HUNTON& WILLIAMS

Client Alert

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Developments in Nanotechnology Regulation in Europe

In Europe, nanomaterials are being increasingly regulated. At this juncture, these nanotech-focused regulations are vertical, rather than horizontal, and specific to certain products. In the near future, however, these regulations may well be supplemented by horizontal nanotech regulation pursuant to the REACH Regulation. Manufacturers and users of nanomaterials that do business in Europe should pay close attention to these developments.

Current product-specific regulations tend to be focused on safety assessment and disclosure and use the broad definition of nanomaterials adopted by the European Commission (the Commission) in 2011[1] as a starting point. This is true for the EU Cosmetic Regulation 1223/2009, which entered into force on 11 July 2013 and replaces the previous EU legislation on cosmetics. Similar to other regulations recently adopted, such as the Biocides Regulation, the Cosmetics Regulation requires safety assessment of nanomaterials, the filing of information with the European Commission and the supply of information to consumers. This cosmetics-specific regulation is only one piece of the expanding body of nanotechnology regulations that have already been adopted or are scheduled for adoption in the near future at both the EU and national levels.

Nanomaterials under the Cosmetic Regulation

The EU Cosmetics Regulation, of course, does much more than merely address nanomaterials. This Hunton & Williams client alert, however, focuses on the nanomaterials-specific provisions of this regulation.

Definition: Under the Cosmetic Regulation, nanomaterial is defined as "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." Unlike the definition proposed by the European Commission in 2011, this definition is limited to man-made nanomaterials that are also insoluble or biopersistant. Under the Commission definition, which is used in connection with REACH, natural and incidental nanomaterials are also covered. It is not clear whether the definition under the Cosmetics Regulation also covers aggregates or agglomerates of nanomaterials, i.e. nanomaterials that are bound together.

Safety Requirements: The Cosmetic Regulation requires that the toxicological profile of all substances included in cosmetics be assessed with particular attention to nanomaterials. This obligation applies to any person responsible for the placing on the market of cosmetics containing nanomaterials.

If a safety concern arises, the Commission must request an opinion from an advisory body. On the basis of this opinion, the Commission may amend the list of substances that are prohibited in cosmetics or subject to restrictions. If this body concludes that the available data are insufficient, the Commission may request that the responsible person provide data within a stated reasonable time.

[1] European Commission, Recommendation of 18 October 2011 on the Definition of Nanomaterial, OJ L 275/38.

Reporting Requirements: Cosmetics containing nanomaterials are subject to notification requirements. Specifically, six months before their placing on the market,[2] the responsible person must report the following information to the Commission:

- Identification of the nanomaterial, including IUPAC and other descriptors;
- Specifications of the nanomaterial, including size of particles and physical and chemical properties;
- Estimate of the annual quantity of nanomaterial in cosmetics intended to be placed on the market;
- Toxicological profile of the nanomaterial or a reference number for the submission of the toxicological profile, if provided by the European Commission;
- Safety data of the nanomaterial relating to the relevant category of cosmetics; and
- Reasonably foreseeable exposure conditions.

Nanomaterials used as colorants, UV-fliters or preservatives are exempt from this notification requirement, except where the Cosmetic Regulation provides otherwise in a specific case.

On the basis of the notifications submitted by 11 January 2014, the Commission must establish and maintain a catalogue of nanomaterials used in cosmetics, specifying the relevant categories of cosmetics and the reasonably foreseeable exposure conditions.

In addition, responsible persons must notify certain general information to the Commission prior to the placing on the market of cosmetics, including the presence of nanomaterials, their identification and reasonably foreseeable exposure conditions (whether the product is a 'rinse off' or a 'leave on' product and the exposure route: dermal, oral and/or inhalation). This obligation applies even if a nanomaterial-specific notification was previously submitted.

Labelling Requirements: Ingredients in the nano-form must be clearly indicated on the label in the list of ingredients, followed by the word 'nano' in brackets.

The Cosmetic Regulation instructs the Commission to periodically review the provisions on nanotechnology in light of scientific progress. The first review is due by July 2018.

National Nanomaterial Reporting

While the Commission is thinking about a EU's general nanotechnology policy, Member States have imposed reporting requirements that go beyond EU law. In general, these obligations are imposed on companies supplying nanomaterials on their own, in mixtures or in products.

Member States that have adopted mandatory nanomaterial reporting requirements include France and Norway. Recently, Denmark and Belgium released draft ordinances imposing such requirements. These regimes tend to rely on the definition of nanomaterials adopted by the European Commission, but in some countries, such as in Belgium, reporting may be limited to engineered nanomaterials. The reporting threshold may be very low; in France, it is fixed at 100 grams per year of nanomaterials, and the draft Belgian law sets forth the same threshold.

III. Trends in Europe

Although the Commission is not convinced of the usefulness of a mandatory registry of nanomaterials at EU level, it is currently conducting a study that may result in additional information requirements for nanomaterials under REACH. Meanwhile, the number of safety assessment and/or labelling

[2] If they were placed on the market before 11 January 2013, the notification had to be made between 11 January 2013 and 11 July 2013.

requirements under specific product regulation is increasing. The following EU legislation currently sets forth nanotech-specific provisions:

- The WEEE-2 Directive (Directive 2012/19) invites the Commission to evaluate the risks of nanomaterials and to amend the rules regarding selective treatment of materials and components of waste electrical and electronic equipment accordingly;
- The Biocidal Product Regulation (Regulation 528/2012) imposes specific assessment and procedural and labelling requirements for nanomaterials;
- The Food Labelling Regulation (Regulation 1169/2011) imposes labelling requirements on nanomaterials' ingredients;
- The RoHS-2 Directive (Directive 2011/65) requires that nanomaterials be examined for possible restrictions as soon as scientific evidence is available;
- The Plastic Food Contact Material Regulation (Regulation 10/2011) imposes specific prohibitions and restrictions on food contact material containing substances in nanoform.

The European Parliament is also reviewing a proposed medical devices regulation that would require conformity assessment of devices that contain or consist of nanoparticles that can be released in the patient's or user's body (such devices would be classified as class III devices). Special care in design and manufacture and specific labelling would apply if a device contains or consists of nanoparticles that can be released to the human body.

In the absence of an EU-wide mandatory register, companies selling nanotech products may expect an increasing number of national registries. In addition, they should prepare for mandatory risk assessment and labelling.

How Hunton & Williams Can Help
Hunton & Williams' regulatory team has extensive experience with advising clients on complex regulatory programs and related risk management. In addition to cosmetics regulation, our practice covers chemical (REACH) and life sciences regulations. Our lawyers have counseled life sciences, cosmetic and chemical companies on both compliance and legislative policy. In addition, we assist with related contracts, investigations and enforcement. For further details on regulation of nanomaterials in general and REACH, see our website at www.reachpsforum.eu.

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