Transition from NICNAS to AICIS

Have you been introducing (importing or manufacturing) a chemical under NICNAS transitional provisions?

Background

At the commencement of AICIS on 1 July 2020, a period of transition commenced, providing time for introducers to ensure their compliance under the Industrial Chemicals Act 2019 and related legislation.

The final day of the transition period is **31 August 2022**. Stakeholders were supported to transition to AICIS through video tutorials and guidance materials published on the AICIS website since 2020. The June 2022 edition of the Industrial Chemicals Regulatory News also highlighted the end of the transition period.

Recent advice indicates that a significant number of introducers have been unable to make the necessary arrangements with their chemical suppliers to meet the categorisation and record keeping requirements under AICIS, in a time of disruption caused by the COVID-19 pandemic.

Ceasing of introduction of these chemicals to avoid non-compliance after 31 August 2022, could jeopardise a range of supply chains critical to Australian economic activity.

From 1 September 2022

To address these issues, a 3 stage response will apply:

1. Listed introductions - administrative arrangement extended

> If you introduced an Inventory-listed chemical under NICNAS and don't know the chemical identity – the administrative arrangement that commenced on 8 December 2021 will continue to apply until **30 November 2023**.

If you are importing or manufacturing (introducing) a chemical that is listed on the AICIS Inventory, and you are introducing it within the terms of the listing, it's called a listed introduction. The Inventory listing for your chemical could include a defined scope of assessment, conditions of introduction or use or specific information requirements. Our record-keeping page has information on the records you need to keep.

If you don't know the identity of the chemical you are introducing, then your chemical supplier (or the person who has this information) will need to provide you with a written undertaking. Organising a written undertaking from your chemical supplier may take you time. Until **30 November 2023**, we will continue to accept:

- the written confirmation from your supplier (or whoever holds the identity of your chemical) that you would have had under NICNAS to confirm that the chemical was listed on the NICNAS Inventory and
- copies of correspondence to show that you have requested a written undertaking be provided for your chemical introduction to meet your AICIS record-keeping obligations.

2. Low volume introductions of chemicals – changes to the Rules will be proposed

> In the coming weeks we will consult on proposed changes to the Industrial Chemicals (General) Rules 2019 (the Rules) for introductions of chemicals at less than or equal to 10 kg in a registration year.

The changes are expected to provide a benefit for introducers of chemicals at low volumes (in the shortest possible timeframe).

Exclusions will apply to maintain continued protections for human health and the environment from the introduction and use of industrial chemicals in Australia.

3. Other changes - chemicals previously introduced under the NICNAS exemptions

error

The transition period for chemicals introduced under the NICNAS exemptions will end 31 August 2022, as scheduled. This period is not being extended.

For these introductions, we'll:

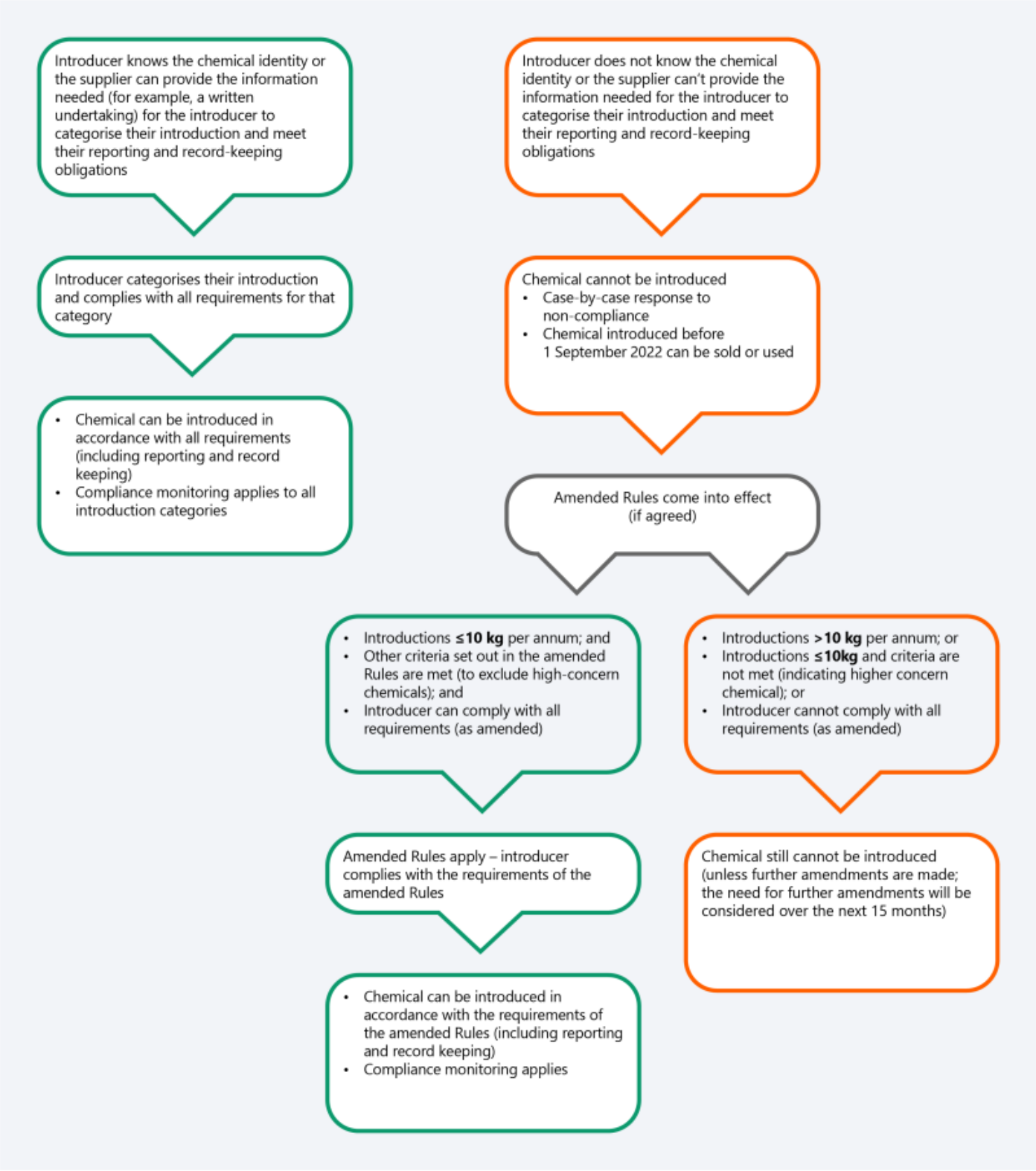
- explore options to the relevant issues raised by stakeholders that are related to the categorisation, reporting and record keeping requirements of these introductions under AICIS.
- consult with stakeholders (including industry and community) on the issues and possible solutions.

