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Notification and Assessment Scheme

Transcript – Step-by-Step Categorisation: Steps 4-6

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Slide 1

Hello! This video will provide a general overview about how to work through the categorisation steps that we are calling steps 4, 5 and 6. This is the third in a series of videos on the topic of categorisation. The first video was called 'Overview of Categorisation', and gave an overview of the whole categorisation process. The second video was called 'Step-by-Step Categorisation: Steps 1-3', and worked through the initial categorisation steps: steps 1, 2 and 3.

Slide 2

Under the new scheme, AICIS, all chemical introductions must be categorised. The 5 main introduction categories are shown here. They are listed – for introductions of chemicals that are listed on the Inventory and whose introduction is within the terms of the Inventory listing. Exempted – for introductions that are very low risk. Reported – for introductions that are low risk. Assessed – for introductions that are medium to high risk. Commercial evaluation authorisations – where you are wanting to determine the commercial potential of your chemical, without any retail exposure. The first categorisation video, which was called 'Overview of Categorisation', went into more detail about each of these categories. The focus of this current video is how to decide between the exempted, reported and assessed introduction categories.

Slide 3

Once you have ruled out the listed category by checking our Inventory, the process of working out your introduction category is summarised by this slide. There are up to 6 steps in this process, and the final outcome you will get to at the end is that your introduction is either exempted, reported or assessed. You could get to this outcome after just 1 or 2 steps, or you might need to go all the way to step 6 to get to your outcome. This depends on the details of your introduction.

The first 3 steps of this process were described in the previous video, called 'Step-by-Step Categorisation: Steps 1-3'. In this current video, we'll describe what is involved in the remaining 3 steps of this process; steps 4, 5 and 6. These are the steps where you'll need to consider the indicative human health and environment risk of your introduction to get to your introduction category.

Slide 4

So we'll first describe step 4, which is the process you need to work through to get to the indicative human health risk of your introduction.

Slide 5

You can find more details about step 4 in section 28 of the Industrial Chemicals General Rules, which we call the General Rules, for short.

There are several different sub-steps within step 4. You need to follow these in the order that they are described in this video to be able to get to your final step 4 outcome of being very low, low, or medium to high indicative risk to human health.

For step 4.1, you need to check if your chemical introduction is one that is considered to be of medium to high indicative risk for human health.

The first of these is where you are introducing a chemical that contains a sequence of 4 to 20 fully fluorinated carbon atoms. These include per- and poly-fluorinated alkyl substances, known as PFAS chemicals.

Also in step 4.1 are introductions of polyhalogenated organic chemicals that are introduced at volumes more than 100kg each year. The chemical, or one or more of its known environmental degradation products, has to meet the definition of 'persistent' for it to be covered by this part of step 4.1. Note that if you introduce one of these chemicals at less than 100kg per year; or if you introduce a polyhalogenated organic chemical that is not persistent and does not have any persistent environmental degradation products, it is not covered by step 4.1. You would need to continue on with the next categorisation steps to get to your indicative human health risk.

Finally in step 4.1 we have certain chemicals at the nanoscale. These are ones where your chemical is not soluble, and the introduction of the nanoscale portion of your chemical is not incidental to the non-nanoscale portion of the chemical. There is more information in the General Rules about what we mean by 'not incidental'.

If your introduction is any of the 3 types that we've described here for step 4.1, this means that your indicative human health risk is medium to high, and you don't need to proceed any further with step 4. This also means that you are in the assessed introduction category, so your categorisation is complete.

If your introduction is **not** any of the 3 types described for step 4.1, move onto step 4.2.

Step 4.2 involves checking if your introduction is one that can be considered to be low indicative risk for human health. If your chemical has been assessed overseas for its human health risk, and you also meet the other criteria, your introduction can be low indicative human health risk. Some of the other criteria include that the overseas assessment was done by a trusted international assessment body; but only those that are named in the General Rules. The overseas assessment must have been for the same end use, and the same or higher concentrations as the end use in Australia, and the risks to human health in Australia are no higher than the risks overseas. Because we trust the outcomes of risk assessments done by these overseas agencies, and because they assessed the chemical for circumstances very similar to what will be happening in Australia, we consider these introductions to be of low indicative human health risk for categorisation purposes. Note that this doesn't mean that they can't be **very low** risk, just that you would have to work through the other parts of step 4 to be able to justify this.

