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The Cosmetic Products (Implementation) Regulations, 2010

The New Cosmetic Products Regulation

On 30 November 2009, was adopted the new Cosmetic Products Regulation, EU Regulation 1223/2009, replacing the Cosmetics Directive.

With the new Cosmetics Regulation Europe is having a robust, internationally recognised regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials.

Most of the provisions of this new regulation will be applicable as from 11 July 2013. The ban and the strict regime aiming at phasing out animal testing were not modified.

You may consult: The European Parliament website - The Council's register of public documents - The Council press release

Regulation (EC) No 1223/2009

of the European Parliament and of the Council of 30 November 2009 on cosmetic products

OJ L 342, 22.12.2009, p. 59-209

Introduction

Council Directive 76/768/EEC relating to cosmetic products, transposed to national legislation by Legal Notice 424 of 2004 (as amended), has been significantly amended on several occasions. Since further amendments are to be made, in this particular case it should be recast as one single text in the interests of clarity. A **Regulation** is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.

This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. This Regulation comprehensively harmonises the rules in the Community in order to **achieve an internal market** for cosmetic products while ensuring a **high level of protection of human health**.

The environmental concerns that substances used in cosmetic products may raise are considered through the application of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, which enables the assessment of environmental safety in a cross-sectoral manner.

Who's responsible?

The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size should not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC concerning products which, appearing to be other than they are, endanger the health or safety of consumers. In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person established within the Community.

An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators.

It is necessary to determine under which conditions a distributor is to be considered as the responsible person. All legal or natural persons in the wholesale trade as well as retailers selling directly to the consumer are covered by reference to the distributor. The obligations of the distributor should therefore be adapted to the respective role and part of the activity of each of these operators.

To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice. For the purpose of effective market surveillance, a product information file (PIF) should be made readily accessible, at one single address within the Community, to the competent authority of the Member State where the file is located. The **PIF shall be made available in at least one of the following languages: Maltese, English, Italian**.

The general principle of the responsibility of the manufacturer or importer for the safety of the product is also supported by restrictions of some substances in Annexes II and III. Moreover, substances which are intended to be used as colorants, preservatives and UV-filters should be listed in the Annexes IV, V and VI to Regulation (EC) 1223/2009 respectively in order to be allowed for these uses. *To avoid ambiguities, it should be clarified that the list of allowed colorants contained in Annex IV includes only substances which colour through absorption and reflection and not substances which colour through photoluminescence, interference, or chemical reaction.*

Use of Nanomaterials

The use of nanomaterials in cosmetic products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Community should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly.

At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials.

Use of CMRs

Given the hazardous properties of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A, 1B and 2, pursuant to the REACH Regulation (EC) No 1272/2008, their use in cosmetic products should be prohibited. However, as a hazardous property of a substance does not necessarily always entail a risk, there should be a possibility to allow the use of substances classified as CMR 2 substances where, in view of exposure and concentration, they have been found safe for use in cosmetic products by the SCCS and are regulated by the Commission in the Annexes to this Regulation. With regard to substances which are classified as CMR 1A or 1B substances, there should be a possibility, in the exceptional case that these substances comply with food safety requirements, inter alia as a result of their naturally occurring in food, and that no suitable alternative substances exist, to use such substances in cosmetic products on the condition that such use has been found safe by the SCCS.

Language requirements for Labelling

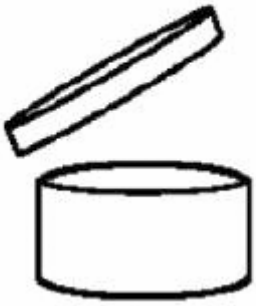
The nominal content, date of durability, precautions and function of the cosmetic product shall be supplied on the label in at least one of the following languages: Maltese, English.

Date of Durability

Date of minimum durability

In order to inform consumers, cosmetic products should bear precise and easily understandable indications concerning their durability for use. Given that consumers should be informed of the date until which the cosmetic product will continue to fulfil its initial function and remain safe, it is important to know the date of minimum durability, i.e. the date by which it is best to use the product. Where the minimum durability is more than 30 months, the consumer should be informed of the period of time after opening that the cosmetic product may be used without any harm to the consumer. However, this requirement should not apply where the concept of the durability after opening is not relevant, that is to say for single-use products, products not at risk of deterioration or products which do not open.

