

**Guidance Document on Administrative Cooperation in the Area of Market Surveillance  
of Cosmetic Products**

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## I. Introduction

### A. General Aspects

This document is intended as a guide to assist the public authorities of Member States in **market surveillance and administrative cooperation** in the area of market surveillance under Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (Cosmetics Directive)<sup>1</sup>. The obligation to cooperate in this fields is in accordance with Art. 7 a § 5 of the Cosmetics Directive and Art. 10 of the EC Treaty, which states that Member States must take all appropriate measures to fulfil their obligations.

The Guidance Document has been developed by the Standing Committee on Cosmetic Products and the Working Group on "Good Administrative Cooperation". It should be noted that the document is informative and advisory and has no legal authority. Individual Member State Cosmetic Products enforcement authorities are bound by their own national legislation and can only apply this guidance within their confines.

Only the text of the Cosmetics Directive is authentic in law. The text of the directive is applicable where there are differences between the provisions of the directive and the contents of this guide. The interpretation of Community law is ultimately the responsibility and the privilege of the European Court of Justice. Any legal analysis set out in this guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.

### B. Objectives

The Cosmetics Directive is aiming at protecting human health by establishing harmonized provisions for the placing on the market of cosmetic products. Member States have to take all necessary measures to ensure that only cosmetic products which conform to the provisions of the Directive may be put on the market. This implies an obligation for Member States to organize and carry out market surveillance in a way that is effective and sufficiently extensive to discover non-compliant products. Market surveillance is to protect not only the interests of consumers, but also the interests of economic operators from unfair competition.

Each Member State can decide upon the market surveillance infrastructure as long as surveillance is sufficient and covers the whole territory. As a result, the legal and administrative market surveillance infrastructure differ from one Member State to another. This requires, in particular, that guidance is given for **coherent market surveillance, cross-border-control** and **efficient administrative cooperation** between competent national

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<sup>1</sup> This guidance document is complemented, if appropriate, by the

- Guidance Document on the Relationship Between the General Product Safety Directive and Certain Sector Directives with Provisions on Product Safety, DG SANCO, November 2003

- Guide to the Implementation of Directives Based on the New Approach and the Global Approach, European Commission, 2000

authorities so that an equivalent level of protection can be ensured throughout the Community.

Administrative cooperation mechanisms between national surveillance authorities needs to be developed to increase the efficiency of surveillance, to minimise the effect of different surveillance practices and to reduce the overlapping of national surveillance operations. Cooperation between market surveillance authorities can also spread good surveillance practice and techniques across the European Union. It can be useful for exchanging views and best practice as well as finding common solutions for relevant market surveillance problems.

Against this background, this document should:

- give guidance on market surveillance activities in the area of cosmetics, including monitoring, corrective measures and exchange of information (II)
- establish mechanisms for good administrative cooperation between national market surveillance authorities (III)
- be reviewed on a regular basis (IV).

## II. Market Surveillance

### A. General Aspects

Cosmetic products must be in compliance with the Cosmetics Directive and other relevant Community legislation, when they are placed on the market. Accordingly, products manufactured in the European Union and all products imported from third countries must meet the provisions of the applicable directives when made available for the first time on the Community market. Market surveillance authorities have an obligation to ensure this in the framework of market surveillance. To this end, market surveillance should entail monitoring activities (B), corrective actions (C) and exchange of information (D).

### B. Monitoring Activities

Market surveillance activities encompass enforcement, monitoring, examination and evaluation of cosmetic related data and information<sup>2</sup>. It includes, in particular, enforcement of marketing and testing bans pursuant to Art. 4, 4 a and 5 of the Cosmetics Directive,

- monitoring of the correct application of the labelling requirements laid down in Art. 6 of the Cosmetics Directive,
- evaluation whether the product information files are complete and provide for reliable information pursuant to Art. 7 a § 1 of the Cosmetics Directive (**completeness and compliance check**).

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<sup>2</sup> Art. 9 of the Directive on General Product Safety 2001/95/EC apply. It obliges Member States, inter alia, to adopt an approach on market surveillance which may include in particular surveillance programmes and follow-up and updating of scientific and technological safety knowledge.

To this end, market surveillance authorities should take all appropriate measures to examine whether cosmetic products comply with the provisions of the Cosmetics Directive, such as taking

- samples for analysis and laboratory testing and to subject them to examination and testing of the qualitative and quantitative composition of the product,
- samples for analysis and laboratory testing in relation to safety assessment.

Given that development and marketing of cosmetic products is an ongoing entrepreneurial activity, market surveillance should be conducted not only in response to specific events but also on a periodical basis. To this end, market surveillance authorities shall have the power, competence and resources:

- to regularly visit commercial, industrial and storage premises,
- to organise periodical, random and spot checks.

Market surveillance authorities have specific responsibilities when it comes to the control of cosmetic products imported from third countries. Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries<sup>3</sup> provides for cooperation rules between customs and market surveillance authorities. Customs authorities are, in particular, requested to suspend the release of goods that display certain characteristics which would give rise to a serious concern as to the existence of a serious and immediate risk to health and safety under normal and foreseeable conditions of use. They must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action.