To be clear, the exploration process will be limited in scope and is not a review of AICIS itself.

In the meantime, all introductions of industrial chemicals must be authorised. You must categorise your introduction as listed, exempted, reported or assessed by following our categorisation guide.

You must meet all obligations associated with the introduction category for your introductions after 31 August 2022 to be authorised.

Pathways available to introducers from 1 September 2022



Download this image as a PDF

Pathways available to introducers from 1 September 2022 [PDF 307KB]

Frequently asked questions about transitional arrangements and NICNAS exemptions

Q. What do I do if my supplier won't give me the identity of my chemical or provide a written undertaking so I can categorise my introduction?

A. If you cannot categorise your chemical introduction and meet the obligations associated with the introduction category, then you cannot introduce your chemical after 31 August 2022. You may need to source the chemical from a different supplier who will give you the information you need to meet your obligations.

Q. If I can't categorise my introduction and can no longer import the chemical, can I still use or sell existing stock that is located in Australia?

A. Yes. If the introduction of the chemical prior to 31 August 2022 was authorised because you met the NICNAS exemption criteria, then you can use or sell the stock that was introduced under that exemption. You must keep records about your introduction.

Presentation: Transitioning to AICIS introductions

Learn how to work out which AICIS category applies to chemicals that are being introduced under one of these NICNAS exemption provisions (which expires on 31 August 2022):

- non-cosmetic use (100 kg or less; no unreasonable risk)
- cosmetic use (100 kg or less; no unreasonable risk)
- cosmetic use (1% or less; non-hazardous chemical)

Transition to AICIS introductions

Read the transcript

Slide 1
Hello everyone. Today I'll be talking to you about how to transition your introductions under NICNAS exemptions, i.e. introductions under the previous industrial chemicals scheme, to the AICIS introduction categories.

Slide 2
This presentation is targeted at those introducing under the NICNAS:
- non-cosmetic use, ≤100 kg, no unreasonable risk exemptions
- cosmetic use, ≤100 kg, no unreasonable risk exemptions and
- cosmetic use, ≤1%, non-hazardous chemical exemptions.

Under the transitional arrangements, introductions in accordance with these NICNAS exemption provisions are authorised until the 31st of August 2022. After this date, the introductions will need to be in accordance with the AICIS categories.

It is important to note that there is no new information in this presentation. Rather, by pulling together content that is already available on our website and providing specific examples, I'm hoping that it will make the categorisation process as simple as possible for those introducers. So, on relevant slides of this presentation you will see links to particular pages on our website and screenshots of web content. If you need more information on a particular aspect of the presentation, please look at our website.

For the purposes of this presentation, it is assumed that the chemicals that are being introduced under the exemption provisions are not listed on our Inventory. In addition, while introductions in accordance with R&D NICNAS exemption provisions are also authorised under the transition arrangements, their categorisation

under AICIS will not be specifically covered here today, as there are already resources available on our website to help you with this.

Slide 3
Firstly, I will provide a brief introduction to AICIS, the Australian Industrial Chemicals Introduction Scheme. I'll then provide some general information on:

- assessed introductions
- the 6-step categorisation process, and
- information you need to categorise

The remainder of the presentation will be spent working through some specific examples. In particular:

- I'll work through the 6-step categorisation process for an example chemical that is introduced at up to 100 kg/year. In this instance it will be categorised as a reported introduction and we'll go step-by-step through the process of submitting a pre-introduction report and the records that they needed to keep for their introduction.
- I'll then talk about how the categorisation process would have differed if the same chemical had been introduced at up to 1% concentration or up to 25 kg in a registration year.
- I'll then work through the 6-step categorisation process for an example chemical that is introduced at up to 10 kg/year. In this instance it will be categorised as an exempted introduction and we'll go step-by-step through the process of submitting a post-introduction declaration and the records that they needed to keep for their introduction.

