

## Nanotechnology regulation on food packaging within the European Union

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Over the last several years, definition and regulation of engineered nanomaterials has emerged as an area of lively debate. This has been prompted in large part by a growing interest in the use of nanomaterials, which spans a multitude of commercial applications, including those in the food packaging arena. Regulation (EC) No. 1935/2004 is a framework regulation that covers all materials and articles intended to come into contact with food. In addition, specific regulations for materials such as active and intelligent materials, ceramics, plastics, coatings, adhesives, rubbers and printing inks exist either on the European Union or the member states level. So far only two of these regulations explicitly refer to nanomaterials in the legal text (Regulation (EC) No 450/2009 on Active and Intelligent Materials and Articles intended to come into Contact with Food, Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into Contact with Food). However, no definition for nanomaterials is given in both regulations. In 2011 however, a recommendation on the definition of a nanomaterial was published by the European Commission to promote consistency in the interpretation of the term "nanomaterial" for legislative and policy purposes in the European Union. This recommendation defines a nanomaterial as a material containing particles, in an unbound state or as an aggregate or 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 1 to 100 nm. The definition is based on an approach that considers only the size of the constituent particles of a material, because size is the only universally applicable, clear and measurable criterion which can be used to identify materials which due to their particle size may exhibit specific properties or risks. The definition is not legally binding but serves as a reference that is broadly applicable across different regulatory sectors and can be adapted to specific product legislation. According to the Regulation (EU) No 10/2011, a substance in nanoform shall only be used in food packaging systems if the nanoform is explicitly authorised and mentioned in the specifications of Annex I of the regulation. An important issue to consider is that nanomaterials in food packaging systems are exempted from the functional barrier concept. The functional barrier consists of one or more layers within food contact materials preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided they fulfil certain criteria. Nanomaterials intended to be used in food packaging systems require a case-by-case risk assessment and can only be used in food contact material if explicitly authorised.

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