CTPA WEBINAR 'COSMETICS: KNOW YOUR UK REACH'
8 SEPTEMBER 2021 - Q&A

REACH is the Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation. EU REACH is applicable in the EU and Northern Ireland; UK REACH is applicable in Great Britain (England, Wales and Scotland).

In order to gain an understanding of REACH and ensure compliance with the relevant obligations, companies are encouraged to read all available guidance and advice.

CTPA Guide on post-Brexit Trade
CTPA REACH Infographics
CTPA webinar 'Cosmetics: Know your UK REACH'
REACH (UK) Reference Zone page (CTPA members only)
UK Regulations for Cosmetics (CTPA members only)

Health and Safety Executive UK REACH page

Question (Q). What is the 'no data, no market' principle for REACH?
Answer (A). The 'no data, no market' principle for REACH means that substances for which no data is available, or no data can be submitted via the registration process, must not be marketed. This is because if there is no information about a chemical, its risks cannot be managed.

Q. Does REACH apply to all tonnage levels of manufacture or import?
A. No, REACH only applies to substances manufactured or imported above 1 tonne/year by each legal entity. The yearly volume is calculated as the average production or import of that substance for the three preceding calendar years. For UK REACH, volumes shall only be considered for 2019 and 2020 quantities.

Q. Are finished cosmetic products within the scope of REACH?
A. REACH applies to substances on their own or within mixtures. Therefore, it applies to cosmetic ingredients when they are on their own or within a finished cosmetic product (mixture). Finished cosmetic products are exempt from REACH.

Q. What is the difference between an importer and a distributor?
A. An importer under UK REACH is a UK-based company placing on the GB market a substance from a third country (e.g. US, Australia, China, France, Germany, etc.). A distributor under UK REACH is a UK-based company selling on the GB market a substance from another UK-based company.

Q. What is the difference between restrictions under the Cosmetics Regulation and REACH?
A. The Cosmetics Regulation regulates the safety of finished cosmetic products and their ingredients from a human safety perspective. The REACH Regulation, instead, regulates the safety of chemicals (including cosmetic ingredients) from an environmental and workplace safety point of view. Therefore, a ban or restriction under the Cosmetics Regulation is the consequence of a safety concern

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in relation to human safety; whereas a ban or restriction under REACH is the consequence of a safety concern in relation to the environment or the workplace.

Furthermore, REACH is a horizontal legislation, meaning that it applies across all chemical sectors. For example, a restriction under REACH on a chemical which is also cosmetic ingredient will not be listed in the Cosmetics Regulation because it comes from a different piece of legislation, but cosmetic companies must still abide by the REACH restriction. Therefore, it is important to make sure you are aware of what's happening under REACH as well as the Cosmetics Regulation.

Q. Is there guidance specifically on exposure scenario implementation under UK REACH SI?
A. We are not aware of separate guidance on exposure scenarios under UK REACH. Companies should continue referring to guidance relevant to EU REACH where relevant and possible. If new guidance under UK REACH becomes available, CTPA will publicise this.

Q. Does the Republic of Ireland follow EU or UK REACH?
A. The Republic of Ireland is an EU Member State and therefore follows EU REACH, as is the case for all other EU Regulations.

Q. How do I know if my supplier has already submitted a registration under UK REACH?
A. CTPA encourages companies to contact and communicate with their suppliers, to understand their plans in regard to UK REACH compliance.

Q. What is the grandfathering process?
A. Under UK REACH, the grandfathering process allows existing holders of EU REACH registrations to submit preliminary information about those substances, in order to allow continuity of supply until the full registration deadlines. The grandfathering process terminated on 30 April 2021, however it is still possible to submit late grandfathering.

Q. Does the raw material supplier have to communicate the actual registration number or are they only obliged to say that the substances are registered?
A. Under UK REACH, there is only a legal obligation to communicate within the supply chain; however, there is no prescribed way of what and how the information should be shared. Some suppliers may wish to share their registration numbers; some suppliers may only share a statement of compliance with REACH. Downstream Users have a due diligence obligation to ensure that the substance they use is registered under REACH and that the registration covers their tonnage.

