

CTPA BREXIT WEBINAR 'WHAT TO DO NOW' Q&A

Cosmetics Regulation

What will be the UK's regulation if we drop out with no deal?

The UK Cosmetics Regulation Statutory Instrument (SI) is part of the [Product Safety & Metrology etc \(Amendment etc\) \(EU Exit\) Regulations 2019](#), specifically in Schedule 34. There have been two amendments for this SI, please visit the [CTPA Brexit page](#) for more details. The UK regulation reflects the EU Cosmetics Regulation for the UK market.

RP

Does the requirement for an RP only apply to finished cosmetic products?

Yes. The RP requirement only applies to finished cosmetic products placed on the EU market, as is currently the situation under the EU Cosmetics Regulation.

What is the difference between a legal person and a natural person?

Under the EU Cosmetics Regulations and the UK 'no deal' Cosmetics Regulation, the RP is defined as a legal or natural person, meaning an individual person or a company.

My products are in the UK, if I do not have an RP in the EU27, do I need to stop customers from Europe purchasing products from my UK Website?

Cosmetic products coming from the UK can continue to be sold in the EU market, but they must comply with the EU Cosmetics Regulation in full as is currently required. This includes ensuring there is an EU27 RP for the product(s).

If I open a local company in EU, can I be the RP via this company, as the company is a legal person based in the EU?

Yes, entities can choose to fulfil their obligations for an EU27 RP by opening a company in one of the EU27 Member States. Alternatively, entities can use a third-party who provides RP services, or appoint one of their importers to act as their RP. More information on this can be found in the [CTPA Brexit Reference Zone](#) for members.

If the RP, prior to exit, is an EU parent company, can they be appointed as the UK RP after exit?

An EU27 entity cannot be a UK RP. A UK subsidiary could be the UK RP, if this is the preferred option. It will have to be an internal decision of the company.

Can a UK brand owner mandate someone in the EU27 to be the RP after Brexit?

Only an EU entity can mandate another EU entity. A mandate is not a commercial agreement: commercial agreements can happen between entities operating under different markets; a mandate is a handover of responsibility that can only happen between two EU entities. More information on this topic can be found in the [CTPA Brexit Reference Zone](#) for members. In a 'no deal' Brexit scenario, the EU importers bringing products into the EU market from the UK will need to mandate the EU RP chosen by that brand. If importers do not do this, then they will be automatically recognised as the RP as stated under the EU Cosmetics Regulation.

Does an EU27 entity have to be appointed as the EU RP before BREXIT?

Yes, we advise to do this before Brexit because compliance with the EU Cosmetics Regulation for products placed on the EU market post-Brexit is expected from day one of Exit. In addition to

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appointing an EU27-based RP, obligations include their name and address appearing on pack, CPNP notifications copied to the new EU27 RP account and the PIF made available via the new EU27 RP address.

In terms of the EU RP, do they simply have to be contactable by postal address?

The EU27 RP requirements are not different from the requirements currently applicable; the EU Cosmetics Regulation doesn't change, and it will still be applicable to the EU market post-Brexit. Therefore, companies must have a legal entity in the EU27 Member States, which has to be available to competent authorities as needed. It should be noted that RPs provide a point of reference for competent authorities if there are any issues with the products on the EU market.

What penalties are likely to be applied to non-compliant products on the UK market?

Penalties under the UK 'no deal' Brexit Cosmetics Regulation are as currently found under the EU Cosmetics Regulation. The UK competent authorities will take a pragmatic approach; however, any enforcement activity will depend on the extent of the infringement and the risk to consumer safety.

Labelling

Can two RP addresses be displayed on one label?

No, there can only be one RP address on the label as there can be only one RP. However, in order to prepare for a 'no deal' Brexit, companies that are selling to both markets may choose to label both the UK and the EU27 RP addresses, highlighting the current RP address.

As the outcome of Brexit is still uncertain, CTPA is suggesting that companies implement a labelling solution that ensures products are compliant in both scenarios. While the UK is still part of the EU (until Exit day 2019 and, in case of a Withdrawal Agreement being in place with transition period) products will have two EU addresses on pack (UK and the EU27 MS of choice). In the presence of more than one EU address on pack, Article 19 of the EU Cosmetics Regulation requires to highlight (underline) the address where the RP is based. Pre-Brexit companies should underline the address where the PIF is currently held. Post-Brexit the UK would ignore an address in the EU27, whether or not underlined, and similarly the EU authorities would ignore a UK address, again whether or not underlined.

