

GROWING ISSUES IN A MINIATURE WORLD: NANOMATERIALS REGISTERS IN THE EUROPEAN UNION

Many scientists believe that the highest growth potential for improved applications lies in nanomaterials. This technology is not without controversy and the law is only now trying to catch up with the technological progress.

Although the risks posed by nanomaterials are still scientifically uncertain and there is no European consensus on how to regulate them at the EU level, some Member States have unilaterally imposed regulations which apply to users and producers doing business in those countries. In particular, France, Denmark and Belgium have introduced registers of nanomaterials put on the market. The Belgian approach in particular imposes significant new obligations which require action before they become effective on 1 January 2016.

What Are Nanomaterials?

Nanomaterials are materials at the atomic, molecular and supramolecular level. The so-called nanoscale is typically defined as a scale between 1 nanometer (nm) (which is one billionth of a meter) and 100 nm. Nanomaterials are used in virtually every industry as the table below illustrates. Some occur naturally but most are produced to enhance the quality of a product or to develop new products. Nanomaterials can also be incidentally produced.

The following table shows the most common nanomaterials and their application.

Most Common Nanomaterials	Where Do We Find It?
carbon black	automotive tires, printer toners, dyes for leather or textiles
titanium dioxide	sunscreens, wall paints, food, toothpaste
zinc oxide	rubber, cement, coatings, paints, medical products, electronics
amorphous silica	adhesives, paints, food additives and dietary supplements
silver nanoparticles	electronic industry, medical products
aluminium oxide	abrasive materials, bone substitutes, melting pots, watch glasses
tungsten disulfide	lubricants
calcium carbonate	adhesives, coatings, paper, paints, plastics



How Are Nanomaterials Currently Regulated in the EU?

There is currently no uniform approach to nanomaterials at the EU level and no EU register. However, nanomaterials are, to a limited extent, covered by EU sector-specific regulation. For instance the Food Information Regulation, the Cosmetics Regulation, the Medical Devices Regulation and the Biocides Regulation contain specific provisions on nanomaterials. While moreover applying to substances in the nano form, the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) does not currently contain specific provisions on nanomaterials.

Why Are There National Nanomaterials Registers?

Due to a lack of consensus at the EU level to amend REACH or create an EU-wide nanomaterials register, three Member States have created their own national registers. France was the first country in the world to do so and its register came into force on 11 January 2013. Denmark also introduced a national register on 18 June 2014 and Belgium will have one by 1 January 2016. The stated objective of the notification requirements in these three EU Member States is to provide their public administrations with a better overview of the nanomaterials which are placed on the market either as such or in mixtures or products.

What is Required Under the National Nanomaterials Registers?

The table below sets out the key parameters of the three registration regimes. In contrast to the French and Danish regimes, the Belgian law applying from 1 January 2016 requires notification before importing or placing the nanomaterial on the market; there are substantial fines of up to €720,000 and even criminal sanctions for failures to notify. Moreover, all nanomaterials placed as such on the Belgian market before 1 January 2016 must be registered before that date. Unlike the Belgian register, the French and Danish regimes allow registration after placement on the market. Nevertheless their scope is broader and they already require the registration of products containing nanomaterials. The Danish register also covers natural and incidental nanomaterials.

National Nano Registers Factsheet			
Parameter	France	Denmark	Belgium
When must the nanomaterial be notified?	After it has been placed on the market	After it has been placed on the market	Before it is placed on the market/Before the entry into force of the regime if it has already been placed on the market
Scope by product	Substance at nanoscale level intentionally produced as such, as part of a mixture or in articles (release)	Mixtures and articles containing nanomaterials (natural, incidental or manufactured) intended for sale to consumers	Manufactured nanoparticle substance as such or as part of a mixture Mixtures (by 1 January 2017) Articles (not yet)
	Fullrenes, graphene flakes and single wall carbon nanotubes with an external dimension below 1 nm	Fullrenes, graphene flakes and single wall carbon nanotubes with an external dimension below 1 nm	Fullrenes, graphene flakes and single wall carbon nanotubes with an external dimension below 1 nm
Production	YES	YES if for B2C	YES
Importation	YES	YES if for B2C	YES
B2B distribution	YES	NO	YES
B2C distribution	NO	NO	NO
Notification threshold	100 grams/year	No threshold	100 grams/year
Penalties	Fine up to €3,000 Daily penalty of €300	Fines (undetermined)	8 days – 1 year jail €312 – 720,000

What Does This Mean in Practice?

The following examples illustrate how the national registers can affect companies active in the EU, and the difficulty caused by their inconsistent application.

Example 1 Company A produces nanomaterials in the United States. Company B is based in Belgium and purchases nanomaterials (>100g) from Company A and uses them in the production of a final product which is then sold across the EU, including to French Company C and Danish Company D. Company B must register the nanomaterials in Belgium as an importer. This applies also if Company B is a subsidiary of Company A. The French Company C must register the nanomaterials in France as a distributor. The Danish Company D must register the final product as an importer only if it is a consumer product.

Example 2 Company D produces nanomaterials and uses them in its own products in the United States and sells the final products to the EU, including to France, Belgium and Denmark. The Belgian importer must currently not register the nanomaterials as they are included in articles. The French importer must register the nanomaterials and the Danish importer must register the nanomaterials only if the products are intended for use by consumers.

Example 3 Company M manufactures in Japan articles for consumer use that naturally include nanomaterials. These articles need not be registered if they are imported to Belgium or France, while they must be registered if they are imported into Denmark because the Danish registration requirements also apply to natural nanomaterials.

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