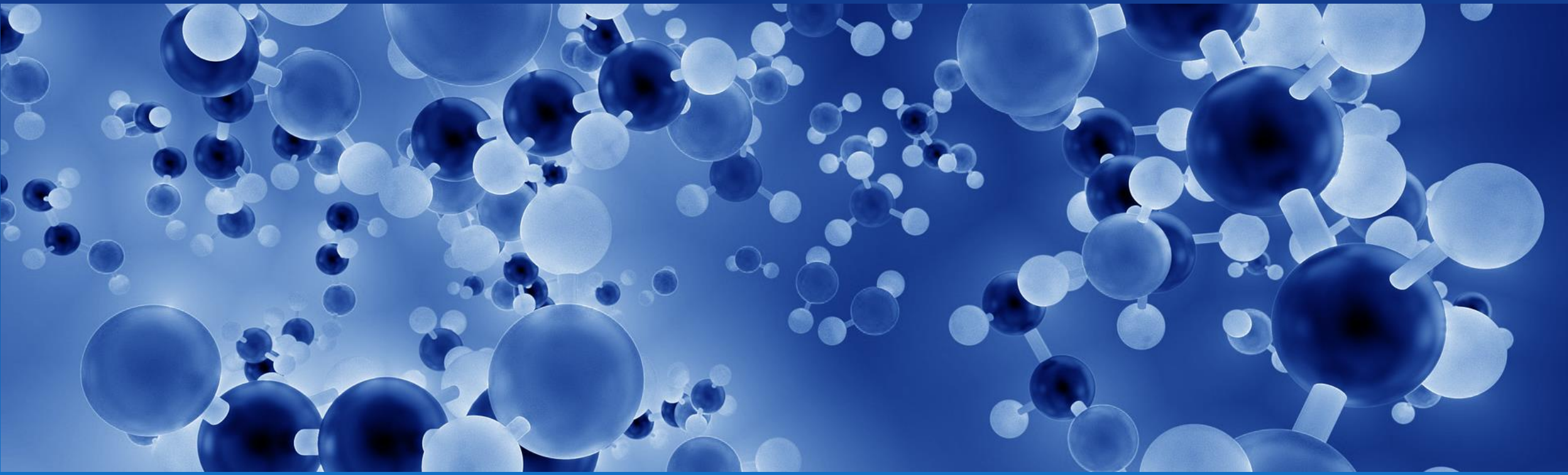
Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme



Step-by-Step Categorisation

Steps 4 - 6

April 2020

Introduction categories

If your chemical introduction is not listed on the Inventory

Listed

- The chemical is on the Inventory
- Can be introduced if it's within the terms of the Inventory listing
- Keep records

Exempted

- It's a very low-risk introduction
- Submit a once-off declaration **after** you introduce
- Keep records

Reported

- It's a low-risk introduction
- Submit a once-off report **before** you introduce
- Keep records

