Alison

It started. There we go.

Janet Greenwood0:07
OK.
Thank you very much Alison, for agreeing to tell us about the findings on this draft update, which is potentially bringing in PBT and vPvB; and &PMT and vP??

Alison 0:22
VM.

Janet Greenwood 0:23

(vP) vM into the EU as allegedly EUH statements, but I think you found out some really interesting things so far, so I'm going to let you talk us through what these changes are.

Alison 0:36

Yeah. So I've been going through the draft Commission regulation.

Essentially that means that it's gonna be brought in as an ATP, and that's notable because it means that there won't be a full legislative procedure, so there won't be a full debate. It will just be brought in.

So the consultation at the moment is open for feedback and the consultation will be open for four weeks. So feedback will stop on the 18th of October (2022).

And if we look at the first two categories, which are four classifications that fall into two hazard classes. The first hazard class being PBT and vPvB, so persistent, bioaccumulative and toxic and very persistent, very bioaccumulative, and the second hazard class being PMT and vPvM so persistent, mobile and toxic and very persistent, very mobile.

Janet Greenwood1:43

Can I just ask a quick question there?

Alison1:45

Yes.

Janet Greenwood1:46

Which is PBT , vPvB. These are already in REACH and this is kind of porting them across as it into CLP?

Alison1:57

It's not a direct shift and lift, so the idea is that the basis for these classifications do come from existing legislation. So there's the annex in REACH that includes them there's also. precedence for them both in the plant Protection products regulation and from the BPR. (The Biocidal Product regulation). But they're not a direct shift and lift. The criteria have been expanded upon.

They're actually fairly well laid out in this new draft amendment, and so the criteria are very well structured.

It's almost in a checklist form so you can tick off.

Does it meet anyone of the following? Does it meet anyone of the of the next set? Does it meet any one of the Third Point? And if it meets all of those then it is classified as, so it's fairly well laid out.

It does require, particularly for the toxic part of the that classification…. there is a reliance on a previous classification under other CLP criteria.

So for it to meet the definition of toxic, it would have to be classified either as a category one carcinogen category or mutagen category one or two reprotox, a STOT repeated exposure one or two, or an endocrine disruptor, which we'll go on to discuss.

So there is a pre reliance on other sections of CLP classification.

Janet Greenwood3:41

Can I just pause a moment there? You're saying that PBT (and obviously not vPvB because that's the non hazardous version of PBT), but the T bit the toxic doesn't include acute toxicity?

Alison3:44

Yeah.
It does not. No.

The definition of toxic does not include acute toxicity classifications.
I think the idea is that it refers to chronic toxicity.

Janet Greenwood4:09

Yeah. Yeah. So you would have them as separate.

You can have something that's gonna be acutely toxic and also that, that that will be PBT potentially.

But the bit that triggers that would be these other long term hazards in the same way that you can, yeah, in the same way that you can have something that's acutely toxic, but it's also carcinogenic, for example.

Alison4:27

Yes, it would have to have a chronic toxicity classification to qualify it as a PMT or a PBT. If it just had an acute toxicity classification, it wouldn't qualify it for one of these classes.

Janet Greenwood4:35

Right.
And when we're talking about the environmental equivalent, which is PMT, (no sniggers at the back there, please, for native British speakers), which is (*also an acronym for*) premenstrual tension.

Janet Greenwood5:09

And with the long term the the non hazardous version for PMT, you'd have to have the chronic aquatic toxicity hazard already, would you?

Alison5:18

So this is interesting. The criteria for classification in these Environmental categories that we're talking about here, there are checkbox criteria.

For example, it must have a. (just my notes and get this correct for you):

When you're talking about persistence, it must either have a degradation half life in marine water over 60 days, or, for example, a degradation half life in freshwater sediment of over 120 days.

So these are direct checkbox. Yes, it meets this. Yes, it meets this.

However, it does have these qualifying phrases whereby it says that you should use all relevant and available data and use a weight of evidence approach, particularly because as we know, not all criteria can be applied directly to all available information, because substance is different and what you can and can't test for differ based on the substance that you have.

So when it comes to the availability of long term chronic test data, you don't always have that available on your substance.

So there are these additional information criteria which are listed which you can go on to include in a weight of evidence approach.

And one of those is that you can use aquatic short term test data, so aquatic acute test data.
If there is no long term, so chronic aquatic test data available, so it's one of these secondary sources of data.