So stick with me. It's quite a long presentation, but I think if you can stick with it until then end, then the categorisation process will be easier for you.

Slide 4
Introduction to AICIS - some of you will be familiar with our scheme but for those that aren't, I obviously can't talk about everything today, but I'll briefly provide an overview.

Slide 5
AICIS replaced NICNAS in July 2020 at which time the transition began. We regulate chemicals at the point of introduction into Australia.

The key functions of AICIS include:

- Registration of introducers
- Pre-market assessment of applications
- Post-market evaluations
- Risk management referrals
- Publication of information
- Inventory management
- Post-introduction monitoring, and
- Compliance investigation and enforcement.

A key feature of AICIS is risk-proportionate regulation. In comparison to our previous scheme, there is less pre-introduction assessment overall by focusing on assessing higher risk introductions and there is more post-introduction monitoring and evaluation to provide assurance that lower risk introduction pathways are working as intended.

Slide 6
So let's take a closer look at the chemical introduction categories. Importantly, it is the introduction that is categorised, not the chemical. There are five main categories, each with its own criteria and regulatory obligations.

Listed introductions are where the chemical is on the Inventory and the introduction and use are within the terms of the Inventory listing, including any conditions.

If the introduction is not listed, then there are 4 categories it could fall into. 3 of them are based on the indicative risk profile of the introduction, with associated obligations that are proportionate to that risk.

- Very-low risk introductions fall into the exempted category, which requires a once off post introduction declaration.
- Low-risk introductions fall into the reported category, which means that a report needs to be submitted before it's introduced.
- Medium- to high-risk introductions fall into the assessed category and these require risk assessment and a certificate to be issued before introduction into Australia. Importantly a chemical will only be added to our inventory if it has undergone an assessment.

There is also a separate category for introductions that are for the sole purpose of commercial evaluation.

Slide 7
Information you need to categorise introductions is contained in our Act, Rules and Categorisation Guidelines. Importantly, the information on how to categorise has been pulled together to form our Categorisation Guide and we encourage you to use this guide when categorising your introduction. We also have lots of extra resources on our website that target specific introduction types, for example:
- chemicals in cosmetics
- polymers
- chemicals in fragrance blends
- polyhalogenated organic chemicals, etc.

I encourage you to look at this page to see if there are any extra resources that can help you.

Slide 8
Before I go any further, I'd like to talk briefly about assessed introductions

Slide 9
Some introductions being introduced under the NICNAS exemption criteria will be categorised as assessed under AICIS. Examples that will likely be categorised as assessed include:
- 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
- Chemicals with certain human health hazard characteristics, such as carcinogenicity and reproductive toxicity, unless specific exposure criteria are met
- Chemicals with certain environment hazard characteristics, such as PBT chemicals
- Chemicals with certain end uses unless significant hazard information is available. These end uses include tattoo inks, personal vaporisers, those used offshore and are released to the ocean, chemicals used in firefighting or that are intentionally released (for example, in town water treatment or soil conditioners).

Slide 10
If an introduction is categorised as assessed, introduction of the chemical cannot occur beyond 31st August 2022, unless an application for an assessment certificate has been submitted and a certificate issued. Introduction thereafter must be in accordance with the terms of that certificate. Importantly, the timeframe for the certificate application process generally takes 70 working days and there is a fee to submit the application. The details of this are on our website.

Note that applications can also be submitted for introductions that are otherwise categorised as exempted and reported, for example, to have the chemical added to our Inventory.

Slide 11
Now I'd like to provide some general information on the 6-step process to categorise introductions.

Slide 12
To decide between the exempted, reported and assessed introduction categories, there is a process that might determine the introduction category in just two steps, or up to a maximum of 6 steps. The category for the majority of introductions meeting the NICNAS exemption criteria will be determined using all 6 steps and we have video guides available on our website to step you through this.

The categorisation process is based on objective criteria and involves consideration of both human health and environmental risks. To be clear, if a chemical was introduced under the NICNAS exemptions, it does not mean that it is an exempted introduction under AICIS – the criteria are not the same. It could be categorised as exempted, reported or assessed.

Slide 13
This slide gives a summary of the 6 steps you need to go through to get to your introduction category.

For step 1, check if your introduction is one that cannot be exempted or reported. For example, chemicals that are listed on the Rotterdam Convention. If it is not one of these, move on to step 2.

For step 2, check if your introduction is one that can automatically be in the exempted category. These are ones that are very low risk to human health and the environment, like a polymer of low concern. If it's not one of these, go to step 3.

In step 3, check if your introduction is one that can automatically be in the reported category. These are ones that are low risk to human health and the environment, like a low risk fragrance blend introduction that meets our specific criteria. If it's one of these, your introduction can be in the reported category, and your categorisation is complete. If it's not one of these, go to step 4.

Step 4 has many smaller steps within it that lead you to work out the indicative human health risk of your introduction. This involves working out your human health exposure band, and considering the human health hazard characteristics of your chemical. At the end of step 4, you will have worked out whether the indicative human health risk of your introduction is medium to high, low or very low.

At step 5, you'll then go through a similar process to work out the indicative environment risk for your introduction.

Finally, step 6 involves taking the outcomes from steps 4 and 5 and working out the highest indicative risk for your introduction, which then correlates with the introduction being in the exempted, reported or assessed category.

