Biocidal products using nanotechnology from a legal perspective

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Marcin Jurewicz

ABSTRACT

Nanotechnology means the design and the manufacture of structures in which at least one size is less than 100 nanometers and which have new properties resulting from the size. Restrictive criteria for the marketing authorisation of biocidal products containing nanomaterials as defined in Regulation 528/2012/EU (separate risk assessment and approval of the active substance in the form of nanomaterial) contribute to the strengthening of their safety for the health and the environment. The purpose of listing on the label of a biocidal product and an article treated with a biocidal product of components present in the form of nanomaterials and the word „nano" in brackets after the name of such components is to inform buyers of the presence of nanomaterials in such products; buyers' knowledge of the atypical properties of nanomaterials, including benefits and potential risks associated with their use, should be increased by means of information activities of the EU institutions and competent authorities of the EU Member States.

KEY WORDS

nanomaterials, biocides, EU legislation

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Corresponding author:

Marcin Jurewicz

Bialystok University of Technology,
Faculty of Management

e-mail:
m.jurewicz@pb.edu.pl

Introduction

Various innovative applications of nanotechnology are available due to atypical properties of nanomaterials in comparison with their macroscopic counterparts; such properties are the result of a small particle size of nanomaterials. Due to specific characteristics of nanomaterials, it is possible to manufacture substances and products with new parameters and applications. Because of their small size, however, nanomaterials may cause hazards to human health and to the environment as their enhanced reactivity and mobility may cause toxic effects. The legal basis for the placing on the market of biocidal products, including those containing nanomaterials, in the EU are Articles 30, 34, and 35 of the Treaty on the Functioning of the European Union – TFEU (OJ C 326, 2012, p. 47) whose purpose is to guarantee a free movement of goods on the single market; these regulations introduced the prohibition to collect customs duties and charges having equivalent effect, as well as the prohibition to impose quantitative restrictions in import and export, and any measures having equivalent effect among the Member States of the EU. The single market, according to Article 26 item 2 of the TFEU, comprises an area without internal frontiers in which the free movement of goods, people, services and capital is guaranteed.

The purpose of this article is to describe and justify the EU legislation and to present the perspective of a legal doctrine in relation to the placing on the market and the use of biocides containing nanomaterials; in addition, this is an attempt to assess the legal regulations in this area – with the use of dogmatic-legal and theoretical-legal research methods.

1. EU NON-BINDING ACTS CONCERNING BIOCIDAL PRODUCTS CONTAINING NANOMATERIALS

The nanotechnology, according to a definition formulated by R. Michalczewski and A. Mazurkiewicz, means the design and the manufacture of structures in which at least one size is less than 100 nanometers and which have new properties resulting from the nanosize (Michalczewski, Mazurkiewicz, 2007, p. 23). E. Stokes points that nanomaterials, due to very small sizes, have a large specific surface area in proportion to their mass so as a consequence they are potentially more reactive and toxic than their conventional, macroscopic counterparts. So despite significant benefits, nanotechnology poses substantial problems – nanomaterials may cause a serious risk to human health and to the environment. In addition, the effects of an exposure to the action of nanomaterials are uncertain due to very limited data and substantial gaps in knowledge in this area (Stokes, 2009). R.D. Porter et al. list key areas where the existing gaps in scientific knowledge of nanomaterials need to be filled: definitions – terminology, nomenclature, classification, characteristics – physical and chemical characteristics of nanomaterials (especially the length, shape, composition, aggregation, catalytic properties, surface chemistry), metrology – measuring methods and instruments, tests – safety tests and risk assessment methods (Porter et al., 2012).