Janet Greenwood6:55
And we're entirely used to that because we do exactly the same thing with chronic (*aquatic toxicity under GHS and CLP*). If there's no chronic data, then we can classify on the basis of acute for aquatic environment.
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Everything sounds very logical so far.

Alison7:14

Yes. And I would say that's the case for for both of these hazard classes. The criteria for classification are very logical.

It says, you know, apply a weight of evidence approach, give the appropriate weighting based on the quality of the data that's available.

Similarly, classification for mixtures is very simple. There's one threshold threshold percentage. It's the same threshold whether you've got a solid liquid or a gas.

The only thing that is anomalous that does stand out is there are no bridging principles permitted for either of these hazard classes.

To me, it's not just that they've missed it because when we go on to talk about the endocrine disrupting classes that are included in this draft Commission, Reg, they've given bridging principles for those.

So it does seem odd that there are no bridging principles for these hazard classes. Environmental bridging principles are present for other hazard classes, so it seems strange that they're not present for these.

Janet Greenwood8:20

That's interesting. It's almost as if the regulators don't have confidence in these new hazard classes if they're requiring data. And of course, in terms of PBT.
That could mean that extra animal testing required potentially.

Alison8:38

It it's one thing that does stand out to me. I would have expected some bridging principles to be permitted, even if it's simply interpolation between two hazard classes, something like that.

Janet Greenwood8:49

Yeah, you would expect some of the the blindingly obvious ones, like if you've got a more concentrated mixture than is already classified you assume that it's classified in the same way. But hmm, interesting, interesting.

Now I've got another question for you, which is are these being brought in as hazard statements yet or are they currently EUH statements?

Alison9:15

So this is particularly interesting.

The phrases themselves are prefixed EUH, however.

They have precautionary statements, they have signal words and the amendments themselves are being made to annex one of CLP.

And where the amendment is being made in.... let me get you the correct annex here.

Where the amendment is being made in Annex three (and Annex 3 for those who aren't 100% sure, are the tables where they literally list all of the hazard phrases, the precautionary phrases, the EUH phrases). Where Annex three is being amended, they are inserting these phrases into the hazard statement tables, not the EUH statement tables. They're putting them in the H statement tables.

So whilst they may be prefixed EUA, to all intents and purposes they are being treated like H statements, so there's no amendment whatsoever to Annex 2 where the rest of the EUH statements live. These are being inserted in Annex 1 and in the table in Annex 3 where H Statements live.

Janet Greenwood10:44

So in effect, what that's telling us Is that the regulators in the EC are steamrollering this through because they are treating them as if they're ordinary hazard statements that have come out of GHS.

And that, to me is a bit of a marker that they're likely to give them the same legal weight. They're not just treating them as labelling statements.

They're saying that even though they've got the EUH prefix at the moment, they're going to give them the same legal weight as a GHS hazard statement and they are going to basically insist that industry goes along with them from the time at which it all comes in.

Am I right in thinking that?

Alison11:33

Legally speaking, because of way they were placed in the legislation, they have the exact same waiting as any other hazard statement. So any other section of Annex one, any other classification, they've got the same weighting.

Now the best case scenario for the regulators is that GHS would adopt them in exactly the same manner and the only amendment they would change would be to strike off the EU at the front of the EUH. So it would (*be if*) the UN would give them the same H statement, and they were just word for word adopt the same amendment that would be ideal for the regulators. I don't know if that that's probably unlikely. I think they have to make several amendments, but we'll see.

Janet Greenwood12:15

What the the state of play at the moment, of course ss that the EU have taken these new PBT and PMT hazard classes along with the endocrine disruptors, to the UN committee, which I think is it Switzerland that sits in?

Alison12:33

I'd have to check.

Janet Greenwood12:33

The UNECE GHS committee with what in sales terms, we would call a "presumptive close", which is "OK, how would you like to pay for this?"

Alison12:47

Yeah, it's very. It's very much "This is what we're doing. I assume you'll do the same", yeah.

Janet Greenwood12:47

Exactly. That's the the "presumptive close"

So we've got., as one part of this proposal that's come from from the EU, we've got these PBT, vPvB and PMT and

Alison13:07
vPvM.

Janet Greenwood13:08
The, the vPvM, yes. (We'll get our heads round it soon enough).

