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"NANOFORCE"
Nanotechnology for Chemical Enterprise -how to link scientific knowledge to the business in the Central Europe space

STATE OF THE ART –

Report On Existing Safety Procedures and Nanotech Related Legislation

Content

Executive Summary

NANOFORCE – State of the Art Report on Existing Safety Procedures and Nanotechnology related Legislation

The State of the Art Report on Existing Safety Procedures and Nanotechnology related Legislation provides an analysis and evaluation of the current regulations for nanomaterials in the European Union. The risks and benefits of nanomaterials are currently being assessed by many research groups, mainly because of the specific effects resulting from their shape, morphology, size, surface area, functionalization, atomic structure and particle chemistry. As part of the process of forming a legal advisory board for chemical enterprises starting up in nanotechnology, an in-depth literature review has been undertaken to illustrate the present status of legislations within the framework of the REACH regulation. In addition, all relevant directives and amendments of REACH within the past decade have been screened to identify needs and gaps within the regulatory framework and to provide possible recommendations to the European Commission.

To standardize the identification of nanomaterials and open new perspectives on risk assessment and safety regulations, a recommended definition of nanomaterials was presented by the European Commission in 2011. When entering the European market all products are subject to a standard authorization procedure guided by the EU directive on general product safety, which determines the security measures that must be applied to products prior to market placement. For the implementation of nanomaterials on the European market, industry is advised to follow the precautionary principle of 'doing your best to avoid possible negative side effects of nanotechnologies', and certainly avoiding any possible dangerous effects on human, animal or plant health and the environment.

Regarding the regulatory framework for the management of chemicals, REACH is the main legislation in nanotechnology for the overall monitoring of production processes, including substances used in production and market placement of articles. The registration of chemicals manufactured in or imported to the EU, as one of the key elements of REACH, is also applicable for nanomaterials.

Regulations with relevance for nanomaterials include the following: 1. Nanomaterials used in cosmetics must be reported to the EU Commission and additionally listed in a catalogue of products placed on the market. 2. Food containing nanomaterials must include the nanomaterials in the labelled list of ingredients. 3. For food additives, a change in particle size means that the additive must be considered as a different agent, requiring a new entry in the community list. 4. For food-contact materials, nanomaterials may only be used following explicit authorization. 5. Products using nanomaterials must be labelled as "biocidal material" with the term 'nano' in brackets. 6. For hazardous substances in electrical and electronic equipment the precautionary principle must be applied, with additional notification provided to the EU commission. The hazardous substances must then substituted by environmentally friendly alternatives, if required.

Beyond the literature review, a questionnaire for producers, downstream users, researchers and financiers was developed with the goal of collecting information about differences in the use of regulations and safety implementation rules on a regional basis, covering seven countries of the NANOFORCE project partners (Austria, Czech Republic, Germany, Italy, Poland, Slovakia and Slovenia). National legislations generally follow EU requirements, although differences can be found, depending on specific nano-initiatives of each nation.

Within REACH there are still issues to be addressed for nanomaterials on the European market; nevertheless, REACH is the most applicable regulation for nanomaterials. Issues still to be addressed include: registration for imported and manufactured nanomaterials <1 tonne/year; standardization of labeling of for nanomaterials; mandatory safety reports with exposure assessment for registered nanomaterials; reporting requirements for all nanomaterials on the market; and adaption of the precautionary principle at all levels of the production cycle.

The findings of the project NANOFORCE have revealed significant needs in the standardization of the regulatory body for nanomaterials: better implementation of and development of simpler and more standardized testing methods; more uniform data collection; better knowledge dissemination; and transparency of data available for stakeholders.

Graz, December 2012

1 Introduction

Goods on the single European market are subject to standardized procedures for product authorization, and therefore the most important rules are to be found on the European level. The 'New Approach' introduced by the Commission in 1999 is the legal framework for various products: through directives, general safety and quality requirements are defined, and a specification of these requirements is described by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Only products that comply with these requirements are marked with a 'CE' symbol. These products may circulate freely on the European internal market, as it is assumed that they have been produced according to defined standards and comply with the EU requirements.

For chemical substances, a new legislation has been introduced: REACH. It grew out of the desire

> *"to produce fewer industrial chemicals, to understand the possible human and ecological hazards of those that are produced, and to insure that any major threat is anticipated, as well as prevented"* [WILLIAMS 2009].

REACH has the broadest coverage of nanomaterials of any European legislation, and the relevance of this monumental regulatory initiative for these new materials will be outlined below. Several additional sector-specific directives - such as those on cosmetics, food additives, food-contact materials and biocides - are also of relevance and will be described.

Note that REACH - an initiative proposed before the new millennium - was not drafted and negotiated with nanotechnology in mind. Nanomaterials entered the stage at a later time, and numerous nano-specific concerns could not be fully addressed or resolved in REACH. This is the reason for several amendments of EU directives, and it is the topic of an on-going dispute between the Commission and the majority of the European Parliament over the need for additional measures to assure adequate regulation of all new materials, applications and products.

1.1 Nanotechnology: Introduction and definitions

Nanotechnology is often described as "those areas of science and engineering where phenomena that take place at dimensions in the nanometer scale are utilized in the design, characterization, production and application of materials, structures, devices and systems" [DG HEALTH 2012]. The British Standards Institution (BSI) defines the ‘nanoscale’ as the "size range from approximately 1 nm to 100 nm", where 'nano' is the prefix denoting one billionth (or 10^{-9}) [BSI 2011]. A 'nanometer', therefore, is one billionth of a meter - and, to gain some sense of scale, a human hair is approximately 80 000 nm in diameter, and a red blood cell about 7 000 nm in diameter.

Nanotechnologies work on the basis that, as particles or structures decrease in size, their characteristics often change, or, as the BSI 'Nanoparticles-Vocabulary' expresses it:

> *"where size- and structure-dependent properties and phenomena, as distinct from those associated with individual atoms or molecules or with bulk materials, can emerge …" [BSI 2011].*

One of the most important properties is the very large surface area in relation to their mass that nano-materials often have. These different properties of materials at the nanoscale are the source of many of their practical applications, such as high reactivity or excellent stability and rigidity, but they are also the source of concern about the potential harmful impacts of these new types of material [LEE 2010].

Although nanoparticles exist in nature (for example, sea-spray and volcanic ash or soot from forest fires contain nanoparticles, and most viruses are nano-sized), recent years have seen increasing efforts" to deliberately engineer nanomaterials for their unique and desirable qualities" [STOKES 2009]. The main driving force of nanotechnology is the positive economic impact it is expected to have - its potential to bring fundamental change in whole technological disciplines, with multiple benefits and novel applications for society: "from energy capture and storage, through water purification solutions to a new generation of lighter and stronger materials for aeronautics" [ETUI 2010].

Since the early 2000s, nanotechnology has become a top priority for many countries, as well as for the European Union, and a number of nanotechnology programs and special funding instruments for nanotechnology research have been created.

However, early on, voices were raised pointing out the risks these new technologies could pose; the nature and scope of those risks has only become known over time. In 2004, the report of the Royal Society & the Royal Academy of Engineering [UK-RS 2004] discussed the hazards of nanotechnologies, while a report presented in 2008 by the Royal Commission on Environmental Pollution [UK-RCEP 2008] examined the pathways by which these nanomaterials could enter the environment and present potential hazards. Similar topics were discussed by the German Advisory Council on the Environment (SRU) in its recent report on 'precautionary strategies for managing nanomaterials' [SRU 2011]. It highlighted the findings of risk research; i.e., that nanomaterials differ from their macro counterparts not only physically and chemically, but also in their behavior and effects in living organisms and the environment; they are also able to move about more easily in environmental media and in living organisms. The experts explained that "the potential risks are heterogeneous and difficult to foresee. This has partly to do with the new properties of the materials themselves and partly with the diversity of their structures, products and applications".

Early on, the European Commission recognized the particular properties of nanomaterials and the resulting need for regulation of risks from nanotechnologies. In its 'Communication on Nanotechnologies' [EC 2004], it stated:

> "*appropriate and timely (nanotechnology) regulation in the area of public health, consumer protection and the environment is essential, also to ensure confidence from consumers, workers and investors. Maximum use should be made of existing regulation. However, the particular nature of nanotechnologies requires their re-examination and possible revision. A proactive approach should be taken ...* " (p. 18)

In 2010, the European Commission asked its 'Scientific Committee on Emerging and Newly Identified Health Risks' (SCENIHR) to provide advice on the essential elements of a science-based definition of nanomaterials. SCENIHR presented a first opinion [SCENIHR 2010] and opened, during the summer, a two-month public consultation. In October 2011, the Commission finally published its proposal for a definition of the term 'nanomaterial' [EU-COM 2011]. According to the Commission, this is just a 'recommendation - addressed to the Member States, Union agencies and economic operators'.
The proposal states:

> *" '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 %."*

Scientific organizations such as the Royal Society of Chemistry [RSC 2011] and non-government organizations (NGOs) [EEB 2010] have previously expressed support for a technical definition because it would enable regulatory activities. The text presented by the Commission, however, was met with dissent from many scientists and from legal advisers [MONDAQ 2012], [STEPTOE 2011], who argued that:

- 'nanomaterials' should be identified solely on the basis of the size of the particles of the material, and not on the basis of any risks;

- the Commission's recommendation for a number size distribution threshold of 50 % for the proportion of particles for the material to be considered a 'nanomaterial' is much higher than the SCENIHR recommendation of 0.15 % (or the 1 % threshold of the original proposal of the Commission), and no scientific reasoning for this change has been given;

- as yet, there are no validated and reliable testing methods for measuring number size distributions, and therefore the practical problems of determining whether materials are 'nanomaterials' will be considerable.

- The Commission envisages that the implementation of new rules concerning nanomaterials will be the subject of amendments to existing legislation. In April 2012, the Chemicals Agency ECHA presented some clarifications under the title of 'Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA)', which describes the procedures for the registration of nanomaterials [ECHA 2012].

1.2 Remarks on regulation and caution

The introduction of new technologies will always have unexpected consequences. The aim of technology policy and regulation in a democratic society is, as nanotoxicologist Prof. Anthony Seaton wrote in a review article, "to reduce harmful risks while not inhibiting the development of beneficial effects" [SEATON 2010]. Discussions of risks and nanotechnology are complex, and it must be kept in mind that "there are also risks associated with not developing new technologies" [LEE 2010], considering that the promises claimed for nanotechnology are enormous and also include health and energy efficiency applications.

The main concern of the European Commission is to increase investment in research and development and then to turn the results into 'wealth-generating products'. The 'health, safety and environmental risks that may be associated with products and applications of nanotechnology … will have to be addressed upfront' [EC 2005], but the evaluation of risks and nanomaterials is accompanied by profound uncertainties.

The report of the Royal Commission on Environmental Pollution stressed that

> *"currently it is extremely difficult to evaluate how safe or how dangerous nanomaterials are because of our complete ignorance about so many aspects of their fate and toxicology ...*" [UK-RCEP 2008, fn 3, 3.12].

1.3 The precautionary principle

In the past, in most jurisdictions, commercial activities could only be restricted on environmental or health grounds when it could be demonstrated that they caused harm. The 'precautionary principle' was discussed and declared as 'Principle 15' at the United Nations Conference in Rio de Janeiro : " *... where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measurements to prevent environmental degradation*" [UNEP 1992].

Article 191(2) of the 'Functioning of the European Union' expresses similar ideas:

> "*Union policy ... shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified at source and that the polluter should pay…*"

The European Court of Justice has confirmed recently, in a case concerning the safety of food, Commission vs. France, that the precautionary principle permits regulatory action "*where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted* ", provided that there has been "*first, identification of the potentially negative consequences for health of the proposed use of processing aids, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research*" [ECJ-2010, fn. 94].

The precautionary principle applies where scientific evidence concerning risks and harms is inconclusive or is being contested between experts. The German SRU-Experts have

concluded that ... "following negative experience, it is now accepted that - subject to a cost-benefit analysis - risks to human health and the environment should be investigated further on a 'precautionary basis'" [SRU 2011].

1.4 Nanotoxicology

The concept that nanoparticles may have unique toxic properties is rather recent, but, as Anthony Seaton described in his review article on 'Nanoparticles, human health hazard and regulation' [SEATON 2010], the thinking behind it is "derived from classical particle toxicology and epidemiology, especially from studies of air pollution"; the toxic component of particulate air pollution seems to be mostly due to the nanometer-sized component. In addition, the ability of nanoparticles to translocate - after inhalation or ingestion - from the portal of entry … "is the basis of much of the concern over manufactured nanoparticles and the fear that existing risk assessment instruments are inadequate".

Many studies have found that nanoparticles have greater potential to damage cells and to cause inflammation than an equal mass of the same material but greater particle size. This holds true for various (including low-toxicity) materials; the total surface area being the main indicator for pro-inflammatory effects. Furthermore, some nanomaterials may be ecotoxic after being discharged into the aquatic environment or the soil.

2 European Level

2.1 EU legislation in nanotechnology - REACH

The continuing presence of a wide variety of chemicals and rising concerns with respect to their possible effects were discussed at meetings of the EU Environmental Council in 1998, where the four existing regulations for chemical substances were evaluated. The lack of toxicological and ecotoxicological data for the 'existing chemicals' that had been in commerce in Europe for many years was quite severe - "for more than 20 % of the high-production volume (HPV) chemicals no data at all were available, for a further 65 % the data were less than required" [WILLIAMS 2009]. In 2001, the European Commission proposed a framework - the 'White Paper: Strategy for a Future Chemicals Policy' that would address these deficits.

The REACH regulation that was proposed in an early version in 2003 was …

> "*an innovative approach to chemicals regulation which required the registration, evaluation, authorization and restriction of chemicals … one of the most controversial legislative proposals in the history of Community law-making. Among the regime's main features are, first and most importantly, an explicit responsibility that is placed on producers and importers for both producing information and for insuring their products do not adversely affect human health or the environment"* [FISHER 2008].

Under REACH, a chemical substance is defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition."

The elements of REACH are, in a nutshell [WILLIAMS 2009]:

- registration - required for all chemicals manufactured or imported into the EU, unless specifically exempted, with registration expected to be a collaborative process among companies for the generation of a dossier containing relevant data on physicochemical properties, as well as (eco-)toxicological properties;

- examination of hazards and risks for many chemicals (i.e. those above certain thresholds of production) on the basis of the data from the dossiers and additional toxicological tests, leading to a 'chemical safety report' (CSR);

- evaluation of the substance and the data from the dossiers by the 'European Chemicals Agency' (ECHA), leading to a decision by ECHA, the Commission and the Member States concerning the identification of those chemicals that may pose unacceptable hazards to human health or the environment and that will be restricted.

2.1.1 Coverage of nanomaterials in REACH

This wide definition of a chemical substance under REACH includes, at least in principle, nanoscale substances. Whether this coverage is also "*enough to cover issues related to nanotechnologies, nanosciences and the potential risk for health and the environment*" [ETUI 2010] is a controversial topic. The Commission has argued that, by and large, current legislation is adequate [BREKELMANS 2009], and the Commissions 'Remarks on Nanomaterials in REACH' [EC 2008 b] state that "*there are no provisions in REACH referring specifically to nanomaterials. However, REACH deals with substance, in whatever size, shape or physical state. Substances at the nanoscale are therefore covered by REACH and its provisions apply. It thus follows that under REACH manufacturers, importers and downstream users have to ensure that their nanomaterials do not adversely affect human health or the environment.*"

A thorough comparison of the regulatory responses to potential nano-risks in the EU and the US [CHATHAM 2009] recognized the numerous challenges that are related to the uncertainties with regard to the further development of nanomaterials, hazards and pathways, and the suitability and effectiveness of existing regulatory frameworks. The most important knowledge gaps - with regard to the environmental health and safety (EHS) risks associated with the production and use of nanomaterials, and to the presence of nanomaterials in commercial products - would have to be closed as soon as possible. In his observation on the regulation of nanotechnology, M. Widmer [WIDMER 2010] remarked that in the near future, when the registration and evaluation phase will have been completed, "REACH has to prove itself an efficient and viable regulatory framework (and not just for nanomaterials)". The first impression is quite positive, according to a report of the US-'General Accounting Office' [GAO 2007] on 'U.S. and European Approaches to Protect against the Risks of Toxic Chemicals', which concluded:

> *"assuming that the EU has the ability to review chemical information in a timely manner, specific provisions under REACH provide a means for addressing long-standing difficulties experienced both under TSCA (the US Toxic Substances Control Act) and previous European chemicals legislation in (a) obtaining information on chemicals' potentially harmful characteristics and their potential exposure to people and the environment and (b) making the chemical industry more accountable for ensuring the safety of their products.*
>
> *Furthermore, REACH is structured to provide a broader range of data about chemicals that could enable people to make more informed decisions about the products they use in their everyday lives*."

The strong point of REACH is that it addresses the deficit of information on the multitude of old 'existing' chemicals that have not been subject to the registration requirements imposed on 'new' chemicals under the previous legislation (in the United States, the 100th Congress debated the proposed 'Kid-Safe Chemicals Act of 2008', that intended to require "*human or environmental toxicity information ... for the vast majority of chemicals used in commercial products (that) have never had any Federal review to evaluate potential toxicity of the produces to infants, children, developing fetuses, or adults …*"; this bill was never passed [US-SENATE 2008]).

A number of studies and reports have discussed gaps in coverage and possible shortcomings of the REACH regulation with respect to the treatment of nanomaterials, such as:

- several reports by the Centre For Business Relationships, Accountability, Sustainability and Society (BRASS) at Cardiff University on REACH and the regulatory environment [BRASS 2006], [BRASS 2008], [BRASS 2010];
- the German study on 'appraisal of nanotechnologies' for the Ministry for Environment, Rechtsgutachten Nano-Technologien [RENATE 2007];
- the recent report of an independent NGO on 'How REACH Is Failing to Regulate Nanomaterials'
  [CIEL 2012];
- the report of the Royal Commission on Environmental Pollution 'Novel Materials in the Environment - The Case of Nanotechnology' [UK-RCEP 2008];
- the report by the German Advisory Council on the Environment: 'Precautionary Strategies for Managing Nanomaterials' [SRU 2011].

These studies describe two major limitations of REACH with respect to nanoparticles:

1 Registration under REACH is based on 'chemical composition', which could result in C60 and carbon nanotubes (CNT) being included under the same registration as carbon black, as 'existing substances'; despite their vastly different chemical and biological properties relative to their macroscale counterparts [BRASS 2006].

2 The requirements for producers and importers to provide toxicological data of their products are based on mass thresholds: data sets are only required for volumes above the threshold of 1 t/year (assessed per manufacturer or importer). The minimal requirement for volumes below 10 t/year is the submission of a technical dossier containing "all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant".

The greater the quantity of the substance manufactured or imported, the more demanding is the information required by the authorities; a crucial threshold is ten tons, where a chemical safety report based on a chemical safety assessment must be supplied. But for many nanoparticles, this threshold might not be reached. In addition, low concentrations of nanoparticles in a finished product might exclude many nanoengineered articles from the REACH legislation, since no registration is required for concentrations below 0.1 %.

In REACH, the physico-chemical modeling is recommended for the assessment of properties and toxicity of substances (methods QSPR and QSAR – quantitative structure-property relationship and quantitative structure-activity relationship). In the general lack of information on the properties and behavior of nanoparticles, the physico-chemical modeling could be also applied as outlined in [ŠIMON & JONER 2008; ŠIMON, BAKOŠ & CHAUDHRY 2008].

The SRU report [SRU 2011] concludes:

> "*Existing chemicals legislation is not sufficient for precautionary regulation of nanomaterials as the nanoform of chemicals. This is partly because it is often unclear how nanomaterials should be dealt with under the law. By definition they are substances and as such are generally subject to regulation but - with few exceptions - they are legally not considered separately from their macroscale counter-parts. This is not justified given that they can potentially have modified properties and nano-specific features. Nanomaterials should therefore generally be treated as separate substances in their own right.*" (p.18).

The EU parliamentarians clearly hold similar views; they do not, in the overwhelming majority, share the "Commission's conclusions that a) current legislation covers in principle the relevant risks relating to nano-materials, and b) that the protection of health, safety and the environment needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks" [EU-PARL 2009, Pt. 3].
In the parliamentarian 'resolution on regulatory aspects of nanomaterials' (2008/2208(INI)) they voted almost unanimously, with 362 votes for, and 4 against- in favor of a call on the Commission:

"concerning inter alia:

- simplified registration for nanomaterials manufactured or imported below one ton,
- consideration of all nanomaterials as new substances,
- a chemical safety report with exposure assessment for all registered nanomaterials,
- notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles…"[EU-PARL 2009, Pt. 11]

Similar objections had already been raised when the European Parliament's Committee on the Environment, Public Health and Food Safety [EU-PARL 2006] recommended a number of significant changes for the second reading on REACH in October 2006. Most of them demanded amendments with respect to the precautionary principle and the treatment of nanomaterials:

Amendment No.	Text proposed by the Committee on Environment, Public Health and Food Safety of the European Parliament (Doc. No. PE 371.746v02-00, 13. October 2006)
Am. No. 87	Art. 57, § 3, Point (ba) -new- : in the form of nanoparticles; or … (Justification) *According to SCENIHR, a wide variety of nanoscale materials and functional nanoscale surfaces are in use in consumer products, including cosmetics and sunscreens, fibres and textiles, dyes, fillers, paints, emulsions and colloids. Given the combination of a) very worrying adverse effects by nanoparticles, b) their widespread use in consumer products and c) the minimal knowledge about the biological fate of nanoparticles, they should be [prioritised within the authorisation] system of REACH*
Am. No. 98	Art. 59, § 1 -changed- The Commission shall be responsible for taking decisions on applications for authorizations in accordance with this Title. The precautionary principle shall apply when such decisions are taken. (Justification) *Reminds that such decisions should be taken based on the precautionary principle.*
Am. No. 161	Art. 137, § 4 a -new- :

	the Commission shall carry out a review of the threshold of 1 ton per year per manufacturer or importer for registration and of the information requirements pursuant to Article 12 for nanoparticles. On the basis of that review, the Commission shall present appropriate legislative proposals to modify the tonnage threshold and the information requirements for nanoparticles to ensure adequate risk assessment, and risk reductions, where necessary, so as to achieve a high level of protection of human health and the environment with regard to nanoparticles. (Justification) *The major gaps in the knowledge for risk assessment of nanoparticles, as stated by SCENIHR, as well as their conclusions stating a need for modifications of existing methods point to the urgent need of a review of the provisions of REACH to ensure adequate risk assessment, and risk reductions, where necessary, with regard to engineered nanoparticles.*
Am. No. 165	Annex III, Point (A) -new- : (aa) nanoparticles, (Justification) *So far, nanoparticles are often only produced in very low quantities. But given their major potential to create adverse biological effects, as a very minimum, nanoparticles between 1 and 10 tonnes should be considered to be priority substances for which at least the whole base set information of Annex VII should be provided in the absence of nanoparticle-specific tests.*

These amendments were not approved. The open issues concerning the coverage of REACH, as well as suggested amendments with respect to nanomaterials, will be negotiated at a later date.

A recent report by the European Consumer Association [BEUC 2012] stated that "the EU regulatory framework had been adjudged by many stakeholders including the European Parliament to be not fit to deal with the new challenges related to the presence of nanomaterials in consumer products."
However, at the insistence of the European Parliament, several EU regulations now contain specific rules with respect to the presence and the possible risks of nanomaterials for defined groups of products.

A British study carried out for Chatham House (the Royal Institute for International Affairs) evaluated the details of the relevant EU regulations with respect to nanotechnologies in detail [CHATHAM 2009]; such a 'sectorial legislation' can be found for several product groups:

(a) cosmetics
(b) food
(c) food contact materials
(d) biocidal material
(e) waste material
(f) regulation at workplaces.

2.2 Guidelines – OECD & WHO

The WHO (world health organization) recently published a background document for a guideline on “Protecting Workers from Potential Risks of Manufactured Nanomaterials” (WHO/NANOH). The aim of this new WHO guideline will be to improve occupational health and safety of workers who are in contact with nanomaterials, either in production or in social environments. It will contain elements of risk assessment and risk management associated

with the development of exposure scenarios of nanomaterials in the context. Moreover, they will provide recommendations for safe handling of nanomaterials for worker protection and worker safety, especially in countries with low to moderate incomes. The background document is used to establish key issues to be dealt within the guideline [WHO 2012].

The OECD the (Organization for Economic Co-operation and Development) developed the OECD Working Party on Manufactured Nanomaterials (WPNM) in 2006, concentrating on health and environmental issues and worker protection in context to manufactured nanomaterials as well as implementation of the OECD Programme on the Safety of Manufactured Nanomaterials. Additionally this aims to ensure high standards of risk assessment and development of exposure scenarios. Within several working programmes, papers and database the OECD provides a high volume of information to assist collaborative research to maintain a great effort and furthermore to identify research gaps [ENV/JM/MONO 2010; OECD ENVIRONMENTAL DIRECTORATE 2011]. The OECD furthermore has a sponsorship programme which funds safety testing of specific manufactured nanomaterials. Therefore the WPMN agreed on a list of specific manufactured nanomaterials to be tested within the member countries as well as some non-member countries and other stakeholders. This list contains 13 manufactured nanomaterials and is shown in table 1.

Table 1 OECD list of manufactured nanomaterials for safety testing

- Aluminium oxide
- Cerium oxide
- Dendrimers
- Fullerenes (C60)
- Gold nanoparticles
- Iron nanoparticles
- MWCNTs
- Nanoclays
- Silicon dioxide
- Silver nanoparticles
- SWCNTs
- Titanium dioxide
- Zinc oxide

[OECD NANOSAFETY 2011]

2.3 Material and Product Specific Regulation

2.3.1 Cosmetics regulation

Nanomaterials are proposed to offer several benefits in cosmetics, such as increased transparency and solubility. A recent report [ETUI 2010] sheds some light on the importance of nanomaterials for the cosmetics industry, quoting the European Patents Office (EPO) database as naming the French cosmetics company L'Oreal as the organization with the highest number of published "nano" patents. However, the fact that lotions containing nanoparticles are applied directly to the skin and are, after their use, released into the

environment has led to concerns. In 2007, the 'Scientific Committee on Consumer Products (SCCP)' of the EU wrote in their 'Opinion on Safety of Nanomaterials in Consumer Products':

> "*should insoluble nanoparticles become systemically available, translocation/transportation and eventual accumulation in secondary target organs may occur. This could become important with repeated application of cosmetic products. Inevitably, insoluble nanoparticles do represent a burden for the environment and a complete life cycle analysis is required*" [SCCP 2007].

Cosmetics are regulated under the new Cosmetics Regulation [EU REGULATION 2009], in which the main emphasis is on human health, leaving environmental protection for the regulation under REACH. The Cosmetics Regulation stresses that cosmetic products should "be safe for human health when used under normal or reasonably foreseeable conditions of use" (Art. 3.).
Among these "substantial pre-market requirements" for cosmetic products [CHATHAM 2009] are: a notification to the Commission and a safety assessment (according to new criteria described in Annex I); both are the obligation of the EU-based manufacturer or importer (Art. 10.). Special consideration must be given "to any possible impacts on exposure due to particle sizes" (in: Annex I., § 6.). An authorization is not required before marketing, but several classes of substances, such as: carcinogenic, mutagenic or toxic for reproduction, are prohibited (s. Annex II., Art. 14. (1.)(a.) or restricted (s. Annex III. Art. 14.(1.)(b)). Furthermore, only those colorants, preservatives and UV filters that have been listed in Annexes IV.-VI. (there in: Art. 14. (1.) c,d,e) may be used. This list of 'permitted substances' can be amended by the Commission, as Art. 31 describes: "… where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a community-wide basis … after consulting the SCCS [Scientific Committee on Consumer Safety]." In addition, the EU regulation "requires responsible parties to maintain, as part of each product information file, existing data on the undesirable effects on human health caused by the product … and to notify the competent authority when a serious undesirable effect occurs" [CHATHAM 2009].

During discussions in Parliament, several nano-specific rules have been introduced by the parliamentarians. Most importantly, notification of nanomaterial-containing cosmetics to the Commission is required six months prior to marketing (Art. 16.) In addition, the Commission can request an opinion on a product containing nanomaterials from the SCCP at any time "… where it has safety concerns, for example due to new information supplied by a third party" (Art. 16.(5)).
According to Art. 16.(2), the general requirements of Art. 16 do not apply to substances that have been listed in the annexes on colorants, preservatives or UV filters, and these annexes also include provisions on the permitted concentration levels of particular substances; such as not more than 25 % of TiO_2 to be contained in a sunscreen lotion. The observation that these requirements do not distinguish between the regular and nano-forms of the components has led to the concern that these provisions could be inappropriately applied to the nano-form of the same substance [LEE 2010].

An innovative and important new aspect of the Cosmetics Regulation concerns information about nanomaterial content that will now be available to consumers. The Commission will publish "a catalogue of all nanomaterials used in cosmetic products placed on the market,

including colorants, preservatives and UV filters" (Art. 16. (10.)(a)), and the cosmetic products are subject to new labeling obligations: the product labels must "list the relevant materials with the word 'nano' in brackets" (Art. 19. (1).).

2.3.2 Food regulation

The multitude of "potential applications in the food sector that may offer benefits to both consumers and industry" has been described in the report of the UK House of Lords on 'Nanotechnologies and Food' [HOL 2010]. Some nanomaterials have been used in food processing for a number of years in the form of additives, such as fumed silica - an anti-caking agent to keep powders flowing freely. Examples of food-contact materials that use nanotechnologies include those where improved barrier properties or anti-microbial properties are useful. Among the potential applications are foods with new flavors and textures, and “healthier” food products with reduced salt, fat or sugar content or increased vitamin and nutrient content. In the summary of their report, the' Science and Technology Committee' of the House of Lords highlights the possible new risks that could result from the new properties of some types of nanomaterials:

> *"... (and) our current understanding of how they behave in the human body is not yet advanced enough to predict with any certainty what kind of impact specific nano-materials may have on human health. Persistent nanomaterials are of particular concern, since they do not break down in the stomach and may have the potential to leave the gut, travel throughout the body, and accumulate in cells with long-term effects that cannot yet be determined. (…) while, in principle, existing legislation should ensure that all nanomaterials used in the food sector undergo a safety assessment before they are allowed on to the market, there are certain ‘grey areas’ where products containing nanomaterials may slip through the regulatory net.*" (p.5).

The significant changes in EU food and feed legislation that resulted in the EU 'General Food Law' [EU REGULATION 2002] haven been explained [CHATHAM 2009, p. 64] by a "series of health and safety scandals, such as bovine spongiform encephalopathy (BSE), infected blood products for transfusions, and dioxin contamination of feedstock for chickens. These changes have brought about a strengthening of EU authority in food regulation, as well as the creation of the EFSA as an independent European agency. Food regulation is now largely determined at EU level, and national food laws in EU member states generally implement decisions taken by EU authorities."

The EU General Food Law contains the requirement that "food shall not be placed on the market if it is unsafe … if it is injurious to human health" (Art. 14).
Hereby, an authorization or prior registration is not required for "food that has been used for human consumption to a significant degree within the Community before 15 May 1997". Food items that have entered the European market after that date are called 'novel food'; for these food items, a revision of the food regulation, including a mandatory pre-market approval system, has been discussed in the European Union since 2008. Suggestions for the inclusion of nanomaterials in food and nano-specific guidelines were presented during the negotiations by the European Parliament.

