Cosmetics Europe
the personal care association

COSMETICS EUROPE:

COSMETIC PRODUCT INFORMATION REQUIREMENTS IN THE EUROPEAN UNION

Updated Guidelines for the Cosmetics Industry based on article 7A of the Cosmetics Directive

SEPTEMBER 2006

C O N T E N T S

Although every effort is made to ensure that the information and concepts presented here are correct to the best knowledge of the authors and editors, neither they nor Colipa accept responsibility for any actions taken on the basis of this information, nor accept any liability for any omissions or errors this publication may contain.

September 1995

PREFACE

Colipa, the European Cosmetic, Toiletry and Perfumery Association, has prepared this brochure to contribute to the development of uniform rules throughout the European Union (EU) concerning the new legal requirement to hold certain information on each marketed product.

These guidelines have been prepared by a group of industry experts coming from many of the EU Member States. They take into account the wide diversity of the cosmetic industry, both in terms of product type and in terms of company size.

The requirements under the new Article 7a of the Cosmetics Directive are explained with the objective of achieving a practical system of data collection. It is the opinion of Colipa that such a system can only work within the EU Single Market if it is based on the principle of mutual recognition of competent bodies between the Member States.

We wish to thank all those who have contributed to the preparation of this brochure.

Source : F.I.P.

INTRODUCTION

The 6th Amendment to the Cosmetics Directive introduces a new requirement for manufacturers and importers of cosmetic products operating in the EU market.

The text of the new requirement reads under Article 7a:

> ***1. "The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6(1)(a)."***

By analogy to some existing national requirements, this new requirement is often referred to as "the dossier" requirement. However, in order to avoid confusion, this requirement will be called "Product Information" by reference to the official text.

Industry supports the move towards greater transparency in the EU market for cosmetics, linked to the overall objective of the Single Market. It sees the function of keeping Product Information available on the safety of cosmetics as an additional assurance to consumers and public health authorities. The cosmetic industry represented by Colipa is, however, concerned that the procedures adopted are practicable and workable.

The cosmetic industry operating in the EU market is very diverse, ranging from large international corporations to many small businesses. Products cover a wide span, from exclusive fine fragrances to a great variety of branded and private label cosmetics and toiletries for the mass market. Therefore any convenient means of providing Product Information can be used, from formal paper files to the most up-to-date information technology. This is particularly important for an industry which has to respond to rapid changes in science and fashion.

In view of the existence of the Single Market, the Product Information should be available at a single place within the EU.

These guidelines have been produced by Colipa to give general background information and advice to industry on how to meet the Product Information requirement. They are aimed at all companies manufacturing within the EU and all companies importing cosmetics from outside the EU. This document provides guidance on how industry can meet this requirement in a flexible way by providing coherent and professional support for marketed products.

These guidelines have been prepared to help companies fulfil their legal obligations. Above all, it should be remembered that Article 2 of the Cosmetics Directive remains as the fundamental requirement to market safe products. The text of this Article now reads:

"A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive."

The ultimate responsibility for ensuring compliance with these legal requirements lies with individual companies operating within the EU market.

LOCATION OF AND ACCESS TO THE PRODUCT INFORMATION

The point of access to the Product Information for the authorities is the address specified on the packaging of the marketed product.

The address must be indicated on the product as specified under Art. 6(1)(a) of the Cosmetics Directive, which reads:

> ***1. "Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and the packaging bear the following information in indelible, easily legible and visible lettering:***
>
> ***(a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community.***
>
> ***Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community."***

Colipa believes that there must be flexibility in the location and access to Product Information so that systems can be based upon existing company structures. Whilst in a simple company organisation all functions (from marketing to R&D and manufacturing) may be on a single site, many companies in the European cosmetic industry have a complex multi-site organisation. Companies may have multiple manufacturing sites or may have non-manufacturing sites, e.g. a head office or a R&D centre.

Each company may choose a single place within the EU where the complete information on the product is accessible. This place need not be a manufacturing site.

Where there is more than one address on the packaging of the marketed product, the single point of access to the Product Information must be underlined.

Product Information is accessible in one of the EU Member States at the discretion of the manufacturer. Should a justified request for information be made by another Member State, such a request is transmitted through the competent authorities of the EU country where the Product Information is accessible. These competent authorities will report the results of their consultation to the competent authority of the EU Member State which made the request.

Any authority that is given access to such information must keep it confidential.

In the case of a product manufactured outside the EU, it would be expected that a Product Information set must be accessible within the EU at the address on the label. If an abbreviated address is used on the label, the complete address must be easily found, for instance by looking it up in the telephone directory.