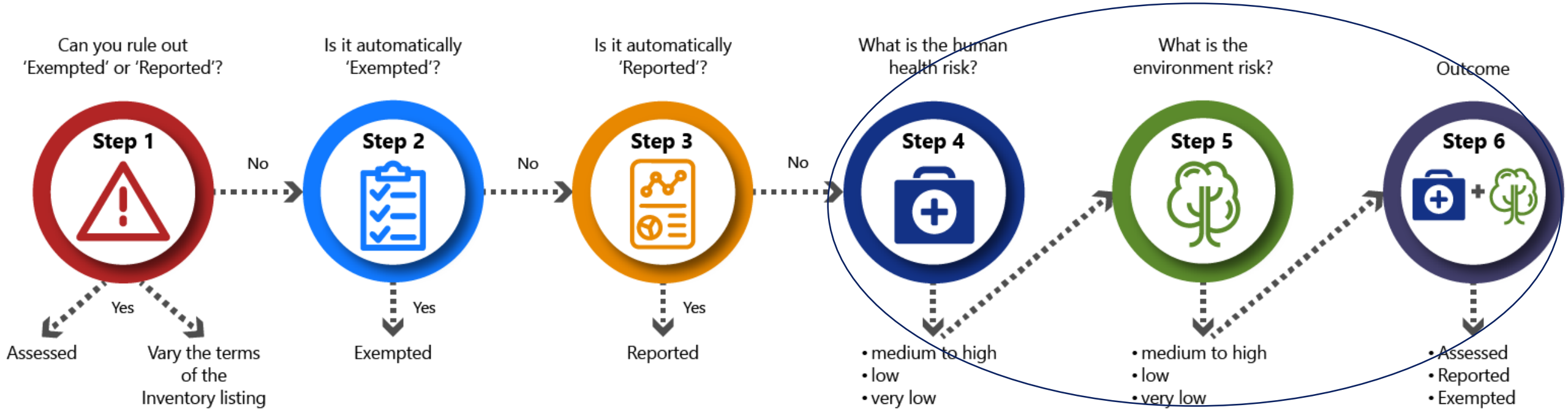
Assessed

- It's a medium- to high-risk introduction
- Apply for an assessment
- Assessment certificate needed **before** you introduce
- Keep records

Commercial Evaluation Authorisation

- Determine the chemical's commercial potential
- Apply for an authorisation
- Commercial Evaluation Authorisation needed **before** you introduce
- Keep records

Work out your introduction category



Outcome = your introduction category

- Exempted OR
- Reported OR
- Assessed

Categorisation

Step 4 – Indicative human health risk

01

Step 4

What is the indicative human health risk? Rules s28

- Step 4.1 - Is it medium to high?
  - Chemicals with sequence of 4 to 20 fully fluorinated carbon atoms
  - Persistent polyhalogenated organic chemicals >100kg/year
  - Certain chemicals at the nanoscale
- Step 4.2 - Is it low?
  - Internationally assessed for human health and other criteria met

Step 4 – What is the indicative human health risk?

- Step 4.3
  Human health exposure band? Rules schedule 1, part 1
- Step 4.4
  Human health hazard characteristics?
  Rules schedule 1, part 1
- Step 4.5
  Indicative human health risk?
  Rules s28

Special cases (at least low risk)

UV filters
Certain chemicals at the nanoscale (incidental to the non-nanoscale)

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Step 4.3 Human health exposure bands

1

- <0.1% at intro and all end uses, and no consumer end uses

2

- HHCV ≤25kg
- <0.1% at intro and all end uses, and includes a consumer end use

3

- HHCV >25kg and ≤100kg
- ≤1% at intro and end use

4

- HHCV >100kg
- End use in tattoo inks or personal vaporisers

HHCV = human health categorisation volume

Step 4.3 Human health categorisation volume (HHCV)

- Methods to calculate HHCV (see Categorisation Guidelines)
  - Method 1: $HHCV = IV$
  - Method 2: $HHCV = IV \times ERF$

where IV = total annual introduction volume

ERF = relevant exposure reduction factor for your end use scenario

Step 4.3 Human health categorisation volume (HHCV)

Exposure reduction factors (ERFs)

End use scenario	ERF
Imported then exported for end use overseas	0
Imported, some handling in Australia, then exported for end use overseas	0.05
Manufactured in Australia, then exported for end use overseas	0.05
Cosmetics and other specified consumer products	1
Others	0.1

Step 4.3 Human health categorisation volume (HHCV)

Method 2: Single end use scenario

$$HHCV = IV \times ERF$$

where

IV = total annual introduction volume

ERF = relevant exposure reduction factor for your end use scenario

Step 4.3 Human health categorisation volume (HHCV)

Method 2: Multiple end use scenarios – Option 1

$$HHCV = IV \times ERF$$

where

IV = total annual introduction volume

ERF = highest exposure reduction factor from all relevant end use scenarios

Step 4.3 Human health categorisation volume (HHCV)

