

# REACH Q A session HSE DEFRA Meeting 20 01 21

**Chair:** Lawrence Hodgson

**Panellists:** Alun Williams; Keith Bailey; Gary Dougherty

## Contents

Introduction.....	1
Grandfathering a EU REACH Registration for UK REACH purposes.....	2
DUINS only applying to imports from EU .....	3
Legal binding aspect to submitting a DUIN .....	3
HSE confirmation after DUIN submission.....	3
Substance of Very High Concern.....	4
IUCLID dossiers .....	4
Registration Fees.....	5
New Registration Fees.....	5
Grandfathering Case Study .....	5
Only Representative Guidance.....	6
Grandfathering .....	6
CAS numbers .....	6
SIEFs .....	7
Consortia approach to substance registration .....	7
Exempt Substances.....	8
'Let's get started with UK REACH' .....	8
DUINS.....	9
Batch Submission of DUINS .....	9
Importing substances after October .....	10
Registering New DUINS.....	10
New importers of Formulations.....	11
Session Close.....	11

## Introduction

[Lawrence Hodgson] You can keep submitting questions to the question and answer function in this room and I do encourage you to keep submitting your questions. If we can't get through them today, we will be taking them away and working on our websites and e-bulletins to cover any gaps that we haven't covered through the question and answer session today. We won't be responding directly to the questions we take away so I just want to remind you, if you have an urgent

## REACH Q A session HSE DEFRA Meeting 20 01 21

question please contact the help desk or helpline and you can see the details there on the screen, to note down.

So having said all that, if our panel is comfortable and ready, I will start and start asking working our way through some of these questions that have been submitted.

### Grandfathering a EU REACH Registration for UK REACH purposes

[Lawrence] First question to go is on grandfathering of registrations: - If a UK-based company decides to grandfather an EU REACH registration for UK REACH purposes, what happens to the EU REACH registration?

Does the company lose this EU REACH registration after the grandfathering final process?

Can I invite someone from the panel to answer that?

[Alun Williams] I can start us off if you like, it might simply be that I'd slightly misunderstood the question, but ultimately what should have happened here anyway is that the registration should have transferred their GB... registration...

...they need to have a registration... on UK REACH and then 2 different registrations, so the one that has been transferred does still exist...so the registration isn't lost in the process there but I suppose I'm really keen to open that to the panel if anyone disagrees with that really? It might be just my interpretation of the question.

[Keith Bailey] Alan, you're completely right, there are two separate systems, so by grandfathering into the UK system you don't lose the EU one but as you say, it was essential that, that was transferred into the EU system at the end of the transition period.

[Alun Williams] Thank you very much Keith.

[Gary Dougherty] Keith and Alan, it's worth pointing out as well that, not all UK registrations are eligible to be transferred, if you're a UK based manufacturer, you can transfer your registration to an OR that you appoint in the EU. If you're an OR...in the UK you can transfer to the OR in the EU.

If you're an importer only in the UK transferring your registration to OR is not so easy, you have to have some sort of asset transfer, that could be some form of exclusivity contract, but as long as there's an asset transfer ECHA will accept that transfer and the registration.

Did you mention before Alan, that ECHA have extended the UK window to be able to do this? To account for 'we didn't know what trade deal we were going to have'. There's still an opportunity to transfer registrations if you're a UK company.

[Alan] Yeah thanks very much Gary and yes indeed, I did cover that very briefly on the presentation.

It's also worth flagging that ECHA did produce a really good piece of guidance about how people can do this from an operational perspective. Also as you flag there, the very different scenarios of which they can transfer that registration and that is very much on the ECHA website at the moment.

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

I strongly recommend someone doing that, because they don't have to look but yeah absolutely, I think the deadline has been extended to March.

### **DUINS only applying to imports from EU**

[Lawrence] Excellent thank you. If I move on to the next question, I've got one on DUINs here. There's a few so we might have a few questions on this, but the first one is:-

Does the DUIN only apply to imports from the EU, EEA and not the rest of the world?

[Keith] Yes it does. Imports from the rest of the world... (Indecipherable)...

[Lawrence] I think you might have just lost your sound there Keith. Will either Gary or Alun just to come in?

[Garry] Keith's sounds off. Yes the 'DUIN process' to qualify as a downstream user, you have to be importing from an EEA or EU 27 supplier and that could be any supplier from inside the EU.

The import has to have taken place before the end of the transition periods.

### **Legal binding aspect to submitting a DUIN**

[Lawrence] So a follow-up question is there: - Any legal binding aspect to submitting a DUIN?

Are you obliged to register afterwards or is it just a notification of interest?

[Gary] It's not a notification of interest because, formally, you've become an importer since we left the EU, you're no longer the downstream user and so formally you have a registration obligation.

So if you fail to submit a DUIN, you still have that registration obligation and so it's not just the registration of interest it actually allows you to defer that registration duty.

