IHK-Series of Events

„REACH 2018 – Register Successfully Now!“

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Federal Institute for Occupational Safety and Health

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Foreword

Helpdesk provides information locally throughout Germany

The third registration phase for chemicals under the REACH Regulation is approaching and will probably affect small and medium sized companies in particular. Companies must register pre-registered substances that are manufactured or imported in a tonnage band of 1 to 100 tonnes per year at the European Chemicals Agency (ECHA) by 31 May 2018.

To support the affected companies, the REACH-CLP Biozid Helpdesk at the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz and Arbeitsmedizin - BAuA), together with various chambers of industry and commerce, offered a series of events entitled: „REACH 2018 – Jetzt erfolgreich registrieren!(Register Successfully Now!)“. Information events took place under the heading „Helpdesk informs locally throughout Germany“ in cities throughout Germany from the end of April to the beginning of November 2016 (28 April in Halle, 9 May in Hanover, 24 May in Kassel, 2 June in Bielefeld, 8 June in Frankfurt, 13 June in Leipzig, 14 June in Berlin, 28 June in Krefeld, 29 June in Ludwigshafen, 20 July in Nürnberg, 9 November in Bremen). The presentation slides are publicly available from the helpdesk‘s website[1].

At all the events, many questions were asked directly in connection with the upcoming registration. The questions were in some cases very similar, but not always the same ones, and were probably equally interesting for all those attended this series of events. For this reason, we have compiled the questions and the corresponding answers below.

This compilation is based on the questions that appeared to us to be particularly interesting for the whole of the group of participants. If you are unable to find your own question, you are welcome to contact the helpdesk directly. You can phone us Monday to Friday from 8.00 to 13.00.

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[1] *www.reach-clp-biozid-helpdesk.de/de/Veranstaltungen/REACH-Veranstaltungen.html*

Topics series 1: registration, deadline, exit scenarios

Does a pre-registered substance have to be registered by 31 May 2018, if the manufacture or the import is reduced to less than 1 tonne after 1 June 2018?[2]

Under Article 6 of the REACH Regulation, substances that are manufactured or imported in a quantity of 1 t/a or more must be registered. According to Article 23(3) this obligation is suspended during a transition period, which ends on 31 May 2018, for substances below 100 t/a, if the substance was pre-registered under Article 28. This means that a pre-registered substance may be manufactured or imported up to 31 May 2018 under 100 t/a without registration.

The quantity calculation for the annual tonnage of phase-in substances results from Article 3 no. 30. According to this, the quantities per year are calculated on the basis of average quantities manufactured or imported in the three immediately preceding calendar years, if the phase-in substance was imported or manufactured in these years.

Two scenarios are considered below using the example of a quantity calculation:

2013: manufactured 8 t
2014: manufactured 9 t
2015: manufactured 11 t
2016: manufactured 9 t, average quantity: 9.3 t/a (years 2013 - 2015)
2017: manufactured 8 t, average quantity: 9.6 t/a (years 2014 - 2016)

Scenario 1 (quantity = 0)

- 1 January - 31 May 2018, manufactured 8 t
- From 1 June 2018, no manufacture/no import

This means that from 1 June 2018 the previous manufacturer/importer no longer has the obligations of a manufacturer/importer. Therefore, they do not have to register the substance, although in the example the average quantity to be calculated for 2018 in the years 2015 to 2017 is over 1 t/a with 9.3 t/a.

Scenario 2 (quantity > 0)

- 1 January - 31 May 2018, manufactured 8 t
- From 1 June 2018, manufacture/import under 1 t

This means that the substance must be registered (even though the quantity from 1 June 2018 is below 1 t). The reason for this is that the transition period ends on

[2] *The interpretation of the phase-in status after 2018 and in this context of the term „per year“ for the calculation of the tonnage is presently subject to a legal examination by the EU Commission. We will publish the decision of the Commission as soon as it is available.*

31 May 2018. Since the substance is still manufactured or imported after 31 May 2018, the result is an average annual tonnage for 2018 of 9.3 t/a on the basis of the years 2015 to 2017.

