



Australian Government

Department of Health

Australian Industrial Chemicals  
Introduction Scheme

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# Reporting and record keeping



May 2020



# Agenda

## ■ Reporting

- Information you need to give us as part of your introduction

## ■ Record keeping

- Records you need to keep and provide us if we ask for them





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# Reporting

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What you need to submit to us

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# What you need to submit to us for:

## Exempted introductions



**Exempted**

- May need to make a once-off declaration called a 'post-introduction declaration'
- Only required the first time you introduce the chemical
- Due by 30 November for the previous registration year you first introduced
- No fee to submit post-introduction declaration



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# What you need to submit to us for:

## Exempted introductions



**Exempted**

Post introduction declaration is only required for exempted introduction where:

- Highest indicative risk is 'very low risk'
- Polymers of low concern
- Low concern biological polymers



## Submit - Prescribed information

### Polymers of low concern and Low concern biological polymers

- The number of different polymers introduced

### Highest indicative risk is 'very low risk'

- Proper name
- CAS number (if assigned)
- Total volume of the industrial chemical introduced in the registration year
- End use
- Max concentration of the chemical at end use
- Circumstances of animal test data use



## Submit — Prescribed information

Highest indicative risk is 'very low risk' and you don't know the proper name and chemical

If chemical introduction equal or less than 10kg

- Names by which you know the chemical (e.g. trade name)
- Name of the chemical identity holder (e.g. your supplier)

If chemical introduction during the year was greater than 10kg

- Names by which you know the chemical
- Name of the chemical identity holder who has provided the
  - proper name of the chemical
  - CAS number (if assigned)



# What you need to submit to us for:

## Reported introductions



- A pre-introduction report
- The report must:
  - contain information prescribed by the rules — see sections 36 to 43
  - be submitted online before the industrial chemical is first introduced.





# What you need to submit to us for:

## Reported introductions types



- Internationally assessed for:
  - 1. Both human health and environment (s38 Rules)
  - 2. Human health only (s39 Rules)
  - 3. Environment only (s40 Rules)
- 4. Solely for use in research and development (s41 Rules)
- 5. Low risk flavour or fragrance blend (s42 Rules)
- 6. Highest indicative risk is low risk (s43 Rules)



# What you need to submit to us for:

## Reported introductions



- You can introduce the chemical immediately after you submit a pre-introduction report
- If any circumstances of your introduction change you must vary your pre-introduction report
- No fee to submit or vary a pre-introduction report
- What if you don't know the proper chemical name?
  - you tell us the name you know the chemical by
  - then you nominate a chemical identity holder who will provide it to us before you can submit



## What you need to submit to us for:

### \*Low risk flavour or fragrance blend introductions



- One pre-introduction report can be for multiple chemicals in the blend.
- If the chemical is not on IFRA Transparency list at time of submission
  - you must also provide the information required under s27(5) of the rules before you first introduce the chemical for it to be an authorised reported introduction



## What you need to submit to us for:

**\*Low risk flavour or fragrance blend introductions**

**Information required under s27(5) of the rules:**



- Chemical's proper name (including the CAS name or IUPAC name)
- Chemical's CAS number (if assigned)
- Any hazard characteristics of the chemical that you know
- The maximum concentration of the chemical in the flavour or fragrance blend at introduction and end use