However if in the period that you're allowed to defer, your supply chain changes, it ceases or some other reason and at the time that you would need to register, you're no longer an importer. Then no, you wouldn't need to go on to register. But it's not just an expression of interest; let's say it's a legal responsibility to allow you to fair registration.

### **HSE confirmation after DUIN submission**

[Lawrence] There's another DUIN related question, I think it follows on from that.

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

Is there a confirmation from HSE sent after the submission of the DUIN?

Such as the generation of a DUIN number and sending requested information to HSE. Is the DUIN number generated in the IT system, comply with UK REACH?

Is that the proof of compliance and submission?

[Gary] The IT system does generate a DUIN submission number and that will be provided by the compliant UK REACH IT system. The follow-up, where you send us an email with the spreadsheet, the two-stage process was developed in consultation with industry because the one that was developed initially was actually quite cumbersome, so this one turned out to be better.

We haven't set up automatic acknowledgements of that yet because it's an email process and there are some issues with automatic sponsors but I think we will look to send a confirmation that, yes you submitted your dossier, but not that we've necessarily checked that everything in it is right.

### **Substance of Very High Concern**

[Lawrence] Okay. If I change the theme then, if we move on. There's a question on Substance of Very High Concern. I see no reference to SVHCs as currently run by ECHA, with a candidate list of substances. Is it envisaged that there will be such a list?

Is there anyone on the panel that could pick that up?

[Keith] I think that might still be an issue ... Possibly, we'll pause that question for now until the sound's working.

[Gary] I can answer that...When we transposed EU REACH across; we carry over the SVHC list as it's stood at the end of the transition period. So the SVHC list on the 31st of December is carried over as a UK SVH list and any future additions to it, will be decided by the UK.

### **IUCLID dossiers**

[Lawrence] Moving on then. I guess another sort of technical question here on IUCLID dossiers: -

Is it possible to complete the grandfathering process without a IUCLID Dossier .i6z file?

[Gary] Simple answers no.

[Alun] Apologies if I'm still cutting in and out, you do actually need one because that's why how it works with the IT system, if people look at the screenshots provided earlier, you'll notice there's a key step in there where you need to provide IUCLID dossier...(indecipherable)

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

### **Registration Fees**

[Lawrence] Okay thank you. We've got a couple of questions on Fees as well: -

Is it correct that there is no fee for registering a grandfathered registration unless it is a higher tonnage band?

[Gary] The registration that you grandfather over should be the registration that you had in the EU at the time that you left. So I'm not sure how you end up being a higher tonnage band after you've left the EU than before it was it's an overnight change.

### **New Registration Fees**

[Lawrence] So if I rephrase that because there's a similar question: - Do we have any information on fees for registering under grandfather rights and new registrants for UK REACH?

[Gary] The grandfathering process is that, you grandfathered the registration that you had at the time of exit so that should be at the same tonnage that you had in the EU.

There is no fee for grandfathering. If you subsequently changed tonnage band, yes you would have to pay a tonnage band upgrade fee. You'd have the new data requirements that would apply.

The fees are all within the statutory instruments and we've converted the figures in Euros into Pounds based on a conversion rate, set at a particular date but all the fees being carried over are currently the same, because they were legally part of the legislation so we have to carry them over as retained law.

[Alun] Thanks very much Gary, and also again you're absolutely right in the legislation and it is also of course, on the HSE website. So if people want to go and have a look at those in detail, yeah, please do so.

### **Grandfathering Case Study**

[Lawrence] We'll sticking with then mechanics around grandfathering then, we've got a sort of a worked example or a case study. See if you can answer this: -

As an example a US company used a UK legal entity as an Only representative for EU REACH, now after Brexit they moved to an EU legal entity so now we have to appoint a UK legal entity for UK REACH and to use the grandfathering, are we obliged to use our former Only representative or can we appoint a new one?

It's the case study question, so to comply with grandfathering, do they have to use the same Only representative that they had previously or are they okay to use a new Only representative, and still have the ability to grandfather their registration across? (Indecipherable).

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

[Gary] Yeah I think legally the grandfathering rights lie with the the company that held the registration at the point of exit and if there's a subsequent change then that has to be through a legal entity transfer.

[Alun] And of course we should also be clear as well...(indecipherable).

### **Only Representative Guidance**

[Lawrence] So following on from that, Will there be detailed guidance on how to prepare the account as an Only Representative and how the parent and child relation is going to work?

[Alun] Yes. All that guidance does exist.

### **Grandfathering**

[Lawrence] Brilliant thank you Alun. So more questions on grand fathering then.

So for grandfathering, are you expecting submission of the EU REACH dossiers or new dossier to be created for UK REACH?

Are you expecting the dossier that was used previously or are you expecting a new one to be created?

