



Brussels, 18 July 2019
REV1 – replaces the notice dated 29
November 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF COSMETIC PRODUCTS

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union (TEU). Following a request by the United Kingdom, the European Council (Article 50) agreed on 11 April 2019¹ to extend further² the period provided for in Article 50(3) TEU until 31 October 2019.³ This means that the United Kingdom will be, as of 1 November 2019 ('the withdrawal date'), a 'third country'.^{4 5}

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the uncertainties surrounding the ratification of the Withdrawal Agreement,⁶ all interested parties, and especially economic operators, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to the transition period provided for in the Withdrawal Agreement,⁷ as of the withdrawal date the EU rules in the field of cosmetic products, in particular Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30

¹ European Council Decision (EU) 2019/584, OJ L 101, 11.4.2019, p. 1.

² Following a request by the United Kingdom, the European Council had decided a first extension on 22 March 2019 (European Council Decision (EU) 2019/476, OJ L 80 I, 22.3.2019, p. 1).

³ On 11 April 2019, following a second request for an extension by the United Kingdom, the European Council also decided that the decision to extend until 31 October 2019 would cease to apply on 31 May 2019 if the United Kingdom had not held elections to the European Parliament and had not ratified the Withdrawal Agreement by 22 May 2019. As the United Kingdom had not ratified the Withdrawal Agreement by 22 May 2019, it held European elections on 23 May 2019.

⁴ A third country is a country not member of the EU.

⁵ In addition, if the Withdrawal Agreement is ratified by both parties before that date, the withdrawal takes place on the first day of the month following the completion of the ratification procedures.

⁶ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ C 144 I, 25.4.2019, p. 1.

⁷ It is recalled that, in order for the transition period to apply, the Withdrawal Agreement has to be ratified by the EU and the United Kingdom.

November 2009 on cosmetic products⁸, no longer apply to the United Kingdom. This has in particular the following consequences for cosmetic products placed on the EU market as of the withdrawal date:

1. RESPONSIBLE PERSON

According to Article 4 of Regulation (EC) No 1223/2009, only cosmetic products for which a legal or natural person is designated within the EU as 'responsible person' shall be placed on the market. The responsible person shall ensure compliance with the relevant obligations set out in Article 5 of Regulation (EC) No 1223/2009.

According to Article 4(3) of Regulation (EC) No 1223/2009, for cosmetic products manufactured within the EU, the responsible person shall be the manufacturer established within the EU (by default) or a person who is established within the EU and is designated by written mandate by the manufacturer and has accepted in writing.

According to Article 4(5) of Regulation (EC) No 1223/2009, for cosmetics imported into the EU from a third country, the importer becomes the responsible person (by default) or can designate by written mandate another person to be the responsible person, also established within the EU, who shall accept in writing.

As of the withdrawal date, responsible persons can no longer be established in the United Kingdom. Rather:

- If the cosmetic product is manufactured in the United Kingdom, the importer in the EU-27 becomes the responsible person (by default) or can designate by written mandate another person to be the responsible person, also established within the EU, who shall accept in writing.
- The same applies if the cosmetic product is manufactured in another third country, imported into the United Kingdom and subsequently imported into the EU-27.

Where, currently, a responsible person established in the United Kingdom is designated by an EU-27 manufacturer/importer, that manufacturer/importer should take the necessary measures to ensure that, after the withdrawal date, a responsible person is established in the EU-27

2. NOTIFICATION IN THE COSMETIC PRODUCT NOTIFICATION PORTAL

According to Article 13(1) of Regulation (EC) No 1223/2009, prior to placing the cosmetic product on the market, the responsible person shall notify a list of information relating to the cosmetic product to the Commission, through the Cosmetic Product Notification Portal⁹ (CPNP).

⁸ OJ L 342, 22.12.2009, p. 59.

⁹ https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en.

As of the withdrawal date, prior to placing a cosmetic product on the EU-27 market, the new responsible person in the EU-27 will have to make product notifications in the CPNP.