For example, if a company currently has the RP based in the UK and it adds the EU27 RP address to the label, the underline should be as below:

UK RP address

EU27 RP address

Whereas, if a company currently has the RP based in the EU27 and it adds the UK RP address to the label, the underline will have to be as below:

UK RP address

EU27 RP address

Bulk is manufactured in the UK, filled in Spain and then shipped back to a UK warehouse as finished cosmetics. Currently the product is labelled 'Made in UK'. Will that be correct going forward?

Yes, the country of origin is defined as the country where the most substantial change occurred. Manufacturing the bulk is a substantial change, however filling is not. Therefore, the country of origin for the label of the product will still be the UK.

Under the EU Cosmetics Regulation, the country of origin must be labelled if the product is imported from outside of the EU; therefore, a product made in the UK will be imported from outside of the EU post-Brexit and the label must therefore feature 'Made in the UK' when marketed in the EU27.

Under the 'no deal' Brexit UK Cosmetics Regulation, a product imported to the UK must be labelled with the country of origin. Therefore, a product made in an EU27 Member State must be labelled 'Made in XXX'. Companies are reminded that the EU is not a country, meaning that 'Made in the EU' will not be compliant.

What will happen to the products on the UK market whose labelling complies with the EU Cosmetics Regulation but not with the new UK requirements?

Cosmetic products without a UK RP address on pack can be made available on the UK market for up to 2 years from Exit day (providing an EU28 RP address is already present). After this time, cosmetics made available on the UK market (to consumers or businesses) must be compliant with the labelling requirements of the UK 'no deal' Brexit Cosmetics Regulation.

Can you please clarify the labelling requirements for a cosmetic product imported from the EU27 to the UK?

The UK 'no deal' Brexit Cosmetics Regulation was created by transposing the EU Cosmetics Regulation into UK law. This means that Article 19 of the UK regulation has the same labelling requirements as the EU Cosmetics Regulation, with the only difference that a UK RP name and address must be labelled on pack. Everything else is as currently required.

Can over labelling be used to bring a product in to compliance, e.g. RP address? Must this be carried out prior to passing through customs??

Oversticking with the correct labelling will be permissible providing that no mandatory labelling information becomes obscured. When products arrive at the UK or EU border, they may be subject to certain checks. Product may need to proceed to a bonded warehouse prior to release if oversticking is to be carried out after arrival. Therefore, it may be advisable to overstick in advance of export, where possible.

If a product displaying a pre-Exit EU compliant label (EU RP address) remains on the UK market two years after Exit (continues to be made available) must this stock be withdrawn?

Product that remains on the market after the cut-off date in the UK legislation may be overlabelled with the correct labelling. Non-compliant stock should not be supplied to businesses or consumers after two years after Exit.

- What about product on the market in the EU which displays a UK address?

Cosmetic products without an EU27 RP address on the label placed on the EU market before Exit day can be sold through for an indefinite time (see Commission guidance). However, cosmetic products being placed on the EU market after Exit day must be compliant from day one of Exit and have the EU27 RP address on pack.

Will UK qualifications be accepted for safety assessments prepared for EU27 Member States?

CTPA is aware that some EU Member States (relevant to where the EU27 RP is located) will not accept UK qualified safety assessors. The Belgian authorities have confirmed that Belgium doesn't accept overseas safety assessors, which will also include the UK as post-Brexit (however, existing safety assessments will remain valid, only new ones will be affected). Companies are advised to contact the competent authorities of the EU Member State where the EU27 RP will be based, in order to check whether their qualifications will be accepted.

The UK Government will continue to accept EU qualifications which are currently recognised as equivalent.

Claims

Will the Technical Document on Cosmetics Claims be enforced in the UK?

The UK 'no deal' Brexit Cosmetics Regulation has the same provisions for claims as are currently required under the EU Cosmetics Regulation.

What impact do you see/anticipate for clinical safety studies?