[Gary] The dossiers should be the same and it's the same template that's being used in the UK System because currently, the information requirements are the same, so yes the dossier that you submitted to ECHA, should be the same.

And if you were a Lead or a Member then that should cover the information requirements that you have so your old IUCLID dossier should be fine.

Which is why we chose to stick with our IUCLID submission format, because companies already have IUCLID dossiers.

### **CAS numbers**

[Lawrence] Okay brilliant. I think this might be more of a technical question again. It's on CAS numbers.

It's a REACH inquiry: -

Is it possible to do an inquiry for a new immediate substance that does not have a CAS number or does a CAS number have to be obtained first?

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

[Gary] The simple answer is yes. It's possible to do an inquiry without a CAS number and there are lots of chemicals that don't have CAS numbers especially when they're newly formed.

So a new intermediate substance may never have a CAS number, because it may never be in the published literature.

[Alun] Would this be the same guidance under the Article 26 inquiry, guidance on HSC website at the moment?

[Gary] I can't remember if it's on the guidance at the moment but it's always been the case.

Under EU REACH, it was always the case that you could register substances that didn't have a CAS number. It's a common occurrence you know ECHA has got like 14 million chemicals with CAS numbers but you know, chemistry moves on and people make new things that didn't exist before.

[Alun] ...4,000 new entries a day apparently....

### **SIEFs**

[Lawrence] New question then: - Can you say something about the process whereby substances are grouped for joint registration, in other words, what's the process analogous to the these SIEFs or SIEFs formation stage in the early days of EU REACH?

[Gary] The process is effectively analogous to the SIEF process in REACH and within the compliant UK REACH IT system, there will be what's called substance groups and anyone who grandfathered the registration will be in the substance group and those people who've submitted successful Article 26 inquiries will be members of the substance group.

[Gary] People who submit downstream user import notifications won't automatically be part of that group and that's an acknowledgement that downstream users may not currently have the correct information and so rather than have substance groups listed with people who may never register or who've misidentified the chemicals in the products they import they don't get automatically entered into the substance groups, and would need to submit an article 26 inquiry when they've worked out exactly what substances they do import and which ones they need to register.

### **Consortia approach to substance registration**

[Lawrence] So I think there's possibly, similar questions coming up about joint registrations maybe.

## REACH Q A session HSE DEFRA Meeting 20 01 21

Will there be a Consortia approach to substance registration like there was with EU REACH? In this case data sharing extends beyond two companies?

[Gary] The data share requirements with REACH are effectively the same as they were in UK which is, the same as EU REACH that all registrants of the same substance should be sharing data and it's compulsory for data that involves verbiage animals and optional for the rest of the data.

Consortia are an industry led approach and they're not formally part of REACH, if industry wish to form Consortia that's up to them and there's no obligation to.

Some parts of industry did, some parts of industry didn't, it's entirely up to them if they want to follow a Consortia approach.

### Exempt Substances

[Lawrence] More of a specific question on a group of substances here: - Are our polymers, and this is a PP and HDPE, exempt from REACH?

[Gary] Not quite, polymers are dealt with in an unusual way in REACH.

And the polymers themselves, so the Polypropylene and high density Polyethylene, those polymers don't need to be registered but the monomers from which they were produced, so in this case Propylene and Ethylene, do need to be registered and this approach was taken because it's possible to get many many millions of polymers from a relatively small number of monomers and polymers are very rarely more hazardous than the monomers that make them.

So this approach was taken when EU REACH negotiated at the EU level and it's been retained to the UK.

### 'Let's get started with UK REACH'

[Lawrence] I've got maybe less of a question, more of a point to be made about the HSE website and I don't know, possibly it might be for you 2 Gary's to see if either you want to comment on this but someone's saying it's difficult to find where you link from the HSE website to the 'Let's get started with UK REACH' and when you do find it then it takes you to a .Gov website.

And they're saying this gets complicated to access, it needs to be simpler and easy to find.

I don't know if any of you would like to or Keith if he sounds back if you'd like to reflect on that, about the difficulty of navigating through the HSE website to the 'Let's get started with UK REACH'.

[Alun] I will put my answers in writing if anyone wants them...struggling to hear me? (Indecipherable).

The feedback received has been that it's pretty straightforward and if you look at the HSE website in particular, it actually goes directly into the UK page...(Indecipherable).

Our intention is also to directly go back to the HSE guidance as well.

## **REACH Q A session HSE DEFRA Meeting 20 01 21**

But of course, we did lots of testing on this beforehand, we did lots of work to engage on comments and guidance, but ultimately we were going to be able to test it when it was live as it were...(indecipherable)

...People are using it regularly and they are finding it... But do let us know (feedback), we are continuing to expand our guidance; this is absolutely something we can look into no problem whatsoever. Thanks for the feedback.

