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Cosmetics Europe
the personal care association

Cosmetic Products that are Refillable at Points of Sale: *Guidance Document*

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1. Purpose of this document

The European cosmetics and personal care industry supports the overarching objective of the European Green Deal and the New Circular Economy Action Plan to accelerate the transition towards a circular economy and the reduction of waste, including through the re-use of packaging. Re-filling of packaging of cosmetic products at the points of sale is an increasing trend and is an option desired by many consumers.

The refilling of cosmetic products in industrial production is subject to high hygienic requirements. To ensure an equivalent level of hygiene where the refilling takes place in a retail setting, there are a number of important considerations to ensure that these products remain in compliance with the requirements of the Cosmetic Products Regulation ('CPR') and any additional requirements that are in place at national level.

This document has been compiled by Cosmetics Europe with the view to providing its members, as well as any interested cosmetic manufacturer or retailer, with guidance regarding essential aspects of refillable cosmetic products and of refill systems in the retail trade. Based on these guidelines, companies are advised to develop more detailed operating procedures, as appropriate for their specific refilling operations.

2. Scope of this document

This Guidance Document refers to finished cosmetic products which are distributed to retailers in larger containers from which they are dispensed on retail premises into smaller (the original or other) containers at the points of sale. Refills that take place elsewhere, e.g. at the manufacturer's site, are outside the scope of this document.

The refilled products should be considered as products that are "packaged at the point of sale at the purchaser's request" as defined in Art. 19 (4) CPR.

There are several scenarios in which a product could be refilled at the point of sale.
Consumers buy a cosmetic product and then, when the product is used up, they return to the point of sale:

A. either with the original container and, according to the instructions of the Responsible Person,
   - o). such container is refilled with the same product without being washed, or
   - i). the container, cleaned by the consumer beforehand, is refilled and returned to the same consumer, or
   - ii). the container is cleaned at the point of sale by the retailer, refilled and returned to the same consumer, or
   - iii). the container is cleaned at the point of sale or elsewhere, by or on behalf of the retailer and assessed for re-use by a subsequent consumer, or
   - iv). the container is assessed at the point of sale by the retailer before a decision is made about which of the options above is the most appropriate,

B. or with another container (than the original one) to be filled with the product.

At the point of sale, the refilling action may be performed by the retail staff or by the consumers themselves, depending on the scenario.

3. Delineation between the obligations of the Responsible Person and those of Retailers regarding the refilling systems and the refilled products

The CPR requires the designation, within the EU, of a Responsible Person for every cosmetic product placed on the EU market. This Person (who may be a natural or legal person) must take responsibility to ensure that every cosmetic product they place on the EU market complies with all the requirements of the CPR. The Responsible Person may be the manufacturer ('Manufacturer'), the importer ('Importer') or a mandated entity. Further information on the roles and responsibilities along the supply chain can be found in the Practical Guide developed by Cosmetics Europe (see the link in Section 6 below).

In order to determine who is the Responsible Person in relation to a cosmetic product which is refilled at the point of sale, two cases need to be considered.

3.1 The refilling system is set up by the Responsible Person for the cosmetic product in the larger container

It is for the Responsible Person to determine whether the product they place on the market is refillable into smaller containers and, if so, under which conditions.

As a matter of principle, it is advisable to reflect the aspects below in contractual arrangements between the Responsible Person and the retailers in order to facilitate the transmission of information and the product's traceability, and to delineate more specifically their respective roles and responsibilities in this context.

If the Responsible Person opts for a refillable product system, they:

i. should ensure that the appropriate safety assessment related to the refill is carried out and is reflected in the Product Information File ('PIF')[1]; therefore, the specific aspects further detailed in section 4 of this document might need to be considered; and
ii. should provide the retailers with the necessary information and instructions regarding the refill including for example:
    a. how the product can be refilled and under which conditions;
    b. information on the hygiene concept of the Responsible Person in particular, the hygiene criteria and procedure for staff and for the product filling (cosmetic Good Manufacturing Practices ('GMP'), including documentation);
    c. whether the retailers must inspect the container returned by the consumer for product residue and/or suitability for refilling; if the container is not clean or appears to be unsuitable for refilling, inform the consumer and possibly refuse the refilling;