If your introduction is not covered by step 4.2, move onto the next step.

Slide 6

The remaining parts of step 4 require you to consider your exposure, then your hazard, to get to your result for the indicative human health risk. The level of your human health exposure is based on the human health exposure band for your introduction. These range from band 1 to band 4, with exposure band 1 having the lowest exposure to humans, and band 4, the highest. You need to consider the criteria for these exposure bands in order to work out the human health exposure band for your introduction. Later slides will go through

more detail about step 4.3, including the criteria for the exposure bands and how you work out which exposure band your introduction will be in.

The human health hazard bands range from hazard band C, for the highest hazards, down to hazard band A, for lower hazards. Later slides will describe more detail for step 4.4, including the hazards that are in each band, and explaining how to work out if your chemical has one of these hazards or not.

For step 4.5 you can then use the diagram shown on this slide to work out your indicative human health risk. Based on the exposure band for your introduction, and the hazard characteristics that your chemical does or does not have, you can then determine if your introduction is of very low, low or medium to high indicative human health risk. More on this in later slides, but just to give you a simple example – if the human health exposure band for your introduction is 2, and you are able to show that your chemical does not have any of the hazard characteristics in hazard band C, the indicative human health risk of your introduction will be very low.

There are also some special cases that may need to be considered after you get to your risk outcome here. In particular, if your chemical is a UV filter, or if it is a chemical at the nanoscale where the introduction of the nanoscale portion of the chemical is incidental to the non-nanoscale portion of the chemical, your introduction cannot be very low risk, regardless of the outcome that you might have come to at step 4.5. It has to be medium to high, or low indicative human health risk.

Slide 7

This slide summarises the criteria for each of the human health exposure bands. All introductions of chemicals that have end uses in tattoo inks or personal vaporisers will be in human health exposure band 4. The other criteria for the exposure bands depend on a number of parameters. These parameters include the concentration at which the chemical is present when it is introduced and during its end use; whether the chemical has a consumer end use or not (where we consider a consumer end use to be where the chemical is made available to the general public); and the human health categorisation volume, which is related to the annual introduction volume. Human health categorisation volume will be explained in more detail in the next few slides. So exposure to humans increases as you move from band 1 to band 4. In band 1, you have very low concentrations and no exposure to consumers, with no upper limit on volume. In band 2, you have either relatively low introduction volumes; or very low concentrations and some exposure to consumers, with no upper limit on the volume. In band 3, you have either a moderate introduction volume; or a low concentration with no upper limit on volume. Then in band 4, you have high introduction volumes.

Slide 8

There are 2 main methods that you can use to work out your human health categorisation volume. You can choose which one best suits your circumstances. More details on these methods are given in the Categorisation Guidelines. The first method is where your human health categorisation volume is just the same as your total annual introduction volume. Method 2 involves multiplying your introduction volume by an exposure reduction factor that is different depending on your chemical's end use.

Slide 9

The exposure reduction factors for different end use scenarios are shown in this table. The values range between 0 and 1. A low exposure reduction factor indicates that we expect that only a small portion of the introduction volume is likely to contribute to human exposure. A higher exposure reduction factor indicates that a higher proportion of the introduction volume could contribute to human exposure. Cosmetics have an exposure reduction factor of 1, and other end use scenarios, where the chemical has its end use in Australia, have an exposure reduction factor of 0.1.

Slide 10

With method 2 for calculating the human health categorisation volume, your introduction volume is multiplied by an exposure reduction factor relevant to your chemical's end use. If you use method 2 rather than method 1, your human health categorisation volume might be lower than your introduction volume. This could mean that your human health exposure band could be lower than it would otherwise have been, which in turn could result in a lower indicative human health risk and a lower overall introduction category.

Method 2 can vary depending on whether your introduction has only a single end use scenario, or multiple end use scenarios. If there is only one end use for your chemical, you just multiply your introduction volume by the relevant exposure reduction factor for your end use scenario.

Slide 11

For multiple end use scenarios, there are also 2 options. For option 1, use the exposure reduction factor that is the highest out of all of the end use scenarios for your chemical to calculate your human health categorisation volume. Note that the introduction volume for this calculation should still be the total annual introduction volume, and **not** just the volume for one of the end uses.