The wording of Article 7a is seen as acknowledging that new information technology (i.e. computers) provides a rational means for recording, storing and distributing such information. The physical location of the actual store of information can be anywhere, as long as the information is readily accessible on request. For many businesses, the use of extensive paper records would be inefficient. Some companies may, of course, find the option of paper records appropriate.

Whichever way a company chooses to fulfil this requirement, authorities will expect that Product Information is made available within a reasonable period of time.

LANGUAGE OF THE PRODUCT INFORMATION

Paragraph 3 of Art. 7a reads:

> ***"The information referred to under paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities."***

The guiding principle concerning the language used to indicate all Product Information required by the law should be that it can be read and understood by the controlling officer when he comes to verify the Product Information.

Whilst it is not mandatory, it is obviously in the interest of the company concerned to make available Product Information in the national language(s) applicable to that country of the EU where the Product Information is held, unless it has been previously established that the competent authority is equally willing to accept another language.

The above advice applies to all the information covered under Art. 7a(1), points (a) to (g) inclusive (see pages 7-11 of this brochure). However, any supporting documentation, be it laboratory reports, letters or publications will, of course, be retained in the language in which they were written, provided it is an official EU language. It would be unjustified to translate such documents into the national language. Efforts should be made to assist control bodies by explaining the content of such documents when the need arises.

DEFINITIONS

To clarify the context in which certain words and expressions are used, the following text definitions are given below. These definitions are not official and are only provided for clarification.

COSMETIC PRODUCT is defined in the 6th Amendment (93/35/EEC) modifying the Cosmetics Directive 76/768/EEC as:

> ***"A cosmetic product shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membrane of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours, and/or protecting them or keeping them in good condition."***

PRODUCT INFORMATION is defined as the information required to meet the requirements of Article 7a of the 6th Amendment.

READILY ACCESSIBLE means that Product Information should be available within a reasonable time (24-72 hours) for control officers. Whilst many items may be rapidly accessible through electronic media, there may be a short delay when information is accessed by other means.

Making Product Information readily accessible does not imply providing copies of any part of the information to control officers.

Should the Authorities request additional information, such as further supporting documentation, it may take a few days to be made available.

PLACE OF MANUFACTURE means any premises where cosmetics are manufactured, including premises where processing and filling in primary packaging of cosmetic products take place. This includes filling of sachets and free samples. It also includes contract manufacture and private label manufacturing operations. A product that is part-manufactured outside the EU (e.g. concentrate manufactured in a non-EU state) is still the subject of a manufacturing process within the EU if it is diluted, and/or filled and assembled into primary packaging in the EU.

PLACING AN IMPORTED COSMETIC ON THE COMMUNITY MARKET refers to the person or the company responsible for the initial marketing on EU territory of an imported cosmetic product.

PRODUCT INFORMATION TO BE MADE AVAILABLE

In order to satisfy any check by competent national authorities, each manufacturer, importer or organisation responsible for marketing a cosmetic product should be able to keep the elements of Product Information specified under points a, b, c, d, e, f and g of Article 7a(1).

a) Product Composition

The official text reads:

> ***(a) "the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier."***

This should be a statement of the complete quantitative composition of the product, covering all raw materials added. This will also meet the specified requirement for qualitative composition.

It will be useful to link the names of the raw materials used to those foreseen under the common EU nomenclature for ingredient labelling.

In the case of perfumes and perfume compositions, the name and code number of the composition and the identity of the supplier only have to be provided.

b) Physico-Chemical and Microbiological Specifications of Raw Materials and Finished Product

The official text reads:

> ***(b) "the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product."***

The specifications (and any related control criteria) of both raw materials and finished products will be determined by the type and use of the raw material concerned and the product type in which it will be used.

The level of detail will obviously vary according to these criteria and the professional judgement of those involved in formulating and manufacturing the product. The standards adopted will obviously reflect regulatory requirements and generally accepted industry practice. It would be inappropriate to define strict protocols for specifications that would be applied to all raw materials or finished products.

Each raw material should be described with relevant information, such as chemical name, formula or description, physico-chemical and/or organoleptic properties. Details of the basic criteria for its identification should be provided. It may be appropriate for typical analytical profiles to be included for reference in the Product Information. There may be circumstances when the analytical profile of a raw material should be part of the specifications (and related control criteria) for this raw material. However, it is not required to hold a "finger print" of any raw material used.

The specifications of the finished product are to be provided. Microbiological criteria/specifications are appropriate for some raw materials and products.

c) Method of Manufacture

> ***(c) "the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation."***

This would be expected to be a brief overview of the method of manufacture including bulk storage and filling and should be generally applicable to the manufacturing site(s) concerned. There should be a summary of the process and a cross-reference to the detailed manufacturing documentation within any specific manufacturing site.

