Legal aspects of nanotechnology

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The essence of EU legal regulations regarding nanotechnology, according to the opinion expressed in *the European Commission Communication on Regulatory Aspects of Nanomaterials (COM 366 of 17.06.2008)*, should be to allow the society to use innovative applications of nanotechnology together with respect for security, health care and environmental protection. The EU laws which relate to nanomaterials have been included in legal acts referring to products, chemicals, worker protection and environmental protection. Within the EU legislation, detailed nanotechnology standards exist with regard to cosmetics, food, and biocides. As far as other products, chemicals, worker protection and environmental protection are concerned, the use of nanomaterials is regulated by general provisions referring to their macro- equivalents.

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Implementation of the EU law in terms of nanotechnology is based on the precautionary principle. According to *the European Commission Communication on the Precautionary Principle (COM 1 of 02.02.2000)*, it means the use of legally binding measures along with non-legally binding measures – harmonized, non-discriminatory, based on cost-benefit analysis of undertaking or desisting actions, having taken into consideration the current state of scientific knowledge. The basic legal acts of the European Union of a non-legally binding character with regard to nanotechnology are those recommendations which refer to the principles of fair scientific research in this field and to the standardized definition of nanomaterials.

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The European Commission Recommendation 2008/345/WE on the code of conduct for responsible nanosciences and nanotechnology research (Official Journal L 116 of 30.04.2008) is a compilation of guidelines which serve creating safe, ethical and effective conditions for nanotechnology research. According to points 4.1.11 and 4.11.12, the priorities for nanotechnology research should be: to determine a standardized terminology in order to improve conveying scientific data, to use standardized measurement methods and proper reference materials for the improvement of scientific data comparability and to develop means of assessing risks concerning nanomaterials.

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The significance of clear and comprehensive legal regulations regarding nanotechnology and the need for knowing these regulations has been stressed in point 4.2.7: *"N&N research funding bodies should launch and coordinate specific research activities in order to gain a better understanding of ethical, legal and societal impacts of the new fields opened by N&N"* and in point 4.3.2: *"(…) N&N research funding bodies should make sure that N&N researchers are aware of all relevant legislation, as well as ethical and social frameworks"*.

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The European Commission Recommendation 2011/696/UE on the definition of nanomaterial (Official Journal L 275 of 20.10.2011) decides to adopt (as the basic nanomaterial defining criterion) the number size distribution, that is the quotient of object number within a given size range and the total number of objects. In certain specific cases, in order to facilitate definition, it is acceptable to apply specific surface area by volume. According to the European Commission Recommendation, the number size distribution has been adopted as a decisive criterion for defining nanomaterials due to the fact that nanomaterials usually contain many particles which exist in different sizes in a given distribution.

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According to point 2 of the 2011/696/UE Recommendation: *„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 %”.*

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Point 5 of the 2011/696/UE Recommendation proclaims that *"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 60m^2/cm^3. 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 60m^2/cm^3"*.

Current changes in legal regulations concerning nanotechnology refer to *cosmetics, biocides and food*.

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Using *cosmetics* in the EU market is regulated by *Regulation No 1223/2009 of the European Parliament and the Council on cosmetic products (Official Journal L 342 of 22.12.2009)* which from *11.07.2013* substituted the Council Directive No 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (Official Journal L 262 of 27.09.1976). In accordance with the 1223/2009 regulation:

- article 2 paragraph 1 point k provides the definition of nanomaterials: "nanomaterial" means 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;

- article 13 paragraph 1 point f states that prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, information to the Commission which includes the presence of substances in the form of nanomaterials and their identification including the chemical name and furthermore, the reasonably foreseeable exposure conditions;

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- article 16 settles that the information notified to the Commission as to a cosmetic product made with the use of nanomaterials shall contain at least the following: the identification of the nanomaterial including its chemical name, the specification of the nanomaterial including size of particles, physical and chemical properties, an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year, the toxicological profile of the nanomaterial, the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products, and the reasonably foreseeable exposure conditions;

- under article 19 paragraph 1, only those cosmetic products shall be available on the market on whose containers and packaging every ingredient used in the form of nanomaterials is clearly mentioned on the ingredient list – after the name of the ingredient the word “nano” is provided in brackets.

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Biocides are regulated under *Regulation No 528/2012 of the European Parliament and the Council concerning the making available on the market and use of biocidal products (Official Journal L 167 of 27.06.2012)* which from *01.09.2013* substituted Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (Official Journal L 123 of 24.04.1998). Regulation No 528/2012 refers to allowing and introducing biocides on the market in the member states, making authorization for biocidal products, mutual recognition of those authorizations in the EU, creating a Community-level list of active substances which may be used in biocides and placing products treated with biocides on the market.

