The Regulatory Company – December 1st **2020** Brexit Update and Preparation Cosmetics (UK >>> EU)

Current Status

The negotiations between the EU and the UK are still ongoing with the date of January 1st 2021 approaching. As of January 1st 2021 EU law will continue to be applicable for products sold in the EU and Northern Ireland (under the Northern Ireland Protocol), excluding Great Britain (England, Scotland, Wales). All products currently notified in EU CPNP under the responsibility (Responsible Person) of a UK-based company need a new EU-based Responsible Person independent from the outcome of the negotiations.

The Regulatory Company (TRC) has prepared to provide regulatory compliance and safety assessment services including servicing as the Responsible Person in both the EU as well as in the UK. To that end, TRC has set up office in the UK under the company The Regulatory Company UK (TRC UK).

TRC invites all UK-based Responsible Persons (e.g. manufacturers/brand-owners/exporters/distributors) to contact TRC for a regulatory Prescan; and a custom made offer for EU Responsible Person services. The Prescan will give you immediate insights in the possibilities, steps to take, lead-times and the resources needed to have your products notified in the EU Cosmetic Products Notification Portal (CPNP) by TRC.

UK >>> EU transfer of Responsible Person - Requirements and Preparations

Time is running out. You have to act now to save costs, prevent supply chain disruptions and corrective actions from EU inspection authorities.

It is most effective and cost efficient to work with a single service provider that provides comprehensive regulatory services (PIF, Safety Assessment, Label & Claim review, CPNP notification, Responsible Person) in both the EU and the UK.

1) **EU Responsible Person**: non-EU companies selling into the EU need to have an EU Responsible Person (EU RP) to be responsible for the products available on the EU market. Every direct importer into the EU will be considered to be the EU RP for the products it imports with all the duties and responsibilities that come with it. Alternatively, TRC can be appointed as the single RP for the EU. In that case, direct importers into the EU will have to mandate TRC to be the EU RP on their behalf and no confidential information needs to be shared with EU importers/distributors.

>>> Contact TRC for EU RP contractual details and service fees

>>> Once you have appointed TRC as your EU RP, TRC will sign RP mandates with the direct importer(s) of your products into the EU

2) EU product notifications: products sold on the EU market need to be notified prior to sale by an EU RP as of January 1st 2021. Existing product notifications can be transferred by a UK RP in CPNP until December 31st 2020. As of January 1st 2021 UK RPs will no longer have access to CPNP. With or without transfer to an EU RP, we advise to make a full portfolio data export of your notifications from CPNP.

>>> Once you have appointed TRC as your EU RP, TRC will prepare to notify your products in CPNP as soon as possible, but only after we have assessed for EU compliance based on your current product information file (PIF)

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3) Product Information File (PIF): for the Dutch authorities (unlike most other EU member state authorities) the EU PIF can be in English including the safety assessment reports (CPSRs). We will make the EU PIF available to the Dutch authorities upon request at the TRC RP address in the Netherlands.

>>> As your EU RP, TRC will have the CPSRs adjusted and ready whenever inspection takes place

- 4) Labelling: as the EU Cosmetics Regulation does not change, there is no grace period (unlike in the UK) to have adjusted labels for products that are make available on the EU market as of January 1st 2021. We urgently advice to adjust labelling on your primary and secondary packaging as short term as feasible. As of January 1st 2021 it is possible to include both the RP for the EU and for the UK on a single label provided that the label is multi-lingual and includes all the applicable languages for the countries where the product is sold.
 - New products and existing products placed on the EU market as of January 1st 2021: product labels
 must include the EU RP details on the label as of January 1st 2021 and must include the country of
 origin on the label for all products manufactured outside the EU including the UK.
 - Existing products on the market before December 31st 2020: no need for re-labelling

>>> Contact TRC for the TRC RP details to be included on the label and other potential label adjustments that may be required before you redesign your labels

Other relevant topics to consider

For UK based companies and companies that worked with an UK RP there is more to take into account than to adjust under the EU Cosmetics Regulation. Other relevant regulations and topics to consider are:

- EU/member state customs and tariffs
- EU REACH
- The Northern Ireland Protocol

More information

You may also find it useful to visit the Brexit Public Advice page on the website of the UK Cosmetic, Toiletry and Perfumery Association (CTPA) at <u>https://www.ctpa.org.uk/brexit-advice</u>. In this page companies and individuals in the cosmetic and personal care industry can access CTPA public advice on Brexit.

For the EU Cosmetics Regulation you can find more information at https://ec.europa.eu/growth/sectors/cosmetics/legislation en.

Contact The Regulatory Company

Feel free to contact to discuss general questions, receive more information about our services, learn more about our Prescan and/or for contractual details.

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