Q. If a UK-based manufacturer imports finished cosmetic products (mixtures) from outside of the UK, is the company an importer or a Downstream User?
A. A company bringing chemicals into the GB or NI market from a third country, be it on their own as raw materials or in finished cosmetics ingredients, is considered an importer. An imported of chemicals will usually have associated the legal responsibility of registrations. However, this responsibility might have been undertaken by another person further up on the supply chain or an Only Representative, who might have conducted a registration including the import tonnage. If this is the case, and for that particular chemical, an importer might have the same responsibilities as a Downstream User.

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It is therefore really important for companies to identify all substances within their portfolio, where they are sourced and what is their REACH compliance status; communication with suppliers within the supply chain is also key. You may find out that you are a DU for all substances, or an importer for all substance, or both depending on the substance.

Q. Is a GB-based contract manufacturer of cosmetic products responsible for UK REACH compliance for the products that are manufactured for customers?
A. Every company in the supply chain will have certain obligations under REACH. First of all, you need to identify your role for each substance; then understand your obligation. A manufacturer that supplies products to other companies might import raw materials in order to be able to make the final products. In this case, the manufacturer might need to register the imported substances or secure alternative sources of supply. In other cases, the manufacturer might be able to retain the role of Downstream User, but there would still be the obligation under the communication requirements to consider. Regardless of the situation, a strong understanding of your roles and responsibilities and a formal contractual agreement of who will undertake these will be advisable.

Q. If I buy a substance from a UK supplier, but the substance is manufactured in the EU, am I considered an importer?
A. If you buy a substance from a UK supplier, you are more likely to be a distributor or a downstream user. If the UK supplier is sourcing the substance from the EU, they might be the importer and have registration obligation; unless the EU supplier has arranged a UK-based Only Representative for REACH compliance. If you know the substance originates from the EU, then it is always recommended to check the status of the substance under REACH.

Q. If a raw material is sourced from different suppliers, does the DUIN have to be submitted for each one of them? Shall all the different SDSs be provided?
A. The DUIN is individual per each substance. Companies are advised to list each substance only once in the excel sheet that has to be submitted as part of the DUIN. It is possible to attach different SDSs for the same substance, explaining that it is sourced from different suppliers.

Q. Can the DUIN only be made on substances placed on the UK market between 1 January 2019 and 31 December 2020?
A. DUINs apply to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance. This means the actor must have traded the substance in the period of 2 years ending on 31 December 2020.

These provisions are designed to help protect existing supply chains. If an actor has not traded a substance in the 2-year period prior to 1 January 2021 this is not considered to be an active supply chain.

Q. What are the consequences for missing the deadline to submit the DUIN?
A. Downstream users are encouraged to take all steps necessary to meet the deadline to avoid being non-compliant with UK REACH.

If a downstream user has not submitted a DUIN by 27 October 2021 and continues to import substances from the EU / EEA into the GB market they may face enforcement action. HSE will consider

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the individual circumstances of each case, including the duty holders' understanding and behaviour, as well as efforts made to achieve compliance.

Q. What information do I need to supply as part of the DUIN?
A. Article 127E of UK REACH gives the list of information that has to be submitted as part of the DUIN:

- identity of the manufacturer/importer;
- identity of the substance;
- classification and labelling of the substance, only if this information is available;
- EU REACH registration number, only if this information is available;
- substance authorisation, if applicable;
- substance restriction, if applicable;
- any other available and relevant information to manage risks.

Q. Is the DUIN applicable for importers of finished cosmetic products or only single substances?
A. REACH applies to substances on their own (single substance) or within mixtures (as part of a finished cosmetic product). Therefore, if you import finished cosmetic products you may have to submit DUINs for the substances within those products.

Q. Why does the Excel sheet of the DUIN have a part that requests information only if available to the company?
A. This is because Article 127E of UK REACH requests certain information only if they are available to the company submitting the DUIN (e.g. companies may not know the classification of the substance, or the registration number).

Q. If a substance is registered under UK REACH to the HSE, will this be automatically registered under EU REACH with the European Chemicals Agency as well?
A. No, UK REACH and EU REACH are two completely separate frameworks; as the HSE and ECHA are two completely separate regulators.

Q. Is the Department for the Environment, Food and Rural Affairs going to publish a Substance List and Public Register?
A. Defra has published a list of the names and CAS / EC numbers for substances that have been notified to HSE under Article 127B(4)(a) of UK REACH ("grandfathered" registrations). The list is not a list of all substances capable of registration under UK REACH and currently in use in GB supply chains. For example, it will not include substances that are only imported by new registrants or downstream users.

