Proposed changes to the List of chemicals with high hazards for categorisation & information on minor changes to the Guidelines

In September 2023, we consulted on proposed changes to the Industrial Chemicals (General) Rules 2019 and Industrial Chemicals Categorisation Guidelines (the Guidelines), which included proposals to refine the List of chemicals with high hazards for categorisation (the List).

In this consultation, we provide further details about proposed changes to the List. For example:

- updating the chemicals that are on the List
- a change related to checking esters and salts of chemicals that are on the List – we're seeking your feedback about the chemicals that we will specify and the details of some exceptions that would apply.

We're also providing details of some other minor changes that we'll be making to the Guidelines.

> Open for comment until 22 February 2024.

Click each topic below for more details

Proposed changes to the List of chemicals with high hazards for categorisation

On this page:

> Have your say by **22 February 2024**

22 February 2024

Background information

The 'List of chemicals with high hazards for categorisation' (the List) is a list of chemicals that trusted national and international sources consider to be highly hazardous to human health or the environment, with hazard characteristics that are in our highest hazard bands – human health hazard band C and environment hazard band C or D.

The list is a screening tool that introducers must use at steps 4-6 of the categorisation process when working out if their introduction can be categorised as exempted or reported. The introducer must check if their chemical is on the List and if it is, then the chemical has one or more of the hazard characteristics in the highest hazard bands. All esters and salts of chemicals on the List are currently considered to have the same high hazard characteristics as the chemical that is on the List. Introductions of chemicals on the List and with hazard characteristics in our highest hazard bands (such as carcinogenicity) could be categorised as assessed (medium to high risk), depending on the circumstances of the introduction.

For many chemicals, data to allow the characterisation of hazards in the highest hazard bands for human health or environment may not be available. It may also be expensive and time-consuming to generate the studies. The List is a screening tool that:

- helps introducers to categorise the introduction of their chemical based on known information and
- prevents chemicals that are known to be of high concern from being categorised as very low risk (exempted introductions) or low risk (reported introductions), depending on the circumstances of the introduction.

The List is defined in Part 6 of the Industrial Chemicals Categorisation Guidelines (the Guidelines), with the sources of the chemicals on the List identified in Appendix 8.1 of the Guidelines.

Changes to the Guidelines text

We propose additions to the definition text in Part 6 of the Guidelines to make it more clearly align with the purpose/function of the List and how it is accessed, in practice. Proposed additions are shown in bold below.

> List of chemicals with high hazards for categorisation means a list of chemicals that have hazard characteristics in human health hazard band C or environment hazard bands D or C based on at least one of the information sources shown in Appendix 8.1 of these Guidelines. This list is **part of Appendix 8.1 of these Guidelines and is** published **as an Excel spreadsheet** on the AICIS website. It is used as a screening tool for categorisation.

We also propose changes to the text at the beginning of Appendix 8.1. Proposed additions are shown in bold below.

> The list of chemicals with high hazards for categorisation **is part of this appendix. It is published as an excel spreadsheet on the AICIS website**. **It** consists of chemicals that are present on the following information sources:

To improve clarity, we also propose to amend the wording in Appendix 8.1 around what substances have been included in the List, for all the sources. Instead of saying *'Included substances are those classified for…'*, it will now state *'Substances included on the list of chemicals with high hazards for categorisation are those classified for…'*. For example, see below.

> **Example** - changes for the source Safe Work Australia's Hazardous Chemical Information System (HCIS) are shown in bold and strike-through:
>
> Safe Work Australia's Hazardous Chemical Information System (HCIS) — list of substances classified for physical-chemical and (eco)toxicological hazards. **Substances** included ~~substances~~ **on the list of chemicals with high hazards for categorisation** are those classified for CMR and PBT.

Adding chemicals to the List based on updates to current sources

In our last consultation, we noted that since originally publishing the List in 2020, the information sources have been updated to include more chemicals and that we would add these chemicals to the List. We are now providing the identities of the chemicals that will be added.

> **View the additions to the List**
>
> Additions to the List of chemicals with high hazards.xlsx

There are nearly 600 unique entries that will be added to the List, as it has not been updated for approximately 4 years. Based on information provided to us in pre-introduction reports and post-introduction declarations, we will contact (or are already in contact with) the very few current introducers of the chemicals being added that could potentially be affected by this update.