Slide 14
Steps 4 and 5 are shown in a little more detail on this slide. You work out the exposure band for the introduction using our criteria, which I'm not going to go into here, you consider the hazard characteristics of the chemical and then you work out the indicative human health risk and indicative environment risk for the introduction. This might seem a little overwhelming at the moment, but will become clearer when we work through the examples.

Slide 15
At step 6, you then use the outcomes from step 4 for human health and step 5 for the environment to work out your introduction category. For example, if the indicative human health risk is low and the indicative environment risk is very low, then it would be a reported introduction.

Slide 16
So how can we make the categorisation process faster? Much of this depends on whether you're aiming for an exempted or reported introduction. The major difference between the reported and exempted categories in terms of obligations is the requirement to submit a pre-introduction report for a reported introduction (versus the post-introduction declaration for exempted introductions). If you're OK with your introduction being categorised as reported, then this may make your categorisation process simpler.

For example, when working out the exposure bands you may need to determine the human health categorisation volume and environment categorisation volume. The quickest option is for these volumes to equal your introduction volume, i.e. to not apply any exposure or release reduction factors to the volume based on how the chemical will be used in Australia. So, if you're currently introducing under the ≤100 kg NICNAS exemption, you could just assume that your human health categorisation volume and environment categorisation volume are ≤100 kg, i.e. equal to the introduction volume. This is the simplest option but may mean your categorisation outcome is reported as opposed to exempted.

Slide 17
Similarly, when working out the hazard characteristics. In the higher exposure bands, there are more hazard characteristics to consider and you need more information to be a very low risk introduction. As an example, if your introduction is in human health exposed band 3, because the human health categorisation volume is ≤100 kg, to be a low risk introduction, you need to be able to demonstrate the absence of hazard characteristics in human health hazard band C, whereas to be a very low risk introduction you need to have information to demonstrate the absence of characteristics in hazard bands C, B and A. So the quick option is to aim for low risk, which will mean the introduction can't be categorised as exempted.

Slide 18
Now I'd like to talk about the information that you need to categorise your introduction.

Slide 19
Firstly, chemical identity - simply put, an introduction cannot be categorised without knowing the chemical identity. Ideally, all chemical suppliers would give you the identity of all chemicals that you are introducing (including CAS name and number, where available). This is option 1 on this slide. If you know the chemical identity, then you may be able to categorise your introduction and meet your ongoing regulatory obligations without much further input from your supplier.

However, we appreciate that chemical identity information may be confidential, and suppliers may not wish to disclose it to you. So, there are two other options that are available:

- Option 2 is for your supplier to give you enough information to allow you to categorise the introduction and
- Option 3 is where your supplier categorises the introduction and then gives you the category, but this is not recommended for exempted and reported introductions, where the categorisation criteria depend on how the chemical will be introduced and used in Australia.

It is important to note that in electing option 2 or 3, your supplier is also choosing to play more of a role in supporting you to meet your ongoing regulatory obligations. So you do need to have a relationship with them.

Slide 20
If you have relied on information that is held by the overseas supplier or manufacturer to categorise your introduction then you must keep a written undertaking from that overseas supplier. The undertaking is a

commitment that they will give us information, if we ask for it, in order to check compliance with the scheme. The information that the undertaking contains varies and depends on the introduction category and the information that is held by that person and more than one undertaking may need to be held for the same introduction.

Slide 21
So with regards to option 2 related to chemical identity, the supplier would give you enough information to allow you to categorise your introduction.

The undertaking needs to contain all of the categorisation elements that require knowledge of the chemical identity. For example:

- whether the chemical is listed on our Inventory or in the Rotterdam or Stockholm convention
- whether the chemical meets the polymer of low concern criteria
- whether it is polyhalogenated or contains certain elements, such as tin, arsenic, cadmium, lead, or mercury
- whether it has any known hazard characteristics or is on 'The list of chemicals with high hazards for categorisation' and
- whether it is a specified class of introduction

So, they need to give you enough information about the chemical and particular features without giving you information that would fully disclose the chemical identity (such as CAS name/number).

Slide 22
The other information that you'll need to categorise the introduction will depend on the circumstances of your introduction, but will likely include:

- maximum introduction volume
- end use
- introduction and end use concentration, for example, confirmation that the concentration at introduction and end use is ≤1% if the exposure band criteria rely on this
- whether the chemical is considered to be a certain chemical at the nanoscale
- the known hazard characteristics of the chemical, and
- details of the information that is available to demonstrate the absence of human health and environment hazard characteristics.

Slide 23
For exempted and reported introductions, the information that is needed to demonstrate the absence of hazard characteristics is set out in our Categorisation Guidelines. As introductions that meet the NICNAS exemption criteria are either low volume (≤100 kg) or low concentration (≤1%) introductions, extensive hazard information is not required to demonstrate that they are low-risk introductions. For example, you may need to indicate that the chemical is not known to have certain hazard characteristics in the highest hazard bands, such as CMR or PBT characteristics, or that the chemical is not on 'The list of chemicals with high hazards for categorization', which is a list published on our website. When searching this list, make sure you follow the instructions that accompany it.

