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REGULATION AND SAFETY IMPLEMENTATION OF NANOTECHNOLOGY FOR CHEMICAL ENTERPRISES IN THE CENTRAL EUROPE SPACE

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Abstract. As result of the gradually increasing nanotechnology sector there is the necessity of a contemporary analysis of the present regulations used for nanomaterials, to outline the current situation of the nanotechnology sector, to promote international cooperation and research's coordination to overcome disciplinary boundaries, to fill the gap between more and less experienced regions and to turn investments in R&D in industrial innovations.

The general objective of the Central Europe project NANOFORCE, which is developed by national and regional chemistry associations and R&D Centres of the Central Europe area, is to foster the innovative nanotechnology-sector networks across Central Europe regions by bringing together public and private organizations to carry out collaborative and interdisciplinary researches on nanomaterials (in the frame of REACH Regulation) and to turn the most promising laboratory results into innovative industrial applications.

To build up a legal advisory board for chemical enterprises starting in nanotechnology, a state of the art report on existing safety procedures and nanotech related regulations was produced to give an overview on currently available regulations used by chemical industries and manufacturing companies within the European region to secure their products. The main emphasis was placed on REACH regulation to search for relevant sections concentrating on nanomaterials which are applicable for nanotechnology. In addition, all relevant directives and amendments of REACH were screened with regard to identify gaps where action is still needed and give possible recommendations for the European Commission. Beyond literature research a questionnaire for producers, users, researchers and financiers was developed with the goal to collect information about the nanotechnology sector in the CE region concerning development, financial status, and international cooperation within joint ventures, safety and nanotoxicology.

Introduction

Nanotechnology and nanosciences are said to be key technologies for future development of new products and materials and have experienced a significant upturn in the past decade within the European economy. The term "nano" is commonly used in research and development for particles and materials at a molecular or atomic scale from 1 to 100 nm, with the result of having specific functions or properties due to the small size. The importance of this new "horizontal" or "enabling" technology is seen in the ability to bring together different research areas benefiting from an interdisciplinary approach towards innovations [1].

According to a report published by the International Labour Organization in 2010 on *emerging risks and new patterns of prevention in a changing world of work* approximately 20% of worldwide produced goods will in some extent be based on nanotechnology [2].

A study has shown that the global volume for products derived from nanotechnology should be growing from €200 billion in 2009 to €2.5 trillion by 2015 [3]. Today's global market is estimated to hold 11 million tonnes of nanomaterials and employing more than 300 000 people in the nanomaterials sector in Europe [4].

The positive economic impact of nanotechnology is said to be the main force to drive fundamental changes within technology sectors leading to benefits and new application [5].

The EU science and research commissioner Janez Potocnik said that *“Europe needs to invest in knowledge to maintain its competitive edge in the global economy – Nanotechnology is a key area where Europe is in the lead, and we must ensure that we stay there. Nanotechnology has enormous potential for European industry and for society in general, so a clear strategy and decisive action is needed for research in this area. At the same time, we must take into account any possible health, safety and environmental risks and address them as early as we can”* [6].

Many different focus areas can be discovered due to the complexity of broad term ‘nanotechnology’, such as

“cosmetic, food, food contact material, biocidal products, plant protection products, waste, energy, bio engineering, etc.”

That has resulted in the need of clear regulations for the safe use and implementation of nanotechnology. Nanomaterials have been under current investigations on risk and benefit assessment in many research groups due to their specific effects resulting from shape, morphology, size including surface area, functionalization, atomic structure and particle chemistry.

Despite the advantages to be seen in the use of nanomaterials for industry and medicine, several concerns have occurred during the past years. Environmental risks as well as health and safety concerns [7] should be addressed by the use of specific risk assessment tools to be performed in the EU and coordinated by authorities. Drawing attention to exposure (risk, hazard) as well as standardization, this is known to be taken into account to be able to draw realistic scenarios about potential risks. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has pointed out that there is a significant uncertainty about the potential risks coming from nanomaterials, therefore a case-by-case risk evaluation has to be done with each single substance [8].

One of the major problems facing nanotechnology and the production of nanomaterials is said to be the lack of knowledge transfer on risks that might be associated with the implementation of new technologies and materials such as nanomaterials. Evidences on toxicity and risk assessments for nanomaterials have been available on a certain level, but are still missing a common approach. This has led to high quantities of disorganized research data, a lot of double work carried out and caused confusion on the consumer and users side. Together with the lack of current available regulations for the safe use of nanomaterials on the market these problems cause barriers for technology transfer of research to innovative applications. Recently, on national level are already started activities to consolidate and structure existing expertise, for example within the European Center for Nanotoxicology which is an Austrian initiative focused on nanotoxicology and nanomedicine [9].

