



Australian Government

Department of Health

National Industrial Chemicals Notification and Assessment Scheme

Consultation on proposed changes to Industrial Chemicals (General) Rules arising from the passage of the Industrial Chemicals Act 2019

Date: 4th April 2019

National Industrial Chemicals Notification and Assessment Scheme

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1 Executive summary

Early in 2018, we consulted on a draft of the Industrial Chemicals (General) Rules 2018 (the General Rules https://www.nicnas.gov.au/_data/assets/pdf_file/0011/65684/Industrial-Chemicals-General-Rules-2018-Exposure-Draft.pdf), to be made under the **Industrial Chemical Act 2019** (the IC Act). The General Rules set out details for the regulation of the import and manufacture of industrial chemicals in Australia under the Australian Industrial Chemicals Introduction Scheme (AICIS), which commences on 1 July 2020.

This consultation paper proposes some changes to the General Rules to take account of amendments made during passage of the IC Act. Stakeholder feedback on the categorisation criteria in the earlier draft in the General Rules was also considered in this process.

This consultation covers:

- Changes related to declarations for exempted introductions including:
 - information we will require in declarations
 - types of introductions that will not require a declaration
- Changes related to the use of new animal test data for introductions where the chemical has multiple end uses, including in cosmetics
- Proposed categorisation criteria changes:
 - Increased volume threshold for non-nanoscale chemicals used for research and development – from 100kg to 250kg
 - Addition of a new reported introduction type – for research and development chemicals remaining under the control of the introducer
 - Addition of a new reported introduction type for chemicals introduced in low concentrations in ‘notified fragrance blends’
 - Introduction of the concept of ‘human health categorisation volume’ for determining the appropriate human health exposure band criterion
 - Increases in volume thresholds for lower exposure bands
 - Change in indicative risk outcome for introductions that are both low hazard and either low volume or low concentration
 - Addition of a new human health exposure band for chemicals used at very low concentrations for which there is no consumer end use.
 - Allowing the following introductions to be exempted if they meet the exposure/hazard band criteria for very low risk:
 - chemicals with an end use in an article with food contact
 - highly branched organic chemicals

2 Introduction

2.1 What this consultation is about

We are seeking your feedback on changes we are proposing to the draft **General Rules** for the new scheme.

This consultation is not a further exposure draft of all the General Rules. It only relates to certain General Rules that are either new or require significant change from the earlier exposure draft as a result of the passage of the IC Act (as amended).

We are continuing to develop the remainder of the General Rules, taking into account the stakeholder feedback received on the exposure drafts in 2018.

After we consider your feedback, we will finalise the General Rules for the Minister to make. These Rules will then be tabled in Parliament.

2.2 Why we are proposing changes to the General Rules

We are proposing changes to the General Rules because:

- the new industrial chemicals legislation establishing AICIS is now Australian law. This new law — the Industrial Chemicals Act 2019 — **contains amendments that bring in new requirements for introducers**
- we need to change the General Rules to reflect these new requirements.

Introducers will now need to make **a once-off declaration for exempted introductions** at the end of the registration year in which the introduction first occurs.

In addition, during passage of the IC Act, the Government agreed to explore how the Rules could limit the use of new animal test data for introductions where the chemical has multiple end uses, including in cosmetics. We are proposing new Rules in this area as well.

Have your say

Your feedback on the proposed changes to the General Rules described in this document is due by **17 May 2019**.

You can submit your comments using our online form – <https://www.nicnas.gov.au/forms/Consultation-on-proposed-changes-to-the-draft-General-Rules> or email us at nicnas.reforms@nicnas.gov.au

3 Declarations for exempted introductions

There are different types of exempted introduction that depend on the particular criteria used by the introducer to determine the indicative risk as **very low to human health and the environment**:

- Chemicals that are imported and subsequently exported, without the packaging being opened
- Chemicals that are introduced solely for use in R&D, in low volumes:
 - for chemicals at the nanoscale, the volume threshold will be 10kg
 - for all other chemicals, the volume threshold will be 250kg
- A chemical that is comparable to a chemical that is listed on the Inventory (comparable chemical)
- A polymer that is comparable to a polymer that is listed on the Inventory (comparable polymer)
- Polymers of low concern (PLCs)
- Low concern biopolymers
- Chemicals where the indicative risk has been determined to be very low for human health and the environment using the exposure and hazard band criteria.

The amendment to the IC Act to require a once-off declaration for exempted introductions includes allowing the General Rules to define the following according to the type of exempted introduction:

- when a declaration of an exempted introduction won't be required
- the information that will need to be included in a declaration

This allows the General Rules to detail a risk-proportionate requirement for these exempted introductions.

3.1 Types of exempted introductions that will not require a declaration

We propose that declarations will not be required for exempted introductions in which:

1. Chemicals are imported and subsequently exported, without the packaging being opened
2. Chemicals are introduced solely for use in R&D, in low volumes for:
 - chemicals at the nanoscale the volume threshold will be 10kg
 - all other chemicals the volume threshold will be 250kg
3. A chemical is comparable to a chemical that is listed on the Inventory (comparable chemical)
4. A polymer is comparable to a polymer that is listed on the Inventory (comparable polymer)

For these types of introductions, the introducer will need to:

- keep records as set out in the General Rules, including records to show that they meet the relevant criteria
- declare that they are using the exempted introduction category as part of their annual compliance declaration.

For 1 and 2 above, this proposal is consistent with the regulatory treatment of comparable introductions in overseas jurisdictions.

Types 3 and 4 above are considered for regulatory purposes to be equivalent to chemicals listed on the Inventory. For this reason, we have aligned the regulatory treatment with listed chemical introductions under the new scheme (i.e. keeping a record of the chemical identity, which will be subject to audit).

3.2 Information required in declarations

For all other types of exempted introductions, an introducer will need to submit a once-off declaration at the end of the first registration year in which the exempted introduction occurs.

