



COSMETICS EUROPE:
COSMETICS DIRECTIVE 76/768/EEC
EXPLANATORY BROCHURE

JANUARY 2004

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I. FOREWORD

Dear reader,

In the early 1970's the Member States of the European Economic Community (now called the European Union - EU) decided to harmonise their national cosmetic regulations in order to ensure a high level of consumer protection and enable the free circulation of cosmetic products within the Community (the legal base for the Cosmetics Directive being Article 95 of the EC Treaty, on the establishment and functioning of an Internal Market).

The Cosmetics Directive was adopted on 27 July 1976 and published in the Official Journal of the European Communities (OJEC) on 27 September 1976, with the reference 76/768/EEC. Since then, it has been amended seven times and has had nearly thirty adaptations to technical progress.

The 7th Amendment to the Cosmetics Directive, adopted on 27 February 2003 and to be transposed by Member States into national law by 11 September 2004, has introduced some new provisions in the Directive, namely on animal testing and consumer information, but has not changed its basic principles. This brochure takes into account the modifications introduced by the 7th Amendment. However, please refer to the 7th Amendment Colipa Technical Guidance Document for more detailed information.

The present brochure has been conceived as an explanatory document on the whole of the Cosmetics Directive. Its purpose is to provide a user-friendly guidance document on the basic principles, requirements and application of the Directive with a view to promoting a good understanding of its principles and main requirements. Please note that at the end of the brochure you will find a Questions & Answers (Q&A) section.

Also available from Colipa is a consolidated version of the text of the Directive, taking into account the successive amendments to the Directive (including the 7th Amendment) and adaptations to technical progress.

I would like to draw your attention to the fact that only the text of the Cosmetics Directive is authentic in law. The text of the Directive prevails in case of discrepancies between the provisions of the Directive and this brochure. This brochure is not an interpretative document of the Directive, the interpretation of Community law being the responsibility and privilege of the European Court of Justice.

I wish you a fruitful reading,



Bertil Heerink
Director-General

II. OBJECTIVES AND SCOPE

The **two key objectives** of the Cosmetics Directive are:

- **Ensuring a high level of consumer protection**

Consumer protection is at the core of the Directive, as laid down in its Article 2. “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.” This most important requirement makes sure that products are safe and will not harm human health, taking into consideration the formulation, the normal or reasonably foreseeable use and the labelling (warnings and instructions for use). This requires, amongst other measures, a safety assessment of each product formulation by a qualified professional.

- **Free circulation of goods**

Another fundamental objective of the Directive is to ensure the free circulation of cosmetic products throughout the EU Single Market. The Directive allows all products in compliance with its provisions to be sold anywhere in the EU without any pre-market registration or any other national barrier to intra-EU trade. It is therefore essential that cosmetic products are subject to the same legislative framework throughout the EU – hence the obligation to fully transpose the “acquis communautaire” (all existing Community legislative acts) for new EU Member States.

In accordance with Article 7.1 of the Cosmetics Directive “Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements...”. The European Court of Justice has ruled that the Cosmetics Directive comprehensively addresses the composition and labelling of cosmetic products. EU Member States may not, therefore, introduce any additional requirements, as this would restrict the single market in cosmetic products. Any Member State going beyond the requirements of the Cosmetics Directive could be subject to legal proceedings before the European Court of Justice.

Scope of the Cosmetics Directive

The Cosmetics Directive covers a well-defined product type. Article 1.1 gives a clear definition of what is meant by a **cosmetic product**:

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 membranes 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.

When considering this definition, one can observe that it is based:

- On one hand, on the target site of application:
 - External parts of the human body
 - Teeth
 - Oral mucous membranes

- On the other hand, on six intended functions:
 - Cleaning
 - Perfuming
 - Changing the appearance
 - Correcting body odours
 - Protecting
 - Keeping in good condition.

The expression “*mainly or exclusively*” shows that the Directive covers not only products intended exclusively for the functions specified under Article 1.1 but also products with other functions, provided that one of the six above-mentioned functions is predominant.

In addition to this definition, Annex I of the Cosmetics Directive provides an illustrative -i.e. not exhaustive - list of products to be considered as cosmetic products within the meaning of this definition. Therefore, other products could also fall under this definition (see Appendix A.).

There are no intermediate product categories in the EU between cosmetics and pharmaceutical or foodstuffs or medical devices. The case law of the European Court of Justice (ECJ) has repeatedly stated that a product can only be either a cosmetic or another type of product (e.g. a pharmaceutical) but cannot be both at the same time.

III: BASIC PRINCIPLES

The underlying philosophy of the Cosmetics Directive is that all safe products meeting the requirements of the Directive should have **equal** and **immediate access** to the market. Each stakeholder has a defined responsibility in this process:

A) The person or company placing the cosmetic product on the market has the main obligation to ensure safety of the products for human health, ensure compliance with the technical requirements of the Directive and provide adequate information, as required by the Directive, to national authorities and consumers.

B) The national governments have the obligation to ensure the transposition of the Directive into national law and to set up an in-market surveillance system to monitor compliance with the requirements of the Directive.

C) The European Commission monitors the implementation and application of the Cosmetic Directive in the EU Member States and takes “risk management” measures when appropriate.

- **No pre-market approval system**

In drafting the Cosmetics Directive it was strongly believed that setting up an in-market control system for cosmetic products (also known as *post-market control*) would be more effective than pre-market approval procedures. Therefore, countries with national pre-market registration had/have to switch to a system of in-market surveillance by governments. Some of the reasons in favour of an in-market control system are given in Appendix B.

- **Harmonisation of the regulation on ingredients and labelling**

Differing national requirements hinder the common market and increase costs for manufacturers and consumers. The free circulation of goods in the single market can only be achieved by having a single set of requirements, which ensures consumer safety. As confirmed by the European Court of Justice, the Cosmetics Directive comprehensively addresses the composition and labelling of cosmetic products. It requires cosmetics to be safe, places restrictions on certain ingredients, specifies the information that must be kept available for inspection by the enforcement authorities, and details some information required to be marked on the packaging.

- **Company’s responsibility for safety and compliance with the Cosmetics Directive**

The person responsible for placing a product on the EU market (manufacturer or first importer into the EU) has the primary responsibility to ensure compliance with the requirements of the Directive that ensures the safety of cosmetic products. Within the framework of the Product Information requirement, the person responsible for placing a product on the market must keep the information readily accessible to competent authorities (see sections IV and V). National authorities are not allowed to set up or maintain a system of pre-market clearance.

- **National competent authorities responsibility for cosmetics on the market**

Each national government has the responsibility to put in place an in-market surveillance system to monitor compliance. The designated public authorities have legal powers to visit retail outlets and/or local manufacturing sites. Samples may be taken for full inspection and laboratory analysis if necessary to check compliance with labelling requirements, ingredients (restrictions) and microbiological quality.

Additionally, if issues merit a deeper investigation, authorities can have access to the product information (see this brochure's sections IV and V) at the address specified on the label.

