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Definition of the term "nanomaterial"

Summary

In order to regulate nanomaterials and to determine mandatory product labelling a generally accepted agreement what the term "nanomaterial" means has to be reached beforehand. The EU Parliament requires that a definition shall be science-based and comprehensive. Furthermore, for regulatory measures in individual sectors, it shall be unambiguous, flexible, easy and practical to handle. During the past few years various institutions came up with suggestions for a definition, leading to a recommendation of the EU commission, which finally is being accepted into new and existing EU legislation. Some provisions in this proposal are controversial and the implementation into specific sectoral legislation constitutes a major challenge.

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Introduction

New and modified characteristics render nanomaterials interesting for the development of products and applications. In recent years various products worldwide have been brought onto the market, which have been promoted with the keyword "nano" or with which a reference to nanotechnology is made[1]. A "nanoproduct" can have many meanings – whether pores in nano size, nanometre thin coatings or addition of nano-particles. In most cases neither consumers nor regulatory authorities have exact knowledge of the composition of the product, thus, in many cases it is not clear whether the product contains nanomaterials and if so, in which form and concentration. Concerning the assessment of a possible environmental or health risk of nanomaterials such knowledge is essential. This information is equally important for an informed consumer choice. Thus, environmental and consumer protection organisations as well as the EU Parliament require a particular regulation of nanomaterials in accordance with the precautionary principle as well as a mandatory product labelling[2]. However, in order to take such measures it is important to reach a generally accepted agreement what the term "nanomaterials" means. In various industry and research sectors this term – and many others related to nanotechnology – is defined completely different, which leads to confusion and misunderstanding. According to the EU Parliament a general definition shall be science-based and comprehensive. Furthermore, concerning regulatory measures in individual sectors, it shall be unambiguous, flexible, easy and practical to handle.

Proposals of various institutions

Internationally, various institutions came up with proposals for such a definition in recent years[3]. The **International Organisation for Standardization (ISO)** in cooperation with the European Committee for Standardization (CEN) has worked on definitions of various terms related to nanotechnology. The ISO defines the relevant terms as follows[4]:

Nanoscale (or nano range): *Size range from approximately 1 nm to 100 nm.*

Nano-object: *Material confined in one, two, or three dimensions at the nanoscale. This includes nanoparticles (all three dimensions in the nanoscale), nanofibres (two dimensions in the nanoscale) and nanoplates (one dimension in the nanoscale). Nanofibres are further divided into nanotubes (hollow nanofibre), nanorods (solid nanofibre) and nanowire (electrically conducting or semiconducting nanofibre).* However, the term nano-object could not prevail.

Particle: *A minute piece of matter with defined physical boundaries. A particle can move as a unit. This general particle definition applies to nano-objects.*

Nanoparticle: *Nano-object with all three external dimensions in the nanoscale.*

Nanomaterial: *Material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.*

Nanostructured material: *Material with an internal or surface structure in the nanoscale.*

The Organisation for Economic Co-operation and Development (OECD) has adopted the ISO-definitions as working definitions.

Scientific Committees of the European Commission as well have dealt with definitional issues. The **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)**[5] defines:

Nanomaterial: Any form of a material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less.

The **Scientific Committee on Consumer Products (SCCP)** in its opinion on security aspects of nanomaterials in cosmetics, on the basis of preliminary work of the British Standards Institution (BSI) defines:[6]

Nanomaterial: Material with one or more external dimensions, or an internal structure, at nanoscale and which could exhibit novel characteristics compared to the same material at a larger scale.

Definitions in legal provisions of the EU

Some legal provisions of the EU already make reference to nanomaterials and define the term sector specific in different ways[7].