Slide 12

Option 2 with multiple end uses can be used if you know the introduction volume that will be allocated to each of your end uses. For each end use, calculate a separate human health categorisation volume using the exposure reduction factor for this end use, and the volume that you will be introducing for this end use. Do this for all of your end uses and then add all of them up to get your total human health categorisation volume. This method will result in a more refined human health categorisation volume. However, keep in mind that if you want to use this method, you'll need to keep track of your introduction volumes for each end use to make sure that your introduction category always remains correct.

Slide 13

This slide shows the hazard characteristics that are in each human health hazard band. In band C, the highest hazard band, there are hazard characteristics like carcinogenicity and genetic toxicity. The next highest is band B, where you find hazard characteristics such as skin and eye damage, fatal or toxic acute toxicity, repeated dose toxicity, and skin

sensitisation. Then in the lowest hazard band, band A, there are hazard characteristics like skin and eye irritation and harmful acute toxicity.

Slide 14

So now for more about step 4.4 where you need to work out what human health hazard characteristics your chemical does or does not have. For details about how to do this, refer to the Categorisation Guidelines. There are a few things to keep in mind about this process of considering the human health hazard characteristics. Firstly, the requirements tend to differ depending on your exposure band. This often means that the hazards you need to consider are different in one exposure band compared to another. For example, if you are in exposure band 3 and you want to show that your introduction has low indicative human health risk, you just need to demonstrate that your chemical does not have any of the hazard characteristics in hazard band C. But if you are in exposure band 4 and you want to show that your introduction has low indicative human health risk, you would need to demonstrate that your chemical does not have any of the hazard characteristics in hazard band C **and** none of those in hazard band B either. The other way in which requirements might differ depending on exposure band is in terms of the type of information that can be used to demonstrate that your chemical does not have a certain hazard characteristic. For example, for certain hazards, in silico information is acceptable in lower exposure bands. However, in silico information may not be acceptable for the same hazard in a higher exposure band.

Another general principle is that you will need more hazard information to justify your chemical being of lower indicative risk. For example, if you are in exposure band 3, to get to low risk, you just need to show that your chemical does not have any of the hazards in hazard band C. To be low risk, it's not necessary to narrow down whether you would fall into band B, A, or the very lowest band, called 'Not A, B or C'. However, if you wanted to try to get to very low risk, you would also need to show that your chemical doesn't have any of the hazards in hazard bands B and A.

There are many options available for information about human health hazard characteristics. In the majority of cases, read across information can be used in place of information on the chemical itself, as long as the read across information is considered to be 'suitable'. You can refer to the Categorisation Guidelines for more details about how we define suitable read across information.

There are also many in silico, in chemico, in vitro and in vivo options that can be used, depending on the hazard characteristic and the exposure band you are in. There are also many information waivers available that mean it's not always necessary to have information from toxicity testing to be able to show that your chemical doesn't have a certain hazard. Instead, we recognise that some types of chemicals are unlikely to have certain hazards. For example, if your chemical is a high molecular weight polymer, in most cases it won't be necessary to have study results to prove that it is not acutely toxic, or that it is not a skin sensitiser.

Slide 15

When considering the human health hazard characteristics of your chemical, first go to your exposure band, which you worked out in step 4.3. You start at the highest hazard band, hazard band C, and work your way down the hazard bands from there. You need to consider all of the hazards within each hazard band. If you happen to determine that your chemical

has a certain hazard characteristic, this is where you would stop. For example, if you are in exposure band 2, and while you are considering the hazards in hazard band C, you discover that your chemical has the genetic toxicity hazard characteristic, there is no need to continue looking at the other hazards in hazard band C, and also no need to look at the hazards in lower hazard bands like B and A. Because it has a hazard in hazard band C, and it's in exposure band 2, this means that its indicative human health risk is medium to high.

Slide 16

As you work through each hazard characteristic within a hazard band, first consider whether your chemical meets the hazard characteristic definition. This consideration should be based on the existing hazard information that you have for your chemical. If it meets the definition, this means that your chemical has this hazard, and you can stop there. If your chemical does not meet the definition, next consider whether you can demonstrate that your chemical does not have the hazard characteristic. The Categorisation Guidelines have lots of options about how you might be able to do this. If you can prove that your chemical doesn't have this hazard, move on to the next hazard, working your way down. If you can't demonstrate that your chemical doesn't have this hazard, you have to stop there. The hazard that you stopped at, and the hazard band that it's in, will determine what the indicative human health risk of your introduction is.