(Published as FAQ 0454)

How long does the manufacture or import of a pre-registered phase-in substance have to pause, if I do not want to register the substance with effect from the obligatory registration on 31 May 2018?

The quantity calculation for the annual tonnage of phase-in substances for the purpose of registration results from Article 3 no. 30 of the REACH Regulation. According to this, quantities per year are calculated on the basis of the average quantities manufactured or imported in the three immediately preceding calendar years, if the phase-in substance was imported or manufactured in these years.

If the substance is no longer manufactured or imported from 1 June 2018 (quantity =0), it may be manufactured or imported from 1 January 2020 in quantities <1 t/a, without having to be registered. A cease of manufacture/import is imposed throughout the calendar year 2019 and the pause therefore lasts 18 months.

If the substance is already no longer manufactured or imported as of 1 January 2018 (quantity = 0), it may be manufactured or imported from 1 January 2019 in quantities <1 t/a without having to be registered. The manufacturing/import stop comprises the whole calendar year 2018 and amounts to 12 months only.

A phase-in substance was registered and continuously manufactured in a quantity range between 1 and 10 t/a manufactured. What does the registrant have to do if the next higher tonnage threshold is reached?

Quantities manufactured in tonnes for individual years are shown below:

2015 1 tonne
2016 1 tonne
2017 1 tonne
2018 13 tonnes
2019 29 tonnes
2020 1 tonne

According to Article 22(1)(c) of the REACH Regulation, the registrant must notify ECHA that the next quantity threshold has been reached without undue delay, i.e. without culpable hesitation. In case of substances (including phase-in substances) that have already been registered, the annually quantity manufactured or imported is calculated on the basis of the calendar year.

This means in the example shown that the annual tonnage for 2018 results **from this calendar year**. Notification to the ECHA is required from 2018 as soon as it can be anticipated that 10 t/a will be exceeded and thus the registrant will reach the next tonnage band.

According to Article 12(2), the registrant must inform the ECHA in the abovementioned notification without delay of the additional information that they require. The ECHA then provides the registrant with the names and addresses of the previous registrants (and of all potential registrants) and with all relevant study summaries that the latter have already submitted, so that existing data can be used jointly. According to Article 22 the registrant must update their registration without delay by means of the relevant new information and submit this to the Agency.

Does the manufacture or import of a registered substance have to cease if the quantity threshold is exceeded until the dossier is updated?

No. The manufacture or import of the substance does not have to cease until the dossier is updated.

However, according to Article 12(2) of the REACH Regulation the registrant must inform the ECHA without undue delay, i.e. without culpable hesitation, of the additional information that he requires. The ECHA then provides the registrant with the names and addresses of the previous registrants (and of all potential registrants) and with all relevant study summaries that the latter have already submitted, so that existing data can be used jointly. Under Article 22, the registrant must update their registration without delay by means of the relevant new information and send this to the Agency.

May a downstream user place a phase-in substance on the market if the pre-registered substance was not registered by the manufacturer or importer up to the registration deadline of 31 May 2018?

If the manufacturer or importer does not register the substance, a difference must be made between the substance that is manufactured or imported before expiry of the registration deadline and the substance that is manufactured or imported after expiry of this deadline.

Pre-registered substances that were manufactured or imported before expiry of the registration deadline may be placed on the market and used by downstream users and retailers. There are no deadlines or quantity restrictions here.

This does not apply to substances that were manufactured or imported after expiry of the registration deadline. In the case of these substances, the manufacturer/importer is in breach of their obligation to register, because they continue to manufacure or import them. Article 5 of the REACH Regulation stipulates the following:

„[…] substances […] shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required."

This means that these substances may not be manufactured or placed on the market in the Community by any actors in a supply chain.

A substance was registered as a transported isolated intermediate product under strictly controlled conditions in the quantity range between 100 and 1000 t/a. Under these conditions, may the substance be transported „open" in a quantity of less than 1 t/year?

Yes. The substance may be used in a quantity of 1 t/year under not strictly controlled conditions without the need for an update of the registration dossier. If this quantity of 1 t/year is exceeded, the dossier must be amended in accordance with the data requirements based on the quantity.