The **EU-Cosmetics Regulation**[8] provides specific safety assessments and notification obligations for nanomaterials. Labelling requirements for cosmetic products, which contain nanomaterials according to the definition shall apply from July 2013. Thus, nanomaterials are defined as follows:

Nanomaterial: An insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

In order to inform consumers about the presence of engineered nanomaterials, the **EU legislation on food labelling**[9] provides labelling requirements for nanomaterials, defined as follows:

Engineered nanomaterial: Any intentionally produced material that has one or more dimensions of the order of 100 nm or 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 to the nanoscale.

The Regulation concerning the making available on the market and use of biocidal products (**Biocides Regulation**)[10] covers comprehensive nano specific rules. Nanomaterials should undergo an individual safety assessment and products, containing nanomaterials shall not be marketed through a simplified approval procedure. The Regulation also contains labelling requirements. In this Regulation the term nanomaterial is defined as follows:

Nanomaterial: A natural or manufactured substance or non-active substance containing particles in an unbound state or as aggregate or as an agglomerate and where, for 50 % or more of the particles in the number of size distribution, one or more external dimensions is in the size range 1 nm-100 nm. Fullerenes, graphene flakes and single wall nanotubes with one or more external dimensions below 1 nm are to be regarded as nanomaterials.

In addition thereto the Biocides Regulation contains definitions of the terms agglomerate and aggregate. The definition of the term nanomaterial in this regulation essentially corresponds in substance (number size, threshold, size range and particular substances) to the recommendation of the EU.

The recommendation of the EU Commission on the definition of nanomaterials

In October 2011 the EU Commission has presented a recommendation regarding the definition of nanomaterials[11] and thus responding to the EU Parliament for the implementation of a comprehensive and science-based definition of the term nanomaterial within the EU legislation. The definition is based upon the preliminary work of the International Organisation for Standardization (ISO) (see above), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Joint Research Centre (JRC).

The opinion of SCENIHR[12]

With the expected increase in the applications of nanotechnology, there is an urgent need to identify what can be considered as a nanomaterial by clear unequivocal descriptions. This need to identify a nanomaterial comes from the uncertainty regarding safety evaluation and the risk assessment of nanomaterials. SCENIHR stresses that the term nanomaterial is merely a categorization of a material due to its size and it neither implies a specific risk, nor does it necessarily mean that this material actually has new hazard properties.

Whereas **physical or chemical properties** of materials may change with size, there is no scientific justification for a single upper and lower size limit associated with these changes. Properties like form, solubility, surface charge, reactivity are important for a risk assessment, however, cannot be taken into a definition as they can differ from nanomaterial to nanomaterial in dependency of chemical composition, a possible surface modification and the environment.

Size is one characteristic, which according to SCENIHR all nanomaterials have in common and thus being the most suitable measured value for a definition. The upper limit in general is 100 nm although there is no reason for this upper limit from a scientific point of view. Perhaps a single upper limit for the classification of nanomaterials might be a too strong limitation and a more differentiated approach would be more suitable. As lower limit 1 nm is suggested, however, in this field a differentiation between molecules, nanocluster and nanoparicles is unclear. In general, molecules should be excluded in a definition. Exceptions such as certain carbon nanotubes are possible.

Nanomaterials with uniform particle size can be produced; however, most of them contain parts in various sizes, thus having a size distribution. A small amount of nanoparticles in a material can contain a large amount of particles. Thus it is not advisable to use the mass concentration (i.e. the mass of a substance based on the volume of a mixture of substances or a solution) for size distribution. The number concentration (i.e. the number of object in a certain size range divided by the total amount of objects) seems more suitable. When defining, account must be taken of this **number size distribution**. If only one part of the material lies within the defined size range, a definition has to include clear information to decide on the threshold from which a material is considered as nanomaterial. This can be reached by a specification of a percentage of the size distribution below a certain size limit value. SCENIHR comes up with the following example: A material might be defined as being a nanomaterial when more than 0.15 % has a diameter below 100 nm. It is essential that the appropriate statistical measure of both average size and size distribution is presented (log-normal distribution[19]).

