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abstract

In the wake of a discussion about a possible saving of packaging materials, systems for the filling of cosmetic products in the retail trade are partly available. Of course all conditions imposed by the EC Cosmetics Regulation as well as the supplementary national regulations in Germany and Austria apply also to the products sold in this form. For these filling stations it is, however, necessary to attach special attention to compliance with the Cosmetics GMP conditions. In these cases the filling, which is subject to high hygienic requirements in industrial production, is outsourced to the retail trade. This is why comprehensive, robust hygiene concepts are necessary in particular for these systems.

The authors have put together some essential aspects which need to be complied with when using such filling stations. In this connection it was taken into account that the organisation of the filling process in the retail trade can be designed quite differently in detail. It is necessary to consider both filling stations which are offered to customers for self-service as well as stations which are operated by retailer staff.

What needs to be taken into account from the point of view of the manufacturer, who acts as responsible person:

Determination of the procedure for the filling. Here, in particular the following scenarios are possible:

1. The customer receives in the store a receptacle intended for (re-)filling and brings the latter along with him for the next filling. He cleans the receptacle before the refilling.
2. The customer brings along another receptacle to fill the product into the latter.

Particularities of the safety assessment:

- Taking into account of the respective scenario – use, (multiple) refilling, (multiple) re-use –, depending on the type of product (rinse-off or leave-on); more particularly, with a view to:
 - The safety of the filling process
 - Possible product residues in the container
 - As well as the risk of microbial contamination.
- A specific hygiene concept should be prepared for the respective filling system. In this connection the product withdrawal by the consumer, the cleaning of the filling nozzle and a possibly insufficient preservation are seen as particularly critical points.
- Additional challenge tests may be necessary for the simulation of the entire refilling cycle (more particularly, for scenario 1). The calling in of a microbiologist with experience in the field of cosmetics makes sense.
- If necessary, it should be checked whether the addition of water and/or detergents (residues of the cleaning process) influences the integrity and safety of the product, which is to be filled into the receptacle.

- Definition of a microbial quality management to comply with the Cosmetics GMP at the refilling.
- When mentioning the period after opening or a date of minimum durability it must be ensured that the information applies during the entire duration of the filling from the large container for each refill receptacle. If necessary, this duration must be restricted accordingly and the date of opening of the large container must be documented.
- If necessary, a number of the maximum possible safe refills of the original receptacle should be defined. Organisational measures for the establishment that this level has been reached, should then be fixed. (scenario 1)
- In the event of receptacles brought along by customers (scenario 2), this should be taken into account at the safety assessment. If necessary, the eligible receptacles must be defined (“only receptacle with certain properties/suitable materials, eg made of glass”) and, if applicable, the use of receptacles which could be confused with foodstuff packaging should be excluded taking into account Art. 3 a) EC Cosmetics Regulation in conjunction with Directive 87/357/EEC.

Securing of training of the staff of the retailer, more particularly concerning the proper implementation of the hygiene concept taking into account Cosmetics GMP (e.g. cleaning of hoses, replacement of the large container, if necessary, visual inspection of the receptacles of the customer to be filled, etc.) and, if necessary, concerning the perishability/limited durability of the products offered.

Information for the customer “on site”

- In the event of self-filling by the customer, the latter should receive clear instructions about the refilling procedure and

the cleaning and/or drying of the refill receptacle. This can be done eg through a public notice at the filling station and, if necessary, be illustrated by easily understandable pictograms. General information of the customer about a possible microbiological contamination of the products at the filling in soiled and/or insufficiently cleaned and/or not dried receptacles might also make sense.

- The labelling of cosmetic products which are packed in the retail trade at the request of the buyer, is governed by the national provisions issued by the respective member state in accordance with Art. 19.4 EC Cosmetics Regulation.
 - In Germany, § 5 of the German Cosmetics Ordinance “for the labelling of not prepacked cosmetic products” must be complied with, according to which mandatory information within the meaning of Article 19.1 EC Cosmetics Regulation must be “be mentioned on an enclosed or attached label, tape, tag or card”.
 - In Austria § 3 of the Cosmetics Implementation Ordinance “Labelling of unpacked cosmetic products” must be complied with, according to which labelling must be carried out in accordance with Art. 19 of the EC Cosmetics Regulation and must be attached on the goods by means of tag, label or in a similar form.
 - According to these provisions the customer must be provided for each refill product with all mandatory information under cosmetics law at least in the form of an “enclosed” paper; this should be made available by the responsible person for the respective large container.
 - Particularly for scenario 1, it must be ensured that the INCI list, the batch identification and the shelf life, which can deviate from the labelling on an original receptacle, are correct.
- In Germany it is recommended to use as a large container a receptacle with a **volume not exceeding 20 litres** taking into account the special provisions on “drum and container warehouses” according to § 31 AwSV (Ordinance on facilities for handling substances that are hazardous to water).
- Clear **contractual agreements of the responsible person with the retailer**, where the cosmetic product is to be filled, are urgently recommended to avoid liability risks.

What needs to be taken into account from the point of view of a retailer?

For refill systems of a manufacturer who acts as responsible person

- Strict compliance with all the conditions imposed by the responsible person. In the event of deviations an own liability of the retailer is possible.
- Implementation and observance of the hygiene concept of the responsible person, more particularly, compliance with the hygiene criteria for staff and for filling of the products (Cosmetics GMP) incl. documentation.
- Training of the employees concerned.
- In the event of a corresponding condition imposed, possibly inspection of the receptacles brought along for identifiable contaminations and/or suitability of the receptacles for the filling. If the receptacles are not clean or appear to

be unsuitable for refilling, the consumer must be informed accordingly and the filling must possibly be refused. In hygienically objectionable receptacles the stated shelf life of the product cannot be guaranteed.

- If necessary, verification whether the receptacles brought along cannot be confused with foodstuff packaging.
- For each filled product handing over (at least as an “enclosure”) of the information made available by the responsible person for the respective product (in Germany in accordance with § 5 of the Cosmetics Ordinance, in Austria in accordance with § 3 of the Cosmetics Implementation Ordinance), taking into account, more particularly, the correct batch identification.
- If necessary, documentation of the date on which the large container was opened.
- Compliance with the specifications of the calibration regulations concerning the labelling of the filling quantity.

For own refill systems (without the support of the supplier of a large container)

- The retailer is the responsible person for the cosmetic products refilled by him, since the filling of a product, which is already on the market, into smaller receptacles represents a modification in such a way that compliance with the applicable requirements may be affected (Art. 4.6 EC Cosmetics Regulation).
- In this case the retailer has all the obligations of a responsible person (see above and under https://www.ikw.org/fileadmin/ikw/downloads/Schoenheitspflege/Leitfaden_Verantwortlichkeiten_02_2013.pdf)

Literature

EC Cosmetics Regulation 1223/2009 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20200501>

DIN EN ISO 22716: <https://www.ikw.org/schoenheitspflege/themen/detail/gute-herstellungspraxis-kosmetik-gmp-heute-eine-selbstverstaendlichkeit-280/>

· Leitlinien für Kosmetik-GMP (Guidelines for Cosmetics GMP)

· Checkliste für Kosmetik-GMP (Check list for Cosmetics GMP)

Germany: Kosmetik-Verordnung https://www.gesetze-im-internet.de/kosmetikv_2014/KosmetikV_2014.pdf

Austria: Lebensmittelsicherheits- und Verbraucherschutzgesetz (LMSVG) BGBl. I Nr. 13/2006 idgF

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