CLP Q A session HSE DEFRA Meeting 20 01 21

Chair: Lawrence Hodgson

Panellists: Francis McGuigan; Andrea Caiten

Contents

Introduction

[Lawrence Hodgson] Well welcome everyone and good afternoon. This is the HSE and I'll be chairing this session... If you have a really urgent question that we're not able to answer today...having said that and I'm hoping the panel are sitting comfortably, I'll kick off.

ATPs and MCLs

[Lawrence] I've got a question on ATPs and MCLs as well...

[Andrea Caiten] Shall I take that one... later in 2021, sorry in 2022 respectively as these are retained pieces of EU law. I understand that there may have been some confusion with the way in which the information has been presented in the Mandatory Classification & Labelling list and we

hope to be able to provide some clarity on that, just to make sure that there's no further confusion.

But the latest dates of compliance are the same as those in the text of the ATPs as published and amended.

[Lawrence] Thank you very much for clearing that up Andrea and as you said, I think we are due to update this and dispelling any confusion there by, by updating the messages we provide on the website.

New Labelling for GB Addresses

I guess similar theme here about the Transitional Arrangements of moving into the new system. Is there any transition period for the labelling of a GB address and telephone number on the packaging of a hazardous substance or mixture? I don't know if anyone will be able to speak to answer that? So is there a transitional period for updating labels for a GB address?

[Andrea] There isn't a transitional period as such; we didn't build in any transitional arrangements into the CLP regulation. However if a substance or mixture has already been placed on the market before the end of the transition period, there is a period of time to allow for changes to be made and the substance or mixture can be supplied through the supply chain, as it currently is labelled. So there is that arrangement for those goods already placed on the market, if that helps to clarify that particular aspect.

Exporting goods to the EU

[Lawrence] I've got a question on exporting goods to the EU.

So taking the example of a GB based supplier here, what do we need to do to export our goods into the EU, with regards to labels and EU supplier contact details? And who actually has the obligations to comply here, is it us in GB or is it the EU based importer?

[Francis McGuigan] I'm happy to take this question, just to say that the person who actually has the obligations to comply in the EU, will be the EU-based customer and importer. The ECHA guidance that's been published has been very clear about those particular requirements. So in terms of what a GB based supplier might need to do in terms of exporting goods into the EU and with regards to the labels, what they will need to do is to speak to their EU supplier and find out from them what information they need and they will require for them to meet their obligations in terms of the EU CLP regulation and other chemicals regulations. Is there anything you want to add Andrea?

[Andrea] No I think you've said everything there Francis thank you.

Selling into the EU market

[Lawrence] Okay then. Similar question then about selling into the EU market, if one sells a hazardous products to GB and EU markets, can the GB and EU addresses be mentioned on both the product label and the SDS? Can the same addresses be used for both GB purposes and EU purposes?

[Andrea] Yeah, as I said in the presentation or in the Q&A after the presentation- For supplying Great Britain, there has to be a GB based supplier on the label, and for supply in the EU there has to be an EU based supplier on the label. It is possible to include on the GB label the address of an additional supplier in the supplemental information labelling section of the label and as I said, the information should be for somebody who can provide information on the substance or the mixture if it's required. There should be that agreement within the supply chain that it's okay to do that.

[Lawrence] Thank you Andrea and just to remind everyone, we've got about another 20 minutes and we're running up to 12.50, so please do make use this time to submit questions if you have them and we'll see what we can get through here.

Hazards not listed under the MCL

I'm just going to take one out of the ones that are coming through from the Skype Q&A and apologies that wasn't in the previous presentation but I think it follows on from some comments you made Andrea, which...was about adding in hazards not listed under the MCL, for MCL liable substances so we use a more severe classification than the MCL, if there is new data available for example, under REACH?

Suggesting this, as providing new information on hazards as they come to light, is a requirement under the Health and Safety of Work Act?