As regards existing notifications made before the withdrawal date by a responsible person established in the United Kingdom, the CPNP offers the possibility to transfer notifications to another responsible person. Thus, a UK-based responsible person can transfer an existing notification to the future EU-27 responsible person. This EU-27 responsible person will then be able to edit the notification and complete it by adding its own required information, such as the name and address of the responsible person (point (b) of the first subparagraph of Article 13(1) of Regulation (EC) No 1223/2009), and the new labelling (Article 13(2) of Regulation (EC) No 1223/2009; see also the section 4 of this notice). However, this transfer in CPNP is only possible until the withdrawal date. As of the withdrawal date, the former UK-based responsible person will no longer have access to the CPNP.

New responsible persons established in the EU-27 can already indicate before the withdrawal date that cosmetic products manufactured in the United Kingdom will be, as of the withdrawal date, imported into the Union from the United Kingdom as a country of origin.

3. PRODUCT INFORMATION FILE (PIF)

According to Article 11 of Regulation (EC) No 1223/2009, when a cosmetic product is placed on the market, the responsible person shall keep a product information file (PIF) for the cosmetic product for a period of ten years.

The PIF shall be readily accessible in electronic or other format at the address of the responsible person, as indicated on the label of the cosmetic product, to the competent authority of the Member State in which the PIF is kept. The information in the PIF shall be available in a language that can be easily understood by the competent authority of the Member State.

As of the withdrawal date, the PIF has to be made available at the address of the responsible person in the EU-27 and adapted in terms of the language requirements of the Member State in question.

4. LABELLING

According to Article 19 of Regulation (EC) No 1223/2009, the name and address of the responsible person shall be indicated on the label of cosmetic products. The country of origin shall be specified for imported cosmetic products.

As of the withdrawal date, cosmetic products manufactured in the United Kingdom and placed on the EU market will be a cosmetic product imported into the EU-27 from a third country. The country of origin will need to be specified for these imported cosmetic products.

5. SAFETY ASSESSOR

According to Article 10(1) of Regulation (EC) No 1223/2009, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is drawn up in accordance with Annex I to Regulation (EC) No 1223/2009 and the related Guidelines laid down in Commission Implementing Decision 2013/674/EU of 25 November 2013.¹⁰ The cosmetic product safety report is included in the PIF.

Pursuant to Article 10(2) of Regulation (EC) No 1223/2009, the cosmetic product safety assessment “*shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State.*”

Section 4.4 of the Guidelines on Annex I to Regulation (EC) No 1223/2009 requires proof of the safety assessor’s qualification (i.e. copy of the diploma and, where needed, proof of equivalence) to be provided with the cosmetic product safety report.

As of the withdrawal date, qualifications from the United Kingdom which have not been recognised as equivalent by an EU-27 Member State can no longer be relied on for the purpose of fulfilling the requirements of Article 10(2) of Regulation (EC) No 1223/2009. It follows that:

- for a cosmetic product placed on the Union (EU-27) market prior to the withdrawal date: cosmetic product safety assessments carried out and safety reports drawn up prior to the withdrawal date by a safety assessor holding qualifications from the United Kingdom will remain valid.
- for any cosmetic product placed on the Union (EU-27) market as of the withdrawal date: the cosmetic product safety assessment must have been carried out and the safety report drawn up by a safety assessor who, on the date of placing on the market, fulfils the requirements of Article 10(2) of Regulation No 1223/2009, i.e. holds the necessary qualifications from an EU-27 Member State.

Safety assessors currently holding qualifications from the United Kingdom are therefore advised to seek, before the withdrawal date, recognition of equivalence from an EU-27 Member State in order for their credentials to remain compliant with the requirements of Article 10(2) of Regulation No 1223/2009.

The website of the Commission on EU rules on cosmetic products (http://ec.europa.eu/growth/sectors/cosmetics/legislation_en) provides general information concerning Union legislation applicable to cosmetics. These pages will be updated with further information, where necessary.

European Commission
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

¹⁰ OJ L 315, 26.11.2013, p. 82.