Future updates to the List will be made yearly unless urgency dictates a shorter period, with a 3-month notice period given in advance of the update taking effect.

Adding an information source

We propose to add the following information source to Appendix 8.1 of the Guidelines. Proposed additions are shown below.

> European Commission Endocrine Disruptor List (https://edlists.org/) – list of substances identified as endocrine disruptors. Substances included on the list of chemicals with high hazards for categorisation are those on List I, identified as endocrine disruptors at EU level.

This list captures chemicals that have been identified as endocrine disruptors at the EU level, so it is appropriate that they are incorporated into the List of chemicals with high hazards for categorisation.

Removing certain chemicals from the List

Last year, we consulted on a proposal to remove:

- some information sources from the List, for example, Class II chemicals on the Chemical Substances Control Law of Japan
- some entries from the List, for example, those that are neither a chemical element, a compound or complex of a chemical element nor, UVCB substance

We will proceed with the removal of these sources/entries and update Appendix 8.1 of the Guidelines accordingly. The full details of all entries that will be removed from the List will be published before the amended Guidelines commencement date. The details are not being published at this time, due to the negligible or very minor expected effect on current introducers, based on the type of entries being removed. Note that while some sources will be removed, in some instances a chemical would still be on the List based on other information sources, or the introductions of the chemicals would still be medium to high risk based on other categorisation steps.

High hazard esters and salts of chemicals on the List

As indicated above, all esters and salts of chemicals on the List are currently considered to have the same high hazard characteristics as the parent chemical that is on the List. Last year, we consulted on a proposal that responded to feedback from introducers that it is both time-consuming and difficult to go through the entire List and work out if their chemical is an ester or salt of any of the chemicals on the List. The proposal was to reduce regulatory burden by making it quicker and easier for introducers to check the List by:

1. removing the current requirement to check for esters and salts of most chemicals on the List
2. separately specifying the chemicals that introducers must check to see if their chemical is an ester or salt of those specified chemicals
3. defining any exceptions that apply for the esters and salts (i.e. if the chemical being introduced meets the exception criteria then it is not considered to have the hazard characteristic).

We have considered all the feedback we received on the general proposal and now seek your views about the identity of the chemicals that we would specify as requiring checking for esters and salts and the associated exceptions – see table below.

To be clear, if these changes proceed, there would not be any additional regulatory burden for introducers. Esters and salts of each of the chemicals in the table below are currently considered to have one or more of the hazard characteristics in human health hazard band C or environment hazard bands C or D. Steps 4 and 5 of the categorisation process would be easier for introducers of salts and esters – to search the List, they would:

1. check, as they must do now, if their chemical is included on the List and

2. check if their chemical is an ester or salt of any of the chemicals identified below (instead of all chemicals on the List as is currently required) and if it is, whether or not an exception applies – there are currently no exceptions.

The following table contains the subset of chemicals already on the List that we propose to specify in the Guidelines as requiring checking for salts and esters, along with the relevant hazard characteristics for each chemical, and any exceptions that would apply.

An ester or salt of any of these chemicals would be considered to have the hazard characteristic (for example reproductive toxicity) unless it meets the exception criteria.

CAS no.	**Chemical name**	**Hazard characteristics that apply to esters/salts**	**Exception criteria[1]**
149-57-5	Hexanoic acid, 2-ethyl (2-EHA)	Developmental toxicity	Salts: no exceptions Esters: 1, 2 or 3 1. The ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the chemical is greater than or equal to 500 g/mol 3. Each product contains 5% or less, calculated as hexanoic acid, 2-ethyl-[3]
104-76-7	1-Hexanol, 2-ethyl-	Developmental toxicity	Salts: no exceptions Esters: 1, 2 or 3 1. The ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the chemical is greater than or equal to 500 g/mol 3. Each product contains 5% or less, calculated as 1-hexanol, 2-ethyl-