Are there transition periods with regard to enforcement if someone does not manage to register?

No, transition periods are not expected. Transition periods were not granted either in the previous registration periods in 2010 and 2013.

Has the ECHA set up any „contingency plan", for example for coregistrants, if the lead registrant suddenly refrains from registration shortly before expiry of the registration deadline?

At present, there are no so-called „emergency plans". However, during the previous registration periods in 2010 and 2013 there were web forms with which, under quite specific conditions, for example, if the lead registrant refrains from registration shortly before expiry of the deadline, it was still possible to carry out the registration with the support of the ECHA. It is not clear whether this will be set up again.

Must the quantity of a use that is exempted from registration (e.g. as a food additive), be added to the quantity that is not exempted (e.g. as an aromatic substance in detergents), and must it fulfil the data requirements in accordance with this tonnage?

No, quantities of a substance that are exempted from registration are not added to the quantity that has to be registered. Tonnage-dependent quantities depend only on the quantities of the substances that have to be registered.

If polymer granulate from China is only stored in the customs port in Hamburg in order to be further processed into an article in Ukraine that is then imported into Germany, does this have to be registered?

Substances as such, in mixtures or in articles which are subject to customs supervision, provided that they do not under go any treatment or processing, and which are in temporary storage, or in a free zone or in a free warehouses with a view to exportation, or in transit, are exempt from the REACH Regulation in accordance with Article 2(1)(b) of the Regulation. As a result, these substances do not have to be registered.

Topics series 2: substance identity/impurities/data requirements

Who checks on the import of a substance whether this substance falls under the definition of naturally occurring substances, or whether it was manufactured synthetically?

The importer is responsible for compliance with the REACH obligations that arise when a substance is imported. This means that the importer must check whether the substance was won in accordance with the methods listed in Article 3 no. 39 of the REACH Regulation and was not chemically modified. If methods are used other than those named there, the substance does not fufil the definition of naturally occurring substance. The importer should therefore check with their non-European supplier whether the conditions of the definition of naturally occurring substance are fulfilled. In general an analysis alone is not sufficient in order to determine that a substance satisfies the definition of naturally occurring substance or was manufactured synthetically.

An imported substance contains an impurity that exceeds the 1 tonne threshold per year. Does this impurity have to be registered?

No. Impurities do not have to be registered. Under Article 3 no. 1 of the REACH Regulation, substances are defined as real substances. With defined substances, along with the main constituent(s) this definition also comprises impurities and stabilisers. You can find further clarifications of how substances are defined and named under REACH in the Guidance for identification and naming of substances under REACH and CLP [ECHA‘s identity guidelines][3]. The registration obligation in accordance with Article 6 thus refers to this real substance including its impurities and/or stabilisers from 1 t/year.

[3] *https://echa.europa.eu/documents/1062/13643/substance_id_de.pdf/eb1721f9-74ec-4f8c-8aa3-1490fd510685*

If the same substances were „incorrectly“ pre-registered, e.g. once as UVCB, once as a multi constituent substance, how do you find yourself in a joint substance information exchange forum (SIEF)?

If two companies have pre-registered substances with the same composition with different identifiers, the substances are assigned to different SIEFs; they are formally not identical.

If the companies are aware of each other, they can compare the substance identities of their substances and agree on the same identity. In the present case, for example, this can be the identification as a multi constituent substance. For the registration this means that the pre-registrant of the UVCB substance has to change the identity for the registration. They have to select the identifiers for the multi constituent substance.

Prerequisite is that the substances comply with the rules for naming multi constituent substances and that changing the substance from UVCB to a multi constituent substance is justified. The basis for this decision is formed by the Guidance for identification and naming of substances under REACH and CLP [ECHA‘s identity guidance][4].

As a formulator, do I have to register mixtures? When is something a mixture? What about two-component mixtures?

No. Mixtures do not have to be registered. According to Article 6 of the REACH Regulation, substances as such or in mixtures have to be registered. Therefore, if you import a mixture or several mixtures, you have to register the substances in the mixture(s) in accordance with Article 6 if their quantity reaches to at least 1 t/year.