IV. RESPONSIBILITY OF THE PERSON PLACING A PRODUCT ON THE MARKET

All cosmetic products put on the market in the European Union are subject to the same requirements, be they local or imported products, consumer goods or professional products, gifts, or promotional products. Big, medium and small and medium enterprises all must abide by the same set of basic rules ¹.

A. PRODUCT SAFETY

The basic requirement of the Cosmetics Directive is that cosmetic products must be safe under normal or reasonably foreseeable conditions of use. The composition of the product, its packaging and consumer information are all important factors when assessing the safety of cosmetic products. All are under the control of the person placing the product on the market. The product safety requirement is indicated in Article 2:

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 authorised agent or by any other person responsible for placing the product on the Community market.

This is not an empty and un-controllable obligation. Indeed, at any time the person responsible for placing the product on the market needs to be in a position to demonstrate the product's safety to the authorities. The proof of safety needs to be included in the so-called Product Information (see below) which must include, *inter alia*, an assessment of the safety for human health of the finished product, taking into consideration the general toxicological profile of the ingredients, their chemical structure and level of exposure (Article 7a).

The person responsible for the safety assessment of the finished product needs to have adequate qualifications and relevant experience. The Cosmetics Directive requires that this 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 ...[Article 7a (e)].

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 or experience. It is obviously in the company's interest that the safety assessment is sound and supportable. It is recommended that substantial experience is appropriate to fulfil adequately this function.

The safety assessor may be a company employee or a consultant. He/she does not need to 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.

¹ Please note that the 7th Amendment to the Cosmetics Directive has introduced new provisions on animal testing. See Questions & Answers (Q&A) - Section on animal testing.

B. PRODUCT COMPOSITION

According to the Cosmetics Directive, ingredients may be used freely in cosmetic products as long as the product fulfils the general requirements of the Cosmetics Directive.

However, for certain types of ingredients, the Cosmetics Directive stipulates specific provisions or restrictions, via the so-called technical annexes.

- **Annex II** lists substances which, due to their toxicity, must not be used;
- **Annex III** lists substances which may be used only subject to certain conditions and restrictions;
- **Annex IV** is a positive list of colouring agents; only those colorants listed in Annex IV may be used in cosmetic products. They may be used only within the conditions laid down. Colouring agents intended solely to colour hair are not subject to this requirement and can be used even if not listed in this annex;
- **Annex V** contains substances that were historically excluded from the scope of the Directive (i.e. not regulated in a harmonised manner across the EU). Today, this annex does not have any longer significance;
- **Annex VI** is a positive list of preservatives; only those preservatives listed in Annex VI may be used in cosmetic products and, where specified, within the limits and conditions laid down. For some of the Annex VI substances, other concentrations may be used for specific, non-preservative purposes apparent from the presentation of the product. These substances are indicated in the annex with the following symbol: (+);
- **Annex VII** is a positive list of UV filters; only those UV filters listed in Annex VII may be used in cosmetic products within the limits and conditions laid down for skin protection. UV filters only used for product protection are not included in this Annex;

Compliance with the technical annexes forms an important but not exclusive part of the product safety; it needs to be augmented by the required product safety assessment, which is based on the toxicological profile of each ingredient in the product composition.

C. INFORMATION TO AUTHORITIES

Notification

The Cosmetics Directive requires notification of the address of the manufacturer or first importer into the EU to the competent authority of only one Member State (Article 7a.4).

According to the Cosmetics Directive, assuming that a product complies with the above-mentioned technical requirements (safety, composition and labelling), the person responsible for placing the product on the EU market needs to carry out a notification of its address only to the competent authority of the Member State where the product is manufactured or, in case of imported products, the country where it first enters the EU.

The required notification of the address of manufacture or first importation allows rapid identification of the product and the person responsible for placing it on the EU market. This notification must be performed before the first product is placed on the market (notification is necessary only once, not per product).

Product Information

The Cosmetics Directive does not require any pre-marketing clearance, registration or certification of the product. Instead, it is based on an in-market control system. This system allows that the competent authorities have access to certain information about marketed products at the address indicated on the product's label.

Article 7a of the Cosmetics Directive lists what type of "Product Information" has to be made readily accessible to the competent authorities upon request: ²

- Product composition:

The International Nomenclature of Cosmetic Ingredients (INCI) should be used.

- Physico-chemical and microbiological specifications of raw materials and finished products :

The physico-chemical specifications of both raw materials and finished products enable consistent quality. Appropriate parameters, which depend on their characteristics, will have been chosen by each company. Relevant information should be given for each raw material used, such as its chemical name, formula or description, physico-chemical and/or organoleptic properties. Listing of microbiological criteria/specifications will be appropriate for some but not necessarily all raw materials and products.

² See section in this brochure "Inspection of the Product Information". See also Guidelines on Product Information Requirements, available from Colipa

- Manufacturing method:

A brief overview of the process should be given. A cross-reference can be made to the detailed information available at any specific manufacturing site. The manufacturing of cosmetic products should be carried out according to cosmetic Good Manufacturing Practices (cGMP) ³.

- Safety assessment of the finished product : ⁴

The safety assessment generally takes the form of a signed statement of opinion by a qualified safety assessor. This person can be either an employee or a consultant and does not need to be based within the EU.

The safety assessment should provide reassurance that the product is safe for its intended cosmetic use, and extend to encompass any reasonably foreseeable use. The assessor should take into consideration any available supporting data, such as raw materials data (toxicological profile/chemical structure), product experience, exposure, etc., regarding the safety of the product. The data on fragrances and raw compositions will be provided by the supplier. If the data are not sufficient to make a sound assessment, the safety assessor may request additional data or that additional tests are carried out. General comments on the safe use of the product, its specific hazards (if any) and the basis upon which the safety assessment has been made might also be included.

Supporting data on the safety of the raw materials and the finished product should be accessible only upon request.

New toxicological studies should be carried out following Good Laboratory Practices. However, existing safety studies of sufficient quality need not be systematically rejected on the grounds that they have not been carried out according to GLP standards.

- Undesirable health effects :

An “undesirable effect” is an adverse effect on human health that occurs from the normal or reasonably foreseeable use of a cosmetic product. It is generally understood that the link of the “undesirable effect” with the product needs to be objectively demonstrated: i.e. undesirable effects do not include anecdotal or ambiguously reported effects or those resulting from abuse or misuse of the product and do not include those related to associated items, such as the packaging.

- Proof of effect: ⁵

Choosing an appropriate way to substantiate a claimed effect depends on the claim itself and also the wording used. When the basic effect is obvious, there is no need to include data on performance (e.g. lipstick to colour lips). A short summary of the technical data supporting the claimed effect should be accessible. It can be cross-referenced to more detailed supporting information, which is not stored as part of the product information.