Slide 17

When you need to demonstrate that your chemical does not have hazard band C hazards, in most cases we don't expect that you would have information available about these high level hazards, such as carcinogenicity. Instead, to demonstrate that your chemical does not have these hazards you can search the list of chemicals with high hazards for categorisation. You can find it on our website. This is a list that we have compiled directly from trusted international sources, and provides you with a single place to search for your chemical to check if it might be known to have these hazards.

Slide 18

Finally for step 4.5, to work out your indicative human health risk, consider your exposure band, together with where your hazard considerations got you to. What hazards does your chemical have? What hazards were you able to show it doesn't have? And where does this place you in the diagram shown here in terms of your indicative human health risk – is it very low, low or medium to high?

If your introduction is in exposure band 1, and your chemical has a hazard characteristic in hazard band C, your indicative human health risk will be low risk. If it's in exposure band 1 and your chemical does **not** have any of the hazards in hazard band C, your indicative human health risk will be very low. You don't need to know which of hazard bands B, A, or 'Not A, B or C' does apply. It's enough just to know that hazard band C does not apply so this means it has very low indicative human health risk.

If your introduction is in exposure band 2, and your chemical has a hazard characteristic in hazard band C, the indicative human health risk will be medium to high. If you're in exposure band 2 and do **not** have any hazards in hazard band C, the indicative human health risk will

be very low. Again, it's not necessary to narrow it down to the precise hazard band, it's enough to know that band C does not apply.

If your introduction is in exposure band 3, and your chemical has a hazard in band C, the indicative human health risk will be medium to high. If it's in EB3 and does **not** have any hazards in band C, this means your indicative human health risk can be low risk. If you wanted to try and see if you could get to very low risk, you need to demonstrate that your chemical has none of the hazards in band B and none of the hazards in band A.

If your introduction is in exposure band 4, and your chemical has a hazard in band C, or a hazard in band B, your indicative human health risk will be medium to high. If it's in exposure band 4 and does **not** have any hazards in band C or band B, the indicative human health risk will be low risk. If you could also show that it doesn't have any hazards in band A, the indicative human health risk could be very low risk.

At the end of this process you should have your indicative human health risk outcome, and now you're ready to move onto step 5. In step 5, you'll do the equivalent steps to come up with your indicative environment risk.

Slide 19

So now we'll describe step 5 of the categorisation process. This will get you to your indicative environment risk. Step 5 involves a lot of similar considerations to what was in step 4.

Slide 20

You can find more details about step 5 in section 29 of the General Rules.

There are several different sub-steps within step 5. You need to follow these in the order that they are described in this video to be able to get to your final step 5 outcome of being very low, low, or medium to high indicative risk to the environment.

For step 5.1, you need to check if your chemical introduction is one that is considered to be of medium to high indicative risk for the environment.

The first 3 that are listed here are exactly the same as the equivalent ones for human health. This means that they are medium to high indicative risk to the environment **and** to human health. These are chemicals with a sequence of 4 to 20 fully fluorinated carbon atoms, persistent polyhalogenated organic chemicals introduced at volumes more than 100 kg per year, and certain chemicals at the nanoscale. So if you were introducing one of these types of chemicals and were following this step-by-step categorisation process, you should have already worked out that your introduction category is assessed because of its indicative human health risk being medium to high. Additionally, you now know that it's also assessed because of its indicative environment risk being medium to high.

For indicative environment risk, there are also 2 other types that are considered to be of medium to high indicative risk for the environment. Firstly, there are gases that meet the definition of 'persistent' that are introduced at more than 100kg each year. And organotin chemicals introduced at more than 10kg per year.

If your introduction is any of the types described here for step 5.1, this means that your indicative environment risk is medium to high, and you don't need to proceed any further with step 5. This also means that you are in the assessed introduction category, so your categorisation is complete.

If your introduction is **not** any of the types described for step 5.1, move onto step 5.2.

