



# Summary of feedback on proposed changes to the Industrial Chemicals General Rules and Transitional Rules

22 November 2021

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# Introduction

We sought feedback from stakeholders on proposed amendments to the Industrial Chemicals (General) Rules 2019 and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019. The proposed amendments were set out in an 'exposure draft' document, which is a formal form of draft legislation that is made available to the public for comment. The consultation ran from 23 August 2021 and 17 September 2021.

We received 7 submissions from industry.

## Abbreviations used in this document

**Exposure draft:** refers to the draft Industrial Chemicals (General) Legislation Amendment (2021 Measures No 1) Rules 2021

**Amending rules:** refers to the Industrial Chemicals (General) Legislation Amendment (2021 Measures No. 1) Rules 2021 as made by the Minister

**AICIS:** Australian Industrial Chemicals Introduction Scheme

**OCS:** Office of Chemical Safety (a division of the Australian Government Department of Health)

**R&D:** research and development

**General Rules:** Industrial Chemicals (General) Rules 2019

**IC (CATP) Rules:** Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019

## Schedule 1, Part 1 – Requirements for industrial chemicals introduced at the nanoscale

### Proposal

**Items 1-19** of the exposure draft set out amendments to clarify:

- the criteria for introductions of chemicals at the nanoscale
- how the nanoscale criteria apply in practice
- the associated record keeping requirements

### Summary of feedback

Stakeholders supported clarifying the criteria for introductions of chemicals at the nanoscale. One submission sought clarification about the need for testing to prove an introduction does not meet the nanoscale criteria for R&D introductions at higher volumes.

## OCS response

The proposed amendment has been made. This means the General Rules have been amended as described in items 1-19 (items 1-19 of the amending rules).

Nanoscale criteria for R&D introductions distinguish between volumes allowed for exempted and reported introductions based on technical criteria that may need testing. The technical criteria include whether the chemical is introduced as a solid/dispersion and particle size information.

## Schedule 1, Part 2 – Pre-introduction reporting requirements for industrial chemicals introduced at the nanoscale

### Proposal

**Item 20** of the exposure draft added a reporting requirement in pre-introduction reports. This would only apply to introductions solely for use in research and development. The reporting requirement is:

'If the industrial chemical is introduced by the person as a solid or in a dispersion—whether the industrial chemical is known to the person to consist of particles, in an unbound state or as an aggregate or agglomerate, where at least 50% (by number size distribution) of the particles have at least one external dimension in the nanoscale'.

### Summary of feedback

We did not receive feedback on item 20.

## OCS response

The proposed amendment has been made. This means that the General Rules have been amended as described in item 20 (item 20 of the amending rules).

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### Proposal

**Item 21** of the exposure draft added a reporting requirement in pre-introduction reports where the highest indicative risk is low risk. The reporting requirement is:

'If the industrial chemical is to be introduced as a solid, in a dispersion or neither'.

### Summary of feedback

Stakeholders had concerns about the regulatory impact of item 21.

## OCS response

The proposed amendment described in item 21 has not been made. This means that the General Rules have **not** been changed to add this reporting requirement.

## Schedule 1, Part 3 – Declaration about data ownership

### Proposal

**Items 22, 24, 26 and 28** of the exposure draft added declarations on data ownership for proving the absence of hazard characteristics for categorisation.

### Summary of feedback

For items 22, 24, 26 and 28, stakeholders raised concerns about the:

- proposal to include declarations on data ownership for proving the absence of hazard for categorisation
- current rules that require them to have either the full study reports or permission from the owner to use them

Stakeholders wanted more clarity on the permission they needed from the data owner.

## OCS response

The proposed amendments described in items 22, 24, 26 and 28 have not been made. This means that the General Rules have **not** been changed to add these declarations.

We will consult on refinements to declarations on data ownership.

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### Proposal

**Items 23, 25 and 27** of the exposure draft added declarations about the introducer having permission to use an international assessment report from the report's owner.

### Summary of feedback

No feedback was received on items 23, 25 and 27.