The information that will need to be included in these declarations will be as follows:

Information required for exempted introduction declarations

Type of exempted introduction	Information required in declaration
A chemical where the indicative risk has been determined to be very low for human health and the environment using the exposure and hazard band criteria	<ul style="list-style-type: none">• Proper chemical name (CAS name or IUPAC name)• CAS number, if assigned• Total introduction volume per year (selected from a picklist of volume ranges)• End-use (selected from a picklist of generalised end use categories)• Maximum concentration at end-use (selected from a picklist of concentration ranges)
Polymers of low concern	Number of polymers introduced
Low concern biopolymers	Number of polymers introduced

During previous consultations, some community stakeholders expressed concern about the exempted introduction type where the indicative risk is determined by the introducer using the exposure and hazard band criteria for human health and the environment. This introduction type relies on the introducer accurately characterising the exposure of the chemical to humans and the environment, and having the relevant level of hazard information to demonstrate that their introduction is very low risk.

For this reason, the declarations for this type of exempted introduction will include information on chemical identity, and the extent of exposure to humans and the environment (the volume, end use and concentration information).

We'll use the information we receive on the extent of exposure to an identified chemical to target our audits.

The chemical identity information will allow us to quickly identify introducers in the future. For example, if any of the chemicals become of concern.

PLC criteria are based on chemical structure, and easier to objectively apply to determine very low risk. They have been in use for many years in Australia and overseas. Because of this, there's less need for detailed information in PLC exempted declarations. The information

required for PLCs aligns with requirements under the US Toxic Substances Control Act. The information we receive will allow us to identify who is using the PLC criteria and to what extent. This in turn will allow us to appropriately target our PLC audits.

Low concern biopolymers are those polymers meeting all the PLC criteria except for the stability criterion. As they are biopolymers we expect them to degrade into chemicals that will not be an environmental concern. Their level of risk is very similar to PLCs and so we are proposing that the information required will be the same as for PLCs.

4 Proposed changes related to the use of new animal test data

While the scope of the ban in the IC Act on the use of new animal test data continues to apply only to chemicals used solely in cosmetics, the Government agreed to explore how the Rules could limit the use of new animal test data for introductions where the chemical has multiple end uses, including in cosmetics. New animal test data means data generated after 1 July 2020.

We are proposing that the General Rules restrict the use of new animal test data for these introductions where the chemical has multiple end uses, including in cosmetics, unless certain exceptions apply to maintain human health and environment protection.

These exceptions would include those that were previously set out in the General Rules for 'sole-use' cosmetic introductions. There would also be an additional exception in circumstances where there was exposure arising from non-cosmetic end uses, and the Executive Director had given prior approval for the use of the new animal test data.

The proposed Rules would set out that for introductions where the chemical has multiple end uses including in cosmetics, new animal test data could not be used in applications for a certificate, or for categorisation into exempted or reported introduction categories, unless one of the following exceptions applies:

1. You have prior written approval from the Executive Director to use the information for categorisation, or in your certificate application, due to human health or environment exposure arising from the non-cosmetic end uses.
2. Your chemical has an environmental hazard characteristic that can only be determined using animal test data. That is, there are no validated alternative tests to determine this characteristic other than animal tests.
3. The animal test data that you want to use are from tests done on a different, but related chemical (not the chemical you are introducing) and this other chemical is not being introduced by you for use only in cosmetics.
4. The animal test data that you have show that your chemical has a hazard characteristic (for example, the data show that your chemical is sensitising to the skin). You must have other non-animal test data or read-across information to meet either the information requirements in the Categorisation Guidelines or the information requirements set out in the certificate application form. In other words, you must not be using animal test data as your only source of information to establish that your chemical has a hazard characteristic. This removes any incentive to generate new animal test data for Australian regulatory requirements.

For the first exception to apply, an introducer or applicant would need to write to the Executive Director outlining the end uses for the chemical they are proposing to introduce, and the new animal test data they would be seeking to use. They would not be able to use these data until they had received an approval in writing from the Executive Director. This approval would be based on whether there was human or environmental exposure expected from the non-cosmetic end uses.

It is expected that only a small subset of introductions that are for multiple end uses, including in cosmetics, would need to use this exception and follow this process. This is because it would only apply to those introductions which:

- Involve high enough volumes and concentrations to require specific hazard information to support their categorisation or application, and
- Do not have alternative non-animal test information, or read across information to fulfil these information requirements.

5 Changes we propose to categorisation criteria

Because of the new declaration requirements (as described in Section 3), we will now know information about chemicals introduced in the exempted introduction category sooner after their introduction. When we first drafted the categorisation criteria in the draft General Rules, we based them on not having information on chemicals introduced in this category until the time of audit, as no requirement for a declaration was envisaged at that stage.

Based on the knowledge we will now have about exempted introductions we are seeking stakeholder views on our proposal to adjust our categorisation criteria, such as increasing the volume thresholds for this category.

Our main goal for these changes is to better:

- reflect the level of risk associated with chemicals in this category
- align the risks of these introductions with the regulatory obligations now associated with the exempted category

In this context, the acceptable level of risk for the exempted category will be different now that we will know more about the introductions in this category sooner.

We are also proposing changes to the categorisation criteria based on your feedback on the exposure draft of the General Rules.

The changes to categorisation we are proposing aim to maintain human health and environment protection while:

- reducing regulatory burden on introducers, where appropriate
- maintaining a risk-proportionate approach
- avoiding complexity.

5.1 Main changes we are proposing to categorisation criteria

In the exposure draft of the General Rules we set out the steps you will need to follow to categorise your introduction, as shown below.



