NEW EU REGULATION ON COSMETIC PRODUCTS ENTERED INTO FORCE ON JANUARY 11, 2010, WITH SPECIAL ATTENTION GIVEN TO NANOMATERIALS

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New cosmetics legislation (Regulation (EC) No. 1223/2009) on cosmetic products entered into force on January 11, 2010. The new regulation is the first European Union (EU) rule to include a dedicated provision expressly designed to review the safety of nanomaterials. It provides a definition for the kinds of nanomaterials that are intended to be subject to the regulation, and establishes specific safety and labeling requirements applicable to cosmetic products containing nanomaterials.

The regulation will apply from July 11, 2013, with the exception of the provisions concerning substances classified as carcinogenic, mutagenic, or toxic to reproduction (CMR) that will apply from December 1, 2010, and the notification requirements applicable to products containing nanomaterials that will apply from January 11, 2013. Due to the significant changes that have been made to the EU regulatory framework for cosmetic products, companies will need to start planning now to be in a position to comply with the new requirements.

The new cosmetics regulation repeals the former Cosmetic Directive (Council Directive 76/768/EEC) as well as the 27 national transposing laws on cosmetic products since it will be directly applicable in all EU Member States. The new regulation clarifies the obligations of the responsible person (manufacturer or importer) and the distributor, and it strengthens in-market controls. All cosmetic products will be now subject to formalized safety assessment and to a centralized premarket notification and approval procedure; furthermore, products containing nanomaterials will be subject to an additional notification and to specific safety and labeling requirements. The new regulation also opens up the opportunity to market products that contain substances considered CMR Category 1A, 1B Part 3 Annex VI of Regulation (EC) No. 1272/2008, provided that the safety of the product can be assured. The relevant provisions of the new regulation are further explained below.

Imposition of Obligations on the Responsible Person and Distributor

The regulation mandates that for each cosmetic product placed on the market a legal or natural person shall be named as the “responsible person.” This “responsible person” will ensure compliance with the relevant obligations set by the regulation (i.e., seeing that a safety assessment is carried out, preparing a cosmetic product safety report, keeping product file information up to date, notifying the cosmetic product).

The responsible person will usually be the manufacturer established within the Community or, if the manufacturer is located outside the Community, a person located within the Community must be designated by written mandate. In the case of imported cosmetic products, each importer will be the responsible person for the specific product it places on the market. The importer can also designate another person by written mandate. Under specific circumstances the distributor may also be considered as the responsible person. This will be the case when the distributor places a cosmetic product on the market under his name or trademark or when the product already placed on the market has been modified up to the point that compliance with the applicable requirements may be affected.

The responsible person will have the obligation to make sure that the products it places on the market are in conformity with the regulation or to take the corrective measures necessary (including withdrawal or recall) to bring the product into conformity. The responsible person will also have the responsibility to inform competent national authorities when the cosmetic product poses a risk to human health. In addition, it will have to cooperate with the authorities to eliminate the risks created by the product.

Obligations also are imposed on distributors, who will have the general responsibility to act with due care and to ensure that the cosmetics products they distribute are in compliance with the labeling, language, and date
of minimum durability requirements specified in the regulation. The distributor will have the same obligations to inform the competent authorities, as well as to cooperate with them, when the product is believed to pose a risk to health, and to take all corrective measures to bring the cosmetic product into conformity with the regulation.

Furthermore, the responsible person and the distributor will have the obligation to inform the competent authority of any serious undesirable effects (i.e., effects that result in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies, or an immediate vital risk or death) of the cosmetic product they have placed on the market and of the corrective measures taken. The notified competent authority will transmit this information to the competent authorities of all Member States.

The regulation imposes traceability requirements on the responsible person and the distributor. Upon request of a competent authority, the responsible person must be able to identify the distributors to whom it supplies the cosmetic product; the distributors must also be able to identify the distributor or responsible person from whom and to whom the product was supplied. The obligation will apply for a period of three years from the date on which the batch of the cosmetic product was made available to the distributor.

**Safety Requirements**

**Safety Assessment**

To ensure the safety of the cosmetic product it places on the market, the responsible person must, prior to placing on the market, guarantee that it has undergone a safety assessment and that a cosmetic product safety report has been set up. The safety assessment already existed under the old directive (Directive 76/768/EEC); however, the new regulation further elaborates on the information required to carry out the assessment.