However, the revision came to a standstill in March 2011 over the issue of food from animals produced by cloning. An agreement could not be reached; the discussions on an updated novel food legislation concluded without the adoption of a new text.

A special feature of the current legislation concerning food is the explicit recognition "that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls" (in: Recital 19.). The following recitals (No. 20. and 21.) describe circumstances "… where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community".

Food additives have been regulated since 1988 under directive 89/107/EC, which is based on the principle that only additives that are explicitly authorized may be used in food [EU REGULATION 1988].

A new European regulation passed in December 2008 [EU REGULATION 2008] introduced a new common authorization procedure for food additives, enzymes and flavorings. All food additives will be listed in future on a list of approved additives, including vitamins and minerals, on the basis of an opinion from the European Food Safety Authority (EFSA). The regulation specifies that when "a food additive that is already included in a Community list and there is a significant change in its production methods ... 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 … shall be required before it can be placed on the market" (Art. 12).

Following a request from the Commission, EFSA published in 2009 a scientific opinion on the 'potential risks arising from nanosciences and nanotechnologies on food and feed safety' [EFSA 2009]. The experts emphasize "that the risk assessment processes are still under development … and under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty … and this situation will remain so until more data on and experience with testing ENMs [engineered nanomaterials] become available. “The scientific committee of EFSA even recommends "a re-evaluation of the risk assessment of such substances that have been approved for use in food and feed, and which have been claimed to also be available in nanoscale dimensions … in view of the concerns about nanoscale preparations".

A program for the re-evaluation of approved food additives was outlined in March 2010 with the Commission Regulation 257/2010 [EU REGULATION 2010]. All food additives, including those already permitted before 2009, will be evaluated by EFSA and the 'Scientific Committee on Food' (SCF). The results will be available before the end of 2015 for food colors, and before Dec. 2018 for sweeteners and all other approved food additives. The declared intention is "to fulfill transparency and public information requirements for this re-evaluation procedure" (Recital No. 16.).
Under Art. 5, 'open calls for data' are described that will specifically look for "information on the data on the safety of the food additive concerned not previously reviewed by the SCF …

and … information on the specifications of the food additives presently in use, including information on particle size and relevant physicochemical characteristics and properties" (Art. 5. § 2.b and c.).

2.3.3 Food-contact materials

Food-contact materials and articles, including food-packaging, cooking utensils, food-processing and -transport equipment, that are "intended to come into contact with food, either directly or indirectly", are the topic of Regulation EC/1935/2204 [EU REGULATION 2011 a]. The Commission or the member states may request that EFSA conduct a safety evaluation of compounds used as food-contact material, and that certain substances be subject to additional measures. The possibility for different toxicological properties of nanoparticles is mentioned explicitly: "new technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale; for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorizations that are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles" (Recital 23.). Art. 13 (4) explicitly forbids the use of 'substances in nanoform' as well as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' materials - not even behind a migration barrier - without specific authorization.

2.3.4 Biocidal products

A diverse group of products, including disinfectants, pest control products and preservatives, are covered by the new 'Biocidal Product Regulation' [EU REGULATION 2012]. Their use is considered to be "necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials". On the other hand, the new regulation recognizes the "risks [of those products] to humans, animals and the environment due to their intrinsic properties and associated use patterns." (Recital 1).

The following paragraph (in Recital 2) describes the restrictions that are therefore considered necessary: "biocidal products should neither be made available on the market nor used unless authorized in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation."

Art. 3.1.(z) contains a definition of 'nanomaterial' as "a natural or manufactured active substance or non-active 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 1 nm - 100 nm…". Art. 3.3. gives the Commission the opportunity to decide ..."at the request of a member state, by means of implementing acts, whether a substance is a nanomaterial, … in accordance with the necessary examination procedure referred to in Article 82(3)."

The requirements concerning authorization of biocidal products containing nanomaterials are more stringent than for non-nano products; Art. 19.1.(f) demands a "separate assessment of the risks to the environment and to health if nanomaterials are used in a product".

These nano-biocides are, according to Art. 25.(c) not eligible for a 'simplified authorization procedure'. Annex III. describes the information requirements for all biocidal products; special consideration is given to the requirement that, for the purpose of authorization only, 'scientifically appropriate' testing methods can be used, and if "test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjustments that have been made in order to respond to the specific characteristics of these materials." (Annex III. 5.).

Users of these products should be given more information that includes the use of nano-materials. For biocides, 'labeling obligations' similar to those already in force for cosmetics have been decided; the new biocide regulation contains the provision that "the person responsible for the placing on the market … shall ensure that the label states the name of all nanomaterials contained in biocidal products, followed by the word 'nano' in brackets". (in Art. 58.3.(d)).

2.3.5 Waste management

Up to now, existing European laws on waste do not contain specific references to engineered nano-particles. The Council Directive No. 91/689/EEC of 12 Dec. 1991 on hazardous waste was repealed by the directive 2008/98/EC after Dec. 2010, and this new directive now mentions the importance of "the precautionary principle and the principle of preventive action … by virtue of those principles, it is for the Community and the member states to establish a framework to prevent, reduce and, in so far as is possible, eliminate from the outset the sources of pollution or nuisance by adopting measures whereby recognized risks are eliminated" (Recital 30.). Annex III. of the new directive lists those 'properties of waste which render it hazardous', such as 'carcinogenic', 'mutagenic', 'toxic for reproduction', 'ecotoxic', etc. Certain nano-waste could be included among one of these categories, but no specific reference to the size of particles has been made in the text of the directive [EU REGULATION 2008 b].

The restriction of the use of several hazardous substances in electrical and electronic equipment is the subject of EU directive No. 2011/65/EU. During the discussion, the Parliamentary Committee on the Environment proposed several nano-specific amendments, such as: "economic operators shall notify the Commission of the use of nanomaterials in electric and electronic equipment (EEE) and provide all relevant data with regard to their safety for human health and the environment over their life cycle … having regard to the information provided by economic operators … the Commission shall assess the safety of nano-materials in EEE for human health and the environment, in particular during use and treatment, and communicate its findings in a report to the European Parliament and the Council" (proposed Art. 5 a).

These amendments have not been approved, but at the plenary debate in January 2012 the EU Commission declared its willingness to evaluate potential nano-risks with a view to

facilitating an agreement. The text of this declaration - a written promise by the Commission to follow the advice of the parliamentarians - was published in a separate document [EU REGULATION 2011 b].

2.3.6 Regulation at workplaces

The EU 'Safety at Workplaces Directive' [EU REGULATION 1989] does not contain any reference to the potential exposure to engineered nanoparticles. The directive on 'the protection ... from the risks related to chemical agents at work' [EU REGULATION 1998] sets guidelines on how to establish occupational exposure limits (OELs) for workers.

A report of the 'European Agency for Safety and Health at Work' on 'Workplace exposure to nano-particles' [EU-OSHA 2009] explains the principal goals of the first of these directives, No. 89/391:

> "... (*it) presents minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace … and there are also definitions of chemical agents and hazardous chemical agents, but nanomaterials are not mentioned specifically*".

Within the European Union, no upper limit for the exposure to nanoparticles exists. Germany has set an OEL for silica dioxide, and the experts of the German Research Foundation (DFG) have suggested a new, significantly lower value for the upper limit of fine particles of TiO_2 at the workplace (0.3 mg m^{-3};i.e., 10 % lower than the previous value). This suggested limit, however, does not apply to ultrafine particles or nanoparticles, although they are proposed to be more toxic to the lungs than the same mass of larger (e.g., micron-sized) TiO_2 [DFG 2011]. Toxicologists [ROLLER 2010] and experts of the German Accident Insurance [IFA 2012] have concluded that biopersistent nanoparticles composed of materials previously thought to be non-toxic (in German : 'Nano-GBS : granuläre bio-beständige Partikel aus Material, das früher als inert bezeichnet wurde') should be treated as potential occupational carcinogens. The German IFA experts expect a further drastic lowering of the limits for ultrafine- and nano GBS particles. The recommended maximum 'acceptable' level ('Akzeptanzrisiko') for toner dust in Germany is already set to be lowered from 0.06 to 0.006 mg m^{-3} as of 2018 [IFA 2012].

The United Kingdom has opted for the use of 'benchmark exposure levels' for nanomaterials, with a value of <20,000 particles per ml for insoluble nanomaterials, and <0.01 fibers per ml for fibrous nanomaterials (to be assessed by scanning or tunneling electron microscopy).

In the United States, the US 'National Institute for Occupational Safety and Health' (NIOSH) recommended in 2011 a new exposure limit of 2.4 mg m^{-3} for fine TiO_2 dust and 0.3 mg m^{-3} for ultrafine (including 'engineered nanoscale') TiO_2 dust. These are supposed to be time-weighted average concentrations for up to 10 hours per day during a 40-hour working week [CDC 2011].

Several major problems associated with the establishment of OELs for workers exposed to nanomaterials have been raised [SATTERSTROM 2008]:

- the establishment of OELs is based on a complete risk assessment procedure, which is currently not available for engineered nanoparticles;
- OELs are based on mass concentration as the most important metric for the determination of toxicity, but this parameter is not well suited for the determination of nanoparticle toxicity;
- the detection and monitoring of nanoparticles at workplaces is notoriously difficult, the development of better instrumentation is currently under way (EU-NANODEVICE, EU-NanoGEM, German research project NanoCare, etc.).

The major specific EU regulations with relevance to nanomaterials can be found in the table below

Sector	***The most relevant special rules on nanomaterials (emphasis added)***
Cosmetics *Regulation No. 1223/2009 on cosmetic products (30. Nov. 2009) - shall apply from 11 July 2013 -* Details : [EU REGULATION 2009]	(Art. 2.1.(k)): '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. (Art. 16.1.): For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured. (Art. 16.3.): In addition to the notification under Article 13, cosmetic products containing nano-materials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market - the information notified to the Commission shall contain at least the following: (a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI; (b) the specification of the nanomaterial including size of particles, physical and chemical properties; (c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year; (d) the toxicological profile of the nanomaterial; (e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products; (f) the reasonably foreseeable exposure conditions. (Art. 16.5.): In the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. The SCCS shall deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available. (Art. 16.4) The Commission may, at any time, invoke the procedure in paragraph 4 where it has any safety concerns, for example due to new information supplied by a third party. (Art. 16.11.): The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions. The first review shall be undertaken by 11 July 2018. (Art. 19.1.): All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.
Food information to Consumers *Regulation No. 1169/2011 No.*	(Recital No. 23): In order to inform consumers of the presence of engineered nanomaterials in food, it is appropriate to provide for a definition of engineered nanomaterials. Taking into account the possibility of food containing or consisting of engineered nanomaterials being a novel food, the appropriate legislative framework

1169/2011 on the provison of food information to consumers (25. Okt. 2011) - shall apply from 13. Dec. 2014 - [EU REGULATION 2011c]	for that definition should be considered in the context of the upcoming review of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients. (Art. 2.2.(t): 'Engineered nanomaterial' means 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: (i) those related to the large specific surface area of the materials considered; and/or (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material; (Art. 18. 3): 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.
Food contact materials *Commission Regulation No. 10/2011 on plastic materials and articles intended to come into contact with food (14. Jan. 2011) - applies after 01.5.2011 -* [EU REGULATION 2011 a]	(Recital No. 23): New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale; for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles. (Art. 9.2): Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I. (Art. 13.4): The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories: (a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in Regulation (EC)No 1272/2008 (b) substances in nanoform.
Food additives *Regulation on food additives (16. Dec. 2008) - applies after 20.1.2010 -* [EU REGULATION 2008 c]	(Art. 12.): 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.
Biocidal products *Regulation concerning the making available on the market and use of biocidal products, No. 528/2012 (22. May 2012) - shall apply from 1. Sept. 2013 -* [EU REGULATION 2012]	(Art. 3.1. (z)): 'Nanomaterial' means a natural or manufactured active substance or non-active 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 1 nm-100 nm; Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nano-materials. For the purposes of the definition of nanomaterial, '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; (Art. 3.3.): The Commission may, at the request of a member state, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard, in particular to Recommendation 2011/696 … (Art. 19.1.(f)): A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met: (…) where nanomaterials are used in that product, the risk to the environment and to health has been assessed separately. (Art. 25.(c)): For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible

	if all the following conditions are met: the biocidal product does not contain a nanomaterial; (Art. 58.3.(d)): the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information: -- the name of all nanomaterials contained in biocidal products, followed by the word 'nano' in brackets. (Art. 58.5.): Notwithstanding the labelling requirements set out in paragraph 3, the supplier of a treated article shall, where a consumer so requests, provide that consumer, within 45 days, free of charge, with information on the biocidal treatment of the treated article. (Art 65.3): Every five years … member states shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular any available information on the adverse environmental effects experienced through using biocidal products; information on the use of nanomaterials in biocidal products and the potential risks. (Art. 69.2.(b)): the label must show clearly and indelibly the following information: whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets. (Annex III.- Information requirements for biocidal products, N.1.): Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are scientifically appropriate , whenever possible internationally recognised and the appropriateness of which must be justified in the application. When test methods are applied to nanomaterials, an explanation shall be provided of their scientific appropriateness for nanomaterials, and, where applicable, of the technical adaptations/adjust-ments that have been made in order to respond to the specific characteristics of these materials.
RoHS - Restriction of Hazardous Substances in Electrical and electronic equipment *Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (8. June 2011)* [EU REGULATION 2011 b]	*The report of the Committee on the Enviroment of the EU Parliament(A7-0196/2010) of June 2010 proposed several amendments -* *(Recital 3 f - new): There is scientific uncertainty about the safety of nanomaterials for human health and the environment, no internationally agreed definition of a nano-material and no internationally agreed test guidelines. The Commission's … SCENIHR adopted on 28-29 September 2005 an opinion on nanotechnologies which concluded that there were "major gaps in the knowledge necessary for risk assessment" and concluded that "existing toxicological and eco-toxicological methods may not be sufficient to address all of the issues arising in relation to nanoparticles". There is increasing scientific evidence that some carbon nanotubes may behave like asbestos fibres and thus have severe impact on human health. The same applies to nanosilver particles which may end up in the environment and may have severe impacts on soil, aquatic and terrestrial organisms.* *(Art. 5 a - new): Nanomaterials -- Economic operators shall notify the Commission of the use of nanomaterials in electric and electronic equipment EEE and provide all relevant data with regard to their safety for human health and the environment over their life cycle… having regard to the information provided by economic operators … the Commission shall assess the safety of nanomaterials in EEE for human health and the environment, in particular during use and treatment, and communicate its findings in a report to the European Parliament and the Council. This report shall be accompanied by a legislative proposal for adequate risk management of nanomaterials in EEE, if necessary……(and) economic operators shall label EEE that contains nanomaterials that can lead to exposure of consumers …* These amendments have not been approved. During the plenary debate of 18 January 2012,the Commission declared its willingness to evaluate potential nano-risks with a view to facilitate an agreement. In a public declaration (Doc. No. 52012PC0139), the Commission declared its position on nanomaterials : The European Parliament and the Council have agreed to invite the Commission to evaluate whether specific treatment may be necessary to address nanomaterials contained in EEE. In this context the Commission understands nanomaterials to be those falling under the definition set out in the Commission Recommendation 696/2011. Potential risks posed by such nanomaterials would be identified with tools

	available under the appropriate legislation for this purpose. Where specific nanomaterials have been shown to pose risks to human health or the environment, the Commis-sion will assess whether specific treatment may be necessary and amend Annex VII as appropriate.

2.4 Nano Regulations in non-European countries

Worldwide there is a constant development of nanotechnology work programmes to study the unknown phenomena of nanoparticles and nanomaterials. Besides Europe and amongst others, several hundred universities from Australia, Asia, South and Nord America offer courses in nanotechnology, still the awareness of the impact of nanomaterials used in research or products is not fully understood. More or less the regulatory framework in those experimenting countries has now to adjust to the enormous wave of new research programmes and industrially used nanoparticles, to secure the safe use of those substances in research and for the consumer.

In Australia, there is currently no existing regulatory system available for nanomaterials. Nevertheless several governmental bodies and agencies are seeking for an integration of nanomaterials in the chemical regulatory framework. First step will be to define wether nanomaterials should be handled as “new chemicals” or if they should be incorporated in the existing chemicals regulations. The Australian Government Department of Industry, Innovation, Science, Research and Tertiary Education (DIISRTE) supports the development of the nanotechnology sector in Australia especially for the industrial sector and provides information on regulations, health and safety information. An agency representing nanotechnology in Australia is the NICNAS, which is involved in regulations of chemicals including nanomaterials for industrial use and research laboratories [NICNAS 2012].

A recent study on the awareness of nanoproducts on the U.S. market showed that the perception of nanotechnologies among U.S. citizens is still low [THE HARRIS POLL 2012]. The U.S. National Nanotechnology Initiative is only one of many bodies to be dealing with the responsible development of nanotechnology. The U.S. Food and Drug Administration (FDA) i.e. handles matters on nanomaterials used in food and cosmetic products, where in April 2012 two new guidance documents were published for the general public to comment on. Those documents include non-binding recommendations for the safe use of nanomaterials [FDA 2012]. The Environmental Protection Agency (EPA) is focusing on the establishment of a secure handling of nanotechnology and an assessment of regulatory body needed for nanomaterials [EPA 2012].

3 Nano Regulation in Austria

In Austria, the debate on possible risks and on special regulation needs with respect to 'nanomaterials' began quite late in comparison to other countries. During the first years of Austria's nano-related activities, the main emphasis was on the encouragement of collaborative industry-led research for nanomaterials. A special funding program ('Förderprogramm Nano') with a budget of ca 5 million € started in 2004 for a five year period, but no additional funds were made available for scientific research or for EHS-related topics.
Nanoregulation and the discussion of possible risks only began in 2007. Several workshops and a number of dossiers produced by a group of researchers at the Institute of Technology Assessment / NanoTrust have contributed.
The 'Austrian Nanotechnology Action Plan' adopted by the Government early in 2010 recommends several measures in the area of the legal framework, especially regarding the protection of workers and the environment.
A recent report of the Institute for Technology Assessment (ITA) on the subject of nano-regulation [ITA 2011 b] concludes that the legal environment in Austria is 'highly complex': European law tends to be more innovative, while the national body of law possesses a more regulatory character and is under strong pressure to adapt, as it is confronted with new regulatory instruments and faces new technical developments. The authors of this report suggest that the 'Austrian Nanotechnology Action Plan' could lead to a change of direction: as a central document that grew out of the collaborative effort of many agencies and actors it 'could [now] assume a structuring and orienting role, concerning nano-regulation'.

The early beginnings – public funding for nano R&D
The first dedicated program for the support of nanotechnologies was recommended in 2002 by an advisory body, the RFT (Council for Research and Technology Development). This suggestion was taken up by the Government, and from 2004 and 2009, public funds of about five Million € were used to support nanotech-related research and development for industrial applications. For all those projects, the participation of an industrial partner was required; basic research or the evaluation of risks by institutes of the universities could therefore not be funded.

Discussions about risks and nano-regulation
Possible risks associated with nanomaterials were not considered during the planning and funding stages.
In 2006, in a report financed by the Ministry of Innovation and Technology (BMVIT), the ITA (Institute of Technology Assessment of the Austrian Academy of Sciences) presented an overview of the accompanying measures that supplemented the R&D (research and development) nano-programs in other countries. The report recommended more dialogues on risks and regulation and the adaptation of existing chemical and product-safety regulation for Austria, where necessary [ITA 2006].

In 2007 in the Austrian Parliament, members of the Green party presented several motions ('parlamentarische Entschliessungsanträge') calling for new regulations of nanomaterials and more research in the field of EHS; however, they were not supported by other factions.

In the following years, delegates of the social democratic party (SPÖ) and the nationalistic 'freedom party' (FPÖ) raised a number of related questions ('parlamentarische Anfragen') addressed to the Ministries of Technology, Health and Environment. Most of them covered regulation, labelling and nano-specific registers; environmental issues and the protection of workers were also mentioned [ITA 2011 a].

With a mandate from the Ministry for Transport, Innovation and Technology, a small project team covering the area of nano risks and nano regulation at the Institute for Technology Assessment (ITA) of the Austrian Academy of Sciences could be funded. This project, 'NanoTrust', is proposed to run for more than three years (until early 2013) and observe the international discussion on EHS and ethical, legal and social issues (ELSI), and to then inform officials and the public about current developments. Several of the NanoTrust-Dossiers deal with regulatory aspects [ITA 2010], [ITA 2011 a], [ITA 2011 b].
An international conference in Vienna in 2008 examined the political and societal aspects of the regulation of nanotechnologies as well as at the current state and the challenges of nanoregulation [ITA 2008].
In 2010, a workshop at the Federal Ministry of Health focused on the topic of regulation for consumer products containing nanomaterials [BMG 2010].

Discussions about risks and nano-regulation in Austria
In 2009, parliamentarians from three political parties (SPÖ, FPÖ, Green Party) asked, in both chambers of parliament ('Nationalrat' and 'Bundesrat') detailed questions about nano-EHS related issues; such as monitoring the use of nanoparticles, health risks associated with nanoparticles and ultrafine particles, the funding of risk research and nano-toxicology, the (insufficient) evaluation of the health risks associated with nanoparticles, and the lack of data about the availability of nano-products in Austria, etc.
The parliamentary sub-committee on science and technology held a discussion in November of 2009 where it stressed the importance of examining the consequences of new technologies, such as GM- and nano-technology, for society, health and the environment. Improved co-operation with the Austrian Academy of Sciences and its 'Institute for Technology Assessment' (ITA) was foreseen, and the department responsible for the funding of nanotechnology (BMVIT) supported this motion. In the summer of 2012, the 'Austrian Council for Research and Technology Development' [ACRT 2012, p. 47] recommended a further strengthening of technological assessment.

3.1 Austrian Nano Action Plan (ANAP)

During the same year, 2009, a wide co-operation of all the stakeholders and interested parts of the public began to work in four different groups (Health and Protection of Employees, Environment, Business, and Science, Research and Development) on a first draft of the Austrian nano action plan ('Österreichischer Aktionsplan für Nanotechnologie').
All of the ministries concerned, as well as agencies, experts and NGOs worked together; the process was managed by the Federal Ministry of Agriculture and Environment with assistance of an external company. After a period of public

consultation, the document was discussed and endorsed at Government level ('Ministerrat') and presented in March 2010 [ANAP 2010].

The intention of the ANAP is "*to push forward innovative developments in a diversity of technology fields and social applications. The potential uses of nanotechnology are manifold, ranging from electronics and automotive technology to consumer products and environmental technology. Austria, too, has decided to make nanotechnology one of its top priorities. It is anticipated that Austria will demonstrate special strength and potential in sensor technology, electronics, materials sciences, chemicals (e.g., paints) and environmental technology*."
At the same time, the ANAP stresses that "… *in order to benefit sustainably and [in] the long term from the opportunities offered by nanotechnology, a practical and transparent debate on the safety of nanotechnology applications is essential. There is thus unanimous agreement that due measure must be given to the identification of nanotechnology's possible risks to health and the environment*."

A key package of measures in the Action Plan is devoted to developing cooperation and reinforcing the dialogue and transparency among all stakeholders, including the general public. The creation of an Austrian nanotechnology information platform (NIP) will rely on experts from different fields and will generate "*practical, high-quality, group-oriented knowledge for all stakeholders, including the general public*".

With respect to EHS risks, the ANAP recommends priority be given to

> "*[filling] the knowledge gaps in the evaluation of nanotechnology's safety, by the bundling of resources and through intensified cooperation and coordination in the European and international context."*

and to

> "*[increasing the] knowledge base of the key stakeholders involved in employee safety, in order to ensure safety and health protection at the workplace when dealing with nanomaterials*."

3.1.1 Definition of 'nanotechnology' in the ANAP

Because no internationally agreed common definition for nanomaterials and nanotechnology was available, it was agreed during the discussion in the working groups of the ANAP to define the term 'nanotechnology' as follows:

> *"The manufacturing or processing of intentionally manufactured nanoscale materials, such as nanotubes or nanoplates, including products made of such materials. Nanoscale means having at least one spatial dimension of 100 nm or less."*

The above definition includes three-dimensional nanoparticles or nanotubes as well as one-dimensional nanofibres or two-dimensional nanolayers. The central aspect of the definition is the deliberate manufacture of the nanoscale materials.

As a result, nanoscale particles or other matter that arise unintentionally, such as asbestos dust or diesel soot, are excluded from the present analysis. Those nanoscale particles that are produced naturally; e.g., by forest fires, volcanic eruptions and sandstorms, are excluded as well.

3.1.2 General recommendations for nano-regulation

As far as regulation is concerned, the summary of the ANAP states that it

> " …. *will be necessary to examine the basic legal framework and to develop it further where necessary, especially with a view to ensuring a high level of protection for the environment and human health. In this respect, the Austrian Action Plan also lays down the main lines of the Austrian position to be taken into account at the European and international levels.* "

The ANAP contains several recommendations in the field of regulation [ANAP 2010, p. 14 ff]

Need for Action / ***Addressees***	**Recommendation**	**Objective /** ***Timeframe***
Regarding the Austrian position on taking nanotechnologies und nanoscale materi-als into account in EU legislation: The process of embedding Nanotechnologies into the EU regulations is in a state of flux. Austria should represent a uniform and coherent position on the individual committees. In this context, compliance with a high level of protection is particularly important. *Addressees : Ministries within whose remit instruments related to nanotechnology are processed*	In all proceedings that deal specifically with nanomaterials and nanotechnologies, it is important to insist on compliance with the precautionary or polluter-pays principle. Solid documentation of the inherent properties as well as the risks resulting from the application should be a prerequisite for entering and remaining on the market. Austria advocates the quick development and interpretation of the existing legal provisions (such as REACH, CLP) in an appropriate form, in order to adequately describe and take into account the properties, risks and effects of nanomaterials. If the relevant legal provisions do not offer the level of protection needed to ensure safe use of nanomaterials, it remains legitimate to require that any nanomaterials in products be declared.	Introducing Austria's position effectively, taking into account especially the requirement of a high level of protection. Winning allies *Short to medium-term*
Definition *Addressees :Policy makers*	An internationally harmonised, short and concise definition of nanomaterials, as generally valid as possible, would be very useful for public debates and legal certainty. Austrian delegates in international and EU Committees should advocate incorporating such a working definition, which should be as uniform as possible and reflect the current state of scientific knowledge, into the various legal regulations (REACH, cosmetics, novel-food, biocides).	Clear, meaningful definition of nanomaterials. To take the discussion of alternatives into account *Short-term*
REACH Regulation: Clearing up uncertainties in the legal framework. Interpreting the regulation and, where necessary, developing it further. References to nanomaterials currently still lacking. Filling information gaps for downstream users in the supply chain, especially SMEs	Basic clarifications, including registration and tonnage limits for nanomaterials. Specifications in a safety data sheet (SDS), specific SDS for nano-applications (characterisation, exposure scenarios, risk management measures). Separate case files for bulk/nanoform, Nanosubstance evaluations. Certain nanomaterials on the list of candidates. (REACH) guidelines for the drafting of SDS (for nanomaterials).	Securing a regulatory framework that enables responsible development of nanotechnologies and ensures an effective basis for risk management for users. Explicit duty to inform knowledge of possible risks. SDS are easier to understand for users when bulk form and

Addressees : Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management. *European Chemicals Agency (ECHA).* *Industrial associations for guidelines*		nanoform are separated. *Short-term*
Examination of the legal framework in employee protection *Addressees :* *Austrian Federal Ministry of Labor, Society and Consumer Protection/Central Labor Inspectorate*	Identifying and, when necessary, defining specific nanoregulations	To ensure a regulatory framework that enables responsible development of nanotechnologies; e.g., by clarifying whether reporting or replacement requirements are necessary for certain nanomaterials *Medium-term*
Examination of the legal framework in consumer protection *Addressees : Policymakers, with the involvement of the relevant institutions*	Examining whether certain 'nanospecific' provisions (e.g., labeling, notification, and registration) are necessary, taking exposure into account. If necessary: Initiatives at EU level	To close any regulatory gaps regarding consumer protection *Medium-term*

3.1.3 Key players in Austria on health- and regulation issues

The ANAP describes the considerable number of institutions that are sharing responsibilities and activities in this field:

The Federal Ministry of Health (BMG) - co-operates with working groups of the European Council and has participated in the creation of the several relevant EU regulations (the Additives Regulation, the Novel Food Regulation and the Cosmetics Regulation); its delegates are also involved in various national and European initiatives.

The Federal Ministry of Labor, Social Affairs and Consumer Protection (BMASK) – helps to safeguard the interests of employee protection through the activities of the 'Central Labor Inspection Authority' in co-operation with the AUVA (Austrian Social Insurance for Occupational Risks). These institutions participate in relevant international conferences, such as the NANOSH (European Commission's 6th Framework Programme) meetings in 2007 and 2009.

The AGES (Federal Austrian Agency for Health and Food Safety) is in charge of food control, public health, veterinary medicine and agriculture; it is the Austrian focal point for the European Food Safety Agency (EFSA). The work of AGES includes risk assessments throughout the entire food chain, the development and use of statistical methods for efficient and scientific assessment of human, animal and plant health, as well as compiling risk databases - including work done on potential risks associated with nanomaterials used in the food sector. Through its direct contacts with the European Food Safety Agency (EFSA), AGES has access to the ongoing projects on food safety and nanotechnologies at the level of the European Commission and its advisory committees.

The Austrian Social Insurance for Occupational Risks (AUVA) has a statutory mandate in Austria to prevent occupational illnesses and accidents. For several years AUVA has been investigating the health impact of ultrafine dust/nanomaterials in the workplace in

co-operation with the Austrian Society of Occupational Medicine (ÖGA). An associated institution, the 'Austrian Dust and Silicosis Control Office' (ÖSBS) has profound expertise in measuring levels of dust exposure at the workplace and in protection measures. Experts from AUVA are represented in numerous international bodies, such as the International Social Security Association (ISSA) which is investigating nanotechnologies in connection with employee protection.

The Environment Agency Austria (Umweltbundesamt GmbH) - on behalf of the Ministry of Life, the Environment Agency Austria performs tasks within the scope of the EU-REACH competent authorities and is therefore involved in the further development of the REACH regulation in the field of nanomaterials.

3.2 Workplace safety

The basic law in Austria for the protection of workers at their workplaces is the Workplace Safety Act ('Arbeitnehmerinnenschutzgesetz') [ASCHG 1994], together with rules regulating the permissible levels of dust; the Threshold Value Ordinance ('Grenzwerteverordnung') [AGVO 2011]. For Federal employees, the Federal Employee Protection Act ('Bundes-Bedienstetenschutzgesetz') and the associated Federal Threshold Value Ordinance ('Bundes-Grenzwerteverordnung') are in force. For all employees, the maximum allowed value (MAK-'Maximale Arbeitsplatzkonzentration') has been defined in the Threshold Value Ordinance as not more than 10 mg m-3 (for the inhalable fraction) and not more than 5 mg m-3 (for the respirable fraction) for non-toxic (biologically inert) fine dust. The MAK value is taken as the average level of dust during a work day of eight hours and a working week of 40 hours; the same ordinance defines several precautions and special requirements for carcinogenic, mutagenic or toxic to reproduction (CMR) substances, for wood dust and for asbestos.
The Workplace Safety Act [ASCHG 1994] defines the instruments for the protection of safety and health at the workplace, and the employer has a special responsibility to guarantee this protection (§ 3.(1)). The employer must also determine and assess dangers to the health and security of their employees and avoid work-related hazards (§3.(2)). In this respect, the employer must refer to the 'latest technical knowledge'. Again, nanomaterials and any risks their production and use may entail are not mentioned explicitly.