[Andrea] For the Mandatory Classification& Labelling, as I said the entry which is in the Mandatory Classification & Labelling List has to be applied as it's written there in. If there's information to show that an additional hazard class or category or differentiation is appropriate, that additional hazard can be added to the classification. If there is information to suggest that the existing mandatory Classification & Labelling is incorrect, whether that should be more severe or less severe, then that has to be dealt with by submitting the information to us and we would then have to make an amendment to the entry in the Mandatory Classification & Labelling List.

Anybody who is familiar with the way things operated in the harmonized system within the EU, that was how things used to operate- it's a similar process, same process now. Would you add anything to that Francis?

[Francis] No I don't think so, I think you've covered the answer there.

Scrutinising RAC Opinions

[Lawrence] So reading back and forth between the different questions we've had submitted and this question, I think is around the scrutinising RAC (Committee for Risk Assessment) opinions in the GB system.

Has there been an official body within HSE or DEFRA (but I think the HSE is the present organisation here), already established to scrutinise EU RAC opinions?

Would it be possible to receive any information on the Terms of Reference for this group?

I guess in the GB system, how will we go about scrutinising RAC opinions and is there any information to share on that process?

[Andrea] Yes. We don't have any intentions to set up a separate body per se or you know, to recreate something such as the an equivalent of the Risk Assessment committee within Great Britain, so the way in which the process will work is that a Technical Report / a Technical Assessment of the RAC opinion will be generated by HSE's scientists that will go through our own Internal scrutiny and assessment. That Technical Report will then be made publicly available for people to view.

There will then be a separate policy process to generate and consider the Technical Report and any further information, before a final agency opinion is generated on the overall RAC opinion.

Again, Francis would you add anything to that with regards to the policy aspects?

[Francis] Yes, thanks very much indeed. The important thing to underline is that it's a full Public Consultation and they will be, as I say, using the HSE Citizen Space, there will be opportunity for people to provide their comments initially on the GB Mandatory Classification & Labelling proposal and of course, that will reflect as well questions around the scientific side, what the Impact and Policy Assessment that we will be providing on each substance.

We'll look at a variety of issues, including what the, as it were, the consequences are, as well as the supply and use profile of the substances provided and whether any litigation may be needed. That will be considered as part of that Impact and Policy Assessment that will be carried out as part of the opinion and that will be the basis as it were. The combination of the Technical Report plus this Impact and Policy Assessment would be the basis on which the Minister and the Devolved Administrations in respect of the Great Britain mandatory Classification & Labelling proposal.

EU and the Labelling and Addresses requirements

[Lawrence] I've got a couple more questions that might have been prompted by the earlier discussion, about exporting to the EU and the Labelling requirements and addresses and such.

I may have already answered them but I'll put them back out there, so if we're an existing GB manufacturer but exporting to the EU and we put two addresses on existing labels, do we need to notify HSE about these changes, so do we need to tell HSE that we're using two addresses?

[Andrea] No there's no requirement to notify us that the information they're putting on the label. The only requirements to notify us come under the notification requirements are part of Article 40 of CLP, so there's no separate requirement to notify us about the addresses on their labels.

[Francis] I completely agree Andrea, just an important point again is that, the GB manufacturer that's exporting a product to the EU has no responsibilities in respect of the EU CLP regulation or the Notification Requirements are under Article 40.

But again, what you may need to do is speak to the person that you're exporting to, the person who's going to be responsible for meeting those requirements and to make sure that they take those into account when they're putting them together. You may need to provide a wider amount of information because of course, they will have responsibilities in terms of notification and to do so, they will need to have evidence or information from you, in terms of the substance that you're exporting or placing on the market.

Only Representative declared as GB importer on the labelling

[Lawrence] Similar question and I hope this makes sense; will the GB importer mentioned on the labelling be the Only Representative? Is that worded in a way that it makes sense?

[Andrea] It does make sense yes. You can answer that one if you want to.

[Francis] Okay thank you. I think the important thing to remember here is first of all is that there are no Only Representatives in respect to the CLP regulation.