Period-after-opening



Notification

Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the European Commission:

(a) the category of cosmetic product and its name or names, enabling its specific identification;
(b) the name and address of the responsible person where the product information file is made readily accessible;
(c) the country of origin in the case of import;
(d) the Member State in which the cosmetic product is to be placed on the market;
(e) the contact details of a physical person to contact in the case of necessity;
(f) the presence of substances in the form of nanomaterials and:
    a. their identification including the chemical name (IUPAC)and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;
    b. the reasonably foreseeable exposure conditions;
(g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;
(h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

This notification procedure shall also apply to cosmetic products notified under Directive 76/768/EEC.

When the cosmetic product is placed on the market, the responsible person shall notify to the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

As from 11 July 2013, a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, by electronic means, the following information to the Commission:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
(b) the Member State in which the cosmetic product is made available;
(c) his name and address;
(d) the name and address of the responsible person where the product information file is made readily accessible.

Where a cosmetic product has been placed on the market before 11 July 2013 but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;
(b) the Member State in which the cosmetic product is made available;
(c) his name and address.

On the basis of that communication, the responsible person shall submit to the Commission, by electronic means, the information referred to in the first paragraph of "Notification", where notifications according to Article 7(3) and Article 7a (4) of Directive76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.

The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1, and in paragraphs 2 and 3 available electronically to all competent authorities. That information may be used by competent authorities only for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

Following is the draft Legal Notice that is being proposed to implement Regulation (EC) No 1223/2009 on Cosmetic Products:-

_____ _____

Chairman, MSA Prime Minister

L.N. of 2010

PRODUCT SAFETY ACT
(CAP. 427)

The Cosmetic Products (Implementation) Regulations, 2010

IN exercise of the powers conferred by article 39 of the Product Safety Act, the Prime Minister, on the advice of the Malta Standards Authority has made the following regulations:

Title.

1. (1) The title of these regulations is The Cosmetic Products (Implementation) Regulations, 2010.

Commencement and Scope.

2. (1) These regulations shall apply as from 11 July 2013. These regulations implement the provisions of Articles 11, 19(5), 34(1), and 37 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

(3) By way of derogation from the Cosmetic Products Regulations, 2004 (L.N. 424 of 2004), cosmetic products which comply with these Regulations may be placed on the market before 11 July 2013.

Establishment of the competent authority.

3. The Regulatory Affairs Directorate within the Malta Standards Authority is the competent authority within the meaning of Article 34(1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

4. The Market Surveillance Directorate within the Malta Standards Authority is responsible for the market surveillance of cosmetic products as described in the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products in particular Chapter VII of the Regulation.

Language requirements for the Product Information File.

5. With reference to Article 11 of Regulation (EC) No 1223/2009 the information contained in the product information file shall be made available in at least one of the following languages: Maltese, English, Italian.

Language requirements for Labelling of Cosmetics.

6. With reference to Article 19(5) of Regulation (EC) No 1223/2009 the language of the following information mentioned in the following points (a) to (d) shall be supplied in at least one of the following languages: Maltese, English.

    (a) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; 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 information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;
    (b) the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3 ('date of minimum durability'). The date itself or details of where it appears on the packaging shall be preceded, by the symbol shown in point 3 of Annex VII of Regulation (EC) No 1223/2009, or the words: 'best used before the end of'. The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol, shown in point 2 of Annex VII of Regulation (EC) No 1223/2009, followed by the period (in months and/or years);
    (c) particular precautions to be observed in use, and at least those listed in Annexes III to VI of Regulation (EC) No 1223/2009 and any special precautionary information on cosmetic products for professional use; and
    (d) the function of the cosmetic product, unless it is clear from its presentation.

Penalties.

7. With reference to Article 37 the penalties applicable for infringement of the provisions of Regulation (EC) No.1223/2009 shall be those provided for in Part IV of the Product Safety Act.

Revokes L.N. 424 of 2004.

8. The Cosmetic Products Regulations, 2004, transposing Directive 76/768/EEC shall be revoked, with effect from 11 July 2013.

The MSA's web page on Cosmetics may be found at:

http://www.msa.org.mt/rad/cosmetics/index.htm

The European Commission's website on Cosmetics may be found at:
http://ec.europa.eu/enterprise/cosmetics/index_en.htm

Your comments on the proposed Regulations are invited. Note that this information document does not seek your views on the European Regulation but on the proposed regulations for implementing it.

Any comments should reach the Directorate in writing or via email by Monday 17th May, 2010.

For any other information kindly contact the Foodstuffs, Chemicals, Cosmetics and Pesticides Unit within the Regulatory Affairs Directorate of the Malta Standards Authority using the following contact details:

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