Presently, there are only a few methods available to measure the size and the results may differ significantly. Some methods (e.g. trans-

mission electron microscopy, atomic force microscopy) measure the size of a particle without a possible organic coating of the particle whereas other methods (e.g. dynamic light scattering) include the coating in this size measurement. The proper measuring method depends on whether nanoparticles are present in form of a powder, distributed in a liquid, coated or integrated in solid material. For a detailed determination of size and size distribution two complementary methods should be used; in order to compare results, validated standard measures would be necessary (see below).

The report of the JRC[13]

Definitions shall help to avoid misunderstandings und to make efficient communication possible. A definition for regulatory purposes shall be clear and simple as possible, and unequivocal and comprehensive at the same time, as the JRC states in its report.

The report suggests that a definition for regulatory purposes should:

- only concern particulate nanomaterials;
- be broadly applicable in EU legislation and in line with other approaches worldwide;
- use size as the only defining property.

Concerning the size range, the JRC suggests that the upper limit shall be high enough in order to capture all types of materials, which, due to their nanoscale size, need particular attention for regulation. If 100 nm are determined as upper limit, additional information might become necessary in order to capture structures as aggregates or agglomerates larger than 100 nm. However, the implementation of a size dimension with fixed limits has enormous advantages for regulatory purposes. From a pragmatic point of view a lower limit of 1 nm and an upper limit of 100 nm seem to be reasonable. The JRC as well as the SCENIHR deem necessary to consider the number size distribution if the definition of the term nanomaterial shall be based on the size of particles. The JRC constitutes that there is no direct, material-independent relationship between size and novel effects or functions. Therefore, no general size limit can be given below which true nanoscale properties are observed. The only characteristic all nanomaterials have in common is their size in the nanoscale. Special physical-chemical characteristics can only be relevant for a certain regulation thus it must be possible to adapt a general definition to the needs of a specific implementation.

The text of the EU definition and explanations

The definition in the recommendation of the EU Commission should be taken as a reference for clarifying whether a material is considered as a "nanomaterial" for legislative or political purposes within the EU. The definition of the term "nanomaterial" in EU legislation shall be based solely on the size of particles from which the material is made of, irrespectively the threats or risks related to a material. This definition, solely based on the size of a material, covers natural nanoobjects such as from combustion processes as well as (artificially) manufactured materials (Para. 4).

1. *Member States, the Union agencies and economic operators are invited to use the following definition of the term "nanomaterial" in the adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies.*
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 m^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 60 m^2/cm^3.*
6. *By December 2014, the definition set out in points 1 to 5 will be reviewed in the light of experience and of scientific and technological developments. The review should particularly focus on whether the number size distribution threshold of 50 % should be increased or decreased.*
7. *This Recommendation is addressed to the Member States, Union agencies and economic operators.*

Size range from 1 to 100 nm

By reference to the opinion of SCENIHR (see above) the EU Commission explains that size is universally applicable to nanomaterials and the most suitable measurand, however, there is no scientific evidence that the upper limit value is appropriate. The use of a single upper limit value might be too limiting for the classification of nanomaterials and a differentiated approach might be more appropriate (Para. 8). Contrary to the ISO definition (see above) the recommendation of the EU Commission abandons the addition "approximately" when referring to the size range, as for legislation precise data are necessary. Moreover, the Commission definition is limited to materials consisting of particles. Excluded are nanostructured materials with an internal or surface structure in the range between 1 nm and 100 nm, such as computer chips[22].

With the determination of a size range as sole defining characteristic of nanomaterials, the proposal of the EU commission differs from definitions in other non-EU countries as for example Canada[14] or Australia[15], where special regulatory fields take consideration of nano-specific size dependent properties in addition to a determination of a size range.

Based on early evidence showing that some particles up to several hundred nanometers share many of the novel properties of nanomaterials under 100 nm, NGOs from areas such as environment, health and consumer protection favour a larger size range from 0.3 to 300 nm to define nanomaterials. This larger size range would allow more research and a better understanding of all nanoma-

terials, and whether particular nanomaterials may present concerns for human health or not and in what size range[16].

