Research article

A comparative analysis of European and British cosmetic products legislation

Patrycja Kramarczuk, Krystian Gałęcki*

Institute of Natural Products and Cosmetics, Lodz University of Technology, Stefanowskiego 2/22, 90-537 Lodz, Poland

*krystian.galecki@p.lodz.pl

Abstract: *Due to the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union (EU), cosmetic products made available in this country are no longer subject to European legislation, but to British cosmetics law. The exit process (Brexit) was a rather chaotic event with not fully known consequences. The legal changes brought about by Brexit are difficult to understand for many cosmetic companies. Therefore, the aim of this work was to compare and demonstrate the legal differences between European and British cosmetic law, resulting from the withdrawal of the United Kingdom from the EU. The main differences concern the issues related to the responsible person, notification, documentation and labelling of the cosmetic product.*

Key words: *cosmetic law; Brexit; regulation 1223/2009*

Introduction

From January 31, 2020, the United Kingdom (UK) is not a member of the European Union (EU), which results in the need to introduce changes to the legislation in many areas. Until December 31, 2020, there was a transitional period in which both EU and British legislation was in force in the UK [1]. During the transitional period, goods that were placed on the UK market could continue to be made available on the market. In practice, during the transitional period, new terms of cooperation were negotiated and new legislation was established [2]. The interested parties were obliged to adapt to the new legal requirements so that after the end of this period they would act legally under British law [3].

The consequences of Great Britain's withdrawal from the EU are not yet fully understood. It is known that any trade distortions between the EU and third countries destabilise the economic security of the Community [1]. The consequences of Brexit that have been observed so far include: depreciation of the British pound, bankruptcies of companies, difficulties in trade, problems with the delivery of export goods [4]. There are assumptions about the reduction of Good manufacturing practice (GDP) and even the economic crisis, but it is still a

dynamic issue (taking into account other factors, e.g. the coronavirus pandemic) . The changes affect many sectors of trade and international exchange of goods [4,5]. The European Commission has prepared over one hundred sectoral notices to prepare businesses and individuals for change. There were also created "Brexit preparedness checklists", which were brief messages with described steps that entrepreneurs from various industries must take in order to prepare for the end of the transition period [4,5].

Cosmetic legislation

Invariably, for all interested parties in the EU, the basic legal act on cosmetic products is Regulation (EC) No 1223/2009 [6] of the European Parliament and of the Council of 30 November 2009 on cosmetic products. This legal act also remains the most important document in Northern Ireland, under the terms of the Protocol on Ireland and Northern Ireland, and will be valid for a period of 4 years from the end of the transition period. The purpose of this document [6] is to ensure the safety of cosmetic products, it organizes and streamlines activities and rules applicable in the cosmetic products sector. The regulation takes into account the latest scientific and technological achievements, defining the conditions of use of individual substances [6].

After the end of the transition period, all cosmetic products marketed exclusively in Great Britain (England, Scotland, and Wales) must only comply with Schedule 34 Amendment of Regulation (EC) No 1223/2009 [7] and related amendments. However, when a cosmetic product is made available only on the Northern Ireland market, only the EU regulation applies. This results from the provisions of the Protocol on Ireland and Northern Ireland, annexed to the agreement on the withdrawal of the United Kingdom from the EU. Despite the existence of separate legal acts, the EU and British regulations agree on the fundamental principles determining the safety of cosmetic products. Pursuant to both legal acts, the definition of a cosmetic product also remains unchanged. So far, the British regulation is largely based on the EU regulation, but it is highly probable that some of its elements will change in the near future [7,8].

Responsible person

The responsible person under both EU and British regulations is a natural or legal person whose duty is to ensure the safety of a cosmetic product placed on the market and its compliance with national legislation. It is its responsibility to have and archive information about the product [6]. Article 4 of the EU regulations [6] says that the responsible person must have its seat in the EU. The role of the responsible person may be fulfilled by:

- a manufacturer based in the EU (this is the most common case),
- an importer located in the EU placing cosmetic products manufactured outside the EU on the market,

• another person established in the Union appointed by the manufacturer or importer by issuing a written authorisation which that person accepts in writing [6].

Before Brexit, a responsible person, who was based in the United Kingdom, could retain the status of a responsible person during the intra-Community acquisition (export) of cosmetic products to the territory of another EU Member State, eg Poland. As a consequence of Brexit, the United Kingdom has become the so-called A "third country" (non-EU country) [3]. Consequently, when products are imported into the Union from a "third country", the importer obtains the Responsible Person status (which is by default). Another option is to designate a responsible person within the Union by written authorisation, with the consent of both parties. The above-mentioned possibilities involve the transfer of many duties, but also information (including confidential data) to the newly appointed responsible person [3]. According to Article 5 of the EU Regulations [6], the main duty of the responsible person is to ensure the safety of the product by preparing and storing the product documentation. It is connected with the obligation of the current responsible person to provide the newly appointed responsible person with all information about the cosmetic product, including its exact composition [6]. However, manufacturers are concerned about disclosing the composition of cosmetic products as this may lead to the creation of copies of their cosmetic formulations. Therefore, very often manufacturers choose the third option of appointing a new responsible person based in the EU. It consists in setting up a branch of the manufacturer in the territory of the Community, which takes over the duties of the responsible person. The same rules apply to the export of cosmetic products from the EU to the United Kingdom [9,10].