We do not foresee any specific impact on the acceptability of clinical or efficacy studies. One factor to consider is the movement of testing samples between the UK and the EU. In a 'no deal' Brexit scenario, testing samples moving between the UK and the EU will require customs clearance, with specific documentation needed. Also, the samples may be subject to different tariffs from those currently in place.

PIF

What countries accept a Product Information File (PIF) in English?

CTPA is aware that Germany, Norway, Netherlands, Sweden and Belgium may accept the PIF in English. Other EU Member States may accept technical information in the PIF in English, however the safety assessment should be in the local language. Companies are advised to contact the competent authorities of the EU Member State where the EU27 RP is located to check local language requirements for the PIF.

CPNP

For products that have been discontinued-will these have to be notified on the UK database?

The UK 'no deal' legislation does not require that discontinued products be notified.

How do the authorities check the UK notification database?

UK competent authorities will have access to the notifications in the UK notification database in the same way that EU competent authorities have access to the notifications in CPNP.

When does the UK notification database go live?

The UK notification database will go live on day one of Exit, only if there is a 'no deal' Brexit.

Will the UK notification database be accessible outside of the UK?

Yes, companies based outside of the UK will be able to access the UK notification database by using the UK RP credentials.

Please can you clarify what information is required to be uploaded on the UK notification database in addition to the zip file?

Companies should only need to provide a small amount of additional information if the xml zip file (from EU CPNP) is submitted.

- Companies who originally notified in the EU CPNP using an upload of their exact formulation or of concentration ranges will need to supply this upload in addition to the zip file.
- We have been advised by BEIS that companies who originally notified in the EU CPNP using a frame formulation **WILL NOT** be required to submit Trigger rule 18 information for pre-Brexit products.

N.B. This is newly received advice.

When a cosmetic is imported into the EU from the UK, should this product be indicated as an imported product on the EU27 CPNP notification?

Yes, such products will have to be ticked as 'Imported' in the CPNP notification. EU27 RPs must submit new notifications. Notifications submitted previously to the EU CPNP by a UK RP will no longer be valid (these do not need to be updated as 'imported').

Can UK RPs continue to access and download from the EU CPNP after Exit day?

No. The European Commission has advised that UK RP access will cease on Exit day.

Trade

Will there be a requirement for specific documentation for importing cosmetics into the UK?

Yes, after a 'no deal' Brexit the UK will not be part of the EU single market, meaning that goods cannot freely move between the UK and the EU. Specific documentation for customs clearance will be required. Companies can find more information in guidance from both the [UK](#) and the [EU](#).

Has the CTPA spoken to the European Commission or regulators in mainland Europe to ask for some leeway if cosmetics arrive at a port without an EU name/address on 1st Nov? For our business we may need to apply stickers in our warehouses for the first few weeks post-Brexit.

Both CTPA and Cosmetics Europe, the EU personal care products association, have been doing advocacy work with the EU Commission. However, the EU has been very clear and strict with their position and cosmetic products placed on the EU market after Exit day must be compliant with the law from day one of Exit.

What tariffs will apply to cosmetics imported in to the UK in case of a 'no deal' Brexit?

In a 'no deal' Brexit, the UK will be trading under World Trade Organisation (WTO) rules and tariffs. However, the majority of tariffs are being liberalised for up to a year to try and mitigate consumer price and supply chain impacts that would occur if tariffs applied to EU imports. CTPA understands that of those tariffs that are likely to be maintained, none are in the cosmetics industry. Further detail can be found [here](#) and on the [UK Trade Tariff Tool](#).

What is the definition of 'placing on the market' for the UK and the EU?

The UK and EU apply the principles set down in the 'Blue Guide', which can be obtained from the Commission website.

Ingredients

Will ingredients that are in a current transition period (HICC/Lyral ban for example) no longer be able to be imported into the UK as the 'placing on the market' deadline has passed prior to Exit day?

Placing on the market commonly correlates with release from customs. However, if companies are able to demonstrate that a product is already placed on the market prior to passing customs (see 'Blue Guide') import may still be permitted.

EU legislation already on the UK statute books will continue to apply after Exit day but the role of actors in the supply chain may vary, which could affect aspects such as placing on the market. Companies are advised to understand their supply chains.

REACH

General

Who will be required to register a substance imported to the UK from outside of the EU? The substance is then exported in a product to the EU.