It is generally recognised that manufacture, packing and storage of cosmetic products should be carried out according to cosmetic Good Manufacturing Practices (GMP). These should be established nationally or internationally or should be industry recognised standards or codes.

The cosmetic GMP and aspects of manufacture should be addressed and cross reference should be made to the full cosmetic GMP documentation at the manufacturing site concerned.

d) Safety Assessment

The official text reads:

> ***d) "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 ingredient, its chemical structure and its level of exposure.***
>
> ***Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned."***

In addition, Article 7a(2) should be taken into account. It reads:

> ***"The assessment of the safety for human health referred to in paragraph 1(d) shall be carried out in accordance with the principles of good laboratory practice laid down in Council Directive 87/18/EEC of December 18, 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and verification of their application for tests on chemical substances."***

It is envisaged that this would generally be in the form of a signed statement of opinion by (a) suitably experienced person(s). This should give reassurance that the product is safe in its intended cosmetic use and take account of foreseeable use. The safety assessor should take into account available data for detailed support information such as data on raw materials, product experience, exposure, etc. which may be made available to support the safety of the product. If data are inadequate to make a proper assessment, the safety assessor may require additional tests to be carried out. In addition, the statement may include some general comments about the safe use of the products, its specific hazards (if any) and the basis upon which the safety assessment has been made.

In the case of fragrance and flavour raw materials, the composition may not be known because of confidentiality. If so, it is strongly recommended to obtain a relevant safety evaluation from the supplier.

The official text states that the safety assessment may be held at a single place of manufacture if there is more than one place of manufacture in the EU. Colipa advises that the signed statement should be held at a single location (which may, for instance, be a non-manufacturing head office or R&D site). This is in line with the spirit of Article 7a.

The support documentation for the safety assessment may not necessarily be on company premises, e.g. it could be at the office of a contract laboratory or consultant. It can also be kept outside the EU. If not held on company premises, the accessibility of the documentation has to be assured.

The official text requires that the assessment of safety should be carried out in accordance with the principles of Good Laboratory Practices (GLP). However, an existing safety study should not be rejected purely on the grounds that it has not been carried out to GLP standards. It is not necessary to repeat such studies merely to meet Product Information requirements.

A new signed statement is required for any change to the existing product which is considered toxicologically relevant.

e) The Safety Assessor

The official text reads:

> ***(e) "the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline."***

A qualified person with a diploma in a "similar discipline" could be, for example, a veterinarian, a biochemist or a chemist with an appropriate background and experience. It is most obviously in a company's interest that the safety assessment should be sound and supportable. It is recommended that substantial experience - in the absence of formal qualifications - may be appropriate for this function to be adequately fulfilled.

The safety assessor may be a company employee or a consultant. The safety assessor need not necessarily be based within the EU.

Safety assessors would generally be expected to report to the senior management of a company to preserve the essential independence and objectivity of the safety function.

f) Undesirable Effects on Human Health

The official text reads:

> ***(f) "existing data on undesirable effects on human health resulting from use of the cosmetic product."***

It is clear that only professionally substantiated reports are relevant to the safety of a cosmetic product. The reports of adverse health effects should not include anecdotal or ambiguously reported incidents. Only clearly documented and appropriately investigated cases should be included. Such investigations should be carried out by a specialist, e.g. a dermatologist, and be adequate to give clear confirmation of an effect.

Information on the number of units of the product sold in a given time may be helpful although this data would not necessarily be included in the Product Information set.

Records of undesirable effects would need to be kept up to date.

It is appropriate that a company may choose to keep the summary information relating to "undesirable" effects centrally and at the same single location as the safety assessment (see (d) above).

g) Proof of Effect

The official text reads:

> ***(g) "proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product."***

The provision of information to support claimed effects should be considered by companies whilst taking account of national rules and guidelines on advertising. Such information is already required under existing regulations. Advice concerning these regulations should be available from National Associations.

The Product Information should contain a short summary of the technical support for the claimed effects. This may be cross referenced to more detailed support information which, however, would not be held as part of the Product Information.

The choice of the appropriate way to substantiate a claim depends on the claims and the wording used. In cases where the basic effect is obvious, there is no need to include data on performance in the Product Information set, e.g. lipsticks to colour the lips or shampoos to wash the hair.

Several ways exist to substantiate claims. These include:

1. Raw materials

Data available on raw materials can often be used and should take into account their concentration in the finished product. The data should be pertinent, significant and must be related to the way the raw material is used. They can include results of physico-chemical, in vitro or in vivo methods. The following examples can be given:

• Reference to literature
Many raw materials and/or combinations of raw materials are described in publications as to their effect.

• Data from suppliers
In most cases, raw material suppliers do have data demonstrating the effects of their ingredients.

