GUIDELINES FOR COMPLIANCE WITH THE "PERIOD AFTER OPENING" REQUIREMENT INTRODUCED BY THE 7TH AMENDMENT TO THE COSMETICS DIRECTIVE

Preamble

The cosmetic industry is committed to the safety of its products used under normal and reasonably foreseeable conditions. Understanding the consumer's interest in having additional information on cosmetic products, a "period after opening" (PAO) during which the product can be used without any harm will be printed - where pertinent - on the label of cosmetic products that have a minimum durability of more than 30 months. The PAO labelling must be applied in all cases where this information allows the consumer to use the cosmetic product in the most appropriate way.

Purpose of this document

The full responsibility for PAO indicated on a cosmetic product's label lies with the person responsible for placing the product on the market.

This document aims at offering guidance on the approach that manufacturers of cosmetic products may take in determining an appropriate PAO for cosmetic products. It is advisable to use this guidance in conjunction with two other Colipa documents:

- The Colipa guidelines on Microbial Quality Management
- The Colipa/CTFA guidelines on Stability of cosmetic products

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PART I

EUROPEAN COMMISSION

Practical implementation of Article 6(1)(c) of the Cosmetics Directive (76/768/EEC)[1]:

LABELLING OF PRODUCT DURABILITY: "PERIOD OF TIME AFTER OPENING"

Please see final draft attached. As soon as it is officially published, the Commission document will be inserted into the Colipa guidelines.

[1] As last modified by the European Parliament and Council Directive 2003/15/EC. OJ L66, 11.03.2003, p. 26

PART II

COLIPA GUIDELINES FOR COMPLIANCE WITH THE "PERIOD AFTER OPENING" REQUIREMENT INTRODUCED BY THE 7TH AMENDMENT TO THE COSMETICS DIRECTIVE

1. Interpretation of the PAO Requirement

The Period after Opening is the minimum period of time after the opening of the cosmetic product during which it can be used without any harm to the consumer. In other words, it is the period during which the product is assured as remaining in conformity with Article 2 of the Cosmetics Directive. It is based on the manufacturer's expertise, if the product is used as intended and stored correctly.

It is important to note that the assessment of the product's safety in use is already an obligation under the Cosmetics Directive and so this is not a new safety requirement. There is a long experience of safety in use for cosmetic products and an extremely low incidence of undesirable effects related to deterioration after opening.

The new requirement under the 7th Amendment of the Cosmetics Directive is a labelling one: an additional piece of information for consumers that they can benefit from in order to optimise their in-use experience of the product.

Evaluation of the general stability of a cosmetic product is an existing requirement under the Cosmetics Directive.

The new Period after Opening labelling requirement refers only to the in-use part of a cosmetic product's life cycle.

For the evaluation of the Period after Opening, consideration of the microbial stability is the key factor as the risk of contamination is related to the physical contact between the consumer and the product. Other potential stability factors will normally have already been considered during product development, taking into account product integrity under relevant conditions of storage, transport and use.

Whilst efficacy is not within the scope of the PAO requirement, there may be cases where a change in efficacy could affect consumer safety (e.g. UV-protection of sunscreen products).

There is no single scientific method for determining the PAO for all cosmetic products. The assessment must take into account the complexity of the range of cosmetic products and the normal and reasonably foreseeable ways in which consumers use them.

2. Practical Guidance

The PAO labelling must be applied in all cases where deterioration after opening may lead to harm to the consumer.

The deterioration may be linked to:

- the deleterious effect of micro-organisms and/or
- physico-chemical degradation

that would lead to:

- harm to the consumer or
- the decrease of efficacy when the modification of the efficacy can affect the safety of the product (e.g. U.V. protection of sun products).

The person responsible for placing the cosmetic product on the market is also responsible for assessing:

- whether a PAO has to be indicated or not on the products packaging and
- the specific period of time, in those cases where the PAO has to be indicated.

A variety of relevant methods may be used to support the PAO labelled on a product, including those used during product development, since there is no officially sanctioned methodology to be used.

2.1 Assessment of the Period After Opening

- The person making this determination will do so based on data from a number of sources that could be qualitative and/or quantitative.

- As there is no single scientific method to determine the appropriate PAO for a product, the assessment must always be a reasoned decision based on a range of different data sources and/or experience.

- The normal and the reasonably foreseeable way in which the consumer can use the product is also relevant information to consider when making the assessment of the appropriate PAO.

2.2 Factors that may influence product stability:

Factors affecting stability may be divided into general stability factors which are taken into account during the development of the formula and those factors related to product usage:

General stability throughout the product life cycle

- Chemical stability
- Physical stability
- Resistance of the formula/packaging to microbial contamination
- Compatibility between the formula and its packaging
- Environmental conditions of storage such as heat, light and humidity.

In-use stability

- The effect of repeated contact between the consumer and the product in the container.