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
69-72-7	Benzoic acid, 2-hydroxy- (salicylic acid)	Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
110-80-5	Ethanol, 2-ethoxy-	Reproductive toxicity Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
109-86-4	Ethanol, 2-methoxy-	Reproductive toxicity Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
111-77-3	Ethanol, 2-(2-methoxyethoxy)-	Developmental toxicity	Salts and esters: 1, 2 or 3 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol 3. The concentration of the salt/ester at introduction and at all end uses is less than 3%

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
98-73-7	Benzoic acid, 4-(1,1-dimethylethyl)-	Reproductive toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
97-99-4	2-Furanmethanol, tetrahydro- (tetrahydro-2-furylmethanol)	Reproductive toxicity Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
Various	Boric acid	Reproductive toxicity Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
80-05-7	Phenol, 4,4'-(1-methylethylidene)bis- (Bisphenol A)	Reproductive toxicity Adverse effects mediated by an endocrine mode of action (human health and environment)	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
80-09-1	Phenol, 4,4'-sulfonylbis- (Bisphenol S)	Reproductive toxicity Adverse effects mediated by an endocrine mode of action (human health and environment) Developmental toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
98-54-4	Phenol, 4-(1,1-dimethylethyl)-	Reproductive toxicity Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
80-46-6	Phenol, 4-(1,1-dimethylpropyl)-	Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
Various	Heptylphenols on the List – includes linear and branched isomers	Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
Various	Octylphenols on the List – includes linear and branched isomers	Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
Various	Nonylphenols on the List – includes linear and branched isomers	Reproductive toxicity Developmental toxicity Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
Various	Dodecylphenols on the List – includes linear and branched isomers	Reproductive toxicity Adverse effects mediated by an endocrine mode of action (health and environment)	Salts and esters: 1 or 2 1. the salt/ester is a high molecular weight polymer that: a. is not an ethoxylate polymer and b. has *low levels of low molecular weight species*[2] 2. the molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
Various	Octyl and Nonylphenol ethoxylates on the List	Adverse effects mediated by an endocrine mode of action (environment)	Salts and esters: no exceptions

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
108-78-1	1,3,5-Triazine-2,4,6-triamine (Melamine)	Carcinogenicity	Salts: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol Esters: not applicable
139-13-9	Glycine, N,N-bis(carboxymethyl)-	Carcinogenicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
90-43-7	[1,1′-Biphenyl]-2-ol	Carcinogenicity Genetic toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
615-05-4	1,3-Benzenediamine, 4-methoxy- (diaminoanisole)	Carcinogenicity Genetic toxicity	Salts: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol Esters: not applicable

CAS no.	Chemical name	Hazard characteristics that apply to esters/salts	Exception criteria[1]
123-30-8	Phenol, 4-amino-	Genetic toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol
95-55-6	Phenol, 2-amino-	Genetic toxicity	Salts and esters: 1 or 2 1. The salt/ester is a high molecular weight polymer, with *low levels of low molecular weight species*[2] 2. The molecular weight of the salt/ester is greater than or equal to 1,000 g/mol

[1] An ester or salt has one or more high hazard characteristics, unless one or more exception criteria are met
[2] *'Low levels of low molecular weight species'* means less than 10% (by mass) of molecules with a molecular weight that is less than 500 g/mol and less than 25% (by mass) of molecules with a molecular weight that is greater than 1,000 g/mol
[3] Consistent with the entry in the Poisons Standard [Therapeutic Goods (Poisons Standard – February 2023) Instrument 2023]

Example 1 – chemical does not have high hazard characteristic

Corinne wants to introduce an ester of benzoic acid, 4-(1,1-dimethylethyl)- that has a molecular weight of 2,000 g/mol. She has reached step 4 in the categorisation process and must check the 'List of chemicals with high hazards for categorisation' when working out if her chemical has any hazard characteristics in the highest human health hazard band (C).

The ester itself is not on the List, but as her chemical is an ester of benzoic acid, 4-(1,1-dimethylethyl)-, she needs to consider whether an exception applies to her chemical. If an exception does not apply, the ester that she wants to introduce would be considered to have the same high hazard characteristics as benzoic acid, 4-(1,1-dimethylethyl)-.