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In accordance with Regulation No 528/2012:

- article 3 paragraph 1 point z provides the definition of nanomaterials compliant with the European Commission Recommendation No 2011/696/UE on the definition of nanomaterial; under article 3 paragraph 3, the European Commission may, at the request of a Member State, decide whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU on the definition of nanomaterial;

- under article 4 paragraph 4, the approval of an active substance shall not cover that substance in the form of nanomaterial, except where explicitly mentioned (active substance is a substance or a microorganism which have affect harmful organisms or act against them);

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- under article 19 paragraph 1 point f, when applying for an authorization for a product where nanomaterials are used, the risk to human health, animal health and the environment shall be assessed separately;

- under article 69 paragraph 2 point b, biocidal product labels must include information about the nanomaterials contained in the product, if any, and any specific related risks and, following each reference to nanomaterials, the word "nano" in brackets; moreover, under article 58 paragaph 3 point d, labels of treated articles must provide information on the name of all nanomaterials contained in the biocidal products, followed by the word "nano" in brackets.

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The issues related to *food* trade are regulated by a number of legal acts. *Regulation No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients (Official Journal L 43 of 14.02.1997),* under article 1 paragraph 2 applies to the placing on the market of food and food ingredients which have not hitherto been used for human consumption to a significant degree and which fall under the categories of food and food ingredients with a new or intentionally modified primary molecular structure, food and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the food or food ingredients which affect their nutritional value, metabolism or level of undesirable substances. This regulation applies to food containing nanomaterials and which are subject to the assessment procedure in order to indicate the food's safety for human health and the natural environment.

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Article 12 of *Regulation No 1333/2008 of the European Parliament and of the Council on food additives (Official Journal L 354 of 31.12.2008)* states that when a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.

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Article 5 paragraph 2 point c of *the Commission Regulation No 450/2009 on active and intelligent materials and articles intended to come into contact with food (Official Journal L 135 of 30.05.2009)*, states that substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale (applies to nanomaterials), may not be the active or intelligent component of a material or product without being placed on the Community list of authorized substances. According to article 9 paragraph 2 of *the Commission Regulation No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal L 12 of 15.01.2011)* substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in the list of authorized substances.

Article 2 paragraph 2 point t of *Regulation No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (Official Journal L 304 of 22.11.2011)*. defines “engineered nanomaterial” as “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include: those related to the large specific surface area of the materials considered or specific physico-chemical properties that are different from those of the non-nanoform of the same material.” According to Article 18 paragraph 3 of Regulation No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets (mandatory from *13.12.2014*).

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Other consumer products which contain nanomaterials and to which the specific provisions of the EU do not apply, are regulated by *Directive 2001/95/EC of the European Parliament and of the Council on general product safety (Official Journal L 11 of 15.01.2002)*. The Directive 2001/95/EC includes requirements as to the protection against any potential danger from products, conditions for their safety assessment and the duties of entities placing products on the market. There are no regulations in the directive 2001/95 which refer directly to products containing nanomaterials, although the directive applies to those products also.

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Conclusions

The multitude and diversity of legal regulations which refer to nanotechnology is a result of using innovative applications of nanomaterials in numerous fields. Intensive progress in nanotechnology and its multifaceted essence indicate the need for creating consistent legal standards. Furthermore, *legal regulations in nanotechnology ought to be harmoniously fused in order to support fair competition and market transparency in this field on an international level.*

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Nanomaterials, being useful in many areas of technology, may be characterized by their specific properties due to the small size of their particles. Therefore, there is a potential risk to the health and the environment because of innovative applications of nanomaterials. *Further scientific research with regard to risk assessment are necessary to improve the legal regulations in terms of nanotechnology. It applies especially to:* physico-chemical characteristics of nanomaterials, their systematization, terminology, measurement methods and reference materials for metrology, data on toxic and ecotoxic properties – effect of nanomaterials on health and environment, as well as methods of testing for obtaining this information, assessment of exposure to the effects in the whole life cycle of the nanomaterials. *In the specific provisions which apply to nanomaterials, their definition ought to be adapted to the Commission Recommendation 2011/696/EU on the definition of nanomaterial. That definition adopts the number size distribution as the basic discriminant of nanomaterials.* Moreover, risk management, its monitoring and reduction to protect the health of people who have contact with nanomaterials, require further research work.

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The obligation to submit comprehensive data by entities that place nanomaterials on the market in the procedures of assessment, creating entries on the Community list of authorized substances, and granting authorizations enable the authorities to verify the properties of nanomaterials and to limit the gaps in scientific knowledge gradually. At the same time it increases nanomaterial use safety. Furthermore, *possessing this detailed data, by reducing the risks of using nanomaterials, facilitates the commercial use of nanomaterials for entities that place them on the market. The obligation to include nanoform ingredients on the ingredient lists on product containers or packaging and the word "nano" provided after the name of the ingredient in brackets serves the purpose of strengthening the position of consumers on the market by giving them the opportunity to make a conscious and deliberate decision on purchasing a product.*