Nanotechnology for Chemical Enterprises

Focusing on the development of innovative public-private partnerships in the nanotechnology sector and bringing together public and private organizations to turn the most promising laboratory results into innovative industrial applications is proposed by the Central Europe project NANOFORCE.

The project consortium has planned to set up an international service hub for nanotechnology including an expertise database to provide stakeholders with tangible sources for nanotechnology and nanotoxicology and to promote data transfer as well as communication and dissemination. Furthermore the implementation of nanotechnology responsible management is aimed together with setting up an information pool for governmental bodies to give recommendations on safe use of nanotechnology. A framework analysis on existing regulations for nanomaterials and their safe use and handling is performed to give possible recommendations on existing needs and gaps to the European Commission.

Firstly presented within a Central Europe Programme are actively performed lab analysis on nanomaterials provided by companies using standardized OECD testing guidelines and evaluation methods with the output to provide safety data sheets and exposure scenarios.

Within the aim of NANOFORCE this paper is focused to introduce the work which has already been done in the project especially on the evaluation of the state of the art on existing safety procedures and nanotechnology related legislations.

Approach for nanomaterials on the EU market

Nanotechnology has been part of a major new technology development that are said to be able to have a significant impact on the economy but to be likely followed by various unexpected consequences [10]. The goal of policy makers and regulations to guarantee the safe manufacturing of products and to promote new technologies as well as to generate benefits while avoiding possible risks that may occur has to be transmitted at a regular basis for the insurance of a safe handling of nanomaterials [11].

When entering the European market each product and good needs to be subjected to a standardized authorization procedure. The EU directive on general product safety determines the security measures of products prior to market placement, to avoid harmful risks to consumers, described by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Products that accomplish these requirements are signed with the 'CE' symbol and may circulate freely on the European market [12].

Nevertheless the precautionary principle should be enabled in any case facing possible dangerous effects on human health, animal or plant health and environmental damages [13]. For the implementation of nanomaterials on the European market, industry should be encouraged to follow the precautionary principle to 'do your best to avoid possible negative side effects of nanotechnologies'.

Definition of Nanomaterial

Furthermore, a point of discussion which has been addressed was the recommendation on a definition for nanomaterials launched in October 2011 by the European Commission, defining a nanomaterial as

"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 %. [...]" [14].

The definition has aimed at providing a standardized identification of nanomaterials and to open new perspectives on risk assessment tools and safety regulations. Due to the lack of knowledge of the specific characteristics and hazards of nanomaterials the new definition has been granted the ability to provide a new opportunity to monitor and assess the proceeding risks. Only risk assessment tools can determine whether nanomaterials are classified as hazardous goods and whether further action is warranted to minimize possible risks. Another fundamental objective of this definition has been to ensure that nanomaterials are handled cross-sectional. The 'Second Regulatory Review on Nanomaterials' published in October 2012 has handled the implementation of the recommendation to be used by Member States, European Union agencies and companies. Standardization measures are carried out to compile existing definitions for nanomaterials and the definition will be evaluated again in 2014 by the European Commission [15].

REACH Regulation for nanomaterials

The regulatory framework for the management of chemicals (REACH) is said to be the main legislation in nanotechnology for the overall controlling of production, product market placement and usage of substances in preparation or in articles. The key elements of REACH also applicable for nanomaterials can be found in registration of chemicals manufactured or imported in the EU, unless specifically exempted. A dossier on physiochemical data and (eco-)toxicological properties has to be included which is generated within collaborations of companies. To examine the potential hazards and risks for chemicals, additional toxicological tests with results to be included in 'chemical safety reports' (CSR) have to be performed. An evaluation of the substance and the data from the dossiers is carried out by the European Chemicals Agency (ECHA) together with the Commission and the Member States to evaluate potential risk on health and safety [16].

According to Bernadette Quinn, PhD from ECHA - substance identification and data sharing unit - within a panel discussion at SENN2012, Helsinki 2012, there have been three registered substances to be 'nano' being followed by four registration after the launch of the recommendation for definition on nanomaterials in October 2011.