Because Corinne's chemical has a molecular weight ≥1,000 g/mol, it meets the exception criteria (exception 2 in this case). Corinne's ester is **not** considered to have the hazard characteristics. Corinne continues through step 4 of the categorisation process.

Example 2 – chemical does not have high hazard characteristic

Joe wants to introduce an ester of hexanoic acid, 2-ethyl-. He has reached step 4 in the categorisation process and must check the 'List of chemicals with high hazards for categorisation' when working out if his chemical has any hazard characteristics in the highest human health hazard band (C).

The ester itself is not on the List, but as his chemical is an ester of hexanoic acid, 2-ethyl-, he needs to consider whether an exception applies to his chemical. If an exception does not apply, the ester that he wants to introduce would be considered to have the same high hazard characteristics as hexanoic acid, 2-ethyl-.

The molecular weight of Joe's ester is 450 g/mol which does not satisfy the molecular weight exception criterion (exception 2 in this case). The maximum concentration of the ester at introduction and all end uses is 9%. Assuming complete hydrolysis of the ester to release the acid, Joe calculates the concentration as hexanoic acid, 2-ethyl- is 3%. Therefore, it meets the concentration exception criteria (exception 3 in this case). Joe's ester is not considered to have the hazard characteristics. Joe continues through step 4 of the categorisation process. band C.

Example 3 – most introductions

Reagan wants to introduce a salt of a chemical other than one proposed in the table above. They have reached step 4 in the categorisation process and must check the 'List of chemicals with high hazards for categorisation' when working out if their chemical has any hazard characteristics in the highest human health hazard band (C).

The salt itself is not on the List, and because their chemical is a salt of a chemical other than one included in the table above, Reagan's check of the List no longer needs to consider the salts of all chemicals on the List, and so their check of the List is complete.

Have your say

Provide your feedback using this online form or opt to provide a file submission.

Note: If you opt to provide a file submission, you will receive instructions.

Email address (required)

Confirm email (required)

Business or organisation name (if applicable)

Your privacy is important - see our Privacy Policy.

What proposals do you want to provide feedback on?

- [ ] List of chemicals with high hazards for categorisation
- [ ] I have other comments

List of chemicals with high hazards for categorisation

- ○ I agree with this proposal
- ○ I do not agree with this proposal
- ○ I partially agree with this proposal
- ○ I want to provide my feedback by uploading a file (for example , PDF or Word document)

Enter your comments.

I have other comments

Enter your comments.

Submit

Minor changes to the Categorisation Guidelines

Planned changes to the Industrial Chemicals Categorisation Guidelines (the Guidelines)

A small part of our September 2023 consultation related to some proposed minor changes to the Guidelines. We indicated that these would be made to clarify information and requirements and that a significant impact on introducers was not expected.

Some stakeholders requested more information about the proposed changes. To be transparent, we are providing further details, none of which change regulatory requirements.

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21 February 2024

Part 1 and Part 2 changes

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Part 1 changes

We are changing the introduction in Part 1 of the Guidelines to clearly inform the reader that Part 6 details the information required to demonstrate the absence of each hazard characteristic. In addition, we are changing the text to avoid the incorrect use of 'section' within the Guidelines, in each incorrect instance.

> **Planned changes** (shown in bold and strikethrough text)
>
> Part 6 of these Guidelines provides meanings for terms that appear in Schedule 1 of the IC General Rules. These include definitions of human health hazard characteristics and environment hazard characteristics used for determining indicative human health risk and indicative environment risk. **It also details the information required to demonstrate the absence of each hazard characteristic for the purposes of section 30 of the IC General Rules.** ~~This section also provides~~ **The** definitions of certain terms that are used within ~~section~~ part 6 of these Guidelines, such as 'suitable read across information' and 'acceptable test guideline' **are also provided**.

Changes to Part 2.1.2 - Environment categorisation volumes

We are making the description of 'Method 2' to work out the environment categorisation volume clearer and more useful to introducers.

