DRAFT for endorsement of the WG in June 2024

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**BACKGROUND DOCUMENT**

**on the procedure laid down in Article 2(4) of Regulation (EC) No 1223/2009 on cosmetic products concerning the adoption of measures by the Commission classifying a product as a cosmetic product**

*This paper aims at facilitating the practical application of this provision from the introduction of the request to the adoption by the Commission of the necessary measures referred to in Article 2(4) of Regulation (EC) No 1223/2009. This document does not have any legal value, and the suggested process can be modified when the experience shows that changes would be necessary or useful.*

# Background

## 1.1 Legal basis in the Cosmetic Products Regulation

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (‘Cosmetics Regulation’) defines ’cosmetic product’ as “*any substance or mixture intended to be placed in contact with the external parts of the human body (…) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours*”.

Article 119 of Regulation (EU) 2017/745 on medical devices[[1]](#footnote-1) (‘Medicinal Devices Regulation’) amended Article 2 of Cosmetics Regulation by adding paragraph 4: *“The Commission may,* *at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition ‘cosmetic product’. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).*’

Recital 9 of Regulation (EU) 2017/745 explains that the possibility of taking a Union-wide decision regarding the regulatory status of a product should be introduced in Regulation (EC) No 1223/2009 as in some cases it is difficult to distinguish between medical devices and cosmetic products.

This new rule applies from 26 May 2021.

## 1.2 Scope of Article 2(4)

Although recital 9 of the Medicinal Devices Regulation refers to potential problems with classification of a product between a cosmetic product and a medical device, this situation is not reflected in the text of Article 2(4) of the Cosmetics Regulation. Therefore, the Commission can decide in the implementing act that a certain product is a ‘cosmetic product’, as defined in Article 2(1)(a) of the Cosmetics Regulation even if the borderline product in question concerns detergents, toys, or any other kind of product. The Commission cannot, however, determine that a product in question is a dual-use product (a cosmetic product and a detergent, for example) or that the product in question falls under a different classification other than a cosmetic product.

## 1.3 Role of the Sub-group on Borderline Products

Certain products available on the EU market have qualities which place them in between cosmetic products and other categories of products. It is crucial for the proper implementation of the Cosmetics Regulation and its enforcement that the national competent authorities of the Member States have a commonly accepted understanding of the category to which the given product belongs. The Sub-group on Borderline Products facilitates the coordination between the Commission, the Member States competent authorities and the stakeholders to ensure a uniform approach as regards the classification of a borderline product as a cosmetic product.

The Sub-group prepares draft entries to the guideline on the scope of application of Article 2(1)(a) of the Cosmetics Regulation (Borderline Manual), for the case-by-case application by the competent authorities which, when endorsed by the **Working Group on Cosmetic Products (WG),** are made available on the Commission website.

## 1.4 Similar provisions in other EU acts

Article 4 of the Medical Devices Regulation contains a similar provision to Article 2(4) of the Cosmetics Regulation:

*1. Without prejudice to Article 2(2) of Directive 2001/83/EC, upon a duly substantiated request of a Member State, the Commission shall, after consulting the Medical Device Coordination Group established under Article 103 of this Regulation (‘MDCG’), by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of ‘medical device’ or ‘accessory for a medical device’. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3) of this Regulation.*

*2. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).*

*3. (…)*

*4. When deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells, biocides or food products, the Commission shall ensure an appropriate level of consultation of the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA), as relevant”.*

Similarly, Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products[[2]](#footnote-2) enables the Commission to decide, at the request of a Member State, by means of implementing acts, (…) whether a specific product or group of products is a biocidal product or a treated article or neither (Article 3(3)).

# 2. Procedure

## 2.1 Step 1 – launch of the procedure by a Member State or the Commission

The recourse to Article 2(4) can be made as a “last resort” measure, for instance when the competent authorities from different Member States apply different classification to a particular type of product and the introduction of an entry into the Borderline Manual cannot be agreed upon or is considered insufficient.

Pursuant to current Article 2(4) of the Cosmetics Regulation, the Commission may adopt the measure “*at the request of a Member State or on its own initiative*”.

A Member State can request the Commission to adopt the measure classifying certain products as cosmetic products under Article 2(1)(a) in a letter from the Member State representative in the **Standing Committee on Cosmetic Products (COSCOM)** or from the Permanent Representation of that Member State to the Director-General, Director or Head of Unit responsible for cosmetics in the Commission.