³ See Questions & Answers (Q&A) – Section on quality

⁴ See Colipa Guidelines for Finished Product Safety Assessment, available from Colipa

⁵ See Colipa Guidelines for the Evaluation of the Efficacy of Cosmetic Products, available from Colipa

It is up to the person putting the product on the market to duly substantiate the proof of effect by using raw material data (references from literature, data from suppliers, etc.) and/or finished product data (instrumental methods, sensory evaluations, in-use tests etc.).

- Data on animal testing

As of 11 September 2004, the Product Information, which is accessible by competent authorities upon request, must include data on any animal tests performed by the manufacturer, his agents or suppliers on cosmetic products and its ingredients, for the development or safety evaluation of the product or its ingredients, including testing carried out in order to meet regulatory requirements of non-EU countries.

Location and language of the Product Information

The location where competent authorities can have access to the Product Information must be indicated on the label of cosmetic products. Many companies in the European cosmetic industry have a complex multi-site organisation – for example, multiple manufacturing sites or a head office and a Research & Development centre that are not manufacturing sites. Each company may choose a single place within the EU from where the complete set of product information is accessible to the competent authorities. This address is not necessarily a manufacturing site. It is also possible to show several addresses on the label, and in that case the address where the product information is accessible to the competent authorities should be underlined.

This means in practice that **the Product Information needs to be accessible in only one location** for the entire European Union market. Please note that there is no obligation to physically store all the data in that location. Electronic or other means can be used to gather the information the competent authorities may require when they access the Product Information at the premises chosen by the company.

In accordance with Article 7a.3, this information should be in the national language(s) of the Member State where the company has chosen to keep the information or in a language readily understood by the competent authorities of that Member State.

D. INFORMATION TO CONSUMERS

Labelling

In order to ensure that the consumer has access to necessary information, Article 6.1 of the Cosmetics Directive sets out the following labelling requirements ⁶:

- name and address of the manufacturer or the importer or distributor of the cosmetic product within the EU (such information may be abbreviated if the abbreviation makes it generally possible to identify the company);
- the nominal content at the time of packaging (by weight or by volume);

⁶ See Questions & Answers (Q&A) – Section on labelling

- the date of minimum durability (for product with a minimum durability of 30 months or less). For products with a minimum durability of more than 30 months, an indication of the period of time after opening for which the product may be used without any harm to the consumer. The “Period after Opening” will be indicated by a symbol (see Appendix C) ⁷.
- particular precautions to be observed in use. It is the responsibility of the person placing a product on the market to determine whether consumers need to be advised of the precautions to be observed before or when using a product. However, the Directive’s annexes may require that specific compulsory precautions or warnings be mentioned on the product when certain substances are used in the product’s composition.
- reference for identifying the goods, e.g. batch number/manufacturing code;
- the function of the product unless clear from the presentation; this is often done with descriptive symbols;
- list of ingredients in INCI nomenclature, as well as the substances, the mention of which is required under the column “other limitations and requirements” in Annex III of the Cosmetics Directive following the 7th Amendment. A procedure exists whereby a company may apply for confidential indication of novel ingredients.

Public Access to Information

From 11 September 2004, in accordance with the Directive’s Article 7a.1(h), consumers will be able to have access to some non-confidential data in the Product Information, namely, the qualitative and, in some cases ⁸, quantitative composition of the product as well as data on undesirable effects related to the product (see section above on “Product Information”).

E. INFORMATION TO POISON INFORMATION CENTRES

The Cosmetics Directive contains provisions to enable information on the composition of a product to be made available to a specific body (Poison Information Centres) for the purpose of prompt and appropriate medical treatment. These cases generally cover emergency situations resulting from a misuse of cosmetics products. The Poison Information Centre, or the designated national body, may require information on ingredients from the person responsible for placing a product on the market. A Pan-European system of Frame Formulations (SYSDECOS) has been developed and is in the process of implementation.

⁷ See Guidelines on Period after Opening, available from Colipa

⁸ See Guidelines on Public Access to Information, available from Colipa

V. RESPONSIBILITY OF THE NATIONAL COMPETENT AUTHORITIES

A. TRANSPOSITION OF THE COSMETICS DIRECTIVE

Community policy is formulated and enacted through different forms of legislative or regulatory action: regulations, directives, decisions, recommendations and opinions. According to Article 249 of the EC Treaty:

“A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.”

Member States have therefore the obligation to transpose the Cosmetics Directive into national law, but Article 249 of the EC Treaty leaves it up to the Member States to choose the form and method of transposition. The implementation tool could be a national law, a regulation or another type of act, provided the act is legally binding and that it transposes correctly the provisions of the Directive.

Directives lay down a deadline for Member States to implement them and often include deadlines for product compliance by the manufacture.

Member States’ responsibility for enforcement of Community law

The EC Treaty provides rules on the obligation of Member States to ensure that the Community actions are fulfilled:

“Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community’s tasks.

They shall abstain from any measure which could jeopardise the attainment of the objectives of this Treaty.”

The European Commission, as the “Guardian of the Treaties”, monitors the transposition of Community law by the Member States into national law and may eventually initiate infringement procedures against a Member State before the European Court of Justice in case a Member State does not fulfil the obligations deriving from Community law. The procedures are described in Articles 226 and 227 of the EC Treaty.

Article 226 reads:

“If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.

If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.”

Article 227 gives also the possibility to Member States to initiate infringement procedures:

“A Member State which considers that another Member State has failed to fulfil an obligation under this Treaty may bring the matter before the Court of Justice.(...)”.

The case law of the European Court of Justice has developed another tool to enforce Community law, the so-called **direct effect** doctrine. Thanks to the direct effect, under some specific conditions, the provisions of a directive may be used to interpret or sometimes discard pre-existing incompatible national provisions even if the directive has not been or has been incorrectly transposed. Furthermore, if the provisions of the directive are sufficiently precise and unconditional, national courts can, after the transposition deadline, enforce the provisions of a directive even in the absence of its domestic legislative implementation. This allows individuals to obtain enforcement of their rights as against the national authorities in cases where the Member State failed to comply with its obligations under Community law.

B. IN-MARKET CONTROL

In enforcing the Cosmetics Directive, Member States must take all necessary measures to ensure that the formulation, manufacturing, labelling and advertising of marketed cosmetic products complies with the requirements of the Cosmetics Directive. To ensure this, products put on the market, as well as supporting product information, may be inspected.

Each Member State must inform the European Commission of which competent authority will be allocated this task and how and when inspections will be performed. The inspection infrastructure varies from one Member State to another. Often, the Ministry of Health is in charge of cosmetic products, although some Member States have designated the department of trade, environment or industry, etc.

Whatever the structure, the competent authorities will assume the same powers: the right to carry out any inspection necessary for monitoring purposes. This might involve: the inspection of industrial premises, checking the availability of the finished product information; taking samples from the industrial premises or from the distribution points such as department stores, supermarkets, small shops, market stalls, etc. Samples may be checked for compliance with labelling requirements or tested in official laboratories.

