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Cosmetics Europe
the personal care association

Cosmetics Europe comments on the Draft Ordinance on the organisation of the certification process of good manufacturing practices for cosmetic products and the authorisation of control officers

(TRIS notification 2023/0537/FR)

Cosmetics Europe, which represents the cosmetics and personal care industry in Europe, would like to share its concerns regarding the draft Ordinance submitted by France through the TRIS process, under the notification number 2023/0537/FR (the "Draft Ordinance").

Context

The Draft Ordinance inserts a new article L. 5131-7 in the French Public Health Code.[1] This new article together with Article 205 of the French Finance Act No 2022-1726[2], impose on certain establishments manufacturing and packaging cosmetic products on the French territory, to have their manufacturing and packaging practices certified by an accredited certification body for compliance with good manufacturing practices ('GMP')[3]. The modalities for implementation of the certification system will be specified by a decree of the French Council of State. This new compulsory pre-requisite certificate differs from the certificate that can be requested in France on a voluntary basis for exporting cosmetic products outside de EU[4].

Principle of compliance with GMP regulated under the Cosmetic Products Regulation

The Cosmetic Products Regulation does not provide, as a prerequisite, the issuance of a certificate to demonstrate the compliance with GMP. It is sufficient, as per article 11.2.(c) of the Cosmetic Products Regulation, that the product information file contains a description of the method of manufacturing and a statement on compliance with GMP.

Likewise, the Cosmetic Products Regulation does not impose a specific method of GMP to be followed. However, Article 8(2) of the Cosmetic Products Regulation introduces a presumption of compliance with the GMP when "*the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union*".

In the frame of the in-market control of Article 22 of the Cosmetic Products Regulation, Member States monitor the compliance with the principles of GMP.

[1] French Public Health Code.
[2] Article 205, Loi n° 2022-1726 du 30 décembre 2022 de finances pour 2023, *JORF*, n° 0303, 31 décembre 2022.
[3] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, *O.J.*, L 342, 22 December 2009, p. 59.
[4] Article R5131-2, French Public Health Code.

New compulsory additional French certification requirements on GMP

Preliminary remark

The French State mentions that the new national provisions introduced by the Draft Ordinance do not impose additional requirements on cosmetic products because these national measures apply only to the establishments manufacturing and packaging cosmetic products on the French territory[5].

However, in practice, it is not possible, with regard to GMP, to dissociate requirements imposed on establishments from requirements on the products manufactured therein and on the obligations of the actors of the supply chain, which are regulated by the Cosmetic Products Regulation.[6]

National measures have to comply with EU harmonised law

Cosmetics Europe would like to make a note of caution regarding the introduction of a compulsory certificate of compliance with GMP for establishments manufacturing cosmetic products in France.

First, any system introduced by a Member State to regulate the compliance by establishments with GMP should be compatible in particular with the principle of self-declaration of compliance with the GMP foreseen by Article 11.2(c) of the Cosmetic Products Regulation.

In addition, Member States should not impose a particular standard to be followed as regards GMP for the manufacturing of cosmetic products as this could be seen to be in infringement of Article 8 of the Cosmetic Products Regulation, which leaves the choice of the GMP method to the manufacturer.

Also, it has to be noted that the monitoring by Member States of the GMP for cosmetic products has to be done in compliance in particular with Article 22 of the Cosmetic Products Regulation in the frame of the in-market control, i.e after the products are placed on the market. It could therefore be questioned whether an a priori certification is compatible with this Article 22.

The power given to Member States, as per Recital 56 of the Cosmetic Products Regulation, to "*regulate, […], the establishment of economic operators in the area of cometic products*", has to be exercised in compliance with EU law, amongst which, the Cosmetic Products Regulation and its articles on GMP (Articles 8.2, 11.2.(c) and 22).

The French Council of State already clarified the scope of Recital 56 of the Cosmetic Products Regulation on the occasion of a national ruling of 2nd October 2017[7], by which it specified that while the Cosmetic Products Regulation does not affect the power of Member States to regulate, in compliance with EU law, the establishment of economic operators in the cosmetic products sector, it prevents Member States to modify the rules which it has exhaustively harmonised for the purpose of the free circulation of cosmetic products in the Internal Market.

Requests to the European Commission

Cosmetics Europe calls on the European Commission to examine the Draft Ordinance towards the EU Cosmetic Products Regulation and to extend the standstill period as necessary.

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[5] See the Notification Message accompanying the TRIS notification number 2023/0537/FR.

[6] As per the Cosmetic Products Regulation, only safe cosmetic products for which a Responsible Person is designated in the EU can be placed on the market (Articles 3 and 4.1). For each cosmetic product placed on the market, the Responsible Person shall ensure compliance with the relevant obligations set out in the Cosmetic Products Regulation (Articles 4.2 and 5), and in particular with Article 8 (compliance with GMP) and Article 11.2.(c) (self-declaration of compliance with GMP in the product information file). As per Article 25 of the Cosmetic Products Regulation, the national authorities could request the Responsible Person to take all appropriate actions in case of non-compliance in particular with the GMP referred to in Article 8 of the Cosmetic Products Regulation.

[7] Conseil d'État, 2nd October 2017, n° 399450.