As a result of the safety assessment, a cosmetic product safety report must be created that will be composed of two parts: product safety information and product safety assessment. Annex I of the regulation provides the data requirements that must be included in the cosmetic product safety report with respect to the product safety part, namely, quantitative and qualitative composition, physical/chemical characteristics, and stability of the cosmetic product; microbiological quality; impurities, traces, and packaging material; exposure to the cosmetic product and to the substances; toxicological profile of the substances; and undesirable and serious undesirable effects. This information must be kept up to date in view of additional information available after the placing of the product on the market.

The safety assessment part of the cosmetic product report will consist of a statement on the safety of the product; labeling warnings and instructions; explanation of the scientific reasoning as well as any specific assessment carried out with respect to products intended for use in children under three years old and in products for use in external intimate hygiene; and proof of the credentials of the safety assessor. The requirement that the safety assessment must be carried out by a person with a recognized degree in pharmacy, toxicology, medicine, or a similar discipline remains unchanged.

The safety assessment and cosmetic product safety report will also apply to cosmetic products notified under the old directive.

**Product Information File**

The regulation imposes an obligation on the responsible person to keep product file information. Although this requirement was already in place under the old directive, the new regulation distinguishes between the information that must be included in the product file information and the information required for carrying out the safety assessment.

This product information file must consist of data concerning the description of the product, the cosmetic product safety report, description of the manufacturing process, and a statement of compliance with good manufacturing practices, proof of the effect claimed for the product, and data on animal testing. The responsible person must make the product information file readily available, by electronic means or other, at the address indicated on the label on the product and must be kept in the national language of the Member
State where the file is kept. The product information file must be kept by the responsible person for a period of ten years from the date when the last batch was placed on the market. This requirement will also apply to cosmetic products notified under the old directive (Directive 76/768/EEC).

Centralized Notification

One significant change introduced by the new regulation is that it establishes a centralized (EU-wide) electronic notification procedure for new cosmetic products. Prior to placing the cosmetic product on the market, the responsible person has to submit a notification to the Commission with the following information: the category of cosmetic product and its name or names; the name and address of the responsible person where the product information file is made readily accessible; country of origin (if imported); Member States where it will be placed on the market; the contact details of a physical person to contact in the case of necessity; the presence of substances in the form of nanomaterials, including the chemical name (IUPAC) and other descriptors, and the reasonably foreseeable exposure conditions; the name and the Chemical Abstracts Service (CAS) or EC number of CMR substances, of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No. 1272/2008; and the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The Commission will make the information submitted with the notification available by electronic means to the competent authorities in all Member States as well as to the poison centers or similar bodies established in the Member States. The centralized notification requirement will also apply to cosmetic products notified under Directive 76/768/EEC. Once the product has been placed on the market, the responsible person will have the obligation to notify the Commission of the original labeling and, where reasonably legible, a photograph of the corresponding packaging.

After July 11, 2013, a distributor will have to submit an electronic notification to the Commission when it translates any element of the labeling of a cosmetic product already placed on the market in another Member State, in order to comply with the national law of the Member State where it makes the product available. Furthermore, it will have the obligation to inform the responsible person, when it introduces in a Member State a product that was on the market prior to July 11, 2013, but is no longer placed on the market. In this case, the responsible person will have the obligation to notify the Commission. The Commission must be informed of any changes to the information submitted with the notification.

Allowance of Use of Category 1A and 1B CMR Substances

The new regulation provides that a substance considered CMR of category 1A and 1B under Part 3 Annex VI of Regulation (EC) No. 1272/2008 (before category 1 and 2 under Annex I of Directive 67/548/EEC) may be used in cosmetics under exceptional circumstances after an evaluation of the Scientific Committee for Consumer Safety (SCCS) has confirmed its safe use in cosmetic products and provided it meets the following requirements: it complies with the food safety requirements as defined in Regulation No. 178/2002 (e.g., safety, traceability, primary obligation of the business operator to ensure safety); no suitable alternative substances are available; the application is made for a particular use of the product category with a known exposure; it has been found safe for use by the SCCS taking into account the overall exposure to the substance as well as taking into account vulnerable population groups. This substance will be subject to specific labeling requirements to avoid misuse.

The use of CMR substances of category 2 under Part 3 Annex VI of Regulation (EC) No. 1272/2008 (formerly category 3 under Annex I of Directive 67/548/EEC) may continue to be used in cosmetic products when they have been scientifically evaluated and found safe for use in cosmetics.