For higher exposure introductions that are to be categorised as exempted or reported, more hazard information may be required. This information is set out in our Categorisation Guidelines. This may be relevant when working out the indicative environment risk for large volume introductions under the ≤1% NICNAS exemption criteria.

Slide 24
Before I move on to the examples, I want to quickly summarise some key messages from the presentation so far. These are:

- that introductions of chemicals under the NICNAS exemption provisions must be categorised under AICIS for the introduction to be authorised beyond 31 August 2022;

- that these introductions may be categorised as exempted, reported or assessed;
- that there is a 6-step process to work out if your introduction can be exempted or reported and we have lots of resources, including our categorisation guide, to help you work out your introduction category;
- and that you need to know certain information about the chemical you are introducing to be able to categorise the introduction under AICIS.

Slide 25
Now I'd like to go through some start-to-finish examples.

Slide 26
The scenario for example 1, is that a chemical is currently being introduced into Australia in accordance with the cosmetic use, ≤100 kg, no unreasonable risk, NICNAS exemption criteria. In preparation for the end of the transition period the introducer now needs to categorise their introduction under AICIS.

The introducer knows:
- the identity of the chemical
- that they import ≤90 kg of chemical per year as a component of shampoo, hand soap and body wash
- the chemical is classified as a skin and eye irritant and it is harmful to aquatic life
- they don't have any tox/ecotox study reports available to them (the hazard classification is based on general information sheets their supplier provided).

Slide 27
So now let's work out the introduction category. Because they know the chemical identity, they can also work out that:
- the chemical isn't listed on our Inventory or on the Rotterdam or Stockholm Convention (this means they can progress past step 1 of the Categorisation Guide)
- the chemical isn't a UVCB or high molecular weight polymer
- it doesn't contain halogens, tin, arsenic, cadmium, lead or mercury
- the chemical isn't on 'The list of chemicals with high hazards for categorisation'
- the introduction is not a 'specified class of introduction'

Slide 28
Moving on to step 2 and 3, we can work out that the introduction is not one that is automatically categorised as exempted or reported. The criteria to be automatically exempted or reported are very specific, such as for polymers of low concern or for chemicals that will only be used in research and development. As indicated earlier on, most of the introductions that are currently being introduced under the NICNAS exemption criteria, will need to be categorised using all 6 categorisation steps.

Slide 29
So that brings us to step 4 – working out the indicative human health risk

Slide 30
Step 4.1 relates to introductions that are always medium to high risk for human health. This doesn't apply to this introduction, because it doesn't contain any halogens, so it's not going to be assessed based on it being fluorinated or polyhalogenated. It's also imported in liquid cosmetic products, so it's not a certain chemical at the nanoscale.

Slide 31
The introduction also doesn't meet the criteria to be internationally assessed for human health. It's important to note that most introductions won't meet these strict criteria. You can look into them if you choose to, but for chemicals being introduced under the NICNAS exemption criteria, which are low volume or low concentration, there's likely to be very little benefit in doing so. For simplicity, you can choose to assume that the introduction doesn't meet the internationally assessed criteria.

The introduction volume is 90 kg and they've determined this to also be the human health categorisation volume. Applying this information to the exposure band criteria, they work out that the human health exposure band for their introduction is 3.

Slide 32
For the indicative human health risk for the introduction to be low, the chemical cannot have any hazard characteristics in human health hazard band C. They don't have any tox or ecotox study reports available, which they would need for a very low risk introduction in exposure band 3, so they just need enough information to show that the chemical doesn't have the hazard characteristics in human health hazard band C, i.e. those of highest concern to human health. In this case, they know the chemical is a skin and eye irritant but these characteristics aren't relevant to hazard band C. Using the categorisation guide, they work out that all they need to demonstrate the absence of the hazard band C characteristics is:

- for the chemical not to be known to have any these characteristics (which it's not) and
- for the chemical not to be on the list of chemicals with high hazard for categorisation (which it isn't)

Slide 33
So they've worked out that the indicative human health risk for their introduction is low. Now they need to move to step 5 and work out the indicative environment risk

Slide 34
Step 5.1 relates to introductions that are always medium to high risk for environment. Again, this doesn't apply to this introduction, because it doesn't contain any halogens or tin, so it's not going to be assessed based on it being fluorinated, polyhalogenated or an organotin. It's also imported in liquid cosmetic products, so it's not a certain chemical at the nanoscale or a gas.

Slide 35
The introduction also doesn't meet the criteria to be internationally assessed for environment. Once again, most introductions won't meet these strict criteria so you can choose to assume that they're not met.

The introduction volume is 90 kg and they've determined this to also be the environment categorisation volume. Applying this information to the exposure band criteria, they work out that the environment exposure band for their introduction is 2.

Slide 36
For the indicative environment risk for the introduction to be low, the chemical cannot have any hazard characteristics in environment hazard band D, i.e. those characteristics of highest concern to environment. In this case, they know the chemical is harmful to aquatic life, but this is not relevant to hazard band D. Similarly to human health, using the categorisation guide, they work out that all they need to demonstrate the absence of the hazard band D characteristics is:

- for the chemical to not be known to have any of these characteristics (which it's not) and
- for the chemical to not be on the list of chemicals with high hazard for categorisation (which it isn't)

Slide 37
So they've worked out that the indicative environment risk for their introduction is low. Now they need to move to step 6 and they work out that the introduction is categorised as reported.