[1] For further information on the PIF, see for example the Cosmetics Europe Guidance document (see the link in Section 6 below)

in hygienically objectionable containers the stated shelf life of the product cannot be guaranteed;
    d. in case of scenario B, whether the retailer must verify that the container brought by the consumer cannot be confused with food packaging;
    e. the information to be provided to consumers for each refilled product, in particular ensuring traceability through correct identification of the batch;
    f. whether the date when the large container was opened needs to be documented;
iii. should consider whether training of the retailers' employees is required and provide it if necessary;
iv. may also provide the retailer with the refilling station/system; in this case:
    a. the Responsible Person should provide instructions on the management of the station/system, notably on its usage (including how to control that it is working well), cleaning and maintenance;
    b. if it is an automatic refilling station, it should comply with the specifications of the calibration regulations concerning the labelling of the refilled quantity.
v. should inspect/audit compliance of the retailer with agreed obligations and requirements.

In this case, it will be the responsibility of the retailers:

- to strictly comply with the conditions defined by the Responsible Person; in case of deviation, the retailers' own liability may be engaged due to the contract they have with the Responsible Person; and
- where appropriate, comply with the specifications of the calibration regulations concerning the labelling of the refilled quantity.

3.2 The refilling system is set up at the own initiative of the retailer

The situation is different if the retailer decides by itself to offer product refills at the points of sale, without the support of the Responsible Person of the product sold in the larger container.

The consequences of the development of such a refill system by a retailer are that:

i. the retailer becomes itself the Responsible Person for the cosmetic products refilled, since the refilling of a cosmetic product which is already on the market into smaller containers should be considered as a modification of the product which may impact on the compliance with the requirements of the CPR (see Article 4.6 of the CPR); in such a case, the retailer will consequently have all the obligations of a Responsible Person, in line with Article 5 of the CPR;
ii. the retailer's initiative may affect the safety of the product, as the product may not have been designed as a refillable product (e.g. with regard to it preservation) and its safety may not have been assessed for this purpose; and
iii. such initiative may infringe upon intellectual property rights.[2]

[2] Cosmetics Europe, Practical Guide on the Roles and Responsibilities along the Supply Chain (see the link in Section 6 below).

4. Specific aspects to be considered by the Responsible Person

4.1 CPNP notification

The Responsible Person has the obligation to notify each cosmetic product, be it refillable or not, to the European Commission, in line with Article 13, paragraphs (1) and (2), of the CPR. A similar obligation, although more limited in terms of the information to be notified, falls on the distributor in line with Article 13(3), namely when the latter makes available in a Member State a cosmetic product already placed on the market in another Member State and translates any element of the product labelling to comply with national law.

For cosmetic products which are (also) distributed in larger containers from which they are dispensed into smaller containers at the points of sale:
- under scenario 3.1, it is the responsibility of the Responsible Person to determine if an existing notification shall be amended (e.g in the case of additional translation on the refilled pack) or if a new notification shall be made (e.g in the case of a different product name between the larger container and the refilled container)
- under scenario 3.2, the product in the small container shall be notified separately as a new product by the retailer (who has become the Responsible Person), depending on the modifications brought to the product, on a case by case basis.

4.2 Product safety assessment / product information file

In the case of refillable cosmetic products, the Responsible Person should include the following considerations during product development and safety assessment:

i. take account of the possible scenario(s) – normal or reasonably foreseeable use, multiple refillings, multiple re-use of the container – depending on the type of product (rinse-off or leave-on);
ii. assess the impact of the refilling process on the product safety; consider all possible contaminations during the process, including traces from cleaning/sanitising process (as defined by the Responsible Person), traces from previous product and risk of microbial contamination;
iii. prepare a specific hygiene concept for the entire system of refilling, including the following critical points: adequate product preservation; product residue removal from the container, cleaning of the filling nozzle and/or other key parts of the dispensing machine;
iv. define the hygienic/microbial quality management of the product, in close cooperation with a microbiologist, in compliance with cosmetic GMP at the refilling station;
v. if deemed appropriate, foresee additional challenge tests for the simulation of the entire refilling cycle, which must be carried out under the supervision of a microbiologist with experience in the field of cosmetics[3];
vi. for post-market surveillance and cosmeto-vigilance it is advisable to manage the reports related to originally-packaged products separately than the ones involving refilled products;