# Annual declaration

## Required for all introduction categories



Listed



Exempted



Reported



Assessed

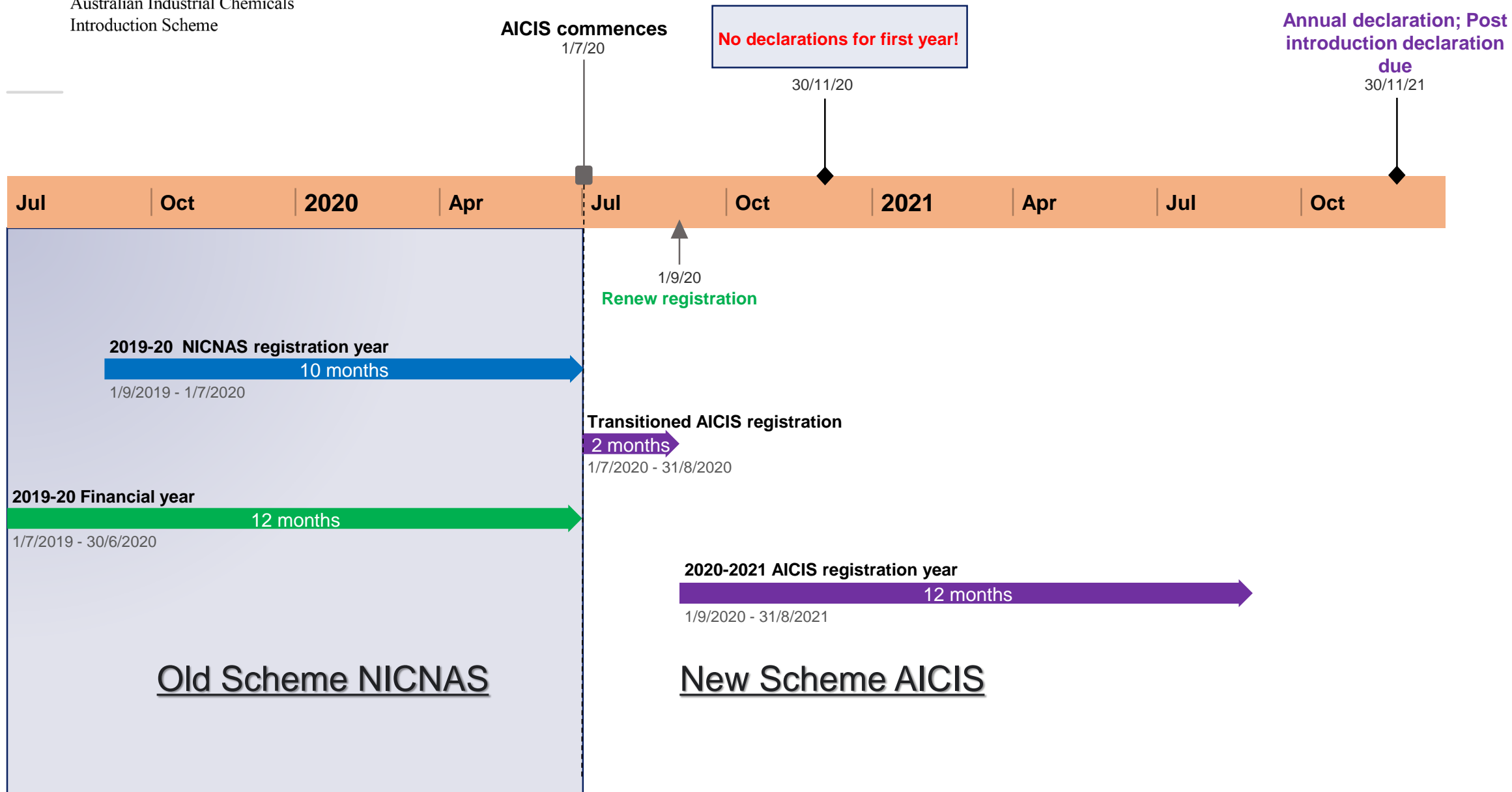


Commercial

- All introducers must make declaration by 30 November
- Applies to all introduction categories
- Declare all introductions were authorised by one of the sections 25 to 30 under the Act
- No chemical specific information is required to be submitted.