2. Finished products

Data on finished products can be generated by the cosmetic manufacturer or, at his request, by a third party. Supporting data from similar products may also be taken into account and may be sufficient. Examples are:

• In-use tests
This involves testing the finished product under realistic conditions on a suitable target population and using the data so obtained. In such cases, the test has to be carried out on a sufficient number of people so as to show the claimed effect.

• Laboratory tests
This involves analytical, physico-chemical, biological or metrological measurements made directly on the product or involving the target application site or making use of an appropriate model.

• Clinical tests
Such tests are performed under the supervision of qualified professionals, e.g. dermatologists, dentists. Assessment under the supervision of professionals is essential and can be based on subjective or objective techniques.

NOTIFICATION OF MANUFACTURING PREMISES

The text of Article 7a(4) reads:

> ***"The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market."***

KEY QUESTIONS ON PRODUCT INFORMATION

This section aims at providing more direct practical support to persons in charge.

Q.: *To whom does the requirement apply?*

A.: To those companies or persons responsible for placing a cosmetic product on the EU market.

Q.: *Are there special rules for small manufacturers?*

A.: No, the same legal requirements apply to all companies marketing cosmetics.

Q.: *Does the requirement apply to perfumery products and to soaps?*

A.: Yes, the requirement applies to all cosmetics as defined under Article 1 of the Cosmetics Directive.

Q.: *Does the requirement apply to professional products?*

A.: Yes.

Q.: *Does the requirement apply to free samples, promotional products, gifts?*

A.: Yes, it applies to all products, however they are put on the market.

Q.: *Does the requirement apply to products imported into the EU?*

A.: Yes, those responsible for initial marketing of a product on EU territory must keep the information accessible. There must be an address in the EU on the label of such products.

Q.: *Does the requirement apply to existing cosmetic products already on the market before entry into force of this new legal requirement?*

A.: Yes, it applies to all products on the market at the moment of entry into force of the requirement and obviously to all products subsequently introduced on the market.

Q.: *If marketing a product in several EU Member States, does one need to hold the Product Information in every one of these Member States?*

A.: No, the information should be accessible only in one of the Member States and at one single place.

Q.: *Should the Product Information be held at the address specified on the label of the marketed product?*

A.: Not necessarily, but the information must be accessible at the address specified on the packaging unless more flexible arrangements can be agreed with the Competent Authorities. “Accessible” means to be available within 24-72 hours.

Q.: *Where should the information be accessible when there is more than one address on the packaging?*

A.: The information has to be accessible at one of the addresses. That address has to be underlined. If there is no underlined address, authorities may expect to have access to the information at each of the addresses.

Q.: *Can parts of the information specified under this legal requirement be held at different places?*

A.: Yes, but the information must be accessible in total (but not necessarily at the time of asking) at one single place in the EU. One may, of course, hold part of the information at additional places within the EU.

Q.: *Can an importer of cosmetics into the EU hold the information outside the EU?*

A.: Yes, but the Product Information must be readily accessible at the address in the EU specified on the packaging. The safety assessment has to be accessible at the same place.

Q.: *Can somebody outside the company be made responsible for the Product Information requirement?*

A.: Yes, one can make anybody responsible for collating and holding the Product Information, but the overall responsibility always lies with the company or person placing the product on the market.

Q.: *Can supporting data (particularly safety information) be held outside the EU?*

A.: Yes, provided that a safety assessment is accessible at one place within the EU. If requested by the authorities, supporting data has to be made accessible at the same place.

Q.: *Who is allowed to check the Product Information?*

A.: The control officers of the competent authority of the EU Member State where the information is accessible.

Q.: *Can a control officer remove or copy any part of the Product Information ?*

A.: No, since the Product Information belongs to the company.

Q.: *If a company engages a contract manufacturer to manufacture a cosmetic product which it then sells under its own brand name, who must fulfill the requirement of Product Information ?*

A.: This responsibility always lies with the company which has its address on the marketed product.

Q.: *To whom does one have to notify any premises used for manufacturing or importing into the EU of any cosmetic product ?*

A.: It has to be notified to the competent authorities in the EU Member State concerned, following national regulations.

Q.: *Is it necessary to notify premises to the competent authorities every time a new cosmetic product is manufactured at an existing notified manufacturing site ?*

A.: No, it is only necessary to notify once any premises for manufacturing or importing cosmetic products into the EU.

COSMETICS EUROPE IS THE EUROPEAN TRADE ASSOCIATION REPRESENTING THE INTEREST OF THE COSMETICS, TOILETRY AND PERFUMERY INDUSTRY

COSMETICS EUROPE – THE PERSONAL CARE ASSOCIATION
AVENUE HERRMANN-DEBROUX 40, 1160 BRUSSELS
T. +32 2 227 66 10, F. +32 2 227 66 27
WWW.COSMETICSEUROPE.EU