[3] As indicated in the SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 9th revision (2016): "The experimental performance of the microbial controls and the challenge tests must be carried out/supervised and validated by a microbiologist."
https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf

vii. if necessary, check whether the addition of water and/detergents (as residues of the cleaning process) may influence the integrity and safety of the refilled product;
viii. ensure that the date of minimum durability / the period after opening applies to the entire duration of the refilling from the large container into each of the smaller containers (except where the concept of 'period after opening' is not relevant[4]); if necessary, restrict this duration accordingly and document the date of opening of the large container;
ix. if necessary, define the maximum number of safe refills of the original container and take organisational measures to establish when that level has been reached (scenario A.o, A.i and A.ii as defined above in section 2);
x. take account of the possible scenario B as defined above in section 2., where the consumer brings a different container than that of the original product; if necessary, define acceptability criteria for container type and material (e.g. should be made of glass) and, where applicable, exclude the use of containers which could be confused with food packaging (in line with Article 3(a) of the CPR in conjunction with Directive 87/357/EEC).

4.3 Cleaning and sanitisation

With refillable containers, the microbial quality management and cosmetic GMP procedures are extremely important; a key consideration is whether the containers are cleaned and sanitised prior to refill/re-use or whether residue from the previous batch could still be present.

If the refillable container is washed (and sanitised, if applicable):

i. the introduction of water may influence the microbial susceptibility of the formulation; therefore, further consideration should be given to the ability to dry the container to minimise risk;
ii. it should also ideally be dried before sanitisation; alternatively, this process itself (e.g. rinsing with ethanol) would dry it anyway.
iii. as sanitization by the consumer is not a common practice, it may be necessary to increase the amount of preservative in the formulation to cope with the increased risk[5];

Traceability of refillable containers should be considered. Containers having previously contained non-cosmetic products may leach substances from the original product they contained and are not recommended for refill with cosmetic products. This is particularly important if cleaning and sanitation is outsourced to a third party who offers this service for refillable containers from different product categories.

In case product residue is left behind:

i. this may have implications for the safety, stability and/or efficacy of the product;
ii. the assessment of the returned container should include the visual cleanliness/dryness to determine which cleaning route is most appropriate before the container is refilled; this may be more difficult for opaque packaging;

[4] See Recital 48 of the Cosmetic Products Regulation https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32009R1223

[5] In this case, the safety assessment should be adapted. This might be a case where the product is not identical to the one that came initially with the original smaller package and may need a separate notification and a slightly different name.

iii. the risk to safety and/or efficacy should be assessed; advice should be obtained on whether an unwashed container may pose less risk than a poorly washed one (e.g. in case of oil-based products where rinsing with water may not remove all the product residue but could leave water behind);
iv. it is strongly recommended to consult a microbiologist with experience in the field of cosmetics;
v. it should be considered whether certain parts of the container, e.g. the lid, may be prone to retaining residue and should, therefore, be handled separately either for cleaning and sanitising before returning to the point of sale or for removing the component for separate recycling.

4.4 GMP and refilling instructions

The refilling of cosmetic products is a manufacturing operation and must therefore comply with the Good Manufacturing Practices ('GMP') as required by art. 8 of CPR.

If the refilling system belongs to the Responsible Person for the larger container, the procedures to be followed by the retailer should be fully defined by the Responsible Person, documented in the Product Information File and scrupulously implemented by the retail staff. This may require thorough and continual training at the points of sale (also see section 5.1 below).

An assessment should be made as to how many times the container can be safely refilled / re-used before it needs to be discarded or recycled; the way in which it can be determined when this stage has been reached should be defined.

Further details regarding the way cosmetic GMP applies to refillable cosmetic products can be found in FEBEA's GMP Guidelines for Cosmetic Products Manufactured/Packaged In-store.

4.5 Weights and measures

Directive 76/211/EEC on the making up by weight or by volume of certain pre-packaged products only applies to products that are pre-packaged without the purchaser present. Therefore, the average fill system and in particular the 'e' mark may not be applicable to products refilled at points of sale in the presence of the purchaser. If the Responsible Person choses to apply the 'e' mark, there is a need for statistical data showing compliance with the requirements of Directive 76/211/EEC. In case of no 'e' mark, the minimum fill system should usually be applied to these products and be accompanied by regular and systematic checking of the equipment and procedures to ensure the minimum declared fill is being achieved. However, national requirements may differ and should in any case be considered.

4.6 Original and refilled product labelling

Where the cosmetic product is first marketed in a small container which will only later be re-filled, this product must be labelled – in indelible, easily legible and visible lettering - in line with the requirements of Article 19 of the CPR.