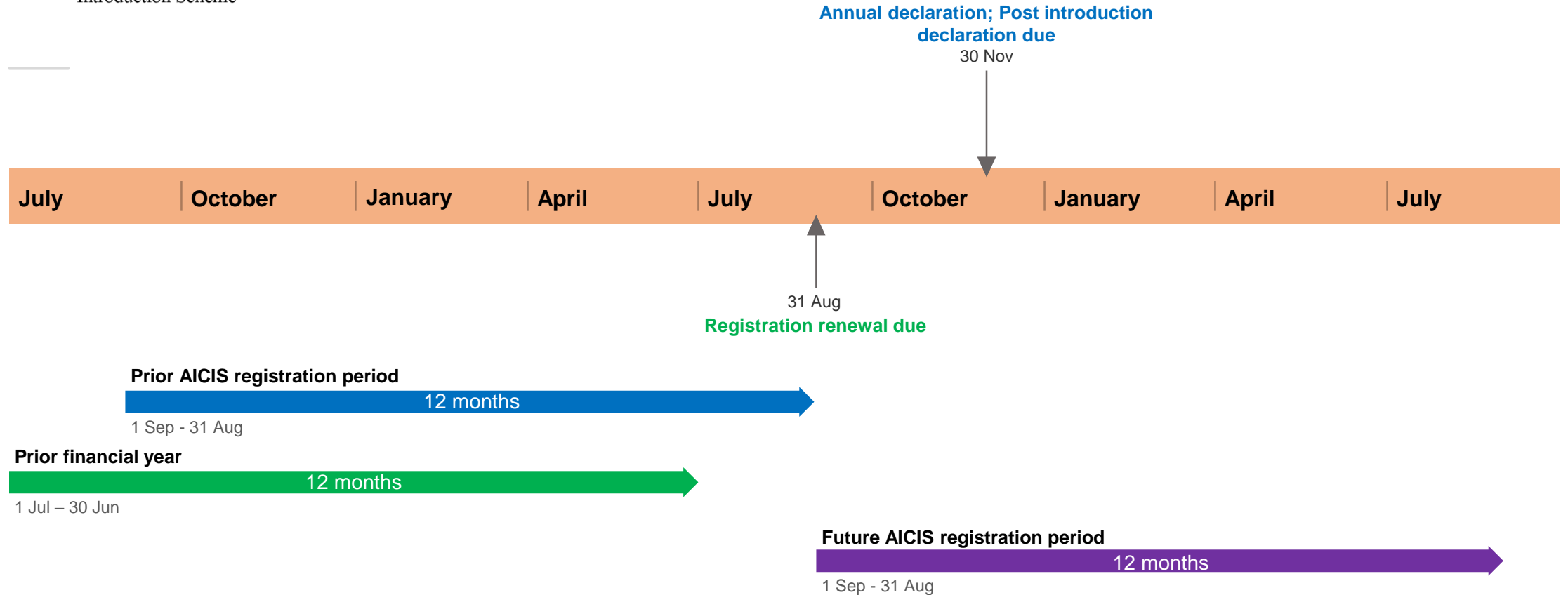


# First year of AICIS





# Future years of AICIS





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# Record keeping

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What records you need to keep

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# Record keeping

## Records that demonstrate:

- You know the details about your introductions
- You have correctly categorised your introduction





# Record keeping

## General requirements for all introduction categories

- Information necessary to demonstrate:
  - what industrial chemicals you introduced during the year
  - introduction categories
  - how you determined categorisation
  - how registration was determined
- Information that is of a kind prescribed by the Rules
- You must keep records for 5 years starting immediately after the end of the registration year



## Record keeping

### Listed introductions

If you know the CAS number:



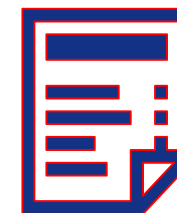
CAS number and CAS  
name

Or



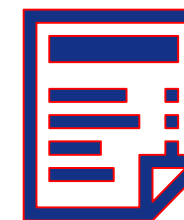
CAS number and INCI  
name

If you don't know the CAS number:

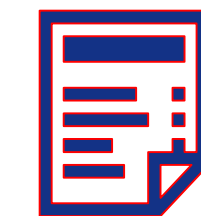


The name by which you  
know the chemical

And



Written undertaking from  
the chemical identity holder



CAS Name

Or



# Record keeping

## Listed introductions cont.

If there...