3.3 Material and Product Specific Regulation in Austria

Nanomaterials are generally covered under the provisions dealing with chemicals, such as REACH. In addition, several specific legal rules exist that describe special requirements or products that contain nanomaterials or that are produced with the help of nanotechnology [ITA 2009].

3.3.1 Chemicals

REACH regulation, as discussed above, was created at the European level and is directly applicable in Austria. The Austrian Chemical Substances Act ('Chemikaliengesetz') defines the implementation measures [CHG 1996].

3.3.2 Biocides

In order to implement the European Biocidal Products Directive, Austria adopted the Biocidal Products Act ('Biozid-Produkte Gesetz'[BPG 2000]). 'Biocidal products' are defined as "active substances containing, in the form in which they reach the user, one or more active components [that] are destined to destroy, deter or render harmless, in a chemical or biological way, harmful organisms" (in : § 2 (2)). Together with the 'Ordinance on Existing Active Biocidal Substances' ('Biozid-Altwirkstoffverordnung') [BPG 2008], the introduction of biocidal products and the monitoring of their use are defined for Austria. In § 1 of the national 'Biocidal Products Act', the basic requirements are defined: "… the overall aim of this federal law is to limit the introduction of biocidal products to those that are - if used in the way they are intended to be used - not harmful to the health of persons or animals (apart from those intended for harmful organisms) and that will not result in unacceptable consequences for the environment". The Act foresees extensive notification, registration and authorization procedures. Specific characteristics (and risks) of nanomaterials that could be used in biocidal products are not mentioned.

3.3.3 Plant protection products

On the European level, pesticides; i.e., 'crop protection' products, are included in the EU regulation for biocides [EU REGULATION 2012]. In Austria, however, they are regulated by a separate act: the Pesticides Act ('Pflanzenschutzmittelgesetz'), which came into force in June 2011 [PSG 2011]. It covers the requirements with respect to the marketing of pesticides in accordance with the relevant EU directives 1107/2009 and 2009/128/EG.

A novelty for Austria is the 'register of approved businesses' (Betriebsregister), which has been required since December 2011: any commercial enterprise that stocks, sells or advertises pesticides in Austria must inform the Federal Austrian Agency for Health and Food Safety (AGES) in advance before commencing commercial activities. The Austrian authorities have no information concerning the registration of pesticides containing nanomaterials [ITA 2011 a].

In their report in 2008, the German 'NanoKommission' [NANOKOM 2008] remarked that, for a number of years, a fortifying agent for plants ('Pflanzenstärkungsmittel') containing nanoparticles of silver and called 'Nano-Argentum 10' of the Swiss company 'NanoSys' had been approved in Germany by the Federal 'Julius-Kühn Institute' for use on flower and vegetable crops in order to "enhance resistance to fungi, viruses and bacteria" [JKI 2009]. The German experts of the 'NanoKommission' recommended a re-evaluation of the assessment of the risks of this product, considering the detrimental effects of nanosilver to aquatic organisms. They stress that such open use, which must lead to the release of nanoparticles to the environment, is a serious matter and should be avoided.

3.3.4 General Product Safety

On the European level, the legislation on product safety [EU REGULATION 2001] imposes on economic operators "the general obligation to market only safe products" (Rec. 3). It covers hazardous products and applies to all products that are not covered by any specific legal framework.

The main responsibility lies with the Member States - they must "take appropriate measures with regard to dangerous products located within their territory" (Recital 29).
The Austrian law in this respect is the 'General Product Safety Act' ('Produktsicherheitsgesetz')
[PSG 2004]; it applies if no other specific product safety regulations apply for those products. It does not apply, however "where the definition of necessary safety requirements falls under the jurisdiction of the Austrian states"; such as agricultural products (§ 2. (3.)). Generally, the "manufacturers and importers are only permitted to introduce products into the market which are safe" (§ 6.(1.)), but the General Product Safety Act does not require official authorization, control or notification procedures before the products enter the market. Compliance with the provisions is ensured "through state market monitoring by the provincial governors and products safety supervisory bodies" (§ 13.(1.)); in addition, the federal minister may also take measures if safety requirements are not met or if dangers are present (§ 12., § 15.).

As all products are, in principle, covered, those containing nanomaterials should also be included. However, nanospecific properties are not mentioned anywhere. The possibility for gaps of coverage has been discussed [ITA 2011 a]:

- as no pre-market requirements exist, determination of the existence of any nano-related risks requires thorough monitoring;

- the Act does not apply to products for which the federal provinces are competent as far as safety requirements are concerned (such as : agricultural products);

- whereas the protection of human life and health is mentioned, potential dangers to the environment are not within the scope of this Act.

3.3.5 Cosmetics

The European regulation on cosmetic products [EU REGULATION 2009] shall enter into force in July 2013 and will replace several domestic provisions in Austria (ordinance on cosmetics, cosmetic-dyes and on cosmetic labelling). Austria had not foreseen an official pre-marketing examination for cosmetics and had assigned the responsibility for a safety assessment to the manufacturer or importer of the cosmetic product. The current labelling requirements do not demand any information on the usage of nanomaterials; this will change as soon as the European regulation applies in Austria.

3.3.6 Food

On the national level, the Austrian 'Food and Consumer Protection Act' (Lebensmittel- und Verbrau-cherschutzgesetz) describes the legal requirements concerning food and drinking water, cosmetics and consumer goods. It builds upon the relevant EU directives (§ 2.(2).
Since 2006, the national Parliament has passed several amendments [LMSVG 2006]. The main provisions aim at the "protection of the health of the consumers and his/her protection against deception" (§ 2.); it is explicitly forbidden "to introduce food that is unhealthy or unfit for human consumption ... or adulterated or of lower value into the market" (§5.(1)). In addition, misleading labels or avertisements concerning food are also forbidden; such as incorrect descriptions of properties, contents, origin, or promises with respect to health-inducing properties (§ 5. (2)).
The safety of food remains the responsibility of the food business, which is obliged to control compliance with legal requirements. Control measures are the responsibility of the privincial governors (§ 24.(1)).
The application of nanotechnology in the production of food, or the use of nanomaterials as components in materials destined for human consumption, is not mentioned anywhere specifically in the Act.

The European regulations concerning food-contact materials can be found in the Framework Regulation (EG 1935/2004)[EU REGULATION 2004], which requires that all those 'materials and articles intended to come into contact with food' are safe and must not 'transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its taste and odor'. An authorization procedure for all food contact materials is required: applicants must submit application to the European Food Safety Authority (EFSA).
The EFSA will evaluate the dossier and provide a statement concerning nanomaterials. The Scientific Committee of EFSA published a report in 2012 concerning the safety evaluation of titanium nitride nanoparticles, stating that "under the intended conditions of use (as a component in polyethylene terephthalate (PET) bottles), no migration of the substance into food is expected and therefore no exposure of the consumer via food is expected. Based on this ... there is no safety concern for the consumer if the substance is used up to 20 mg/kg in only PET plastics intended for contact with all types of foodstuffs under conditions of any duration of time …" [EFSA 2012].

The EU directive on 'good manufacturing practice for materials and articles intended to come into contact with food' [EU DIRECTIVE 2006] complements the list of authorized substances. It describes, again for food-contact materials, the "total sum of the organized and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use" (Art. 3. (b)).

3.3.7 Medical Devices and Medicinal Products

Medicinal Products

The manufacturing and marketing of medical products and devices is regulated under the EU directive 93/42/EWG [EU REGULATION 1993] and, at the national level, under

the Austrian Medical Product Act (Arzneimittelgesetz) [AMG 1983]. In general, these products are subject to an official authorization process. The devices "must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety" (Annex I, P. 1). Devices are grouped into different classes - I, IIa, IIb, and III (Art. 9, and Annex IX) - and the manufacturer must present to the administrative authority proof of 'conformity' to qualitative standards.

Medical devices
The specific rules in Austria are contained in the Medical Devices Act ('Bundesgesetz betreffend Medi-zinprodukte') [APMG 1996], which defines as its main task ensuring "the safety and quality of medical devices, their production, marketing, construction, maintenance, use, control …". The background is defined by the European regulatory landscape; i.e. product standardization on the internal market allowing the distribution and use of the products equipped with the 'CE' label (§ 15). In addition, Austria has defined an advisory council ('Abgrenzungs- und Klassifizierungsbeirat', § 5b.). The Federal Bureau for Safety in the Health Sector ('Bundesamt für Sicherheit im Gesundheitswesen') is responsible for clinical tests (§ 40.). There is also a national register containing data on all commercial agents importing or distributing medical devices (§ 60.).
Any existing dangers resulting from nanomaterials already in use or planned to use, such as coating of implants for better bio-compatibility or antiseptic properties, and special nano-dyes used in diagnostics, will be dealt with as part of the fundamental safety requirements.

The EU Agency for Medicines presented in 2006 a 'reflection paper' on nanotechnology-based medical products [EMEA 2006]. The EMEA experts point out that "many novel applications of nanotechnology will span the regulatory boundaries between medicinal products and medical devices … (those) nanomedicinal products may exhibit a complex mechanism of action combining mechanical, chemical, pharmacological and immunological properties and combining diagnostic and therapeutic functions. Furthermore, additional specialized expertise may be required for the evaluation of the quality, safety, efficacy and risk management of such nanomedicinal products."

Austrian law does not mention nanomaterials and their associated risks (or any nanomedicinal products), but in § 5b. the question of regulatory boundaries was raised: the advisory council will give its scientific expertise "concerning questions of boundaries between medical products and other types of products".

3.3.8 Industrial Law and Environmental Protection

In Austria, industrial installations are ruled by the Industrial Code ('Gewerbeordnung'). They are subject to approval by the authorities if they might be a source of nuisance to neighbors or of hazards to human life and health or to water bodies (§ 74) [AGO 1994]. An installation must be approved if both specific pollution and emission criteria are

fulfilled (§ 77.). Elimination (or reduction to an 'acceptable level') must be done according to 'the state of technical knowledge' (§ 71.a, § 77.) and the 'state of medical science or other relevant areas of science' (§ 77.).
For the emission of particles and gases into the air, § 77.3 refers to the Air Pollution Control Act, ('Immissionsschutzgesetz-Luft') [AIGL 1997], which was amended recently in order to fulfill the EU directive on 'ambient air quality and cleaner air for Europe' [EU REGULATION 2008 a]. Threshold limits for the emission of air pollutants must be set, as a minimum requirement, according to 'the state of technical knowledge'. In areas where significant levels of air pollutants have previously been measured, approval for a new industrial installation can be given only if it can be shown that it will bring no significant contribution to the total pollution load.

In Europe, the major industrial production processes have been subject to special set of rules since 1996 [EU Regulation 1996] under the heading 'integrated pollution prevention and control (IPPC)'. On the national level, Annex 3 of the Austrian Industrial Code defines additional requirements for approval for this special class of IPPC installations (large plants for steel and ore, the energy sector, the chemical and food industries, etc.) in order to avoid or reduce emissions of pollutants into water, air and soil. The study of the German Öko-Institut on 'legal appraisal of nano technologies' [UBA 2007] describes the relevant EU directives in greater detail. Nanomaterials are not mentioned explicitly in the European IPPC directive or in Austrian law. However, § 77 a. of Austrian law contains a general provision that may cover possible risks due to nanomaterial emissions from industrial installations; § 77 declares: "beyond those measures that are required with respect to § 77. … it must be safeguarded that those industrial installations take all suitable safety precautions against damage to the environment that is caused by the release of substances - whether through a direct or an indirect path - that may result in damage to human health or the quality of the environment."

Rules concerning 'very dangerous industrial accidents' are laid down in Annex 5 of the Austrian Industrial Code. For several types of industrial installations ('Seveso-II-establishments') that use a toxic, flammable or explosive substance listed in Annex 5, specific precautionary procedures must be followed; again, nanoparticles are not mentioned here.

The Austrian Industrial Code does, however, only cover commercial installations; i.e., "all those immobile installations that are destined to be used on a regular basis as part of a commercial enterprise" (§ 74.). Exemptions are possible; § 74.7. empowers the Minister for Industrial Affairs to issue a declaration covering defined types of industrial enterprises "… if it can be expected that they would pose no hazard to human life and health or to water bodies ", which would nullify the obligation to seek approval.

As Annex 3 (P.1.) describes, an important group of installations are already explicitly exempted from this norm; i.e., "(all) installations which merely function as scientific, development and testing installations for new products and procedures" (Annex 3, Pt. 1.).

The importance of such a possible 'loophole' has been discussed intensively in Germany; in 2010, 'Bayer MaterialScience' opened a very large 'pilot facility' for the production of up to 200 tons of carbon nanotubes (CNT) in Leverkusen. According to the company, it is the world's largest pilot facility for these nanomaterials; an upgrade to a capacity of 3000 ton per year has been announced for the near future [Plastics 2010]. Yet this facility is still considered to be only a pilot installation. A regular approval process, which would have necessitated public participation and an assessment of the effects for the environment [EU Regulation 1985] has thus been avoided.

The district government has declared that "this material (CNTs) has not been declared in the SDS as dangerous" [NRW 2010]. The Government has set limits for exposure in the work place on the basis of a suggestion by the company [VDI 2011]; the allowed value is 0.05 mg m^{-3} (or 50 µg), considerably higher than a recent proposal of the US National Institute for Occupational Safety and Health (NIOSH); i.e., less than 7.µg CNT m^{-3}) [ITA 2012].

In a previous case, the authorities in Germany's southern province Baden-Württemberg approved a production facility for nano-powders in 1999 and had imposed a low emission level (1 % of the permitted level for fine diesel soot) [UBA 2007, p. 12]. This decision was contested by neighboring residents, but the German Supreme Court for Administrative Matters in Leipzig ('Bundesverwaltungsgericht') confirmed the original decision by the authorities in 2003. In the opinion of the Supreme Court judges, the original decision was based on an independent assessment of the risks and was not arbitrary; the potential health risk seemed negligible [BVWERG 2003].

Environmental Protection

The recent report of the independent German Advisory Council on the Environment on 'Precautionary Strategies for Managing Nanomaterials' [SRU 2011] describes as the "basic problem in protecting the environment from nanomaterials is … the patchy knowledge about their environmental release, behavior and impacts" due to the lack of scientific information. The experts assume that, currently, "only a small number of synthetic nanomaterials enter the environment to a significant extent". As this volume is expected to increase, however, they see an "urgent need to ensure that nanomaterials enter the environment in the smallest possible quantities".

The conclusion of the SRU report identifies as priorities:

- changes to the legislation governing industrial facilities: the use of insoluble or barely soluble nanomaterials should require approval under pollution law, and consideration should be given to the introduction of a notification requirement for all production processes and industrial uses of nanomaterials;

- protection of environmental media: faster assessments and decisions are necessary with respect to emission limits (or prohibitions) for individual nanomaterials or identifiable groups of nanomaterials; in addition, the

emission of nanomaterials for which 'an abstract concern' has been identified should be limited as far as possible;

- waste: for precautionary reasons (and until more specific knowledge of the behavior of nanomaterials in the waste stream is available), at least production waste containing nanomaterials should be classified as 'hazardous waste'; for certain waste containing nanomaterials, thought should be given to establishing 'take-back schemes' to prevent those materials from being disposed of as part of municipal waste.

Austria does not currently have a law encompassing all aspects of environmental protection. The Austrian Federal Act on Comprehensive Protection of the Environment ('Bundesverfassungsgesetz über den umfassenden Umweltschutz') - a short declaration with not more than three paragraphs - describes the general goal as "comprehensive environmental protection means the safeguarding of the natural environment that is the basis for human life" (§ 1.(2)) [AUWG 1984].

For the protection of the air, the Air Pollution Control Act ('Immissionsschutzgesetz-Luft') is the most important measure [AIGL 1997], it was discussed above in connection with industrial law.
Rules concerning protection of the soil can be found in various regulations of the provincial governments, such as the law of the province of Styria and the associated Ordinance [STMK 1987].

As far as water is concerned, the relevant Austrian regulations are part of the Federal Water Act ('Wasserrechtsgesetz') [AWRG 1959], which states that "all bodies of water - including the ground water - must be kept clean and protected such that the health of human beings and animals cannot be endangered, that aquatic ecosystems are protected and improved, and that the long-term protection of the available resources must be ensured." (§ 30.). Groundwater and spring water must be kept clean; its use as drinking water should be possible.
Industrial specific provisions are to be found in § 9 and § 10; if the surface water or ground-water is intended for domestic or commercial use, an approval by the public authority ('Wasserrechtsbehörde') must be sought. Intended industrial uses that are in contradiction to the public interest (§ 105.) will not be approved. The state of technical knowledge will be the guide for all technical installations and uses (§ 12 a.). According to § 31., everyone is obliged to exercise diligence so that the installations are constructed, maintained and operated in such a way that the protective goals (§ 30.) are observed and all pollution is avoided.

Annex E of the Water Act contains a non-exhaustive list of several important pollutants, together with a list of 'priority materials' taken from several European directives (No. 2455/2001/EG, No. 82/176/EWG, No. 83/513/EWG, No. 84/156/EWG, No. 84/491/EWG, and No. 86/280/EWG).

Neither the Austrian Water Act nor the relevant EU directives mention specific requirements for nanomaterials.

3.4 Literature Overview

Introduction, European Level and Nano Regulation in Austria

Short Title	Description
ACRT 2012	Austria - Rat für Forschung und Technologieentwicklung (Juni 2012), 'Bericht zur wissenschaftlichen und technologischen Leistungsfähigkeit Österreichs 2012', http://www.rat-fte.at/tl_files/uploads/Leistungsberichte/Leistungsbericht2012.pdf
AGVO 2011	Austria - Rechtsvorschrift für Grenzwerteverordnung (2011) http://www.ris.bka.gv.at/Bund/Gesetzesnummer=20001418
AGO 1994	Austria - Gewerbeordnung (1994), In : BGBl. Nr. 194/1994, http://www.ris.bka.gv.at/ …. Gesetzesnummer=10007517
AIGL 1997	Austria - Immissionschutzgesetz-Luft (I-GL), (1997), BGBl. I Nr. 115/1997, rev. Fassung aus 2012, http://www.ris.bka.gv.at/... Gesetzesnummer=10011027
AMPG 1996	Austria - Bundesgesetz betreffend Medizinprodukte, in : BGBl. Nr. 657/1996 und div. Novellierungen, http://bmg.gv.at/cms/home/attachments/ 7/9/0/CH1095/CMS1228212263945/medizinproduktegesetz_kompiliert.pdf
AMG 1983	Austria - Arzneimittelgesetz vom 2. März 1983, in der novellierten Fassung (28.06.2012), http://www.ris.bka.gv.at/GeltendeFassung/Bundesnormen/ 10010441/AMG%2c%20Fassung%20vom%2028.06.2012.pdf
ANAP 2010	Austrian Nanotechnology Action Plan - Lebensministerium (Ed.), (2009/2010), http://www.nanoinitiative.at/1560_EN.pdf
ASCHG 1994	Austria - 'Bundesgesetz über Sicherheit und Gesundheitsschutz bei der Arbeit' (Arbeitnehmerinnenschutzgesetz - ASCHG) http://www.ris.bka.gv.at/Bund/Gesetzesnummer=10008910
AUWG 1984	Austria - Bundesverfassungsgesetz über den umfassenden Umweltschutz, in : BGBl. Nr. 491/1984, novelliert mit BGBl. Nr. 685/1988, http://www.ris.bka.gv.at/Dokumente/BgblPdf/1984_490_0/1984_490_0.pdf
AWRG 1959	Austria - Wasserrechtsgesetz (1959),Fassung vom 1.7.2012, http://www.ris.bka.gv.at/... Gesetzesnummer=10010290
BEUC 2009	European Consumers Organization (BEUC) and European Association for the Consumer Representation in Standardization (ANEC): 'Nanotechnology: Small is beautiful but is it safe?', (Nov. 2009), http://www.steptoe.com/assets/htmldocuments/BEUC_Nanotechnology%20-%20Small%20is%20beautiful%20but%20is%20it%20safe_Oct2009.pdf
BEUC 2012	European Consumers Organization (BEUC) : 'Nano- very small and everywhere - a technological magic silver bullet or a serious safety risk ?' (Juni 2012), http://docshare.beuc.org/Common/GetFile.asp?ID=43295&mfd=off&LogonName=Guesten
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4 Nano Regulation in Czech Republic

4.1 Czech Nano Action Plan

The regulatory status of nanomaterials in the Czech Republic is currently very similar to the rest of Europe and many other countries. Responsible Czech authorities will co-ordinate legislation process in this field with other countries (mainly EU members) - from this reason in CZ do not exist a relevant Action plan. Czech experts actively cooperate in the preparation of appropriate legislation on the international level. Czech government recognizes that problem of nanomaterials and nanotechnology is very serious and important pursuant to below facts.

In last five years, nanomaterials and nanotechnology and its application experienced a steep growth in almost all areas of human activities. This is valid despite of fact that in many cases, the real properties of those new materials regarding their effects on living organisms and environment are mostly unknown or unprecised. Nanomaterials act differently than their relatives in macro-form – e.g. nanoparticles have ability to pass barriers where standard-size particles are stopped. So far, the same approach was chosen as for general material, but not every time it is the most correct one.

Few published works dealing with potential risk properties of nanomaterials show that while many substances present in their standard form do not reveal any biological activity, nano forms of same substances have negative ecotoxicological test outcome. Thus, another question arise: what is the key acting factor? In the testing process, nanomaterials aggregate very easily into larger groups often larger than the nano size limitation. Currently, the most appropriate toxicological and ecotoxicological testing procedures for nanomaterials are examined by one workplace in the Czech Republic. The research is granted under the R&D programme of Ministry of Industry and Trade of the Czech Republic.

Due to the specific properties, nanomaterials are able to pass biological barriers, penetrate organisms and potentially induce negative biological effects.[1] The key area in the assessment of human health related risks of nanomaterials is genotoxicology. Studies performed on artificial nanomaterials show that mechanism of genotoxic effect can be connected to induction of chromosomal fragmentation and creation of DNA breaks, point mutations and oxidation adducts of the DNA.[2] The first step in the nanomaterials risk assessment is the exact definition and characterization of properties and understand interactions with relevant biological systems.[3] Although, it exists an incertitude on which of physic-chemical properties of nanomaterials have the most important effect on their biological activity. Amongst others, one can consider: size, shape, crystalline structure, degree of agglomeration, charge and chemical composition of surface.[4]

A number of available studies dealing with mechanism of “catching” nanomaterials by various types of cells and distribution of nanoparticles prove that it is not possible to describe

[1] Neenu Singh, Bella Manshian, Gareth J.S. Jenkins, Sioned M. Griffiths, Paul M. Williams,Thierry G.G. Maffeis, Chris J. Wright, Shareen H. Doak, *Biomaterials **30**, 3891–3914 (2009)*

[2] Saber M. Hussain, Laura K. Braydich-Stolle, Amanda M. Schrand, Richard C. Murdock, Kyung O. Yu, David M. Mattie, John J. Schlager, Mauricio Terrones, *Adv. Mater. **21**, 1549–1559 (2009)*

[3] Saber M. Hussain, Laura K. Braydich-Stolle, Amanda M. Schrand, Richard C. Murdock, Kyung O. Yu, David M. Mattie, John J. Schlager, Mauricio Terrones, *Adv. Mater. **21**, 1549–1559 (2009)*

[4] Neenu Singh, Bella Manshian, Gareth J.S. Jenkins, Sioned M. Griffiths, Paul M. Williams,Thierry G.G. Maffeis, Chris J. Wright, Shareen H. Doak, *Biomaterials **30**, 3891–3914 (2009)*

this with one common mechanism.[5] The most important mechanism are diffusion through the plasmatic membrane – either directly or via membrane channels 10 to 30 nm wide – and endocytosis. The last mentioned mechanism is preferred for the internalisation of nanoparticles and particles up to 200 nm in size. Also, inhalation toxicity studies show that nanomaterials are more toxic in comparison with their relevant standard forms. They more easily penetrate lungs a place themselves in different types of cells.
The problematic of nanomaterials testing procedures is for more over 5 years studied by OECD programme. On 48th Joint Meeting of the Chemiclas Committee and the Working Party on Chemicals, Pesticides and Biotechnology in February 2012, the results of thw working programme were summarized. One of the essential recommendation of this working group is to continue in research and development of new toxicological and ecotoxicological tests where current methods described in Technical Guidelines for Testing are not sufficient. Groups of experts also stated that current testing methods are sufficient but it is necessary to adapt them to properties of nanoparticles.

Situation in the Czech Republic
In 2011, there was 272 projects dealing with nanotechnology and/or nanomaterials in the R&D sector. According to data from ČSNMT (The Czech Society for New Materials and Technologies), the interest in nanomaterials is growing:

Subject	2005	2008	2011
Academy of Sciences	18	26	28
Universities	13	15	18
Faculties	28	37	45
Private research institutions	9	15	23
Allowance organizations	4	9	16
Large companies	6	12	16
SME‘s	19	57	126
TOTAL	**97**	**171**	**272**

The system of support of R&D in Czech Republic is somehow scattered and thus not totally clear. The sum of resources allocated by State and potentially from the European structural funds in 2008 can be estimated to 1,85 billion CZK. In the following years, the amount was conserved or slightly upgraded.
In the past, eight regional R&D centres were created who are conducting research in the field of nanotechnology and nanomaterials side by side to their practical applications. Their creation and financing is supported from structural funds and state budget (around 4,2 billion CZK).
The Czech Society for New Materials and Technologies published in its report on nanotechnology and nanomaterials: “More than 230 subjects counting public and private sector together are dealing with nanotechnologies. The interest in this future-bound area is constantly growing mainly between private companies. Often, private companies understand nanotechnology as opportunity to take a step ahead of their competition and start industrial application of nanotechnology, mainly production of nanomaterials.”

[5] Saber M. Hussain, Laura K. Braydich-Stolle, Amanda M. Schrand, Richard C. Murdock, Kyung O. Yu, David M. Mattie, John J. Schlager, Mauricio Terrones, *Adv. Mater.* ***21****, 1549–1559 (2009)*

With regard to above-mentioned, it is clear that also the future development of nano-sector will have a fast entry into application level. Some of the unique applications are listed as follows:

- all-round method of modifying solid materials by nanosilver (Olomouc)
- production of nanofibers by electro spinning (Liberec)
- sound absorbing material (Liberec)
- filters with antimicrobial effects (Liberec)
- nanofibers from biopolymers for health care (Dolní Dobrouč)
- teeth implants using nanotitanium (Ostrava)
- photocatalytical active paints (Praha, Kaňovice)
- nanoparticles of iron – contamination removal (Rajhrad u Brna)
- spintronica parts for electronics using anti-ferromagnetic principle (Praha)
- nanocomposites for diagnostics of tumor disease (Praha)

Surely enough, another momentum powering (mainly applied) research will be provided by creation of Competency centres. There, a major part of subjects are planning to concentrate their activities in nano-field. In the first four years of existence, the funding is counting on with several tens of billions CZK from which a part will be spent on necessary technical background and consecutively on research of new materials and their applications.

The Czech Society for New Materials and Technologies is currently the biggest and the most important professional association. Members come from R&D facilities and produciton units and group in Nanosection founded in 2002. Today, this section counts more than 130 members. The section aims to:

- develop creative capabilities and knowledge of members in nanotechnology area
- stimulate closer cooperation of research teams and innovation oriented companies in Czech Republic
- support member involvement in the international cooperation in R&D
- promote Czech nanotechnology scene and its results in foreign countries

The Nanosection activities are mainly

- organisation of expert conferences, workshops and forum on nanotechnology and nanomaterials
- publishing
- consultancy and services in nanotechnology
- conducting international dialogue and mapping safe research and development of nanotechnology and application of results with regard to human health and environment
- mapping process of standardization of nanoapplications
- support of education in nanotechnology at Universities
- international cooperation focused on R&D support for nanotechnologie

The section organises the biggest event in the nano-field in the Czech Republic – NANOCON – where more than 350 experts from 28 countries participated last year. This year event NANOCON 2012 will be held between 23rd and 25th November in Brno.

4.2 Workplace safety

The regulatory status of nanomaterials in the Czech Republic is currently very similar to the rest of Europe and many other countries (see above). There is no special legislation act which would regulate a safe research, development, production, distribution or use of nanomaterials and/or nanomaterial-containing products. The issue is considered very

sensitive to general public because it has direct impact on both human health and environment. As the mechanism of action is different in the case of nanoparticles, commonly used systems for risk assessment fail. Much more, no validated testing methods are known to obtain necessary data. Both issues are inspected and researched by OECD but results cannot be expected earlier than few years from now. Eventually, another delay can be expected in the transposition to national legislation.

For the same reason as mentioned, there are no national safety or hygienic regulations to work with nanomaterials. The nano-issue is solved individually and separately in different organisations/subjects dealing with nanomaterials. In general, those can be called “in-house” rules which respect conditions of relevant workplace, material, type of activity together with prescribed personal protective equipment or modification of operational conditions, e.g. installation of air-conditioning to preserve stable air-pressure. But sometimes, the safety of handling nanomaterials is not dealt with at all. Usually, it is recommended to apply the same risk management measures as in microbiological workplace. Unfortunately, such RMMs cannot be regarded as sufficient.

The risk assessment of nanoparticles as such is not performed. In case a nanomaterial is a new substance, a general approach is used as it would be a standard new chemical substance – as such, the substance can be subject to registration according the REACH regulation and/or classification and labelling rules described in the CLP regulation. With regard to above mentioned part on toxicology and ecotoxicology, it is clear that such approach can be easily considered insufficient and large waste of resources of a registrant because of discussable applicability of current testing methods.

4.3 Material and Product Specific Regulation in Czech Republic

4.3.1 Chemicals

Same as in the whole EU, manufacture, placing on the market and handling of chemicals is generally regulated by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).[6] This Regulation requires gathering of wide spectrum of information on substance properties for all substances manufactured or placed on market in the European Union. The Regulation cancelled previously valid national pieces of legislation which usually required gathering of information only for new substances.

Chemicals in Czech Republic are regulated by Act no. 350/2011 Coll. so called “chemical law”.[7] The main goal of the new Chemical Act is to provide compliance of the Czech legislation with the European REACH and CLP regulation[8].

The classification, labelling and packaging of chemical substances is described and carried out in the CLP regulation which is the European adaptation of the UN GHS (Global Harmonised System).