Number size distribution

Paragraph 10 of the recommendation states, that the number size distribution should cover for the fact that nanomaterials most typically consist of many particles present in different sizes in a particular distribution. Without specifying the number size distribution, it would be difficult to determine if a specific material complies with the definition where some particles are below 100 nm while others are not. The size distribution of a material should be presented as size distribution based on the number concentration and not on the mass fraction of nanoscale particles as a small mass fraction may contain the larger number of particles (Para. 8).

The threshold of 50 %

In its scientific report SCENIHR uses a threshold value of 0.15 % thus this value is based solely on a mathematical respectively scientific approach (see above). Given the widespread occurrence of materials that would be covered by such a threshold and the need to tailor the scope of the definition for use in a regulatory context, the threshold, according to the European Commission, should be higher (Para. 11). The previous suggestion of the Commission, presented already in October 2010, provided a threshold of 1 %. The public consultation[17] covers 195 statements thus a majority, in particular from the industry, pointed out that such a low threshold would lead to the fact that many materials would be considered as nanomaterials. The EU Commission took account of these objections.

A nanomaterial as defined in this recommendation should consist for 50 % or more of particles having a size between 1 nm-100 nm. Nevertheless there may be specific legislative cases where concerns for the environment, health, safety or competitiveness warrant the application of a threshold below 50 % (Para. 11).

When the particle size distribution does not deviate strongly from a normal[18] or log-normal[19] distribution, the median (50 %) can be determined relatively easily. However, when a threshold below 50 % is determined, as indicated for special cases in the EU recommendation, further details on the particle size distribution are required to determine whether a material is a nanomaterial or not. The extent to which this is feasible depends on the availability of analysis methods[20].

Various definitions of the term "nanomaterial"

ISO/CEN (2008, 2011): *Material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.*

SCENIHR (2007): *Any form of a material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nm or less.*

SCCP (2007): *Material with one or more external dimensions, or an internal structure, at nanoscale and which could exhibit novel characteristics compared to the same material at a larger scale.*

U Cosmetics Regulation (2009): *An insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.*

EU Regulation on food-labelling (2011): *Any intentionally produced material that has one or more dimensions of the order of 100 nm or 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 to the nanoscale.*

EU Biocides Regulation (2012): *A natural or manufactured substance or non-active substance containing particles in an unbound state or as aggregate or as an agglomerate and where, for 50 % or more of the particles in the number of size distribution, one or more external dimensions is in the size range 1 nm-100 nm. Fullerenes, graphene flakes and single wall nanutubes with one or more external dimensions below 1 nm are to be regarded as nanomaterials.*

Recommendation of the EU Commission (2012): *"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 %.*

Agglomerate and Aggregate

Paragraph 12 of the recommendation explains, that agglomerated or aggregated particles may exhibit the same properties as the unbound particles. Moreover, there can be cases during the life-cycle of nanomaterial where the particles are released from the agglomerates or aggregates. Thus, the definition includes particles of which aggregates and agglomerates are composed. The number size distribution and the threshold refer only to constituent particles and not to aggregates or agglomerates themselves.

Specific surface/volume ratio

The smaller the particle the larger is its surface in relation to its volume. As explained in paragraph 13 of the recommendation of the EU commission, it is possible to measure the specific surface area by volume for dry solid materials or powders with the nitrogen adsorption method ("BET-method"). In those cases the specific surface area can be used as a proxy to identify a potential nanomaterial. New scientific knowledge may expand the possibility to use this and other methods to other types of materials in the future. There can be a discrepancy between the measurement of the specific surface area and the number size distribution from one material to another. Therefore it should be specified that results for number size distribution should prevail and it should not be possible to use the specific surface area to demonstrate that a material is not a nanomaterial.