The Only Representative only appears in respect of the requirements of REACH. Effectively it means that the duty holders, that's the manufacturers, importers and downstream users will have responsibilities under the CLP regulation and effectively again, the responsibility for meeting the requirements in respect of a requirement in terms of labelling.

It will be the GB import is the person who has a responsibility under the CLP regulation and that's why their name and their telephone number will appear in the notification under Article 40 of the regulation. I'm trying to think there's anything else I need to add. Andrea, is there anything you want to add?

[Andrea] No I don't think so, as you say Only Representative is a term that is used in REACH and the Only Representative is a nicely defined term under CLP so they don't actually have any official roles under CLP as Francis said. So it's the duties rest with the manufacturers, importers, downstream users etc.

Whose responsibility is it to register mixtures with ECHA

[Lawrence] I think this is a question on CLP but it might be on REACH terms because it mentions registering and they might mean notifying.

The question is:- Our customers in the EU are saying it's our responsibility to register our mixtures with ECHA, how do we achieve this, with us not being an EU entity?

Is that more of a REACH question or is that CLP or notifying?

[Andrea] It's possibly could mean a number of things, because it refers to mixtures, whether it's actually referring to the requirement to submit information to Poison Centres. Well it strikes me as referring to, in terms of those obligations as I said earlier, in the presentation in Great Britain. I know that wasn't the question but in Great Britain, we haven't retained Annex 8 and so the requirements are different. We no longer have access to the ECHA notification portal and all that kind of stuff.

In regards to Goods that are going into the EU, it is getting the EU importer who is responsible for any activity required as part of the EU regulation now in order to achieve that they may well need assistance from the GB based exporters, so it might be that they need to supply their EU counterparts with information.

But in terms of where the actual duty rests, it rests as I understand it, with the EU based importer.

[Francis] Yes completely, I certainly agree. One additional point of course is that, it is not possible for a UK based company to actually access the ECHA Poison Centre notification portal so it wouldn't be possible for them to do it in the first place.

But the duty and responsibility, which of course came in on the first of January 2021, is they rest with the EU based importer.

Poison Centres in a GB context

[Lawrence] Thank you Francis. I've got a follow-up question on poison centres, but in the GB context:-

Could you please clarify if it is mandatory to apply for an Article 45 mixture notification in GB or if it is on a voluntary basis?

[Francis] I'm happy to answer that question. The answer is it's a voluntary requirement in terms of, notifying details of mixtures but again, the responsibility for making that voluntary notification of the using the Safety Data Sheet to the National Poisons Information Service will be the responsibility of the GB based importer...

Within Great Britain we would certainly encourage everyone to send the information to the National Poisons Information Service, because this information can be used for the purposes of Emergency Response and also for providing information in terms of, developing policy in relation to mixtures.

But again, I think the important thing to say it's not a mandatory requirement in Great Britain, but in Northern Ireland, where the EU CLP regulation applies, it is a mandatory requirement as a result of Annex 8 which came in on the First, which entered into force as well before that, but applies from the first of January 2021.

Is there anything you want to add Andrea?

[Andrea] No I don't think so, as you said, I think we would encourage people to submit information within Great Britain to the National Poison Information Service, the requirement itself is relatively straightforward, it can just be the submission of a Safety Data Sheet so it's not the compilation of lots of different information.

I think it's something we would encourage, but as Francis said, it's not mandatory.

Precautionary Codes

[Lawrence] Thanks. I've got a question on Precautionary Codes:- Will we need to use Precautionary Codes in GB CLP as they are used in EU CLP?

[Andrea] Yes, the Precautionary Statements will continue to apply and the basic guidance requirements for the application of all of the labelling elements will remain the same, as it did in the EU system. So Precautionary Statements will continue to be used, Precautionary Statements aren't part of like the Mandatory Classification Labelling requirements and it is pretty much the responsibility of the supplier to determine that the appropriate Precautionary Statements to apply to their labels.

[Lawrence] Brilliant thanks and just a reminder, we're running into the last five minutes here but please keep submitting your questions because what's not answered here we will be taking it away.

Grouping GB CLP Notifications

[Lawrence] Can we group GB CLP notifications for products with the same hazard classification and labelling, is that possible?

