ARNOLD & PORTER LLP

ADVISORY

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PROPOSED EU REGULATION INTRODUCES CONTROLS ON THE USE OF NANOMATERIALS IN COSMETICS

A new, proposed regulation, which will replace the unwieldy, and much amended, EU Cosmetics Directive (76/768/EEC) was recently approved by the European Parliament.[1] The Regulation is awaiting its first reading by the Council of Ministers.

BACKGROUND

The new Regulation replaces the existing Cosmetics Directive, which has been criticized by the European Commission as being a "patchwork" of 55 amendments and lacking coherent terminology.[2] Differences in implementation of the Directive between the different Member States created additional costs without contributing to product safety. The Regulation recasts the existing Directive (which requires implementation in all the Member States) as a directly applicable Regulation. The change in the form is intended to achieve a uniform regulatory framework throughout the EU, to assist manufacturers with compliance across the EU.

A proposed Regulation was first published in February 2008 and has subsequently been amended to take account of the European Parliament's concerns about the treatment of nanomaterials, which, according to the European Commission, were present in about 5% of cosmetics (including sun protection products and anti-aging creams) on the EU market in 2006. However, until the Regulation enters into force, the use of nanomaterials in cosmetics will not be regulated by specific EU legislation.

In December 2007, the European Commission's Scientific Committee on Consumer Products (SCCP) published an Opinion on Safety of Nanomaterials in Cosmetic Products. This Opinion was requested following a report from the Royal Society and the Royal Academy of Engineering, which suggested that nanomaterials should be treated as new chemicals from a risk point of view and evaluation of skin absorption should be considered in both "normal" and diseased skins. The SCCP was then requested to address the safety evaluation of nanomaterials for use in cosmetic products and to consider the implications on animal testing.

Nanoparticles can be divided into two categories: soluble and/or biodegradable nanoparticles, which disintegrate upon application to the skin; and insoluble and/or biopersistent particles. A nanomaterial is defined by the Regulation as "an insoluble

1 Proposed Regulation: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0158#BKMD-15

2 Consolidated version of Directive 76/768: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20090112:EN:PDF

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or bio-resistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." Notably, the definition of nanomaterials in the Regulation only refers to insoluble or bio-resistant nanomaterials, and so the provisions set out in the Regulation and summarized here will not apply to soluble and/or biodegradable nanoparticles, which will be subject to the "traditional" risk assessment for cosmetics. However, the Regulation provides that the Commission shall no later than 18 months after the entry into force of the Regulation, adapt this definition to take into account various definitions of nanomaterials adopted by different bodies and scientific and technical developments in nanotechnology.

A conventional risk assessment process will apply to soluble and/or biodegradable nanoparticles. This is not a positive approval process, and is essentially a self-assessment of compliance by the manufacturer that the product conforms to the provisions set out in the Regulation. However, for insoluble/biopersistent nanoparticles, other methods of risk assessment are required and it is primarily in relation to the possible uptake of insoluble particles that health concerns arise (*i.e.*, if the particles become systemically available, accumulation in the body may occur). There are also environmental issues associated with insoluble nanoparticles.

SAFETY ASSESSMENT FOR NANOPARTICLES

The current methods for safety assessment for cosmetics set out in the amended Cosmetics Directive have not been validated with reference substances. These include nanomaterials and the 7th amendment to the Directive, which impose animal testing bans that prohibit the *in vivo* testing of cosmetics now and of their ingredients in the near future.[3] Animal testing is considered essential for translocation and accumulation studies and chronic toxicity studies for insoluble biopersistent nanoparticles. Currently, there is no scientific consensus regarding risk assessment methods (both *in vivo* and *in vitro*) for nanomaterials. However, under the new Regulation, the SCCP is due to provide guidance on test methodologies for nanomaterials and the provisions on nanomaterials should be regularly updated to take account of scientific progress.

A separate safety assessment procedure will be established by SCCP for nanomaterials used as colorants, preservatives, or as ultraviolet filters. Nanomaterials for these purposes can only be used when they have been approved (following safety assessment by the SCCP) and are listed in the relevant annexes to the Regulation.

NOTIFICATION

One year *before* the date of application of the Regulation, manufacturers shall notify the Commission of all existing products that contain nanomaterials. After this point, any manufacturer adding nanomaterials to a beauty product will be required to inform the European Commission six months before the product's launch. Certain information should be provided to the Commission, including the toxicological profile of the nanomaterial, exposure conditions, and safety data related to the cosmetic product which contains it. If the Commission has safety concerns about the nanomaterial, it will then consult the Scientific Committee for safety opinion. This should be provided within six months from the date of request and will be made publicly available.

LABELLING

Cosmetic manufacturers will be required to name any nanomaterials present in the ingredients list on the packaging. The names of such ingredients shall be followed by: "(nano)" (see Article 19(1)(g): http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-0158#BKMD-15).

CATALOGUE

A catalogue of all cosmetic products which contain nanomaterials will also be made available to the public by the European Commission.

PUBLIC CONSULTATION

A public consultation on the simplification of the Cosmetics Directive was launched on January 12, 2007 and closed on March 16, 2007. Stakeholder responses to

3 The 7th amendment to the Cosmetics Directive is Directive 2003/15/EC, and can be found at: http://europa.eu/eur-lex/pri/en/oj/dat/2003/l_066/l_06620030311en00260035.pdf

the public consultation are available online at: http://ec.europa.eu/enterprise/cosmetics/html/cosm_simpl_dir_en.htm#respons.

WHEN WILL THE CHANGES APPLY?

The proposal is awaiting its first reading by the Council of Ministers, and depending on any changes made by the Council, there could be further readings by both Parliament and the Council. It is possible that it could take as long as two years for the Regulation to be adopted and its final form may differ from the draft currently under review.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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