Current Text	Planned text
Method 2 Work out the ECV by multiplying the introduction volume (IV) by the default release reduction factor (RRF) relevant for the intended end use scenario (refer to Table 1). That is, ***Environment categorisation volume (ECV) = introduction volume (IV) x release reduction factor (RRF)*** Where the industrial chemical will have a *single end use scenario*, the introduction volume you should use to calculate the ECV is the total volume that you will introduce in a registration year. The release reduction factor you should use is the relevant release reduction factor for your end use scenario. Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the ECV: • Option 1: The simplest approach is to allocate the total introduction volume to the end use scenario that has the highest release reduction factor, and use the equation above. • Option 2: If you know the introduction volume to be allocated to each end use scenario, you can calculate a separate environment categorisation volume for each end use scenario (using the introduction volumes allocated to each end use scenario and the relevant release reduction factors for each end use scenario), and then add these together to get a total ECV, using the equation: ***$ECV = (IV_1 \times RRF_1) + (IV_2 \times RRF_2) + \ldots + (IV_n \times RRF_n)$***	**Method 2** In this method, the ECV is determined by multiplying introduction volumes by a default release reduction factor (RRF). The way you do this depends on whether you will introduce the industrial chemical for a single end use or multiple end uses. ***Single end use scenario*** Where the industrial chemical will have a *single end use scenario* the ECV is calculated by multiplying the total introduction volume (IV) of the industrial chemical that you will introduce in a registration year by the RRF relevant for the intended end use scenario (refer to Table 1). That is, *Environment categorisation volume (ECV) = total introduction volume (IV) x release reduction factor (RRF)* ***Multiple end use scenarios*** Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the ECV: • Option 1: ○ Step 1 – determine the default RRFs (refer to Table 1) that are relevant to each of your end use scenarios ○ Step 2 – of these RRFs, choose the one with the highest value ○ Step 3 - multiply the total introduction volume of the industrial chemical that you will introduce in a registration year by the RRF you chose in step 2. That is, *Environment categorisation volume (ECV) = total introduction volume (IV) x highest release reduction factor (RRF)* • Option 2:

Current Text	Planned text
	○ Step 1 – determine the introduction volume of industrial chemical in a registration year for each end use scenario (these introduction volumes should add up to the total introduction volume of the industrial chemical that you will introduce in a registration year) ○ Step 2 – determine the default RRFs (refer to Table 1) that are relevant to each of your end use scenarios ○ Step 3 – multiply the introduction volumes allocated to each end use scenario (from Step 1) by the relevant RRF for each end use scenario (from Step 2), and then add these together to get a total ECV, using the equation: $ECV = (IV_1 \times RRF_1) + (IV_2 \times RRF_2) + \ldots + (IV_n \times RRF_n)$

Changes to Part 2.1.3 - Human health categorisation volumes

We are making the description of 'Method 2' to work out the human health categorisation volume clearer and more useful to introducers.

Current text	Planned text
Method 2 Work out the HHCV by multiplying the introduction volume (IV) by the default exposure reduction factor (ERF) relevant for the intended end use scenario (refer to Table 2). That is, ***Human health categorisation volume (HHCV) = total introduction volume (IV) x exposure reduction factor (ERF)*** Where the industrial chemical will have a *single end use scenario*, the introduction volume you should use to calculate the HHCV is the total volume of the industrial chemical that you will introduce in a registration year. The exposure reduction factor that you should use is the relevant exposure reduction factor for your end use scenario. Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the human health categorisation volume: • Option 1: The simplest approach is to allocate the total introduction volume to the end use scenario that has the highest exposure reduction factor, and use the equation above. • Option 2: If you know the introduction volume to be allocated to each end use scenario, you can calculate a separate human health categorisation volume for each end use scenario (using the introduction volumes allocated to each end use scenario and the relevant exposure reduction factors for each end use scenario), and then add these together to get a total HHCV, using the equation: ***HHCV = (IV_1 x ERF_1) + (IV_2 x ERF_2) + … + (IV_n x ERF_n)***	**Method 2** In this method, the HHCV is determined by multiplying introduction volumes by a default exposure reduction factor (ERF). The way you do this depends on whether you will introduce the industrial chemical for a single end use or multiple end uses. ***Single end use scenario*** Where the industrial chemical will have a *single end use scenario*, the HHCV is calculated by multiplying the total introduction volume (IV) of the industrial chemical that you will introduce in a registration year by the ERF relevant for the intended end use scenario (refer to Table 2). That is, *Human health categorisation volume (HHCV) = total introduction volume (IV) x exposure reduction factor (ERF)* ***Multiple end use scenarios*** Where the industrial chemical will have *multiple end use scenarios*, there are two options to calculate the HHCV: • Option 1: ○ Step 1 – determine the default ERFs (refer to Table 2) that are relevant to each of your end use scenarios ○ Step 2 – of these ERFs, choose the one with the highest value ○ Step 3 - multiply the total introduction volume of the industrial chemical that you will introduce in a registration year by the ERF you chose in step 2. That is,

