

Created in 2001 at the initiative of 15 major European MasterBatch and Compounds producers, the European Masterbatchers and Compounders (EuMBC) is a sector group of the European Plastics Converters, and is particularly active in all the fields related to the plastic industry (REACH, Food Contact, New Technologies).

EuMBC compounders and masterbatchers provide effective solutions to the plastic converters in a safe way. Enhancing the properties of the original raw materials and providing a wide range of colours and solutions, EuMBC members are present in all the market (Packaging, Building & Construction, Food Packaging, Health Care, Automotive, Electrical & Electronic, to name but a few).

In 1959, Richard Feynman presented the concept of what later became known as nanotechnology in a speech titled "[Plenty of Room at the Bottom](#)", since then many kinds of nanotechnology and nanomaterials have been developed. It has been estimated that new nanotechnology consumer products are coming on the market at the rate of 3 – 4 per week¹. Each leading to different advances and adding some form of value to human society.

Such new nanotechnology often uses Engineered Nanomaterials (e.g. Carbon Nanotubes, Quantum Dots), which is intentionally manufactured for unique properties that are due to their dimension. However, it should be noted that many material that has been used for decades – if not centuries – has only recently "become" nanomaterial due to the introduction of nanomaterials definitions (e.g. Carbon Black, Pigments²). Such historic Nanomaterial therefore has a long history of safe use and regulatory action resulting from concerns related to Engineered Nanomaterial, often affect such historic nanomaterial as well.

Increased use of Engineered Nanomaterial has led to the increased human exposure and environmental prevalence of Engineered Nanomaterials, prompting concerns about potential toxicity of these materials¹. Such concerns have led to calls for greater traceability of Nanomaterial within value chains.

Currently there is no European Union Nanomaterial Product Registry. In the absence of such an EU Nanomaterial Product registry several Member States have developed National Nanomaterial Product Registries.

EuMBC would like to stress that although there are some concerns regarding the safety of nanomaterial, it is questionable if the regulatory measures that have been taken in the form of these National Nanomaterial Product Registries are addressing these concerns and are in any case not proportional to the level of concern.

¹ Ray, Yu, and Fu (2010) - [Toxicity and Environmental Risks of Nanomaterials: Challenges and Future Needs](#)

² Pigment Colourants have for several centuries been ground to as fine a dust as possible to maximise the colouring effect. Thus there is a considerable history of use and only later were these pigments classified as nanomaterial.

Currently Nanomaterial Product Registries are only used to generate statistics on the use of nanomaterial. Currently these registries are not used for any other purpose (e.g. risk assessment). The value to Member States can thus be understood as relatively low.

Furthermore, whenever substances are incorporated in a polymer matrix, as is the case in masterbatches and compounds that EuMBC members put on the market, any potential hazard related to nanomaterial is either removed or substantially reduced. The OECD in its [Emission Scenario Document for Plastics Additives](#) states that colourants, a historic nanomaterial, releases 0.01% during its service life. A recent critical review of the migration potential of nanoparticles in food contact plastics confirms that nanomaterial embedded in a polymer matrix will not lead to consumer exposure³.

Moreover, the particle size distribution of the plastics masterbatches and compounds is not fulfilling the definition of nanomaterial. For these reasons the EuMBC believes that the burden placed on masterbatchers and compounders is especially disproportionate.

Increasing regulatory requirements result in an increasing burden for European Industry and can harm competitiveness and job growth. Therefore it is vital to compare the costs of to be introduced regulatory requirements in terms of competitiveness and job growth with the expected gain in benefits for human health and/or environment.

It should also be remembered that in the field of Engineered Nanomaterial there is also a considerable potential for innovation that can immensely benefit society. In Richard Feynman's speech the audience is encouraged to imagine the possibilities of the extremely small scale, now in 2017 we see situations were different regulatory environments result in different rates of adoption of nanomaterials which were wild fantasy in 1959⁴. Increasing regulatory requirements for nanomaterial may stifle innovation and harm the progress of society towards a more prosperous and advanced future.

Therefore, EuMBC recommends the following measures to the Members States that currently have developed national nanomaterial product registries or are considering to do so in the future: harmonise the definition of nanomaterial that is used in the different legislations (see annex I for the list of current definitions) and to develop one harmonised (electronic) data submission format.

Furthermore, in general EuMBC recommends that an exemption from reporting and registration should be provided for nanomaterial in a polymer matrix, as it has been demonstrated that there is no risk to human health and environment.

³ [A. Störmer, J. Bott, D. Kemmer, R. Franz \(2017\) - Critical review of the migration potential of nanoparticles in food contact plastics](#)

⁴ See the example of nanoclay in food contact material plastics on page 41 of [A. Störmer, J. Bott, D. Kemmer, R. Franz \(2017\) - Critical review of the migration potential of nanoparticles in food contact plastics](#)

Annex I Difference in Definition

Definitions

European, Norwegian and Danish Nanomaterial Product Registries

The Commission Recommendation provides a definition of nanomaterial that has been adopted in the Norwegian and Danish National Product Registries.

2. *'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.*
3. *By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.*
4. *For the purposes of point 2, 'particle', 'agglomerate' and 'aggregate' are defined as follows:*
 - (a) *'particle' means a minute piece of matter with defined physical boundaries;*
 - (b) *'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;*
 - (c) *'aggregate' means a particle comprising of strongly bound or fused particles.*
5. *Where technically feasible and requested in specific legislation, compliance with the definition in point 2 may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition in point 2 where the specific surface area by volume of the material is greater than 60 m²/cm³. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition in point 2 even if the material has a specific surface area lower than 60 m²/cm³.*

French Nanomaterial Product Registry

The French Decree no. 2012-232 of 17 February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment code concerns "Substances at nanoscale":

"Substance at nanoscale": substance as defined in article 3 of EC regulation no. 1907/2006, intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for a minimum proportion of particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm. "In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, this minimum

proportion may be reduced. This minimum proportion is specified in a joint order issued by the Ministers of environment, agriculture, health, labour and industry. By derogation from this definition, fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as substances at nanoscale.

For the purposes of this definition, the terms "particle", "agglomerate" and "aggregate" are defined as follows:

- a) "Particle" means a minute piece of matter with defined physical boundaries,
- b) "Aggregate" means a particle comprising of strongly bound or fused particles,
- c) "Agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

Belgian Nanomaterial Product Registry

The Belgian royal decree of 27 May 2014 Concerning the placing on the market of substances in nanoparticulate state technically does not concern nanomaterial but "Substances produced in nanoparticulate state":

substance produced in nanoparticulate state: a substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range of one nanometer to one hundred nanometers, with the exception of natural, non-chemically modified substances and the substances of which the fraction between one nanometer and one hundred nanometers is a by-product of human activity. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below one nanometre shall be deemed to be substances produced in nanoparticulate state.

Swiss Nanomaterial Product Registry

[Swiss Federal Office of Public Health and Federal Office for the Environment](#) utilizes two different approaches, the first one is the EU proposed definition and the second: "Specifically manufactured materials are considered as nano-relevant which comprise particles in the unbound state, as an aggregate or agglomerate and in which one or more external dimensions are between 1 and 500 nm. Respirable materials up to 10 µm with nanoscale side branches can likewise trigger nanospecific effects and are likewise considered to be nano-relevant."

Conclusion

There are already four (slightly) different definitions of nanomaterial, each technically requiring separate consideration by a company's regulatory department.