Substances result from a chemical reaction or are extracted from a naturally occurring substance, for example. In all cases, the substances can result in more or less high degree of purity, e.g. a main constituent with over 95%, there may be multi constituent substances. However, there are also substances that are extracted with a more complex composition, e.g. from crude oil fractions or from plants. In all these cases we refer to substances.

If you mix several substances without a chemical reaction taking place (formulation), this is a mixture as defined in Article 3 no. 3.

[4] *https://echa.europa.eu/documents/1062/13643/substance_id_de.pdf/eb1721f9-74ec-4f8c-8aa3-1490fd510685*

A joint registration can comprise the same substances with different impurities and thus possibly different characteristics. How is such a substance registered? Do all the tests have to be carried out again for the substance with the impurity, which may have an effect on the toxicological characteristics? When would this be the case?

Under the definition in Article 3 no. 1 of the REACH Regulation, substances are defined as real substances. This means that substances are registered as they are manufactured, that is, along with the main constituent(s), with impurities and stabilisers. Such a real substance of this type can have different impurities if it is manufactured by different companies, and different characteristics as well, dependent on this. However, it is the same substance. Each registrant must indicate the different impurity profiles in their registration dossier and assess their effect on the properties in the joint dossier. Depending on the impurities, this can lead to the result that, because of the impurity profile, the real substance of one manufacturer has to be classified differently from the identical real substance of another manufacturer.

Two companies manufacture the same substance X. In contrast to the substance from company A, the substance from company B contains a CMR impurity. Both submit a joint dossier. Does manufacturer A have to provide data on the CMR impurity, even though it is not contained in its substance?

The joint dossier must contain sufficient data and information to characterise all the substances it covers. This means that sufficient information has to be available for establishing the CMR (carcinogenic, mutagenic or reprotoxic) properties of the substance because of an impurity in the substance from company B. If this is information that goes beyond the information needs of the other companies, company B (substance with CMR impurity) must submit this information/data.

What do I have to do if a test of a substance is available to me that disproves the classification of the same substance from a competitor as skin sensitising?

As long as the classification of the substance is not harmonised, the manufacturer/importer must classify this substance as skin sensitising, if they are in possession of corresponding information. If you have other information/data, you do not have to classify the substance as skin sensitising.

If you want to register the substance and are in a SIEF with other enterprises, you should try to agree on a common classification in the joint dossier. If this is not possible, Article 11 (3) of the REACH Regulation provides you with a possibility of opting out, i.e. submitting your information separately.

If a substance that was or will be registered is ground into a powder or rolled out into a foil, does it have to be registered again? If no, not even if the powder is dangerous?

A substance is registered on the basis of its chemical composition. If only the form, but not the chemical composition, is altered through mechanical processing of the substance, e.g. grinding or rolling, a substance that is processed in this way does not have to be registered again. This applies even if the powder has dangerous, e.g. pyrophorous properties, in comparison with a block. You are the downstream user and must then implement the necessary risk management measures.

Am I obliged to register if I import a ball pen? What about pencils?

Ball pens consist among other things of a plastic cover, a cap, a refill for containing the ink, a metal tip, which holds a metal ball, among other things, and possibly other parts. The complete ball pen is a more or less complex product that is composed of individual articles (e.g. cap), including as well a container (refill), which itself contains a substance/a mixture (ink).

Articles do not have to be registered. However, you may have obligations to notify and inform under Article 7 and Article 33 of the REACH Regulation.

Registration obligations may arise in accordance with Article 6 for the substances contained in the ink (mixture), if their total quantity is over 1 t/year.

A pencil is a container (wooden handle) with a substance (usually graphite). Graphite must be registered in accordance with Article 6 if the total import quantity reaches 1 t/year.

What is the difference between a chemical safety assessment (CSA) and a chemical safety report (CSR), and when do I have to prepare these?

A chemical safety assessment (CSA) must be carried out for substances that are registered in quantities of 10 t and more per year and registrant. In this framework, the registrant checks whether a substance must be classified as dangerous (in accordance with the CLP Regulation), or whether the substance has persistent, bioaccumulative and toxic (PBT) properties or very persistent and very bioaccumulative (vPvB) properties.