Method 2: Multiple end use scenarios – Option 2

$$HHCV = (IV_1 \times ERF_1) + (IV_2 \times ERF_2) + \ldots\ldots + (IV_n \times ERF_n)$$

where

IV_n = annual introduction volume for end use scenario *n*

ERF_n = exposure reduction factor for end use scenario *n*

Step 4.4 Human health hazard bands

A	B	C

•HMW polymer that has lung overloading potential
•Aspiration hazard
•Acute toxicity (harmful)
•Specific target organ toxicity after a single exposure (harmful or transient effects)
•Skin/eye irritation
	• HMW polymer that is water absorbing
	• Acute toxicity (fatal or toxic)
	• Specific target organ toxicity:
	  • after a single exposure (significant toxicity)
	  • after repeated exposure
	• Skin/respiratory corrosion
	• Eye damage
	• Skin/respiratory sensitisation
		• Carcinogenicity
		• Reproductive toxicity
		• Developmental toxicity
		• Adverse effects mediated by an endocrine mode of action
		• Genetic toxicity

Step 4.4 Human health hazard characteristics

- Details in Categorisation Guidelines
- Exposure band dependent:
  - hazards that must be considered
  - type of acceptable information
- More information needed to get to lower indicative risk
- Read across information
- In silico, in chemico, in vitro, in vivo options
- Waivers available

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Step 4.4 Human health hazard characteristics

- Go to your exposure band
- Start at Hazard Band C then work down
- If you determine that your chemical has a hazard, STOP there

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Step 4.4 Human health hazard characteristics

- Does your chemical meet the hazard characteristic definition?
  - Yes = STOP
  - No = Continue
- Can you demonstrate that your chemical does not have the hazard characteristic? See Guidelines for options
  - Yes = Continue
  - No = STOP

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Step 4.4 Human health hazard characteristics

Demonstrating that a chemical does not have certain hazards

- Hazard Band C hazards
  - In most cases, can just check the **List of chemicals with high hazards for categorisation***

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

* Available on website

Step 4.5 Indicative human health risk

- What hazards does your chemical have?
- What hazards could you rule out?
- Where does this place you?
  - What's your indicative human health risk?
    - Very low
    - Low
    - Medium to high

		Human health exposure band			
		1	2	3	4
Human health hazard band	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	Low risk	Low risk
	Not A, B, or C	Very low risk	Very low risk	Very low risk	Very low risk

Categorisation

Step 5 – Indicative environment risk

02

Step 5

What is the indicative environment risk? Rules s29

- Step 5.1 - Is it medium to high?
  - Chemicals with a sequence of 4 to 20 fully fluorinated carbon atoms
  - Persistent polyhalogenated organic chemicals >100kg/year
  - Certain chemicals at the nanoscale
  - Persistent gases > 100kg/year
  - Organotin chemicals > 10kg/year
- Step 5.2 - Is it low?
  - Internationally assessed for environment and other criteria met

Step 5 – What is the indicative environment risk?

Step 5.3
Environment exposure band? Rules schedule 1, part 2

Step 5.4
Environment hazard characteristics?
Rules schedule 1, part 2

Step 5.5 - Indicative environment risk?
Rules s29

Special cases (at least low risk)

Organotin chemicals
Polyhalogenated organic chemicals
Biocidal actives
Certain chemicals at the nanoscale (incidental to the non-nanoscale)

Environment hazard band	Environment exposure band 1	2	3	4
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

Step 5.3 Environment exposure bands

1	2	3	4
ECV ≤ 25kg	ECV >25kg and ≤1,000kg	ECV >1,000kg and ≤10,000kg	▪ Designated kind of release ▪ ECV >10,000kg

ECV = environment categorisation volume

Step 5.3 Environment exposure bands

- Designated kind of release into the environment includes:
  - Intentional release during use to:
    - land, biota, natural waterways or municipal water supplies
    - air (other than solely domestic or personal use)
  - Release (intentional and unintentional) into the environment when introduced for an end use:
    - in fire-fighting
    - offshore (into ocean)