Persons responsible for market surveillance must have initial training for the specific requirements of inspections, product and product information file check. They must also undertake ongoing training in order to preserve their expertise in this sector in which innovation is important both as regards ingredients used and the test methods applied.

### **C. Corrective Actions**

Market surveillance authorities must take action, when they discover that a cosmetic product is not in compliance with the Cosmetics Directive. Non-compliance in this context means, that the cosmetic product is not in conformity with the provisions of the Cosmetics Directive (Art. 3). In case of non-compliance, market surveillance authorities must take action to enforce conformity with the provisions of the Cosmetics Directive.

The corrective action depends on the degree of non-compliance and, thus, must be in accordance with the principle of proportionality. However, the difference between non-substantial and substantial non-compliance is not always clear, and must be decided on a case by case basis.

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<sup>3</sup> OJ L 40, 17.02.1993, p.1

Since the Cosmetics Directive does not specify any penalty, Art. 7 of the Directive on General Product Safety 2001/95/EC apply. Member States remain free to choose the sanctions to be used when infringements take place. These penalties must be analogous to those applicable to infringements of national law of a similar nature and importance. In addition, these penalties must be effective, proportionate and dissuasive.

The authority shall restrict or prohibit the placing on the market of the product and ensure that it is withdrawn from the market, if no other measures are sufficient to protect human health. In other cases, it might be sufficient to take appropriate action to enforce conformity with the provisions of the Cosmetics Directive.

Action to prohibit or restrict the placing on the market may first be temporary to allow the market surveillance authority to obtain sufficient evidence about the danger or other substantial non-compliance of the product. Any decision taken by national authorities to restrict or prohibit the placing on the market or to withdraw products from the market must state the exact grounds on which it is based. The party concerned – in particular, the manufacturer or the person responsible for placing the product on the market – shall be notified.

Unless the matter is urgent (for example the product presents a serious and immediate hazard to the health and safety of persons, or in case of critical lack of safety demonstration), the manufacturer or the responsible person for placing the product on the market, should have an opportunity to be consulted in advance, before the surveillance authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or another responsible person has been provided with an opportunity to react.

When a competent authority decides to restrict or prohibit the placing on the market of a product, or to withdraw it from the market, it should also consider whether or not it would be necessary to restrict the use of products that have been restricted or prohibited.

#### **D. Exchange of Information**

Art. 11 of the Directive on General Product Safety 2001/95/EC obliges Member States to inform the Commission of “all measures which restrict the placing on the market of products – or require their withdrawal or recall”. Only measures such as those provided for in Art. 8 para 1 of Directive 2001/95/EC, i.e. measures that are taken to ensure that products are safe, have to be notified. The obligation to notify such measures is waived if notification is already required under Art. 12 of Directive 2001/95 (**RAPEX**) or Art. 12 of the Cosmetics Directive (**safeguard clause**)<sup>4</sup>.

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<sup>4</sup> For further information in relation to the different notification systems see “Guidance Document on the Relationship Between the General Product Safety Directive and Certain Sector Directives with Provisions on Product Safety” [http://ec.europa.eu/consumers/cons\\_safe/prod\\_safe/gpsd/guidance\\_gpsd\\_en.pdf](http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf) as well as the “Guidelines for the Management of the Community Rapid Information System (RAPEX) and for Notifications Presented in Accordance with Art. 11 of Directive 2001/95/EC”, [http://ec.europa.eu/consumers/cons\\_safe/prod\\_safe/gpsd/rapex\\_guid\\_en.pdf](http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/rapex_guid_en.pdf)

## **1. RAPEX**

The Directive on General Product Safety 2001/95/EC provides a legal basis for a specific information exchange system for emergency situations. RAPEX is a general and horizontal early warning and monitoring system. It is designed for handling urgent situations caused by products that present a serious and immediate risk to the health and safety of consumers. Its essential aim is to provide information in order to allow authorities of all Member States to take immediate and appropriate action when a serious risk arising from a product has been detected.

The notification should be made through the national RAPEX contact point in the Commission.

## **2. Safeguard Clause**

The safeguard clause provided by Art. 12 of the Cosmetics Directive apply in cases where the cosmetic product represents a hazard to human health although it complies with the requirements of the Cosmetics Directive. Compliance in this context means conformity with the provisions of the Cosmetics Directive, except the general safety requirements provided by Art. 12 of the Cosmetics Directive.

## **III. Administrative Cooperation**

### **A. General Aspects of Cooperation**

#### **1. Objectives**

For the achievement of effective market surveillance in the European Union, it is important that national surveillance authorities inform and assist each other. Market surveillance authorities shall provide administrative assistance upon request, or spontaneously when the course of investigations so requires.