2.3 Data Sources

2.3.1 Microbiology

- Some products are inherently hostile to microbial growth. Examples may include products with high alcohol content (e.g. perfumes), anhydrous products (e.g. lipsticks), or those with either a very high or a very low pH. In these cases, there is no need for investigation of microbial stability.

- Other products may require preservation. The preservation system of a product must be robust enough to prevent harmful organisms from growing in a product, under normal and reasonably foreseeable conditions of use. The effectiveness of the preservation system is determined with appropriate microbiological tests. This is a key factor in assessing a meaningful PAO.

- In addition, certain products are sold in containers or dispensers specially designed to reduce, or even eliminate, contact with the consumer. This will need to be taken into account when assessing the microbiological stability of the product.

For more details, please see Annex 1 “The evaluation of a PAO in relation to microbial risk” and the Colipa guidelines on Microbial Quality Management, 1997.

2.3.2 Analytical knowledge and data

- The data and existing test methods currently available to each company should be sufficient in determining the appropriate PAO. However, based on the understanding of the formulation and on existing data, in cases where product changes may occur, it may be necessary to perform tests in order to obtain additional information.

- The variation of any pertinent parameters (e.g. preservative levels, variation of U.V. filters in sun products) observed during general stability should be considered.

For more details, please see the Commission of the European Communities and Colipa joint publication on Analytical Methods in Cosmetics, 2004 ***(Note: this will be published in the near future)***.

2.3.3 The Effect of Packaging

- It is clear that the type of packaging used may affect the in use stability of the product. Some packages minimise or even prohibit direct contact between the consumer and the product in the container, and this should be taken into account.

- In the case of products particularly sensitive to deterioration by micro-organisms, and when handling in the shop is foreseeable, the person responsible for placing the product on the Community market must consider appropriate measures to avoid the opening of the product before it reaches the final consumer.

2.3.4 Experience with similar formulations and products

- Considering the diversity of cosmetic products, the expertise for determining an appropriate PAO must lie with the company responsible for marketing. The latter understands the product, the way it is used and the likely effects over time. Thus the company responsible for marketing can determine a PAO that is reasonable when the product is used and stored appropriately.

- In-market experience with relevant existing products is essential data in determining the PAO of new products that will be used in the same fashion.

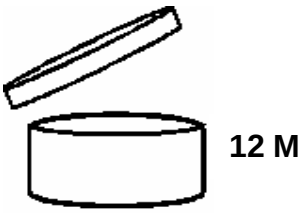
2.3.5 Consumer habits and Practices

Consumers use products in many different ways. However, the predictable ways the product is normally used and stored can be understood and considered in the PAO assessment. This can be especially useful if the consumer use may increase the potential for microbial contamination. For example, factors to consider may be:

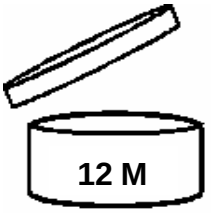
- Where does the consumer usually keep and use the product?
- How many times a day is the product used?
- How much product is used and how long does the consumer normally take to use up the product?
- Where is the product applied (for example, just in the eye area or all over the body)
- How much direct contact there is between the consumer and the remaining product in the container?
- Is it a rinse-off or leave-on product?
- Is the product a "family product", shared by more than one user?

2.4 Recommendations for labelling

Symbol for "Period After Opening": the "open jar" symbol was published by the European Commission[2]. Below is an example for a product with a PAO of 12 months:



OR



The PAO, expressed in months or in years, can be printed either inside or alongside the symbol. There is no specific requirement as to the size of the symbol, as long as it is easily legible, in compliance with Article 6.1 of the Cosmetics Directive.

Unit of measurement: while the legislation allows the PAO to be expressed either in months or in years, the industry's recommendation is that this should be expressed in months only. The main reason for this is to ensure consistency in the market and to avoid confusion in the minds of the public. The period of time expressed in months may be indicated by a number followed by the letter "M" which stands for Menses (i.e. months in Latin). This would avoid the need to print (and translate into up to 21 different languages) the words "months" on the package.

Place on the product

The PAO needs to be printed on both the primary and the secondary packaging (i.e. the container and the outer package, if any).

[2] OJEC L224 of 6.09.2003 p. 27.

ANNEX

THE EVALUATION OF A PERIOD AFTER OPENING (PAO) IN RELATION TO MICROBIAL RISK

There is a direct link between the period of time during which a cosmetic product can be used without harm to the consumer and microbiological risk. The estimation of this period of time must take into account:

1. **The risk of microbial contamination of the product**, which could arise from contact between the product and the consumer's skin.
   NOTE: As cosmetic products are not manufactured in aseptic conditions, simply opening them (for example to smell their fragrance) does not present an additional risk of microbial contamination.