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[7] Zákon č. 350/2011 Sb., o chemických látkách a chemických směsích a o změně některých zákonů

[8] Regulation (EC) No 1272/2008 of the EU Parliament and the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

In 2010, an electronic register of chemical preparations (mixtures) was implemented as an add-on to the system of safe handling of chemicals by Notice no. 265/2010 Coll.[9] This notice set up the institute of Toxicological Information Centre (TIS) where information on mixtures and emergency medical help in case of accident are stored and available if necessary.
With regard to the previously mentioned, nanomaterials are not directly regulated but regarded as standard chemicals. Obviously, some nanomaterials are already registered according to the REACH regulation (e.g. titanium dioxide nano-fraction).

4.3.2 Biocides

Biocidal products and active substances that are placed on market in the Czech Republic is compliant with the EU legislation. This is provided by Act. nr. 12/2002 Coll.[10], lately amended by Act. 342/2011 Coll.[11] Actually, new pan-European legisaltin act is under preparation which, e.g. transfer competencies to ECHA. Nevertheless, the draft of new biocide regulation does not contain any special parts dedicated to handling biocides with nanomaterial forms.

4.3.3 Plant protection products

The placing on market of pesticides and their use was recently regulated by Act n.326/2004 Coll. Unfortunately, this Act was not compliant with Regulation of European Parliament and Council (EC) n.1107/2009 dated October 21, 2009 on placing plants protection products on the market and as such was amended by Act n. 245/2001 Coll. Again, no special attention or requirements on nanomaterials as part of plant protection products.

4.3.4 General Product Safety

Products which do not fall under regime of special legislation act (like chemicals, biocides etc.) are usually marketed in Czech Republic after testing of safety performed by authorised person acknowledged by procedure according to Act 22/1997[12]. Such authorized persons (formerly State Examination Institutes) are granted permission and obligation of Czech office for standards, metrology and testing for testing various products and product types. The Act itself was repeatedly amended, latest amendment date from 2011. Notices to this Act define what types of products are regulated by this legislation (e.g. toys, some electric products..). All legislation is aligned with European regulations.
The goal of general product safety regulations is to assure safety of product and protect the health of consumer. National legislation is used where no European direct or implementing legislation exists. Other organisations controlling safety of products are called Certification institutes acting according to national norm ČSN EN ISO 450011 and respecting European criteria of product safety. Both institutes focus on mechanical, fire resistance and human health fitness. The latter also includes analytical check of potentially harmful substances. Although there is a number of different products containing nanomaterials on the market

[9] Vyhláška Ministerstva zdravotnictví 268/2010 Sb o poskytování informací o některých nebezpečných chemických přípravcích
[10] Zákon č. 120/2002 Sb., o podmínkách uvádění biocidních přípravků a účinných látek na trh a o změně některých souvisejících zákonů
[11] Zákon 342/2011 Sb., kterým se mění zákon č. 120/2002 Sb., o podmínkách uvádění biocidních přípravků a účinných látek na trh a o změně některých souvisejících zákonů,ve znění pozdějších předpisů
[12] Zákon č. 22/1997 Sb.o technických požadavcích na výrobky a o změně a doplnění některých zákonů

(mainly textiles, plastics), nanomaterials are not controlled yet but such focus is planned together with new European legislation.
Finally, it is correct to point out that supervision on product safety is in long term evaluated as one of very high quality in Europe. Certificates issued by authorized persons are usually internationally acknowledged.

4.3.5 Cosmetics

Cosmetic products are regulated by Act 258/2000 Coll.[13] and related notices[14] describing hygienic requirements on cosmetic products. Those regulations demand testing of dangerous properties or potential risks of cosmetic products before their placement on market. Naturally, this measure is to be taken mainly in case of new components added to traditionally marketed and well known products. Eventual content of nanomaterials or nanoparticles in cosmetic products should be clearly stated on the label of product.

4.3.6 Food

Czech republic has a high level of control for food contact materials. The competent authority is Ministry of Health. The basic regulatory legislation is Act n.258/2000 Coll. on protection of public health[15]. Together with relevant notices, European legislation[16] [17]is implemented in Czech environment. Eventual testing involves mainly microbiological, sensoric and chemicals contamination analysis.
In general, every food contact material has to undergo very strict procedure to be allowed (exemptions exist) and such procedure is valid also for nanomaterial/naoparticles content. A good example of food contact material containing nanoparticles approved for use is drinking water bottle with content of nano-silver.
Additional substances for food are tested mainly for human health fitness and quality of food under the regime of Act 224/2008 Coll., Act 110/1997 Coll. and Act 281/2009 Coll.[18] Every act is guaranteed by Ministry of Health which published many submerged technical directives. Usually, those deal with allowed concentrations of different additional substances for food, forbidden substances, contaminating and toxicologically important substances, microbiological values and limits etc.
Again, nanomaterial or nanoparticles issue is not solved in this area by any special regulation and if in case (very low probability) a nanomaterial would be used, it would be assessed in the same manner as standard-form. Anyway, such procedure would require prior inquiry to Ministry of Health according to Directive 89/107/EEC[19] listing all nanomaterials used for technical or technological reasons.

[13] Zákon č. 258/2000 Sb. o ochraně veřejného zdraví a o změně některých souvisejících zákonů
[14] Vyhláška Ministerstva zdravotnictví č. 448/2009 Sb.o stanovení hygienických požadavků na kosmetické prostředky
[15] Zákon č. 258/2000 Sb. o ochraně veřejného zdraví a o změně některých souvisejících zákonů
[16] Nařízení Evropského parlamentu a Rady (ES) č. 1935/2004 o materiálech a předmětech určených pro styk s potravinami a o zrušení směrnic 80/590/EHS a 89/109/EHS
[17] Nařízení Komise (ES) č. 450/2009 o aktivních a inteligentních materiálech a předmětech určených pro styk s potravinami
[18] Zákon č. 224/2008 Sb. o potravinách a tabákových výrobcích, Zákon č. 110/1997 Sb., o potravinách a tabákových výrobcích a o změně a doplnění některých souvisejících zákonů, Zákon č. 281/2009 Sb., kterým se mění některé zákony v souvislosti s přijetím daňového řádu

4.3.7 Medical Devices and Medicinal Products

The field of medical devices and medicinal products is under supervision of Ministry of Health and is very strictly regulated. The competent authority is State Institute of Drug Control, in some cases other bureaus can be invited to cooperate.
The basic regulatory element in the pharmacy sector is Act 278/2007 Coll.[20], last amendment by Act 375/2011 Coll. [21] The Act respect international standards and requirements and does not eliminate use of nanoparticles and/or nanomaterials but requires detailed test studies for all types of material which would lead to eliminate the risks.
Medicinal products have to fulfil requirements of Act N.123/2000 Coll.[22] and Government Regulation providing details on technical aspects of the legislation. All regulatory acts are aligned with European legislation and implement all regulations and notices (e.g. on implants, substitutions, diagnoses etc.). It is acknowledged that use of nanomaterials after proper testing is allowed.

4.3.8 Industrial Law and Environmental Protection

Czech Ministry of Industry and Trade plays very special role in the field of industry. Most of factories and other production facilities are private. That is the reason that ministry is able to directly rule only very few number of state plants. From this reason this ministry has mainly co-ordination function and small role in legislation system and control of specific laws (water, air, wastes, ozone layer, energy, industrial accidents)[23-28]. It is necessary to stress that none of these references to dealing with nanoproblematics. The observance of duties from these acts is the main task of special agencies and control authorities above all Česká inspekce životního prostředí (Czech Environmental Inspection), Česká obchodní inspekce (Czech Commerce Inspection) and Státní úřad inspekce práce (State Labor Inspection).
Protection of the environment in ČR is operated by the specialised ministry - Ministry for the Environment (MŽP). This ministry co-ordinates all activities in the field of the environment, is also responsible authority for the registration of chemicals and participates on the biocide registration process etc. The main legislation acts is the environmental act[29] and "component" laws[23-25,28,30,31]. With respect to nanomaterials and nanotechnologies is the situation similar to other acts – there is no reflection.

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[20] Zákon č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů
[21] Zákon č. 375/2011 Sb., kterým se mění některé zákony v souvislosti s přijetím zákona o zdravotních službách, zákona o specifických zdravotních službách a zákona o zdravotnické záchranné službě
[22] Zákon č. 123/2000 Sb. o zdravotnických prostředcích a o změně některých souvisejících zákonů
[23] Zákon č. 254/2001 Sb. - o vodách a související předpisy
[24] Zákon č. 185/2001 Sb. o odpadech a o změně některých dalších zákonů
[25] Zákon č. 86/2002 Sb. o ochraně ovzduší a o změně některých dalších zákonů
[26] Zákon č. 458/2000 Sb. - energetický zákon a související předpisy
[27] Zákon 59/2006 Sb. o prevenci závažných havárií
[28] Zákon č. 86/1995 Sb. na ochranu ozónové vrstvy
[29] Zákon č. 17/1992 Sb., o životním prostředí, ve znění pozdějších předpisů
[30] Zákon č. 114/1992 Sb., o ochraně přírody a krajiny
[31] Zákon č. 100/2001 Sb.,o posuzování vlivů na životní prostředí (EIA)

5 Nano Regulation in Germany

Due to the Community dimension of the issue, which derives not least from EC legislation on chemicals, Community law is prevalent. The main goal of this regional report is to identify German national features relevant to nano regulation. The most comprehensive overview of German nano regulation in recent years is “Legal appraisal of nano technologies; Existing legal framework, the need for regulation and regulative options at a European and a national level“; UMWELTFORSCHUNGSPLAN DES BUNDESMINISTERIUMS FÜR UMWELT, NATURSCHUTZ UND REAKTORSICHERHEIT, Forschungsbericht 363 01 108 UBA-FB 000996, 2007. (Abbreviated for reference: LEGAL APPRAISAL). In the LEGAL APPRAISAL the description of the existing legal framework follows the "life-cycle approach", beginning with research and development, and continuing with the manufacture and industrial use of nano materials, the marketing of substances and products, transport, use and disposal. In order to maintain the given structure of this report the relevant sections of the LEGAL APPRAISAL are allocated to the various chapters with the major focus on 1.3.8.
It should be noted that many regulations addressed in this short regional report already present regulations for all the different sectors addressed here in 1.3.X (REACH, CLP, GefStoffV (Dangerous Substances Decree), BImSchV, the Wasch- und Reinigungsmittelgesetz (WRMG / German Detergents Act), TA Luft (technical instructions for the maintenance of air purity) AbflKlärV,….).
Hence, also due to the numerous and qualitatively high standards and regulations it seems crucial not to add a “nano-specific” regulation interfering with the approved and well-established regulations such as REACh, TA Luft or BImSchV. Ideally, nano-issues are to be addressed in the existing legislation and a product- and market specific regulation in the existing legislation is preferred with respect be nanomaterials being generally regulated.

5.1 German Nano Action Plan

According to the Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011, the Federal Government “will develop nanotechnology in a responsible way. From a regulatory point of view, it will be vital to adequately control the risks potentially arising from nanotechnology and, at the same time, to use the societal and economic potentials.” The Action Plan addresses various sectors broadly corresponding to the structure of this report. Whenever relevant regulatory indications are given by the Action Plan, then they are documented in this report in the appropriate chapter.

Despite the fact that there is strictly speaking no existing and implemented nanotech national legislation in Germany in addition to the European regulations (REACH), there are several national directives concerning the safety of workers and consumers relevant to nanotechnology actors. The results from a survey that was realized within the framework of NANOFORCE project among German nanotech players are in line to this finding.

5.2 Workplace safety

The Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011, states that “the safe handling of nanomaterials at the workplace is a central demand, in particular made by manufacturers and users. In the field of safety and health of employees,

the BAuA has set the focus on the exposure at the workplace, toxicological risk characterization and contributions to the prevention strategy. Actions (…):

- Workplace exposure in case of activities involving nanomaterials. The reliable detection of the exposure of employees to nanomaterials requires suitable measuring processes and strategies. In this context, important topics are the acquisition of experimental knowledge about the exposition of employees, the validation and standardization, the material differentiation and distinction from background exposure, adequate filtering technology, personalized sampling as well as the characterization of the dust emission behaviour of nanomaterials.
- Contributions to the prevention strategy for nanomaterials at work. Pending the rectification of the deficits regarding the evaluation of health risks at the workplace caused by nanomaterials, strict occupational safety measures as defined by the precautionary principle are taken, which will be gradually adapted to the actual health risks according to the increasing gain of scientific knowledge. In this process, the BAuA supports the regulatory actions with expertise, projects and guidelines on legal and sublegal level as well as the self-responsibility of enterprises in the field of nanotechnology.
- Advising enterprises on the handling of nanomaterials with regard to occupational safety nanotechnological materials innovations shall be accompanied by safety research and advice which sets in already at the threshold from laboratory stage to pilot production/application technology. Due to the high tonnage threshold and the limited test programme, the requirements of the REACH-regulation take effect late, in particular for SME and start-up enterprises, to accommodate their important desire for user-safe products at an early stage – also an important aspect from a liability point of view. For this purpose, the BAuA provides advice and support in measuring the emission of nanoparticles."

The Federal Institute for Occupational Safety and Health (BAuA) and the Association of the Chemical Industry (VCI) published in 2007 a document on Guidance for Handling and Use of Nanomaterials at the Workplace:
(http://www.baua.de/cae/servlet/contentblob/675748/publicationFile/49868/Leitfaden-Nanomaterialien.pdf)

5.3 Material and Product Specific Regulation in Germany

5.3.1 Chemicals

The Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011, states that "Apart from the sectoral provisions for cosmetics and food, the European law on chemicals, in particular the European Directives REACH (Registration of Chemicals) and CLP (Classification and Labeling of Chemicals), is currently the most important framework for the legislative handling of nanomaterials. The Federal Government assumes that the REACH-provisions are basically well suited to cover nanospecific properties of chemicals. With its European partners, the Government is discussing a comprehensive concept of how to regulate nanomaterials under consideration of the precautionary principle. A sub-working group of CARACAL (Competent Authorities for REACH and CLP), the CASG Nano (Competent Authorities Subgroup Nano), establishes recommendations for the treatment of nanomaterials in REACH. They refer to amendments in the provisions, in

particular to the definition of nanomaterials and the addition of specific standard test programmes. With these adaptations and the risk-assessment instruments already provided by REACH, nanotechnology can meet the requirements of occupational, environmental and consumer protection."

The LEGAL APPRAISAL indicates throughout the report that REACH entails regulatory gaps with respect to nano materials. It mentions (LEGAL APPRAISAL p 26) that the German Dangerous Substances Decree (GefStoffV: Verordnung zum Schutz vor Gefahrstoffen (Gefahrstoffverordnung) (Dangerous Substances Decree) of 23.12.2004, Fed. Gazette I, p. 3758, last amended on 23 December 2004 (Fed. Gazette I, 3855) as well as by Article 2 of the 10th Chemicals Law Amending Decree of 11.7.2006 (Fed. Gazette I, 1575) could – potentially – compensate for some of the REACH deficits.

5.3.2 Biocides

(cf 5.3.3 Plant Protection Products)

5.3.3 Plant protection products

The Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011 indicates that there are no specific national legislation in Germany for nanomaterials in plant protection products. The framework conditions for the field of "Plant Protection/Pesticides" are generally covered by applicable EU-law and the national plant protection law. Suitable test methods for special issues are still to be devised (OECD-test methods). The same applies, mutatis mutandis, to biocides according to the EU-guideline 98/8EC.

The Federal Institute for Risk Assessment, the Max-Rubner-Institute, the Federal Research Institute for Nutrition and Food as well as other research institutions provide accompanying and safety research on nanotechnology in the agricultural and food sector. For the coordination of their activities, they have established a senate working group for "Synthetic Nanomaterials". The corresponding working group internet site does not provide for any preliminary results (http://www.bmelv-forschung.de/de/startseite/forschung/senatsarbeitsgruppen/synthetische-nanomaterialien.html) ..

5.3.4 General Product Safety

Nanospecific legislation in general product safety has not yet been produced in Germany. However, many studies on various risks have been executed, for example in universities: This work could indicate that relevant legislation might be developed in the years to come. One key institutional player is the Bundesinstitut für Risikobewertung (BfR, Federal Institute of Risk Assessment), providing a study overview at http://www.bfr.bund.de/de/a-z_index/nanotechnologie-7585.html?index=78&index_id=7585. An example for the risk assessment in "general products" can be found in the field of fuels and fuel additives: Directive 98/70/EEC on the quality of petrol and diesel fuels86 (incorporated into German law by the 10th BImSchV87), which has to be observed in the case of nano materials in fuel or fuel additives, contains no nano-specific requirements. (LEGAL APPRAISAL, p 32)

5.3.5 Cosmetics

The Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011 indicates no specific national legislation in Germany for nanomaterials in cosmetics: “The Regulation (EC) No. 1223/2009, the nanorelevant provisions of which need to be applied from 2013 on, contains for the first time regulations regarding nanomaterials in cosmetic agents. It includes a definition for nanomaterials that leans towards the definition of the Scientific Committee on Consumer Products (SCCP), a labelling requirement as well as a notification procedure, which is to be carried out by the EU-Commission before the product is placed on the market and which shall include a number of additional information. This information refers to the particle size, to toxicological aspects and to the quantity of the amount that shall be brought to the market. The Commission committed itself to compile a list of all nanomaterials which are intended for use in cosmetic means. (…)

Nanoparticles in cosmetic substances are often present in agglomerated form. Penetration into and/or absorption through the skin is thus unlikely. As long as it is guaranteed that these products are used on healthy skin and on the assumption of exclusively dermal exposition to nanoparticles with a size of over > 20 nanometers, there are no signs of direct risks for consumers so far.”

The LEGAL APPRAISAL (p. 31-32) specifies the use of nanomaterials in detergents: “As far as the use of nanomaterials in detergents is concerned, Regulation 648/2004/EC on detergents (hereafter: EC Regulation) and the German Detergents Act (WRMG) have to be observed. In so far as nanomaterials are detergents, certain surfactants for detergents or other products that belong to detergents, the EC Regulation has to be observed. The draft WRMG should also be applicable to surfactant-based cosmetic products for cleansing pur suant to Article 2 (5) LFGB (code on food, consumer products and animal feed) (for example, soaps and shampoos). Nano materials as detergents are subject to the EC Regulation and should also be covered by the draft WRMG when substances or preparations are involved that contain surfactants and are intended for washing and cleaning processes (Article 2 No. 1 EC Regulation). The important definitions of substance and preparation in connection with detergents as defined in Article 2 Nos. 4 and 5 of the EC Regulation are more or less identical with those in REACh. Corresponding to the findings of this study on the applicability of the term substance to nano materials (see Section 5.3.2), nanomaterials are subject as surfactants in detergents to the EC Regulation and the draft Detergents Act (WRMG). It therefore also applies to nanomaterials as surfactants, that they may be placed on the market in detergents when the criteria in Annex III on ultimate aerobic biodegradation are fulfilled (Article 4 (1) EC Regulation). Where the level of ultimate aerobic biodegradation is lower than that stipulated, derogation may be granted under certain circumstances for "classical" detergents as well as for such nanomaterials as industrial or institutional detergents (Article 4 (2) and Article 6 (2) EC Regulation). Finally, the EC Regulation contains no specifications for nanomaterials when organic contents of detergents are involved that are not surfactants, or when substances are involved that are subject to anaerobic biodegradation.“

5.3.6 Food

The Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011 indicates that there has not yet been implemented any nanospecific food legislation: “Just as to other foodstuffs, the general food legislation, in particular the Directive (EC) No. 178/2002, as well as the German Food and Feed Code (LFGB) apply to food that contains nanoparticulate ingredients. Accordingly, only safe food may be released on the market. Furthermore, depending on the kind of food/food ingredient, specific regulations are relevant:

With a view to the potential application of nanoparticles in the food sector, great emphasis was also placed on the topic of nanotechnology in the revision of the EU-regulations on food additives. The Regulation (EC) No. 1333/2008 provides for a re-evaluation of safety and, if necessary, for the new approval of food additives, which shall not be used in the conventional, already tested form, but e.g. in nanoscale dimensions.

In case nanoparticulate ingredients are applied in food for other than technological purposes, e.g. for nutritional reasons, the Directive (EC) No. 258/97 on novel food and novel food ingredients will apply under certain conditions. Thus, they are subject to the approval procedure set out in the Directive (EC) No. 258/97, which includes a comprehensive safety assessment.

The regulations on novel food are presently revised on EU-level. According to the current state of negotiations, provisions for further regulations on nanotechnology are made in addition to the already existing law. Accordingly, food which contains engineered nanomaterials or which consists of those, shall generally be covered under the scope of the regulation on novel food and thus under the approval and assessment procedures stipulated therein, regardless of whether or not a significant change in the foodstuff was caused. As before, specific labelling requirements can be defined within the framework of the approval. The consultations on the new regulation are not yet concluded. (…)
The Federal Institute for Risk Assessment and the Max-Rubner-Institute invest considerable physical resources and human resource capacities in the development of nanoanalytics in the food matrices.
With the wide diffusion of nanotechnology-based products, such as cosmetics, cleaning agents and household articles, consumer protection and food safety are gaining more and more importance.
As yet, there are no legal regulations on the information about the use of nanomaterials in products and their indication is generally subject to the decision of the product manufacturer. In application fields, for which approval procedures are planned, the relevant information will be available within the scope of the respective approval application. As of 2013, the marking of nanoscale components in cosmetics on the basis of the Regulation (EC) No. 223/2009 will also be obligatory in Europe.

In 2009, the European Food Safety Authority (EFSA) has published a statement regarding the evaluation of nanomaterials in foodstuffs. The EFSA Scientific Committee came to the view that the proven international approaches for risk assessment can also be applied to engineered nanomaterials (ENM) [Scientific Opinion of the Scientific Committee on a request from the European Commission on the Potential Risks Arising from Nanoscience and

Nanotechnologies on Food and Feed Safety. The EFSA Journal (2009) 958, 1–39]. They drew the conclusion that a case-by-case approach is required."

5.3.7 Medical Devices and Medicinal Products

According to the Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011 there are no specific national legislation in Germany for nanomaterials in the drugs and medical products sector: "For the field of drugs and medical products, the framework conditions are already covered by the applicable EU-law and the national law. New regulations are not required, the addition of individual nanospecific aspects, e.g. in evaluation processes, depends on further insights.

Drugs may only be used when their safety for the patients is tested and confirmed. In the case of drugs, this evaluation occurs within the framework of the official approval procedure, and in case of medical products through the conformity assessment procedure. The same applies to products covered by the generic term "nanomedicine". On EU- and international level, strategies for the further development of the risk assessment for nanomedicine products are currently being discussed."

5.3.8 Industrial Law and Environmental Protection

With respect to research and development and the environmental regulation thereof (LEGAL APPRAISAL, p. 7), "R & D activities are the subject of legal regulation only in exceptional circumstances, as in the area of genetic engineering. Special regulations in legislation on industrial installations take effect only when the laboratory scale is overstepped and the sampling phase in pilot plant facilities is reached. Installations on a laboratory or pilot plant scale have been generally exempt since 1997 from licence requirements in accordance with Article 1(6) of the 4th Federal Immission Control Decree (BImSchV). Beyond that, installations listed in the Annex to the 4th BImSchV are subject to licensing; however, according to Article 2 (3) of the 4th BImSchV, a simplified licensing procedure (without public participation) applies in the case of "testing installations". Material demands on testing installations do not differ from those on actual production installations, which is why reference can be made to comments in the following section.
Where a licensing obligation according to Articles 4 ff. BImSchG is not effective, laboratory and pilot-plant installations require planning permission. In the planning approval procedure the demands contained in Articles 22 ff. BImSchG have also to be examined. In examining whether adverse effects on the environment from air impurity are to be expected, reference must be made to "TA Luft" (technical instructions for the maintenance of air purity) and its specifications in No. 4 (Chapter 1, TA Luft). Here, reference is also made to the comments in the following section.
In the R & D area, regulations in legislation on water and waste have also to be observed, but there are no peculiarities from a legal point of view. On the other hand, it could be difficult to register inputs of nano materials from research and development."

The LEGAL APPRAISAL (p. 8-13) discusses extensively the production-related nano regulations in Germany and comes to the conclusion that none of the regulations in place addresses the specific risk situation of nanomaterials.

Legislation on Installations

The production and industrial use of nanomaterials falls under the jurisdiction of the Federal Immission Control Act (BImSchG) (LEGAL APPRAISAL (p. 8-11)
). Other than the title of the Act suggests, it is not merely an air purity act, but has rather – for installations subject to licensing – the character of a comprehensive law governing the licensing of industrial installations, and thus continues the tradition of trade regulations. In recent years the focus has been on an integrative approach. IPPC Directive 96/61/EC is responsible for this development, which, together with other aspects of Community law, has determined the legal situation in Germany. The following description is therefore largely restricted to the IPPC Directive.

Authorization requirement

The IPPC Directive applies to all installations mentioned in Annex 1 of the Directive. The Annex is arranged – similar to the 4th Federal Immission Control Decree (BImSchV) – by industry. Articles 4 and 12 of the IPPC Directive make clear that both new installations and changes in installations made by operators are covered.

Production of nanomaterials

The production of nanomaterials is subject to authorization pursuant to Annex 1 (4) to the IPPC Directive whenever this is carried out in an "installation" and the outcome is the "production on an industrial scale by chemical processing of substances or groups of substances listed in Sections 4.1 to 4.6".

The definition of installation – just as that of substance – is met entirely. What is therefore decisive is whether the manufacture of nanomaterials is carried out by way of "chemical processing". This question can be answered in the affirmative in the case of most manufacturing processes. Only purely mechanical manufacturing methods are not covered.

Further industrial use

Besides manufacturing, the further use of nanomaterials in other stages of production is subject to authorization. This concerns, for instances, surface treatment processes, as detailed in Nr. 4 of Annex I to the IPPC Directive.

The decisive criterion, however, is not the "nano property" of surface coating, but rather the type and quantity of solvent used. When, for instance, nano particles are used during surface treatment, the authorization requirement takes effect only with the overstepping of the quantitative thresholds of the respective solvent. There is no authorization requirement directed specifically at the risks of nanomaterials.

Material demands

The IPPC Directive lays down in Article 3 – analogous to Article 5 BImSchG – basic obligations ("general principles governing the basic obligations of the operator"). Installations should be operated in such a way that no "significant environmental pollution" is caused and preventative measures are taken through "application of the best available techniques".

Emission-side demands

These demands are to be implemented by competent authorities in the form of "conditions of the permit" in accordance with Article 9 IPPC Directive, and emission limit values should be laid down for all relevant pollutants, based on "best available techniques". Beyond that, the conditions of the permit should contain provisions on the minimization of long-distance and transboundary pollution and ensure a high level of protection for the environment as a whole.

Finally, according to Article 9 (5) IPPC Directive the permit should contain suitable release monitoring requirements.

Immission-side demands

Article 10 establishes a relationship between permit content and environment quality standards. Here, the limit value for fine particles and ultrafine particles and very fine dust, as laid down in Community air quality law, is a possibility. This is still several times the size of nano particles, and is therefore not appropriate for coping adequately with the specific risks of nano particles.

Article 2 (7) of the IPPC Directive defines environmental quality standard as "the set of requirements which must be fulfilled at a given time by a given environment or particular part thereof, as set out in Community legislation". Whether such legislation will in future also include PNEC1 values, which are to be applied according to REACh within the scope of substance-related risk management, remains to be seen. After all, it concerns quality values that have been deduced on the basis of an EC Regulation according to a procedure laid down in Community law. Requirements aimed at the "control of major-accident hazards involving dangerous substances" are contained in Directive 96/82/EC (Seveso II Directive); adopted in Germany in the 12th Federal Immission Control Decree (BImSchV). The directive is applied when certain quantitative thresholds in "operational areas" can be exceeded. It is characterized – in great contrast to its earlier connection with installations – by its primary substance-related orientation. Quantitative thresholds are set so high (mostly in the four- to six-digit kilogram range), however, that they do not cover nanomaterials. This applies both to quantitative thresholds linked to hazard characteristics and to thresholds laid down for individual substances. The essence of the directive is the demand for a "major action prevention policy" (Article 7 Seveso II Directive). This policy has to be drawn up in writing by the operator before the installation is put into operation, properly implemented and – if a business is involved that is subject to basic obligations – made available to the competent authorities. Businesses subject to extended obligations have to document compliance with this requirement in the area of safety.

Updating the permit

According to Article 13 of the IPPC Directive, competent authorities have to "periodically reconsider and, where necessary, update permit conditions." The reason for this could be the need to revise emission limit values or include new values in the permit, or also new developments in emission reduction technology.

Should the regulation have a practical effect, concretization is necessary not only of immission specifications but also of requirements concerning the latest developments in technology.

The basic obligations of the law on immission control, as contained in Article 5 BImSchG, apply to installations subject to licensing. Decrees according to Article 7 as well as administrative regulations issued according to Article 48 implement these basic obligations. Subsequent orders can be based on Article 17 BimSchG.

The basic obligations of Article 5 cover the effects of an installation on rights protected by law. Where air-borne emissions are involved, the requirements of the implementation order on the Federal Immission Control Act21 as well as of TA Luft (technical instructions for the maintenance of air purity) take effect, which, however, contains no special requirements at all regarding nano particles.

In the case of an installation for the production of different nano powders, which was the subject of a judgement of the Higher Administrative Court of the State of Baden-Württemberg, the competent authority adopted much more stringent requirements in its decision than those in TA Luft. Whether it was obliged by law to do so is unresolved even after the judgement of the Higher Administrative Court, since the permit was objected to by an affected third party whose action was unsuccessful because he could not prove that "adverse effects on the environment", pursuant to the law, emanated from the nano powders. It was shown during the court hearing, with the help of a expert opinion from Professor Greim (Munich), that immission exposure would remain less than 1% that of the immission value of diesel soot regarded as tolerable by the LAI.23 The resulting restriction – which was reduced in a disclaimer by the operator by a factor of 100 during appeal proceedings – remained unchallenged in the decision of the Federal Administrative Court (Bundesverwaltungsgericht – BVerwG): "Where a scientifically ascertainable effect threshold is lacking, it is free of arbitrariness, in the absence of better knowledge, when consideration of irrelevance is based for the purpose of orientation on the criteria for judging the carcinogenic effects of comparable substances evolved in the LAI study on "Cancer risks from air impurities" (1991). Beyond such an irrelevance threshold, which marks the area of inevitable residual risk, the immission-control-related legal obligation of protection and preclusion is meaningless."

The outcome was that violation of the protection and preclusion obligation deriving from Article 5 (1) no. 1 BImSchG (which merely protects third parties) had to be denied. It would be a mistake, however, to deduce from the judgement that present knowledge of the effects of nano materials are satisfactory or that the formulation of legislation on installations is not in need or capable of improvement. The Federal Administrative Court merely observed that the decision of the authority was "free of arbitrariness". Possibly, emission-limiting measures were either too stringent or even, measured on the obligation for precaution (that excludes third-party protection), not far-reaching enough.

It can therefore be maintained that, on the basis of material obligations on the part of installation operators, the authorities are quite able to respond to the specific dangers of nano particles released into the environment. However, they must determine and evaluate the risk independently. As yet, no support is to be found in non-statutory regulations. Authorities can merely use the interpretive support of the LAI on carcinogenic air pollutants ("TA Krebs" – [technical instructions concerning cancer]). These allow – risk-based – analogous consideration without, however, addressing more precisely the specific effects of nano materials. This is problematic, since the effects of nano materials on human health must by no means be restricted to their carcinogenic potential.