The registrant documents the findings of the chemical safety assessment in the chemical safety report (CSR). It must be shown in the chemical safety report that safe use of the substance is possible in pure form or in mixtures. For this purpose, exposure assessments for humans and the environment with regard to the substance over its whole life cycle and specifications for safe use in exposure scenarios must be summarised. Exposure scenarios that are relevant for downstream users are passed on in the supply chain as an annex to the safety data sheet, which is also referred to as an extended safety data sheet (eSDS) with this annex.

You can find detailed information in „REACH Info Nr 11: REACH: Expositionsabschätzung für den Arbeitsplatz“ (only available in German)[5] or the ECHA‘s „Guidance on Information Requirements and Chemical Safety assessment“[6].

Topics series 3: Joint submission/SIEF/data sharing/ costs

How can I find out or estimate the price for an impending registration/LoA?

The price of a so-called letter of access (LoA) depends on very many factors, e.g. the scope of the tests to be carried out, the number of registrants and much more. The easiest way is to ask the lead registrant about the costs of the LoA and to request a cost breakdown.

Can an enterprise divide the imported or manufactured quantities among its subsidiaries so that the annual tonnage in each case remains below 1 t/a?

Manufacturers and importers that manufacture or import a substance as such or in one or several mixtures in quantities of 1 t/year or more are obliged to register. Manufacturers and importers are defined as „natural or legal persons established within the Community“ that manufacture or import a substance. The subsidiary must therefore be an independent legal person that manufacturers/imports the substance in order to be able to register the substance. For example, if the parent company is responsible for the complete import in the framework of a group, the quantity must not be spread over several subsidiaries to circumvent registration. The subsidiary must only register the quantity it imports if it actually is the importer for the purposes of REACH.

[5] *http://www.reach-clp-biozid-helpdesk.de/de/Publikationen/Broschueren/REACH-Broschueren.html*

[6] *https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment*

If I have two locations, can I register the same substance twice to remain, circumstances permitting, below the 10 t/a threshold?

If the two locations are independent legal persons, two registrations are required. If it is a matter of two locations of the same legal person, only one registration is required and the manufacture quantities must be added together.

Is it not possible just to form „letterbox companies“ and circumvent registration in this way?

The obligation to register a substance is linked to the legal person that manufactures or imports the substance. The registration obligation cannot be transferred to another legal person. Therefore the registration obligation cannot be circumvented by forming a „letterbox company“.

Can I cancel a pre-registration?

It is not possible to cancel a pre-registration and it is not necessary either, because there are no legal consequences associated with it. The pre-registrant can set the status of the pre-registration in REACH-IT to inactive, so that the other SIEF members can see that registration is not intended.

Does a registrant have to share in the costs for the studies that are the basis for the DNEL/PNEC derivation in the chemical safety assessment, even if they do not require registration because of their low tonnage band?

In this case, registrants do not have to share in the costs. In certain circumstances, if they make use of DNEL values for their risk assessments, they have to share in the costs of deriving the values.

A substance was registered in 2010 and classified as toxic for reproduction on the basis of a study on reproductive toxicity. Does a registrant that wishes to register this substance in the quantity range of 1 to 10 tonnes have to take over this classification, even if he is not in possession of the study? Does he have to share in the costs of the study?

The data is available to the registrant through its publication by the ECHA. Therefore, the registrant must classify the same substance as toxic for reproduction, even if they do not have access to the study, as long as they do not have other information on this endpoint. Under Article 41 of the CLP Regulation, manufacturers and importers of the same substance must make efforts to agree on classification and labelling.

However, this does not mean that a registrant in the 1–10 tonne range has to share in the costs for the study, because they do not need the study in their tonnage band. They „only“ have to take over the classification and labelling.

(Published as FAQ 0463)

What is the difference between a pre-SIEF and a SIEF?

All enterprises that have pre-registered the substance are in the pre-SIEF. Membership is oriented basically towards the EINECS number. If the potential registrants have finally clarified the substance identity, the pre-SIEF passes automatically into the SIEF. The SIEF is the exchange forum in which potential registrants „meet“ to exchange data for the joint submission of the registration dossier.