The list can be found on GOV.UK at https://www.gov.uk/government/publications/uk-reach-grandfathered-registrations-notified-substances-list.

Under Article 77(2)(e) HSE is required to make available an online "Public Register" of information from REACH registrations. This "Public Register" will be published once all of the required information has been made available, i.e., once dossiers have been submitted by grandfathered and new registrants.

While there are certain information requirements under Article 77(2)(e) that must be met, the UK REACH Public Register will not automatically mirror ECHA's list of registered substances. Instead, we

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will soon be conducting research to understand what users need from a Public Register and how we might best present that information.

Q. If a company submits a DUIN, is it mandatory to also submit the full registration within the 2/4/6 years deadline?
A. Having notified under Article 127E, a company is not obliged to register unless they wish to continue importing the notified substance after the relevant deadline for registration. The deadline to register will be 300 days plus either 2, 4 or 6 years after the end of the transition period, depending on the tonnage and/or hazard profile.

If a company wishes to continue to import the notified substance after the relevant deadline, a complete UK registration will be required within the relevant deadlines.

If the non-GB based manufacturer or formulator appoints a GB-based OR to register the notified substance within the relevant deadlines on behalf of their GB customers, the GB importer would be treated as a downstream user under UK REACH and would therefore not need to become registrants themselves.

Q. Especially with mixtures or fragrance ingredients, individual components are confidential and protected by Intellectual Property rights. How can I submit the DUIN or the full registration if I don't have information on the individual components?
A. Only substances should be notified and not mixtures. If you import mixtures, you will need to consider the individual substances within those mixtures and calculate if any will be imported at or above one tonne per year.

Where information about a substance is not available to you, that information need not be provided. This is of particular relevance to importers of mixtures, where your supplier may not wish to divulge the composition of their products.

When it comes to making the registration, information on the individual substance components is required, therefore companies need to know the annual volumes in order to meet registration data requirements. The registrant will need to find out the information required for registration before the relevant deadline in order to submit the registration dossier. It is indeed complicated to submit the registration dossier without being able to access the data that is specifically required. In this instance, companies shall negotiate with their supplier access to that data, or arrange for additional testing to generate the data to be carried out.

Please note that the non-GB manufacturer or formulator may have the possibility designate an 'Only Representative' (OR) to cover imports into Great Britain and therefore relieve UK customers from registration obligations.

Q. Why is it not possible to use for UK REACH the same registration dossiers submitted to ECHA under EU REACH?
A. The data submitted to ECHA under EU REACH is protected by Intellectual Property rights by the companies who own the data, but also the dossier can only be legally used for the purposes of EU REACH.

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Also, under the UK/EU Trade and Cooperation Agreement (TCA), the UK was not allowed to retain access to the registration dossiers held by the ECHA. Therefore, a new registration dossier has to be created for submission to the HSE under UK REACH. In particular and in order to build the UK registration dossier, access to the data used for EU REACH has to be negotiated by companies. Companies are encouraged to make use of data and information already generated under EU REACH, by seeking/agreeing on the extension of EU data access for UK REACH purpose.

Q. Is it possible to submit a DUIN if we don't know yet what are the intentions of our suppliers?
A. Yes. Companies are advised to submit DUINs if they import or use chemicals that are sourced from the EU. It is even more important to submit DUINs if your supplier does not intend to comply with UK REACH, or the intentions are not yet clear.

Q. If my supplier is not certain they will do a registration under UK REACH, do you advise to submit the DUIN or wait for more clarity from the supplier? Of if the supplier has confirmed they will register under UK REACH, so I don't do the DUIN, but then the supplier changes it plans; what can I do?
A. Companies are advised to submit DUINs in both scenarios. This will ensure compliance and continuity of supply until the deadlines for full registration. In the meantime, please continue to liaise with your suppliers to understand their intentions or actions in the future. Companies will still have to make decisions on whether to register the substance or change supply chain, based on the suppliers' intentions or actions.

Q. What happens if a substance was below 1 tonne/year before the DUIN deadline and then its quantity increases above 1 tonne/year?
A. A GB-based downstream user under EU REACH may be treated as a downstream user under UK REACH under Article 127E.

A GB-based downstream user under Article 127E who imports a substance into GB in a quantity of less than 1 tonne per annum before the DUIN deadline (October 27 2021) is not required to submit a DUIN in order to maintain that downstream user status.