While these steps will not change, some of the criteria for the steps will change:

- Step 1:
 - This section will be restructured to make it clearer.
- Step 2:
 - Increased volume threshold for non-nanoscale chemicals used for research and development – from 100kg to 250kg
- Step 3:
 - Addition of a new reported introduction type – for research and development chemicals remaining under the control of the introducer
 - Addition of a new reported introduction type for chemicals introduced in low concentrations in 'notified fragrance blends'
- Step 4:
 - Introduction of the concept of 'human health categorisation volume' for determining the appropriate human health exposure band criterion
 - Increases in volume thresholds in the lower exposure bands
 - Change in indicative risk outcome for introductions that are both low hazard and either low volume or low concentration
 - Allowing chemicals with an end use in an article with food contact to be exempted if they meet the exposure/hazard band criteria for very low risk.
- Step 5:
 - Increases in volume threshold in the lowest exposure band
 - Change in indicative risk outcome for introductions that have both low volume and low hazard.
 - Allowing highly branched organic chemicals to be exempted if they meet the exposure/hazard band criteria for very low risk

You can read about these changes in more detail below as part of the **new proposed categorisation criteria** for the new scheme.

5.2 Step 1 – Ruling out exempted or reported

The draft General Rules specifically detail certain introductions that **cannot be exempted or reported** as they are considered medium to high risk for human health and the environment. These types of introductions must always be categorised as **Assessed** (unless

they meet the criteria for a Commercial Evaluation or Exceptional Circumstances Authorisation).

There was feedback from stakeholders that the structure of this section of the draft General Rules was not very clear, given all the exceptions that needed to be addressed.

5.2.1 Proposed restructure of the General Rules for introductions that cannot be exempted or reported

We're proposing to restructure the General Rules so only introductions that are **always excluded from being exempted or reported** are dealt with in this section.

The General Rules will detail that introductions of the following chemicals **cannot ever** be exempted or reported:

- chemicals listed on the Rotterdam or Stockholm Conventions, where no action has yet been taken to restrict these chemicals in Australia.¹
- a chemical listed on the Inventory with conditions, for which the introducer intends to introduce outside these conditions.

Because of these changes, the following introductions will now be **considered later** on in the categorisation process (as part of Step 4 and Step 5) as **medium to high indicative risk** for both human health and the environment:

- 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.
- Fluorinated organic chemicals that contain a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms.
- Persistent polyhalogenated organic chemicals introduced in volumes greater than 100 kg/year.

The introduction of persistent gases introduced in volumes greater than 100 kg/year will be considered as **medium to high indicative risk** for the environment.

5.3 Step 2 - Exempted introductions

The General Rules will specifically name certain **very low risk introductions** that can be categorised as exempted introductions. These will be introductions of:

1. Chemicals that are imported and subsequently exported
2. Chemicals that are introduced solely for use in research and development*, in low volumes:

¹ Note that chemicals listed on these Conventions for which action to restrict them in Australia **has** been taken will be subject to Part 9 of the IC Act. Under this part these chemicals will be either prohibited or cannot be introduced without first seeking the approval of the Executive Director.

- a. For chemicals at the nanoscale the volume threshold will be 10kg
- b. For all other chemicals the volume threshold will be 250kg
3. A polymer that is comparable to a polymer that is listed on the Inventory (comparable polymer)
4. A chemical that is comparable to a chemical that is listed on the Inventory (comparable chemical)
5. Polymers of low concern
6. Low concern biopolymers

***The only significant change** to this section compared to the exposure draft of the General Rules is to **increase the volume threshold for chemicals that are introduced solely for use in research and development and are not at the nanoscale.**

This change is as a result of stakeholder feedback suggesting that the volume threshold should allow a standard size drum to be imported (as this is sometimes the smallest size they can purchase from an overseas chemical supplier). We have agreed with this practical suggestion as the difference in risk between volumes of 100kg and 250kg over a year for this research and development use is not significant.

5.4 Step 3 – Reported introductions

5.4.1 Proposal to add a further research and development (R&D) type to the General Rules

In the exposure draft of the General Rules, only one type of R&D introduction was categorised as reported, being chemicals at the nanoscale in volumes between 10 and 100kg. This introduction type will remain as reported.

We're proposing the addition of the following R&D reported introduction type.

This new **reported introduction type** will be for chemicals introduced solely for R&D and:

- the chemical is not at the nanoscale
- the chemical is not available to the public in any form
- control measures are used to eliminate or minimise the risks to:
 - persons involved in the research and development for which the industrial chemical is introduced; and
 - the environment
- the chemical remains under the control of the introducer
- the chemical is introduced in volumes greater than 250kg

In the exposure draft of the Rules, this introduction type was a specific exposure band scenario for human health, which would have most likely resulted in a determination of low risk for human health. There was no similar scenario in the environment exposure band criteria. Making this a separate reported introduction type will streamline the process for these low risk introductions, and make their regulatory treatment more aligned with similar categories overseas.

5.4.2 Proposal of a new introduction type in the General Rules - chemicals in a notified fragrance blend

We're proposing to introduce the concept of a notified fragrance blend introduction as a new introduction type that would be considered **low risk for human health and the environment**. This is an additional option that introducers can choose to use if their introduction meets the criteria for this introduction type.

We're proposing this change to address stakeholder concerns that the categorisation approach set out in the exposure draft of the General Rules did not adequately deal with chemicals introduced as fragrance ingredients.

Fragrance blends are usually made up of a large number of different chemicals, some of which may be unlisted industrial chemicals (chemicals not on the Inventory). Due to proprietary issues the fragrance houses may not disclose the chemicals and concentrations to the introducers (making it difficult for them to meet their responsibilities under the IC Act).

Key considerations in forming the below proposal included:

- fragrance ingredients are usually used at low concentrations
- introduction volumes are typically low and release will be dispersed (considering current rates of fragrance chemical introduction and volume information from the international fragrance association (IFRA))
- the categorisation outcome for introductions of chemicals with hazard characteristics of highest concern (human health hazard band C (e.g. carcinogens, reprotoxins) or environment hazard band D (e.g. persistent, bioaccumulative and toxic)) should **remain as assessed** and it is not appropriate for such introductions to be reported, despite the low introduction volume and/or use concentration.
- the information to be provided by the introducers of fragrance blends in products should be information that is meaningful and relatively easy for them to obtain, in order to facilitate compliance.