Installations not subject to licensing

As mentioned in Section 5.1, the Federal Immission Control Act (BImSchG) also lays down demands for installations that are not subject to licensing under emission-control law. Requirements according to Articles 22 ff. BImSchG have then to be observed within the framework of planning approval. As yet, there is no corresponding regulation at the EC level.

Other regulations at the EC level

Community legislation on installations is not restricted to the IPPC Directive. On the one hand, there are regulations for specific groups of substances, such as the VOC Directive, which regulates not only the production but also the further use of VOC substances, provided

that the respective installation size or quantitative thresholds laid down in this directive – which do not correspond with those of the IPPC Directive – are achieved. At the same time, there are further special installation-related standards in Community law, such as those for large fossil-based incinerating plants or waste processing plants.

Water-related nano regulations in Germany

The LEGAL APPRAISAL (p. 14-16) discusses the water-related nano regulations in Germany and comes to the conclusion that none of the regulations in place addresses the specific risk situation of nano materials: “It can be regarded as a deficit that for the discharge of nano particles there are either no limit values for nano materials or existing limit values and quality standards for pollutants do not cover nano-specific characteristics (the examination of corresponding German regulations produces the same result). Furthermore, available technologies for restricting the discharge of nano particles must either be adopted in BREFs or newly developed.”

Post-consumption and Disposal

A similar result is drawn by the LEGAL APPRAISAL (p. 17-18), referring to the post-consumption and disposal conclusions. On page 33 the LEGAL APPRAISAL states that: “Legislation on waste is substantially determined by Community regulations, which is why these are in the foreground of the following analysis. Where German legislation fills the gaps in Community law or contains important concretization, these are dealt with.“

Waste-flow

The LEGAL APPRAISAL (p. 33-34) 5.6.1.1 Control (monitoring) claims that ”it has not yet been resolved whether and how individual nano materials in the form of liquid, solid or sludge waste are to be classified as hazardous or non-hazardous waste according to European law. According to the European Waste List,88 which was adopted in Germany in the Waste List Decree (AVV),89 normative classification of every single waste has to be carried out. Wastes listed in Annexes I and II of Directive 91/689/EEC are regarded as hazardous throughout the EU. In the lists in Annexes I and II (wastes classified as hazardous on account of their constituents or the activities that generated them, or wastes having properties listed in Annex III, such as medicinal products or printing ink) nano-specific properties are as yet not considered. This is not alarming, however, since the classification of wastes refers to the Directive on Hazardous Substances (see no. 5 in the Annex to Decision 2000/532/EC concerning a Waste List).90 Test methods to be applied are therefore contained in the most current version of Annex V to Directive 67/548/EWG91. According to Article 1 IV of Directive 91/689/EEC hazardous waste must demonstrate one of the hazard properties (H 1 to H 14) listed in Annex III to the Directive; they must, for example, be mutagenic or ecotoxic. Nano-specific hazards can be considered in classification, since the substances / constituents in Annexes I and II demonstrate hazard-relevant properties listed in Annex III to Directive 91/689/EWG. This can also be the case for production waste with nano materials. It will be decisive in this case that nano-specific hazards are determined under chemicals law, in order that they can also be considered in classification according to waste law.

If assessments according to the law on dangerous substances or classification according to the law on waste do not exist, or waste from nano materials occurs that cannot be assigned to an existing waste code, there is the possibility to subsume these under "back-up" Chapter 16 of the Waste List. Separate listing with a specific waste code and safe disposal appear to be necessary, in particular, for waste from nano materials giving cause for considerable

concern, as long as there is no corresponding classification under the law on dangerous substances.
According to the German Closed-cycle Substance and Waste Management Act (KrW-/(AbfG)92, a separate storage order can be issued for waste for recycling in accordance with Article 5 (2) sentence 4 KrW-/AbfG. The standards that have to be met are laid down in Articles 4 and 5 KrW-/AbfG and have, in particular, the objective of ensuring proper and safe recycling.93 An order for separate storage arises in respect of waste for disposal from Article 11 (2) KrW-/AbfG), which refers to the standards in Article 10 KrW-/AbfG regarding the extent and limitation of the separate storage order. An order for separate storage of waste that cannot be recycled is accordingly required in so far as it is necessary for permanent exclusion of wastes from closed-cycle management and for the maintenance of waste disposal compatible with the common good (Article 10 (1) KrW-/AbfG). Moreover, the Federal Administrative Court (BVerwG)94 has approved a so-called "intercategorical separate storage order". This concerns the mixing of waste for disposal and waste for recycling in accordance with Articles 11 (2) and 10 KrW-/AbfG. If nothing is known about the composition and danger of wastes from the manufacture or use of nano materials (in particular in research and development, see comments in Section 4.3) and at the same time there is considerable cause for concern, such waste should be separately stored not only at the place of occurrence but also in further disposal. This way, appropriate wastes can be excluded from the substance cycle until such time as relevant knowledge is available and, depending on the cost-effectiveness of the disposal path, disposed at a landfill site in such a way that, should a risk for groundwater arise, they can be disposed of more safely. What is more, special requirements for hazardous waste disposal at specified hazardous waste dumps or plants could be considered in accordance with Article 41 (1) and (2) KrW-/AbfG."

Waste deposit sites
The LEGAL APPRAISAL (p. 35) discusses waste deposit sites and waste acceptance procedures with landfill disposal.
The setting up and operation of waste deposit sites are subject to authorization in accordance with Article 9 of Landfill Directive 1999/31/EC95, according to which a special authorization procedure has to be conducted for all landfill categories in accordance with the general authorization requirements in Article 9 of Directive 2006/12/EC96 and Article 9 of the IPPC Directive 96/61/EC.97 According to the landfill directive, different landfill categories have to be distinguished for hazardous waste, non-hazardous waste and inert waste. The assignment of waste to a landfill category takes place on the basis of certain criteria, which are laid down in Council Decision 2003/33/EG.98 These criteria are based on leaching limit values for certain substances and limit values for the total content of organic parameters (LOI or TOC). Whether these criteria cover the potential dangers of nano materials, however, and therefore enable disposal of nano materials compatible with the common good, is not clear.

Monitoring
The LEGAL APPRAISAL (p. 35) claims with respect to monitoring of emissions / immissions:
Nano materials that enter groundwater from a landfill body are not covered by the measuring and monitoring programme carried out by landfill operators during the operation (Article 12 Landfill Directive) and after the final closure of a landfill (Article 13 Landfill Directive). For the specifications in Annex II to the Landfill Directive contain no nano-specific requirements. In so far as nano materials lead to a mobilization of pollutants in waste or soil as a result of landfill leachate – for example, with non-degradable nano carrier materials such as C-60

fullerenes, these are covered by the existing measuring and monitoring programme. Research has to be carried out into appropriate parameters, in order that measuring and monitoring programmes also cover nano materials that give rise to a danger for groundwater. These could be laid down for groundwater measurement in No. 4 B of Annex III to the Landfill Directive.LEGAL APPRAISAL (p. 35) 5.6.2 Recycling of sewage sludge (Sewage Sludge Decree)
Nano materials in sewage sludge from domestic waste-water treatment plants can become a problem. A large part of sewage sludge in Germany is incinerated, and depositing on agricultural land is diminishing. However, so long as there is no general ban on depositing – as, for instance, in Switzerland – and the composting of sewage sludge is still possible, nano materials from cosmetics and detergents can enter domestic waste water and subsequently, by way of sewage sludge, groundwater. Research has not yet been made into the behaviour of nano materials in sewage treatment plants and the resulting degradation products (see comments in Section 4.3).
The German Sewage Sludge Decree (AbflKlärV), which implements the EC Sewage Sludge Directive, makes it possible to confront the possible dangers of nano materials in sewage sludge from domestic waste. The specific demands of the Sewage Sludge Decree have shortcomings, however, in as much as the sampling of sewage sludge for the investigation of soils used for depositing (Article 3 II to VI AbflKlärV) and for the limitation of maximum pollutant content in sewage sludge (Article 4 VIII to XIII AbfKlärV) does not take nano-specific properties into consideration. Here, possible carrier effects of nano materials, such as fullerenes, should be borne in mind, which can discharge nutrients and pollutants from soil into groundwater.“

5.4 Literature Overview

Extensive literature search for the purpose of producing this report showed that the most comprehensive and recent overview of German nano regulation is “Legal appraisal of nano technologies; Existing legal framework, the need for regulation and regulative options at a European and a national level“; UMWELTFORSCHUNGSPLAN DES BUNDESMINISTERIUMS FÜR UMWELT, NATURSCHUTZ UND REAKTORSICHERHEIT, Forschungsbericht 363 01 108 UBA-FB 000996, 2007”. The corresponding abbreviation used in this report is: LEGAL APPRAISAL. Except for few chapters of this report, the LEGAL APPAISAL is the single source document of this work, being credited with full acknowledgement of its respective authorship and copyright.
Apart from the LEGAL APPRAISAL the documents that have been most relevant for preparing this report are listed in the following overview:

1) Action Plan Nanotechnology 2015, Federal Ministry of Education and Research (BMBF), 2011.

2) Federal Institute for Occupational Safety and Health (BAuA) and the Association of the Chemical Industry (VCI), 2007, Guidance for Handling and Use of Nanomaterials at the Workplace.

3) Bundesinstitut für Risikobewertung (BfR, Federal Institute of Risk Assessment), Study overview (http://www.bfr.bund.de/de/a-z_index/nanotechnologie-7585.html?index=78&index_id=7585), February 2012

4) David Azoulay, The Center for International Environmental Law (CIEL) Report 2012, Just Out of Reach.

5) SRU Sachverständigenrat für Umweltfragen, Report 2011, Vorsorgestrategien für Nanomaterialien.

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6 Nano Regulation in Italy

6.1 Italian Nano Action Plan

In Italy there isn't a national Action Plan for nanotechnology. As a matter of fact, the research for nanotechnology isn't financed through specific funds: nanotechnology is often considered as cross-technologies, basic for the development of R & D. The policy for national research in the last months it is, indeed, going to follow the guidelines of the European funding programs.
The Italian Association for Industrial Research (AIRI) has pushed in recent years for the launch of a National Initiative for Nanotechnology which, by mobilizing adequate financial resources would involve industry, the scientific community and the government authorities. Through this initiative Italy could be able to promote the responsible development of nanotechnology and an aware exploitation of these emerging technologies.
In Italy, however, there are some research centers for the development of nanotechnology, such as districts and consortia, set up through national and regional fund. For example we can mention Veneto Nanotech in Veneto and technological districts in Sicily, Puglia, Lombardy and Umbria. Their role is to promote collaboration between large and small-medium enterprise for innovative projects.

6.2 Workplace safety

Although there is no specific legislation for the management of nanomaterials, it's possible to point out some laws; for example the Legislative Decree 81/2008 deals with the protection of the health and safety of workers. In particular, this decree binds the employer to assess all the risks and to identify the right measures for the prevention and the management (Article 28) taking into account the evolution of techniques (Article 29).

6.3 Material and Product Specific Regulation in Italy

It should be noted that Italy, like other European countries (France, Belgium...) is moving to the preparation of an inventory for registration of nanomaterials, which are manufactured or placed on the market. This inventory should be a voluntary survey among companies and universities on the Italian territory and it will be linked with the inventory required at European level by the European Parliament to the European Commission.

6.4 Environmental Protection

Moreover regarding the environmental protection at the national level, the relevant legislation is Decree-Law 152/2006 which defines for water, air emissions and remediation the quality objectives and / or emission limits, as well as measures for the management of waste.

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7 Nano Regulation in Poland

Comparative lack of scientific knowledge on the effects of nanomaterials has led to concern over the environmental, health and safety risks potentially associated with nanotechnology and its products. International standardization will play a critical role in ensuring that the full potential of nanotechnology is realized and that nanotechnology is safely integrated into society. Priority has been given to developing horizontal standards for terminology and nomenclature, measurement and characterization, health, safety and the environmental (HSE) and nanomaterials characterization[23].
Three main body responsible for the planning, development and adoption of International Standards is ISO (International Organization for Standardization), the member of which is Polish Committee for Standardization (Polski Komitet Normalizacyjny PKN). PKN is the National Standards Body for all fields of standardization.
In 2005 there was established ISO Technical Committee 229 “Nanotechnologies” (ISO/TC229) gathering 34 participating and 10 observing countries. Polish Committee for Standardization (PKN) represents Poland in TC 229.
In ISO, between 2008-2011, there were published 3 norms and 16 documents (ISO/TR Technical report and TS Technical Specification) concerning nanotechnology.

These data are available under following web address: *http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983*)

7.1 Norms in Poland

ISO 10801:2010 Nanotechnologies -- Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method.
SO 10801:2010 gives requirements and recommendations for generating metal nanoparticles as aerosols suitable for inhalation toxicity testing by the evaporation/condensation method. Its application is limited to metals such as gold and silver which have been proven to generate nanoparticles suitable for inhalation toxicity testing using the technique specified.

ISO 10808:2010 Nanotechnologies -- Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing.
ISO 10808:2010 specifies requirements for, and gives guidance on, the characterization of airborne nanoparticles in inhalation exposure chambers for the purpose of inhalation toxicity studies in terms of particle mass, size distribution, number concentration and composition.

ISO 29701:2010 Nanotechnologies -- Endotoxin test on nanomaterial samples for in vitro systems -- Limulus amebocyte lysate (LAL) test.
ISO 29701:2010 describes the application of a test using *Limulus* amebocyte lysate (LAL) reagent for the evaluation of nanomaterials intended for cell-based *in vitro* biological test systems. The test is suitable for use with nanomaterial samples dispersed in aqueous

[23] ISO/TC 229 Business Plan (Date: 12/01/2011), Version: Draft 4
http://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/ISO_TC_229__Nanotechnologies_.pdf?nodeid=6507632&vernum=-2

media, e.g. water, serum or reaction medium, and to such media incubated with nanomaterials for an appropriate duration at 37 °C. ISO 29701:2010 is restricted to test samples for *in vitro* systems, but the methods can also be adapted to nanomaterials to be administered to animals by parenteral routes.

Poland represented by Polish Committee for Standardization is one of the members of ISO. On 17th November 2011 was held Establishing Meeting for Technical Committee for Nanotechnology (within Polish Committee for Standardization), with following members:

1. Fundation for Supporting Nanosciences and Nanotechnology NANONET,
2. Institute for Industrial Chemistry by the name of prof. Ignacy Mościcki,
3. Central Institute for Labour Protection – National Research Institute,
4. Metal Forming Institute,
5. Institute for Advanced Steelmaking Technologies,
6. Wroclaw Centre for Research EIT Lmt.,
7. West Pomeranian Technical University in Szczecin.

There are also published documents and norms according to Technical Committee activities:
PN-EN ISO 10801:2010
PN-EN ISO 10808:2010
PN-EN ISO 29701:2010

7.2 Polish Nano Action Plan

Term “nano-“ more frequently appears not only as nanomaterials being object of interest of the selected branches of industry like e.g., electronic, textile, biomedical, food or cosmetic industries in Poland. They are becoming the subject of variety research and development studies thanks to their specific new and differentiated properties in comparison to the ‘conventional’ bulk materials corresponding to them. Application of nanomaterials in variety of different products is more and more common. Legal admission to marketing and use of such products in Poland currently is regulated by the EU and domestic ‘conventional’ legislation and generally there is no any specific law in Poland dedicated specially to the nanomaterials or nanotechnology.
However, taking into account their specific dimensions – there are scientific communications and reports more frequently visible about increased reactivity posing new problems for the human health and toxic or harmful effects for biological organisms. This louder public discussion on the European level slowly moves also into the Polish market and economy. For the sake of poor information or even lack of this information about special properties of nanomaterials, their real directions of application and use and in this light potential hazards and benefits resulted from their use – up-to-date Polish legal system does not contain any acts or regulations directly intended for nanomaterials.
Polish “stakeholders” interested in this topic are aware of Commission Recommendation of a Definition for Nanomaterials (2011/696/EU) published on 18 November 2011. According to this document points 2, 3, 4, 5 and 6 sound respectively, as follows:

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.***

Proposal of this definition has evoked a lot of disputes, concerns and doubts as regards its rightness. Among other things problem of choosing the particles' external dimensions instead of specific properties of these materials, as well as the number size distribution instead of mass distribution and also justification for 50 % threshold have been questioned for example by the European Chemical Industry Council (CEFIC).

This general discussion is thoroughly observed by Polish "stakeholders" including particularly Polish Competent Authorities (Polish Bureau for Chemical Substances, Łódź, Poland). On its website (http://www.chemikalia.gov.pl), in the link "News and recent events" there is an information of 19.10.2011 concerning mentioned above Commission Recommendation with Polish text of the mentioned above definition. There is also an additional comment that *"mentioned above definition of 'nanomaterial' will be applied to the purposes of adoption and implementation of legislation and policy and research programmes concerning products of nanotechnologies".*

In Poland recently we had few initiatives of great importance which give the hope that in near future nanomaterials and nanotechnology will have more and more possibility to develop.

Between others in October 2008, the new "National Programme for Research Investigations and Development" was established. The main goal for this programme it is priority to improve research investigations especially in the field of advanced technologies, in order to find an materials which could become "polish speciality" in constructions but also branches. Nanotechnology for functional materials for application in informatics, electronics, photonics, energetic, transportation, biomedical engineering and food industry. Development of

advanced techniques in material engineering in order to control properties of materials and development of energy-saving and pro-ecological methods of their production.
At the Jagiellonian University in Cracow, at the Department of Physics, Astronomy and Applied Informatics was opened Nanostructure Laboratory in the frame of the project" Investigation on the systems in atomic scale: science for innovative economy" with the acronym ATOMIN, realization 2009-2012.

7.3 Workplace safety

Framework Directive 89/391/EEC[24] places a number of obligations on employers to take measures necessary for the safety and health protection of workers. It applies to all substances and work activities including manufacturing and use of chemicals at all levels of the production process, regardless of the number of workers involved and quantities of materials produced or technologies used.
This Directive fully applies to nanomaterials. Employers, therefore, must carry out a risk assessment and, where a risk is identified, take measures to eliminate this risk. The planning and introduction of new technologies must be subject to consultation with the workers or their representatives, as regards the working conditions and the working environment in accordance with Articles 11 and 12 of the Framework Directive 89/391/EEC.
The Directive foresees the possibility to adopt individual directives laying down more specific provisions with respect to particular aspects of safety and health. Relevant directives thus adopted relate to risks related to exposure to carcinogens or mutagens at work[25], risks related to chemical agents at work[26], the use of work equipment by workers at work[27], the use of personal protective equipment at the workplace[28] and safety and health protection of workers potentially at risk from explosive atmospheres[29].
As these Directives introduce minimum requirements, national authorities have the possibility to introduce more stringent rules. For example, the working group for nanomaterials under REACH has made progress and published initial results: http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf
Resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI))
Opinion of 25 February 2009 on the Communication on Regulatory Aspects of Nanomaterials, INT/456; http://eesc.europa.eu/documents/opinions/avis_en.asp?type=en

Next legislative packet concerns occupational exposure limits (OEL) and intensity of noxious agents on the work places. Here the main legal text is Regulation of the Minister of Labour and Social Policy of 29 November 2002 concerning occupational exposure limits and intensity of noxious agents for human health at the work places (Polish Official Journal 2002 No. 217, item 1833), amended in the meantime five times, as the decisions on new OEL values have been taken by the special Commission appointed by the Prime Minister (as regards the special Commission – the legal basis of its operation is the Regulation of the Prime Minister of 15 December 2008 concerning appointment of Intergovernmental

[24] OJ L 183, 29.6.1989
[25] Directive 2004/37/EC of 29 4 2004; OJ L 158, 30.4.2004
[26] Directive 98/24/EC of 7 4 1998; OJ L 131, 5.5.1998
[27] Directive 89/655/EEC of 30 11 1989; OJ L 393, 30.12.1989
[28] Directive 89/656/EEC of 30 11 1989; OJ L 393, 30.12.1989
[29] Directive 1999/92/EC of 16 12 1999; OJ L 23, 28.1.2000

Commission for the Occupational Exposure Limits and Intensity of Noxious Agents for Human Health at the Work Places Affairs). According to mentioned above regulation of the Minister of Labour and Social Policy and its consecutive amendments some dozens of chemicals have been object of standardization in the terms of OELs, among them some chemicals which might be in nanoform, e.g., titanium dioxide dusts, silicon dioxide dusts in differentiated forms, coal and graphite dusts, cement dusts, man-made fibre dusts, talc dusts, tungsten dusts, titanium, tantalum, silver dusts, platinum, nickel, molybdenum, copper, aluminium, cobalt, chromium, tin and some selected oxides of mentioned metals.

Also in this block one executive regulation of the Minister of Health can be found: Regulation of the Minister of Health of 2 February 2011 concerning tests and measurements of the noxious agents for human health at the work places (Polish Official Journal 2011 No. 33, item 166). According to this regulation an employer is obliged to establish register of noxious agents for human health appearing at the work places (if such agents exist) and periodically (at least one time for every two years, one time annually or even more frequently – frequency is dependent on previously measured OELs) to conduct tests and measurements of them and to report the results on a special card of tests and measurements which template is enclosed as annex to this regulation.

Very similar block corresponding especially to the last described above regulation – is packet concerning substances preparations and agents or technological processes with carcinogenic or mutagenic activity. In this group of national legislation two executive regulations can be mentioned:

- Regulation of the Minister of Health of 1 December 2004 concerning substances, preparations and agents or technological processes with carcinogenic or mutagenic activity at the work places (Polish Official Journal 2004 No. 280, item 2771);
- Regulation of the Minister of Health of 10 August 2005 amending the regulation concerning substances, preparations and agents or technological processes with carcinogenic or mutagenic activity at the work places (Polish Official Journal 2005 No. 160, item 1356).

According to these regulations again some obligations for employers associated with this type of chemicals are established. In annex 1 there is an inventory of substances, preparations and agents or technological processes with carcinogenic or mutagenic activity. Any employer who has the work places with possibility of such exposure should conduct a special register and to report to the Sanitary Inspection adequately to the pattern of submitted information included in annex 2. This obligation is also in force for the employers handling with nanomaterials if they pose carcinogenic or mutagenic effects at the work places.

Next in turn national Polish legal packet which should be first of all linked with the environmental protection is associated with management and control of asbestos. There are four executive regulations and two announcements of the Minister of Economy as well as two executive regulations of the Minister of Health in this field. However, this packet concerns very specific issue of safety devices and disposal of waste containing asbestos, so rather does not need to be mentioned in detail and discussed in the light of nanomaterials in this report.

7.4 Material and Product Specific Regulation in Poland

Products

Product legislation lays down requirements regarding specific products, such as medicinal products, plant protection products (PPP), cosmetics, food and feed additives, etc. Consumer products that are not governed by specific legislation have to meet the requirements of the General Product Safety Directive[30].

Community regulation in these areas contains provisions in relation to health and safety of consumers, workers, patients and users, but not necessarily in relation to environmental protection. To the extent that nanomaterials contained in such products qualify as substances under REACH, they are subject under REACH to an assessment on their environmental impact.

Virtually all product legislation imposes a risk assessment and the adoption of risk management measures. Nanomaterials are not excluded from this obligation.

Where products are subject to a pre-market control or pre-market notification, e.g. medicinal products, novel foods, plant protection products, the assessment and management of risks in relation to nanomaterials can be verified by authorities (or Notified Bodies under the New Approach) before placing on the market. Implementation of these procedures will lead either to implementing legislation (e.g. listing of new substances on a positive or a negative list) or to binding administrative decisions (e.g. market authorizations), that will also specify marketing conditions.

Particularly relevant is the obligation to review, modify or cancel authorizations if there are indications that any of the relevant requirements are not longer satisfied, or if developments in scientific and technical knowledge require such action. Similarly, the holder of an authorization or certificate must immediately notify the relevant authority or body of all new information on risks.

Where products can be placed on the market without specific pre-market procedural requirements (e.g. cosmetics, consumer products subject to the general product safety directive, various products regulated under the New Approach), compliance with legal requirements must be verified at the level of market surveillance. This does not exclude the possibility to undertake action restricting the placing on the market, or requiring advice from the various EU Scientific Committees. At all times authorities can verify the risk assessment and risk management strategy at the premises of the manufacturer.

In order to increase the level of protection, regulatory change has been proposed with respect to cosmetic products, placed on the market without pre-market control. The requirements regarding the risk assessment will be clarified. Furthermore, manufacturers will be obliged to indicate whether their products contain nanomaterials when notifying their placing on the market and to set up a mechanism in order to monitor the health effects on cosmetic products placed on the market[31].

As regards medical devices, Commission services will examine the possibility to make the placing on the market of devices presenting risks associated with nanomaterials subject to a systematic pre-market intervention.

Information to users

There are no provisions in Community legislation dealing specifically with nanomaterials. However, without excluding the possibility that a need would be identified for specific labeling

[30] Directive 2001/95/EC; OJ L 11, 15.1.2002

[31] COM(2008)49 final 2008/0025 (COD); 5.2.2008

requirements, nanomaterials have to comply with the existing provisions of Community law addressing the labeling of products, warnings to consumers and users based on the properties of products, instructions for use, or any other information requirements.
Also relevant are the provisions in REACH with obligations of data dissemination about environment, safety and health risks via Safety Data Sheets up and down the supply chain, to industrial users and via the Internet to the public at large. Chemical safety reports will be produced for substances placed on the market in quantities at or above 10 tonnes[32] and a data base with the purpose to make publicly available non confidential data about chemical substances will be kept by the European Chemicals Agency.
Attention is also drawn to provisions in Community law creating a right of access to information in relation to programmes mainly implementing legislation on environmental protection.
The obligation to provide information in relation to the use of nanomaterials and nano technologies should be distinguished from manufacturers' claims regarding the presence of particular characteristics associated with the use of nanomaterials and nano technologies. Community provisions on false or misleading advertising could be evoked if such claims are not justified[33].

7.4.1 Chemicals

Chemicals like probably in other EU Member States are regulated mainly by two EU regulations, where especially the first mentioned below is one of the most complex legislation published recently within the EU:

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006; corrected by OJ L 136, 29.5.2007);
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008).

The first one introduces among other issues an obligation to register at the European Chemicals Agency (ECHA) located in Helsinki, Finland – all substances, either on their own or in one or more preparation(s) (according to CLP regulation: mixture(s)), and also under some selected cases in articles, by the European manufacturer or importer in quantities of 1 tonne or more per year. A special transition period for registration has been established described in article 23 of this regulation, namely:

- Substances:

a) **classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2**, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities **reaching 1 tonne or more per year per manufacturer or per importer**;

[32] See also Article 14(4) and Annex III of the REACH Regulation (EC) No 1907/2006.

[33] Directive 84/450/EEC of 10 9 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising

b) **classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment** (R50/53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities **reaching 100 tonnes or more per year per manufacturer or per importer**;
c) manufactured in the Community or imported, in quantities **reaching 1 000 tonnes or more per year per manufacturer or per importer**;

- had to be registered **before 1 December 2010**;
- Substances manufactured in the Community or imported, in tonnage band **100 – 1000 tonnes per year per manufacturer or per importer** will have to be registered **before 1 June 2013**;
- Substances manufactured in the Community or imported, in tonnage band **1 – 100 tonnes per year per manufacturer or per importer** will have to be registered **before 1 June 2018**;

The overall principle in the whole procedure, as indicated above, is that the higher the volume, the more data is required, and the earlier registration deadline. According to the classification of a substance, but mainly according to the tonnage band a potential registrant had to or will have to prepare registration dossier with required data specified in relevant annexes to this regulation and prove that risk management measures are adequately controlled and applied in practice.
It is also obvious that regulation being in force on the European level currently does not define nanomaterials separately, so it leaves to the registrant's final decision to determine in the registration dossier, whether a substance being registered is a nanomaterial or not. As a result, the final decision to identify substances as nanomaterials is made by the registrants according to their own criteria. However, any Polish registrant, if aware of current discussion on regulatory status of nanomaterials, should be able to indicate in the registration dossier, especially in identified uses description that its substance might be used as nanomaterial or in nanotechnology and to take at least all legal requirements in this area to meet the currently in force criteria for nanomaterial identification. . The European Chemicals Agency (ECHA), Helsinki, Finland, a unit responsible among other things for taking delivery of REACH registration dossier from companies, is currently preparing an update of its Guidance on Information Requirements and Chemical Safety Assessment based on the output of the European Commission's REACH Implementation Projects on Nanomaterials: http://echa.europa.eu/view-article/-/journal_content/d2809a13-f2e7-4ce9-9815-c5c7f3f02009
ECHA's objective is to have the guidance on Information Requirements and Chemical Safety Assessment updated by mid-year of 2012. Most probably the update of the nano part could fit as an annex to the documents.
In the meantime update of IUCLID[34] 5 and its manual is on-going and probably new fields for required information about registered substances are now (or will be) dedicated also to nanomaterials.
The second mentioned above regulation, commonly so called 'CLP regulation' is a practical implementation of the Global Harmonised System (GHS) of classification, labelling and packaging of chemicals – system recommended by the United Nations Economic Commission for Europe (UNECE). The main purpose of entering into force of the CLP

[34] IUCLID - International Uniform Chemical Information Database – a software application and main tool to capture, store, maintain and exchange data on chemical substances used among other things for registration of substances and such dossier of data submission to the European Chemicals Agency (ECHA). The tool is available for free of charge. It can be downloaded from the Website: http://iuclid.eu

regulation was introduction to the European Community the same platform for classification, labelling and packaging of chemicals as in the other regions of the world (Japan, New Zealand, Taiwan, Korea, etc.) as well as to extend this system on those world regions, where there is lack of any legal provisions concerning classification, labelling and packaging in order to make easier and more efficient international trade of chemicals.

Currently except mentioned above main legal act – two Adaptations to the Technical and Scientific Progress (ATPs) have been published in the EU Official Journal:

- Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 235, 5.9.2009, p. 1–439);
- Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 83, 30.3.2011, p. 1–53).

In the first ATP additional list of officially classified substances is added. In the second ATP some amendments and supplements to the legal text and annexes has been incorporated and they will be in force since 1 December 2012.

Generally in the CLP regulation the ‘old’ European system of classification, labelling and packaging has been already started to be replaced in respect to the substances and will be gradually replaced as regards mixtures by the new system described in detail in the CLP regulation. Deadline for re-classification and re-labelling of substances has already passed on 1 December 2010. The main purpose of such deadline creation was to enable the companies / potential REACH registrants by this deadline to include additional ‘new’ classification of a substance in the registration dossier according to the ‘new’ system in order to avoid almost immediate updating of dossier resulted from CLP implementation later on. Concerning mixtures – companies have transitional period for re-classification and re-labelling mixtures until 1 June 2015. After this deadline only CLP regulation will be in force. Old system resulted from the Dangerous Substances Directive – DSD (96/548/EEC) and Dangerous Preparations Directive – DPD (1999/45/EC) practically will expire. Only products already placed on the market:

- In case of substances: before 1 December 2010 – until 1 December 2012 may remain with ‘old’ label and packaging (two years of additional transitional period for substances being already ‘on shelves’);
- In case of mixtures: before 1 June 2015 – until 1 June 2017 may remain with ‘old’ label and packaging (two years of additional transitional period for mixtures being already ‘on shelves’).

