SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES

INSTRUCTION

ON THE ACTIVITY OF PACKAGING AT THE POINT OF SALE OF COSMETIC PRODUCTS

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

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1. OBJECTIVE

The objective of the recommendations that appear in this document is to ensure that cosmetic products packaged at the point of sale is safe for the consumer. For this reason, these recommendations must be followed by material manufacturers, the responsible persons of the products and the sales personnel who package the cosmetics at the point of sale.

2. INTRODUCTION

This document has been prepared in response to the high level of non-compliances detected during the National Market Surveillance Campaign 2019: “Products that are not pre-packaged or are packaged at the point of sale”.

The practice of separately packaging and labelling these cosmetic products at the point of sale may affect their safety, the traceability of the batches and reception of the guaranteed information on the part of the consumers.

The Technical Inspection Committee of the AEMPS, (hereinafter CTI), at the request of the Working Group on cosmetic products, aware that the practice of individually packaging and labelling cosmetic products incorrectly could represent a risk for the health of consumers, has prepared and published this Guide for the Activity of Packaging Cosmetic Products at the Point of Sale.

It establishes a series of recommendations to observe to ensure the correct packaging of cosmetic products at the point of sale. It is intended for the material manufacturers of these products, the responsible persons and the personnel who package the cosmetic products and sell them separately to consumers at the point of sale.

3. DEFINITIONS AND TECHNICAL ASPECTS

Definitions

The following definitions apply for the purpose of this document:

- **Cosmetic product:** any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) 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. (Definition art 2.1 Regulation 1223/2009[1] on cosmetic products, hereinafter Regulation).
- **Cosmetic product intended for packaging at the point of sale (CPFP):** a cosmetic product that is packaged at the point of sale in accordance with a series of instructions provided by the Responsible Person, for example, a bar of soap that is divided into small pieces.

[1] Regulation (EC) nº 1223/2009 of the European Parliament and Council, of 30 November 2009, on cosmetic products.

- **Packaging at the point of sale:** product handling at the point of sale through which the CPFP is divided into smaller units that are then acquired by consumers.
- **Individual unit of sale:** cosmetic product packaged at the point of sale purchased by the consumer.
- **Responsible person:** a natural or legal person as established by the European Union who ensures compliance with all the requirements set out in the Regulation, and whose name and address appear on the labelling of cosmetic products.
- **Material manufacturer:** a natural or legal person who carries out the activity of manufacturing the cosmetic product.
- **Lowmicrobiological risk products:** cosmetic products whose compositional characteristics together with their production and packaging conditions, and a combination of these factors, do not promote the proliferation of undesirable microorganisms, as they create a hostile environment that does not allow growth and/or microbial survival,

Technical considerations and the basis for the recommendations

1. During the process of packaging the CPFP at the point of sale, these are exposed to the air, and therefore to the risk of microbiological contamination.

Applying the recommendations of this document when packaging the CPFP at the point of sale will reduce the risk of microbiological contamination of the cosmetic product.

2. In accordance with the standard UNE-EN ISO 29621[2] the risk of microbiological contamination of a cosmetic product depends on factors such as its composition, conditions of production and its packaging. This means that we can classify cosmetic products as:
    - Cosmetic products with low microbiological risk, such as colognes and soaps.
    - Cosmetic products which do not have a low microbiological risk, such as creams, shampoos, shower gels, etc.

Careful precautions must be taken when packaging at the point of sale cosmetic products which are not considered to be low microbiological risk. The packaging at the point of sale must be carried out to guarantee the microbiological quality of the products, to ensure that they are safe until their date of minimum durability

The recommendations in this document must be applied in accordance with this evaluation of microbiological risk.

[2] UNE-EN ISO 29621
Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products

3. The microbiological limits used as references for cosmetic products are as follows[2]:

UNE-EN ISO 17516. COSMETICS. MICROBIOLOGY. MICROBIOLOGICAL LIMITS		
Types of micro-organisms	Products specifically intended for children aged under 3, for the eyes or mucous membranes	Other products
Total aerobic micro-organisms Mesophilic (Bacteria plus yeasts and moulds)	≤ 1x10$_2$ UFC/g or ml[a]	≤ 1x103 UFC/g or ml[b]
Escherichia coli	Absence in 1 g or ml	Absence in 1 g or ml
Pseudomonas aeruginosa	Absence in 1 g or ml	Absence in 1 g or ml
Staphyloccocus aureus	Absence in 1 g or ml	Absence in 1 g or ml
Candida albicans	Absence in 1 g or ml	Absence in 1 g or ml

Due to the inherent variation in the method of plate counting, according to Chapter 61 of the USP or Chapter 2.6.12 of the EP, Interpretation of the results, the results are considered to exceed the limits when:
[a]> 200 UFC/g or ml
[b]> 2000 UFC/g or ml
NOTE: Sabouraud Dextrose with antibiotics can be used when bacteria colonies are detected in Sabouraud Dextrose agar.