If no one reacts after several SIEF enquiries, can I simply register alone? Do I have to inform the SIEF of this?

The original task of the SIEF is to organise the exchange of studies. In addition, the SIEF provides a suitable platform for organising the joint submission, because all potential registrants are listed here. If members do not react in spite of several enquiries, it is highly likely that there is no interest in registration. If you satisfy the conditions for registration, inform all participants of the SIEF of your intention to submit a dossier. You can then carry out an individual registration. You can also submit a dossier as a lead registrant so that you do not have to change the status of the registration in the event that other enterprises want to share in the registration.

Am I still a member of a SIEF, even if I no longer manufacture or import?

All pre-registrants of the same substance are and remain members of a SIEF. This applies as well to a potential registrant that does not have to carry out a registration. They remain obliged to exchange information that they have available, at least with regard to studies of tests on vertebrate animals.

Who has to register in the case of contract manufacturing?

The manufacturer or importer of a substance is always obliged to register. This means that the toll manufacturer is obliged to register.

If I have the same substance manufactured by two toll manufacturers, do I have to register twice, or does this substance have to be registered by each of the toll manufacturers?

All manufacturers of a substance are obliged to register. If two contract manufacturers are commissioned, each toll manufacturer has to register under the conditions of Article 6 of the REACH Regulation, and not the customer.

Topics series 4: Exceptions/recycling:

If zinc is converted into molten zinc, is this a recycling process?

If recycling waste or recovery of the substance from waste (recycling) takes place, according to REACH this is to be equated with the manufacture of a substance. In the recycling step it does not matter whether the recycling operation carries out mechanical processing, chemical conversion or an isolating step. If the zinc in question is therefore waste as defined in the Waste Directive (2008/98/EC), conversion into molten zinc is a recycling process.

The exception from the registration obligation in accordance with Article 2(7)(d) of the REACH Regulation applies to substances that are recovered from waste by means of recycling in the Community. Prerequisite is that the identical substance was already registered and the information in accordance with Article 31 (safety data sheet) or 32 is available. Registration does not have to take place within the supply chain.

If I remove the coolant from a motor vehicle (here: an end-of-life vehicle) and reuse it in a new motor vehicle, is this a recycling process? Could this lead to registration obligations?

The following applies if the end-of-life vehicle is waste as defined in the Waste Directive (2008/98/EC):

If recycling of a waste or recovery of a substance from waste (recycling) takes place in the Community, according to REACH this is to be equated with the manufacture of a substance. It does not matter whether the recycling operation carries out mechanical processing, chemical conversion or an isolating step.

In accordance with Article 3 no. 15 of the Waste Directive the definition of recovery means any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy.

Accordingly, the process described here, recovery of coolant from waste, is a recycling process.

Does microcrystalline cellulose fall under the entry in Annex IV?

The substance cellulose (CAS No 9004-34-6, EC No 232-674-9) is not listed in Annex IV of the REACH Regulation. What is listed is cellulose pulp (CAS No 65996-61-4, EC No 265-995-8), which is not identical with cellulose. Cellulose is not covered by the entry for cellulose pulp in Annex IV.

However, it should be noted that (microcrystalline) cellulose, which is extracted from natural materials, is to be considered as a natural polymer. (The term „natural polymer“ is not defined in greater detail in REACH. It is to be understood as polymers that are isolated from naturally occurring organisms.) Natural polymers are polymers for the purposes of REACH, if they comply with the polymer definition in Article 3 no. 5 of the REACH Regulation. This means that natural polymers in accordance with Article 2(9) do not have to be registered under this prerequisite. The underlying monomers are regarded as non-isolated intermediates and are therefore exempted from REACH. However, any posttreatment reagents that are used must be registered in accordance with Article 6(3) if they are chemically bound.

Topics series 5: Non-EU manufacturers/only representatives

Can a non-EU manufacturer import a substance into the EU?

An importer for the purposes of REACH is only a natural or legal person established in the EU. Non-EU manufacturers are not importers.

Can an only representative represent different non-European manufacturers? Is there an upper limit?