Taking into account CLP regulation and its amendments and ATPs there exist no provisions directly intended to substances or mixtures in nano form. This indicates that new system of classification, labelling and packaging is applied both to the bulk substances and mixtures and their nano form as well.

Poland being one of the EU Member States except two mentioned above European regulations being in force for the Polish Economy, has also its own domestic chemicals’ legal system. Here the main legislation in this area is first of all the Polish Act on Chemical Substances and their Mixtures of 25 February 2011 (Polish Official Journal 2011 No. 63, item 322). This Act introduces amendments and changes to the previous relevant legal acts resulted mainly from the implementation of REACH & CLP regulations. In this scope this Act:

- Assigns Competent Authorities in Poland and indicates their scope of competence;

- Defines Enforcement Authorities and their scope of competence;
- Establishes penalties, legal and financial sanctions resulted from the provisions' infringements;
- Gives a description of executive regulations to this act;
- Formulates deadlines for certain obligations resulted from this act provisions.

According to article 15 of this act each producer or downstream user of dangerous mixture and also importer or such mixture recipient placing this mixture on the territory of Poland are obliged to notify about this fact Inspector for Chemical Substances, Łódź, Poland. This notification should include:

- Contact details of the company making notification;
- Trade name of the mixture;
- Safety Data Sheet of the relevant mixture.

Notification to the mentioned above Inspector should be made in the day of mixture formulation or its placing on the territory of Poland, at the latest.

According to the article 18 producers, importers and distributors of the substances officially not classified according to CLP regulation (not mentioned in the table 3.1 and 3.2 of the annex VI to the CLP regulation described earlier in this report) are obliged to gather credible information concerning potential harmful effects for human health and the environment resulted from their intrinsic physicochemical and biological properties and to make them available to such substances' recipients according to principles described in REACH provisions.

According to the article 25 each producer, importer and downstream user have obligation to create, keep and update an inventory of manufactured, imported and used dangerous substances and mixtures. This provision does not concern distributors.

According to the article 26 Minister of Economy in agreement with relevant Ministers of Health, Environment or Agriculture has the right to publish executive regulations concerning restrictions in manufacturing, placing on the market and use of dangerous substances or mixtures which pose unjustified risk for human health or environment or in case, if such decision results from international agreements.

According to the article 27, item 1 – Inspector for Chemical Substances has the right to ban temporarily (not longer than for three months) placing on the market a mixture which is object of suspicion that it creates unacceptable hazard for human health or environment. According to the article 27, item 2 – the same decision can be made on request of Chief Sanitary Inspector or Chief Environmental Inspector.

According to the article 28, item 1 – similar right has again mentioned above Inspector (after receiving an opinion from the Chief Sanitary Inspector or Chief Environmental Inspector) in case of ban or cancel the ban of detergents placed on the market. The decisions are made for the period not longer than 6 months and then according to article 28, item 2 after the consultations Inspector for Chemical Substances prolongs or cancels his decision. According to the article 28, item 4 the same decision can be made on request of Chief Sanitary Inspector, Chief Environmental Inspector or President of the Office of Competition and Consumer Protection.

As mentioned above there are several provisions resulted from the discussed act which regulate internally some cases of hazards or unacceptable risk resulted from dangerous substances or dangerous mixtures manufacturing, placing on the market or use. These provisions are not directly intended to nanomaterials but in case of nanomaterials posing analogous problems – these provisions apply also to them.

The next pack of internal Polish executive regulations concerns classification and labelling of chemical substances and preparations (mixtures). This legislation in majority cases is consequence of the 'old' system of classification, labelling and packaging. Taking into account CLP regulation – Poland as the other EU Member States is in the transitional period: substances since 1 December 2010 until 1 June 2015 should be classified both according to 'old' Dangerous Substances Directive (DSD) 67/548/EEC and 'new' CLP regulation, also in the safety data sheets (SDSs) should be both classifications used, however labelling and packaging should be made according to the 'new' system resulted from CLP. After 1 June 2015 DSD will expire and only CLP provisions will be in force. In case of mixtures situation is even more complex, while since 1 December 2010 until 1 June 2015 classification of mixtures should be made obligatorily according to the 'old' Dangerous Preparations Directive (DPD) 1999/45/EC, classification according to CLP has currently the voluntary character. However way of operation concerning labelling and packaging of mixtures as well as information in the safety data sheets (SDSs) is strongly dependent on decisions made as regards classification. If classification has been made according to 'old' DPD – also labelling and packaging as well as information in the SDS should comply with DPD. If classification has been made according to DPD and additionally to CLP – labelling and packaging should comply solely with CLP and information in SDSs should be given in both systems. Analogically like in case of substances after 1 June 2015 DPD will expire and only CLP provisions will be in force.

This complicated transitional period justifies fact that mentioned above internal executive regulations mainly of the Minister of Health concerning 'old' classification – are still in force. Moreover, there are some cases of the new draft preparation concerning some selected regulations which in fact refer to 'old' system of classification and labelling but are result of relatively 'fresh' CLP regulation followed by the Act on Chemical Substances and their Mixtures of 25 February 2011.

In this legal block the following regulations could be mentioned:

- Regulation of the Minister of Health of 29 April 2010 concerning packaging of certain dangerous substances and dangerous preparations, which should be fitted with child-resistant fastenings and carry a tactile warning of danger (Polish Official Journal 2010 No. 83, item 544);
- Regulation of the Minister of Economy of 20 July 2009 on detailed requirements concerning labelling of packed goods (Polish Official Journal 2009 No. 122, item 1010);
- Regulation of the Minister of Health of 5 March 2009 concerning labelling of packaging of dangerous substances and dangerous preparations and selected chemical preparations (Polish Official Journal 2009 No. 53, item 439);
- Regulation of the Minister of Health of 5 March 2009 amending regulation on the criteria and way of classification of the chemical substances and preparations (Polish Official Journal 2009 No. 43, item 353);
- Regulation of the Minister of Health of 4 September 2007 amending regulation on the criteria and way of classification of the chemical substances and preparations (Polish Official Journal 2007 No. 174, item 1222);
- Regulation of the Minister of Health of 29 October 2004 amending regulation on the criteria and way of classification of the chemical substances and preparations (Polish Official Journal 2004 No. 243, item 2440);

- Regulation of the Minister of Health of 2 September 2003 on the criteria and way of classification of the chemical substances and preparations (Polish Official Journal 2003 No. 171, item 1666).

In the same packet three drafts of Polish regulations are foreseen:

- Draft of the Regulation of the Minister of Health of 29 August 2011 on the criteria and way of classification of the chemical substances and mixtures;
- Draft of the Regulation of the Minister of Health of 23 November 2011 on labelling of packaging of dangerous substances and dangerous mixtures and selected mixtures;
- Draft of the Regulation of the Minister of Health of 23 November 2011 on way of labelling the places, pipelines, containers and tanks used for storage or containing dangerous substances or dangerous mixtures.

All mentioned above regulations and draft regulations do not contain any specific provisions dedicated to the nanomaterials. However, any substance or mixture in the form of nano if fulfil criteria for classification, labelling and packaging according to its dangerous properties should comply with mentioned above regulations exactly like bulk substances or mixtures.

7.4.2 Biocides

First of all it is worth emphasizing that probably in the nearest future biocides will be regulated (similarly like chemicals by the REACH regulation 1907/2006) by the regulation published on the European level. On 12 June 2009 a Proposal for a *Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products* [COM (2009) 267 final] has been published in the Official Journal of the EU. According to this proposal an official register of biocidal products will be conducted on the Community level. Currently all legislation in Poland concerning biocides is a result of the Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998).

Thus, basic act in Polish legal system in this discipline is Polish Act of 13 September 2002 on biocidal products (Polish Official Journal 2002 No. 175, item 1433) further amended by the Polish Act of 28 July 2005 concerning amendment of the act on biocidal products (Polish Official Journal 2005 No. 180, item 1491) and then amended for the second time by the Polish Act of 29 October 2010 amending the act on biocidal products and the act amending act on biocidal products (Polish Official Journal 2010 No. 225, item 1464). Executive regulations resulted from the mentioned above act and its amendments are as follows:

- Regulation of the Minister of Health of 17 January 2003 concerning categories and groups of biocidal products according to their applications and identified use (Polish Official Journal 2003 No. 16, item 150);
- Regulation of the Minister of Health of 6 January 2004 concerning uniform procedures of evaluation of the biocidal product's documentation and criteria of operation during the biocidal product's evaluation (Polish Official Journal 2004 No. 9, item 74);
- Regulation of the Minister of Health of 13 July 2005 concerning detailed requirements to be met by documentation needed for biocidal product's evaluation (Polish Official Journal 2005 No. 147, item 1229);
- Regulation of the Minister of Health of 6 September 2006 concerning way and procedure of making changes in data comprising by the consent, temporary consent or entry to the register and changes in documentation being basis for the consent, temporary consent or entry to the register (Polish Official Journal 2006 No. 167, item 1190);

- Regulation of the Minister of Health of 12 January 2007 concerning fees resulted from the decision permitting to place biocidal product on the market (Polish Official Journal 2007 No. 8, item 62);
- Announcement of the Minister of Health of 20 December 2007 concerning inventory of active substances permitted to use in the biocidal products (Official Gazette of the Government of the Republic of Poland 2007 No. 100, item 1091);
- Announcement of the Minister of Health of 15 October 2008 concerning inventory of active substances permitted to use in the biocidal products and low risk biocidal products (Official Gazette of the Government of the Republic of Poland 2008 No. 85, item 750);
- Regulation of the Minister of Health of 28 May 2008 concerning template of application for entry made to the register, consent or temporary consent delivery, way of preparation of documentation and requirements to be met by documentation needed for active substance and biocidal product's evaluation (Polish Official Journal 2008 No. 101, item 650;
- Regulation of the Minister of Health of 28 May 2008 concerning uniform procedures of evaluation of the biocidal product's documentation and criteria of operation during the biocidal product's evaluation (Polish Official Journal 2008 No. 101, item 651);
- Announcement of the Minister of Health of 8 May 2009 concerning inventory of active substances permitted to use in the biocidal products and low risk biocidal products (Official Gazette of the Government of the Republic of Poland 2009 No. 32, item 473);
- Regulation of the Minister of Health of 12 May 2009 amending regulation concerning inventory of toxicological centers responsible for the control of poisoning by biocidal products and entities obliged to such poisoning notification (Polish Official Journal 2009 No. 81, item 686);
- Announcement of the Minister of Health of 2 April 2010 concerning inventory of active substances permitted to use in the biocidal products and low risk biocidal products (Official Gazette of the Government of the Republic of Poland 2010 No. 34, item 484);
- Announcement of the Minister of Health of 22 October 2010 concerning inventory of active substances permitted to use in the biocidal products and low risk biocidal products (Official Gazette of the Government of the Republic of Poland 2010 No. 79, item 973);
- Regulation of the Minister of Health of 8 April 2011 concerning values of fees resulted from the decision permitting to carry out research and development studies (Polish Official Journal 2011 No. 86, item. 479).

Mentioned above acts, regulations and legal announcements describe in detail the whole procedure of conditions and requirements to be met in order to legally place active substances and biocides on the market. Elementary principle is to register active substance and biocide to specially appointed for these purposes in Poland – the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. This registration should be preceded by relevant required tests and submission of detailed documentation as an application for permission concerning placing the biocide on the market. The same procedure concerns the biocides containing nanomaterials.

It is also worth to highlight that if active substances manufactured or imported for use solely in biocidal products, if registered according to mentioned above legislation – shall be regarded as being registered in REACH and therefore as fulfilling the REACH requirements [Article 15 (2) of the REACH regulation 1907/2006].

Polish legal acts operating as the basis for functioning and operation of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products are mentioned below in order from the most recent to the up-to-date one:

- Polish Act of 6 September 2001 on provisions introducing the act – Pharmaceutical Code, the act on medical devices and the act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Polish Official Journal 2001 No. 126, item 1382);
- Order No. 37 of the Prime Minister of 14 June 2011 concerning decision to confer charter of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Official Gazette of the Government of the Republic of Poland 2011 No. 50, item. 555);
- Already mentioned in the chapter 8.3.1. *"Chemicals"* act on chemical substances and their mixtures of 25 February 2011 (Polish Official Journal 2011 No. 63, item 322);
- Act of 18 March 2011 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Polish Official Journal 2011 No. 82, item 451);
- Regulation of the Minister of Health of 29 June 2011 concerning Commissions operating within the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Polish Official Journal 2011 No. 159, item 953).

The most recent regulations concerning use and commercialisation of biocides in Poland is Act changing former regulations about biocides of 29th October 2010 (Polish Official Journal 2010, item 1464, proclaimed by President of Poland). This act is based on European Parliament and European Council Directory 2009/107/WE of 16th September 2009 (European Official Journal UE L 262 of 06.10.2009, pp.40)
Of course former regulation are obligatory as well, the definition of biocides we can find in Polish Official Journal No. 175, item. 1433; categories are described in Polish Official Journal No 16, item. 150; and conditions for market entrance are listed in Polish Official Journal No. 175, item. 1433 with further changes. The main regulations about biocides in Poland are dated of 15th September 2002 when "Act of biocides products" were established in frame of initiative to unify Polish and EU legal system before Poland finally entered EU in 2004. (Polish Official Journal, 2002 No. 175, item.1433).

7.4.3 Plant protection products

Starting to discuss subject of plant protection products one remark might be concluded just at the beginning. The legal system in Poland concerning plant protection products is very similar to the system obligatory in biocides' sector. Each company placing the plant protection product on the market has to have a relevant permission for such activity. There is only one difference in comparison to the system operating in biocides' sector. Instead of previously mentioned the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products as a competent authority to release suitable consents – in case of plant protection products a competent authority to take decision on permit such product for marketing – is Minister of Agriculture and Rural Development himself with strong support from the Plant Health and Seed Inspection Main Inspector and after receiving a positive opinion of the Commission for Plant Protection Products Affairs appointed by the Ministry according to article 42 of the mentioned below act. The whole procedure of permits for placing on the market plant protection products is included in chapter 3 of the Polish act of 18

December 2003 on plant protection (Polish Official Journal 2004 No. 11, item 94). This basic act has been amended two times: by the Polish act of 27 April 2006 amending the act on seed production and the act on plant protection (Polish Official Journal 2006 No. 92, item: 639) and second time by the Polish act of 30 March 2007 amending the act on plant protection and some other acts (Polish Official Journal 2007 No. 80, item 541). Unified text of this main legislation has been published in the Polish Official Journal 2008 No. 133, item 849 with further amendments.

Generally this act regulates following issues:

- Plant protection against pests;
- Consents for placing on the market plant protection products and for application of active substances to them;
- Prevention of hazard for human health, animals' welfare and environment, which may occur as a result of marketing and use of plant protection products;
- Organization of the Main Inspectorate of Plant Health and Seed Inspection.

For the needs of this report the second and fourth bullet seems to be the most significant.

According to the article 38 of this act permission for placing the plant protection product on the market is granted, if this pesticide:

- Contains active substance allowed for use in pesticides by the European Commission and meets conditions associated with its use in a plant protection product, determined by the Commission;
- Is effective in pest control;
- Does not indicate undesired effects on plants and vegetable products;
- Does not creates needles suffering in control of vertebrates population;
- Is used accordingly to the appropriation:
  - Does not indicate any hazard for human health, animals or environment, and in particular for surface and subterranean waters, including drinking water, by respecting complex of processes, which active substance and preparation may be subject to in the soil, water and air, as well as biotic and abiotic transformations and these processes' kinetics, called further „behaviour and fate",
  - Does not indicate undesired effect on organisms being not target of its application;
- Whether physicochemical properties of the plant protection product have been determined and whether they are appropriate to the scope of its application, storage and transport;
- Whether using method indicated by applicant for permission is it possible to determine:
  - Type and content of the active substance and other substances as components of this pesticide, including contaminants with toxicological and ecotoxicological hazards,
  - Pesticide's residues resulted from its use according to ways of application;
- Whether maximum allowable level of residues in relevant for this pesticide food have been determined according to the Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005) or provisions concerning safety of food and nutrition;
- An inventory of active substances allowed for use in plant protection products and conditions associated with their use in a pesticide is determined in Annex 1 to the Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1–32);

- Labelling and packaging of the plant protection product have been determined according to the provisions on chemical substances and their mixtures;
- Commission for Plant Protection Products Affairs has issued a positive opinion.

The requirement of additional national permission for application of an active substance in the plant protection product issued by the European Commission, is not applied in the case, when such pesticide contains active substance for which the European Commission has already taken decision confirming submission of the application for active substance use in the pesticide including required documentation.

Article 39 of this act describes the whole procedure of application for such permission:

- Each entity producing or marketing any plant protection product may apply for permission concerning placing the plant protection product on the Polish market. Such entity is further called an “applicant”. It should be located on the territory of Poland or in one of the EU member states.
- Application form is submitted to the Minister of Agriculture and Rural Development.
- It includes:
- Full name, address and contact details of the applicant and / or producer of the pesticide, if applicant is not simultaneously its producer;
- Full name, address and contact details of the importer or distributor of the pesticide, if producer is not located on the territory of Poland;
- Name and type of the pesticide and its form of use;
- Chemical and customary trade name of active substance, its concentration in the plant protection product as well as name, address and location of this substance producer;
- Date and signature of the applicant.

The following documents should be included to the application:

- Document confirming economical activity in the area of plant protection product manufacturing or marketing;
- Safety data sheet of both: active substance and plant protection product itself according to the template described in detail in the Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 133, 31.5.2010, p. 1–43);
- Tests results, including results of efficacy evaluation, data and evaluations concerning the plant protection product (according to the article 60, item 1);
- Tests results, information, data and evaluations concerning active substance (according to the article 60, item 2);
- Label draft with use manual of the pesticide prepared in Polish;
- Samples of the plant protection product, active substance and residual substances and if required by the Minister of Agriculture and Rural Development – design of pesticide packaging;
- Receipt of registration fee payment according to article 59, item 1.

Tests themselves of the pesticide, excluding efficacy evaluation testing, tests of active substance mentioned in item 4, points 3 and 4 are performed:

- According to the Good Laboratory Practice scheme described in the provisions on chemical substances and their mixtures;
- In laboratory units possessing Good Laboratory Practice certificate according to the provisions on chemical substances and their mixtures;

- With help of the methods determined on the basis of article 13 of the regulation 1907/2006 (REACH);
- If a pesticide contains an active substance allowed by the European Commission for use in the plant protection products and this substance does not differ significantly with grade of purity, type of contaminants and fulfils requirements specified in detailed provisions of the European Commission for this substance – tests results, information, data and evaluations concerning identification and properties of this substance made by the European Commission should be additionally included to the application;
- Tests results, information, data and evaluations mentioned in item 4, points 3 and 4 are submitted in Polish or in English, excluding tests results of efficacy evaluation of the plant protection product, which should be submitted exclusively in Polish.

From mentioned above considerations it can be concluded that if a plant protection product would contain any active substance or co-formulant in form of nanomaterial it should be subject of the same procedure of permission like standard 'traditional' pesticide.

It is also obvious that similarly like in case of biocides – if active substances and also co-formulants manufactured or imported for use solely in plant protection products, and if registered according to mentioned above legislation at the Ministry of Agriculture and Rural Development – shall be regarded as being registered in REACH and therefore as fulfilling the REACH requirements [Article 15 (1) of the REACH regulation 1907/2006].

The basic act on plant protection is of course equipped with relevant set of executive regulations published mainly at the Polish Official Journal by the Minister of Agriculture and Rural Development. In this set directly intended for plant protection products the following regulations should be mentioned:

- Regulation of the Minister of Agriculture and Rural Development of 24 June 2002 on occupational health and safety by using and storage of plant protection products, mineral fertilizers, and mixture of organic and mineral fertilizers (Polish Official Journal 2002 No. 99, item 896);
- Regulation of the Minister of Agriculture and Rural Development of 8 June 2004 concerning requirements on content of label – instruction manual of the plant protection product (Polish Official Journal 2004 No. 141, item 1498);
- Regulation of the Minister of Agriculture and Rural Development of 4 August 2004 on efficacy evaluation of plant protection products (Polish Official Journal 2004 No. 183, item 1890);
- Regulation of the Minister of Agriculture and Rural Development of 1 September 2004 amending regulation concerning requirements on content of label – instruction manual of the plant protection product (Polish Official Journal 2004 No. 202, item 2074);
- Ordinance of the Minister of Agriculture and Rural Development of 14 April 2005 amending ordinance on efficacy evaluation of plant protection products (Polish Official Journal of 2 May 2005 No. 76, item 670);
- Regulation of the Minister of Agriculture and Rural Development of 5 May 2005 amending regulation on occupational health and safety by using and storage of plant protection products, mineral fertilizers, and mixture of organic and mineral fertilizers (Polish Official Journal 2005 No. 88, item 752);
- Regulation of the Minister of Agriculture and Rural Development of 31 May 2005 concerning fees for the activities made by the local stations responsible for the chemical and rural affairs (Polish Official Journal 2005 No. 99, item 833);

- Regulation of the Minister of Agriculture and Rural Development of 21 August 2006 concerning fees for the activities made by the local stations responsible for the chemical and rural affairs (Polish Official Journal 2006 No. 148, item 1071);
- Regulation of the Minister of Agriculture and Rural Development of 3 July 2007 amending regulation concerning registration fees for the activities associated with issue of decision concerning plant protection products and active substances as well as mode of their payment (Polish Official Journal 2007 No. 133, item 927);
- Regulation of the Minister of Health of 17 October 2007 concerning food sampling in order to determine levels of plant protection products residues (Polish Official Journal 2007 No. 207, item 1502);
- Regulation of the Minister of Agriculture and Rural Development of 24 June 2008 concerning fees for the services performed by the Health and Seed Inspection Main Inspectorate and for publishing labels, passports of plants or official leaden seals (Polish Official Journal 2008 No. 122, item 789);
- Regulation of the Prime Minister of 28 July 2008 concerning authorizing of the officials of Veterinary Inspection, Agricultural and Food Quality Inspection and Health and Seed Inspection Main Inspectorate to impose a fine (Polish Official Journal 2008 No. 137, item 861);
- Regulation of the Minister of Agriculture and Rural Development of 16 December 2010 concerning training in the range of plant protection (Polish Official Journal 2010 No. 256, item 1721);
- Regulation of the Minister of Agriculture and Rural Development of 16 December 2010 concerning integrated production of plants (Polish Official Journal 2010 No. 256, item 1722);

Current legal regulation in that field in Poland are included in Order of Minister for Agriculture and Rural Area Development of 22 December 2011 (Polish Official Journal 2011, No. 284, item. 1673), especially terms of the specific conditions which should be fulfilled when listed chemical substances are in question.
This substances required special study, cart of characteristic, information and assessment before entrance of the market.
2 (E)-5-deceno-1-ol (E,E)-8,10-dodecadieno-1-ol, (Z)-8-dodeceno-1-ol, (Z)-9-heksadecenal (Z)-11-heksadecenal, (Z)-11-heksadeceno-1-ol, (Z)-13-oktadecenal, (Z)-7-tetradecenal.
(Mostly organic substances, there are also non-organic chemical substances but nano- is not separately treated).
Mentioned above order is prepared according to the European Commission executive directive 2011/60/UE of Official EU Journal UE L136 of 24.05.2011, pp.58.
There is also former regulation concerning list of active substances, which can not be used in plant protection products. This is Order of Minister for Agriculture and Rural Area Development of 22 November 2010 (Polish Official Journal, 2010 No.235, item. 1547). This list contains organic substances, additionally Cd and it's compounds, Se and it's derivatives , Pb and compounds of mercury. There are not mentioned nano-substances but it is possible to occur nano materials with mentioned above elements.

7.4.4 General Product Safety

In Poland recently we have Act about chemical substances and their mixtures of 25 February 2011 (Polish Official Journal 2011, Dz.U.11.63.322 of 24th March 2011). This act described responsibility and duties of official administrative authorities in Poland. It was prepared according to regulations of EC, European Parliament and earlier regulations like EWG. In this same time this act describes fields which are excluded from it and different regulations are obligatory. Former regulation in that field is dated 12 December 2003, Act described general product safety. There is also given definition of safety product, which is product which in normal conditions or predictable conditions of use, do not cause any hazard for the users or very low dangerous conditions which could be connected with it's normal use.
Distributors of the products are also obliged to not distribute dangerous and hazardous products.

7.4.5 Cosmetics

In Poland actual obligatory regulations concerning cosmetics, their productions and commercialisations are according to the Act on cosmetics of 30 March 2001 (Polish Official Journal 2001, No. 42, item. 437), before that time very ancient from 1928 and 1939 regulations were used on that field. Mentioned above act should in the first place unified regulations between Poland and EU on cosmetology (especially directive 76/768, which is the main law source about cosmetics). From the safety of cosmetics point of view there are three categories of requirements: concerning content of product, labelling of the product and full information about product is required.
List and minimal content of substances which are forbidden and those which could be only used in special conditions are described in Minister of Health Order - Polish Official Journal 2005, No. 72, item 642. The General Sanitary Inspector has power to decide about possibility to keep in secret some agents which are used in production of cosmetics, only human health safety rules can decided about such decision. There is in Poland also National Register of all information concerning cosmetics on the market, this information is open to public.
If any cosmetics got official request to be not further distributed due to some information received by the General Sanitary Inspector, this decision is passed to European Commission as well.
Since nanomaterials are more and more present in products on the market, there was European legislation initiative which is European Parliament directive (WE) No. 1223/2009 of 30 November 2009 (UE L 09.342.59), this legal act is of great importance for cosmetic industry in Europe. There is given unified definition of nanomaterials and also risk assessment procedures of their use are given. Before product entrance to the market all nanomaterials must be listed. European Commission on the base of received applications will start safety verification procedure, ask for expertise from Scientific Committee Consumers Safety (SCCS). Until the date of 11 July 2013 when the regulation of this directive will be in force, the rules of using nanomaterials will remain unchanged.

7.4.6 Food

There are several obligatory regulations concerning food, food industry and packaging.

1. Minister of Health Order of 18th February 2011 (Polish Official Journal 2011, No. 52, item 272) concerning extraction solvents which can be used in food industry. The only possible is use of ether diethyl, methanol, 2-propanol.
2. Minister of Health Order of 16th September 2010 (Polish Official Journal 2010, No. 174, item 1184) concerning enriching substances as addition to food, it means vitamins, salt, folic acid in proper concentrations.
3. Minister of Health Order of 16th September 2010 (Polish Official Journal 2010, No. 180, item 1214) concerning special nutrition items for special purposes, like for newborn babies, dietetically products
4. Minister of Agriculture and Rural Area Development Order of 10 July 2007 concerning labelling and packaging of nutrition agents. There is obligatory to give name of the agent, content of the agent, expiry date, mode of preparation, detailed description of packaging conditions (like use of neutral gases), sugar addition, conservative agents, solvents etc.

Mentioned above regulations are based between others on following directives of European Commission and Council: 87/250 of 15 April 1987 (WE L 113 of 30.04.1987, p.37; 2001/101/WE of 26 November 2001 (WE L 310 of. 28.11.2001, p.19); 2003/89/WE of 10 November 2003 (UE L 308 of 25.11.2003, p. 15); 2007/68 /WE of 27 November 2007 (UE L 310 of 28.11.2007, p. 11); 2008/5/WE of 30 January 2008 (UE L 27 of 31.01.2008, p. 12); 2000/13/WE of 20 March 2000 (WE L 109 of 06.05.2000, p. 29).

5. Act on commercial values of agricultural - food articles, of 21 December 2000 (Polish Official Journal 2001, No.5 item.44) gives specific description about required quality, classification, packaging and labelling of commercial food articles.
6. President of Poland Act of 22nd October 2010 about safety of food and nutrition (Polish Official Journal 2010, No. 230, item 1511) which is based on European Parliament directive WE No.767/2009 of 13 July 2009; European Commission directive 82/475/EWG of 23 June 1982 (WE L 213 of 21.07.1982, p. 27); European Council directive 90/167/EWG of 26 March 1990 (WE L 92 of 07.04.1990, p.42); European Council directive 98/51/WE of 9 July 1998 (WE L 208 of 24.07.1998, p. 43); European Commission directive 98/68/WE of 10 September 1998 (WE L 261 of 24.09.1998, p. 32); European Parliament and Council directive 2002/32/WE of 7th May 2002 (WE L 140 of 30.05.2002, p. 10); European Commission directive 2008/38/WE of 5th March 2008 (UE L 62 of 06.03.2008, p. 9).

7.4.7 Medical Devices and Medicinal Products

Medical devices for different purposes are classified for: I, IIa, IIb and III, it depends on the potential risk assessment on human body according to Article 13 passage 1 about medical devices (Act of medical devices of 20 May 2010 – Polish Official Journal, 2010, No. 107, item. 679), Classification rules were proclaimed in Health Minister Order on classification of medical devices for different purposes, of 30th April 2004 (Polish Official Journal 2004, No.100, item 1027). This order adopted European Council directive on medical devices, 93/42/EWG of 14 June 1993.

Medical devices for in vitro diagnostics are classified for groups according to potential hazard when are applied. There are groups and lists A, B and devices for self use, medical devices for in vitro diagnostics and others (Article 14 and 15 of this edict). During this classification

process is taken into account their time of exposure at human body, the place of contact, level of invasiveness, local and general activity, function and applied technologies. There are not mentioned nano-materials. According to this Act, proper Authorities proclaim executive regulations which are obligatory on this field.

There is also more recent regulation concerning medical devices. Act on medical devices of 20th May 2010. This act described rules obligatory before products are presented on the market and for general use. Between other such medical devices like active medical devices for implantations. Definition given for active medical devices is as follows: active medical device it means medical device with appropriate equipment, which use other type of energy than only this generated by human body or the force of gravity, which is to be insert (as a whole or a part) during surgery operation or other medical procedure into human body or into natural whole in human body and it will remain after this in human body. This regulation is not applicable to cosmetics and pharmaceutics which are regulated separately. This act does not concern products with international certificates, also devices used for assessment of laboratory work (like calibrators, control materials). But this act should be applied for all medical devices and active medical devices which include as integral part substances which could be used separately as blood derivatives or medicine and can support human body according to medical device or active medical device for implantation.

This mentioned above Act is based on following European regulations:

1. Council directive on the unification of law regulations concerning medical devices of active settlement 90/385/EWG of 20 June 1990 (European Community Official Journal WE L 189 of 20.07.1990, pp. 17) in case of active medical devices for implantations.
2. Council directive concerning medical devices 93/42/EWG of 14 June 1993 (European Community Official Journal WE L 169 of 12.07.1993, pp. 1)
3. Council directive concerning medical devices for in vitro diagnostics 98/79/WE of 27 October 1998 (European Community Official Journal WE L 331 of 07.12.1998, pp. 1)

The Act on the system of compliance assessment of 30th August 2002 (Polish Official Journal 2004, No. 204, item.2087). This act described general rules about application of system of compliance assessment with general and detailed requirements concerning products. Rules and methods to applying of accreditation and authorisations. The way of submission authorised laboratories and authorised units to the European Commission and European Union member countries. Tasks for Polish Accreditation Centre and working rules for compliance assessment system for products entering market. The main goal of this act it is elimination of hazardous influence on human health and life as well as environmental pollutions caused by medical devices. The other goal it is decent assessment of products provided by independent institutions.