Products whose safety depends on stricter microbiological limits: those specifically intended for children under 3 years of age or for the eyes or mucous membranes should not be re-packaged at the point of sale.

4. One of the sections that the cosmetic product safety report must include is the stability of the product under reasonably foreseeable storage conditions. This study must include:

- Storageconditions: humidity, temperature, light.
- Type of packaging: airtightness, sealing material, etc.
- Packaging materials: compatibility, permeability, absorption/seepage of substances from/into the cosmetic product.
- Use: filling volume and free space with air, frequency of normal use, etc.

Similarly, there are 4 main parameters that can cause risk of microbiological contamination:

- The intrinsic resistance of the formula of the cosmetic product to microbiological contamination.
- Contact between the product and the environment.
- The expected use (volume, dose, frequency of use, etc.).
- The area of application.
- The population it is aimed at.

[3] UNE-EN ISO 17516:2014 Cosmetics - Microbiology - Microbiological limits
[4] Recommandations relatives a l'estimation de la periode après ouverture (PAO) of the AFSSAPS.

Each parameter contributes to the risk of contamination and the multiplication of the risk of each of them results in the total microbiological risk, and with it the period after opening. The time after the packaging at the point of sale is therefore very important, so that the more time that has passed since the packaging at the point of sale, the greater the risk of increasing the microbiological load is.

Due to the large variety of parameters to take into account in the stability studies for products packaged at the point of sale, and the technical complexity that this entails, it is recommended to reduce the date of minimum durability considerably in view of the microbiological risk of the product after packaging at the point of sale. It is recommended not to exceed three months.

4. RECOMMENDATIONS TO BE CONSIDERED BY THE RESPONSIBLE PERSON

4.1. With Regard to Products

They are considered as finished products. Therefore, the responsible person for them must comply with all the requirements set out in article 4 of the Regulation before they can be made available on the market. The product information file in the safety assessmentmust also take into account:

- The instructions for handling the CPFP at the point of sale.
- How the individual unit of sale should be labelled.
- The stability studies that confirm the date of minimum durability, both for the CPFP and the sales units acquired by the consumers.

The responsible person will ensure that both the CPFP and the product packaged at the point of sale offer all guarantees of safety and information. To ensure this, the responsible person must provide the personnel at the point of sale with instructions for making the packaging at the point of sale and individual labelling of the product correctly. These instructions must contain at least the following information:

- Storage conditions.
- Cleaning and maintenance instructions of the dosing system.
- Hygiene standards
- Conditions for handling.
- Prohibition of transferring the cosmetic to a container other than that of the end client.
- Prohibition of adding ingredients.
- Prohibition of refilling the containers.
- Prohibition of handling the product at the point of sale differently from the packaging at the point of sale indicated by the responsible person and described in their product information file.
- Description of the packaging of the sales unit whose compatibility has been determined by thesafety assessment.

The labelling of the container must be in accordance with the content of article 19.1 of the regulation.

The does not require CLP labelling.

4.2. In relation with the manufacturing and packaging process for CPFP

The material manufacturers of the CPFP and importers must have submitted the corresponding declaration of responsability for manufacturing or import activities to the AEMPS.

The manufacture of cosmetic products intended to be packaged at the point of sale must be made following good manufacturing practice (GMP) from production to control and storage until the product is issued by the manufacturer to the point of sale where the cosmetic product is to be packaged.

The same conditions must be ensured from products that are imported.

It should be recalled that, like any other cosmetic product, the must be packaged in containers that offer appropriate protection against any damage and/or contamination that may occur during transport and storage. These containers must be clean, inert and suitable for the products that they contain, and they must have a sealing system that ensures that they are protected from the outside environment.

Transport to the place where they are packaged (point of sale) must avoid any alteration of the , contamination by microorganisms or chemical products, or their decomposition/deterioration due to exposure to environmental conditions.

In any case, the containers must be stored so that they are not in direct contact with the ground.

Besides, as a prolongation of the application of GMP, for the purpose of protecting the quality and safety of the cosmetic product, and thereby of the end user, it is recommended that the manufacturer adopts a series of additional measures.

These additional measures are necessary because the CPFP are not packaged at the point of sale immediately after manufacture nor in the same facilities, so it is necessary to control aspects such as the storage conditions, stability, transport conditions, identification of the packaging, the place where the product is packaged and the point of sale, etc.

These additional measures, which must be adopted by the material manufacturers of the cosmetic product are:

1. The containers must have a system that makes it possible to dose the content in hygienic conditions, minimizing the risk of accumulating product and reducing the risk of microbiological contamination. Depending on the type of product, this could be replaceable nozzles or another system.
2. If the CPFPcontainers are returned to the manufacturer by the packager at the point of sale to be reused using the same process, there must be a procedure for cleaning the containers that lists the method, the products to be used and the expiry date of this cleaning.
3. The establishment must be provided with instructions and warnings for handling and packaging the product at the point of sale, to ensure that the product maintains the same quality as when it was manufactured, (if the material manufacturer is not responsible for the product in the market, the responsible person must provide these instructions and warnings).