Market surveillance authorities should assist each other in solving market surveillance problems by exchanging information, experience, enforcement and monitoring of the implementation of the provisions of the Cosmetics Directive in areas such as

- product information files,
- good laboratory practice and laboratory test results,
- borderline products<sup>5</sup>,

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<sup>5</sup> For various guidance documents in relation to borderline products see [http://ec.europa.eu/enterprise/cosmetics/html/cosm\\_borderline\\_docs.htm](http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm)

- control of products intended for professional use only<sup>6</sup>,
- analytical methods,
- safety data on ingredients and exposure, product categories and concentrations,
- corrective measures,
- notifications pursuant to Art. 7 a § 4 of the Cosmetics Directive.

## **2. Contact Points**

Each Member State shall designate one or more market surveillance authorities to liaise as appropriate with other Member States' market surveillance authorities. The role of such contact points shall be to assist and coordinate communication between market surveillance authorities and, in particular, the transmission and reception of requests for assistance, if appropriate.

## **3. Assistance on Request**

Upon receiving a reasoned request, the requested market surveillance authority shall ensure that the requesting market surveillance authority is with appropriate priority provided with all necessary information and documents.

Requests should be addressed to the respective contact point by clearly indicating the subject and specifying the query. The request should also indicate a deadline by when a reply is needed.

The original sources of information do not have to be made physically available. Information and documents should be provided in a pragmatic (summary, extracts), informal (email/fax) and timely manner without undue delay.

## **4. Assistance without Request**

When a market surveillance authority becomes aware of non-compliance of a cosmetic product, and if such non-compliance may have implications for another Member State or States, it shall pass such information to the other Member State (s) without prior request and without delay.

Member States receiving such information shall investigate the matter and inform the Member States that provided the information of the results of this investigation and, where appropriate, of any measure taken.

Legal notification and information requirements for Member States remain unaffected

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<sup>6</sup> For guidance in relation to “professional uses” see [http://ec.europa.eu/enterprise/cosmetics/doc/guidelines\\_prof\\_use.pdf](http://ec.europa.eu/enterprise/cosmetics/doc/guidelines_prof_use.pdf)

## 5. Confidentiality

Information exchanged between national surveillance authorities has to be covered by professional secrecy, according to principles of the national or community legal system in question, and it has to enjoy the protection extended to similar information under law. Therefore, this guidance document shall not prejudice national rules applicable to the release of documents that are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons' commercial interests.

Where a Member State has rules permitting free access by persons to information held by market surveillance authorities, this fact must be revealed at the time of the request to another surveillance authority, or during the exchange of information if no such request occurs. If the sending authority indicates that the information involves matters of professional or commercial secrecy, the receiving authority should ensure that this can be provided for. Otherwise the sending authority is entitled to withhold the information.

### B. Platform of European Market Surveillance Authorities for Cosmetics

#### 1. Objective

The market surveillance authorities of all Member States establish a **Platform of European Market Surveillance Authorities for Cosmetics, PEMSAC**. The aim of this network is, in particular, to facilitate a cooperation framework by:

- coordination of activities,
- exchange of information,
- development and implementation of joint projects,
- exchange of expertise and best practices in the field of cosmetics market surveillance.

Additionally, PEMSAC should provide the European Commission with matters which could possibly require further regulation under the Cosmetics Directive and problems arising from the enforcement and monitoring of the application of the provisions of the Cosmetics Directive.

#### 2. Structure

- PEMSAC is made up of representatives of market surveillance authorities of all Member States.
- The Platform sets up more detailed internal rules for the structure and working modalities.
- PEMSAC will meet two times a year. The meeting will be chaired by the European Commission, DG Enterprise and Industry.
- Some technical groups may be created in parallel to the PEMSAC. At the workshop of 14 May 2007 aimed at reflecting on the PEMSAC structure and aim it was decided that two specific groups should be created on vigilance and on analytical methods.

- The chair of the meeting should report on the implementation of the work programme to the members of the Standing Committee on Cosmetic Products.

### **3. Work programme**

A two-year monitoring work programme should be established by PEMSAC. The work programme should contribute to efficient administrative cooperation between national authorities towards coherent market surveillance in the area of cosmetic products throughout the European Union.

- The work programme should establish a two-year enforcement and monitoring strategy, covering , in particular,
- priority products, ingredients and inspection locations to be monitored;
- monitoring mechanisms to be applied, including on site inspections, samples to be taken, methods to be applied;
- cooperation between laboratories in the member states involved in market surveillance, including proficiency and collaborative studies between laboratories to validate analytical method and test laboratory performance;
- a catalogue of corrective measures to be taken if a cosmetic product does not comply with the requirements of the Cosmetics Directive;
- exchange of experts e.g. for cooperation with on-site inspections, and inspections of the product information file.

It is foreseen that the first monitoring work programme should be agreed on September 2007. It could include an inventory of market surveillance practices in all Member States, if appropriate.

The work programmes will be implemented by market surveillance authorities in all Member States. Member States will report on the implementation on an annual basis to PEMSAC. The report will be made publicly available.

### **IV. Review**

The guidance document should be regularly reviewed and adapted by the Standing Committee on Cosmetic Products in the light of experience gained in PEMSAC. To this end, particular attention should be given to the establishment of possible mechanisms concerning cosmetovigilance.