We are proposing that an introduction by a person of an industrial chemical will be a notified fragrance blend introduction if:

- (a) the industrial chemical:
 - i. is introduced as part of a fragrance blend, including where the fragrance blend is introduced as part of a formulated product;
 - ii. is introduced at a concentration of less than or equal to 1%; and
 - iii. does not have any of the hazard characteristics in Human Health Hazard Band C or Environment Hazard Band D².
- (b) **all** of the following information has been notified to the Executive Director:
 - i. the proper name (including the CAS name or the IUPAC name) and the CAS number (if assigned) of the industrial chemical;
 - ii. the known hazards of the industrial chemical;
 - iii. the maximum concentration of the industrial chemical in the fragrance blend;

² See sections 5.5.3 and 5.6.3 for details of the hazard characteristics in each of these hazard bands.

- iv. the name of the fragrance blend the industrial chemical is a part of;
- v. a written undertaking that the industrial chemical does not have any of the hazard characteristics detailed at (a)(iii) above;
- vi. a written undertaking that the information relating to the hazard characteristics of the industrial chemical will be given to the Executive Director if requested.

For the purpose of the General Rules, we'll define a fragrance blend as a mixture of industrial chemicals formulated to impart a scent or to cover a malodour.

In practice, we expect the provision will operate as follows:

- An international fragrance house (distinct from the introducer) can choose to notify the Executive Director of the fragrance blend they propose supplying to introducers in Australia.
- For each of the unlisted chemicals in the fragrance blend, the international fragrance house will provide the information detailed at (b) above.
- If a fragrance house has notified (such that (b) above has been satisfied) a company wishing to introduce the fragrance blend may do so by categorising the unlisted chemicals in the blend as reported introductions, as long as the introduction concentration for each unlisted chemical will not be greater than 1%.
- Such reported introductions would have different pre-introduction reporting (including a consolidated pre-introduction report for all unlisted chemicals in the fragrance blend) and record keeping requirements. This would be information more readily available and easier to track for the introducer, such as concentration of the fragrance blend in products rather than tracking and reporting on the individual chemicals.

5.5 Step 4 - Determining indicative human health risk for an introduction

5.5.1 Medium to high indicative risk for human health

The following introductions will be determined as **medium to high indicative risk for human health**, without having to consider the detailed exposure and hazard band criteria:

- 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.
- Fluorinated organic chemicals that contain a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms.
- Persistent polyhalogenated organic chemicals introduced in volumes greater than 100 kg/year.

These introduction types have been moved from Step 1, but the detailed criteria for each of these have not changed from the exposure draft of the General Rules.

Moving these introductions to this part of the categorisation process does not change the categorisation outcomes from those in the exposure draft of the General Rules. It makes it clearer that they **can still be exempted or reported if they meet the criteria outlined in steps 2 and 3**. It also allows for distinction between human health and environment risk, where relevant.

5.5.2 Low indicative risk for human health

5.5.2.1 Introductions that are internationally-assessed for human health

Introductions that meet the criteria of internationally-assessed for human health will be determined to be low indicative risk for human health.

This definition and requirements have not significantly changed from the exposure draft of the General Rules, except for the following changes to the table of trusted international bodies and type of assessments:

- Addition of opinions from the European Food Safety Authority (EFSA) on materials and articles intended to come into contact with food
- Removal of risk assessments done by applicants for authorisation under REACH (as the resulting authorisation is specific to the company and the context of the application in the EU)
- Amendments to the description of SCCS opinions to make it clear that:
 - once finalised by the SCCS they will be accepted (i.e. the processes conducted by the European Commission as a result of the opinion do not have to be finalised before it can be used)
 - the opinion must have terms of reference that include a question about the safety of a chemical in a cosmetic product; and a conclusion of safety with respect to this term of reference must have been made by the SCCS.

These changes are as a result of stakeholder feedback.

5.5.2.2 Introductions that will be at least low risk for human health

There will be certain classes of introductions that will be **at least low risk for human health**. This means that they can never be exempted but they may be assessed if they meet the criteria for medium to high risk either:

- by meeting one of the criteria in section 5.5.1. above, or
- if they are determined to be medium to high risk based on exposure and hazard criteria).

By making these introductions to at least fall in the reported category, we can consider them soon after their introduction if we need to.

We propose that the above will apply where the **industrial chemical is a UV filter**.

The following class of introduction (that was in the exposure draft of the General Rules) will be removed:

'the introduction is for an end use in an article with food contact, other than where the industrial chemical is of low concern following migration to food'.

The removal of this class will allow these food contact end uses to be categorised as exempted, if they meet the exposure and hazard band criteria for being very low risk. This change is a result of the new exempted introduction declaration which will now allow us to know more about these introductions.

5.5.3 Determining indicative human health risk based on exposure and hazard criteria

We have reconsidered exposure band and hazard band criteria in light of stakeholder feedback on the exposure draft of the General Rules and the amendments to the Bill requiring a once-off declaration for exempted introductions. Now that we will know more about exempted introductions, we have expanded the introductions that will be considered 'very low risk' and therefore eligible for this category.

The following diagram (the human health risk indicative matrix) illustrates the indicative risk outcomes for human health, and includes the new proposed exposure band criteria.

Human health indicative risk matrix

C	Low risk	Medium to high risk	Medium to high risk	Medium to high risk
B	Very low risk	Very low risk	Low risk	Medium to high risk
A	Very low risk	Very low risk	Very low risk	Low risk
Not A, B or C	Very low risk	Very low risk	Very low risk	Very low risk
	1	2	3	4
	1. <0.1% at introduction and end use and no consumer end uses	2 HHCV ≤25 kg and no end use in TI/PV 3. <0.1% at introduction and end use and includes a consumer end use (except TI/PV)	4. HHCV >25kg and ≤100 kg and no end use in TI/PV 5. ≤1% at introduction and end use and no end use in TI/PV	6. HHCV >100 kg 7. End use in tattoo inks or personal vaporisers

HHCV = human health categorisation volume

TI/PV = tattoo inks/personal vaporisers

Consumer end use means an end use for the industrial chemical that involves making the industrial chemical available to the general public:

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

You can compare this to the human health risk indicative matrix for the criteria in the exposure draft of the General Rules, which is shown in Appendix A.