Inspection of the Product Information ⁹

The mandatory Product Information has to be accessible to the competent authorities through the address given on the product label.

The Product Information should be “readily accessible” to the competent authorities upon their request. This is generally understood as a period of time between 24 and 72 hours from when the competent authority informs the company (normally in writing) of its intention to have access to the Product Information. If supporting data in excess

⁹ See section on Product Information

of the Product Information are required, additional time should be allowed.

The Product Information does not have to take the form of a “dossier” (i.e. an extensive collection of paper records stored in a specific location). The physical location of the information (potentially in electronic format) can be anywhere, as long as the information is readily accessible on request.

Making the Product Information readily accessible does not involve providing copies of any part of the information for inspectors. All the data are and remain the confidential property of the company. In this way, intellectual property rights are protected and, in addition, this ensures that the latest version of the Product Information is inspected. The Product Information is readily accessible for consultation on-site. The authorities are not entitled, under normal circumstances, to copy or remove information from the premises.

Data in foreign languages do not need to be translated as long as they are written in a language readily understood by the inspection bodies. The company’s representative, present during the inspection, can provide assistance.

The competent authorities can carry out the following controls of products on the market for different reasons:

- Random controls for general compliance (labelling, composition, claims, etc.) of cosmetic products.
- Controls for specific categories of cosmetic products for which they believe there is a general public interest e.g., children’s cosmetic products, sunscreens, etc.
- Control carried out on a specific cosmetic product further to a recurrent complaint.
- Control compliance of cosmetic products on the market with a recently implemented regulation; the concentration of a newly regulated substance or the labelling of new warnings might be assessed, for example.

When the Product Information is examined, the inspectors do not need to verify all the data available systematically. For example, the subject of the inspection can be solely the safety assessment of the cosmetic product, or the claim substantiation etc. Different types of information might be required for the safety evaluation. Summaries are normally sufficient but, under some circumstances, further data can be given if more detail is needed.

Once the inspection has taken place, a written report, summing up the observations noted during the inspection, should be sent promptly to the manufacturer.

Monitoring and analysis of products on the market

A product sampled on the market or at the manufacturing site can be examined for different elements: ingredient labelling, compulsory warning statements, claims, concentration of regulated ingredients, presence of banned substances, microbiological quality of the finished product etc.

Analytical controls on products from retail outlets or from the manufacturing sites, sampled by inspectors, are carried out in Member States' analytical laboratories. These official inspecting laboratories must possess adequate and appropriate analytical equipment or have access to external laboratories providing the same.

In accordance with Article 8.1 of the Cosmetics Directive, the European Commission has validated and published a number of official analytical methods for checking the composition of cosmetic products. This means that official testing of cosmetic products by laboratories of any kind (national, inspecting, etc.) has to be carried out in line with the official European methods described in these specific Directives on analytical methods.

Additional analytical test methods have been gathered in a publication that is to be published by Colipa together with the Joint Research Centre of the European Commission (the publication is expected to be available in February 2004).

Manufacturers/importers are free to use other methods to check their products. However, if requested to do so by the authorities, they must be able to justify the method used.

Sanctions in case of non-compliance

If it is found that the requirements of the Cosmetics Directive have not been properly met, the person responsible for placing the product on the market may be penalised. Penalties differ according to the seriousness of the infringement and may vary from warnings and requests for corrective action to larger fines, product withdrawal and even imprisonment. Negative publicity, brand damage and lost revenue are additional powerful incentives not to breach the Directive.

Sanctions will depend on the legal system in the individual Member State. In case of infringement, the authorities may have the right to seize the non-compliant cosmetic products or to order their withdrawal from the market. Manufacturers may also be prosecuted and fined and/or imprisoned. These sanctions are usually reserved for occasions when there is a serious consumer safety issue.

However, the authorities are also entitled to resolve the issue directly with the manufacturer or importer by discussing the problem and agreeing on product changes such as reformulation, new labelling, modification of the claim, etc. This freedom allows the authorities to respond accordingly to each situation, based on the seriousness of the violation and the extent of the commitment of the company to resolve it.

Administrative co-operation

Given that cross-border inspections are not possible, the Cosmetics Directive requires that Member States authorities co-operate in areas where such co-operation is necessary for the smooth application of the Cosmetics Directive.

In practice, if a competent national authority in a Member State “A” wants to have access to the Product Information located in a Member State “B” (this is determined by looking at the address on the product label) the competent authority in “B” checks the Product Information upon reasoned request from the competent authority in A. Subsequently, the competent authority in “B” informs the competent authority in “A” of the results obtained. Throughout this process, it is very important that confidentiality is kept regarding intellectual property rights and commercially sensitive information.

C. SAFEGUARD CLAUSE

A provision has been made to cover exceptional circumstances where, despite complying with the technical requirements of the Cosmetics Directive, a product may represent a hazard to health based on market experience.

In such circumstances, as stated in Article 12.1 *“a Member State may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision”*.

In that case, the Member State has to inform the Commission and the other Member States, providing them with the precise reasons for taking this measure. The Commission then consults the Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) and subsequently issues a proposal leading either to appropriate restrictions in the EU Cosmetics Directive or to a withdrawal of the national measures.

This “safeguard clause” does not allow Member States to ban or restrict unilaterally the use of a substance in cosmetics products. As it clearly reads from the wording of Article 12.1, this clause refers only to finished products.

The safeguard clause of Article 12.1 has almost never been applied in practice.

VI. AMENDMENTS AND ADAPTATIONS TO TECHNICAL PROGRESS

The articles of the Cosmetics Directive are amended (changed) through the co-decision procedure involving the Commission, the European Parliament (EP) and Council, whereas the annexes are updated by Adaptations to Technical Progress (ATP).

A. AMENDMENTS TO THE COSMETICS DIRECTIVE

Article 95 of the EC Treaty (on the establishment and functioning of the Internal Market) is the legal base for the Cosmetics Directive 76/768/EEC. In this field, the co-decision procedure applies (in accordance with Article 251 of the EC Treaty) each time the text (articles) of the Directive is amended.

The co-decision procedure

In this procedure, the European Parliament shares the legislative power with the Council of Ministers. The procedure can involve up to three readings, including a conciliation procedure in the event of disagreement between the European Parliament and the Council of Ministers. Its main steps are (see for more details Article 251 of the EC Treaty):

First reading:

The initial proposal of the European Commission is sent formally to the European Parliament and to the Council.



The Parliament issues an opinion. The Parliament may approve the Commission proposal, reject it or ask for amendments.



The Council may by qualified majority, after obtaining the Parliament's opinion:

- a) If Parliament does not propose amendments → The Council may adopt the act
- b) If Council approves all the amendments contained in the Parliament's opinion → The Council may adopt the act
- c) Otherwise, the Council will adopt a Common Position → See second reading

Second reading:

If, within 3 months after the Parliament has received the text of the Common Position, the Parliament:

- a) approves the Common Position or does not take a decision → The act is adopted (in accordance with the Common Position)

b) rejects the Common Position (by absolute majority) → The act is deemed not adopted

c) proposes amendments to the Common Position (by absolute majority) → The text is forwarded to the Council and the Commission

The Council examines the amendments to the Common Position proposed by the Parliament. If the Council:

a) adopts the Common Position as amended by the Parliament → The act is adopted (in accordance with the amended Common Position)

b) does not approve all the amendments proposed by the Parliament → See conciliation procedure (third reading).