5. RECOMMENDATIONS TO BE TAKEN INTO ACCOUNT BY THE POINT OF SALE.

5.1 In relation with the CPFP packaging

The establishments that carry out the packaging at the point of sale of the cosmetics intended for this purpose do not have to submit a declaration of responsibility for cosmetic manufacturing activities.

The personnel who carry out this action of packaging the at the point of sale must follow the instructions provided by the responsible person, taking special care with regard to the following aspects:

1. Storage conditions and shelf life of the CPFP (before and after opening) and of the products packaged at the point of sale.
2. The storage conditions of the CPFP and the product once packaged at the point of sale.
3. Instructions for carrying out the packaging at the point of sale itself.
4. The hygiene standards that must be observed in the facilities (for example, separation of the spaces), materials and personnel in the packaging at the point of sale operations.
5. Cleaning instructions for the nozzles and other utensils and containers used in the packaging at the point of sale.
6. Indications that the CPFP cannot be transferred to another container other than that of the end client.
7. Indications that no other ingredient can be added to the PCDF, nor can it be subject to any manipulation at the point of sale other than the packaging at the point of sale indicated by the manufacturer/ responsible person and written in its product information file.
8. Description of the containers whose compatibility has been confirmed by the responsible person. If consumers decide to use their own containers without observing these recommendations, it is at their own responsibility.

5.2 In relation with the labelling in the display area and the individual unit of sale

In accordance with their nature, the CPFP must offer the information required at the point of sale under article 19.1 of Regulation 1223/2009 in two places:

1. Where they are on public display, because consumers must have the information that enables them to make informed choices at the time when they are buying products.

The following information will be visible in this area, as a minimum:

- Name of the product or the reference that identifies it
- Name and address of the responsible person
- Specific precautions for its use
- The purpose of the product
- A list of ingredients
- The country of origin if it is imported

It is not essential that the nominal content or batch number be displayed, because they will not influence the decision made by the consumer. The instructions for packaging and labelling at the point of sale must guarantee the traceability of the batch (this data must be indicated in the sales unit acquired by the consumer).

2. On the individual unit of sale acquired by the consumer, because this information must accompany the product during its working life.

- Name of the product or the reference that identifies it
- Name and address of the responsible person
- The nominal content
- Date of minimum durability
- Specific precautions for its use
- Batch number
- The purpose of the product
- A list of ingredients
- The country of origin if it is imported

6. THE RE-PACKAGING OF COSMETIC PRODUCTS NOT INTENDED FOR THIS PURPOSE

As indicated throughout this document, the packaging of cosmetic products at the point of sale entails certain risks that may have an impact on health.

Sometimes cosmetic products which are sold in large containers are re-packaged into smaller containers for use in places such as hairdressers', gymnasiums, public toilets in hotels, restaurants, offices, etc.

Among other risks, the re-packaging is made without any instructions, it has not being considered when preparing the safety assessment of the product, and it does not guarantee the information on the label. The use of refillable containers also means that the dosing devices build up a residue liable to contamination, which is another health risk.

Because of this, cosmetic products which are not intended to be packaged at the point of sale should not be packaged at the point of sale.

7. CONCLUSIONS

We are witnessing the changes that manufacturers of cosmetic products are making in their facilities, looking for products, packaging and manufacturing processes that are more sustainable and better for the environment.

At the same time, the practice of packaging cosmetic products at the point of sale is becoming more and more frequent. This activity also promotes the circular economy, in line with the current "3R" policy of the European Union; reduce, recycle and reuse containers, although when not done correctly, this may entail a risk for consumer safety.

The AEMPS and the CTI have prepared this instruction to help to ensure that this practice is carried out so as to guarantee the safety of the cosmetic products.

8. LEGAL AND BIBLIOGRAPHIC REFERENCES

- Regulation (EC) no. 1223/2009 of the European Parliament and Council, of 30 November 2009, on cosmetic products.
- Royal Decree 85/2018, of 23 February, regulating cosmetic products.
- Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on guarantees and the rational use of medicines and medical devices.
- UNE EN ISO 29621:2011 Cosmetics - Microbiology - Guidelines for the risk assessment and identification of microbiologically low-risk products
- UNE-EN ISO 17516:2014 Cosmetics - Microbiology - Microbiological limits
- The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation. 9th revision.
- Resolution CM/ResAP (2012) on safety criteria for cosmetic products intended for infants, published by the Council of Europe and translated by AEMPS.
- Recommendations for estimating the period after opening from the “Direction de l’évaluation de la publicité des produits cosmetiques, et biocides” of the “Agence française de sécurité sanitaire des produits de santé”, of 2006.