5.5.3.1 Proposed changes to human health exposure band criteria

The human health categorisation volume (HHCV) is a new concept. It's similar to the environment categorisation volume proposed in the exposure draft of the General Rules. The determination of the HHCV will involve a formula where the introduction volume is multiplied by a default exposure factor based on the end use for the introduction. Introducers can choose to either simply use their introduction volume as the HHCV or to apply the formula set out in the Guidelines in order to obtain a lower HHCV.

The concept of 'human health categorisation volume' has been introduced to address 2 issues raised by stakeholders:

1. The portion of introduced chemical that is exported without opening the packaging should not be included in the calculation of volume used for categorisation purposes. An example of this is where a shipment of product is introduced into Australia – some remains and enters the Australian market, while some is exported to New Zealand.
2. Some chemicals are introduced for both cosmetic and non-cosmetic end uses, with the non-cosmetic being the larger proportion. Stakeholders did not want their total volume of introduction to be subjected to the lower volume thresholds that would apply to cosmetic products.

The human health categorisation volume formula to be set out in the Guidelines will involve:

- The proportion of chemical imported then exported will have an exposure factor of 0, such that it is essentially subtracted from the introduction volume
- The proportion of chemical used in the following end uses will have an exposure factor of 1 such that if these are the only end uses the HHCV will be equal to the introduction volume (minus any imported/exported volume):
 - Cosmetics
 - Chewing gum
 - Non-therapeutic nasal sprays
 - Other end uses excluded by the Therapeutic Goods Administration (TGA) but not meeting the definition of cosmetics.³
- All other end uses will have an exposure factor of 0.1 such that if they are the only end uses the HHCV will be equal to 10% of the introduction volume (minus any imported/exported volume)

³ These are currently being considered and would be set out specifically in the Guidelines.

- If an introduction has a combination of the previous 2 types of end uses then an introducer may choose to either use the exposure factor of 1 or to calculate (and track) a combined HHCV using both exposure factors to lower their categorisation volume.

Other changes that are proposed to the exposure band criteria, compared to the exposure draft of the General Rules are:

- Adding a new lowest exposure band so that there can be a different indicative risk outcome for chemicals used at very low concentrations (below the GHS thresholds for classification in the workplace) and only in end uses with no consumer exposure.
- Increasing the volume threshold in the lower exposure band from 10kg to 250kg for introductions that only have end uses for which the exposure factor of 0.1 can be applied. This more closely aligns internationally and allows the importation of a standard size drum to be very low risk (as long as the chemical does not have any of the highest hazards)
- Removing the exposure band scenario for introductions with end uses in cosmetics that required **both** very low volume and very low concentration. Now that we will know more about exempted introductions we are proposing to replace this with two separate exposure band scenarios. In exposure band 2 there is now proposed to be a very low volume scenario (equivalent to up to 25kg per year) and a very low concentration scenario (less than 0.1%). These would be considered very low risk to human health as long as the chemical does not have any of the highest hazards.
- Introductions for end uses in tattoo inks or personal vaporisers are proposed to always be in the highest exposure band, in recognition of the higher exposure expected from these end uses where the chemicals are directly injected or inhaled. This will mean an introducer of chemicals with these end uses will need more information to be able to categorise their introduction as very low or low risk and any chemicals with hazards in the two highest bands will be assessed by us prior to introduction.

5.5.3.2 Proposed changes to human health hazard band criteria

The human health hazard band criteria are set out in the table below. Only the following minor changes are being proposed:

- A re-ordering of the items in the table to allow a more logical presentation in the Guidelines
- 'Respiratory corrosion' has been changed to 'corrosive to the respiratory tract' to better align with GHS terminology
- The hazard characteristic 'high molecular weight polymer that contains certain chemical elements' has been moved from hazard band B to hazard band A.
- The hazard characteristics mutagenicity and genotoxicity have been replaced with a single characteristic called 'genetic toxicity'

Human health hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The human health hazard band that applies to the hazard characteristic is ...
Hazard band C		
1	carcinogenicity (within the meaning given by the Guidelines)	C
2	reproductive toxicity (within the meaning given by the Guidelines)	C
3	developmental toxicity (within the meaning given by the Guidelines)	C
4	adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines)	C
5	genetic toxicity (within the meaning given by the Guidelines)	C
Hazard band B		
6	high molecular weight polymer that is water absorbing (within the meaning given by the Guidelines)	B
7	high molecular weight polymer that is reactive (within the meaning given by the Guidelines)	B
8	respiratory sensitisation (within the meaning given by the Guidelines)	B
9	corrosive to the respiratory tract (within the meaning given by the Guidelines)	B
10	specific target organ toxicity after a single exposure (significant toxicity) (within the meaning given by the Guidelines)	B
11	skin corrosion (within the meaning given by the Guidelines)	B
12	eye damage (within the meaning given by the Guidelines)	B
13	skin sensitisation (within the meaning given by the Guidelines)	B
14	acute toxicity (fatal or toxic) (within the meaning given by the Guidelines)	B

Human health hazard band		
Item	If the industrial chemical has this hazard characteristic ...	The human health hazard band that applies to the hazard characteristic is ...
15	specific target organ toxicity after repeated exposure (within the meaning given by the Guidelines)	B
Hazard band A		
16	high molecular weight polymer that has lung overloading potential (within the meaning given by the Guidelines)	A
17	high molecular weight polymer with other potential hazards (within the meaning given by the Guidelines)	A
18	high molecular weight polymer that contains certain chemical elements (within the meaning given by the Guidelines)	A
19	aspiration hazard (within the meaning given by the Guidelines)	A
20	specific target organ toxicity after a single exposure (harmful or transient effects) (within the meaning given by the Guidelines)	A
21	skin irritation (within the meaning given by the Guidelines)	A
22	eye irritation (within the meaning given by the Guidelines)	A
23	acute toxicity (harmful) (within the meaning given by the Guidelines)	A