Step 5.2 involves checking if your introduction is one that can be considered to be low indicative risk for the environment. If your chemical has been assessed overseas for its environment risk, and you also meet the other criteria, your introduction can be low indicative environment risk. Some of the other criteria include that the overseas assessment was done by a trusted international assessment body; but only those that are named in the General Rules. The overseas assessment must have been for the same end use, and the same or higher volumes as in Australia, and the risks to the environment in Australia are no higher than the risks overseas. Because we trust the outcomes of risk assessments done by these overseas agencies, and because they assessed the chemical for circumstances very similar to what will be happening in Australia, we consider these introductions to be of low indicative environment risk for categorisation purposes. It is possible that your introduction could be **very low** risk, but you would have to work through the other parts of step 5 to see if you meet all the criteria.

Just to clarify the steps that you need to take to work out if you can use international assessments of your chemical for categorisation purposes. You need to separately consider whether you meet the criteria to be low indicative risk for human health, under step 4.2, and low indicative risk for environment, under step 5.2. You could do this based on a single international assessment that considers both human health and environment risk, or you could do this based on 2 separate international assessments of your chemical, one that looked at the human health risk, and another that looked at the environment risk. If you meet all the criteria for both, then your introduction will be in the reported category.

If your introduction is not covered by step 5.2, move onto the next step.

Slide 21

The remaining parts of step 5 require you to consider your exposure, then your hazard, to get to your result for the indicative environment risk. The level of your environment exposure is based on the environment exposure band for your introduction. These range from band 1 to band 4, with exposure band 1 having the lowest exposure to the environment, and band 4, the highest. You need to consider the criteria for these exposure bands in order to work out the environment exposure band for your introduction. Later slides will go through more detail about step 5.3, including the criteria for the exposure bands and how you work out which exposure band your introduction will be in.

The environment hazard bands range from hazard band D, for the highest hazards, down to hazard band A, for lower hazards. Later slides will describe more detail for step 5.4, including the hazards that are in each band, and explaining how to work out if your chemical has one of these hazards or not.

For step 5.5 you can then use the diagram shown on this slide to work out your indicative environment risk. Based on the exposure band for your introduction, and the hazard characteristics that your chemical does or does not have, you can then determine if your introduction is of very low, low, or medium to high indicative environment risk. More on this in later slides, but just to give you a simple example – if the environment exposure band for your introduction is 2, and you are able to show that your chemical does not have any of the hazard characteristics in hazard band D, the indicative environment risk of your introduction will be low.

There are also some special cases that may need to be considered after you get to your risk outcome here. These are cases where your introduction can't be very low risk, regardless of the outcome that you might have come to at step 5.5. It has to be medium to high, or low indicative environment risk. This applies if your chemical is an organotin chemical, a polyhalogenated organic chemical, a biocidal active, or if it's a chemical at the nanoscale where the introduction of the nanoscale portion of the chemical is incidental to the non-nanoscale portion of the chemical.

Slide 22

This slide summarises the criteria for each of the environment exposure bands. All introductions of chemicals that involve a designated kind of release into the environment will be in environment exposure band 4. More detail about what this is on the next slide. The other exposure bands depend on the environment categorisation volume, which is related to the annual introduction volume. Environment categorisation volume will be explained in more detail in later slides. So exposure to the environment increases as you move from band 1 to band 4.

Slide 23

Introductions that involve a designated kind of release into the environment will be in environment exposure band 4. A designated kind of release into the environment include intentional releases during use to land, biota, natural waterways, municipal water supplies and air (unless it's only for domestic or personal use). It also includes any releases to the environment from fire-fighting end uses and releases into the ocean.

Slide 24

There are 2 main methods that you can use to work out your environment categorisation volume. You can choose which one best suits your circumstances. More details on these methods are given in the Categorisation Guidelines. The first method is where your environment categorisation volume is just the same as your total annual introduction volume. Method 2 involves multiplying your introduction volume by a release reduction factor that is different depending on your chemical's end use.

Slide 25

The release reduction factors for some end use scenarios are shown in this table. The full list, including how we define each end use scenario, is in the Categorisation Guidelines. Note that only the values given in the Guidelines for your end use scenario can be used for the purpose of calculating your environment categorisation volume. The values range between 0 and 1. A low release reduction factor indicates that we expect that only a small portion of the introduction volume is likely to contribute to environmental exposure. A higher release reduction factor indicates that a higher proportion of the introduction volume could contribute to environment exposure. For example, most personal care products have a release reduction factor of 1, whereas adhesive and sealant products have a release reduction factor of 0.05.