Slide 38
As is shown in this image.

Slide 39
Now that they've worked out that their introduction is categorised as a reported introduction, before they can introduce the chemical they need to:

- submit a pre introduction report and

- they also need to make sure that they can meet their record keeping obligations.

We have detailed guidance available on our website on submitting a pre introduction report and meeting the record keeping obligations.

They then need to make sure that all introductions are in accordance with the terms of their pre-introduction report, and to vary their report if their introduction circumstances change (provide that it remains a reported introduction). They need to keep records about their introduction, and they need to indicate that they are introducing chemicals in the reported category in their annual declaration.

Slide 40

So let's talk a little bit more about pre-introduction reports. The Australian introducer or an agent, must submit a pre-introduction report. They submit this via our online business portal.

The content of the pre-introduction report differs depending on the type of reported introduction. The main type is 'highest indicative risk is low and the other types do not apply'. Chemical identity information is required for this type and if you don't know it, then the overseas supplier (or whomever holds this information) can provide it securely into our portal. To do this, they need to be enrolled in and then login to our portal.

We have a step-by-step guide on our website for completing and submitting reports of this type. I encourage you to use it when completing your report as it contains many hints and tips to avoid errors and it will make it less likely for us to have to follow-up with you about your introduction.

Slide 41

Over the coming slides, I'm going to show screenshots of the information the introducer would have entered into their pre-introduction report as it was being completed for the example that we've just categorised as reported.

So firstly, they selected the pre-introduction report type as 'highest indicative risk is low risk and the other types do not apply'. They then entered the name of the chemical, which in this section can be the trade name or marketing name. They also indicated that they know the proper name of the chemical. If they hadn't known the proper name, then they would be prompted to provide the details of the chemical identity holder.

Slide 42

In the next part of the report, they enter the CAS name and number for their chemical (whatever that may be). They also indicate that the chemical isn't a UVCB or high molecular weight polymer.

Slide 43

They indicate that the chemical is imported at ≤100 kg per year and that the end use is in 'personal care products not covered by other end uses', they then specify that it's used in shampoo, hand soap and body wash. Note that the volume selected should align with the human health and environment exposure band criteria. Also note that if your chemical is used in cosmetics, the appropriate category is 'personal care products not covered by other end uses' unless it will only be used in limited environmental release products such as nail polish.

Slide 44

They then indicate that:

- the introduction does not belong to a specified class of introduction
- the introduction doesn't involve a designated kind of release into the environment
- the introduction will have an end use in cosmetics and that they didn't use animal test data from tests conducted on or after 1 July 2020 to determine the highest indicative risk for the introduction.

The relevant notes from this slide are that cosmetic use is not a designated kind of release into the environment and, if it's a reported introduction and human health exposure band 2 or 3, then animal test data was not used to determine the human health indicative risk for the introduction. This is because the

categorisation was based on the known hazard characteristics of the chemical and simply checking that it was not on the 'List of chemicals with high hazards for categorisation', i.e. no animal test data was needed to demonstrate the absence of hazard characteristics.

Slide 45
They then enter that the chemical has a human health hazard characteristic and select these and similarly that the chemical has an environment hazard characteristic and select this

Slide 46
They then enter the human health and environment exposure bands and exposure band criteria for the introduction. Note that the item numbers for the criteria are shown in our step-by-step guide on our website. In this case for a ≤100 kg introduction, they select human health exposure band 3 (item 4) and environment exposure band 2 (item 2).

Slide 47
In this case, they indicate that they don't wish to flag any of the information in their report as confidential and they then make a declaration before submitting the report. In essence, they are declaring that:

- they had regard to the known hazard characteristics of the chemical and the information that is required to demonstrate the absence of the hazard characteristics to be a low risk introduction and
- that the information that they've given in the report is true, correct and complete.

Once the report is submitted, it will be reflected as such in the PIR dashboard and you will also get an email from us, but the expectation is that before you submit a report, you're confident that it meets the criteria to be a reported introduction. A pre-introduction report is not an application, so we can't approve or reject it, however, we do monitor reported introductions and may request information to demonstrate the categorisation of your introduction.

Slide 48
I'd now like to talk a little bit about keeping records. Introducers must keep records about their introductions, and these must be held for five years, including for chemicals that are no longer being introduced. The types of records differ depending on the type of introduction and our guidance provides details, checklists and examples of records. On this slide you can see a screenshot of our web page on record keeping requirements for reported introductions where the highest indicative risk is low risk, which is the reported introduction type corresponding to the example that we've just worked through.

Slide 49
The diagram on this slide provides an overview of the process for us requesting information. As previously indicated, introducers must keep records.

As part of our compliance monitoring programme, we may ask you for information related to the introduction of your chemicals. If you hold a written undertaking from an overseas supplier, you may ask them to provide the information that they hold directly to us. Once the requested information has been submitted, we'll review it to confirm that the introduction is authorised.

Slide 50
So, for the example that we just worked through, what sorts of records would they have kept? Our expectation is that introducer's hold information to demonstrate how they reached the categorisation outcome and to support the information that they provided in the pre-introduction report. In this case, they hold a signed and dated document indicating:

- the CAS number and name of the chemical
- that it isn't an Inventory listed or Rotterdam or Stockholm convention listed
- it isn't a UVCB or high molecular weight polymer

- it isn’t halogen, tin, arsenic, cadmium, lead or mercury containing
- it wasn't on the ‘List of chemicals with high hazards for categorisation’ and
- it isn't a specified class of introduction.