Compared to approximately 4000 registered substances, nanomaterials have taken up a relatively small proportion on registered chemicals. Due to upcoming deadlines and the implementation of the definition on nanomaterials a change is expected [17]:

- *REACH: 1 Dec. 2010 phase-in substances produced or imported with volumes of over 1,000 tonnes/year.*
- *REACH: 1 Dec. 2013 phase-in substances with volumes of over 100 tonnes/year.*
- *REACH: 1 Dec. 2018 phase-in substances with volumes over 1 tonnes/year.*

The REACH regulation is determined to be the most appropriate framework for dealing with potential risks of nanomaterials, but specific adaptations on REACH for nanomaterials and the preparation of design modifications as well as amendments are expected to be necessary [15].

To study the ability of REACH to cover nanomaterials altogether a recent (unpublished) state of the art report on existing safety procedures and nanotechnology related regulations was produced within the NANOFORCE project, with several regulations with relevance for nanomaterials to be found for cosmetics, food, food contact material, food additives, biocidal products and restriction of hazardous substances in electrical and electronic equipment.

Cosmetics

At present, there is said to be an inadequate information on the risks associated with nanomaterials; still the need to ensure a high level of protection to human health for every cosmetic product that contains nanomaterials is assessed. Additionally cosmetic products containing nanomaterials have to be notified to the Commission by the responsible person six months prior to market placement, except where they have already been placed on the market by the same responsible person before 11 January 2013. To guarantee the safety of consumers and to follow information demands "a catalogue of all nanomaterials used in cosmetic products placed on the market, including colorants, preservatives and UV filters" (Art. 16. (10.)(a)), will be published by the Commission with additional labelling obligations to "list the relevant materials with the word 'nano' in brackets" (Art. 19. (1.)) [18]

Food

Regulations for the presence of engineered nanomaterials in food should ensure the information of consumers by clearly indicating the nanomaterial in the list of ingredients and labelling such ingredient with the word 'nano' in brackets [19].

Food contact material and food additives

Nanoparticles are defined as engineered substances with significant changes in size and physical properties which might be leading to changes in the toxicity. Those have to be addressed on a case-by-case basis for risk assessment. Nanoparticles which are used in food contact materials should therefore only be used prior to an explicit authorization [20]. Food additives which are produced by new or significantly changed methods like nanotechnology leading to alterations in particle size need to be considered as different agents requiring a new entry in the community list or change in the specification prior to market placement [21].

Biocidal products

Nanomaterials used in biocidal products are managed differently than any active substance except where explicitly mentioned. Biocidal products containing nanomaterials need to be labeled 'nano' in brackets next to the material itself. Beginning in September 2015 Member States have to report to the Commission the correct implementation of the regulation providing information on the use of nanomaterials in biocidal products including risks. Nevertheless the Commission is encouraged to review the scientific progress of the provision on nanomaterials on a regular basis [22].

Restriction of hazardous substances in electrical and electronic equipment

Following the precautionary principle, electrical and electronic equipment produced with or using nanotechnology and nanomaterials have to be notified to the Commission. Hazardous or possible hazardous substances are said to be substituted by environmentally friendly alternatives to ensure the safe use as well as human and environmental health over their life cycle [23].

Conclusion

Based on current knowledge, it can be assumed that nanomaterials show similarities in toxicity to customary chemical substances. Therefore risk assessment has to be tailored to the individual case and on the information available (case-by-case) for the material. The definition on nanomaterials which was presented by the European Commission in 2011 will be integrated into EU regulations keeping in mind that the overall coverage of nanomaterials is managed by REACH which is discovered to be the most appropriate framework for dealing with potential risks of nanomaterials. One of the problems has been addressed for nanomaterials to have entered a very late point of discussion in REACH which will lead to additional changes and comments and an essential control of further developments to be monitored carefully by the Commission including a new report to be presented in three years.

Within REACH there are still issues to be addressed for nanomaterials to proceed with the safe implementation of nanotechnology on the European market:

- registration for imported and manufactured nanomaterials <1 tonne/year
- harmonized labeling of nanomaterials
- safety reports with exposure assessment for registered nanomaterials
- reporting requirements for all nanomaterials on the market
- adaption of the precautionary principle at all levels of the production cycle

Not only regulations but several guidelines with focus on needs of the good implementation of nanomaterials in products including a safe market placement are placed at disposal for consumers and producers to help ensuring the correct use of the new technology. Safety research and standardization - addressed via bottom-up approach by consolidation of national expertise (ref. to www.EURO-NanoTox.eu) - shall assist the safe implementation of nanotechnological applications and products. However, findings of the project NANOFORCE have shown significant needs in the standardization of the regulatory body for nanomaterials, a better implementation and development of simple and standardized testing methods, a uniform data collection and harmonization tools for a better knowledge dissemination and transparency for data to be available for stakeholders.

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