



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES

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dated 18 July 2019

NOTICE TO STAKEHOLDERS

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

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a ‘third country’.¹ The Withdrawal Agreement² provides for a transition period ending on 31 December 2020.³ Until that date, EU law in its entirety applies to and in the United Kingdom⁴.

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom’s participation in the internal market,⁵ in the EU Customs Union, and in the VAT and excise duty area.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation applicable as of the end of the transition period (Part A below). This notice also explains certain relevant separation provisions of the Withdrawal Agreement (Part B below), as well as the rules applicable to Northern Ireland as of the end of the transition period (Part C below).

¹ A third country is a country not member of the EU.

² 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 L 29, 31.1.2020, p. 7 (“Withdrawal Agreement”).

³ The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

⁴ Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

⁵ In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the ‘country of origin principle’, and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

Advice to stakeholders:

To address the consequences set out in this notice, stakeholders are in particular advised to:

- ensure establishment in the EU, and reflect this in the corresponding labelling;
- ensure compliance of the safety assessment (qualifications of safety assessor); and
- take the necessary steps to update the Cosmetic Product Notification Portal (CPNP).

A. LEGAL SITUATION APPLICABLE AS OF THE END OF THE TRANSITION PERIOD

As of the end of the transition period, 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 November 2009 on cosmetic products⁶, no longer apply to the United Kingdom.⁷ This has in particular the following consequences:

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 end of the transition period, 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 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;

⁶ OJ L 342, 22.12.2009, p. 59.

⁷ Regarding the applicability of Regulation (EC) No 1223/2009 to Northern Ireland, see Part C of this notice.

- the same applies if the cosmetic product is manufactured in another third country, imported into the United Kingdom and subsequently imported into the EU.

Where, currently, a responsible person established in the United Kingdom is designated by an EU manufacturer/importer, that manufacturer/importer should take the necessary measures to ensure that, as of the end of the transition period, a responsible person is established in the EU.

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 Portal⁸ (CPNP).

As of the end of the transition period, prior to placing a cosmetic product on the EU market, the new responsible person in the EU will have to make product notifications in the CPNP.

As regards existing notifications made before the end of the transition period 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 responsible person. This EU 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 section A.4 of this notice). However, this transfer in CPNP is only possible until the end of the transition period. As of the end of the transition period, the former UK-based responsible person will no longer have access to the CPNP.

New responsible persons established in the EU can already indicate before the end of the transition period that cosmetic products manufactured in the United Kingdom will be, as of the end of the transition period, imported into the EU 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.

⁸ https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en.

As of the end of the transition period, the PIF has to be made available at the address of the responsible person in the EU 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 end of the transition period, cosmetic products manufactured in the United Kingdom and placed on the EU market will be a cosmetic product imported into the EU 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 2013.⁹ 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 end of the transition period, qualifications from the United Kingdom which have not been recognised as equivalent by an EU 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 any cosmetic product placed on the EU market as of the end of the transition period – the 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 Member State.

Safety assessors currently holding qualifications from the United Kingdom are therefore advised to seek, before the end of the transition period, recognition of

⁹ OJ L 315, 26.11.2013, p. 82.

equivalence from an EU Member State in order for their credentials to remain compliant with the requirements of Article 10(2) of Regulation No 1223/2009.

B. COSMETIC PRODUCTS PLACED ON THE EU OR THE UK MARKET BEFORE THE END OF THE TRANSITION PERIOD

Article 41 of the Withdrawal Agreement provides that an existing and individually identifiable good lawfully placed on the market in the EU or the United Kingdom before the end of the transition period may be further made available on the market of the EU or of the United Kingdom and circulate between these two markets until it reaches its end-user.

The economic operator relying on that provision bears the burden of proof of demonstrating on the basis of any relevant document that the good was placed on the market in the EU or the United Kingdom before the end of the transition period.¹⁰

For the purposes of these provisions, “placing on the market” means the first supply of a good for distribution, consumption or use on the market in the course of a commercial activity, whether in return or payment or free of charge.¹¹ ‘Supply’ means that ‘an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or is the subject matter of an offer to a legal or natural person or persons to conclude such an agreement.’¹²

Example: An individual cosmetic product sold before the end of the transition period by a UK-based producer to a UK-based wholesaler and labelled with a responsible person established in the United Kingdom can still be imported into the EU without the need for re-labelling the cosmetic product.

C. APPLICABLE RULES IN NORTHERN IRELAND AFTER THE END OF THE TRANSITION PERIOD

As from the end of the transition period, the Protocol on Ireland/Northern Ireland (‘IE/NI Protocol’) applies.¹³ The IE/NI Protocol is subject to periodic consent of the Northern Ireland Executive and Assembly, the initial period of application extending to 4 years after the end of the transition period.¹⁴

The IE/NI Protocol makes certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland. It also provides that insofar as EU rules

¹⁰ Article 42 of the Withdrawal Agreement.

¹¹ Article 40(a) and (b) of the Withdrawal Agreement.

¹² Article 40(c) of the Withdrawal Agreement.

¹³ Article 185 of the Withdrawal Agreement.

¹⁴ Article 18 of the IE/NI Protocol.

apply to and in the United Kingdom in respect of Northern Ireland, it is assimilated to a Member State.¹⁵

The IE/Ni Protocol provides that Regulation (EC) No 1223/2009 applies to and in the United Kingdom in respect of Northern Ireland.¹⁶

This means that references to the EU in Parts A and B of this notice have to be understood as including Northern Ireland, whereas references to the United Kingdom have to be understood as referring only to Great Britain.

More specifically, this means *inter alia* the following:

- a cosmetic product placed on the market in Northern Ireland has to comply with Regulation (EC) No 1223/2009;
- a cosmetic product manufactured in Northern Ireland and shipped to the EU is not an imported cosmetic product for the purpose of labelling (see above, section A.4);
- a cosmetic product shipped from Great Britain to Northern Ireland is an imported cosmetic product (see above, sections A.1 and A.4);
- the responsible person may be established in Northern Ireland (see above, section A.1).

However, the IE/Ni Protocol excludes the possibility for the United Kingdom in respect of Northern Ireland to

- participate in the decision-making and decision-shaping of the Union;¹⁷
- initiate objections, safeguard or arbitration procedures to the extent that they concern regulations, standards, assessments, registrations, certificates, approvals and authorisations issued or carried out by EU Member States;¹⁸
- act as leading authority for assessments, examinations and authorisations;¹⁹
- invoke the country of origin principle or mutual recognition for products placed legally on the market in Northern Ireland.²⁰

The website of the Commission on EU rules on cosmetic products (http://ec.europa.eu/growth/sectors/cosmetics/legislation_en) provides general

¹⁵ Article 7(1) of the Withdrawal Agreement in combination with Article 13(1) of the IE/Ni Protocol.

¹⁶ Article 5(4) and section 17 of annex 2 to the IE/Ni Protocol.

¹⁷ Where an information exchange or mutual consultation is necessary, this will take place in the joint consultative working group established by Article 15 of the IE/Ni Protocol.

¹⁸ Fifth subparagraph of Article 7(3) of the IE/Ni Protocol.

¹⁹ Article 13(6) of the IE/Ni Protocol.

²⁰ First subparagraph of Article 7(3) of the IE/Ni Protocol.

information concerning Union legislation applicable to cosmetics. These pages will be updated with further information, where necessary.

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