### **DUINs**

[Lawrence] Got a couple more questions coming on DUINs: -

If my company appoints an Only representative in the UK for substances coming from the EU, can the Only Representative also submit the DUINs?

[Keith] Basically yes.

[Lawrence] Oh thanks Keith, hearing you loud and clear. Good, okay.

### **Batch Submission of DUINs**

[Lawrence] Another question then on DUINs, well a couple of the follow-up questions on DUINs: -  
Is it possible to do batch submission or do we need to do DUINs for each substance manually?

[Alun] Please correct me guys but I think that if you go on to submit a DUIN at the moment, you get a spreadsheet which allows you to put in a number of different entries there, so you could put it in as a batch entry, but please do correct if I'm wrong.

[Gary] Not wrong but the process is that you go into the REACH IT system, you register your company, you say you're submitting your DUIN, you indicate how many substances you are submitting a DUIN for and then in a separate spreadsheet, which is available from HSE website, you would list all the substances and the information that you have available.

That spreadsheet is set out into the information that you must have and the information that you have if it's available to you and then you submit one spreadsheet that covers all the substances that you we're importing from the EU before we left the EU.

## REACH Q A session HSE DEFRA Meeting 20 01 21

### Importing substances after October

[Lawrence] Is there late DUIN... i.e. if I need to import a substance after October, what is the process?

[Gary] If you're importing the chemicals the first time after October, it doesn't qualify for DUIN anyway because it wasn't the substance that you were importing from the EU before we left, so that would be a new registration if it was above a tonne.

[Lawrence] Just conscious we've got a few more minutes left and just to make everyone aware that the session ends at half 11 and then there will be a break.

### Registering New DUINs

I think with the remaining time, we do have a couple more DUIN related questions: -

So bringing new chemicals to the UK market, we cannot do DUINs, does this mean we have to wait for two, four, six years till we have the new registration?

I think you might have just answered that in the previous new registration...

[Gary] The answers to the question is no.

Because you need to make your registration at the time that you start this new import, depending on the nature of the chemical. If it was a novel chemical that had never been registered, you'd need to register in full and provide data.

If it was a novel chemical that had already been registered with the EU then we are calling these New Registrants of Existing Substances, which generally get shortened to NRES and we have a process by which new registrants will be able to submit their registration and join the Article 26 process, which they have to follow.

We will give them instructions on what they need to do, the general idea that they won't need to submit all the data immediately, and the date of submission will be aligned with the other people who are either grandfathered in the registration or are new registrants in the same way.

So eventually all the people who grandfathered were for DUINs or have submitted Article 26 inquiries, would be registered at the same time and that way we don't need to have people do extra testing for substances where we know there's already data available.

[Lawrence] We've got a couple more minutes left so...

Sorry Alun, did you want to come in?

## REACH Q A session HSE DEFRA Meeting 20 01 21

[Alun] There is a question on here about the fact that historically people have used IUCLID dossier that is of an earlier version (I can see it at the top of the Q&A there). What do they then do...to update the version of that IUCLID dossier... go onto our UK website and update that dossier to the newest version and it sort of, gives you a step-by-step process about how you do that. I've seen it in a couple of places here so I just wanted to clarify that.

[Lawrence] No thanks Alun, that's really helpful.

### New importers of Formulations

I'm just going to sort of throw one last question and then maybe we can call the session to a close and there's a 20-minute break.

A final one on DUINs: - For new importers of formulations and often they do not know the exact composition, so what would you be your advice there?

[Gary] The advice is what we gave to people before we left the EU, if you were a new importer of a formulation, you needed to speak to your supplier to determine what chemicals are in it, the nature of how much information you'll be given, also depends on how much chemical you're importing so if you're importing 10 tons of a product, anything in there at less than 10% can't be above a tonne.

So you won't need to register it and so your supplier doesn't need to tell you about things like less than 10%. When you get to 20 tons a year, it goes down to 5% and then you know, the amount of detail you need on the composition decreases, when you import less.

So the more you import, the more you need to know about the composition. Your supplier can give you that information, you can have the product analysed, there are opportunities for non-UK based suppliers to point to Only representatives and the Only representative is given the details of the composition, and that way the people who are importing don't necessarily need all that information, because the Only representatives taking on their registration duty.

That was one of the principal reasons for Only Representatives to exist because it allows non-UK suppliers to keep the formulation details confidential.

### Session Close

[Lawrence] Brilliant, well thanks Gary.

I think with that I'd just like to say thank you to Alun, to Gary and Keith for answering your questions here in this Breakout Session.

I can see we've received over a couple of hundred questions here, so we will be taking them away and working on them and filling in gaps on our website and our e-bulletins and what not, that we haven't answered here and as I said at the start, if you have a really urgent question, do please contact the help desk or the helpline and their details have been shared.

But otherwise I just want to say thank you again to the panel and there's now a 20-minute break. Thanks everybody!