It is advisable for the EU institutions and the competent authorities of EU Member States to carry out information and educational activities addressed to the public, on benefits and potential hazards resulting from specific properties of nanomaterials. R. Falkner et al. stress the necessity for a significant increase in funding of scientific research related to the risks for the human health and the environment associated with nanomaterials. They also emphasise the advisability of information exchange related to such risks among the EU institutions and the competent authorities of EU Member States. It is essential to increase the mandatory requirements regarding the data transmitted by entities placing nanomaterials on the market and the commercial applications of nanomaterials; there is a lack of comprehensive knowledge of the presence of nanomaterials in products placed on the market (Falkner et al, 2010). J. Ejdys and E. Krawczyk-Dembicka state that the development of nanotechnology should be supported by relevant cooperation at the international level. In the recent years, an increase in the financial support from the EU, both for the scientific research and the industrial applications in the field of nanotechnology, has been observed. An important role of nanoscience and nanotechnology in the contemporary world was also presented in documents that specified the directions of research planned to be financed and developed within the 7th EU Framework Programme. The fourth thematic area of the 7th EU Framework Programme was dedicated to the research in the field of nanosciences, nanotechnologies, materials, and new production technologies. In accordance with the assumptions of the 7th EU Framework Programme, nanoscience and nanotechnology, materials, and new production technologies are very significant to the industry, and their integration for sectoral applications may be accomplished, inter alia, through actions in the field of chemistry as well as nanoelectronics, industrial production, power generation, steel sector, transport, construction industry, industrial safety, textile industry, ceramics and wood industries, and nanomedicine. In the course of the 7th EU Framework Programme, also an analysis of the impact of nanotechnology on the society and the significance of nanoscience and nanotechnology in solving social problems were included (Ejdys, Krawczyk-Dembicka, 2013). Currently, in the course of the Horizon 2020 EU Framework Programme, the research in the area of nanotechnology, advanced materials, advanced manufacturing and processing systems, and in biotechnology is a part of a specific objective „Leadership in enabling and industrial technologies". Activities in these areas are aimed at stimulating the development of the European industry, creating new jobs, and meeting the needs of the society (http://www.kpk.gov.pl, 24.01.2015).

According to the „Opinion of the European Economic and Social Committee on the Proposal for a Regulation of the European Parliament and the Council concerning the placing on the market and the use of biocidal products" (COM 2009/267, 2010), the European Economic and Social Committee supports the introduction of the Regulation of the European Parliament and the Council 528/2012/EU concerning the making available on the market and the use of biocidal products (OJ L 167, 2012, p. 1) as a legal act directly applicable in the legal systems of the

EU Member States – facilitating the standardisation of legal regulations concerning the marketing authorisation of biocides within the EU territory. The European Economic and Social Committee states that the Regulation 528/2012/EU should contribute to an increase in free movement of biocidal products in the EU by simplifying the licensing procedure and reducing administrative barriers to entities placing biocides on the market. In terms of the marketing authorisation and the use of biocidal products, including those composed of nanomaterials, a major role in facilitating the interpretation legal provisions to entities placing such products on the market is fulfilled by informal measures, in particular the guides and guidelines of the European Chemicals Agency (ECHA) related to the Regulation 528/2012/EU. These are, among others: „Guidance on Human Health Risk Assessment", „Guidance on Applications for Technical Equivalence", „Guidance on Information Requirements", „Guidance on Active Substance Suppliers" and „Guidance on Data Sharing" (http://echa.europa.eu, 24.01.2015).

Examples of improved products available on the market with biocidal properties containing nanomaterials and products treated with biocides containing nanomaterials are: household and industrial chemicals, sport products including handle plating composed of nanoparticles of silver, dressings containing silver nanoparticles, joints, silicones and adhesive mortars, dental fillings, toothbrushes, equipment casings, products for the manufacture of biocidal protective coatings applied on virtually all surface types, products for surface protection, cleaning, and maintenance, household appliances including washing machines and refrigerators (http://www.nano-technologie.pl, 24.01.2015).

2. Description of research methods applied

The dogmatic-legal and theoretical-legal research methods were used in the research. The dogmatic-legal method refers to an interpretative and descriptive way of analysing and explaining the texts of EU legal acts relating to the placing on the market and the use of biocidal products containing nanomaterials; these are interpretative activities that is the interpretation of the law consisting in reconstructing the standards of conduct from legal regulations and commenting on their contents. The theoretical-legal method consists in analysing opinions in the legal literature in the field of nanotechnology. Based on the conducted analysis, conclusions concerning the implementation of the EU legislation's objective in relation to the marketing of biocides containing nanomaterials – the use of innovative applications of nanotechnology by the society in a way that is safe for the health and the environment – were drawn.