Notification

Article 13 of the EU Regulations [6] provides for the need to notify a cosmetic product through the EU CPNP (Cosmetic Products Notification Portal). The responsible person is obliged to notify the cosmetic product by providing the list of information about the product. The notification on the CPNP portal must be made before the product is placed on the market in the EU [6]. As part of the withdrawal of the United Kingdom from the Community, a separate portal was established for the notification of cosmetic products placed on the market in the United Kingdom. The SCPN (Submit Cosmetic Product Notification) portal replaces the CPNP portal in the United Kingdom. The portal is available from January 1, 2021. As with CPNP, notification must be made on the SCPN portal prior to placing the product on the market [11].

Therefore, the following notification scenarios for cosmetic products placed on the UK market are possible:

• When a cosmetic product is manufactured in the EU and placed and made available on the market and exported to the United Kingdom: notification of the cosmetic product is required on both websites, both CPNP and SCPN,

• When the product is manufactured in the territory of the United Kingdom and is placed on the market only in its territory: the product must be notified on the SCPN portal, as the previous notification on the CPNP portal only applies to the EU market.

Documentation

Article 11 of the EU regulation [6] mentions the necessity to keep the documentation of a cosmetic product (the so-called Product Information File). This obligation rests with the responsible person for ten years after the cosmetic product has been placed on the Union market. The documentation should be available to the competent authorities of the Member State where the responsible person is established [3]. Also, European exporters, after designating a responsible person in the United Kingdom, are required to provide documentation, which must be translated into English. This issue is also troublesome for manufacturers, as it forces them to provide confidential data on a cosmetic product so that full documentation is available at the address of the new responsible person. The necessity to translate the documentation into the language of a given country also generates additional costs [6,10].

Labelling

Pursuant to Article 19 of Regulation (EC) No 1223/2009 [6], the label of the cosmetic product should contain the data of the responsible person placing the cosmetic product on the EU market, i.e. the name and surname or the name of the registered company, together with the address of the responsible person. As additional information, contact details such as e-mail address or telephone number are often provided on the label [6]. For the consumer, it is information about whom he can contact in the event of questions, doubts or willingness to report a complaint. Following the changes related to the circulation of cosmetic products between the Community and the United Kingdom market after Brexit, for products imported into the United Kingdom from the EU, it will be necessary to provide the details of the responsible person who places the cosmetic product on the United Kingdom market, based on its territory. Similarly, the responsible person importing cosmetics into the territory of the Community will be required to provide his data on the label of the imported cosmetic product [9,11].

Another element that should be taken into account is the language in which the label of the cosmetic product is made. It is required that the label for the British market is in English, and for the European market in the official language of a given Member State. In the case of cosmetic products introduced to European markets outside the EU, a label is developed containing the legally required elements and being an adaptation to Regulation (EC) No 1223/2009 [6], the so-called "Sticker". Such a label is translated into the official language of a given country and placed in the vicinity of the original cosmetic label. The same principle now applies to the export of cosmetics to the UK market [7]. In the event of possible legal changes to the British labelling of cosmetic products in

the future, it will be necessary to adapt this element to the British legislation on the new label. In addition, the country of origin must be indicated on the label for all cosmetic products placed on the EU market that are manufactured in a "third country" [7]. Likewise, the country of origin must be indicated on the label when exporting a cosmetic product to the UK market [12].

Safety assessor

In order to fully analyse the safety of a cosmetic product and collect all information about it, a cosmetic product safety report is prepared before it is placed on the market. It is a mandatory document pursuant to Art. 10 of the EU cosmetic regulation [6]. Its structure and the required elements are specified in Annex I to Regulation (EC) No. 1233/2009. Pursuant to Art. 10 of this regulation, the safety assessment of a cosmetic product and preparation of a report should be performed by a person with appropriate knowledge and qualifications in fields such as pharmacy, toxicology, medicine or related areas. This person is called a safety assessor. Qualifications should be confirmed by a diploma of completion of the relevant studies or a course recognised as equivalent in the given country. According to section 4.4 of Appendix I of the [6], proof of qualification must be presented with the safety report. In connection with this provision, the safety assessor should make sure that his qualifications are recognised as equivalent in the country where the cosmetic product is placed on the market. Until the end of the transitional period, i.e. until December 31, 2020, the recognition of qualifications in the EU was carried out pursuant to Directive 2005/36 / EC [13]. After this period, the recognition of EU qualifications in Great Britain takes place under British law. Therefore, it is recommended that safety assessors make sure that their qualifications are equivalent and, if necessary, turn to the relevant British authorities. Similarly, safety assessors with British qualifications who carry out a safety assessment of a cosmetic product placed on the EU market should also check whether their qualifications are recognised in the EU [3, 10].

Summary

As a result of Brexit on January 31, 2020, the UK has a separate cosmetic legislation. So far, the changes in regulations have been small (table 1), but nevertheless manufacturers have to face real difficulties in the cosmetics trade. These problems include: an increase in the cost of introducing a cosmetic product to the market, additional documentation, the need to adapt the content of labels, issues related to customs aspects and online sales.

Table 1. The main differences between European and British cosmetic law

	European regulations	British regulations
Cosmetic legislations	Regulation (EC) No 1223/2009	Schedule 34 Amendment of Regulation *(EC) No 1223/2009*
Responsible person	A natural or legal person based in the EU	A natural or legal person based in the UK
Notification	Obligation to notify a cosmetic product on the CPNP portal	Obligation to notify a cosmetic product on the SCPN portal
Documentation	Documentation in the official language of the EU country	Documentation in English
Labelling	Cosmetic product label in the official language of the EU country	Cosmetic product label in English
Safety assessor	Qualifications according to national legislation	Qualifications according to British legislation

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