Special Requirements for Cosmetics Containing Nanomaterials

Starting in 2013, the new regulation provides a definition of nanomaterials, and establishes specific
safety and labeling requirements applicable to cosmetic products containing them. Regulated nanomaterials are defined as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.” This definition will be adapted once a common definition has been agreed at the international level.

Besides the electronic notification procedure to which all cosmetic products will be subject, electronic notification for cosmetic products containing nanomaterials, with a few exceptions, will have to be accomplished six months prior to being placed on the market. The following information must be provided with the notification: identification of the nanomaterial including its chemical name (IUPAC) and other descriptors; the specifications of the nanomaterials (particle size, physical and chemical properties); an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year; toxicological profile of the nanomaterial; safety data of the nanomaterial relating to the category of cosmetic product; and reasonable foreseeable exposure conditions.

If the Commission has concerns regarding the safety of the nanomaterial notified, it will request the SCCS to give its opinion on the safety of the nanomaterial. In addition, nanomaterials will have to be clearly indicated in the list of ingredients as “nano.”

The regulation also requires that the Commission compile a catalogue of all nanomaterials used in cosmetic products as well as submit an annual report to the Parliament and the Council on developments in the use of nanomaterials in cosmetics.

Note from the defined scope of coverage that the nanomaterials subject to these special provisions are those determined to be insoluble or biopersistent. The criteria for this determination are unclear from the regulation itself. Article 16(2) further excludes even these materials from its requirements when “used as colorants, UV-filters or preservatives regulated under Article 14, unless expressly specified.” In addition, if used under the conditions for specific substances specified in Annex III, notification under Article 16 is not needed.

Recitation 29 of the regulation signals an intent to keep current with any internationally adopted definition. It states:

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.

Article 2(3) further provides:

In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

Informing developments in this area, it is worth noting that in 2010 the International Organization for Standardization (ISO) will publish ISO TS-80004-1, a vocabulary document with definitions for “core terms” related to nanotechnology, including “nanomaterial.” It remains to be seen whether regulators will determine the need to continue to apply different definitions of a “nanomaterial,” to account for program-specific considerations among agencies and countries.

The mandatory label notation of “nano” has shortcomings as well. It seems unlikely that the EU
would permit a notified nanomaterial ingredient deemed to be biopersistent to be used, given the strong focus that the EU has to encourage the substitution of biopersistent substances under REACH, for example. In the case of nanomaterials that are cleared for use in cosmetics, awareness that a safety review is behind the designation will need to be understood by the general public. Without this needed context, the designation could lead to product deselection by European consumers who could view the designation as a version of a “hazard” label.

**Consumer Information**

**Product Claims**
The regulation also requires that the advertising of cosmetic products (text, names, trademarks, pictures and figurative, or other signs) must not be used to imply that the product has properties it does not have. For this purpose, the Commission, in cooperation with the Member States and after consulting the SCCS, will adopt a list of common criteria for claims which may be used in cosmetic products. The Commission must submit a report to the Parliament and the Council about the conformity of claims used in cosmetic products with the common criteria adopted.

**Access to Information for the Public**
The responsible person must make easily accessible to the public the following information: qualitative and quantitative composition of the cosmetic product; for perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier; and existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product. This requirement is without prejudice to the protection of commercial secrecy and intellectual property rights.

**Member States’ Enforcement Obligations**
The regulation emphasizes the need to have effective market surveillance in order to guarantee compliance with the requirements established therein. Member States will have the obligation to monitor compliance via in-market controls. Market surveillance authorities will perform checks on the cosmetic products, on the economic operators through the product information file, and, when applicable, physical and laboratory checks. Compliance with good manufacturing practices must also be monitored.

To ensure enforcement, the regulation stresses the need for competent authorities of the Member States to cooperate with each other and the Commission, and that all information necessary to uniformly apply the regulation be transmitted among them. Additionally, competent authorities must cooperate with each other in order to verify that the product information file satisfies the requirements of the regulation and that it provides evidence of the safety of the product. For this purpose, the competent authority of the Member State where the cosmetic product is made available must formally request the competent authority of the Member State where the product information file is kept to carry out the verification.

Besides the changes mentioned above, a new symbol is introduced which will be used to indicate the date of minimum durability or “best used before date.” However, this requirement is not mandatory for cosmetic products with a minimum durability of more than thirty months.


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