Current text	Planned text
	Human health categorisation volume (HHCV) = total introduction volume (IV) x exposure reduction factor (ERF) • Option 2: ○ Step 1 – determine the introduction volume of industrial chemical in a registration year for each end use scenario (these introduction volumes should add up to the total introduction volume of the industrial chemical that you will introduce in a registration year) ○ Step 2 – determine the default ERFs (refer to Table 2) that are relevant to each of your end use scenarios ○ Step 3 – multiply the introduction volumes allocated to each end use scenario (from Step 1) by the relevant ERF for each end use scenario (from Step 2), and then add these together to get a total HHCV, using the equation: $HHCV = (IV_1 \times ERF_1) + (IV_2 \times ERF_2) + \ldots + (IV_n \times ERF_n)$

Changes to Part 2.1.6 - Definition of 'persistent'

We are making the definition of 'persistent' consistent with other parts of the Guidelines. Currently, the text in part 2.1.6 specifies that results from OECD test guidelines 301 or 308 are required to demonstrate that a polyhalogenated organic chemical, or its known environmental degradation products, do not meet the definition of 'persistent'.

We will change the text to instead refer to 'an acceptable test guideline for ready biodegradability' or 'an acceptable test guideline for transformation in aquatic sediment systems'. Any future updates to the acceptable test guidelines in Appendix 8.4.2 of the Guidelines would then be catered for, such as the addition of OECD test guideline 310, as we consulted on in last year's consultation.

Parts 3, 4 and 5 changes

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Changes to Part 3 - Repeating definition of 'polymer is stable'

We will place the existing definition of **'Polymer is stable'** into part 3 of the Guidelines. The definition is currently only in part 7, whereas the term appears in both Chapter 2, Part 2 of the Industrial Chemicals (General) Rules 2019 (the Rules) and in Schedule 2 to the Rules, i.e. the sections of the Rules to which parts 3 and 7 of the Categorisation Guidelines refer. The definition text will be repeated, but not changed.

Change to Part 4.2.2 to clarify persistent, bioaccumulative and toxic (PBT) criteria considerations

To clarify the information that is already required to be considered, we will change the fourth dot point by adding text shown in bold:
PBT (persistence, bioaccumulation and toxicity) criteria **(each of persistence, bioaccumulation and toxicity must be considered)**.

Change to Part 5.1 - Potential for industrial chemical to migrate to food - NOAEL criteria

We will change the last dot point so that specific OECD Test Guidelines are not mentioned. Instead, part 5.1 will generally state that an acceptable test guideline for subacute oral toxicity or subchronic oral toxicity is required. Introducers would then look either in Appendix 8.4.1 of the Guidelines to find what these tests are or our online categorisation guide.

Any future updates to the acceptable test guidelines in Appendix 8.4.2 of the Guidelines would then be catered for.

Change to Part 5.3 - Toxicokinetics information

We will delete the text in brackets, '(the full study report or the outcomes of the study and a written undertaking that the full study report will be provided to the Executive Director if requested)'. This text was present in error.