   The factors influencing the risk of contamination during use are as follows:

- The product's physico-chemical characteristics: The optimum pH for the growth of most micro-organisms is in the region of neutrality (6.5-7.5). An extreme pH, whether acid or alkaline, can completely inhibit microbial proliferation. It can therefore be considered that the risk of microbial contamination in cosmetic products with a pH lower than 1.5 or higher than 11 is negligible.
  As with the pH, the minimal water activity value (Aw) tolerated varies depending on the micro-organisms. Generally speaking, it can be stated that the risk of microbial development in a product whose Aw value is equal to or lower than 0.6 is negligible.
  The effective concentration to inhibit microbial proliferation varies depending on the type of micro-organisms. When the ethanol concentration of a cosmetic product is higher than 20%, it can be deemed to be effectively protected against microbial contamination.

- The effectiveness of the preservative system: Cosmetic products that are not intrinsically hostile to the growth of micro-organisms and whose packaging is not totally protective in respect of microbial contamination need the addition of preservatives. The effectiveness of these preservatives must be assessed *in situ*, for example by the challenge-test method.

- The type of packaging: The influence of the packaging on the contamination risk of a cosmetic or pharmaceutical product during its use has been described in a number of works. A product packaged in a pump bottle has a lower risk of contamination during use than the same product packaged in a jar with a wide aperture. This aspect can be taken into account either when developing the preservative system, or when defining the PAO.

2. **The risk of undesirable effects for the consumer**, which could be linked to the use of a contaminated cosmetic product. As the quality of cosmetic products is excellent, this risk is extremely low, as confirmed by the few cases reported. Nevertheless, in the event of microbial contamination of a cosmetic product, the risk for the consumer depends on:

- His/her sensitivity: children under 3 years of age are considered to be more sensitive generally and to microbial contamination in particular, than the rest of the population.

- The part of the body where the product is applied: the eye area and mucus membranes provide a less effective barrier against possible microbial contamination than the skin.
  These two product categories are very carefully monitored throughout their development and their manufacture. Recommendations concerning the maximal level of microbial contamination of these products when they are put on the market are significantly stricter than those concerning other products

REFERENCES

Part 1:

Cosmetics Directive (76/768/EEC), 7th Amendment, Directive 2003/15/EC, OJ L 66, 11.03.2003.

Commission Directive 2003/80/EC, OJ L 224 of 06.09.2003, p 27.

Part 2:

Colipa guidelines on stability of cosmetic products, 2004.

Colipa guidelines on microbial quality management, 1997.

Commission of European Communities and Colipa, Analytical Methods for Cosmetics, 2004.

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Microbial Quality Assurance in Pharmaceuticals, Cosmetics and Toiletries ; S.F. Bloomfield, R. Baird, R.E. Leak, R. Leech ; Ellis Horwood Series in Pharmaceuticals Technology ; p 78 ;1988.

Guide to microbiological control in pharmaceuticals; S. Denyers and R. Baird ; p 16-17; 1990.

Antimicrobial food additives ; characteristics, uses, effects; E. Lück, M. Jager ; Ed. Springer ; p 122-124 ; 1995.

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Cosmetic and drug preservation – Principles and practice ; Ed. J.J. Kabara ; p 403-440 ; 1984.

E. Sandell and L. Ernerot. A package for avoiding microbial contamination of nasal drops during use. *Acta Pharmaceutica Suecica*. 9 (5) : 499-502 (1972).

D. K. Brannan and J. C. Dille. Type of closure prevents microbial contamination of cosmetics during consumer use. *Appl. Environ. Microbiol*. 56(5):1476-1479 (1990).

D.S. Orth, R.F. Barlow and L.A. Gregory. The required D-value : evaluating product preservation in relation to packaging and consumer use/abuse. *Cosmetics & Toiletries*. 107 : 39-43 (1992).

D.K. Brannan. Packaging's role in preservation. *Cosmetics & Toiletries. 113 : 79-90 (1998).*

D.S. Orth, D.C. Steinberg. The safety factor in preservative efficacy testing. *Cosmetics & Toiletries*. 118 : 51-58 (2003).

Cosmetics Directive (76/768/EEC), 7th Amendment, article 7(a)(d) *… accesibility of the following information : …assessment of the safety for human health of the finished product. To that end, the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. Their shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.*

F. R. Reid and T. O. Wood. Pseudomonas corneal ulcer. The causative role of contaminated eye cosmetics. *Arch. Ophthalmol*. 97:1640-1641 (1979).

Colipa Guidelines on Microbial quality Management , 1997.

The Scientific Committee on Cosmetic Products and Non-Food Products intended for consumers, Notes of guidance for testing of cosmetic ingredients for their safety evaluation, 5th Revision, 2003 – Guidelines on microbiological quality of the finished cosmetic product: *Skin and mucous membranes are protected from microbial attack by a natural mechanical barrier and defense mechanisms. However, the protective integument may be damaged and slight trauma may be caused by the action of some cosmetics that may enhance microbial infection. This may become of particular concern when cosmetics are used around the eyes, on mucous membranes in general, on damaged skin, on children under 3 years, on elderly people and persons showing compromised immune responses. Consequently, two separate categories of cosmetic products are defined in the microbiological quality control limits.*