There is also different Act for medical devices of 20 April 2004 (Polish Official Journal 2004, No. 93, item.896) which is valid in other kind of medical devices not mentioned before.

The most recent regulation it is Edict about criteria of claiming medical incidents and activity concerning product safety, prepared by Minister of Health, of 2 February 2011 (Polish Official Journal 2011, No. 33, item 167). This act contains as well the template of report FSCA and NCAR (as well as forms for medical incidents notification and urgent field safety notice) and procedures which should be follow when such medical incident occurs.

7.4.8 Industrial Law and Environmental Protection

Environmental regulation relevant in this context relates in particular to integrated pollution prevention and control (IPPC), the control of major accident hazards involving dangerous substances (Seveso II), the water framework directive and a number of waste directives.

The IPPC Directive[35] covers approximately 52,000 industrial installations across the EU and requires installations falling under its scope to operate in accordance with permits including emission limit values based on the application of best available techniques (BAT). In principle, the IPPC Directive could be used to control environmental impacts of nanomaterials and nanomaterials issues at IPPC installations through the inclusion of such considerations into the Commission's BAT Reference Document (BREFs) process should the need arise.

The Seveso II Directive[36] applies to establishments where named dangerous substances (or substances falling within certain classification categories) are present above specific quantities (or thresholds). It imposes a general obligation on operators to take all measures necessary to prevent major accidents and to limit their consequences for man and the environment. If certain nanomaterials are found to demonstrate a major accident hazard, they may be categorized, together with appropriate thresholds, in the context of the Directive.

The Water Framework Directive (2000/60)[37] sets common principles and an overall framework for action to improve the aquatic environment and to progressively reduce the pollution from priority substances and phasing out emissions, discharges and losses of priority hazardous substances to water. A list of 33 priority substances has been established in 2001[38]. Nanomaterials could be included among the Priority Substances depending on their hazardous properties. Environment Quality Standards would in these cases be proposed by the Commission. For groundwater[39], Member States will have to establish quality standards for pollutants representing a risk, in which case nanomaterials may also be included.

Directive 2006/12/EC on waste[40] sets the general framework and imposes an obligation on Member States to ensure that waste treatment does not adversely affect health and the environment. The hazardous waste Directive[41] defines which wastes are hazardous and lays down stricter provisions regarding such waste. Hazardous waste must display certain properties set out in an Annex to the Directive and feature on the European Waste List as hazardous. Wastes containing nanomaterials could be classified as hazardous, if the nanomaterial displays relevant properties which render the waste hazardous.

Specific legislation has been adopted to deal with particular waste streams[42] or specific waste treatment processes, such as incineration[43] and landfill[44]. Current EU waste legislation covers general requirements for the protection of health and the environment during waste

[35] Council Directive 2008/1/EC concerning integrated pollution prevention and control; OJ L 24 29.01.2008

[36] Directive 96/82 on the control of major-accident hazards involving dangerous substances; OJ L10 of 14.1.1997

[37] Directive 2000/60/EC ,OJ L 327, 22.12.2000

[38] Decision No 2455/2001/EC, OJ L 331, 15.12.2001

[39] Directive 2006/118/EC; OJ L 372, 27.12.2006

[40] Directive 2006/12/EC; OJ L 114, 27 4 2006

[41] Directive 91/689/EEC; OJ L 377, 31.12.1991

[42] E.g. electrical and electronic equipment, end of life vehicles, packaging and packaging materials, batteries, titanium dioxide

[43] Directive 2001/80/EC; OJ L 309, 27.11.2001

[44] Directive 1999/31/EC; OJ L 182 , 16.07.1999

management. It also includes requirements for the management of specific waste materials that may contain nanomaterials whilst not explicitly addressing the risks of nanomaterials. If the need for more specific provisions is established, appropriate action can be proposed or implemented under the current legislative framework. Similarly, action can be taken by Member States in implementing current provisions in the framework of national policies.

The environmental protection it is concern of Polish Government according to our constitutional rights. There are regulations concerning all kind of activity in different branches of industry, agriculture, construction, transport etc. This regulations are based on appropriate European Parliament and Council directives, which some were mentioned above.
The Polish regulations concerning environmental protection it is Act on Environmental Protection Law with the most recent changes of 29th October 2010 (Polish Official Journal 2010, No.229, item 1498) was established on 27th April 2001 (changes were published in Polish Official Journal 2008, Mo. 25, item.150 with further changes). It is obligatory regulation and our government pay attention to include all necessary European Parliament and Council directives. Below it is list of the most important current regulations.

- Act about Environmental Protection Law on 27th April 2001 (full text and changes were published in Polish Official Journal 2008, No. 25, item.150 with further changes),
- Act on introduction into practice act about environmental protection law, waste handling and changing some other acts, of 27th July 2001 (Polish Official Journal 2001, No. 100, item. 1085),
- Act on publicity of information about environment and it's protection, participation of the society in environmental protection and about assessment of influence on the environment, of 3rd October 2008 (Polish Official Journal 2008, No. 199, item. 1227),
- Act on prevention of damages in the environment and it's improvement, of 13th April 2007 (Polish Official Journal 2007, No. 75, item. 493),
- Act on nature protection of 16th April 2004 (Polish Official Journal 2004, No.92, item. 880), Act on nature protection of 16th April 2004 (Polish Official Journal 2004, No.92, item. 880),
- Act on forests of 28th September 1991 (Polish Official Journal 1991, No.101, item. 444),
- Act on protection of agricultural and forest areas of 3rd February 1995 (Polish Official Journal 1995, No.16, item. 78),
- Act on the system of governance of greenhouse gases and other substances, of 17th July 2009 (Polish Official Journal 2009, No.130, item. 1070),
- Act on plant protection of 18th December 2003 (Polish Official Journal 2004, No.11, item. 94),
- Act on animals protection of 21st August 1997 (Polish Official Journal 1997, No.111, item. 724),
- Act on genetically modified organisms of 22nd June 2001 (Polish Official Journal 2004, No.92, item. 880),
- Act on nature protection of 16th April 2004 (Polish Official Journal 2001, No.76, item. 811),
- Act on protecting continuation of national character of strategic natural resources, of 6th July 2001 (Polish Official Journal 2001, No.97, item. 1051),

- Act on geological and mining law of 4th February 1994 (Polish Official Journal 1994, No.27, item. 96),
- Act on atomic law of 29th November 2000 (Polish Official Journal 2001, No.3, item. 18),
- Act on wastes of 27th April 2001 (Polish Official Journal 2001, No.62, item. 628),
- Act on packaging and packaging wastes of 11th May 2001 (Polish Official Journal 2001, No.63, item. 638),
- Act on entrepreneurs obligations concerning treatment of some kind of wastes as well as about products payment and deposits payment, of 11th May 2001 (Polish Official Journal 2001, No.63, item. 639),
- Act on international transfer of the wastes of 29th June 2007 (Polish Official Journal 2007, No.124, item. 859),
- Act on worn out electrical and electronic devices of 29th July 2005 (Polish Official Journal 2005, No.180, item. 1495),
- Act on batteries and accumulators of 24th April 2009 (Polish Official Journal 2009, No.79, item. 666),
- Act on recycling of worn out vehicles of 20th January 2005 (Polish Official Journal 2005, No.25, item. 202),
- Act on output mining wastes of 10th July 2008 (Polish Official Journal 2008, No.138, item. 865),
- Act on the trade of the permissions to emit greenhouse gases and other substances to the air, of 22nd December 2004 (Polish Official Journal 2004, No.281, item. 2784),
- Act on marine code of 18th September 2001 (Polish Official Journal 2001, No.138, item. 1545),
- Act on water law of 18th July 2001 (Polish Official Journal 2001, No.115, item. 1229),
- Act on special solutions concerning flood (of May and June) damages removing, of 24th June 2010 (Polish Official Journal 2010, No.123, item. 835),
- Act on hunting law of 13th October 1995 (Polish Official Journal 1995, No.147, item. 713),
- Act on fishery of 19th February 2004 (Polish Official Journal 2004, No.62, item. 574),
- Act on ecological agriculture of 25th June 2009 (Polish Official Journal 2009, No.116, item. 975),
- Act on food and nutrition safety of 25th August 2006 (Polish Official Journal 2006, No.171, item. 1225),
- Act on road transportation of 06th September 2001 (Polish Official Journal 2001, No.125, item. 1371),
- Act on inland fishery of 18th April 1985 (Polish Official Journal 1985, No.21, item. 91),
- Act on inland navigation of 21st December 2000 (Polish Official Journal 2001, No.5, item. 43),
- Act on protection sea pollution by ships of 16th March 1995 (Polish Official Journal 1995, No.47, item. 243),
- Act on forest reproduction material of 7th June 2001 (Polish Official Journal 2001, No.73, item. 761),
- Act on fertilizers and fertilization of 10th July 2007 (Polish Official Journal 2007, No.147, item. 1033),
- Act on prohibition of using product with asbestos of 19th June 1997 (Polish Official Journal 1997, No.101, item. 628),

- Act on chemical substances of 11th January 2001 (Polish Official Journal 2001, No.11, item. 84),
- Act on bio-copouts and bio-fuels of 25th August 2006 (Polish Official Journal 2006, No.169, item. 1199),
- Act on substances which impoverish ozone layer of 20th April 2004 (Polish Official Journal 2004, No.121, item. 1263),
- Act on Inspection of Environmental Protection of 20th July 1991 (Polish Official Journal 1991, No.77, item. 335),
- Act on cleaning and order rules in districts of 13th September 1996 (Polish Official Journal 1996, No.132, item. 622),
- Act on the national system of eco-management and adit of 15th July 2011 (Polish Official Journal 2011, No.178, item. 1060),
- Act on planning and spatial development of 27th March 2003 (Polish Official Journal 2003, No.80, item. 717),
- Act on construction law of 7th July 1994 (Polish Official Journal 1994, No.89, item. 414),

Act on code of administrative conduct of 14th June 1960 (Polish Official Journal 1960, No.30, item. 168),

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8 Nano Regulation in Slovakia

8.1 Slovak Nano Action Plan

Legislation: Regarding legislation, nowadays there is no plan to develop new legislative acts, our priority is to be in line with European legislation. Communication among various stakeholders has been launched on nano issues. Representatives of Slovak Authorities actively participated in working groups at OECD and EU level.
Standardisation: In Priority Objectives of the Slovak Office of Standards, Metrology and Testing - Concept of State Policy for the year 2011, there is an expectation of development of new areas of metrology, which will require new technology, low carbon energy, new systems of production and economy, which will use the new generation of materials (nanomaterials) replacing the resource- and energy- intensive materials used in the traditional systems of production and economy. The industry comes with new requirements for production quality assurance, while the new measurement techniques and affordable measuring devices remain absent.

8.2 Workplace safety

Based on the analysis of current legislative environment, it can be concluded that none of the laws on safety and health protection at workplace mentions either one of the terms "nano", or „nano particles“, or „nano technology“.

The performed survey shows that implementation of the term "nano" in the Slovak legislation is currently at the stage of preparation. On the other hand, there are four Slovak Technical Standards (STN) dealing with either nanoparticles, or nanotechnologies. All four of the aformentioned STN standards are adopted EN standards.

Legislation in preparation

Invitation for offer of submission No. VT/2011/039 (valid until: 07/2011)
Objective - *"to determine the potential impact of nanomaterials and nanotechnology in the workplace, to assess the scope and requirements for possible modification of the relevant EU legislation in the field of safety and health protection in the workplace and to produce a manual taking account of the relevant risks / concerns to ensure the most appropriate health protection and safety of workers against risks associated with the exposure to nanomaterials, or with the use of nanotechnology."*

Identification of difficulties with the definition and measurement of nanoparticles at workplace:

(?) There is no available / prescribed method and technology to measure the size of free nanoparticles in the workplace
(?) There is no prescribed and/or proven personal protective equipment for safe handling of nanomaterials (nanoparticles)
(?) There is no known effective and validated method for monitoring the concentration of free nano particles in the air (in the workplace)
(?) There is a lack of concentration limits (NPEL, DNEL, etc.) for airborne nanoparticles

(?) There is a lack of data and measurements of direct (acute) effects on human health resulting from the exposure to nanoparticles
(?) Information is missing regarding the indirect (long-term) effects of the exposure to nanoparticles

Overview of legislation governing the health and safety at work in the Slovak Republic

Act No. 311/2001 *on Labour Code*, as amended
Act No. 124/2006 *on Safety and Occupational Health,* amending certain acts, as amended
Government Ordinance No. 272/2004 establishing a list of occupations and workplaces that are forbidden for pregnant women, mothers until the ninth month of gestation period and nursing women, list of occupations and workplaces linked to specific risks for pregnant women, mothers until the ninth month of gestation period and for breastfeeding women, and establishing certain obligations for their employers
Government Ordinance No. 286/2004 establishing a list of occupations and workplaces that are forbidden for adolescent employees, and establishing certain obligations for employers hiring adolescent employees
Government Ordinance No. 338/2006 on Health Protection of Workers from Risks Related to Exposure to Biological Agents at Work
Government Ordinance No. 355/2006 on Protection of Workers from Risks Related to Exposure to Chemical Agents at Work, as amended by the Government Ordinance No. 300/2007
Government Ordinance No. 356/2006 on Health Protection of Workers from Risks Related to Exposure to Carcinogenic and Mutagenic Factors at Work, as amended by the Government Ordinance No. 301/2007.
Government Ordinance no. 387/2006 on the Requirements to Ensure the Safety and Health Labeling at Work
Government Ordinance no. 391/2006 on the Minimum Safety and Health Requirements for Work
Government Ordinance no. 392/2006 on the Minimum Safety and Health Requirements for the Use of Work Equipment
Government Ordinance No. 395/2006 on the Minimum Requirements for the Provision and Use of Personal Protective Equipment
Ministry of Health Decree No. 504/2006 on How to Report, File and Register Occupational Diseases and Hazards arising from Occupational Diseases
Ministry of Health Decree No. 448/2007 on Details of Work and Workplace Related to the Categorization of Work in Terms of Health Risks and the Details of the Proposal for Occupational Categories
Ministry of Health Decree No. 520/2007 establishing the Extent of Required Knowledge Proficiency, for Details on Setting Up a Commission for Work Proficiency and Content of Competency Certificates
Ministry of Health Decree No. 542/2007 on the Details of Health Protection Against Physical Stress at Work, Mental Workload and Sensorial Stress at Work
Decree No. 292/2008 on Details regarding the Scope and Content of the Activities of Occupational Health Services, the Composition of the Team of Experts and the Requirements for their Professional Competence

Overview of legislation governing the health and safety requirements for products

Act No. 264/1999 on Technical Requirements for Products and Conformity Assessment, amending certain acts, as amended
Government Ordinance No. 404/2007 on The General Product Safety
Government Ordinance No. 35/2008 laying down the Technical Details on Requirements and Conformity Assessment Procedures for Personal Protective Equipment

Overview of legislation governing the chemical substances and major industrial accidents:

Act No. 67/2010 on the Technical Requirements for Chemical Substances and Mixtures Placed on the Market *(Chemical Act)*, amending certain acts
Act No. 261/2002 on the Prevention of Industrial Accidents, amending and supplementing certain acts
Decree of the Ministry of the Environment No. 489/2002 implementing certain provisions of the Prevention of Major Industrial Accidents, amending certain acts, as amended by the Ministry of Environment Decree No. 451/2005
Vocational Guidance of the Ministry of Health of the Slovak Republic No. 10525/2010 regarding the Content of Preventive Medical Examinations in Relation to Work

8.3 Material and Product Specific Regulation in Slovakia

8.3.1 Chemicals

Definition:
Chemical substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Legislation in force
Slovak legislation:
Act No. 67/2010 on Introducing the Chemical Substances and Mixtures on the Market (transposition of the EU legislation – Directive No. 67/548/EEC, as amended, including ATP and its implementing regulations).

EU legislation:
EP and Council Regulation No. 1097/2006/EC REACH *(as amended)*
EP and Council Regulation No. 1272/2008/EC CLP *(as amended)*

Chemical legislation in the Slovak Republic is fully covered by the EU Regulations. The term "nano material" or "nano particle" is currently not to be found in the Slovak legislation on chemicals. However, the legislation in field of classification, packaging and labeling of chemicals when placed on the Slovak market does not set a quantity limit or deal with the substance´s chemical structure or particle size distribution (rules apply to all substances equaly - hence also for nanomaterials).

However, it is necessary to focus on chemicals, whose character could meet the definition of nanomaterial and which are used in everyday industrial production (eg. carbon).

Commission Regulation (EC) No. 987/2008 amending and supplementing the European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration,

Evaluation, Authorisation and Restriction of Chemicals (REACH), with regards to **Annexes IV and V (exemption from registration):**

Excerpt – ... „*the review conducted by the Commission under Article 138., paragraph 4, revealed that **three substances listed in Annex IV** should be excluded from this Annex due to lack of information based on which the substances could be considered as causing minimum risk related to their intrinsic properties" ...*
*This is also the case of carbon and graphite, particularly because of their respective EINECS and/or CAS numbers which are used to identify **forms of carbon or graphite at the nanoscale**, and which do not meet the criteria for inclusion in Annex IV.*

8.3.2 Biocides

Definition:
Biocidal product is a product which contains the active biocidal substance intended to destroy, deter, render harmless, or to achieve other regulatory action.

Legislation in force
Slovak Legislation:
Act No. 217/2003 on Conditions for Placing Biocidal Products on the Market, as amended (transposition of the EU legislation – Directive No. 98/8/EC as amended by the EP and Council Directive (EC) No. 2009/107) and its implementing regulations. The term "nanomaterial" is not to be found in the current legislative regulations concerning biocidal products. From commonly used nano materials, the silver metal is a key biocidal substance having strong antimicrobial properties.

EU legislation:
Commission Regulation No. 1454/2007/EC, which replaces the Commission Regulation (EC) No. 2032/2003.

With respect to the EU Regulations concerning biocidal substances - After May 2014, all active substances must be authorized before being permitted on the market. At present, there is a transitional period – which means an unregulated market. In the future, only substances with an acceptable risk should be placed on the market. Currently, there are eight types of widely used silver (Ag) nanoparticle-based compounds on the Slovak market: silver adsorbed on silicon dioxide (SiO_2) and titanium dioxide (TiO_2), silver chlorate (AgCl) adsorbed on titanium dioxide (TiO_2), silver-zinc (Ag-Zn) zeolite, silver-copper (Ag-Cu) zeolite, silver-phosphate glass, silver carbonate (Ag_2CO_3) and silver oxide (Ag_2O). The rate of release of silver ions depends on the substance which it is bound to, pH, ionic strength, and other conditions.

Silver compounds are used for their biocidal (antimicrobial) properties in various applications (eg. disinfection products, cosmetics, etc.). There are silver compounds exerting properties which can meet the definition of nanomaterials, as for example: silver (EC 231-131-3), silver carbonate (EC 208-590-3), silver nitrate (EC 231853 9), silver chloride (EC 232-033-3), silver oxide (EC 243-957-1), mixture of silver and zeolite, and others).

The risk assessment of silver compounds is performed according to the ***Directive (EC) No. 98/8/EC (Biocidal Product Directive)***. The directive distinguishes between an *active biocidal substance*, *biocidal product* containing either single active substance, or a mixture of several active substances, as well as the *means of product application* - the use of single biocidal product versus the use of multiple biocidal products resulting in synergic biocidal effect.

At the national level, the substance risk assessment is based on the active substance evaluation performed at the European level. The substance authorisation process is then performed at the national level. When submitting an application for authorization (national level) of biocidal product, one should prepare and submit a compound-, or a substance-specific information data sheet (dossier) with the results of mandatory toxicity tests (e.g. skin / eye irritation, skin sensitization, mutagenicity, etc.).

Some compounds act in biocidal products as their active agents, but when **"nano quantities"** of the same compound are used in non-biocidal products, they can act as preservatives - such compound is the mixture of **isothizolines** and **chlorine-isothizolines**; These agents are governed by the chemical legislation on classification, labeling and packaging (CLP), but since these compounds are believed to be produced in quantities lesser than 1 ton per annum, they are not subject to registration in accordance with the ***EP and Council Regulation (EC) No. 1907/2006 (REACH).***

8.3.3 Plant protection products

Based on the analysis of the current legislative environment, it can be concluded that plant protection and plant supplement products containing nano-particles, as well as the plant protection products manufactured using nanotechnologies are commercially available in the Slovak Republic at least since 2008. The possible health risks associated with the use and therefore exposure to these nano-based products are to-date neither controlled, nor approved based on the size of particles, but rather on the basis of its chemical composition.

The legislative environment (Central Controlling and Testing Institute in Agriculture - CCTIA)

The Plant Protection Department of the CCTIA - The Plant Protection Department is governed by ***Act No. 193/2005*** on Plant Health Care, via the ***Ministry of Agriculture´s Decree No. 41/2002***, which establishes the details on performing the plant health care along with the Governmental Regulations. The implementation of those laws in practice determines the most important role of the Department in protecting the territory of the Slovak Republic against introduction and spread of harmful organisms during the plant production (cultivation), as well as during the proces of importing and exporting plants and plant products. The Slovak national legislation concerning plant protection is fully harmonized with the legislation of the European Community.

Act No. 45/2009, amending and supplementing the Act No. 193/2005:

CCTIA issues the judgement (decision) on phytosanitary measures based on the results of phyto inspection:

- *The decision on registration of plant protection product*

- *The decision to reject an application for registration of plant protection product*
- *The issuance of binding evaluations and/or certificates based on the performed analysis*

Excerpt from § 11, section 2 of the Act. No. 45/2009:

"(2) Applicant for registration of plant protection product or other type of product is not obliged to submit the active substance dossier except for the data concerning the active substance chemical name, structural formula, manufacturers identity, method of production, specification of purity, identification of substance isomers, impurities and additives, and the batch (lot) analytical profile. If the active substance is included in the list of registered active substances and the control institute or registration office of a Member State has confirmed that the active substance does not significantly differ in the degree of purity, the nature and proportion of impurities from the composition of the active substance already included in the list of active substances, and the registrant proves ownership of the registration dossier's data or received the data owner´s consent to use it."

8.3.4 General Product Safety

Based on the analysis of current legislative environment, it can be concluded that there is no legislation in the Slovak Republic mentioning either the use of nanoparticles in consumer products, or the safe use of products containing nanoparticles. However, the ***Regulation (EC) No. 1223/2009*** will come into force in the year 2013 – The Regulation governs requirements for registration of cosmetic products containing nano particles.

Legislation of the Slovak Republic concerning the General Product Safety:

Excerpt from ***§3 of the Government Regulation No. 404/2007 on General Product Safety:***

"General requirements for product safety:
(1) Safe product is a product governed (overseen) by a specific regulation.
(4) To determine whether a product is considered safe, following product properties are particularly evaluated

a) properties of the product - its composition, durability, packaging, instructions for product installation (assembly) and its commissioning, the recommended method of use including a definition of conditions under which the product should be used, warning labels, maintenance and disposal instructions, proper conditions of storage, conditions of product shipment and any other data and information provided by the manufacturer; all these data and information must be provided in the official language and written in a consumer-friendly manner,

b) the product's effect on other products, where it is expected that it will be used along with them,

c) the planned way of product presentation and marketing,

d) the groups of consumers who may be at health risk when using the product, especially the children and elderly."

Unspecified products must comply with the provisions of the ***Government Ordinance No. 404/2007 on General Product Safety***. However, in many cases there are *no technical standards* available for these products. In such cases, the manufacturer is obliged to search and gather information about the state of scientific and technical knowledge regarding the

product, or similar products. The manufacturer should than maintain an overview of how the other world-renowned manufacturers ensure safety of their similar products; If their level of knowledge is respected and implemented by the manufacturer, the design and production of safe (unspecified) product shall be mantained.

8.3.5 Cosmetics

Legislation in force
EU legislation:

Regulation (EC) No. 1223/2009 on Cosmetic Products

Excerpt from the *Regulation (EC) No. 1223/2009:*
Provisions related to nanomaterials - *"Nanomaterial is an insoluble material produced on atomic and molecular levels. A number of consumer goods such as cosmetics are made using nanostructures enhancing their performance. The Regulation imposes an obligation to report nanomaterials contained in cosmetics (nano-based cosmetics) to the European Commission no later than six months prior to their use/inclusion in the cosmetic product."*

In the Slovak Republic, the cosmetic products are monitored by the Office of Public Health. At present, the cosmetic products (either raw materials or finished products) are guided by the legislation of the European Union (EU): ***Regulation (EC) No. 1223/2009 on Cosmetic Products; The Directive No. 76/768/EEC on Cosmetic Products; The REACH (EC No. 1907/2006) and CLP (EC No. 1272/2008) Regulations.*** Finished cosmetic products and/or cosmetic ingredients must comply with these regulations before they are marketed in the EU.

The key deadlines for implementation of ***the Regulation (EC) No. 1223/2009*** are as follows:
22.12.2009 – Publication of the Regulation
01.12.2010 – CRM substances
01.01.2012 – Notification obligation
11.01.2013 – Nanomaterials
11.07.2013 – Entry into force of the Regulation

Evaluation of the product safety and the required product-related documentation

Cosmetic products available to consumers must be safe (Article 3 of the Regulation).
For this reason, each product must have the safety assessment performed (Article 10 of the Regulation) and submitted in the form of product safety report prepared according to Annex I of the Regulation; The product-related documentation including the product safety report must be available for inspection bodies.

Each product must have the safety assessment performed and set of relevant product-related documentation. In practice this means that a subject (company or person) may carry out single safety assessment and provide single set of documentation for a group (variety) of identical products:

All cosmetic products placed on the market must be safe. In addition, according to the Regulation (EC) No. 1223/2009, all cosmetic products must have the product safety reports

prepared in accordance with Annex I of the Regulation. Joint safety assessment and joint documentation could be submitted for similar products starting on July 11th, 2013.

Cosmetic products placed into market circulation (i.e. into the distribution chain) prior to the aforementioned date will not however be affected by these new requirements:
Cosmetic products that have been placed on the market before the Regulation enters into force, must have the safety assessment prepared only in case that the products will remain on the market after the new requirements apply. Products that will no longer be placed on the market after this date do not have to undergo re-evaluation of their safety and the products remaining on the market can be sold off in accordance with the requirements of the Regulation. Product documentation should be archived for a period of 10 years after products´ removal from the market. Documentation pursuant to Article 7 of the Directive must be available for inspection bodies until 11th of July 2020 (Article 38, paragraph 4 of the Regulation).

In case that the cosmetic product is placed on the market before July 2013, the responsible person can choose to follow transitional provisions (Article 39, paragraph 1 of the Regulation), Articles 10 and 11 instead of the requirements of the Directive (Article 7 of the Directive):

Cosmetic products placed on the market before the Regulation enters into force on 11th July 2013 may have the product safety assessment ellaborated in accordance with the Regulation´s requirements before it enters into force.

Nanomaterials in cosmetic products

In addition to the provisions of Article 13 on the notification, the Article 16 sets out an individual reporting regime for cosmetic products containing "nanomaterials“ other than dyes, UV filters, preservatives or nanomaterials, which are in accordance with the requirements set out in Annex III of the Regulation.

Notification of cosmetic products containing nanomaterials is submitted by the responsible person except for cases as detailed further in Article 16 (3) of the fifth paragraph:
„Reporting obligations for nanomaterials is obligatory for all nanomaterials other than dyes, UV filters and preservatives. The responsible person may in writing authorize another person to perform the notification.“

When notifying nanomaterials two scenarios can occur:

(1) Products containing nanomaterials already placed on the market before 11th July 2013

Products placed on the market before the above stated date must be notified between 11.01.2013 and 11.07.2013 according to the Article 16 of the Regulation:
„Products containing nanomaterials placed into circulation before 11.01.2013 and will be after this date featured on the market, must be reported in accordance with Art. 13 between 11.1.2013 and 11.7.2013“

(2) Products containing nanomaterials placed on the market after 11th July 2013

Products must be notified six months prior to being placed on the market, unless the responsible person already placed the product (similar products) on the market before 11.07.2013 (Article 16 (3), first paragraph of the Regulation), and the product was notified as

described above. In case the responsible person fails to market a cosmetic product containing nanomaterials before 11.07.2013, the product can then be placed on the market only after 11.07.2013.

Current legislation of the Slovak Republic concerning the cosmetic products:

The Act No. 335/2007 on the Protection, Promotion and Development of Public Health, amending the *Government Ordinance No. 658/2005,* which lays down the Requirements for Cosmetic Products

Amendments to ***the Government Ordinance No. 658/2005*** laying down the Requirements for Cosmetic Products, as amended:
Government Ordinance No. 538/2006
Government Ordinance No. 108/2007
Government Ordinance No. 538/2006
Government Ordinance No. 418/2007
Government Ordinance No. 124/2008
Government Ordinance No. 374/2008
Government Ordinance No. 141/2009
Government Ordinance No. 522/2009

8.3.6 Food

In the Slovak Republic, there is currently no specific legislation concerning the presence of nanoparticles in food- or feedstuffs. On the other hand, this fact does not mean that food and/or feed, which contain nanomaterials could intentionally be placed on the national market; In line with the EU legislation there is the ***Act No. 152/1995*** on Foodstuffs, as amended, which imposes an obligation on any subject placing so called “novel food“ on the Slovak market (applies to all member states) to posses an authorization issued by the Slovak Ministry of Health - Office of Public Health.

The category of „novel foods“ consists of all foodstuffs containing some new components, whether these are plants not used commonly, or the actual nanoparticles, or foodstuffs produced using a novel technology. Therefore, every novel food manufacturer or importer must first contact the Office of Public Health and submit all the supportive documentation – (dossiers) prior to placement of the novel food on the national market.

In case that the novel food ingredient is not already permitted in the EU, the request (referring to first placement on the EU market) will be discussed at the EC Standing Committee - if necessary the Committee will request from EFSA a risk assessment. If the EFSA gives a positive opinion, the request will be returned back to the EC Standing Committee for final decision. If the Committee approves the novel food, then each individual member state has the right to approve or reject the novel food for their national markets. At this moment, according to Public Health Authority of the Slovak Republic there is officially no single product containing nanoparticles present in our market.

The EU legislation concerning the novel foods is governed by ***the Regulation (EC) No. 258/97 of the European Parliament and the Council*** concerning novel foods and novel

food ingredients. The Regulation was issued on 28th January 1997, and its revision is currently in preparation. Moreover, at the level of the EU and falling under the EFSA, the Scientific Network for Risk Assessment of Nanotechnology in Food and Feed is established.

8.3.7 Medical Devices and Medicinal Products

Based on the analysis of current legislative environment, it can be concluded that none of the laws on medical Devices and Medicinal products mentions either one of the terms "nano", or „nano particles“, or „nano technology“.

Current legislation of the Slovak Republic concerning the cosmetic products:
Act No. 362/2011 *on medicines and medical devices*

8.3.8 Industrial Law and Environmental Protection

Nanomaterials, or nano-sized particles can also act as environmental pollutants (particularly those originating from industrial air emissions). Based on the survey, the nanotechnology can also find its application in measuring, monitoring, and minimizing the effect of such environmental pollutants.