5.6 Step 5 - Determining indicative environment risk for an introduction

5.6.1 Medium to high indicative risk for the environment

The following introductions will be determined as medium to high indicative risk for the environment, without having to consider the detailed exposure and hazard band criteria:

- 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.
- Fluorinated organic chemicals that contain a sequence of greater than or equal to 4, but no more than 20, fully fluorinated carbon atoms.
- Persistent polyhalogenated organic chemicals introduced in volumes greater than 100 kg/year.
- Persistent gases introduced in volumes greater than 100 kg/year.
- Organotin chemicals introduced in volumes greater than 10 kg/year.

These introduction types have been moved from Step 1, but the detailed criteria for each of these have not changed from the exposure draft of the Rules. Organotin chemicals are a new addition, and will be defined as chemicals that contain at least one tin atom that is covalently bound to at least one carbon atom.

Moving these introductions to this part of the categorisation process does not change the categorisation outcomes from those in the exposure draft of the General Rules. It makes it clearer that they can still be exempted or reported if they meet the criteria outlined in steps 2 and 3. In addition, it allows for distinction between human health and environment risk, where relevant.

5.6.2 Low indicative risk for the environment

5.6.2.1 *Introductions that are internationally-assessed for the environment*

Introductions that meet the criteria of internationally-assessed for the environment will be determined to be low indicative risk for the environment. This definition and requirements have not significantly changed from the exposure draft of the Rules, except for the changes to the table of trusted international bodies and type of assessments, as outlined in section 5.5.2.1 above

5.6.2.2 *Introductions that will be at least low risk for the environment*

There will be certain classes of introductions that will be at **least low risk for the environment**. This means that they can never be exempted but they may be assessed if they meet the criteria for medium to high risk either:

- by meeting one of the criteria in section 5.6.1 above, or
- if they are determined to be medium to high risk (based on exposure and hazard criteria).

These classes of introduction will be:

- the industrial chemical is a polyhalogenated organic chemical;
- the introduction of the industrial chemical is for an end use as a biocide;
- the industrial chemical is an organotin chemical

The exposure draft of the Rules had an additional class in this list – where the ‘the industrial chemical is a highly branched organic chemical’. The removal of this class will allow these introductions of highly branched organic chemicals to now be categorised as exempted, if they meet the exposure and hazard band criteria for being very low risk.

5.6.3 Determining indicative environment risk based on exposure and hazard criteria

We have reconsidered exposure band and hazard band criteria in light of stakeholder feedback on the exposure draft of the General Rules and the IC Act (as amended) requiring a once-off declaration for exempted introductions. Now that we will know more about exempted introduction sooner, we have expanded the introductions that will be considered 'very low risk' and therefore eligible for this category

The following diagram (the environment risk indicative matrix) illustrates the indicative risk outcomes for the environment, and includes the new proposed exposure band criteria.

Environment indicative risk matrix

D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
C	Low risk	Low risk	Medium to high risk	Medium to high risk
B	Very low risk	Low risk	Low risk	Medium to high risk
A	Very low risk	Very low risk	Very low risk	Low risk
Not A, B, C, or D	Very low risk	Very low risk	Very low risk	Very low risk
	1	2	3	4
	1. ECV ≤25kg; no designated kind of release	2. ECV >25kg and ≤1,000 kg; no designated kind of release	3. ECV >1,000kg and ≤10,000 kg; no designated kind of release	4. Designated kind of release 5. ECV >10,000 kg

ECV = environment categorisation volume

Designated kind of release into the environment is any of the following:

- i. intentional release during use to land, biota, natural waterways or municipal water supplies;
- ii. intentional release to air during use (other than solely domestic or personal use);
- iii. if the industrial chemical is introduced for an end use in fire fighting—release (intentional or otherwise) into the environment;
- iv. if the industrial chemical is introduced for an end use in offshore operations—release (intentional or otherwise) into the ocean.

You can compare this to the environment indicative risk matrix for the criteria in the exposure draft of the general Rules, which is shown in Appendix A.

5.6.3.1 Proposed changes to environment exposure band criteria

Changes proposed to the environment exposure band criteria are:

- The calculation of the ECV set out in the Guidelines will be changed so that the proportion of chemical imported then exported will have a reduction factor of 0, such that it is essentially subtracted from the introduction volume
- Increasing the ECV threshold in the lowest exposure band from 10kg to 25kg. This more closely aligns internationally and allows the importation of a standard size drum to be very low risk (as long as the chemical does not have any of the higher hazards)
- Defining all releases into the ocean from off-shore end uses as designated kinds of release to the environment- not just off-shore drilling

5.6.3.2 Proposed changes to the environment hazard band criteria

The environment hazard band criteria are set out in the table below. The only minor change is a re-ordering of the items in the table to allow a more logical presentation in the Guidelines.