3. The use of nanotechnology in biocidal products according to the legal regulations of the European Union

The purpose of the Regulation of the European Parliament and the Council 528/2012/EU concerning the making available and the use of biocidal products, according to Article 1 item 1, is to improve the functioning of the EU single market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. Biocidal products, in particular those containing nanomaterials, commonly used in everyday life to combat harmful organisms, may pose a threat to the health and the environment; the facilitation of a free movement of biocides in the EU should therefore be carried out taking into account both advantages and risks associated with the abolition of administrative restrictions in this area.

The Regulation 528/2012/EU applies to biocidal products, including those containing nanomaterials, and articles treated with biocidal products (Article 2 item 1). A biocidal product, according to Article 3 item 1 letter a, means any substance or mixture consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. Based on Annex V, biocidal products are divided into the following product groups: disinfectants, preservatives, products used to combat pests, and other biocidal products. An article exposed to the action of biocidal products, in accordance with Article 3 item 1 letter l, is any

substance, mixture or article that has been exposed to the action of at least one biocidal product or as a result of an intentional action contains at least one biocidal product.

According to Article 3 item 1 letter z of the Regulation 528/2012/EU, „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 1-100 nm"; furthermore: „Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials"; at request of one of the EU Member States, the European Commission, pursuant to Article 3 item 3, may decide by means of implementing acts whether a given substance is a nanomaterial, considering in particular the Recommendation of the European Commission 2011/696 on the definition of nanomaterial (OJ L 275, 2011, p. 38). It should be noted that a harmonised definition of nanomaterial introduced by the Regulation 528/2012/EU is adapted to the current state of scientific knowledge and compliant with the definition of nanomaterial expressed in the Recommendation 2011/696/EU on the definition of nanomaterial. Both definitions specified in the Regulation 528/2012/EU and in the Recommendation 2011/696/EU are based on the material's component particle size as a parameter which should be used to determine whether a given material is a nanomaterial; this factor determines specific properties of nanomaterials in consequence of which they may pose a risk to the health and the environment. The purpose of the establishment of the definition of nanomaterial by the Regulation 528/2012/EU is to assure the transparency of legal regulations with respect to entities operating on the market of biocidal products by determining whether additional conditions for placing on the market of biocidal products containing nanomaterials apply to a given material; restrictive criteria for the marketing authorisation of such biocidal products (separate risk assessment and approval of the active substance in the form of nanomaterial) contribute to their safety for the health and the environment.

An approval for the placing on the market of a biocidal product, including those containing nanomaterials, includes conditions relating to the making available and the use of a given biocidal product or a group of biocidal products and the characteristics of the biocidal product (Article 22 item 1); it is granted for a period not exceeding 10 years (Article 17 item 4). An approval under Article 19 item 1 is granted if the criteria of sufficient effectiveness and absence of unacceptable effects on target organisms, both human and animal health, and the environment are met. An active substance contained in a biocidal product is approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the abovementioned criteria (Article 4 item 1). The Regulation 528/2012/EU also applies to the placing on the market of articles treated with biocides. An article exposed to the action of biocidal products may be approved for the market only if all active substances contained in biocidal products to whose action it has been exposed or which it contains have been approved in the EU (Article 58 item 2).

Applicants who place biocidal products on the market may apply for an EU authorisation (granted by the European Commission based on an evaluation of the application by the competent authority in an EU Member State and the opinion of the ECHA), a national authorisation (issued by the competent authority of an EU Member State) or an authorisation through mutual recognition of national authorisations by other EU Member States (Article 17 item 2). A simplified authorisation procedure according to Article 25 applies to a biocidal product which meets the following conditions: all active substances contained in that biocidal product appear in Annex I and satisfy any restriction on their use specified in that Annex, the biocidal product does not contain any substance of concern and any nanomaterials, the biocidal product is sufficiently effective and the handling of the biocidal product and its intended use do not require personal protective equipment. If a product meets the above conditions, the applicant may submit an application to the ECHA, informing it of the name of the competent authority of an EU Member State that it proposes should evaluate the application (Article 26 item 1). If the authority gives an authorisation in the simplified procedure, the biocidal product may be made available on the market in all EU Member States without the requirement of mutual recognition (Article 27 item 1).

