Beyond REACh: Nanomaterials in the European Union

Confusion Swirls around Definition and Registration

Companies manufacturing, importing or distributing nanomaterials into the territory of the European Union do not only have to comply with the Registration, Evaluation, Authorization and Restriction of Chemicals (REACh). Two sector-based regulations and three EU member states oblige them to register substances, mixtures and articles containing nanomaterials. In addition to uncertainty about the legal definition of nanomaterials, the European Union currently has no coherent framework for registration.

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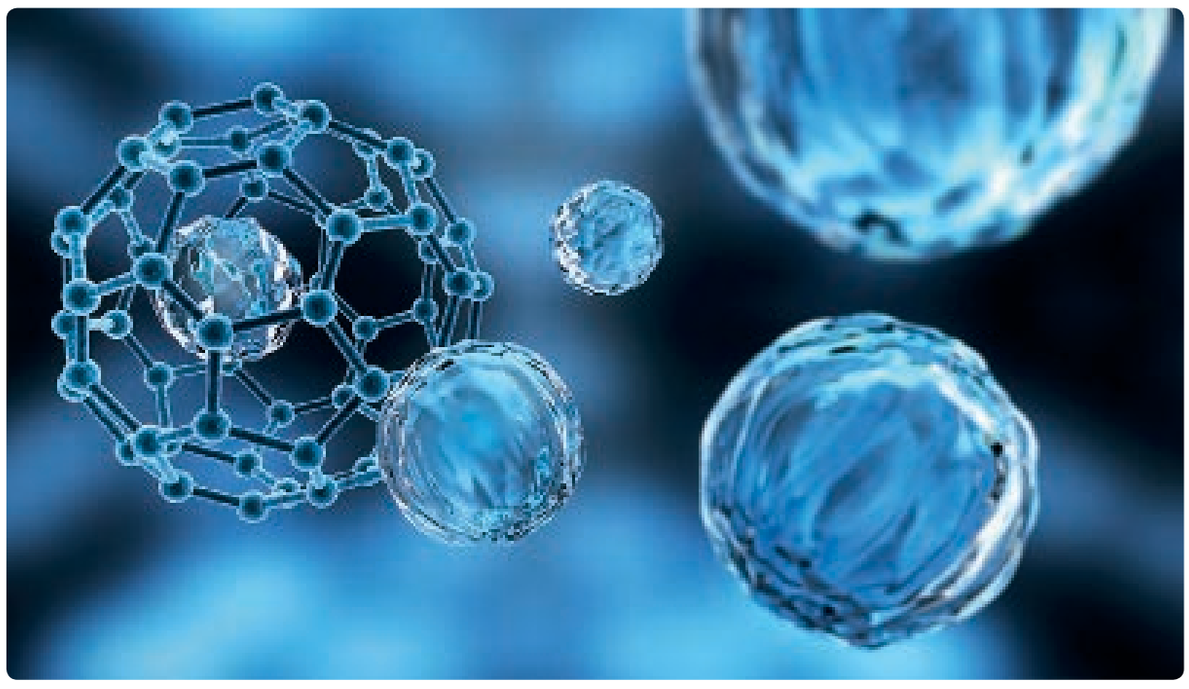

The International Standards Organization (ISO) defines nanomaterials as materials "with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale." The so-called nanoscale is generally sized between 1 and 100 nm, a nanometer being a billionth of a meter. Materials with at least one dimension sized at the nanoscale generally have different physical or chemical properties than their form at a higher scale.

Though some nanomaterials exist naturally, most of them are engineered to make use of these specific properties that, according to some scientists, could have potentially hazardous effects on human health or on the environment. For these reasons, several EU regulations, mainly relating to the food sector, but also on cosmetics and biocides, contain requirements about the inclusion of nanomaterials in consumer products.

As most of these regulations do not identically define nanomaterials, the European Commission proposed a single definition of the term "nanomaterial" with its recommendation on Oct. 18, 2011. This EU definition differs from the ISO as it does not merely use the nanoscale criterion to define nanomaterials. Though it provides some exceptions, this definition excludes from its scope materials with less than 50% of particles in the number size distribution having at least an external dimension in the nanoscale. This 50% threshold has been the source of disagreements between the commission and the European Parliament, as the latter would prefer to lower it to 10% to define nanomaterials in food-related regulations.

The European Parliament also has blocked attempts by the commission to harmonize the definitions in the pre-2011 regulations. The current debate about the new Novel Food Regulation shows that instead of having a legal framework based on a single definition of the term nanomaterial, the European Union has a legal patchwork that is further complicated by national initiatives imposing requirements on companies that go beyond those laid down in REACh.

Nanomaterials under REACh: Size Does Not Matter

Though it does not explicitly mention them, REACh applies to nanomaterials as its scope does not take the scale of materials into account. Leaving aside the issue with the tonnage threshold of REACh that excludes most of the nanomaterials from registration, some stakeholders consider that the registration requirements under REACh are simply insufficient to collect data on nanomaterials and that public authorities should act beyond REACh to get such information. As EU member states have failed to agree on amending REACh or adopting an EU-wide nanomaterials register, three member states have decided to legislate beyond REACh and have their own national register.

This undeniably entails legal certainty about REACh, as it provides that member states have no competence to further regulate substances already covered by the regulation itself. Even if the adoption of national registers would be admissible under REACh, it must nevertheless not infringe the EU Treaty rules on the free movement of goods within the EU internal market. Although member states may restrict the free movement of goods on grounds such as the protection of public health or the environment, any restriction must still be necessary, objective and proportionate to the aim pursued. In light of this, it is not surprising that the legal service of the commission expressed concerns about the legality of the three national regimes in its reasoned opinion issued before their respective entries into force.

Nanomaterials Registers in EU Member States

In 2013, France became the first member state to impose the registration of nanomaterials, mixtures or articles containing them. Denmark became the second state in 2014, and Belgium will follow as of Jan. 1, 2016. The French and Belgian registers apply when the quantity of nanomaterials placed on the market exceeds 100 g/y, while there is no threshold at all in Denmark. While the latter applies to the distribution of articles to consumers, the two others apply to the distribution to professional users only. The scope of the Danish restriction is wider as it also covers naturally occurring nanomaterials and not only engineered nanomaterials. The French experience shows that there was initially little awareness about the existence of a national register though the number of addressees is potentially huge. With the approaching signing of a cooperation agreement between France and Belgium, companies can expect to face substantial fines if they fail to register their nanomaterials in these two countries, especially in Belgium where the so-called registration must be made before the substance, mixture or article is placed on the market, while France and Denmark only impose a post yearly notification.

EU-Specific Registration Requirements for Nanomaterials in Cosmetics and Biocides

Besides those concerning the food sector, two other EU regulations contain provisions on nanomaterials, which require companies to provide additional data before their products can access the internal market. Pursuant to the Cosmetics Regulation, the Cosmetics Products Notification Portal (CPNP) now has a separate section for the notification of cosmetic products containing a nanomaterial. In cases where there are doubts about safety, the commission will request the Scientific Committee for Consumer Safety (SCCS) to issue an opinion. The Biocidal Products Regulation also contains provisions on nanomaterials. It notably indicates that, unless it explicitly mentions it, the approval of an active substance does not cover nanomaterials. As a result, the simplified authorization procedure is not available when the biocidal products contain nanomaterials.

Future Developments

With Sweden aiming at adopting its own national register by the end of 2015 and with the recent proposal of the US Environmental Protection Agency advocating the reporting of nanoscale materials, there is little doubt that the question of the harmonization of registration requirements will be on the agenda of the European Union over the next few years.

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