[Andrea] Technically no, notifications have to be submitted for individual substances, so if the individual substance is within the scope of the notification requirements, then the individual substance has to be notified.

Notification applies to substances which are classified as hazardous and which are placed on the market by themselves or as part of a mixture, where they contribute to the classification of the mixture or whether, subject to registration under REACH, but as I said earlier where something is registered under REACH there is no requirement to submit a separate notification, notification has to be approached on a substance by substance basis.

Safety Data Sheets

[Lawrence] Got a question on Safety Data Sheets, has the content changed for Safety Data Sheets with the transition to GB CLP and UK REACH, are they the same?

[Andrea] Safety sheets are part of the REACH regulation so I think we're limited in what we can say. I think that would have to be directed to the REACH help desk specifically for specific information on the exact changes to Safety Data Sheets.

Duty to Notify

[Lawrence] Going back a step to the notification process, the data notifiers for example, to notify a change of classification to HSE have to be based in GB?

[Andrea] Well the actual duty to notify only applies to GB based manufacturers and importers and Northern Ireland based suppliers, who are directly placing qualifying Northern Ireland goods onto the GB market, so they are the actual duty holders who are responsible for submitting the information.

I suppose technically, someone could submit the notification for them but they do still remain legally responsible for the information submitted and have the duty to notify. Would you agree Francis on that one?

[Francis] Yes, I certainly agree with what you said. I think the most important thing to kind of point out is that, the reason why we have this duty is that the GB based employer that notifies the information on the substance to the CLP notification database. The purpose of this is to ensure uh that we continue to protect Human Health and the Environment... Especially as it's more likely to be a more severe hazard classification.

It's important that, that information is distributed and made available, not just in terms of as it were, to the regulator, but also in terms of what appears on the actual labels themselves.

So again it would be very very difficult I think, for somebody that was outside of Great Britain to be able to respond with sufficient speed in terms of being able to reply to that, making sure that they have that responsibility to keep the information about the hazard up to date.

HSE scientific assessment of RAC opinions

[Lawrence] Now, in the earlier discussion there was mention of the RAC opinions and how HSE will scrutinise those, I think that prompted a sort of follow-up question here which is:-

Will there be a formal public consultation on the HSE scientific assessment of RAC opinions?

Would either you be able to comment on that?

[Andrea] Not routinely, there is a public consultation step during the RAC opinion development stage itself and so we haven't envisaged having a separate routine public consultation, as part of the GB process. But as I said, there will be other opportunities to input and to contribute as part of the policy assessment and that side of things, but not a direct public consultation.

[Lawrence] For products placed on the market prior to the end of the transition period, what period of time is allowed for making changes to the CLP information provided on a product label in terms of EU and GB contact details?

What is the transitional arrangement’s here for moving into the new system post exit for updating the information for products, that were already on the market before that change?

[Andrea] So the product was already on the market before the end of the transition period and it was labelled accordingly, at that time. Then that can continue to be supplied through the supply chain, I believe, until the end of the supply chain.

However if changes need to be made to the label or there's a difference between the classification, the Mandatory Classification & Labelling during that time, then updates would need to be made sooner to those labels.

[Francis] I just confirmed that this is covered under the Withdrawal Agreement, which allows it and applies not just to products manufactured in the United Kingdom but also to products in the EU.

If it's been placed on the market before the end of the transition period, it still has this time as it were, to go through the supply chain and reach its end user.

Session Close

[Lawrence] Brilliant so I'm just conscious of time here, so I want to say thank you to both Andrea and Francis for this session and for answering so many questions!

As I mentioned, questions we haven't answered, we will be taking away and we will be updating our guidance, our e-bulletins and whatnot, where there are gaps that clearly have been identified here.

I'd just like to point attendees, if you switch back over to the main room, I think there's just going to be a roundup now with the Director of CRD Richard Daniels to summarise the day.

Just to say again, thank you to our Panellists and thank you to those attending- this session has now come to a close, so thanks.