The letter should present the problem and provide justification why Article 2(4) should be used and the respective implementing act should be elaborated. The letter should describe the main characteristics of the product and should distinguish the information obtained from the manufacturer and those acquired from other sources. The following information should be provided, **when available and if relevant**:

1. the name or names of the product enabling its identification,
2. the category of the product – if a product is marketed as a cosmetic, its CPNP registration number,
3. its presentation and claims (explicit and/or implied) – including marketing strategy;
4. the mode of application;
5. its function(s);
6. the ingredients information:
	1. quantitative list of the ingredients
7. function of each ingredient
8. if herbal substance is used, details such as the plant part, extract ratios, conditions of extraction regime, chemical profile etc.
9. the instructions of use;
10. the name and address of the manufacturer;
11. the labelling information including a photo of a product;
12. the list of Member State markets where the product is made available;
13. the classification of the product in the requesting Member State; if it is considered a borderline case – with which category of products;
14. the manufacturer or the responsible person justification for the product to be a cosmetic product or otherwise;
15. other relevant information.

If the Commission decides to launch the procedure from its own initiative, it should prepare a document containing the explanation and the information listed above and address it to the members of COSCOM.

## 2.2. Step 2 – Transmission of the explanation to the WG and COSCOM members

The Commission informs without delay about the letter received from a Member State the members of the WG and members of the COSCOM through a commonly agreed electronic system (CIRCABC).

If it appears from the letter received from a Member State that the product in question is borderline with another category of products subject to EU harmonisation legislation, the Commission will also inform the relevant Commission services and through them – the relevant national authorities responsible for market surveillance responsible for that other category of product, about the received request. The Commission will also request information about any issues or discussions which might have taken place on the classification of this product in the relevant expert groups. When the Commission takes the initiative, it will consult other relevant Commission services before informing the WG.

## 2.3. Step 3 – Discussion in the WG

The Commission will introduce the discussion on the request at the next meeting of the WG. The Chair of the other expert group, managed by the relevant Commission service, will be invited to present the position of that group.

The Chair of the WG decides, in the light of the discussions, whether to continue the exchange of views in the WG, also with the participation of other interested stakeholders, in the Sub-group on Borderline Products, or to prepare a draft implementing act.

## 2.4 Step 4 – Discussion in the COSCOM

If the Commission considers in the light of the discussion that there is a clear added value in classifying a specific product or group of products as a cosmetic product it proceeds in preparing a draft implementing act following the same procedure as laid down in Article 32(2) of the Cosmetics Regulation.

## 2.5 Step 5 – Public consultation

The decision could have an important impact on some producers, who might have to change their labelling and their conformity assessment. This creates the need for greater transparency and consultation before the act is adopted. Hence, the public must be able to give feedback on the draft act.

The draft text will be published to the public at large on the ‘Have Your Say’ Portal. This feedback period can take place after, or in parallel to, the consultation of Member State experts. In any case, should the draft act change following the feedback received, the Member State experts should be consulted again, on the final version of the draft before its adoption.

## 2.6 Step 6 –Vote in the COSCOM

The Commission submits the final draft implementing act to the Standing Committee on Cosmetic Products (COSCOM) for voting. Article 32(2) of the Cosmetics Regulation refers to Article 5 and 7 of Decision 1999/468/EC. Regulation (EU) No 182/2011 repealed Decision 1999/468/EC (though it maintained the effects of its Article 5a) and its Article 13(1)(c) provides that “where the basic act makes reference to Article 5 of Decision 1999/468/EC, the examination procedure referred to in Article 5 of that Regulation applies and the basic act shall be deemed to provide that, in the absence of an opinion, the Commission may not adopt the draft implementing act (…).” Therefore, COSCOM will deliver its opinion in the examination procedure by the majority laid down in Article 16(4) and (5) of the TEU (the qualified majority).

1. Adoption by the Commission of the implementing act

The Commission can adopt the implementing act, when the COSCOM adopts a positive opinion. To ensure legal certainty, the classification as a cosmetic will apply after the elapse of the transitional period which will be laid down in the implementing act.

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [↑](#footnote-ref-1)
2. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. [↑](#footnote-ref-2)