Assuming the substance is imported into the UK market above 1 tonne per year, the substance will have to be registered under UK REACH by the importer into the UK. The importer of the product, in which the substance is contained, into the EU market will have to register the substance under EU REACH. This is unless the supplier of the substance hasn't already registered it under UK or EU REACH respectively.

Can a Downstream User register a substance under UK REACH if another company is the importer for that material?

A Downstream User would not have registration obligations under UK REACH. The importer of that substance into the UK market is the entity who has registration obligations under UK REACH.

Does an Irish Only Representative need to register a UK-based company in order to comply with UK REACH?

Yes, EU-based companies who want to register substances under UK REACH for the UK market must appoint a UK-based Only Representative.

If a manufacturer in the EU appoints a UK Only Representative and registers for UK REACH, can a UK distributor (who has now become an importer) simply 'piggy back' off the manufacturer's compliance without any additional action?

In this scenario the distributor (who becomes importer after Brexit) will be a Downstream User (DU), as the UK Only Representative for the EU manufacturer has registered that substance. DUs have due diligence obligations under the REACH Regulation, meaning that they need to ensure and prove that the substance they are using is registered by someone else within the supply chain and they do not have any registration obligations.

Can an overseas third party force an existing appointed OR to conduct UK-REACH registrations after Brexit?

Companies cannot force other companies to take commercial decisions. It will be up to the EU-based OR to decide whether they wish to set up an OR in the UK to comply with UK REACH.

Finished products are imported to the UK and then exported to Ireland by retailers. Will a EU REACH registration be required for the substances contained in the products when they are imported in to Ireland?

Yes, the Irish retailers importing products from their UK affiliates will be importers into the EU and will therefore have registration obligations under EU REACH. However, if the substances within these products are already registered under EU REACH by the manufacturer, the Irish retailers will benefit from a re-import exemption. Therefore, they will need to have proof that they are re-importing substances already registered under EU REACH (registration numbers, invoices, etc.). We are aware that Irish competent authorities will actively check if re-import exemptions are valid.

Under UK REACH, will there be a one substance/one registration system like in EU REACH?

Yes, the same one substance/one registration principles will apply to UK REACH. UK REACH will give the possibility to companies to work in a consortium as is currently the case under EU REACH. The consortium for a specific substance will do a joint submission for one registration.

If a supplier in an EU27 Member State has designated a UK Only Representative to comply with their duties of UK REACH for a substance used in finished cosmetics, manufactured in EU27, but then import the products in UK above of 1 tonne, will this activity be covered by the registration made by the UK OR?

In this scenario the substance imported into the UK market is a substance that is already registered by the supplier further down in the supply chain. Therefore, the importing company is likely to be a Downstream User and has due diligence obligations to have proof that the substance being used is already registered under UK REACH.

REACH-IT

Will a guidance document be provided for UK REACH-IT before Exit day?

Yes, the Department for the Environment, Food and Rural Affairs (Defra) will publish guidance on how to use the UK REACH-IT system. However, the system will not be available for use by companies before Exit day; companies are reminded that this regulatory framework is only for a 'no deal' Brexit and will come into force only in this scenario.

In relation to the UK REACH-IT system, does it only apply to ingredients/substances which are imported into the UK, or does it also apply to finished cosmetics products?

As it is currently stated under EU REACH, finished cosmetic products are exempted from REACH. However, REACH applies to substances on their own or within mixtures. Therefore, single ingredients within cosmetic products that are manufactured or imported above 1 tonne per year must be registered under EU REACH. The same applies to UK REACH for the UK market.

Others

Will Trade Marks need to be registered elsewhere?

Changes to Trade Mark laws if there is a 'no deal' Brexit can be found [here](#). Further information is also available [here](#).

In terms of CITES what will be the requirements? Is there a grace period for import permits for CITES?

CITES requirements will continue to apply after the UK leaves the EU. In the EU, CITES is implemented via the EU Wildlife Trade Regulations, which set requirements for trade in certain

species within, to and from the EU and the rest of the world. Currently, this means that the movement of CITES-controlled goods can occur between the UK and EU without the need for permits. Following the UK's exit from the EU, movement of all species controlled under CITES between the UK and the EU will no longer take place freely. Import, export and re-export permits will be required. More detailed information is available [here](#).