Conciliation procedure (third reading):

In case the Council does not approve all the amendments proposed by the European Parliament in second reading, the President of the Council will convene the Conciliation Committee in agreement with the President of the Parliament. This Committee is composed of the members of the Council or their representatives and an equal number of representatives of Parliament. The Commission is also involved and fulfils a coordination role.

The Committee has six weeks (extendable) to reach an agreement on a joint text.

If the Conciliation Committee:

a) does not approve a joint text → The act is deemed not adopted

b) approves a joint text → The Parliament, by absolute majority and the Council, by qualified majority, each have a period of six weeks in which they have to adopt an act in accordance with the joint text.

If either of the two institutions eventually fails to approve the joint text within that period → The act is deemed not adopted.

B. ADAPTATIONS TO TECHNICAL PROGRESS

Regulatory process

Specific ingredient review and (possibly) regulation in the Annexes of the Cosmetics Directive can be started upon the initiative of the industry, generally with a view either to introducing a new ingredient listed on a positive list or to introducing a change in concentration/use. The initiative can also come from a national competent authority as a result of concerns over the safety of a specific substance, which is brought to the attention of the European Commission.

When the initiative comes from industry, a company normally prepares a safety dossier, which is transmitted for review to the Commission's scientific advisory body, the Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP). Generally, prior to submission, the full dossier is sent by the company to Colipa for evaluation by its scientific department, which helps – if necessary – in preparing the final version of the safety dossier. In these cases, the safety dossier is submitted by Colipa to the European Commission DG Health and Consumer Protection (DG SANCO).

The SCCNFP reviews the submission and issues an opinion, which is transmitted back to the European Commission. The opinion will be the basis for a proposal to change the Annexes of the Cosmetics Directive – or it may result in a demand for further information. If the SCCNFP is of the opinion that data for the evaluation are missing, it will request further data and the dossier will be re-evaluated after the submission of the missing data.

Once the final SCCNFP opinion becomes available, it is discussed as a basis for ingredient regulation at the Ad Hoc Working Party (AHWP = a working group notably composed of representatives of the Member States Authorities in charge of cosmetic products, of industry delegations and of a delegation representing European consumers). A debate takes place on how the SCCNFP opinion should best be translated into regulation.

If an agreement is reached, the European Commission drafts an official proposal for adaptation to the Annexes of the Cosmetics Directive, to be discussed at the COSCOM level (Standing Committee for Cosmetic Products: same membership as the AHWP, but without industry or consumer representatives).

During the COSCOM meeting, the Commission's proposal is submitted for approval by qualified majority voting. The Commission acts as chairman but does not vote.

If the proposal is accepted, it is sent to the College of Commissioners for formal approval, translated into all national languages and published in the Official Journal of the European Union (OJEU).

Stakeholders involved in the adaptations to technical progress

European Commission

The European Commission has the exclusive right to propose changes to the Cosmetics Directive. Two Directorate-Generals (DGs) are involved: DG Enterprise, as a "risk manager" and administrator of the Cosmetics Directive, and DG SANCO (Health and Consumer Protection) for the coordination and administration of the scientific work of the SCCNFP (see below).

The College of Commissioners

This decision-making body, composed of the President of the Commission and the Commissioners needs to eventually approve all changes to the Cosmetics Directive, after the adoption at the COSCOM (see below). Only once this formal vote is cast, adaptations to the Cosmetics Directive can be translated into the EU official languages

and published in the Official Journal of the EU.

The Scientific Committee for Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP)

Within the area of cosmetic product safety, the SCCNFP, consisting of 18 independent scientists, is the scientific advisory body of the European Commission. The Commission cannot make a proposal to regulate a substance without a SCCNFP opinion. This body evaluates substances used in cosmetics on which safety concerns are raised or which the industry would like to add to a positive list (or modify its permitted concentration/use). The SCCNFP Plenary meets three to four times a year to adopt final opinions on the submissions received.

The Standing Committee for Cosmetic Products (COSCOM)

The Standing Committee for Cosmetic Products (or COSCOM) is made up of the national competent authorities from each EU Member State, chaired by the European Commission. This committee may decide to ban/restrict ingredients based on clear scientific data. This will only be after consultation with the SCCNFP.

The Ad Hoc Working Party on Cosmetics (AHWP)

The AHWP is a stakeholder working group which meets regularly to discuss issues relevant to the management and implementation of the Cosmetics Directive, including the Commission's proposals for the adaptation to technical progress. Through an exchange of views between all interested parties, these discussions guarantee the transparency of the regulatory process and ensure that decisions are taken on the basis of all available and relevant information. Discussions in the AHWP also enable the Commission to assess the level of common understanding of support for the policy it proposes.

The AHWP is composed of:

- representatives from the European Commission;
- representatives of the ministries in charge of cosmetics in each Member State;
- observers from EFTA countries;
- industry delegation(s)
- delegation representing the European consumer associations

VII. QUESTIONS AND ANSWERS - (Q&A)

Please note that the Questions & Answers have been classified into the following sections:

1. General questions
2. Labelling
3. Quality
4. Safety
5. Animal testing
6. In-market control
7. Technical annexes

1) GENERAL QUESTIONS

Can Member States have tighter limits and controls than those prescribed by the Cosmetics Directive?

National Authorities cannot go beyond the requirements of the Cosmetics Directive, which has to be implemented at national level without any deviation. If Member States transpose the Directive wrongly, an infringement procedure can be initiated against them before the European Court of Justice (ECJ). If the ECJ found the national law not to be in line with the Cosmetics Directive, the Member State concerned would be required to change national law to comply with the judgement.

Are the requirements for cosmetics imported into the EU different from those for products manufactured within the EU?

The Cosmetics Directive does not differentiate between products manufactured in the EU and products imported from third countries. They are treated equally. However, in case of products imported from outside the EU, some EU Member States may require products to indicate their country of origin on the packaging.

How does the Cosmetics Directive deal with “borderline products” (e.g. cosmeceuticals, cosmetic drugs)?

The category “borderline product” does not exist in the EU legislation on cosmetic products. There are therefore no intermediate product categories between cosmetics and pharmaceutical or foodstuffs or medical devices. This means that a product is either a cosmetic or another type of product (e.g. a pharmaceutical) but cannot be both at the same time.

Nevertheless, questions may be raised in cases of doubt on the classification of a product at the borderline between the definitions of a cosmetic product and other types of products. For these situations, the European Court of Justice has repeatedly stated that in seeking to classify products, not only the legal definition but all the characteristics of the products must be taken into account on a case-by-case basis (*inter alia*, the composition of the product, its properties, the way in which it is used, the extent to which it is sold, its familiarity to the consumer and the risks which its use may entail)

before classifying one product within one or another product category.

