

Explanatory note of the Commission's services¹ regarding transitional provisions and dates of application of the Cosmetics Regulation

1. Introduction

As a **general rule**, Council Directive 76/768/EEC (the Cosmetics Directive) and EC Regulation 1223/2009 (the Cosmetics Regulation) are applicable **successively**. Therefore, as from 11 July 2013, when the Cosmetics Regulation is applicable, the Cosmetics Directive is repealed (Articles 38 and 40 of the Cosmetics Regulation²).

However, an **exception** exists for provisions relating to **CMR substances** regarding the date of application, which is 1st December 2010, instead of 11 July 2013. Therefore, at that date, Article 4b of the Cosmetics Directive is repealed (Article 38) and Article 15 (1) and (2) is applicable in connection with Articles 14, 31 and 32 for the inscription of CMR substances within annexes of the Cosmetics Regulation (Article 40(2), 1st indent).

Furthermore, in order to allow a smooth transition and to not request from one day to the other the respect of adapted or new requirements provided by the Cosmetics Regulation, the text provides for transitional provisions (recital 67). Indeed, cosmetic products complying with the Regulation **may be placed on the market, even though it is before 11 July 2013** (Article 39 paragraph 1). In such situation, although the Cosmetics Directive would not be repealed, a derogation from this Directive is provided. In the specific case of the **notification requirement** (Article 13), the derogation from the Cosmetics Directive (Articles 7(3) and 7a(4)) applies **only as from 11 January 2012**³ (recital 25, Article 39, paragraph 2).

While providing that cosmetic products complying with the Regulation can be placed on the market before 11 July 2013, the Regulation does not specify if all its requirements have to be fulfilled. Considering that the Regulation is applicable as from 11 July 2013 and that all its requirements are opposable to third parties only as from that date, it can be concluded that it is possible to **partially apply** the Regulation before 11 July 2013. Therefore it may be possible, for example, to notify the product in application of Article 13, but to not have yet a product information file according to Article 11.

2. Safety assessment and product information file

Cosmetic products made available on the market must be safe (Article 3). To that end a **safety assessment** of the product must be performed (article 10) and this safety must be demonstrated through a **product safety report** (Annex I). For that purpose, a **product information file**, inter alia composed of the product safety report, must be available to competent authorities (Article 11).

¹ This explanatory document is not legally binding. The ultimate interpretation of Community law lies with the European Court of Justice.

² The articles mentioned in this note are those of the Cosmetics Regulation, except when an express reference is made to the Cosmetics Directive.

³ The European database necessary to notify cosmetics products according to Article 13 of the Cosmetics Regulation should be available by that date (11 January 2012).

Each cosmetic product (item) is supposed to have been the object of a safety assessment and a product information file must be available for each of them. However, in practical term the responsible person will perform one safety assessment and have one product information file in relation to one cosmetic product (for several identical items).

These requirements⁴ apply to cosmetic products (items) placed on the market as from 11 July 2013. Therefore, the introduction of these new requirements does not lead to the withdrawal of cosmetic products already available on the market (in the distribution chain) when the new requirements apply.

As mentioned above, in order to allow smooth transition, cosmetic products which comply with the Cosmetics Regulation safety assessment requirements (Articles 10 and 11 and Annex I) may be placed on the market before 11 July 2013 (recital 67 and article 39, paragraph 1), without having to comply with the Cosmetics Directive requirements (Article 7a of this directive).

Therefore, **on 11 July 2013**, the **following cases** must be considered:

- The cosmetic product was placed on the market **according to the Cosmetics Directive requirements** (Article 7a). As from 11 July 2013, safety information according to Articles 10 and 11 of the Cosmetics Regulation must be readily accessible. Indeed, Articles 10, paragraph 1 and 11, paragraph 4 provide that these requirements “*shall also apply to cosmetic products that have been notified under Directive 76/768/EEC*”. Therefore, cosmetic products already available on the market on 11 July 2013 **have to fulfil these requirements** if the responsible person continues to place them on the market after that date. It is considered that these products (new items) are placed on the market after the date of application of the Regulation.

However, for cosmetic products already available on the market on 11 July 2013, but for which **further items are no longer placed on the market** by the responsible person as from that date, the responsible person **does not have to make readily accessible the safety information** in application of Articles 10 and 11 of the Cosmetics Regulation. The information collected pursuant to Article 7a of the Cosmetics Directive would then have to be kept readily accessible by the responsible person until 11 July 2020 (Article 38 paragraph 4).

- The cosmetic product was placed on the market before 11 July 2013 and the responsible person decided, in application of the transitional provision (Article 39, paragraph 1) **to already apply Articles 10 and 11 of the Cosmetics Regulation** instead of the Cosmetics Directive requirements (Article 7a of this directive).

⁴ These requirements of the Cosmetics Regulation correspond to requirements contained in the Cosmetics Directive (Article 7a), which have been adapted, and complemented by Annex I of the Cosmetics Regulation.

3. Notification

Article 13 provides that before being placed on the market a cosmetic product must be notified⁵ to the Commission (European database). Each cosmetic product (item) is supposed to be notified. However, in practical term the responsible person will do one notification in relation to one cosmetic product (for identical items).

This requirement applies to cosmetic products placed on the market as from 11 July 2013. Therefore, the introduction of this new requirement does not lead to the withdrawal of cosmetic products already available on the market (distribution chain) when the new requirement applies.

As mentioned above, in order to allow smooth transition, cosmetic products may be notified according to Article 13, as from 11 January 2012 (recital 67 and Article 39, paragraph 2), without having to comply with the Cosmetics Directive requirements (Articles 7(3) and 7a(4) of this directive).