Measurement techniques

As stated in paragraph 6 of the recommendation, measuring size and size distributions in nanomaterials is challenging in many cases and different measurement methods may not provide comparable results. Harmonised measurement methods must be developed with a view to ensuring that the application of the definition leads to consistent results across materials and over time. Until harmonised measurement methods are available, best available alternative methods

should be applied. In order to facilitate the application of the definition in a specific legislative context the EU commission suggests to develop guidance and standardised measurement methods, where feasible and with reliable results. Knowledge of typical concentrations of nanoparticles in representative materials should be gained. The JRC analyses in its report[21] from 2012 the requirements on measurements for implementing the EU recommendation and concludes that at present no available methods are suitable in order to determine for all nanomaterials their correspondence with the definition.

Origin of nanomaterial

The definition of the EU Commission covers natural materials as well as materials occurring in the course of processes or manufactured materials. Thus no distinction is made regarding the origin of the material. The justification for this choice is that properties or risks posed by a nano-sized material are not determined by the intention of the manufacturer and do not differ depending on whether the nanomaterial is natural, produced incidentially, or the result of a manufacturing process with or without the explicit intention to produce a nanomaterial. This means that if a specific piece of legislation only addresses manufactured materials, the same limitation would also apply to nanomaterials[22].

The definition will be subject to a review by December 2014 to ensure that it corresponds to the needs (Para. 14). In particular, the review should assess whether the number size distribution threshold of 50 % should be increased or decreased and whether to include materials with internal structure or surface structure in the nanoscale (e.g. complex nano-component nanomaterials including nano-porous and nano-composite materials that are used in some sectors).

The implementation of the EU recommendation

The recommendation of the EU commission for a definition of the term nanomaterial shall be applied with the introduction of new legislation as well as with amendments of existing laws. Whereas the new biocides regulation already relies on the recommendation of the Commission, the cosmetics and food-labelling regulation contain definitions, which partly differ significantly from the commission's recommendation[23]. Present, there are discussions how this could be adapted adequately in order to correspond the commission's recommendation and to satisfy specific sectoral needs. The recommendation itself will be evaluated by December 2014. Experiences and new findings from scientific and technologic development will prove whether changes in the defined size range from 1 nm to 100 nm as well as in the threshold of 50 % for the number size distribution will become necessary.

Conclusions

A standardised, comprehensive and simple definition of the term nanomaterial is equally necessary for risk assessment as well as for regulatory purposes. Thus the recommendation for a definition of the term nanomaterial of the EU commission on the basis of preparatory works of international institutions and scientific committees is welcomed. The recommendation is adopted into EU legislation, thus an adequate adaption for specific sectoral needs constitutes a major challenge. Further, the recommendation contains some controversial provisions like the determined size range or the threshold at which a material is considered to be a nanomaterial. This also raises the issue of suitable measuring methods. For the analysis of nanomaterial being pure starting materials or ingredients of products some measuring methods already exist. However, these are not yet validated and standardised. The analysis of nanomaterials in complex media as in cosmetics or food constitutes a major technical challenge. This area still lacks of practical and cost-effective procedures. Monitoring the compliance with nanospecific legislation as labelling requirements highly depends on the development of suitable measuring methods.

Notes and References

[1] See e.g. Nano Trust Dossier 009.

[2] See Nano Trust Dossier 031en.

[3] For an overview of various proposals of a definition see e.g. Lövestam, G., et al., 2010, *Considerations on a Definition of Nanomaterial for Regulatory Purposes*, No. EUR 24403 EN: Joint Research Center (JRC) of the EU Commission; ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf.

[4] ISO/TS 27687:2008 Nanotechnologies – Terminology and definitions for nano-objects – Nanoparticle, nanofibre and nanoplate; www.iso.org/obp/ui/#iso:std:iso:ts:27687:ed-1:v1:en:term:2.2.
ISO/TS 80004-4:2011 Nanotechnologies – Vocabulary – Part 4: Nanostructured materials; www.iso.org/obp/ui/#iso:std:iso:ts:80004:-4:ed-1:v1:en:term:2.2.