What is the relationship between the Cosmetics Directive and general consumer or product safety legislation?

The *lex specialis* principle states that specific legislation prevails from general legislation. According to this principle, the provisions of the Cosmetics Directive prevail vis-à-vis requirements from more general legislation (consumer protection law, general product safety, etc.) in all those aspects that are already covered by the Cosmetics Directive.

2) LABELLING

Is it necessary to label cosmetics in the national language of the countries where the product is distributed?

In accordance with Article 7.2 of the Cosmetics Directive, Member States may require that the following information be labelled in their own national or official language(s):

- nominal content;
- date of minimum durability (where necessary);
- particular precautions to be observed in use (where necessary);
- function of the product (where necessary).

Is the ingredient labelling required to be in the national language or alphabet?

No. Ingredient labelling must be given in the International Nomenclature for Cosmetic Ingredients, known as INCI. This includes the use of the words “parfum” and “aroma” to refer to perfume and aromatic compositions and their raw materials. In the INCI system, the list of ingredients must begin with the heading “INGREDIENTS”.

The 7th Amendment to the Cosmetics Directive allows the use of the symbol “+/-“ instead of the words “may contain” when indicating what colouring agents are present in a product with colour ranges.

This harmonised implementation of the labelling requirements contributes to the free circulation of goods within the European Union, which will have 20 official languages from 1 May 2004.

Which nomenclature is used for ingredients labelling?

The nomenclature used for ingredient labelling is INCI, i.e. the International Nomenclature for Cosmetic Ingredients. INCI is a common nomenclature for all ingredients used in cosmetic products. This nomenclature was developed by the European and American cosmetic industries. Used by pharmacists and scientists world-wide, it is accepted by the 15 European Union Member States (25 Member States from 1 May 2004) and by a growing number of other countries in Europe and beyond, including, for example, the United States of America, Canada, Australia, Singapore and South Africa.

Is INCI understood by the average consumer?

The average consumer can, with help of the INCI name, recognise ingredients on the label when buying a cosmetic product anywhere in the EU. Allergy sufferers in particular benefit from the declaration: Once they have identified their individual allergen with the help of a dermatologist, they can reliably recognise the relevant allergenic substances from the INCI names on the ingredients list before purchase and avoid corresponding products.

What is the European Inventory of Cosmetic Ingredients?

The European inventory is an indicative list of substances used in cosmetic products and is the basis for the common nomenclature (INCI = International Nomenclature of Cosmetic Ingredients). The inventory is not a positive list and does not refer to the safety of a substance. The inventory is adopted and published by the EU Commission.

With notable exceptions (trivial names, botanicals, colouring agents as listed in Annex IV) the nomenclature in the inventory is the same as that used in the USA. This means that the International Cosmetics Ingredients Dictionary and Handbook, published in the USA (CTFA) and regularly reviewed and updated, may be a useful source of information for ingredients not yet published in the EU inventory. In addition, CTFA-ON LINE, which is a subscription service, may be consulted for the latest information between editions of the inventory.

Please note that Colipa should be informed of substances used within the EU that are not yet in the European inventory. This will allow Colipa to work with the Commission to update the latter.

Are formulations containing ingredients that are not in the European Inventory of Cosmetics Ingredients allowed in the EU?

Yes, provided that the product is safe (Article 2) and complies with the various annexes of the Cosmetics Directive. The inventory is not a positive, closed list of the ingredients authorised on the EU market.

Is it obligatory to indicate the date of minimum durability of a cosmetic product on the label?

It is mandatory to indicate the date of minimum durability of a cosmetic product when its minimum durability is equal to or less than 30 months. In these cases, the appropriate date will be indicated by the term "*best used before the end*", followed by either the date itself, or details of where it appears on the packaging.

What is the "Period after Opening" requirement?

The 7th Amendment to the Cosmetics Directive has introduced a new requirement on the labelling of cosmetic products. Products with a minimum durability of more than 30 months must indicate the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by the symbol shown in Appendix C of this brochure and the period itself in months and/or

years. For products with a minimum durability of more than 30 months, it is not allowed to indicate the minimum durability instead of the “Period after Opening”.

For more details, please refer to the relevant guidelines on Period after Opening, available from Colipa.

Is the indication of the manufacturing date necessary on cosmetic products?

No. The indication of the manufacturing date is not required. There is however a batch number allocated by the manufacturer on each product’s packaging for identification purposes. This allows full traceability of all parameters, including manufacturing date.

Do all cosmetic products need to meet the same labelling requirements?

All products, including gifts, samples and testers are subject to the same labelling requirements. However, for practical reasons, some specific products may have slightly different requirements.

Where it is impracticable, for reasons of size or shape, to indicate the precautions to be observed in use [where necessary, in accordance with Article 6.1.d)] and the list of ingredients [see Article 6.1.g)], these shall appear on a label, tape or card enclosed or attached to the cosmetic product. For soap, bath balls and other small products where this is impracticable, the ingredient labelling shall appear on a notice in immediate proximity to the container in which the cosmetic product is displayed for sale.

As far as the nominal content at the time of packaging is concerned [(Article 6.1.b)], this requirement needs not be labelled for free samples, for packaging containing less than 5 grams or 5 millimetres, or for single-application packs. Testers, however, may be labelled in some Member States but not in others.

For pre-packages normally sold as a number of items for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging (this number does not need to be written if the number of items is easy to see from the outside or if the product is normally sold individually).

Are other warning statements than those foreseen in Annexes III, IV, VI and VII allowed?

Yes. In certain cases, given that the manufacturer is responsible for the safety of a cosmetic product under reasonably foreseeable conditions of use, he may wish to provide additional warning statements on a voluntary basis based on experience or special concern.

3) QUALITY

Is quality certification necessary? Who guarantees the quality of cosmetic products?

The responsible national authorities closely monitor compliance with the Cosmetics Directive. Competent Authority investigations on potentially non-complying products can be initiated following input from the consumer, the trade, competitors or from its own regular market surveys. Quality certification on a general level is not necessary.

Is conformity with ISO 9000 obligatory?

No, ISO 9000 is an optional standard for any manufacturer. It is up to the manufacturer whether he wishes to subscribe to a quality certification scheme.

Are standards on finished products necessary?

Finished cosmetic products must comply with the requirements of the Cosmetics Directive and its annexes. Cosmetic products are not required to meet any other standards.

Have Cosmetics Good Manufacturing Practices (GMP) been published in the EU?

Good Manufacturing Practice (GMP) is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. Commitment and responsibility for the application of Good Manufacturing Practice lie with the senior management of any given company who should make available all the resources, training and facilities necessary to meet the requirements.