Essentially, all of the things that they were able to work out as part of the categorisation by knowing the identity of the chemical. In addition:

- they also had product information sheets containing information to support the stated end use and supporting that it's imported in liquid form
- they had shipping documents for the imported shampoo, hand soap and body wash and the maximum (generic) concentration of chemical in those products, to support the names of the products imported and that the introduction volume of the chemical is ≤100 kg in a registration year and
- they had information from the supplier indicating that the chemical’s a skin and eye irritant and harmful to aquatic life.

So, it's a lower exposure band introduction and we're not expecting masses of documents to be kept. In general, it’s just enough information to show that the categorisation criteria were and continue to be met.

Slide 51

So, what if the same chemical from example 1 was being introduced under the cosmetic, ≤1% NICNAS exemption provisions, instead of the cosmetic ≤100 kg scenario that we’ve just worked through – how would the categorisation process and obligations differ? Simply put, it’s all very similar and this is shown through this slide.

The categorisation process is the same - you'd still need to work through steps 1-6 of the categorisation guide and the human health exposure band for the introduction would still be 3. However, the environment exposure band for the introduction may be different, if the volume of chemical introduced was significantly higher than 100 kg/year.

Assuming that the introduction is still categorised as reported, the pre-introduction report types would be the same and very similar information inputted. The main difference, would be in the item numbers corresponding to the human health and environment exposure band criteria, for example, item 5 not 4 for human health. The record keeping requirements would also be very similar, but there would be an additional requirement that there is a record of the maximum concentration of the chemical at introduction and end use, so that they could demonstrate that the ≤1% criteria had been met.

Slide 52

Moving on to example 3 now – what if the same chemical was being introduced at ≤25 kg per year (instead of 100 kg) – how would the categorisation process and obligations differ? The process would be the same, but the introduction category may be exempted instead of reported, based on the highest indicative risk for the introduction being very low. How you categorise this introduction is going to depend on the preferences of your business. I hope this will be clearer from the information in the following slide.

Slide 53

On this slide, I’m comparing some of the features of a reported introduction (≤100 kg) vs an exempted introduction (≤25 kg) and also an exempted introduction (≤10 kg).

As mentioned earlier in the presentation, the main difference between the reported and exempted categories, is the requirement to submit a pre-introduction report for reported introductions vs a post-introduction declaration at the completion of the first registration year for exempted introductions. There is no fee to submit a PIR or a PID.

If you elected to categorise the introduction as reported, then there would be less ongoing monitoring of introduction volumes by you. What I mean by this, is that if you knew the volume wasn't going to exceed 25 kg, then it certainly wouldn't exceed 100 kg, so while you would still need to keep records of the volume introduced, you would be more confident that the volume limit is not going to be breached and the introduction needing to be re-categorised. There are also less record keeping requirements for reported introductions, because more information on your introduction as part of your pre-introduction report.

Another point to consider is chemical identity information. In this case, the introducer knew the identity of their chemical and they'd need to provide this information in both the PIR and the PID. If they didn't know the chemical identity, then the person that knew it, would need to provide it in the pre-introduction report and the post-introduction declaration for the ≤25 kg introduction. However, if they were submitting a post-introduction declaration for a ≤10 kg introduction, then the identity of the chemical would not be required as part of the declaration, but they'd still need to keep a written undertaking from the person that knew that information.

So, this slide is providing information and shows that there is some flexibility for businesses to make their own choice, depending on their own introduction circumstances. If you do opt to submit a pre-introduction report based on the introduction volume being ≤100 kg, make sure you're consistent with this information in the report, i.e. select 100 kg as the volume (not 25) and the exposure band criteria based on up to 100 kg – this is because you always have to introduce in accordance with the terms of your pre-introduction report, so by putting in 100 kg, you know that you're not going to be in breach of that limit.

Slide 54
I'd now like to work through an example where they did choose to be categorised as exempted when they could have categorised as reported. The scenario for example 4, is that a chemical is currently being introduced into Australia in accordance with the non-cosmetic use, ≤100 kg, no unreasonable risk, NICNAS exemption criteria. In preparation for the end of the transition period the introducer now needs to categorise their introduction under AICIS.

- The introducer knows the chemical as "Adhesive additive Y" (but not the CAS number or name)
- They have a relationship with their supplier "Super Adhesives Inc." who know the identity of the chemical and they'll provide them with a written undertaking so they can categorise their introduction
- They import ≤10 kg of the chemical in a specialist adhesive
- The concentration of the chemical is in the range of 0.1-1%, and
- The chemical is a skin sensitiser

Slide 55
So now let's work out the introduction category. Based on the written undertaking provided by their supplier, they know:
- the chemical isn't listed on our Inventory or on the Rotterdam or Stockholm Convention (this means they can progress past step 1 of the Categorisation Guide)
- the chemical isn't a UVCB or high molecular weight polymer
- it doesn't contain halogens, tin, arsenic, cadmium, lead or mercury
- the chemical isn't on 'The list of chemicals with high hazards for categorisation'
- the introduction is not a 'specified class of introduction'

Slide 56
Moving on to step 2 and 3, I won't go through these in any detail, as we went through it previously, but we can work out that the introduction is not one that is automatically categorised as exempted or reported.