You must keep records that demonstrate...

is a defined scope of assessment

that you are introducing or using the industrial chemical in accordance with that defined scope

are any conditions relating to the introduction or use of the chemical

that you are complying with the conditions

are any specific requirements to provide information to AICIS in relation to the introduction of the industrial chemical

that you are meeting these requirements



# Record keeping

## Reported introductions

- Additional to information you provide in your pre-introduction report
- Generally, documentation to support the information you provided in your pre-introduction report
- We'll accept written undertakings you have received from a chemical identity holder (e.g chemical supplier) that confirm:
  - applicable categorisation criteria have been met
  - all relevant information will be given to AICIS if requested



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# Reported – where highest indicative risk is low risk

## S57 of the rules – Records to demonstrate:

### 1. Chemical ID

- Chemical name
- The names of products containing your chemical
- Extra records if the chemical is a high molecular weight polymer and human health exposure band is 4

### 2. Not medium to high risk

- Not listed on Rotterdam, Stockholm, or the Inventory with conditions
- Not fully fluorinated
- Not polyhalogenated if >100 kg/registration year.
- Not at the nanoscale
- Not a persistent gas if introduced at >100kg/ registration year.
- Not an organotin if introduced at >10kg/ registration year

### 3. Use and exposure

- End use
- Concentration if a concentration limit applies to the exposure band
- Human health categorisation volume if a HHCV limit applies to the exposure band
- Environment categorisation volume if an ECV limit applies to the exposure band
- Which designated kind of release to the environment if the chemical involves a designated kind of release to the environment.

### 4. Hazard characteristics

- Hazard classification
- The absence of hazard characteristics that would result in the highest indicative risk for your introduction to be medium to high risk.

### 5. Specified classes of introduction

- Additional records required if your chemical is one is the specified classes:
- Involves a designated kind of release to the environment
- Is a biochemical
- Is a GM product
- Is a UV filter
- For an end use in an article with food contact
- For an end use in an article that is a children's toy or children's care product



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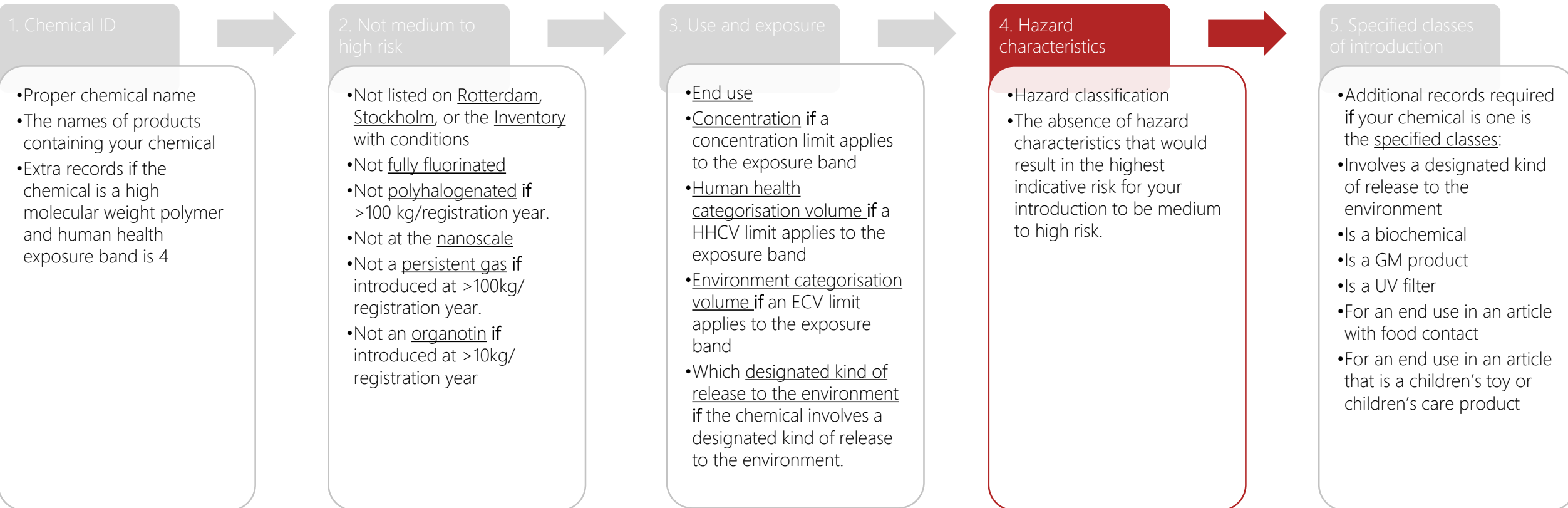
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# Record keeping

## What information we can ask for

- We can ask you for any information introducers are required to keep
- You must give it to us within 20 working days





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**Thank you!**