Article 7a.1 (c) of the Cosmetics Directive requires that the method of manufacture should comply with the Good Manufacturing Practices laid down by Community law or, failing that, laid down by the law of the Member State concerned. To date, no mandatory cosmetics GMP have been published, either in the EU or in the EU Member States.

The European Commission is currently finalising a guidance document on cosmetic GMP; this is expected to be published in the first quarter of 2004.

At present, the Colipa cosmetics GMP guidelines are largely used by industry and are recognised by competent authorities of the Member States. It is noteworthy that these Colipa Guidelines have been taken into consideration by countries outside the EU, for example by the Mercosur Member States (Argentina, Brazil, Paraguay, Uruguay) in the Resolution 96-66.

The Council of Europe has also issued guidelines on cosmetics GMP. These guidelines are similar in nature to the Colipa Guidelines and are usually recognised by the competent authorities of the Member States but they are rarely used.

Have Good Laboratory Practices (GLP) been published in the EU?

Good Laboratory Practice (GLP) is a set of procedures that ensure that tests and assays are performed correctly, according to scientifically sound methods and conditions. GLP ensures the reliability of the results of the tests and assays.

GLP tackles the following issues:

- organisation and personnel ;
- facilities ;
- quality assurance program ;
- equipment and reagents ;
- test systems ;
- test and reference substances ;
- standard operating methods ;
- conducting studies ;
- reporting the results of studies ;
- storage and preservation of records and documents.

GLP, in particular, makes the participants aware of their responsibilities through a clear and readable documentation, enabling the traceability of all laboratory activities; i.e. the functioning of the laboratory, equipment, studies undertaken.

Article 7a.2 requests that the safety assessment of cosmetic products is carried out according to the principles of GLP as laid down by Council Directive 87/18/EEC of 18 December 1986. Therefore, new safety studies should be carried out following GLP. However, existing safety studies of sufficient quality should not be systematically rejected on the grounds that it has not been carried out according to GLP standards.

Directive 1999/12/EC on the inspection and verification of GLP stipulates that the inspection of test facilities and study audits should be carried out in order to guarantee the quality and integrity of the resulting data and to assess the degree of compliance with GLP principles. The inspectors perform this work on behalf of the GLP Monitoring body created by the National Authorities.

4) SAFETY

Who advises the European Commission on the safety of cosmetic ingredients?

The Scientific Committee for Cosmetics and Non-Food Products intended for Consumers (or SCCNFP) is an expert group made up of leading specialists from various scientific disciplines including pharmacology, toxicology, dermatology and microbiology.

The European Commission regularly asks for the SCCNFP's advice. However, whilst it is mandatory for the Commission to consult the SCCNFP, the latter does not take part in the legislative decision-making process.

Does the EU Cosmetics Directive distinguish between what is safe for adults and what is safe for children?

The requirements of the Cosmetics Directive are rigorous enough to ensure that products are safe for use by all consumers under normal or reasonably foreseeable conditions of use. Nevertheless, the 7th Amendment to the Cosmetics Directive requires that the Product Information, which is accessible to the competent authorities, includes a specific safety assessment for those cosmetic products intended for use on children under the age of three. The annexes of the Directive also regulate where special care has to be taken for specific ingredients where children are concerned (e.g. via specific warnings).

What is the difference between the hazard and the risk of a chemical substance?

The hazard describes the intrinsic ability of a chemical substance to cause adverse effects. The risk is the probability that such effects will occur in the various applications in which the chemical will be used and discharged (exposure scenarios).

How must the precautionary principle be applied?

The precautionary principle, which relates to the use of precaution by decision-makers in the management of risks, is mentioned in Article 174 of the EC Treaty.

The Treaty contains no explicit definition of the precautionary principle. On several occasions, however, the Court of Justice and the Court of First Instance have had the opportunity to specify its meaning and determine its scope of application. Also, in order to clarify when and how the precautionary principle applies in practice, the Commission issued a Communication on 27 February 2000 [Communication from the Commission on the Precautionary Principle, COM (2000) 1 final].

Although the precautionary principle is mentioned in the EC Treaty only in relation to the protection of the environment, the principle should also guide measures taken by the Community Institutions for the protection of human health, as repeatedly stated by the Courts and the Commission Communication.

As also specified by the Commission and the Courts, the precautionary principle is to be applied only in circumstances of scientific uncertainty when an objective evaluation of the data available show that there are reasonable grounds for concern, although the reality and extent of the risk cannot be fully demonstrated by conclusive scientific evidence.

The precautionary principle does not provide grounds for taking preventive measures merely based on the hazard of a substance. The application of the principle has to be justified by scientific data supporting the possibility of a risk linked to the specific use of the substance.

As the Tribunal of First Instance stated in the case *Alpharma v. the Council*, (Judgment of 11 September 2002, case T-70/99), the Community Institutions, when applying the principle, cannot take a “*purely hypothetical approach to risk*” and “*base their decision on a “zero-risk*”. The implementation of the principle necessarily implies an assess-

ment of the degree of probability that a certain product has adverse effects for human health, including the seriousness of any such adverse effects.

5) ANIMAL TESTING

Are tests on animals allowed?

The old provision on animal testing of the Cosmetics Directive (Article 4.1(i) of the Cosmetics Directive, as introduced by the 6th Amendment) was explicitly deleted by the 7th Amendment. According to the new Article 4a, introduced by the 7th Amendment, as of 11 September 2004, animal tests on finished cosmetic products in order to meet the requirements of the Directive will be banned in the EU.

For tests performed in the EU on ingredients or combination of ingredients, the ban on animal testing in order to meet the requirements of the Cosmetics Directive will apply by the date on which such tests must be replaced by validated alternative methods listed in Annex V of Directive 67/548/EEC (on the classification, packaging and labelling of dangerous substances) or in the new Annex IX to the Cosmetics Directive. This cannot be later than 11 March 2009.

No later than 11 September 2004, the Commission (in consultation with the SCCNFP, ECVAM and considering progress in validation within OECD) shall establish timetables including deadlines for the phasing out of the various animal tests and also what is listed in Annex IX of the Directive, in consultation with the SCCNFP.

Can products or substances that have been tested on animals be placed on the market?

The old provision on animal testing of the Cosmetics Directive (article 4.1(i) of the Directive, as introduced by the 6th Amendment) was explicitly deleted by the 7th Amendment. According to the new Article 4a, added to the Cosmetics Directive by the 7th Amendment, as of 11 September 2004, the marketing of cosmetic products that have been tested on animals or contain ingredients or combinations of ingredients that have been tested on animals to meet the requirements of the Cosmetics Directive will be banned. The ban will take effect once such animal test methods have to be replaced by one or more validated alternative methods adopted at Community level with due regard to the procedures of OECD. These provisions apply to animal testing carried out both within or outside the EU.

As foreseen by the 7th Amendment, the Commission is currently in the process of establishing a timetable for the phasing out of various animal tests. This timetable will be made available to the public no later than 11 September 2004.