With regard to the use of nanotechnology in biocidal products, the Regulation 528/2012/EU provides in Article 4 item 4 that the approval of the

use of an active substance in a biocidal product does not cover such substance in the form of nanomaterial except where explicitly mentioned; where the tests presented for the purpose of obtaining the approval of an active substance in a biocidal product are applied to nanomaterials, an explanation of their scientific relevance in relation to nanomaterials should be provided, and if appropriate – technical adjustments or changes made in order to take into account special properties of nanomaterials. Where nanomaterials are used in a biocidal product, when applying for the authorisation of that product, a separate assessment of risks to human and animal health and to the environment is to be made (Article 19 item 1 letter f). In addition, a biocidal product may be placed on the market under a simplified authorisation procedure if it does not contain any nanomaterials (Article 25 letter c). It should be emphasised that the properties of a substance in the form of nanomaterial contained in biocidal products are atypical in relation to substances in the traditional form. Substances with nanoscale particles may have toxic effects, and the state of scientific knowledge of their safety to the health and the environment requires improvement. The assessment of the risks associated with biocidal products containing nanomaterials is therefore, according to the Regulation 528/2012/EU, carried out individually in each case. In addition, the approval of an active substance in the traditional form in a biocidal product does not apply in principle to this substance in the form of nanomaterial which requires a separate approval.

The EU Member States are required to monitor the biocidal products placed on the market, including products containing nanomaterials and articles treated with biocidal products – through official controls (Article 65 items 1 and 2), and the obligation of authorisation holders to keep records and make available the documentation relating to biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier (Article 68 item 1). In addition, the EU Member States are required to submit to the European Commission every 5 years, commencing from 01 September 2015, a report on the implementation of the abovementioned Regulation in their respective territories; such report includes in particular information on the use of nanomaterials in biocidal products and the potential risks thereof and is published on the website of the European Commission (Article 65 item 3). So the purpose of the obligation of the EU Member States to exercise control over biocides placed on the market and to submit reports to the European Commission on the implementation of the Regulation 528/2012/EU in their respective territories, containing the data on the use of nanomaterials in biocidal products, is to determine the degree of implementation of the objective of that Regulation with regard to biocides containing nanomaterials. This objective is to ensure a free movement on the single market of biocidal products containing nanomaterials and to minimise the risks to human and animal health and to the environment associated with the use of nanomaterials in such products.

In accordance with the Regulation 528/2012/EU, a label of a biocidal product must contain information (legible and indelible) on nanomaterials which are contained in the product and on any specific related risks, and, following each reference to nanomaterials – the word „nano" in brackets (Article 69 item 2 letter b); in addition, a label of an article treated with biocidal products must also include the names of all nanomaterials contained in the biocidal products, followed by the word „nano" in brackets (Article 58 item 3 letter d). The purpose of listing on the label of a biocidal product and an article treated with a biocidal product of components present in the form of nanomaterials and the word „nano" in brackets following the name of such components is to inform buyers of the presence of nanomaterials in such products. The EU institutions and the competent authorities of the EU Member States should also carry out information activities to provide buyers of nanoproducts with the knowledge of specific properties of nanomaterials in order to enable them to make conscious decisions when buying such products.

Conclusions

Products with enhanced biocidal properties containing nanomaterials are currently widely available on the market. However, atypical characteristics of nanomaterials, especially their increased reactivity and mobility as a result of their small size, may cause hazards to human and animal health and to the environment associated with the use of such biocidal products. Successive research

studies are required, in particular to obtain information on potential toxic and ecotoxic effects of nanomaterials. The purpose of precise requirements for the placing of biocidal products containing nanomaterials on the market in accordance with the Regulation 528/2012/EU, including a risk assessment prepared individually in each case and the approval of an active substance in the form of nanomaterial is to ensure the safety of their use for the health and the environment. However, the very detailed data that need to be submitted by entities placing biocidal products containing nanomaterials on the market together with an application for the authorisation of such products may hinder the development of such innovative articles. Legal regulations concerning biocides containing nanomaterials should therefore take into account the balance of reducing administrative barriers to the marketing authorisation and the use thereof in a way that is safe for the health and the environment.

The purpose of the obligation of listing on the label of a biocidal product and an article treated with a biocidal product of components present in the form of nanomaterials and the word „nano" in brackets following the name of such components is to inform buyers of the presence of nanomaterials in such products; at the same time, it is advisable for the EU institutions and the competent authorities of the EU Member States to carry out information activities in relation to specific properties of nanomaterials in order to increase the knowledge of buyers on the benefits as well as the potential risks related to the use thereof.

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