[5] SCENIHR, 2007, *Opinion on the Scientific Aspects of the existing and proposed Definitions relating to products of Nanoscience and Nanotechnologies*, 29 November 2007: Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR); ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_012.pdf.

[6] SCCP, 2007, *Opinion on Safety of Nanomaterials in Cosmetic Products:* Scientific Committee on Consumer Products; ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf.

[7] See NanoTrust Dossiers 017en and 031en.

[8] Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Official Journal of the EU L 342/59.

[9] Regulation (EC) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. Official Journal of the EU L 304/18.

[10] Regulation (EC) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. Official Journal of the EU L 167/1.

[11] Official Journal of EU, 2011, 2011/696/EU *Commission Recommendation of 18 October 2011 on the definition of nanomaterial* (20. 10.2011) L 275/38 S. 3; eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:DE:PDF.

[12] SCENIHR, 2010, *Opinion on the Scientific Basis for the Definition of the Term "nanomaterial"*, 8 December 2010: Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR); ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_032.pdf.

[13] Lövestam, G., et al., 2010, *Considerations on a Definition of Nanomaterial for Regulatory Purposes*, Nr. EUR 24403 EN: Joint Research Center (JRC) of the European Commission; ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf.

[14] Policy Statement on Health Canada's Working Definition for Nanomaterial; www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php (6.2.13).

[15] Australia Announces Adjustments to NICNAS New Chemicals Processes For Industrial Nanomaterials; nanotech.lawbc.com/2010/10/articles/international/other/australia-announces-adjustments-to-nicnas-new-chemicals-processes-for-industrial-nanomaterials (6.2.13).

[16] NGO recommendations for the European definition of Nanomaterials (no date); www.eeb.org/EEB/?LinkServID=786D7972-E60E-4E4B-62D10C1688545001 (7.2.13).

[17] Consultation of the EU Commission: Proposal for a definition of the term Nanomaterial that the EU Commission intends to use as an overarching, broadly applicable reference term for any European Union communication or legislation addressing Nanomaterials. 21.10.-19.11.10; ec.europa.eu/environment/consultations/nanomaterials.htm (7.2.13).

[18] The normal distribution is a symmetric distribution form of numeric data and is also known as Gaussian bell-curve – according to the German mathematics Carl Friedrich Gauß. The normal distribution is a distribution model of statistics. Its curve progression is symmetric, median and average value are identical. The normal distribution is frequently used with basic units – for example, the body height in Germany is distributed log-normally. Approximately two-thirds of all measured values lie within the distance of a standard deviation from the average value. With a distance of two standard deviations the percentage is already over 95 percent. The normal distribution serves as basis for an approximative description, explanation and forecast of facts in the fields of natural and social sciences.

[19] The logarithmic normal distribution (short log-normal distribution) is a continuous probability distribution of the amount of positive real numbers. It describes the distribution of a random variable x if ln(x) is distributed normally.

[20] Bleeker, E., et al., 2012, *Interpretation and implications of the European Commission Recommendation on the definition of nanomaterial*, No. 601358001/2012 RIVM Letter Report: National Institute for Public Health and the Environment (RIVM); www.rivm.nl/dsresource?objectid=rivmp:181801&type=org&disposition=inline.

[21] Linsinger, T., et al., 2012, *Requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial"*, No. EUR 25404 EN: Joint Research Centre; publications.jrc.ec.europa.eu/repository/bitstream/111111111/26399/2/irmm_nanomaterials%20%28online%29.pdf.

[22] EU Commission: Nanomaterials. Questions and Answers on the Commission Recommendation on the definition of Nanomaterial. October, 18th 2011; europa.eu/rapid/press-release_MEMO-11-704_en.htm.

[23] See NanoTrust Dossier 031en.

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