Environment hazard band		
Item	If the industrial chemical has this environment hazard characteristic ...	The environment hazard band that applies to the hazard characteristic is ...
Hazard band D		
1	contains arsenic, cadmium, lead or mercury	D
2	ozone depleting chemicals (within the meaning given by the Guidelines)	D
3	synthetic greenhouse gas (within the meaning given by the Guidelines)	D
4	adverse effects mediated by an endocrine mode of action (within the meaning given by the Guidelines)	D
5	persistent, bioaccumulative and toxic (within the meaning given by the Guidelines)	D
Hazard band C		
6	very toxic to any aquatic life (within the meaning given by the Guidelines)	C

Environment hazard band		
Item	If the industrial chemical has this environment hazard characteristic ...	The environment hazard band that applies to the hazard characteristic is ...
7	persistent and bioaccumulative (within the meaning given by the Guidelines)	C
Hazard band B		
8	toxic to any aquatic life (within the meaning given by the Guidelines)	B
Hazard band A		
9	contains aluminium, chromium, copper, nickel, selenium, silver or zinc	A
10	polymers that have an overall cationic charge at pH 4 to 9 (determined in accordance with the Guidelines)	A
11	polymers that are not stable (within the meaning given by the Guidelines)	A
12	has bioaccumulation potential (within the meaning given by the Guidelines)	A
13	industrial chemicals (other than polymers) that do not meet the criteria for ready biodegradability (within the meaning given by the Guidelines)	A
14	harmful to any aquatic life (within the meaning given by the Guidelines)	A

6 Acronyms and definitions

The following acronyms or terms are referenced within this document:

Term/Acronym	Meaning
AICIS	Australian Industrial Chemicals Introduction Scheme
Animal test data	Data or information that results from: <ul style="list-style-type: none"> - the application of an industrial chemical, either on its own or in combination with one or more other chemicals, to a live vertebrate animal (other than a human); or - experimentation using a live vertebrate animal (other than a human) to test any effects of an industrial chemical, either on its own or in combination with one or more other chemicals.
Assessed introductions	Generally an industrial chemical introduction that poses a medium to high risk to human health or the environment. If an industrial chemical does not fall within the definition of an exempted or reported introduction and is not listed on the Inventory, it is generally an assessed introduction. (Refer s28 of the IC Act.)
Biochemical	An industrial chemical that is: <p>Directly produced by living, or once living, cells or cellular components.</p> <p>or</p> <p>A derivative or modification of such an industrial chemical, in which the original industrial chemical remains substantially intact.</p>
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.
Biopolymer	A polymer that is a biochemical
CAS name	The Chemical Abstracts Index Name for the industrial chemical.
CAS number	The Chemical Abstracts Service Registry Number for the industrial chemical

Term/Acronym	Meaning
Categorisation	<p>Categorisation is the process of determining the relevant introduction category for an industrial chemical.</p> <p>There are 6 category types for the introduction of industrial chemicals into Australia: listed, exempted, reported, assessed, commercial evaluation authorisations, exceptional circumstances authorisations (Refer sections 24-30 of the IC Act.)</p>
Comparable chemical	<p>An industrial chemical that has been determined to be comparable to a listed industrial chemical and specified in the table under section 21(5) of the General Rules</p>
Comparable polymer	<p>An industrial chemical that is a polymer that:</p> <ul style="list-style-type: none"> (a) contains each of the reactants that another polymer that is listed on the Inventory (the listed polymer) does; and (b) contains one or more other reactants (the additional reactants) that the listed polymer does not; and (c) each additional reactant does not constitute more than 2% by weight of the polymer; and (d) the introduction complies with the terms of the Inventory listing for the listed polymer.
Commercial evaluation authorisations	<p>Authorisations granted to introduce an industrial chemical for the purpose of ascertaining the industrial chemical's potential for commercial application. (Refer Division 4, Section 53 of the IC Act.)</p>

Term/Acronym	Meaning
Cosmetic	<p>A substance or preparation intended for placement in contact with any external part of the human body, including:</p> <ul style="list-style-type: none"> • the mucous membranes of the oral cavity • the teeth <p>with a view to:</p> <ul style="list-style-type: none"> • altering the odours of the body • changing its appearance • cleansing it • maintaining it in good condition • perfuming it, or • protecting it <p>but does not include:</p> <p>c) A therapeutic good within the meaning of the Therapeutic Goods Act 1989</p> <p>Note: An ingredient or component of a cosmetic could be an industrial chemical.</p>
End use	<p>For an industrial chemical, means a purpose to which the industrial chemical can be applied.</p>
End use in an article with food contact	<p>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:</p> <p>(a) where the end use of the industrial chemical is at the non-food contact surface of a glass or metal article; or</p> <p>(b) if the food that the article will come into contact with is rainwater—where the contact with the rainwater is transient.</p>
Environment categorisation volume (ECV)	<p>The environment categorisation volume for an industrial chemical that is worked out in accordance with the Guidelines</p>
Exceptional circumstances authorisations	<p>Authorisations granted by the Minister for the introduction of an industrial chemical. (Refer Division 5, Section 67 of the IC Act.)</p>
Executive Director	<p>The person appointed as the Executive Director of the new scheme under section 143 of the IC Act.</p>
Exempted introductions	<p>An introduction of an industrial chemical that poses a very low risk to human health and the environment. (Refer s26 of the IC Act.)</p>

Term/Acronym	Meaning
Exposure bands	Groupings of introduction and use scenarios with similar levels of potential exposure to human health or the environment
Fragrance blend	A mixture of industrial chemicals formulated to impart a scent or to cover a malodour
General Rules	The draft Industrial Chemicals (General) Rules 2018
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
Guidelines	The Industrial Chemicals Categorisation Guidelines
Hazard bands	Groupings of hazard characteristics based either on similar levels of concern for human health or the environment, or on achieving the same regulatory outcome (e.g. assessed)
Hazard characteristics	The effects an industrial chemical may have on human health (e.g. reproductive toxicity) or the environment (e.g. toxic to aquatic life), or properties that may lead to effects on human health (e.g. high molecular weight polymer that has lung overloading potential) or the environment (e.g. polymers that have overall cationic charge at pH 4 to 9).
Highly branched organic chemical	An industrial chemical that is branched at: <ul style="list-style-type: none"> • more than one tertiary carbon • more than one quaternary carbon, or • a combination of tertiary and quaternary carbons
High molecular weight polymer	A polymer that has a number average molecular weight that is greater than or equal to 1,000 g/mol.
Human health categorisation volume (HHCV)	The human health categorisation volume for an industrial chemical that is worked out in accordance with the Guidelines
IC Act	Industrial Chemicals Act 2019
IFRA	International Fragrance Association
Introduce	Import, or manufacture in Australia, the industrial chemical.
Inventory	Australian Inventory of Industrial Chemicals
IUPAC name	International Union of Pure and Applied Chemistry – a naming method for chemicals