Slide 26

With method 2 for calculating the environment categorisation volume, your introduction volume is multiplied by a release reduction factor relevant to your chemical's end use. If you use method 2 rather than method 1, your environment categorisation volume might be lower than your introduction volume. This could mean that your environment exposure band could be lower than it would otherwise have been, which in turn could result in a lower indicative environment risk and a lower overall introduction category.

Method 2 can vary depending on whether your introduction has only a single end use scenario, or multiple end use scenarios. If there is only one end use for your chemical, you just multiply your introduction volume by the relevant release reduction factor for your end use scenario.

Slide 27

For multiple end use scenarios, there are also 2 options. For option 1, use the release reduction factor that is the highest out of all of the end use scenarios for your chemical to calculate your environment categorisation volume. Note that the introduction volume for this calculation should still be the total annual introduction volume, and not just the volume for one of the end uses.

Slide 28

Option 2 with multiple end uses can be used if you know the introduction volume that will be allocated to each of your end uses. For each end use, calculate a separate environment categorisation volume using the release reduction factor for this end use, and the volume that you will be introducing for this end use. Do this for all of your end uses and then add all of them up to get your total environment categorisation volume. This method will result in a more refined environment categorisation volume. However, keep in mind that if you want to use this method, you'll need to keep track of your introduction volumes for each end use to make sure that your introduction category always remains correct.

Slide 29

This slide shows the hazard characteristics that are in each environment hazard band. In band D, the highest hazard band, there are hazard characteristics like persistent, bioaccumulative and toxic, and ozone depleting chemicals. The next highest is band C, where you find the hazard characteristics persistent and bioaccumulative, and very toxic to aquatic life. In hazard band B, there is toxic to aquatic life. The in the lowest hazard band, band A, there are hazard characteristics like bioaccumulation potential, harmful to aquatic life, polymers that don't have a low cationic density, and polymers that are not stable.

Slide 30

So now for more about step 5.4 where you need to work out what environment hazard characteristics your chemical does or does not have. For details about how to do this, refer to the Categorisation Guidelines. There are a few things to keep in mind about this process of considering the environment hazard characteristics. These are basically the same as for the equivalent human health step, which was step 4.4. Firstly, the requirements tend to differ

depending on your exposure band. This often means that the hazards you need to consider are different in one exposure band compared to another. For example, if you are in exposure band 3 and you want to show that your introduction has low indicative environment risk, you need to demonstrate that your chemical does not have any of the hazard characteristics in hazard band D and C. But if you are in exposure band 4 and you want to show that your introduction has low indicative environment risk, you would need to demonstrate that your chemical does not have any of the hazard characteristics in hazard band D, C **and** also none of those in hazard band B. The other way in which requirements might differ depending on exposure band is in terms of the type of information that can be used to demonstrate that your chemical does not have a certain hazard characteristic. For example, in environment exposure band 1, to demonstrate that your chemical is not persistent, bioaccumulative and toxic, known as PBT, you just need to check if it's on the list of chemicals with high hazards for categorisation. However, if you are in exposure band 4, you need more than just checking this list to prove that your chemical is not PBT. You might need a test result or an in silico prediction.

Another general principle is that you will need more hazard information to justify your chemical being of lower indicative risk. For example, if you are in exposure band 3, to get to low risk, you need to show that your chemical does not have any of the hazards in hazard band D and C, noting that it's not necessary to narrow down whether you would fall into band B, A, or the very lowest band, called 'Not A, B or C'. However, if you wanted to try to get to **very** low risk, you would also need to show that your chemical doesn't have any of the hazards in hazard bands B and A.

There are many options available for information about environment hazard characteristics. In the majority of cases, read across information can be used in place of information on the chemical itself, as long as the read across information is considered to be 'suitable'. You can refer to the Categorisation Guidelines for more details about how we define suitable read across information.

There are many in silico, in vitro and in vivo options that can be used, depending on the hazard characteristic and the exposure band you are in. There are also many information waivers available that mean it's not always necessary to have information from toxicity testing to be able to show that your chemical doesn't have a certain hazard. Instead, we recognise that some types of chemicals are unlikely to have certain hazards. For example, if your chemical is a high molecular weight polymer, in most cases it won't be necessary to have study results to prove that it is not toxic to aquatic life.