## OCS response

The proposed amendments have been made. This means that the General Rules have been amended as described in items 23, 25 and 27 (items 21-23 of the amending rules).

## Schedule 1, Part 4 – Annual declarations

### Proposal

**Item 29** of the exposure draft added a requirement for post-introduction declarations. It will require a person to provide information on the 'types' of exempted introductions that they have made during the registration year.

### Summary of feedback

One submission supported this amendment.

Others felt that it was an extra regulatory burden to provide information on the types of their exempted introductions. They were unsure about the need for this information to be collected at the time of the annual declaration.

### OCS response

The proposed amendment described in item 29 has not been made. This means that the General Rules have **not** been changed to add this requirement.

The proposal's goal was to reduce the information we asked an introducer to give us at audit. This aimed to make our audit campaign better targeted and minimise mandatory information requests. We will further consider the design of the audit program and the regulatory burden of any changes.

## Schedule 1, Part 5 – Record keeping for listed introductions

### Proposal

**Item 30** of the exposure draft affected listed introductions. The proposed changes were:

- add an extra option for the chemical identity record if the introducer does not know the CAS name and number
- add a timeframe of 20 working days for the CAS name and number to be provided to us if it is covered by a written undertaking and we request them

### Summary of feedback

Stakeholders did not oppose the addition of an extra option for the chemical identity record.

Stakeholders wrote that the proposed amendment to have 20 working days as the timeframe for the written undertaking was too short. Some proposed to extend the time frame to 60 working days.

Stakeholders also raised concerns with the current record keeping requirements for listed introductions. They had issues seeking engagement of their overseas suppliers in complying with these requirements.

## OCS response

The proposed amendment has been made, but with changes to item 30 (item 24 of the amending rules). The timeframe to provide CAS names and numbers is now **40 working days** instead of 20. The extra option for the chemical identity record has been added.

The proposed time frame of 20 working days was based on current experience with written undertakings. However, to administer an efficient audit process while allowing time to liaise with overseas suppliers, there will be a compromised timeframe of 40 working days.

We will talk to stakeholders to better understand:

- the burden of current record keeping requirements for listed introductions
- the request to transition supplier records they got under the past scheme (NICNAS)

## Schedule 1, Part 6 – Record keeping for specified classes

### Proposal

**Items 31-38** of the exposure draft added options for record keeping of specified classes of introductions. They would allow for more flexibility when the introducer cannot get the relevant information.

### Summary of feedback

One submission supported this proposed amendment. Another wanted the flexibility for this to apply to all Exempted introductions.

### OCS response

The proposed amendment has been made. This means that the General Rules have been amended as described in items 31-38 (items 25-32 of the amending rules).

The flexibility in record keeping is for specific situations. It is for introducers who cannot get the required information because their overseas suppliers claim it as confidential. It is not suitable for extension to all records. Introducers should have knowledge of the information they need to hold as records.

## Schedule 1, Part 7 – Record keeping for designated releases to the environment

### Proposal

**Items 39-41** of the exposure draft cleared up the requirements for record keeping of introductions with a 'designated kind of release to the environment'.

## Summary of feedback

One submission was about the proposal to add 'if practicable'. While in support, they asked for more consultation with industry on the guidance material.

Air fresheners used in non-domestic settings such as hospitality and aged care facilities are currently a 'designated kind of release into the environment'. The same submission raised concerns with record-keeping requirements for this.

The submission also questioned the need to keep 'the quantity of chemical released into the environment' as a record for exempted introductions.

## OCS response

The proposed amendment has been made. This means that the General Rules have been amended as described in items 39-41 (items 33-35 of the amending rules).

We will complete further stakeholder consultation before we publish the supporting guidance.

Schedule 1, Part 2, clause 3, paragraph 2(b) of the General Rules has also been amended to exclude all introductions for an end use in air fresheners from being a 'designated kind of release to the environment'. This means that an introduction of a chemical with an end use in air fresheners will no longer be considered a 'designated kind of release into the environment'. This approach clarifies the original intent of this requirement.