Similarly, the consumer should be provided, for the refilled product, with information required by Article 19 of the CPR, including the batch identifier relevant to each refill (if different from the original batch). In addition, as applicable to the refilled product, the date of minimum durability and/or the period after opening should be provided (if different from the date/period provided on the original container).

Since refilled products are "packaged at the point of sale at the purchaser's request", the provisions of Article 19(4) of the CPR apply, namely Member States may have detailed rules[6] in place with regard to the form in which the information required according to Article 19 must be provided. These rules may allow the use of a label or leaflet, tape, tag or card which is handed out to the consumer at the point of sale where the product is being refilled.

4.7 Consumer information: on site (point of sale) and off site (digital)

Consumers should be provided with clear instructions on the procedure for obtaining a refill and whether they need to wash/dry the containers before refill/re-use. Advice from the relevant areas of the product development should be sought (e.g. microbiology, formulation, safety assessment) to determine whether the introduction of water and/or detergents could impact the integrity and safety of the refilled product. Further instructions should be provided with regard to the types of containers that may be considered for refilling, namely only using the original containers and/or also using any other containers that the consumer supplies, as well as their acceptability criteria.

Clear contractual arrangements between the Responsible Person and the retailer – as advised in section 3 above – might make particular sense to avoid liability risks.

The information outlined above should be available at the point of sale. However, the Responsible Person and/or the retailer may also consider the provision of this and/or of additional information by digital means.

5. Further considerations

5.1 Training of retail staff

Retail staff should be trained in relation to cosmetic product refills to minimise safety risks to consumers and themselves. In particular, this training should emphasize the proper implementation of the hygiene concept taking into account cosmetics GMP (e.g. cleaning of hoses; replacement of the larger container, if necessary; visual inspection of the containers to be refilled, etc.) and, where relevant, the (limited) durability of the refills, etc.

5.2 Packaging and sustainability

When considering whether to launch a refillable product, it may be appropriate to consider the various scenarios available before selecting the most suitable container/packaging with which to

[6] For specific rules applicable in the Member States, please contact the local trade associations: https://cosmeticseurope.eu/about-us/our-members/active-association-members

move forward. There should be consideration of the longevity and practicality of a refill/re-use scheme; it is also important to consider the whole product life-cycle when deciding upon a refill model.

Some of the key considerations will be:

i. To make packaging durable for multiple uses, it may need to be produced more robustly (heavy weighting). However, the EU Packaging and Packaging Waste Directive, which is implemented within each EU Member State, is designed to ensure that the overuse of packing does not exist. A heavier bottle will also require additional energy and material to produce and being more solid may make the product more difficult to dispense. The packaging should bear a clear indication that it is designed to be reused with a refill option.

ii. Ultimately, the packaging will end up as waste so should ideally be designed and use materials that can be recycled and be able to be recycled again and again in the future.

iii. Depending on the respective national regulations, labels may need to be produced to be applied in store over/replacing existing labels so that CPR Article 19 information, relevant to the filled batch, is visible on the product container. In this case, two situations can be envisaged: (a) the container is identical to the original container: the label should mention the batch number and the INCI list if they differ from the information on the original container and (b) the container is different from the original one: the label should include all the information required by Article 19 of the CPR. Where national legislation does not allow the use of a leaflet which is given to the consumer, such labels will need to be durable for use but easily removable for when the bottles are cleaned and refilled. These labels should then not ultimately hinder the final recyclability of the packaging.

iv. If used packaging is being transported to a facility for cleaning and sanitisation before being returned to store for refilling, additional transportation and storage costs and environmental impacts should also be considered.

6. Reference documents

The Cosmetic Products Regulation:
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (europa.eu)

Cosmetics Europe guidelines on roles and responsibilities along the supply chain:
COMPLIANCE WITH REGULATION 1223/2009 ON COSMETIC PRODUCTS (cosmeticseurope.eu)

Cosmetics Europe guidelines on the Product Information File requirement:
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The Packaging & Packaging Waste Directive:
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SPICE initiative on sustainable packaging:
Publications - SPICE (open-spice.com)

ISO standard on cosmetic Good Manufacturing Practices
ISO 22716: 2007 Cosmetics – Good Manufacturing Practices

FEBEA, GMP Guidelines for Cosmetic Products Manufactured/Packaged In-store

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