Therefore, **on 11 July 2013**, the **following cases** must be considered:

- The cosmetic product was notified **according to the Cosmetics Directive requirements** (Articles 7(3) and 7a(4)). As from 11 July 2013 a notification will have to be done according to Article 13 of the Cosmetics Regulation. Indeed, Article 13(1) provides that this requirement “*shall also apply to cosmetic products that have been notified under Directive 76/768/EEC*”. Therefore, cosmetic products already available on the market on 11 July 2013 **have to fulfil the requirements** of Article 13 if the responsible person continues to place them on the market after that date. It is considered that these products (new items) are placed on the market after the date of application of the Regulation.

However, for cosmetic products already available on the market on 11 July 2013, but for which **further items are no longer placed on the market** by the responsible person as from that date, the responsible person **does not have to make a notification** in application of article 13 of the Cosmetics Regulation. The information collected by Member States in application of the Cosmetics Directive (Articles 7(3) and 7a(4)) would then have to be kept until 11 July 2020 (Article 38 paragraph 4).

Nevertheless, in case these cosmetic products would be **transferred by a distributor** from one Member State to another after 11 July 2013, that distributor shall communicate to the responsible person relevant information in order that the notification is done by the latter in the European database where notifications according to Article 7 (3) and Article 7a(4) of Directive 76/768/EEC had not been carried out in the Member State in which the cosmetic product is made available. (Article 13(4)).

- The cosmetic product (item) was placed on the market **between 11 January 2012 and 11 July 2013** and, in application of the transitional provision (Article 39, paragraph 2), the responsible person decided **to notify according to Article 13 of the Cosmetics Regulation**. In this case, the responsible person will not have to notify the placing on

⁵ This obligation of the Cosmetics Regulation corresponds to requirements of the Cosmetics Directive (Articles 7(3) and 7a(4)), which have been modified.

the market of cosmetic products (similar items) as from 11 July 2013, the notification having been already made.

When as from 11 July 2013 a distributor makes available on a national market a cosmetic product already available in another Member State, and for that purpose **translates at his initiative** the elements of labelling **in order to comply with national law**, then a notification obligation falls under his responsibility (Article 13(3)). This **simplified notification** will be linked, in the European database, to the original notification made by the responsible person for the same cosmetic product. This will allow the competent authorities and the antipoison center of the Member State where the distributor has introduced the product to have access to the complete information related to this product.

4. Nanomaterials

In addition to Article 13 on notification, Article 16 provides **a specific notification regime** for cosmetic products containing **nanomaterials**, which are not colorants, UV-filters or preservatives or nanomaterials which are in conformity with requirements set out in Annex III (in the following paragraphs of this note, when mentioning “cosmetic products containing nanomaterials”, it will have to be understood “nanomaterials except colorants, UV-filters or preservatives or nanomaterials which are in conformity with requirements set out in Annex III”).

The notification of a cosmetic product containing nanomaterials is **the responsibility of the related responsible person**, except in case of delegation as provided by Article 16(3), 5nd subparagraph.

Two situations must be considered:

- Cosmetic products containing nanomaterials which will be **available on the market on 11 January 2013**, because they have been placed on the market before that date, will have to be notified between 11 January and 11 July 2013 according to Article 16 requirements if the responsible person continues to place them (new item) on the market after 11 January 2013 (Articles 16(3) 2nd subparagraph and 40(2), 2nd indent).
- Cosmetic products containing nanomaterials **intended to be placed on the market** by a responsible person **after 11 January 2013**, have to be notified **six months prior** to being placed on the market according to Article 16 requirements, except if **this responsible person** has already placed this product (similar items) on the market before 11 January 2013 (Article 16 (3) 1st subparagraph), as in this case, this product would have been already notified as mentioned above.

Consequently, when a responsible person has not placed on the market a cosmetic product containing nanomaterials before 11 January 2013, the placement on the market of this product can be done only as from 11 July 2013.

5. Annexes

The Cosmetics Regulation is applicable as from 11 July 2013. However, as mentioned above, in order to allow smooth transition, cosmetic products which comply with the

Cosmetics Regulation may be placed on the market before that date (recital 67 and Article 39, paragraph 1).

However, the **annexes of the Cosmetics Regulation** adopted on 30 November 2009 reflect the situation of the science **at the time of the adoption of the proposal by the Commission on 5 February 2008**. Since that date, annexes of the Cosmetics Directive have been updated. These changes need to be included within Annexes of the Cosmetics Regulation in accordance with Article 31 of the Cosmetics Regulation. However, in the meantime, in view of the possibility to voluntarily anticipate the application of the Cosmetics Regulation, a contradiction between the two texts may appear. Indeed, in theory, the responsible person would have the choice between the respect of annexes of the Cosmetics Directive or of the Cosmetics Regulation. However, as long as the update would have not been done, although annexes of the Regulation would not be updated, **cosmetic products shall be safe** in compliance with Article 3 of the Regulation. The **conformity with the annexes of the Cosmetics Directive** would then be **necessary** in order to respect the safety requirement of Article 3 of the Regulation.

Furthermore, the situation is **peculiar** regarding **CMR substances**. As from 1st December 2010, Article 4b of the Cosmetics Directive dealing with CMR substances is repealed and Article 15 (1) and (2) of the Cosmetics Regulation, is applicable. Therefore, possible technical modifications of Annexes in order to take into account new classification of substances as CMR 1A, 1B and 2 by Regulation 1272/2008 will concern only annexes of the Regulation and not those of the Directive.