And they're behaving like hazard classes.

But there was one thing that I think I missed when you were describing what happened.

Do any of these new hazard classes have any pictograms associated with them?

Alison13:14

Yeah. They do not have pictograms,

So what you have is you have the EUH phrase. You have a signal word, you have P phrases. So the only thing they are missing is the pictogram themselves. It doesn't have a pictogram.

Janet Greenwood13:41
That's really interesting, but of course we know that some GHS hazard statements don't have a pictogram either.

Now the only kind of analogue to what the CR bringing in is the situation where we've got corrosive materials that may acquire the corrosive to the respiratory tract, EUH statement EUH 071 is it.

Alison14:04
Yes, 70th toxic to the eye,-71, corrosive to respiratory tract

Janet Greenwood14:04
And that one, if it is by basically by human experience, corrosive to the respiratory tract and it doesn't already have the corrosive symbol, you can apply that corrosive symbol.

But as we discussed earlier, when we were thinking about all of this, it's highly unlikely that you've got something that's only corrosive to the respiratory tract.

Usually it's gonna be corrosive to skin or especially to eyes. So it's very rare that you're actually going to apply that pictogram, when it doesn't already exist, but in that case, sorry, on you go.

Alison14:41

In reality, in reality you would only consider a corrosive jurisdiction direct classification if the product is already corrosive to either eyes or skin. So you realistically you've already got that hazard pictogram applied to the product.

Janet Greenwood14:51

Yeah. So, but, but when we're thinking about EUH statements that attract other things, that (*EUH071*) does not have a signal word and it does not have any P statements.

So it's kind of just a, it's almost like an insurance policy just in case somebody comes across something and goes, you know what it's supposed just to be irritating, but I think it's corrosive. Therefore, I'm going to slap it (*the pictogram*) on just to be absolutely sure.

Whereas what we have now is we have just like any other hazard statement we have "This is the classification and out of that then drops no pictogram, we know, but we also have the signal word and we have the P statements" and like any other P statements, they'll go into the pot of P statements and you'll choose the most appropriate ones.

Alison15:42

Yeah, I think we're very lucky in this instance that they haven't assigned a pictogram because, as it stands right now, products which have an environmental pictogram are also hazardous for transport.

So if they had assigned any additional hazard classes which required an environmental pictogram, that would make it difficult for people.

Janet Greenwood16:06

I think as well one of the questions we get from time to time at TT environmental is people are like what's the difference between the the GHS hazards and the transport hazards and we've got quite a neat little diagram that shows the GHS hazards that are within transport.

And when you look at it in diagram form, it's blindingly obvious that what Transport is interested in is, first of all, all of the physical hazards. But in terms of health, it's only the immediate health hazards. None of the long term health hazards are Included and it's only the high level long term aquatic toxicity hazards that are included.

So you can see why they wouldn't want to give it again.

They wouldn't want to give it a pictogram because they're not the kind of hazards that transport of dangerous goods is interested in, which is how is this gonna hurt people if there's an in transit problem, which is the people who have to deal with the clean up, the people who move it, and the people who are unfortunate enough to be nearby when an incident happens.

Alison17:08

Yeah.

Janet Greenwood17:08

Umm so. So we covered kind of the first part of it, which is in a way it's like the the less contentious part of all of this, isn't it?

Alison17:17

Yes, I certainly think that's gonna be. the easier classifications to address, primarily because the criteria are much more clean cut, so much more easier to apply.

Janet Greenwood17:29

Uh. And they've been brought across, as you said, right at the start from existing regulations.

Alison17:34
Yes.

Janet Greenwood17:35

So that's the that's the tick for the easy bit. Do you want to dive into the bit we're all worried about, which is our friends, endocrine disruptors.

Alison17:44

Endocrine disrupting substances, yes. So again.
These are in a similar way, they're being brought in as technically EUH phrases, but again, they're being inserted into the table of hazard statements and they have precautionary statements and a signal word. No pictogram but precautionary statements and a signal word.

Janet Greenwood18:12

Sorry. That's a phone call or for me.

Alison18:21

That's alright, Janet. Would you like to pause?

Janet Greenwood18:22

So we ‘ll pause and come back if that's OK.

Alison18:30

Yes, we'll do a Part 2. Thank you.

Janet Greenwood18:31

Thank you.