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Nanotechnology in the EU cosmetics regulation

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ABSTRACT: Nanomaterials are being increasingly used in commercial products, a clear indication of the unique potential that nanotechnology represents for industry. This has particularly been the case in the field of cosmetics, where products containing nanomaterials have shown enhanced product performance. Given the perceived risks that nanoparticles pose to human health and the environment, any regulation will have to carefully balance safety concerns with the need to avoid stifling one of Europe's fastest growth industries. The European Union will soon adopt a Regulation on cosmetic products that includes provisions on nanotechnology. This contribution briefly analyses the use of nanotechnology in cosmetic products as well as the relevant provisions in the new Regulation, concluding by placing this development in the broader context of nanotechnology governance at the European level.

KEYWORDS: Nanotechnology, cosmetic products, regulation, consumer protection, European Union.

REGULATORY BACKGROUND

The original Cosmetics Directive (1) was adopted in 1976 with the aim of establishing a single market for cosmetic products in the European Union, ensuring a high level of protection for consumers. Relying on Article 95 of the EC Treaty (2), the Directive set out to harmonise Member States' restrictions on the ingredients of cosmetic products, as well as the divergent national labelling rules. The Directive takes the principle of "manufacturer responsibility" as its basis, whereby the manufacturer placing a product on the market is responsible for the safety of the product in question. In addition to this general principle, the Directive details a long list of specific substances which are to be banned or restricted as ingredients in cosmetic products.

An important feature of the cosmetics industry is the perpetual reformulation of product composition, a phenomenon which has contributed to the need to amend the Cosmetics Directive on a regular basis (3). Linked to this innovative feature is the frequent use of new ingredients in cosmetic products. Nanomaterials (4) are increasingly among these "new" ingredients, a significant proportion of cosmetic products now being estimated to contain nanomaterials (5).

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THE USE OF NANOTECHNOLOGY IN COSMETIC PRODUCTS

The increased usage of nanomaterials in cosmetic products is indicative of the huge potential nanotechnology represents for the cosmetics industry and its consumers. A number of nanomaterial types are already in use, including nanoemulsions (6), and nanoparticles (7) of minerals present in our natural environment, such as titanium dioxide (TiO₂), zinc oxide (ZnO), alumina, silver, silicon dioxide, calcium fluoride and copper.

The rationale for the use of nanomaterials in cosmetic products is, of course, that they offer added value in terms of product performance. The unique properties and behaviour of nanomaterials mean that nanotechnologies could profoundly transform industry and every day life. Nanoemulsions, for example, are transparent and have particular rheological properties that have yet to be obtained by other formulation methods (8). This allows them to increase the content of nutritious oils while preserving not only the transparency but also the lightness of formulas. Certain mineral nanoparticles, such as TiO₂ and ZnO, are highly efficient UV-filters, able to reflect and scatter the visible part of solar radiation while absorbing UV light. Given these properties, they are extensively used in sunscreens.

Other examples of nanocosmetic products on the market include body firming lotion, bronzer, exfoliant scrub, eye liner, and styling gel, to name but a few. Friends of the Earth go as far as stating that "[their] research demonstrates that nanoparticles have entered just about every personal care product on the market, including deodorant, soap, toothpaste, shampoo, hair conditioner, anti-wrinkle cream, moisturizer, foundation, face powder, lipstick, blush, eye shadow, nail polish, perfume and after-shave lotion" (9).

Despite already being used in a plethora of consumer products, however, uncertainties still surround the perceived risks the commercial use of nanotechnology poses to human health and the environment. Crucially, the physical and chemical properties of particles at the nanoscale can differ greatly from those of the same substance at a larger scale. Some argue that the smaller a particle is, the more likely it will be toxic, due to a greater surface area to volume ratio (10). The inability to properly assess these risks is mainly due to a limited understanding of the behaviour of nanoparticles. More specifically, "there is insufficient knowledge and data concerning

nanoparticle characterisation, their detection and measurement, the fate (and especially the persistence) of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles" (11). It is these perceived risks that have dominated policy debates, at risk of upsetting the important balancing act between safety concerns and the need to avoid stifling one of Europe's fastest growth industries.

THE INCLUSION OF NANOTECHNOLOGY IN THE COSMETICS REGULATION

In February of 2008, the European Commission ("Commission") proposed to simplify the 1976 Cosmetics Directive and replace it with a new Cosmetics Regulation, arguing that the directive had "become a 'patchwork' of 55 amendments without coherent terminology" (12). The amended proposal has reached the last stage of the legislative procedure and is currently being translated into the 23 official languages of the EU, political agreement having been reached among the EU institutions.

