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EU Cosmetic Regulation: Quality Enhancement of Consumer and Environment Protection, Market Development

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Abstract: The purpose of this article is to outline the main features of the recent European recast of the Cosmetics Regulation (Regulation EC No. 1223/2009), focusing on the core aims of the legislator: harmonization throughout member states (hence the choice of a Regulation as the appropriate legal instrument) and the reduction of administrative burden and ambiguities, to enhance the protection of human health and the environment, thus fostering quality in the market to the benefit of consumers, who may rely on strengthened in-market controls. Specific attention is also paid to the justification of claims, in order to lead consumers to make informed choices based on clear, transparent, and honest claims, counting on a set of 'common criteria' laid down in the specific Regulation (EC) No. 655/2013. This framework makes room for innovation in cosmetic research, since it regulates the use of nanomaterials in cosmetic products, respecting the environment.

1. Introduction

A revision of regulations governing cosmetics has recently taken place in Europe thanks to the (EU) Regulation no. 1223, adopted on 30 November 2009, which came into force for all member states on 11 July 2013 [1].

The new regulation is a re-casting of the rules on cosmetics adopted with directive 76/768—which was the object of as many as 65 amendments—and is a fundamental step in the enhancement of the quality of cosmetics, both in terms of consumer safety and market development. Although consumer safety has taken a place of pride in the legislator's production, the latter has made clear that quality and safety are the main pro-competitive elements, holding equal prominence, which may be beneficial to market development [2].

2. Main Features of the Regulation

Although the Regulation appears at times to be a harmonized coding of the previous regulations, it does in fact sum up almost 40 years' experience in the application of the rules in question, taking this experience to heart and thus setting the stage for an even more effective protection. Thus, the issue of safety is a lynchpin

concept to such an extent that Article 3 prescribes that "cosmetic products made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use...". From this initial indication, one may well understand the kind of responsibility that companies are required to shoulder if they intend to place cosmetic products on the market.

The safety of cosmetics is pursued using a number of different "tools":

- the Regulations are accompanied by Annexes that list the substances that are subject to prohibitions or restrictions to safeguard health (these lists may be modified over time based on scientific advancements),
- for the purpose of imputing cosmetics on to the market, they must be subjected to a safety assessment (the EU Commission on 25 November 2013 issued the specific guidelines for the performance of an appropriate safety evaluation) [3].
- cosmetic production must take place while complying with good manufacturing practices,
- to ensure supervision and guarantee compliance with the obligations indicated in the Regulations, the figure of the 'responsible person' has been introduced in Article 4 (for example, the importer is, according to the law, a responsible person),
- a system has been introduced that enables the identification of the supply chain in order to guarantee the traceability of the cosmetics, supported by the institution of a centralized notification procedure through an EU portal managed by the Commission (so called CPNP—Cosmetic Products Notification Portal) and the identification of the subjects that operate in various capacities in the production process (manufacturer; importer; distributor) that have been assigned specific obligations,
- reinforced surveillance procedures have been outlined, to be implemented by the authorities with the aim of curtailing the counterfeiting that even afflicts the cosmetic sector and may be detrimental to the consumer's health; this system is based on the principle of cooperation between the various authorities and envisages the active participation of the responsible person and other subjects involved in the production process,
- customer protection is also achieved through a cosmetic vigilance program that involves the reporting and collection of information on undesirable effects; a specific reporting of serious undesirable effect (SUE) has been introduced and is ongoing in each member state,
- the Regulation also envisages a special protection related to the claims made by cosmetics to ensure that the consumer can make informed decisions based on objective and not deceitful elements; this has meant the introduction of "common criteria" (with EU Commission Regulation No. 655 of 10 July 2013) to "inform end users about the characteristics and quality of products" seeing

as these are "essential in order to differentiate between products" and help to "stimulate innovation and foster competition" [4,5].

- concerning the environment, special recommendations have been expressed by the Unfair Commercial Practices Directive (UCPD) Guidance Document to encourage industries to make good and accurate environmental claims, avoiding the use of "green claims" regarding the composition and process of products if not well-documented or not documented at all. Greenwashing is in fact a coined expression to underline the act of potentially misleading consumers regarding the environment practices of a company or the environmental benefits of a product or service. According to the revision of the UCPD Criteria Guidelines on Environmental Claims [6] completed on May 25, 2016, a definition for "environmental claims" has been provided (the expressions "environmental claims" or "green claims" refer to the practice of suggesting or otherwise creating the impression (in the context of a commercial communication, marketing, or advertising) that a product or a service is environmentally friendly (i.e., it has a positive impact on the environment) or is less damaging to the environment than competing goods or services. This may be due to, for example, its composition, the way it has been manufactured or produced, the way it can be disposed of, and the reduction in energy or pollution which can be expected from its use. When such claims are not true or cannot be verified, this practice can be described as "greenwashing"). Furthermore, a couple of main principles address the behavior of traders that: (i) must, above all, present their environmental claims in a specific, accurate, and unambiguous manner; and (ii) must have scientific evidence to support their claims and be ready to provide it in an understandable way in case the claim is challenged [7].