Term/Acronym	Meaning
Listed introductions	Authorised introduction of an industrial chemical where the chemical is listed on the Inventory and the introduction is in accordance with terms of the Inventory listing. (Refer s25 of the IC Act.)
Low concern biopolymers	A biopolymer that would otherwise be a PLC, except that it fails the stability requirement.
Nanoscale	The particle size range of 1 to 100 nm
New scheme	The Australian Industrial Chemicals Introduction Scheme (AICIS) which commences on 1 July 2020.
Organotin chemical	A chemical that contains at least one tin atom that is covalently bound to at least one carbon atom
Personal vaporiser	<p>A device that produces a vapour or aerosol that is intended to be inhaled into the lungs, including the following devices:</p> <ul style="list-style-type: none"> • e-cigarettes • e-cigars • e-hookah pens • e-pens • e-pipes • vape pens
PLCs	Polymers of low concern – those polymers meeting the criteria set out in Schedule 1 of the General Rules
Polyhalogenated organic chemical	<p>A chemical that:</p> <ul style="list-style-type: none"> • is carbon based, and • contains more than one covalently bonded bromine, chlorine, fluorine or iodine substituent

Term/Acronym	Meaning
Polymer	<p>A chemical that consists of molecules that are:</p> <ul style="list-style-type: none"> • characterised by the sequence of one or more types of monomer units • 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 • greater than 50% by weight of which have a sequence of at least 3 monomer units covalently bound to at least one other: <ul style="list-style-type: none"> ○ monomer unit, or ○ molecule that is linked to one or more sequences 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
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH is a regulation of the European Union.
Registration year	12 months beginning on 1 September of each year
Research and development (R&D)	<p>Research and Development. An introduction is for R&D if it is:</p> <ul style="list-style-type: none"> - for the purposes of systematic investigation and research, by means of experimentation or analysis; and - not for distribution of the industrial chemical, or a product containing the industrial chemical, to potential customers in order to explore market capability in a competitive situation
Reported introductions	<p>A reported introduction is an industrial chemical introduction that poses a low risk to human health or the environment. (Refer s27 of the IC Act.)</p>
Rotterdam Convention	<p>The Rotterdam Convention is a multilateral environmental agreement on the import and export of certain hazardous chemicals. Countries make informed decisions to accept the chemicals they are prepared to receive, and exclude those they decide they cannot manage safely.</p>
SCCS	<p>The Scientific Committee on Consumer Safety. The SCCS provides opinions on health and safety risks of non-food consumer products to the European Commission</p>

Term/Acronym	Meaning
Stockholm Convention	The Stockholm Convention is an international treaty that aims to protect human health and the environment from the effects of persistent organic pollutants (POPs), which persist in ecosystems around the world and accumulate in the fatty tissue of humans and wildlife.
Tattoo ink	A combination of industrial chemicals that: <ul style="list-style-type: none">• contains one or more colouring agents, and• is applied to the dermal layer of the skin for the purposes of colouring the skin
Unlisted chemical introduction	Introduction of an industrial chemical not listed on the Inventory, or introduction of a listed chemical that is not in accordance with the terms of listing.
UV filter	An industrial chemical that 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.

Appendix A – Previous indicative risk matrices (2018)

The previous indicative risk matrices illustrating the proposals in the exposure draft of the Rules are shown below for comparison purposes with the proposals in this consultation paper.

Human health indicative risk matrix – exposure draft version (2018)

C	Medium to high risk	Medium to high risk	Medium to high risk
B	Very low risk	Low risk	Medium to high risk
A	Very low risk	Low risk	Low risk
Not A, B or C	Very low risk	Very low risk	Very low risk
	1	2	3
	1. IV ≤10 kg and no end use in cosmetics, TI or PV 2. <0.1% at introduction and end use; no end use in cosmetics, TI or PV 3. IV ≤10 kg; <0.1% at introduction and end use; includes an end use in cosmetics, TI or PV	4. IV >10kg and ≤1,000 kg; no end use in cosmetics, TI or PV 5. IV ≤10 kg; ≥0.1% at introduction and end use; includes an end use in cosmetics, TI or PV 6. R&D >100kg, subject to introducer control 7. ≤1% at introduction and end use 8. IV >10kg and ≤100 kg; includes an end use in cosmetics, TI or PV	9. IV >1,000 kg; no end use in cosmetics, TI or PV 10. IV >100kg; includes an end use in cosmetics, TI or PV

IV = introduction volume

TI = tattoo inks

PV = personal vaporisers

Environment indicative risk matrix – exposure draft version (2018)

D	Medium to high risk	Medium to high risk	Medium to high risk	Medium to high risk
C	Low risk	Low risk	Medium to high risk	Medium to high risk
B	Very low risk	Low risk	Low risk	Medium to high risk
A	Very low risk	Very low risk	Low risk	Low risk
Not A, B, C or D	Very low risk	Very low risk	Very low risk	Very low risk
	1	2	3	4
	1. ECV ≤10kg; no designated kind of release	2. ECV >10kg and ≤1,000 kg; no designated kind of release	3. ECV >1,000kg and ≤10,000 kg; no designated kind of release	4. Designated kind of release 5. ECV >10,000 kg

ECV = environment categorisation volume

Designated kind of release into the environment is any of the following:

- i. intentional release during use to land, biota, natural waterways or municipal water supplies;
- ii. intentional release to air during use (other than solely domestic or personal use);
- iii. if the industrial chemical is introduced for an end use in fire fighting—release (intentional or otherwise) into the environment;
- iv. if the industrial chemical is introduced for an end use in offshore drilling—release (intentional or otherwise) into the ocean.