The simplification of the Cosmetics Directive had four specific objectives, namely:

- i. To improve legal clarity and remove inconsistencies;
- ii. To remove divergences between national law;
- iii. To ensure that cosmetic products placed on the EU market are safe in the light of innovation in this sector;
- iv. To introduce a possibility in exceptional cases to regulate categories "1" and "2" of carcinogenic, mutagenic and reprotoxic substances on the basis of their actual risk.

The legal technique used here is known as vertical recasting, in that the Cosmetics Directive and the 55 amendments it has undergone will be brought under a single legislative act. The new act passes through the full legislative process and repeals all the acts being recast, but also introduces new substantive changes, such as an updatable glossary of cosmetics ingredients (13), safety assessment requirements, and a strengthening of in-market controls, to be ensured via a simplified, centralised and electronic notification system, physical checks, and a product information file to be kept during a period of ten years following the date when the product was placed on the market.

Also among these changes were certain additional requirements for cosmetic products containing nanoparticles. Although not dealt with by the

The inclusion of nanotechnology provisions in the Cosmetics Regulation marks the first time nanomaterials have been addressed in EU legislation

Commission's legislative

Nanotechnologies could profoundly transform industry and everyday life

proposal, the perceived regulatory vacuum on the use of nanotechnologies in cosmetic products was filled by the amendments made to the proposed text by the European

Parliament ("Parliament") during its first and only reading of the proposed text. A new Article inserted by the Parliament outlines the information that must be notified to the Commission in addition to that already required for nanomaterial-free cosmetic products.

The new Regulation defines a nanomaterial as an "insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale of 1 to 100 nm" (14). This is based on the definition developed by the Scientific Committee on Consumer Products ("SCCP") in December 2007 (15), and has three main elements to it:

- i. Characteristics: although the SCCP keeps this aspect of the definition open by referring to materials "which could exhibit novel characteristics compared to the same material without nanoscale features" (16), the Cosmetics Regulation is more specific, specifying solubility and biopersistence as the two properties of relevance. Nanoparticles that are either non-degradable or insoluble are said to pose the greatest risk to human health and the environment.
- ii. Agglomeration/aggregation state: by referring to materials "with one or more external dimensions, or an internal structure" on the scale of 1 to 100nm, the Parliament has ascertained that nanomaterials forming part of an agglomerate/aggregate that is larger than 100nm should fall within the scope of the Regulation. The justification for this is that nanomaterials forming part of such agglomerates may retain the specific physicochemical properties which are characteristic for individual nanomaterials.
- iii. Size: the Parliament's definition adopts 1 to 100nm as the nanoscale range. While this benchmark is not universally agreed to, 100nm is the most commonly used figure when defining nanoparticles.

Given that the field of nanotechnology is moving at a very fast pace, the Commission will have to adapt the definition in line with scientific and technological developments, as well as definitions subsequently agreed at international level. Pursuant to the Regulation, this shall be done no later than 18 months after its entry into force. As referred to above, the Article also sets out a specific safety assessment procedure for all products containing nanomaterials, whereby any such product can be prohibited or restricted if a risk to human health is deemed to exist. Under this procedure, when the Commission has doubts regarding the safety of a nanomaterial, it is obliged to request an opinion from its Scientific Committee for Consumer Safety ("SCCS") (17) on both the safety and reasonably foreseeable exposure conditions of the nanomaterial in question, whose findings shall be made publicly available. In addition, the Commission is required to compile and regularly update a public catalogue of all nanomaterials used in cosmetic products that have been placed on the market.

The Regulation also requires the Commission to submit an annual status report to the European Parliament and the Council of the European Union containing information on developments in the use of nanomaterials in cosmetics products throughout the internal market.

Furthermore, the legal or natural person responsible (18) for a nanocosmetic product shall notify the Commission of the existence of the product through electronic means six months prior to placing it on the market.



In addition to these procedures, the Parliament introduced a nanotechnology labelling requirement, whereby "[a]ll ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients [of a cosmetic product]. The names of such ingredients shall be followed by the word 'nano' in brackets" (19).

Although formal adoption is scheduled for after the summer, a transitional period means that the majority of the Regulation's provisions will only take effect 42 months after its entry into force.