3. Innovation

The theme of innovation in a cosmetic context, often referred to by the legislator, offers scope for a brief consideration of the room that the regulations allow for innovative products, both in terms of the research and development of molecules, formulae, and technologies, as well as new kinds of products.

Thus, research is stimulated by the fact that the restrictions already imposed on the use of certain substances do not curtail the development and research of other substances, formulae, and technologies, the use of which will then have to be further investigated through the safety assessment procedures that the manufacturer is responsible for carrying out. The manufacturer is therefore fully entitled to head down innovative paths, being fully aware of the parameters that the company is required to comply with.

In relation to product types, it should be recalled that the legislator has underlined the need to hold firm on a clear demarcation between cosmetics and

similar health products (medicines, medical devices, biocides, food integrators) in an attempt to avoid overlapping classifications relative to so-called borderline situations so that the correct sector regulations that apply can be identified.

Thus, by way of example, plenty of discussions and comparisons have been held on the cosmetic—or other—nature of certain products such as teeth whitening chewing gum, mascara that enhances eyelash growth, and adhesive patches used to fight unsightly body fat deposits (or cellulite) or to improve hair growth. There are many other interesting examples that have been assessed in an EU Commission manual on borderline products (Manual on the Scope of Application of the Cosmetic Regulation EC No. 1223/2009, November 2013), which has turned out to be a very useful tool not only for those seeking to interpret the regulations but also, and especially, for those engaged in product research and development [8].

The issue of innovation and development in the field of cosmetics finds its natural source in the very definition of the cosmetic product, which, as we know, is based on what one may term a binary system, which refers to the application site of the cosmetic product (external surfaces of the human body: epidermis, hair and hair follicle, nails, lips, external genital organs, teeth, mouth mucous) and the functions that are prevailingly or primarily performed (cleaning, perfuming, change of appearance, protection, maintenance, correction of body odors). Thus, the function of cosmetics, despite being established at a legal level, leaves plenty of scope for research, development and innovation in terms of functions such as "protection" and "maintenance", onto which one may graft the most advanced cosmetic qualities that are in a position to establish said products as functional cosmetics, even if they are also recommended in other specific or complementary contexts such as therapeutic contexts (while maintaining the prohibition of boasting therapeutic effects).

The easiest example, and also the most significant one, is found in the dermatological context, where the treatment for relevant pathologies is not only based on innovative medicinal products, but also on the contribution provided by functional cosmetics that enable the patient to improve their quality of life from every point of view. Thus, the cosmetic product plays an important complementary role to the therapy.

4. Nanomaterials

It is worth spending a few words on the issue of "nanomaterials", which have been specifically regulated by the European Cosmetics Regulation No. 1223/2009 as well as from a legal point of view, as an explicit acknowledgement that these ingredients are undergoing considerable development.

The Regulation has introduced several articles with implications for products containing nanomaterials, starting with the definition of a nanomaterial, for the purposes of the Cosmetics Regulation, provided under Article 2.1 (k) as "an insoluble

or bio persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm". While it is the responsibility of the manufacturer (under the aegis of the responsible person) to decide whether any ingredients they are using are nanomaterials (to this end, it is important to acquire proper information from raw material suppliers), the Regulation states (Article 16) that a high level of protection of human health should be ensured for any cosmetic products containing nanomaterials. Moreover, the Regulation requires that a specific evaluation be carried out, as part of the safety assessment, in order to determine any toxicological effects due to particle sizes, including nanomaterials (i.e., Annex 1—Cosmetic Safety Report). To help assessors evaluate nanomaterials appropriately, the Scientific Committee on Consumer Safety (SCCS) has published a report entitled Guidance on the Safety Assessment of Nanomaterials in Cosmetics [9,10].

Both the authorities and consumers shall be specifically informed about the presence of nanomaterials in cosmetic products: the former by means of a centralized notification procedure (cosmetic products that contain nanomaterials will need to be notified six months before the product is placed on the market), and the latter by means of the product label (all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients followed by the word 'nano' in brackets, so as to enable consumers to make informed decisions).

There are some exemptions for nanomaterials intended to be used as colorants, preservatives, and UV filters, which should be listed in Annexes IV to VI in order to be permitted for such uses: these are never subject to the nano-notification requirements, irrespective of the size of the ingredients, since the positive listing in the Annexes supersedes the need for nano-notification. Products containing ingredients listed in Annex III (list of substances which cosmetic products must not contain except subject to the restrictions laid down) in the form of a nanomaterial need not be notified.

Conflicts of Interest: The author declares no conflict of interest.

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