Step 5.3 Environment categorisation volume (ECV)

- Methods to calculate ECV (see Categorisation Guidelines)
  - Method 1: $ECV = IV$
  - Method 2: $ECV = IV \times RRF$

where IV = total annual introduction volume

RRF = relevant release reduction factor for your end use scenario

Step 5.3 Environment categorisation volume (ECV)

Release reduction factors (RRFs)

End use scenario (examples)	RRF
Adhesive and sealant products	0.05
Personal care products (limited environmental release)	0.05
Paint and coating products	0.05
Plastic and polymer products	0.05
Ink, toner and colourant products	0.8
Other personal care products	1
Cleaning and furniture care products	1
Automotive care products	1

See Categorisation Guidelines for full list

Step 5.3 Environment categorisation volume (ECV)

Method 2: Single end use scenario

$$ECV = IV \times RRF$$

where

IV = total annual introduction volume

RRF = relevant release reduction factor for your end use scenario

Step 5.3 Environment categorisation volume (ECV)

Method 2: Multiple end use scenarios – Option 1

$$ECV = IV \times RRF$$

where

IV = total annual introduction volume

RRF = highest release reduction factor from all relevant end use scenarios

Step 5.3 Environment categorisation volume (ECV)

Method 2: Multiple end use scenarios – Option 2

$$ECV = (IV_1 \times RRF_1) + (IV_2 \times RRF_2) + \ldots\ldots + (IV_n \times RRF_n)$$

where

IV_n = annual introduction volume for end use scenario *n*

RRF_n = release reduction factor for end use scenario *n*

Step 5.4 - Environment hazard bands

A	B	C	D
• Contains aluminium, chromium, copper, nickel, selenium, silver or zinc • Polymers that do not have a low cationic density • Polymers that are not stable • Bioaccumulation potential • Industrial chemicals (other than polymers) that do not meet the criteria for ready biodegradability • Harmful to any aquatic life	• Toxic to any aquatic life	• Very toxic to any aquatic life • Persistent and bioaccumulative	• Contains arsenic, cadmium, lead or mercury • Ozone depleting chemicals • Synthetic greenhouse gas • Adverse effects mediated by an endocrine mode of action • Persistent, bioaccumulative and toxic

Step 5.4 Environment hazard characteristics

- Details in Categorisation Guidelines
- Exposure band dependent:
  - hazards that must be considered
  - type of acceptable information
- More information needed to get to lower indicative risk
- Read across information
- In silico, in vitro, in vivo options
- Waivers available

		Environment exposure band			
		1	2	3	4
Environment hazard band	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

Step 5.4 Environment hazard characteristics

- Go to your exposure band
- Start at Hazard Band D then work down
- If you determine that your chemical has a hazard, STOP there

Environment hazard band	Environment exposure band 1	2	3	4
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

Step 5.4 Environment hazard characteristics

- Does your chemical meet the hazard characteristic definition?
  - Yes = STOP
  - No = Continue
- Can you demonstrate that your chemical does not have the hazard characteristic? See Guidelines for options
  - Yes = Continue
  - No = STOP

		Environment exposure band			
		1	2	3	4
Environment hazard band	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

Step 5.5 Indicative environment risk

- What hazards does your chemical have?
- What hazards could you rule out?
- Where does this place you?
  - What is your indicative environment risk?
    - Very low
    - Low
    - Medium to high

Environment hazard band	Environment exposure band 1	2	3	4
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

Categorisation

Step 6 – Introduction category

03

Step 6

What is the highest indicative risk for your introduction?

- Use results from Step 4 (human health) and Step 5 (environment)

Indicative environment risk	Indicative human health risk: Very low	Low	Medium to high
Very low	Exempted	Reported	Assessed
Low	Reported	Reported	Assessed
Medium to high	Assessed	Assessed	Assessed

What is your introduction category?

Exempted

Reported

Assessed

Thank you!