If this GB based downstream user continued to import a substance in a quantity of less than 1 tonne per annum they would remain below the registration threshold under UK REACH. If the quantity increases above 1 tonne per annum then a UK REACH registration will be required if the downstream user wants to continue importing after the relevant period (27 October 2023, 27 October 2025 or 27 October 2027, depending on the tonnage/hazard profile of the substance imported).

It is important to keep monitoring import tonnages. If you think that your tonnage level is close to 1 tonne/year, we advise to submit the DUIN anyway so that the substance is covered, should its quantities increase.

Q. Is it possible to check if another company has already submitted a DUIN for the same substance that I use?
A. The DUIN applies to individual companies. Each legal entity identified as a Downstream User or distributor who is importing substances from the EU market has the obligation to submit DUINs, to ensure continuity of supply until the full registration deadline. The DUINs submitted by another company are not related to the DUINs you have to submit.

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Q. Does the DUIN also apply to chemicals that were not registered under EU REACH? If not, what do I do for those substances?
A. The DUIN provision is intended to enable existing supply chains to continue unbroken and provide time for businesses to comply with their new obligations as an importer under UK REACH.

The measure therefore applies only to existing GB downstream users or distributors under EU REACH who were, at any time in the 2-year period before 1st January 2021, already a downstream user or distributor under EU REACH established in GB in relation to a substance. This also applies to GB-based legal entities that were importing substances and mixtures into GB from outside of the EU, under an OR agreement held by an EU-based entity.

From 1 January 2021 companies wishing to register new chemicals for the GB market, for which the transitional provisions of grandfathering and DUINs do not apply, would need to submit a new registration to HSE using the Comply with UK REACH IT system.

Q. What is the '12 year rule'?
A. Under EU REACH, studies submitted at least within the previous 12 years can be used without compensation, for the purposes of EU REACH registration. More information can be found in the ECHA Guidance on Data Sharing https://echa.europa.eu/regulations/reach/registration/data-sharing. It is currently understood that in the UK the relevant existing study summaries will reach the end of the '12 year rule' under UK REACH at the same time as they do under EU REACH, irrespective of when the substance is registered under UK REACH. At present it is unclear how the UK provision will be implemented by the HSE in practical terms.

Q. Should polymers or monomers be considered for submission of the DUIN?
A. The definition and registration requirements of polymers and monomers under UK REACH mirror that of EU REACH.

The exemption to the registration of polymers which apply under Article 2 (9) of EU REACH has been carried over into UK REACH and therefore do not need to be considered for submission in a DUIN.

Monomers and other substances manufactured or imported into GB which are subject to registration will need to be registered with the HSE, and so should be considered for submission in a DUIN in order to make use of the transitional provision.

Q. Will the duplication of registration requirements impact animal testing? In particular, will there be a need for new testing?
A. The UK REACH framework has only been in force since 1 January 2021, and therefore is still in the process of being fully implemented. New registrations will be needed to ensure continued supply of chemicals to the UK, and unfortunately this might mean that some animal testing is required to prove safety for the environment and the workforce. Registration of substances which were not grandfathered under UK REACH from the EU might require a certain amount of duplication. For most substances, negotiation for access to the existing data with the owner of the intellectual property under EU REACH would allow UK companies to register substances without having to recreate the data. Should this not be available, the UK company would be required to conduct the necessary testing once more. In the cosmetics industry, the ban on animal testing for cosmetic products and ingredients is still in place in the UK to prove consumer safety in the use of cosmetic products. While the ban does

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not extend to cover UK REACH, the cosmetics industry in the UK remains against the use of animal testing.

UK REACH is a new and evolving piece of legislation. This means that whilst new registrations need to be made for the purpose of accessing the UK market, the extent to whether animal tests may need to be repeated is an unknown factor at present. Having to re-register a substance under UK REACH may require duplication of data. However, there are two options to prepare the registration dossiers: the company preparing the registration dossier can negotiate access to existing data with the owner of the Intellectual Property and of the EU REACH dossier; or the company shall re-create the data. The latter may require unnecessary animal testing to be repeated; however, this is something that the cosmetics industry cannot condone, as there is an animal testing ban under the UK Cosmetics Regulation.

The HSE will evaluate each testing proposal and the first batch of these is currently open for consultation.

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