Slide 57
So that brings us to step 4 – working out the indicative human health risk

Slide 58
The introduction isn't always medium to high risk for human health because it doesn't contain any halogens and is imported in a liquid adhesive.

Slide 59
The introduction also doesn't meet the criteria to be internationally assessed for human health.

The introduction volume is 10 kg and they've determined this to also be the human health categorisation volume (so for simplicity, they've not applied an exposure reduction factor based on use in adhesive). Applying this information to the exposure band criteria, they work out that the human health exposure band for their introduction is 2.

Slide 60
For the indicative human health risk for the introduction to be very low, the chemical cannot have any hazard characteristics in human health hazard band C. In this case, they know the chemical is a skin sensitiser but this isn't relevant to hazard band C. Using the categorisation guide, they work out that all they need to demonstrate the absence of the hazard band C characteristics is:

- for the chemical not to be known to have any these characteristics (which it's not) and
- for the chemical not to be on the list of chemicals with high hazard for categorisation (which it isn't)

Slide 61
So they've worked out that the indicative human health risk for their introduction is very low. Now they need to move to step 5 and work out the indicative environment risk.

Slide 62
The introduction isn't always medium to high risk for environment because it doesn't contain any tin or halogens and is imported in a liquid adhesive.

Slide 63
The introduction also doesn't meet the criteria to be internationally assessed for environment.

The introduction volume is 10 kg and they've determined this to also be the environment categorisation volume (so for simplicity, they've not applied a release reduction factor based on use in adhesive). Applying this information to the exposure band criteria, they work out that the human health exposure band for their introduction is 1.

Slide 64
For the indicative environment risk for the introduction to be very low, the chemical cannot have any hazard characteristics in environment hazard bands D or C. Similarly to human health, using the categorisation guide, they work out that all they need to demonstrate the absence of the hazard band D characteristics is:

- for the chemical to not be known to have any these characteristics (which it's not) and
- for the chemical to not be on the list of chemicals with high hazard for categorisation (which it isn't)

Slide 65
The hazard band C characteristics, require the same thing, i.e.

- that the chemical is not known to have the characteristics (which it's not) and
- that the chemical isn't on the list of chemicals with high hazard for categorisation (which it isn't)

Slide 66
So they've worked out that the indicative environment risk for their introduction is very low and they use the outcomes from steps 4 and 5 to work out that the introduction is categorised as exempted.

Slide 67
Now that they've worked out that their introduction is categorised as an exempted introduction, before they can introduce the chemical they just need to make sure that they can meet their record keeping obligations – you can see the information on our website for more information.

They need to keep records about their introduction. They also need to submit a post-introduction declaration at the end of the registration year and indicate that they are introducing chemicals in the exempted category in their annual declaration.

Slide 68
In this case, the records they would have kept include:
- the written undertaking from their supplier with the information that the information that they needed to categorise their introduction, and which confirmed that information (including CAS number and name) would be provided to us on request
- a document containing the categorisation steps/outcomes (including exposure band criteria)
- product information sheets containing information on the end use of the product containing the chemical (and supporting that it's imported in a liquid adhesive)
- Shipping documents to support the introduction volume (and names of products imported) and
- The SDS for the chemical, which indicates that it's a skin sensitiser

Slide 69
Now let's talk about the post-introduction declaration or PID. The Australian introducer or an agent, must submit a PID and they submit this via our online business portal.

The contents of the PID differs depending on the type of exempted introduction. The main type is 'highest indicative risk is very low risk'. Chemical identity information is required for this type. If you don't know the chemical identity, then the overseas supplier (or whomever holds this information) can provide it securely into our portal. The exception to this, as we'll see in the coming slides is where the introduction volume is ≤10kg, where you just need to provide the details of the chemical identity holder.

Slide 70
Over the coming slides, I'm going to show screenshots of the information the introducer would have entered into their post-introduction declaration as it was being completed for the example that we've just categorised as exempted.

So firstly, they selected the applicable registration year and the introduction type as 'highest indicative risk is very low risk'. They then entered the name of the chemical, i.e. "Adhesive Additive Y" and indicated that they didn't know the proper name of the chemical. They also indicated that they introduced ≤10 kg of chemical.

Slide 71
This then prompts them to enter the name of the chemical identity holder. As previously indicated, if the volume had been >10 kg then the identity holder would have needed to provide the identity as part of the declaration.

Slide 72
They then select the volume pf chemical introduced in the registration year and that it will be used in "Adhesive and sealant products"

Slide 73
They select maximum concentration at end use and indicate that the chemical will not have an end use in cosmetics.

They then make a declaration that the information that they've given is true, correct and complete.

Once the declaration is submitted, it will be reflected as such in the PID dashboard and you will also get an email from us. Again, it's not an application, so we can't approve or reject it, however, we do monitor exempted introductions and may request information to demonstrate the categorisation of your introduction.

Slide 74
That brings me to the end of this talk. You've been given a lot of information today, but I hope that it will make is as simple as possible for you to transition your introductions under the NICNAS exemptions to the AICIS introduction categories.

Thank you for your time and if you need any further information, please visit our website.

Last updated
1 September 2022