The marketing ban will therefore gradually come into effect, according to progress with the timetable for the phasing out of animal testing methods, with a deadline on 11 March 2009. However, for tests relating to repeated-dose toxicity, reproductive toxicity and toxicokinetics, the deadlines is extended until 11 March 2013, unless this date is postponed.

Can animal testing claims be made?

In accordance with the new wording of Article 6(3), a manufacturer or a person putting a product on the market may take advantage of the fact that no animal tests were carried out or commissioned by them during the development of the cosmetic product. However, the Directive recognizes that there is the potential for such claims to mislead the consumer. Therefore the Commission is currently developing guidelines in this regard in consultation with Member States.

6) IN-MARKET CONTROL

How does a competent authority or a consumer learn from undesirable effects of a given product to other consumers?

Article 7a.1 of the Cosmetics Directive specifies what product information must be made readily accessible at the request of national competent authorities (see sections “Responsibility of the person placing a product on the market” and “Responsibility of the National Competent Authorities”). Amongst other data, information on the undesirable effects derived from the use of a cosmetic product must be included. Colipa estimates that around five billion units are sold in the EU each year. Experience at national level suggests that there is roughly one confirmed adverse reaction in a million units sold (mainly, mild irritation or even less frequently, allergenic reaction).

As far as consumers are concerned, following its 7th Amendment, the Cosmetics Directive foresees that consumers may have easy access to data on the undesirable effects of a product (see Article 7a.1 *in fine*). Please refer to the relevant guidelines on Public Access to Information, available from Colipa.

What happens in case of exaggerated claims about a product?

Article 7a.1(g) requires that proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product, must be made available to the national competent authority on request as part of the product information. Other EU legislation, such as the Misleading Advertising Directive, places additional controls on claims made by producers.

7) TECHNICAL ANNEXES

How often are the annexes of the Cosmetics Directive updated?

The annexes of the Cosmetics Directive are frequently updated (often annually). In case of an urgent safety matter, the European Commission may decide to update them at any time.

Who decides to ban or restrict ingredients?

The COSCOM does. COSCOM stands for the Standing Committee for Cosmetic Products, made up of the competent national authorities from each EU Member State, and chaired by the European Commission. This committee is the only body that may decide to ban or restrict ingredients, based on clear scientific data. This will only be after consultation with the SCCNFP.

However, via the safeguard clause (i.e. Article 12 of the Cosmetics Directive), a Member State may temporarily prohibit the marketing of a certain product for presumed health reasons. In this case, that Member State has to inform the Commission and the other Member States, providing them with the precise reasons. The Commission then consults the SCCNFP and subsequently issues a proposal to deal with the temporary ban.

What are the standards for chemical or microbiological impurities?

No official standard of purity for finished products has been published in the EU. Some ingredients are subject to purity criteria in the annexes of the Cosmetics Directive. Colipa has developed guidelines on Microbial Quality Management (MQM).

Small traces of forbidden substances (Annex II) are tolerated only if they are technically unavoidable in good manufacturing practices and that the cosmetic product does not cause damage to human health.

Can substances from Annex VI be used for purposes other than preservation of cosmetics? Are there any restrictions?

Yes. Preservatives listed in Annex VI and marked with the symbol (+) may be used at higher concentrations than those laid down in this annex for other specific purposes apparent from the presentation of the products (e.g. as deodorants in soap or as anti-dandruff agents in shampoos). Nevertheless, the Commission is in the process of regulating these other uses of preservatives. If accepted by the SCCNFP, they will be added to Annex III as is already the case for the other uses of formaldehyde (III.1.13), phenoxypropanol (III.1.54) and benzalkonium salts (III.1.65).

Are preservatives not listed in Annex VI allowed for use in cosmetics?

Only those preservatives listed in Annex VI can be used as preservatives for cosmetic products. Nevertheless, some substances such as essential oils or some alcohols may have anti-microbial properties and thus help in the preservation of the product. However, they are not included in Annex VI as preservation is not their primary function in the formulation of the product.

Are UV filters not listed in Annex VII permitted for the protection of the cosmetic product itself?

Annex VII regulates only the UV filters for skin protection against harmful UV radiation. UV filters not listed in Annex VII may be used for protecting the product itself against UV rays.

APPENDIX A

(Note: This appendix reproduces the illustrative list of cosmetic products in Annex I of the Cosmetics Directive)

ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of chemical peeling products).
- Anti-wrinkle products.
- Tinted bases (liquids, pastes, powders).

- Toilet soaps, deodorant soaps, etc.
- Bath and shower preparations (salts, foams, oils, gels, etc.).

- Perfumes, toilet waters and eau de Cologne.
- Deodorants and anti-perspirants.

- Depilatories.
- Shaving products (creams, foams, lotions, etc.).

- Hair care products:
 - hair tints and bleaches,
 - products for waving, straightening and fixing,
 - setting products,
 - cleansing products (lotions, powders, shampoos),
 - conditioning products (lotions, creams, oils),
 - hairdressing products (lotions, lacquers, brilliantines).

- Make-up powders, after-bath powders, hygienic powders, etc.
- Products for nail care and make-up.
- Products for making-up and removing make-up from the face and the eyes.

- Products intended for application to the lips.
- Products for care of the teeth and the mouth.

- Products for external intimate hygiene.

- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.

APPENDIX B

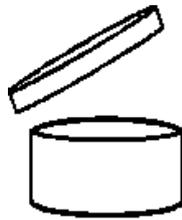
Comparison of an in-market control vs. a pre-market registration system:

In-market control	Pre-market registration
Products may be marketed immediately	Delays (e.g. registration, notification, etc.) for new products reaching the market
All products – including new ones – are immediately available to the consumer. Innovation is encouraged.	Standards for testing have to be set; this restricts availability of products containing new ingredients for the consumer until the standards are revised.
The cost is met by the State and companies found to be non-compliant; no direct costs to complying companies/importers or consumers.	Pre-market control can be expensive for all companies/importers, which means the direct costs are passed on to the consumer.
Only offending companies/importers will be penalised	All companies/importers incur costs, expense and delays.
In-market inspectors will be trained to check for non-conforming products: resources are concentrated in one area.	Surveillance and in-market control also have to take place. This means that resources (inspectors, control appliances, etc.) have to be split between pre-market and in-market controls.
Every product on the market may be inspected. This means that every product must be safe.	Unethical companies may give one set of samples to the authorities for registration but may still put a different set of products on the market. This could lead to unsafe products being available to the consumer.
In order to survive in the marketplace, companies must exercise strict self-control. Any weakness will be identified by competitors, consumers (their Associations) and other interested stakeholders e.g. NGOs.	State responsibility means less incentive for self-control.

APPENDIX C

PERIOD AFTER OPENING

Symbol in Annex VIIIa of the Cosmetics Directive 76/768/EEC, representing an open cream jar, as provided for its Article 6(1)(c), modified by Directive 2003/15/EC of 27 February 2003 (“7th Amendment”).



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

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