Designated kinds of release to the environment result in direct release of the chemical into the environment as part of its intended use. Thus, introducers must continue to keep information about the quantity of the chemical released into the environment, particularly because it would be difficult to obtain this information retrospectively. This information assists in risk management or remediation measures if it is required in the future. For example, if new information means a chemical that was initially categorised as exempted is now in a higher risk category.

## Schedule 1, Part 8 – Record keeping for internationally-assessed introductions

### Proposal

**Items 42-45** of the exposure draft corrected an omission about volume records that introducers need to keep for internationally assessed introductions.

### Summary of feedback

Stakeholders gave feedback that the wording of the proposed amendments were ambiguous. They said the proposed wording should be changed to make it clearer.

## OCS response

The proposed amendment has been made, but with changes to items 42-45 (items 36-39 of the amending rules).

The changes clarify that introducers must keep **both of the following**:

- records to prove that the volume introduced in a registration year did not exceed the volume reported in the pre-introduction report
- records to prove that the volume introduced in a registration year did not exceed the volume assessed in the international assessment or evaluation

## Schedule 1, Part 9 – Movement of industrial chemicals into or out of Australia

### Proposal

**Items 46-56** of the exposure draft proposed changes to better align the General Rules with the scope of international conventions.

### Summary of feedback

We did not receive any feedback.

## OCS response

The proposed amendments have been made. This means that the General Rules have been amended as described in items 46-56 (items 40-50 of the amending rules).

## Schedule 1, Part 10 – Other amendments

### Proposal

**Items 57-61** of the exposure draft sought to correct errors and omissions in the General Rules.

- Correct an error in the name of the European Commission Scientific Committee on Consumer Safety.
- Correct an error in the table of industrial chemicals that are comparable to listed industrial chemicals.
- Correct an omission by adding circumstances to the list for when an AICIS Approved Chemical Name (AACN) or generalised end use must be used.
- Allow the consideration period for an application to be 'paused'.

### Summary of feedback

One submission told us that they had no concerns with the proposed amendments.



## OCS response

The proposed amendments have been made. This means that the General Rules have been amended as described in items 57-61 (items 51-56 of the amending rules).

## Schedule 1, Part 11 – Transitional provisions

### Proposal

**Items 62 and 63** of the exposure draft added provisions allowing certain changes in this amending instrument to only apply after certain dates.

### Summary of feedback

One submission gave feedback to support these transitional provisions. They suggested to include a transitional period of 10 December 2021 for the amendments to record keeping for designated kinds of release into the environment (Part 7).

## OCS response

The proposed amendments have been made. This means that the General Rules have been amended as described in items 62 and 63 (items 57 and 58 of the amending rules).

In addition, the record keeping for designated kinds of release into the environment (Part 7) will apply from 10 December 2021.

## Schedule 2 – Amendments to IC (CATP) Rules

### Proposal

**Item 1** of the exposure draft added a new transitional rule. When a chemical that was issued a transitioned assessment certificate gets added to the Inventory, the conditions of that assessment certificate will also be added onto the Inventory listing.

**Item 2** of the exposure draft removed certain rows from the table showing chemicals with a NICNAS 'conditions of use' that are transitioned to 'defined scopes of assessment' under AICIS.

### Summary of feedback

One stakeholder indicated they did not oppose these proposals.

## OCS response

The proposed amendments have been made. This means that the Transitional Rules have been amended as described in items 1 and 2.

## Other issues raised by stakeholders

### Summary of feedback

A submission raised an issue that that could be considered in the future. It relates to pre-introduction reports for low risk fragrance blend introductions.

Another submission raised two more issues. They recognised that these would be outside of the current policy. These were:

- declaration of data ownership/how to use public data
- the limit of 1% on low-risk fragrance blend introductions

### OCS response

We have recorded these issues for future discussions with stakeholders to better understand their concerns, the issues and find solutions, or further consider policy authority.