Part 6 changes

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Changes to Part 6.1 - Definition of 'suitable in silico prediction'

We will change the last dot point of the definition of 'suitable in silico prediction' to more clearly reflect chemicals being introduced as solid particles. Proposed changes are shown in bold and strikethrough text below:

- the industrial chemical is not any of the following types of chemicals:
    - UVCB substance
    - polymer
    - surfactant
    - inorganic chemical
    - organometallic chemical
    - a chemical that is:
        - a solid or in a dispersion, **at the time of introduction**; and
        - consists of **solid** particles in an unbound state or as an aggregate or agglomerate, **where** at least 50% (by number size distribution) of **the particles** ~~which~~ have at least one external dimension in the nanoscale, and
        - is not soluble

Changes to Part 6.9 - Respiratory sensitisation, 6.10 - Corrosive to the respiratory tract, 6.11 - Specific target organ toxicity after a single exposure (significant toxicity)

We will change the wording in parts 6.9.2, 6.10.2 and 6.11.2 to make it clear that the 'information that demonstrates that the chemical has this hazard characteristic' is detailed in the relevant preceding part (that is, in parts 6.9.1, 6.10.1 and 6.11.1, respectively). For clarity, we'll also add a footnote to part 6.9.2. Changes are shown in **bold text**.

Changes to Part 6.9.2

> For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules there are no information requirements to demonstrate the absence of the hazard characteristic, respiratory sensitisation. If you do not have any **of the** information **detailed in part 6.9.1**[1] that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.
>
> **[1]The information can include that the chemical is an enzyme or a polymer that contains one or more free isocyanate groups.**

Changes to Part 6.10.2

> For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules there are no information requirements to demonstrate the absence of the hazard characteristic, corrosive to the respiratory tract. If you do not have any **of the** information **detailed in part 6.10.1** that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Changes to Part 6.11.2

> For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules there are no information requirements to demonstrate the absence of the hazard characteristic, specific target organ toxicity after a single exposure (significant toxicity). If you do not have any **of the** information **detailed in part 6.11.1** that demonstrates that the chemical has this hazard characteristic, then you can assume it does not for the purposes of categorisation.

Changes to Part 6.26 - Persistent, bioaccumulative and toxic

We will change the wording for one of the options in part 6.26.2 to:

- clarify the information required and
  add an additional footnote to make it clearer that a combination of acute and chronic aquatic toxicity endpoints can be used. This applies to chemicals that are not biocidal actives and not persistent, highly branched organic chemicals.

The changes to this part are shown in **bold text** below (changes relate to main dot point 14):

> - if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[1] – information on aquatic toxicity for all three trophic levels (fish, invertebrates, and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with **at least one** of the following results for ~~all~~ **each of the** three trophic levels[2]:
>   - acute aquatic toxicity > 1 mg/L (96 h LC50 (fish), or 48 h EC50 (invertebrates) or 72 or 96 h ErC50 (algae)), or
>   - chronic aquatic toxicity NOEC or EC10 > 0.1 mg/L (for chemicals that are not readily biodegradable), or
>   - **chronic aquatic toxicity NOEC or EC_{10} > 0.01 mg/L (for chemicals that are readily biodegradable), or .....**
>
> Footnotes
> [1]If the chemical is a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the toxicity aspect of the persistent, bioaccumulative and toxic hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable.
>
> **[2] A combination of the following acute and chronic aquatic toxicity endpoints can be used.**

Changes to 6.27 - very toxic to any aquatic life

In Part 6.27.1 we are correcting one instance of the error - *'very toxic to aquatic life'* to instead say *'very toxic to **any** aquatic life'* in the second main dot point.

In part 6.27.2 we are changing the wording and adding an additional footnote (footnote 2) to make it clearer that a combination of acute and chronic aquatic toxicity endpoints can be used. This applies to chemicals that are **not** biocidal actives and **not** persistent, highly branched organic chemicals. The changes to this part are shown in **bold text** below:

- if the chemical is not a biocidal active and not a persistent, highly branched organic chemical[1] – information on aquatic toxicity for all three trophic levels (fish, invertebrates, and algae), from suitable in silico predictions on the chemical or in vivo studies on the chemical or from suitable read-across information conducted following acceptable test guidelines for aquatic toxicity, with at least one of the following results for ~~all~~ **each of the** three trophic levels[2]:
    - acute aquatic toxicity >1 mg/L (LC50 (fish), or EC50 (invertebrates) or ErC50 (algae)), or
    - chronic aquatic toxicity NOEC or EC10 > 0.1 mg/L (for chemicals that are not readily biodegradable), or
    - chronic aquatic toxicity NOEC or EC10 > 0.01 mg/L (for chemicals that are readily biodegradable), or

Footnotes

[1]If the chemical *is* a biocidal active or a persistent, highly branched organic chemical, in silico predictions cannot be used to demonstrate that the chemical does not have the very toxic to any aquatic life hazard characteristic – only in vivo chronic aquatic toxicity studies, as described in the next dot point, are acceptable.