Only representatives are free to decide how many non-European manufacturers they represent.

If the only representative was appointed, for example, by two non-European manufacturers to register the same substance, the only representative must submit two registrations. It should be noted here that an own REACH-IT access at the European Chemicals Agency must be established for each represented enterprise.

Can a non-European manufacturer name several only representatives?

While it is possible that the non-EU manufacturer appoints different only representatives for different substances, it is not possible to divide the tonnage for a substance among different only representatives. This should be seen against the background that dividing the tonnage could, in certain circumstances, reduce the information requirements. It is not intended to circumvent greater information requirements, because this is contrary to the protective aims of the REACH Regulation. In addition, non-EU manufacturers and manufacturers established in the EU would be treated unequally.

Does the importer have to buy the substance from the only representative or from the manufacturer?

Under Article 8 of the REACH Regulation, manufacturers that are not established in the EU may make use of the possibility of naming an only representative established in the EU that fulfils the importers‘ obligations. The non-European manufacturer can then supply to buyers in the EU, who are covered by this registration. It is not necessary to buy the substance from the only representative (see FAQ 0025).

Topics series 6: Brexit/discontinuation of the lead registrant

[Disclaimer: It is not foreseeable how Brexit will change the legal situation because it has not yet been implemented. For this reason, legally watertight information is not possible.]

On 23 June 2016, voters in the United Kingdom (UK) voted with a majority to leave the European Union. What effect will Brexit have on the rights and obligations under REACH?

Some of these questions are summarised below.

- Have UK enterprises now registered to no purpose? What will happen with the registrations?
- Will the chemicals industry in the UK boom because UK enterprises do not have to register now?
- Can we simply relocate the manufacture of chemicals to the non-EU UK to produce articles there, and the articles that are not obliged to be registered are then imported to the EU?
- What will happen to the only representatives in the UK, will they simply have to relocate to Germany?

Brexit has not been implemented yet. For this reason, answers to most of the questions are completely open and the subject of future negotiations between the EU and the UK. There are two conceivable scenarios: REACH will continue to apply, or it will no longer apply, whereby the open questions refer only to the latter case.

Once the UK is „out“ and REACH is no longer valid there, it is regarded as a non-EU country. In this case, existing registrations of British companies would be obsolete. Whether the registrations of UK enterprises will really lose their validity, or the enterprises remain registrants under Article 3 no. 7 of the REACH Regulation, will have to be clarified in the negotiations between the EU and the UK.

The cases in which a UK enterprise is the lead registrant in a SIEF are problematic. It is possible that these enterprises can or may no longer fulfil the function. It is then for the participants in the SIEF to negotiate the change of LR.

EU enterprises that obtain substances from the UK are regarded as importers and are subject where applicable to the obligations to register.

The exit negotiations will probably end after 30 May 2018, the last transition period for pre-registered substances. For this reason it is very probable that manufacturers and importers from the UK will have to comply with this period and register the substances in time.

A large number of only representatives (OR) are located in the UK. It is to be expected that the OR will have to relocate to an EU member state.

Once the UK is „out“ and REACH should no longer be valid, it cannot be assumed that enterprises will not have any obligations with regard to the manufacture and import of chemicals. However, a statement on which model will apply to a registration to take effect cannot be made here, for example, whether there will be additional costs for registrants that have to register again, or whether a registration will be less expensive.

Can the registration of a lead registrant (LR) be transferred to another registrant if, for example, the LR no longer manufactures the substance or is established in the UK? In this context, can the registration of a company be transferred to another company that does not even manufacture or import the substance?

Transfer of a registration from one manufacturer/importer to another is not possible without transfer of ownership of the enterprise or the manufacture plant. A transfer cannot be enabled by means of private contracts either. If a transfer or ownership takes place, a transfer of the registration may be possible.

You can see the conditions under which a change of the identity of legal persons is possible in the ECHA „Practical guide 8: How to report changes in identity of legal entities“[7].

However, the question may also be the subject of Brexit negotiations and lead to a different result.

[7] *https://echa.europa.eu/documents/10162/13643/pg_8_legal_entity_change_en.pdf*