Slide 31

When considering the environment hazard characteristics of your chemical, first go to your exposure band, which you worked out in step 5.3. You start at the highest hazard band, hazard band D, and work your way down the hazard bands from there. You need to consider all of the hazards within each hazard band. If you happen to determine that your chemical has a certain hazard characteristic, this is where you would stop. For example, if you are in exposure band 2, and while you are considering the hazards in hazard band D, you discover that your chemical has the PBT hazard characteristic, there is no need to continue looking at the other hazards in hazard band D, and also no need to look at the hazards in lower hazard bands like C, B and A. Because it has a hazard in hazard band D, and it's in exposure band 2, this means that its indicative human health risk is medium to high.

Slide 32

As you work through each hazard characteristic within a hazard band, first consider whether your chemical meets the hazard characteristic definition. This consideration should be based on the existing hazard information that you have for your chemical. If it meets the definition, this means that your chemical has this hazard, and you can stop there. If your chemical does not meet the definition, next consider whether you can demonstrate that your chemical does not have the hazard characteristic. The Categorisation Guidelines have lots of options about how you might be able to do this. If you can prove that your chemical doesn't have this hazard, move on to the next hazard, working your way down. If you **can't** demonstrate that your chemical doesn't have this hazard, you have to stop there. The hazard that you stopped at, and the hazard band that it's in, will determine what the indicative environment risk of your introduction is.

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Finally for step 5.5, to work out your indicative environment risk, consider your exposure band, together with where your hazard considerations got you to. What hazards does your chemical have? What hazards were you able to show it doesn't have? And where does this place you in the diagram shown here in terms of your indicative environment risk – is it very low, low or medium to high?

If your introduction is in exposure band 1, and your chemical has a hazard characteristic in hazard band D, your indicative environment risk will be medium to high risk. If it's in exposure band 1 and your chemical does **not** have any of the hazards in hazard band D, your indicative environment risk will be low. You don't need to know which of hazard bands C, B, A, or 'Not A, B, C or D' does apply. It's enough just to know that hazard band D does not apply so this means it can have a low indicative environment risk. If you wanted to get to **very** low risk, you would also need to demonstrate that your chemical does not have any band C hazards.

If your introduction is in exposure band 2, and your chemical has a hazard characteristic in hazard band D, the indicative environment risk will be medium to high. If you're in exposure band 2 and do **not** have any hazards in hazard band D, the indicative environment risk will be low. Again, it's not necessary to narrow it down to the precise hazard band, it's enough to know that band D does not apply. If you wanted to get to very low risk, you also need to demonstrate that your chemical doesn't have any hazards in bands C and B.

If your introduction is in exposure band 3, and your chemical has a hazard in band D, or a hazard in band C the indicative environment risk will be medium to high. If it's in exposure band 3 and does **not** have any hazards in band D or C, this means your indicative environment risk can be low risk. If you wanted to try and see if you could get to **very** low risk, you also need to demonstrate that your chemical has none of the hazards in band B and none of the hazards in band A.

If your introduction is in exposure band 4, and your chemical has a hazard in band D, or C, or B, your indicative environment risk will be medium to high. If it's in exposure band 4 and does **not** have any hazards in band D, C, or B the indicative environment risk will be low risk. If you could also show that it doesn't have any hazards in band A, the indicative environment risk could be very low risk.

At the end of this process you should have your indicative environment risk outcome, and now you're ready to move onto step 6.

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Now we are up to step 6, where you will work out your final introduction category.

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Step 6 involves working out your introduction category of exempted, reported or assessed. To do this, you need to use your results from step 4 for human health, and step 5 for environment. Your introduction category will be based on which of these 2 gave you the highest indicative risk for your introduction. You can use the diagram here to help you.

If your indicative risk for either human health or environment or both of them is medium to high, your highest indicative risk is also medium to high. This means that your introduction category will be assessed. This is the case even if for one aspect you had an indicative risk of low or very low.

To be in the reported introduction category, either you would have a low indicative risk for both human health and environment; or you would have low for one and very low for the other.

To be in the exempted category, your indicative risk for both human health and the environment would need to be very low.

You've now completed your categorisation, and you should have your introduction category of exempted, reported or assessed.

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Thank you for joining us for this video taking you through steps 4, 5 and 6 of categorisation, where we worked through the indicative human health and environment risk of your introduction to get to your introduction category. Later videos will guide you through some examples of introduction scenarios and the process you would go through to get to your introduction category, based on the information that's available about your introduction. You can also find further information on our website, including guidance material and links to our legislation.