) monomer unit, or (ii) molecule that is linked to one or more sequences	2

Term	Definition	Source
	of monomer units but cannot, under the conditions of the relevant reaction used for the particular process of polymer formation, become a repeating unit in the polymer structure.	
Polymer of low concern	The meaning given by Schedule 1 of the draft Industrial Chemicals (General) Rules 2018.	2
Process category	Indicates the activities or procedures in the workplace scenario. Selection is from >20 options, including items such as mixing or blending in batch processes or industrial spraying.	3
Product category	Indicates the type of products the final form of the chemical is contained in. Selection is from >40 options, including items such as air care products, fuels and inks and toners.	
Read-across information	Information derived using a read-across approach for the purpose of filling information gaps in what is known for the properties and effects of a chemical. A read-across approach predicts the hazard characteristics of a chemical (target chemical) by using information from one or more other chemicals (source chemical/s). There are two read-across techniques: • Analogue approach – you use a single chemical as the source chemical (this single chemical is then known as the 'analogue chemical'). • Category approach – you use a group of chemicals as the source chemicals.	3
Registration year	12 months beginning on 1 September of each year.	1
Reported introduction	An introduction meeting the rules made under subsection 27(2) of the Industrial Chemicals Bill 2017, and for which a pre-introduction report has been submitted, and the introduction is in accordance with the terms of that pre-introduction report. A reported introduction is an industrial chemical introduction that poses a low risk to human health or the environment.	1
Sector of end use	Indicates the market sector of the chemical's end use.	3

Term	Definition	Source
	Selection is from >20 options, including items such as manufacture of plastics products or building and construction work.	
Specified class of introduction	A class of introduction specified in section 7 of the draft Industrial Chemicals (General) Rules 2018. This includes: (1) An introduction of an industrial chemical is a specified class of introduction, if: (a) the introduction is not solely for the industrial chemical to be used in research and development; and (b) subsection (2), (3) or (4) applies to the introduction. (2) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions: (a) introductions of an industrial chemical that is a gas (other than a gas that is not persistent); (b) introductions of a highly branched organic chemical; (c) introductions of an industrial chemical for an end use as a biocide; (d) introductions of an industrial chemical that involve a designated kind of release into the environment. (3) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions: (a) introductions of a biochemical; (b) introductions of a monohalogenated organic chemical (other than an acyl halide); (c) introductions of an industrial chemical that is a GM product; (d) introductions of an industrial chemical that is a polyhalogenated organic chemical. (4) For the purposes of paragraph (1)(b), this subsection applies to the following classes of introductions: (a) introductions of a UV filter; (b) introductions of an industrial chemical for an end use in an article with food contact; (c) introductions of an industrial chemical for an end use in a personal vaporiser; (d) introductions of an industrial chemical for an end use in tattoo ink.	2

Term	Definition	Source
Tattoo ink	A combination of industrial chemicals that: (a) contains one or more colouring agents, and (b) is applied to the dermal layer of the skin for the purposes of colouring the skin.	2
Technical function of the chemical	Indicates the specific function of the chemical as used in a process category. For example, selection could include items such as catalyst, fragrance or dye.	3
Use	For an industrial chemical, includes any of the following activities involving the industrial chemical: (a) processing; (b) formulating; (c) storing; (d) transporting; (e) filling into containers; (f) transferring from a container to another container; (g) handling; (h) mixing; (i) sampling and testing; (j) producing an article; (k) releasing into the environment (with or without prior treatment); (l) activities relating to an end use for the industrial chemical; (m) any other activity prescribed by the rules for the purposes of this paragraph; but does not include an activity prescribed by the rules for the purposes of this definition. Note: The draft (General) Rules do not currently prescribe any activities.	1
UVCB substance	(unknown variable composition or biological substance) – (a) a chemical of unknown or variable composition; (b) a complex product of a chemical reaction; (c) biological material, other than a whole animal or a whole plant.	1
UVCB substance description	A description of the UVCB substance that provides specific identity information about the UVCB substance including one or more of the following: (a) the manufacturing process for the UVCB substance;	2

Term	Definition	Source
	(b) raw material sources of the UVCB substance; (c) carbon number ranges for the UVCB substance; (d) physical property ranges for the UVCB substance; (e) biological sources of the UVCB substance.	
UV filter	An industrial chemical is a UV filter if the industrial chemical is intended to protect the skin against ultraviolet radiation in the range of 290 to 400 nm by absorption, reflection or scattering of ultraviolet radiation.	2
Water absorbing	A high molecular weight polymer is water absorbing, if it is a polymer that: • has a number average molecular weight that is ≥10,000 g/mol, and • is capable of absorbing its own weight, or more, in water, and • is in particulate form, and • contains particles with a particle size <10 micrometres (microns) This can be assumed if the polymer: • forms a gel in water that does not dissolve upon the addition of further water, or • is a cross-linked polymer containing hydrophilic monomers such as acrylic acid (and its salts) and acrylamide.	3