Environmental protection - Air
Slovak legislation in force:
The Act No. 137/2010 on Air is the transposition of EU directives, which are listed in Appendix 4 of the Act. The term "nanomaterial" is not present in either the Law itself, or the Law implementing regulations. The Law provides a definition of the air pollutant which does not distinguish between the substance structure and size of particles:

„b) an air pollutant is any substance resulting from human activities, directly or indirectly released into the atmosphere, and which was proven to, or is suspected to have harmful effects on human health or the environment, except for the substances whose release into the environment is governed by specific provisions (regulations)“

The Act No. 137/2010 (Annex 1) includes a list of pollutants for the purpose of air quality evaluation and management**:**
1. sulfur dioxide
2. nitrogen dioxide and nitric oxide (nitrogen oxides)
3. **PM10 and PM2,5 (solid respirable particles)**
4. lead
5. ozone
6. benzene
7. carbon monoxide
8. Polycyclic aromatic hydrocarbons (benzo (a) pyrene)
9. cadmium
10. arsenic
11. nickel
12. mercury

The Slovak Ministry of Environment Decree No. 705/2002 on Air Quality - Annex 6 of the Decree contains reference methods for measurement and analysis of pollutants in the air, as follows:

IV. Solid Respirable Particles - PM10
The PM10 reference method for sampling and measuring of solid airborne particles is a method of sampling the PM10 fraction of airborne particulate matter by means of collection on the filter and subsequent gravimetric mass determination according to technical norm.(5)

V. Solid Respirable particles - PM2,5
The PM2,5 reference method for sampling and measuring of solid airborne particles is a method of collecting the PM2,5 particles on the filter and further gravimetric weight determination according to the technical norm.(6)

Other Provisions:

STN EN 12341**:** Air Protection. Determination of the PM10 fraction of airborne particles - Reference method and field test procedure demonstrating the reference equivalence in measurement methods (83 4602).

CEN TC/264 WG 15**:** Air Protection. Determination of the PM2,5 fraction of airborne particles - Reference gravimetric method for mass fraction determination of the PM2,5 airborne particles.

Instructions for determination of the PM2,5 – Based on the *EMEP manual for sampling and chemical analysis, edition - May 2002.* „EMEP“ is an abbreviation that stands for Cooperative Programme for Monitoring and Evaluation of Long-range Transmission of Air Pollutants in Europe as a part of the Convention on Long Range Transboundary Air Pollution.

Definition of solid particles
Airborne dust represents the sum of all airborne particles of different sizes freely suspended in the air. Their origin can be found in various technological processes, but mainly in the combustion of solid fuels and the exhaust fumes of vehicles powered by combustion engines. There is also a secondary dust, which originates from whirling of dust (earth) particles over the Earth´s surface.

Category of particles known as the *PM10 consists of 50% particles having an aerodynamic parameter less than 10 μm*. The only exposure route through which the PM-sized particles could enter a human body is by means of inhalation. The effect of dust inhalation on human health depends on the size of particles. While the larger particles (greater than 10 *μ*m) can enter only the upper respiratory tract causing irritation manifested as coughing, sneezing and irritation conjunctivitis, the smaller particles are carried to the lower respiratory tract where particles with dimensions below 2.5 μm can penetrate the alveoli either settling in the lungs, or penetrating the bloodstream.

Environmental Protection - Water

Slovak Legislation in force:
Act No. 364/2004 on Water
Act No. 384/2009 amending and supplementing the Act No. 364/2004 on Water
Act No. 134/2010 amending and supplementing the Act No. 364/2004 on Water, and amending the Act of Slovak National Council No. 372/1990 (Water Act) on Offences, as amended
Act No. 134/2010 sets standards for water quality, including nano-scale contaminant concentration limits - The water contaminants are being monitored at nano concentrations.

8.3.9 Nanoparticles and Technical Standards

Priority Objectives of the Slovak Office of Standards, Metrology and Testing - Concept of State Policy for the year 2011

Opening of the EU Member State markets creates new competitive environment, which often prevents the Member States from keeping the old approach and old national standards, which are more strict than the new approach.

With the markets opening, a European technical standardization process must follow towards the adoption of new technical standards for the EU. Technical standards are currently considered as recommendations, while the metrological provisions considered as binding. The gradual implementation of process approach toward the assurance of quality management within companies is now gaining its own role in metrology. In metrological services, the quality manual is a mandatory part of documentations and generally binding procedures for providing of metrological services.

There is an expectation of development of new areas of metrology, which will require new technology, low carbon energy, new systems of production and economy, which will use the new generation of materials (nanomaterials) replacing the resource- and energy- intensive materials used in the traditional systems of production and economy. The industry comes with new requirements for production quality assurance, while the new measurement techniques and affordable measuring devices remain absent. A new trend of contracting or outsourcing metrology services and covering the areas of industrial metrology outside of the nation begins to appear.

The international metrology area, in which the Slovak Republic represents itself based on international agreements, the membership in metrology associations and the active participation in working groups are divided based on their focus between the Slovak Office of Standards, Metrology and Testing (SOSMT), the Slovak Institute for Metrology (SIM) and the office of Slovak Legal Metrology (SLM). Usually, the represnation concerns the design of new metrological legislation in the EU concerning the field of legal metrology. An idividual area of development is comprised by metrology projects, where the SIM is particulary active (iMERA-e, iMERA-Plus and the EMRP projects of the EURAMET association).

The metrology is now shifting from macro- to nano- world, which means that a new definitions of meter, kilogram and other variables will be needed. Next in the line are also the electrical parameters – its the coming of nanoelectronics; This area is also included in the concept for further development. We have a lot of catching up to be done,- we begin by mapping the situation and searching for pioneers of nanometrology within the Slovak Republic.

Sources:

http://www.primetrology.com/post/prioritne-ciele-unms-sr-a-podliehajucich-organizacii-koncepcia-statnej-politiky-12/

http://www.euroinfo.gov.sk/nove-pravidla-oznacovania-potravin-v-eu-a-sr/?pg=2

Technical Standards Overview

In this chapter, an up-to-date overview of standards focusing on nanotechnology, nanoparticles and nanomaterials is provided: Slovak (STN) and international (ISO) standards. The ISO standards are included due to likebility of their adoption into European (EN) system of standards and their subsequent adoption into Slovak (STN) system of standards. As an example of „nano" standard in preparation it is worth mentioning the *Fpr CEN ISO/TR 11811*.

Slovak Technical Standards (STN)

STN P CEN ISO/TS 27687 *(01 5505)*

Nanotechnologies. Terminology and definitions for nano-objects. Nanoparticle, nano- fibre and nanoplate (ISO/TS 27687: 2008)

Date of Issue: 1.4.2010 **Removal Date:**
Date of Approval: 18.12.2009 **Effective Date:**
Level of incorporation: idt. CEN ISO/TS 27687: 2009, idt. ISO/TS 27687: 2008
Method od adoption: Translation **Language:** sk
Standard being supplemented: *STN P CEN ISO/TS 27687: 2009*
Subject of the Standard: The standard lists unambiguous terms and definitions related to particles in the field of nanotechnologies. It is intended to facilitate communications between organizations and individuals in industry and those who interact with them.

STN EN ISO 10801 *(60 3001)*

Nanotechnologies. Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010) **)**

Date of Issue: 1.8.2011 **Removal Date:**
Date of Approval: 6.5.2011 **Effective Date:**
Level of incorporation: idt. EN ISO 10801: 2010, idt. ISO 10801: 2010
Method of Adoption: Adoption by anouncement in the Journal **Language:** en
Subject of the Standard: The standard gives requirements and recommendations for generating metal nanoparticles as aerosols suitable for inhalation toxicity testing by the evaporation/condensation method. Its application is limited to metals such as gold and silver

which have been proven to generate nanoparticles suitable for inhalation toxicity testing using the technique specified.

STN EN ISO 10808 *(60 3001)*
Nanotechnologies. Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808: 2010) **)**

Date of Issue: 1.8.2011 **Removal Date:**
Date of Approval: 6.5.2011 **Effective Date:**
Level of Incorporation: idt. EN ISO 10808: 2010, idt. ISO 10808: 2010
Method of Adoption: Adoption by anouncement in the Journal **Language:** en
Subject of the Standard: The standard specifies requirements for, and gives guidance on, the characterization of airborne nanoparticles in inhalation exposure chambers for the purpose of inhalation toxicity studies in terms of particle mass, size distribution, number concentration and composition.

STN EN ISO 29701 *(60 3001)*
Nanotechnologies. Endotoxin test on nanomaterial samples for in vitro systems. Limulus amebocyte lysate (LAL) test (ISO 29701: 2010) **)**

Date of Issue: 1.3.2011 **Removal Date:**
Date of Approval: 7.12.2010 **Effective Date:**
Level of Incorporation: idt. EN ISO 29701: 2010, idt. ISO 29701: 2010
Method of Adoption: Adoption by anouncement in the Journal **Language:** en
Subject of the Standard: The standard describes the application of a test using *Limulus* amebocyte lysate (LAL) reagent for the evaluation of nanomaterials intended for cell-based *in vitro* biological test systems. The test is suitable for use with nanomaterial samples dispersed in aqueous media, e.g. water, serum or reaction medium, and to such media incubated with nanomaterials for an appropriate duration at 37 °C.

ISO Technical Standards

Origin code	IX
Document identifier	ISO/TR 12885
Publication date	2008-10-00
Title (English)	Nanotechnologies - Health and safety practices in occupational settings relevant to nanotechnologies
Title (German)	Nanotechnologien - Gesundheits- und Sicherheitsvorkehrungen an Arbeitsstätten in Bezug auf Nanotechnologien
Original language	en
Format/Pages	79
Price	W

Descriptors (English)	Dangerous materials* Detrimental to health* Harmful substances* Hazards* Health hazards* Health protection* Materials* Nanotechnology* Occupational safety* Particles* Pollutants* Processing* Protective clothing* Respiratory protections* Safety* Safety measures* Safety provisions* Work places* Working place concentration* Working places* Workplace safety* Operating stations* Treatment*Machining
Descriptors (German)	Arbeitsplatz*Arbeitsplatzkonzentration*Arbeitsschutz*Arbeitssicherheit*Arbeitsstätte*Atemschutz*Bearbeitung*Gefährdung*gefährlicher Arbeitsstoff*Gesundheitsgefährdung*gesundheitsgefährlicher Arbeitsstoff*gesundheitsschädlich*Gesundheitsschutz*Material*Nanotechnik*Partikel*Schadstoff*Schutzbekleidung*Sicherheit*Sicherheitsmaßnahme*Sicherheitsvorkehrung*Verarbeitung

Origin code	IX
Document identifier	ISO/TR 13121
Publication date	2011-05-00
Title (English)	Nanotechnologies - Nanomaterial risk evaluation
Title (German)	Nanotechnologien - Risikobewertung von Nanomaterialien
Original language	en
Format/Pages	58
Price	U
Descriptors (English)	Dangers analysis* Distribution* Evaluations* Hazard analysis* Life cycles* Materials* Nanotechnology* Production* Proofs of utilization* Range of application* Risk analysis* Risk management* Safety
Descriptors (German)	Bewertung* Gefährdungsanalyse* Gefahrenanalyse* Herstellung* Lebenszyklus* Material* Nanotechnik* Risikoanalyse* Risikomanagement* Sicherheit* Vertrieb* Verwendungsbereich* Verwendungsnachweis

Origin code	IX
Document identifier	ISO/TS 13278
Publication date	2011-11-00
Title (English)	Nanotechnologies - Determination of elemental impurities in samples of carbon nanotubes using inductively coupled plasma mass spectrometry
Title (German)	Nanotechnologien - Bestimmung elementarer Verunreinigungen in Kohlenstoff-Nanoröhrchenproben mit Massenspektroskopie mit induktiv gekoppeltem Plasma
Original language	en
Format/Pages	19
Price	K

Descriptors (English)	Carbon* Carbon materials* Definitions* Impurities* Inductive* Mass spectrometry* Mass spectroscopy* Materials* Nano tubes* Nanotechnology* Plasma* Terminology
Descriptors (German)	Begriffe*Definition*induktiv*Kohlenstoff*Kohlenstoffmaterial*Massenspektrometrie*Massenspektroskopie*Nanoröhrchen*Nanotechnik*Plasma*Terminologie*Verunreinigung*Werkstoff

Origin code	IX
Document identifier	ISO/TR 14187
Publication date	2011-08-00
Title (English)	Surface chemical analysis - Characterization of nanostructured materials
Title (German)	Chemische Oberflächenanalyse - Charakterisierung nanostrukturierter Materialien
Original language	en
Format/Pages	38
Price	R
Descriptors (English)	Auger electron spectroscopy*Chemical analysis and testing*Crystal structure*Electron spectroscopy*Finishes*Mass spectroscopy*Microscopy*Nano tubes*Nanotechnology*Particle size analysis*Scanning electron microscopes*Secondary-ion mass spectrometry*Surface properties*Testing*X-ray spectrometry
Descriptors (German)	Auger-Elektronenspektroskopie*chemische Analyse*Elektronenspektroskopie*Kristallstruktur*Massenspektroskopie*Mikroskopie*Nanoröhrchen*Nanotechnik*Oberflächenbeschaffenheit*Oberflächeneigenschaft*Prüfung*Prüfverfahren*Rasterelektronenmikroskop*Röntgenspektrometrie*Sekundärionenmassenspektrometrie*Teilchengrößenanalyse

Origin code	IX
Document identifier	ISO/TS 80004-1
Publication date	2010-10-00
Title (English)	Nanotechnologies - Vocabulary - Part 1: Core terms
Title (German)	Nanotechnologien - Fachwörterverzeichnis - Teil 1: Kernbegriffe
Original language	en
Format/Pages	4
Price	B
Descriptors (English)	Definitions*Molecular physics*Nanotechnology*Physics*Technical vocabulary*Terminology*Terms*Vocabulary
Descriptors (German)	Begriffe*Benennung*Definition*Fachwörterbuch*Molekularphysik*Nanotechnik*Physik*Terminologie*Vokabular

Origin code	IX
Document identifier	ISO/TS 80004-3
Publication date	2010-05-00
Title (English)	Nanotechnologies - Vocabulary - Part 3: Carbon nano-objects
Title (German)	Nanotechnologien - Fachwörterverzeichnis - Teil 3: Nanoobjekte aus Kohlenstoff
Original language	en
Format/Pages	7
Price	D
Descriptors (English)	Carbon*Carbon materials*Definitions*Materials*Nanotechnology*Technical term*Terminology*Vocabulary
Descriptors (German)	Begriffe*Definition*Fachbegriff*Fachwort*Kohlenstoff*Kohlenstoffmaterial*Nanotechnik*Terminologie*Werkstoff*Wörterbuch

Origin code	IX
Document identifier	ISO/TS 80004-7
Publication date	2011-10-00
Title (English)	Nanotechnologies - Vocabulary - Part 7: Diagnostics and therapeutics for healthcare
Title (German)	Nanotechnologien - Fachwörterverzeichnis - Teil 7: Diagnostik und Therapeutik
Original language	en*fr
Format/Pages	8
Price	D
Descriptors (English)	Definitions*Diagnosis*Molecular physics*Nanotechnology*Physics*Public health*Technical vocabulary*Terminology*Terms*Therapeutics*Vocabulary
Descriptors (German)	Begriffe*Benennung*Definition*Diagnostik*Fachwörterbuch*Gesundheitswesen*Molekularphysik*Nanotechnik*Physik*Terminologie*Therapie*Vokabular

Origin code	IX
Document identifier	08/345/EGEmpf*08/345/ECEmpf*08/345/CEEmpf
Publication date	2008-02-07
Title (English)	Commission Recommendation of 7 February 2008 on a code of conduct for responsible nanosciences and nanotechnologies research
Title (German)	Empfehlung der Kommission vom 7. Februar 2008 für einen Verhaltenskodex für verantwortungsvolle Forschung im Bereich der Nanowissenschaften und -technologien
Original language	de
Format/Pages	7
Price	-

Descriptors (English)	Behaviour*Coordination*Definitions*Dotted lines*European Communities*Health protection*Measure*Nanotechnology*Object*Pollution control*Principles*Quality assurance*Research*Safety*Sciences*Technology
Descriptors (German)	Begriffe*Definition*Europäische Gemeinschaften*Forschung*Gesundheitsschutz*Grundsatz*Koordinierung*Leitlinie*Maßnahme*Nanotechnik*Objekt*Qualitätssicherung*Sicherheit*Technologie*Umweltschutz*Verhalten*Wissenschaft*Zusammenarbeit

Origin code	IX
Document identifier	11/696/EUEmpf*11/696/EUEmpf*11/696/UEEmpf
Publication date	2011-10-18
Title (English)	Commission Recommendation of 18 October 2011 on the definition of nanomaterial
Title (German)	Empfehlung der Kommission vom 18. Oktober 2011 zur Definition von Nanomaterialien
Original language	de
Format/Pages	3
Price	-
Descriptors (English)	Definitions*European Communities*Generating sets*Materials*Nano tubes*Nanotechnology*Particles*Terminology*Vocabulary
Descriptors (German)	Aggregat*Begriffe*Definition*Europäische Gemeinschaften*Europäische Union*Material*Nanoröhrchen*Nanotechnik*Partikel*Terminologie*Vokabular

Origin code	IX
Document identifier	IEC 62624*CEI 62624
Publication date	2009-08-00
Title (English)	Test methods for measurement of electrical properties of carbon nanotubes
Title (German)	Prüfmethoden für die Messung der elektrischen Eigenschaften von Kohlenstoff-Nanoröhren
Abstract (English)	
Abstract (German)	
Replaces	IEC 113/58/FDIS (2009-03)*IEC 113/58A/FDIS (2009-04)
Original language	en
Format/Pages	17
Price	Q

Descriptors (English)	Carbon*Definitions*Dimensions*Electrical properties*Electrodes*Errors in measuring*Fabrication*Impedance measurement*Linear electrical resistance*Measurement*Measuring incertainity*Measuring techniques*Nano tubes*Nanotechnology*Production*Properties*Testing*Electrical properties and phenomena
Descriptors (German)	Abmessung*Begriffe*Definition*Eigenschaft*elektrische Eigenschaft*Elektrode*Fabrikation*Herstellung*Kohlenstoff*Messfehler*Messung*Messunsicherheit*Messverfahren*Nanoröhrchen*Nanotechnik*ohmscher Widerstand*Prüfung*Prüfverfahren*Scheinwiderstandsmessung

Origin code	IX
Document identifier	ISO/TS 10798
Publication date	2011-07-00
Title (English)	Nanotechnologies - Charaterization of single-wall carbon nanotubes using scanning electron microscopy and energy dispersive X-ray spectrometry analysis
Title (German)	Nanotechnologien - Charakterisierung einwandiger Kohlenstoff-Nanoröhrchen mit der Rasterelektronenmikroskopie und energiedispersiver Röntgenspektrometrieanalyse
Original language	en
Format/Pages	26
Price	M
Descriptors (English)	Carbon*Characterisations*Definitions*Electromagnetic properties*Electron microscopes*Electron microscopy*Energy dispersiv*Mechanical properties*Nano tubes*Nanotechnology*Scanning electron microscopes*Single-walled*Testing*Thermal properties*Tubes*X-ray spectrometry
Descriptors (German)	Begriffe*Charakterisierung*Definition*einwandig*elektromagnetische Eigenschaft*Elektronenmikroskop*Elektronenmikroskopie*energiedispersiv*Kohlenstoff*mechanische Eigenschaft*Nanoröhrchen*Nanotechnik*Prüfung*Prüfverfahren*Rasterelektronenmikroskop*Röhre*Röntgenspektrometrie*thermische Eigenschaft

Origin code	IX
Document identifier	ISO/TS 10867
Publication date	2010-09-00
Title (English)	Nanotechnologies - Characterization of single-wall carbon nanotubes using near infrared photoluminescence spectroscopy

Title (German)	Nanotechnologien - Charakterisierung von einwandigen Kohlenstoff-Nanoröhren mit Nah-Infrarot-Photolumineszenz-Spektroskopie
Original language	en
Format/Pages	14
Price	G
Descriptors (English)	Carbon*Definitions*Infrared spectroscopy*Measuring techniques*Nano tubes*Nanotechnology*Optical activity*Optics*Photoluminescence*Pipes*Properties*Semiconductors*Single-walled*Testing*Tubes*Vector calculations
Descriptors (German)	Begriffe*Definition*Eigenschaft*einwandig*Halbleiter*Infrarotspektroskopie*Kohlenstoff*Messverfahren*Nanoröhrchen*Nanotechnik*Optik*optische Aktivität*Photolumineszenz*Prüfung*Prüfverfahren*Röhrchen*Rohr*Vektorrechnung

Origin code	IX
Document identifier	ISO/TS 10868
Publication date	2011-09-00
Title (English)	Nanotechnologies - Characterization of single-wall carbon nanotubes using ultraviolet-visible-near infrared (UV-Vis-NIR) absorption spectroscopy
Title (German)	Nanotechnologien - Charakterisierung einwandiger Kohlenstoff-Nanoröhrchen durch UV-Vis-NIR-Absorptionsspektroskopie
Original language	en
Format/Pages	19
Price	K
Descriptors (English)	Absorption spectrophotometry*Carbon*Definitions*Fractions*Infrared spectroscopy*Measuring techniques*Nano tubes*Nanotechnology*Optical measurement*Optics*Properties*Semiconductors*Single-walled*Testing*Tubes
Descriptors (German)	Absorptionsspektrometrie*Begriffe*Definition*Eigenschaft*einwandig*Fraktion*Halbleiter*Infrarotspektroskopie*Kohlenstoff*Messverfahren*Nanoröhrchen*Nanotechnik*Optik*optische Messung*Prüfung*Prüfverfahren*Röhrchen

Origin code	IX
Document identifier	ISO/TS 11251
Publication date	2010-11-00
Title (English)	Nanotechnologies - Characterization of volatile components in single-wall carbon nanotube samples using evolved gas analysis/gas chromatograph-mass spectrometry

Title (German)	Nanotechnologien - Charkterisierung flüchtiger Bestandteile in Proben von einwandigen Kohlenstoffnanoröhren mit der Emissionsgasanalyse/gaschromatograpie-Massenspektrometrie
Original language	en
Format/Pages	10
Price	E
Descriptors (English)	Carbon*Chemical properties*Definitions*Electrical engineering*Electrical properties*Emission spectrophotometry*Gas chromatography*Gas spectrometry*Mass spectrometry*Mechanical properties*Nano tubes*Nanotechnology*Properties*Specification (approval)*Specifications*Electrical properties and phenomena*Gas phase chromatography
Descriptors (German)	Anforderung*Begriffe*chemische Eigenschaft*Definition*Eigenschaft*elektrische Eigenschaft*Elektrotechnik*Emissionsspektrometrie*Gaschromatographie*Gasspektrometrie*Kohlenstoff*Massenspektrometrie*mechanische Eigenschaft*Nanoröhrchen*Nanotechnik*technische Spezifikation

Origin code	IX
Document identifier	ISO/TS 11308
Publication date	2011-11-00
Title (English)	Nanotechnologies - Characterization of single-wall carbon nanotubes using thermogravimetric analysis
Title (German)	Nanotechnologien - Charakterisierung einwandiger Kohlenstoff-Nanoröhrchen mit thermogravimetrischer Analyse
Original language	en
Format/Pages	22
Price	L
Descriptors (English)	Carbon*Characterisations*Definitions*Impurities*Nano tubes*Nanotechnology*Single-walled*Testing*Thermal properties*Thermogravimetric analysis
Descriptors (German)	Begriffe*Charakterisierung*Definition*einwandig*Kohlenstoff*Nanoröhrchen*Nanotechnik*Prüfung*Prüfverfahren*thermische Eigenschaft*thermogravimetrische Analyse*Verunreinigung

Origin code	IX
Document identifier	ISO/TR 11360
Publication date	2010-07-00
Title (English)	Nanotechnologies - Methodology for the classification and categorization of nanomaterials
Title (German)	Nanotechnologien - Methodik für die Klassifizierung und Kategorisierung von Nanomaterialien

Original language	en
Format/Pages	25
Price	M
Descriptors (English)	Categories*Classification*Materials*Nanotechnology*Processing*Product design*Products*Properties*Use*Product development
Descriptors (German)	Eigenschaft*Einteilung*Kategorie*Klassifizierung*Material*Nanotechnik*Produkt*Produktentwicklung*Verarbeitung*Verwendung*Werkstoff

Origin code	IX
Document identifier	ISO/TR 12802
Publication date	2010-11-00
Title (English)	Nanotechnologies - Model taxonomic framework for use in developing vocabularies - Core concepts
Title (German)	Nanotechnologien - Taxonomisches Rahmenmodell zur Verwendung bei der Entwicklung von Fachwörterverzeichnissen - Kernkonzepte
Original language	en
Format/Pages	21
Price	L
Descriptors (English)	Classification systems*Concepts*Definitions*Hierarchy*Nanotechnology*Relation*Taxonomy*Vocabulary
Descriptors (German)	Begriffe*Beziehung*Definition*Hierarchie*Klassifikation*Konzept*Nanotechnik*Taxonomie*Vokabular

Origin code	IX
Document identifier	ISO/TS 12805
Publication date	2011-11-00
Title (English)	Nanotechnologies - Materials specifications - Guidance on specifying nano-objects
Title (German)	Nanotechnologien - Werkstoffspezifikationen - Leitfaden zur Spezifizierung von Nanoobjekten
Original language	en
Format/Pages	21
Price	L
Descriptors (English)	Agglomeration*Chemical composition*Crystal structure*Definitions*Finishes*Geometrical properties*Materials specification*Morphology*Nanotechnology*Particle size*Porosity*Properties*Specification*Specification (approval)*Specifications

Descriptors (German)	Agglomeration*Anforderung*Begriffe*chemische Zusammensetzung*Definition*Eigenschaft*geometrische Eigenschaft*Kristallstruktur*Materialanforderung*Morphologie*Nanotechnik*Oberflächenbeschaffenheit*Partikelgröße*Porosität*Spezifikation*technische Spezifikation

Origin code	IX
Document identifier	ISO/TS 11888
Publication date	2011-11-00
Title (English)	Nanotechnologies - Characterization of multiwall carbon nanotubes - Mesoscopic shape factors
Title (German)	Nanotechnologien - Charakterisierung von mehrwandigen Kohlenstoff-Nanoröhrchen - Mesoskopische Formfaktoren
Original language	en
Format/Pages	17
Price	J
Descriptors (English)	Carbon*Characterisations*Definitions*Electron microscopy*Light scatter measurement*Nano tubes*Nanotechnology*Properties*Sample preparation*Scattered light*Shape*Viscosimetry*Viscosity*Specimen preparation
Descriptors (German)	Begriffe*Charakterisierung*Definition*Eigenschaft*Elektronenmikroskopie*Form*Kohlenstoff*Nanoröhrchen*Nanotechnik*Probenvorbereitung*Streulicht*Streulichtmessung*Viskosimetrie*Viskosität

Origin code	IX
Document identifier	FprCEN ISO/TR 11811
Publication date	2010-04-00
Title (English)	Nanotechnologies - Guidance on methods for nanotribology measurements (ISO/DTR 11811:2010)
Title (German)	Leitfaden für nanotribologische Messverfahren (ISO/DTR 11811:2010)
Abstract (English)	

Abstract (German)	Der Anwendungsbereich dieses Technischen Berichts ist auf die Prüftechniken zur Bewertung des tribologischen Verhaltens von Gleitkontakten auf einer lateralen Skala von einigen Nanometern bis 10 µm. Dieser Technische Bericht berücksichtigt nicht die bestehenden Raster-Sonden-Mikroskopieverfahren wie Reibungskraftmikroskopie und Rasterkraftmikroskopie (AFM). Dieser Technische Bericht behandelt Techniken mit aufgebrachten Lasten zwischen 50 µN und 100 mN. Das Dokument beschreibt nicht nur die Verfahren zur Durchführung dieser Messungen sondern bietet auch einen Leitfaden bezüglich des Einflusses der Messparameter auf die Prüfergebnisse.
Original language	en
Format/Pages	3
Descriptors (English)	Friction*Guide books*Measurement*Measuring techniques*Methods of analysis*Metrology*Nanotechnology*Tribology*Wear
Descriptors (German)	Analyseverfahren*Leitfaden*Messtechnik*Messung*Messverfahren*Nanotechnik*Reibung*Tribologie*Verschleiß

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9 Nano Regulation in Slovenia

Generally, Slovenia has no particular regulation in regards to nanotechnology regulation. The legal framework is adopted according to the EU legislation, including REACH and GHS regulation and other sectoral legislation. Although Slovenia participates in EU nanotechnology regulation, it did not produce any national specific nano legislation.

Besides EU framework, the only Slovenian existing legislation potentially applicable for nanomaterials is part of the chemical legislation (Law on Chemicals) that covers dangerous substances when their production exceeds 100 kg. However, as the nanomaterials are not regarded as dangerous unless their status not been classified as dangerous, the Law might render unsuitable for majority of nanomaterials. Nevertheless, there are several articles which provisions covers dangerous chemical in particular cases and could, if no other legislation in place cover nanomaterials in exceptional cases. The four below mentioned articles refer to chemicals, general and workplace safety and environmental protection, respectively.

Article 4 applies mutatis mutandis principle to dangerous products for which the Minister responsible for health on the basis of an expert evaluation determines that during normal use they could be damaging to people or the environment.

Article 6 covers liability of legal and natural persons. The producers of dangerous chemicals or place them on the market must provide instructions for safe use of the dangerous chemical and for the disposal of wastes in accordance with regulations on wastes, and must accept liability for any damage that may arise during production or trade.

Article 7 deals with the liability of users whereby all users must assure that during use and handling of dangerous chemicals they do not endanger their own life or that of other persons, and do not cause adverse effects to people or the environment.

Article 42 covers the topic of less dangerous alternatives. Legal and natural persons producing, storage or placing dangerous chemicals on the market must ensure such conditions so as to prevent or reduce the risk for people and the environment.

More specifically for Slovenian space, Article 50 introduces the interim measures stating that when there is a justified reason to suspect that a certain chemical may due to the geographic, environmental and health characteristic of Slovenia have worse or irreparable consequences for human health and the environment, the Government of the Republic of Slovenia may pose a temporary restriction or ban on its manufacturing, trade or use, introduce measures for steering its manufacturing, trade or use.

In conclusion, R&D on nanotechnology in the Slovenian space is relatively well-developed, but current legislation is considerably lagging behind. Although a need for special national legislation, complemented with precautionary principle, has been recognized, it awaits further warranty.

9.1 Slovenian Nano Action Plan

Slovenia recently started to prepare Nano Action Plan. Action Plan should increase the communication and cooperation between stakeholders in Slovenia, inform the public about chances and risks of Nanomaterials and link Slovenian activities in the field of Nano to the work done in EU and on international level. Furthermore, Slovenia has been actively participating in working groups at OECD and EU level for managing the occupational and consumer risks and through these activities launched education for stakeholders and public awareness campaigns. Currently, database including more detailed analyses of company's production/placing on the market and their products list is being created.

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