[2] A combination of the following acute and chronic aquatic toxicity endpoints can be used.

Other footnotes to be added to Part 6

We will add 2 footnote types 'A' and 'B' to the information required to demonstrate the absence of a number of hazard characteristics to make it clearer which options are currently available for introductions in human health exposure band 3 only, versus those available for introductions in human health exposure bands 3 or 4.

New footnotes
Footnote A - This option is available for introductions in human health exposure bands 3 or 4.
Footnote B - This option is only available for introductions in human health exposure band 3.

These footnotes will be added to:

- 6.12.2 – skin corrosion
- 6.13.2 – eye damage – also includes a minor clarification of text (shown below)
- 6.14.2 – skin sensitisation
- 6.15.2 – acute toxicity (fatal or toxic)
- 6.20.2 – skin irritation
- 6.21.2 – eye irritation
- 6.22.2 **–** acute toxicity (harmful)

The following example shows the footnotes we propose to add to *Part 6.13.2 – Eye damage – information required to demonstrate the absence of hazard characteristics* with changes in **bold text**. There is also a minor text addition **('category 1')** in the last dot point.

For the purposes of subparagraph 30(2)(c)(iv) of the IC General Rules, the information required to demonstrate that a chemical does not have the hazard characteristic, eye damage, is at least one of the following:

- information[A] that demonstrates that the chemical is a high molecular weight polymer that does not contain any of the following reactive functional groups:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- • information[A] that demonstrates that the chemical is a high molecular weight polymer that contains any of the following reactive functional groups with a combined functional group equivalent weight of ≥1,000 g/mol:
    - anhydride, or
    - epoxide, or
    - sulfonic acid, or
    - amine, or
- if the human health exposure band for the introduction is 3[B] - a suitable in silico prediction indicating that the chemical is not irritating to the eye, or
- test results[A] from an in vitro study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye damage, which predicts the chemical would not induce serious eye damage
- test results[A] from an in vivo study on the chemical or from suitable read across information, conducted following an acceptable test guideline for eye irritation, which does not result in effects on the eye, as described for eye damage **(category 1)** in chapter 3.3 of the GHS.

Footnotes
A - This option is available for introductions in human health exposure bands 3 or 4
B - This option is only available for introductions in human health exposure band 3

Part 8 changes

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Change to Part 8.2 - title change to 'In silico predictions'

We will change the title from ‘8.2 In silico information’ to ‘8.2 In silico predictions’. This will also be reflected in the list of appendices mentioned at the end of part 1.

Changes to Part 8.4.1 - Acceptable test guidelines for human health hazard characteristics

We are making several editorial changes, including:

- Removing the word ‘draft’ from in front of OECD test guideline 433.
- Correcting errors in footnote numbering.
- Formatting changes.

Changes to Part 8.4.2 - Acceptable test guidelines for environment hazard characteristics and properties

The following changes will be made:

- Add the equivalent test guideline OPPTS 835.3140 for OECD TG 310.
- Add the equivalent test guidelines OPP 162-3 and OPP 162-4 for OECD TG 308.

Other changes

We will make other changes that are editorial in nature, for example:

- Minor consistency changes, such as replacing the words ‘greater than or equal to’ with the symbol ‘≥’
- Updating incorrect footnote numbers/links
- Updating website URLs, if required

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Note: If you opt to provide a file submission, you will receive instructions.

Email address (required)

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Your privacy is important - see our Privacy Policy.

What proposals do you want to provide feedback on?

- [ ] List of chemicals with high hazards for categorisation
- [ ] I have other comments

List of chemicals with high hazards for categorisation

- ( ) I agree with this proposal
- ( ) I do not agree with this proposal
- ( ) I partially agree with this proposal
- ( ) I want to provide my feedback by uploading a file (for example , PDF or Word document)

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