COMMENT

The new framework established by the Cosmetics Regulation will ensure a case-by-case review, whereby safety will remain the number one priority, very much in line with the Commission's approach to product safety. Given the innovative nature of the cosmetics industry, it is crucial to have a regulatory system in place that can deal with the challenge presented by the constant influx of new products on the market. The nanotechnology revolution is at the centre of this challenge, representing somewhat of a moving target for regulators.

Given that the industrial uses of this enabling technology are expected to mushroom in the coming years, regulators have been active in eliciting opinion and fostering debate on nanotechnology governance, indicating that the regulation of this field is likely to occur sooner rather than later. Indeed, the Cosmetics Regulation will be the latest of the few instances in which nanomaterials have been specifically addressed at the European level. The European Parliament recently adopted a Resolution on the regulatory aspects of nanomaterials (20) calling for tighter controls on nanotechnology, notably via the "no data, no market" principle that is also the basis of the REACH Regulation (21). This political statement could lead to increasing reference to nanotechnology in binding EU legislation. Placed in context, however, it is important to emphasise that the inclusion of nanotechnology provisions in the Cosmetics Regulation represents one of the first steps in what will undoubtedly be a long and complex process. Given the uncertainty that surrounds nanomaterials' characterisation and behaviour, striking an appropriate balance between consumer protection and industrial competitiveness represents a significant challenge for regulators.

Our knowledge of numerous crucial aspects of nanomaterials remains primitive

Industrial uses of this enabling technology are expected to mushroom in the coming years

7. A nanoparticle is defined as a "particle with one or more dimensions at the nanoscale", *Ibid.*, p.10 (nanoscale: <100nm).
8. *Ibid.*, p.12.
9. Source: Comments to U.S. Food and Drug Administration, FDA Regulated Products Containing Nanotechnology Materials, Docket number: 2006N-0107, <http://www.fda.gov/ohrms/dockets/98fr/06-6867.htm>.
10. Institute of Occupational Medicine for the Health and Safety Executive 2004, *Nanoparticles: An occupational hygiene review*, 2004, <http://www.hse.gov.uk/research/rpdf/r274.pdf>.
11. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), modified Opinion on *The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotech*, SCENIHR/002/05, http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf.
12. European Commission Press Release, IP/08/184, "New cosmetic regulation to strengthen product safety and to cut red tape", 05/02/2008, <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/184&format=HTML&aged=0&language=EN&guiLanguage=en>.
13. It is estimated that 10,000 ingredients are used in the cosmetics industry, see inventory contained within Commission Decision 2006/257/EC, *Off. J. Eur. Communities.*, **97**, pp. 1-528 (2006), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:097:0001:0528:EN:PDF>.
14. Article 2(k) of provisional text for Cosmetics Regulation, <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0158>.
15. SCCP, *op. cit.*, p.59.
16. *Ibid.*
17. The SCCS was set up by Commission Decision 2004/210/EC, *Off. J. Eur. Communities.*, L 65, p.45, see http://ec.europa.eu/health/ph_risk/committees/09_sccs/09_sccs_en.htm.
18. Defined in Article 4 of provisional text for Cosmetics Regulation, *op. cit.*
19. Article 19(1) of provisional text for Cosmetics Regulation, *op. cit.*
20. European Parliament, Report on regulatory aspects of nanomaterials (2008/2208(INI)), ENVI Committee, <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A6-2009-0255+0+DOC+PDF+V0//EN&language=EN>.
21. Regulation 1907/2006/EC, *Off. J. Eur. Communities.*, **396**, pp.1-848 (2006).

REFERENCES AND NOTES

1. Council Directive 76/768/EEC, *Off. J. Eur. Communities.*, L 262, pp.169-200 (1976), as amended.
2. Article 95 EC bases itself on the objectives set out in Article 14 EC, namely, the establishment of the internal market.
3. The Cosmetics Directive has been amended 55 times since its adoption.
4. A Nanomaterial is defined as a "material with one or more external dimensions, or an internal structure, on the nanoscale, which could exhibit novel characteristics compared to the same material without nanoscale features", SCCP (Scientific Committee on Consumer Products), 18 December 2007, Safety of nanomaterials in cosmetic products, p.10.
5. See the *Consumer Products inventory* compiled by The Project on Emerging Nanotechnologies, which lists 800+ manufacturer-identified nanotechnology-based consumer products currently on the market (125 of which are categorised as cosmetic products: http://www.nanotechproject.org/inventories/consumer/browse/categories/health_fitness/cosmetics/).
6. Emulsions with smaller droplet sizes (10-100nm) than ordinary cosmetic emulsions (100-100,000nm), SCCP, *op. cit.*, p.12.

