

Review article

Received: **12.09.2017**

Accepted: **25.10.2017**

Published: **20.12.2017**

The fundingsources for the publication:**author's own resources**

Authors' Contribution:

(A) Study Design

(B) Data Collection

(C) Statistical Analysis

(D) Data Interpretation

(E) Manuscript Preparation

(F) **Literature Search**

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THE PRECAUTIONARY PRINCIPLE AS THE BASIS FOR LEGAL REGULATIONS IN THE FIELD OF NANOTECHNOLOGY

INTRODUCTION

Nanotechnology means the design, creation and use of materials with at least one dimension ranging from 1 nanometre(10^{-9} m) to 100 nanometres (10^{-7} m)¹. Nanotechnology, through innovative applications in many sectors, contributes to the implementation of societal challenges. Micro- and nanoelectronics, nanotechnology, photonics, advanced materials, industrial biotechnology and advanced production technologies, in line with economic analyses of market trends and their usefulness in solving social challenges, are referred to as EU key enabling technologies (KET)².The use of these technologies is a major factor in the development of various industries in the world, the emergence of new goods and services³. At the same time, due to the microscopic size, nanomaterials may

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¹ R. Kelsall, I. W. Hamley, M. Geoghegan, *Nanotechnology*, Warszawa 2012, p. 1.

² Communication from the European Commission "A European strategy for key enabling technologies - a way to growth and jobs", COM(2012) 341 of 26.06.2012.

³ Communication from the European Commission "Preparing for the future: developing a common strategy for key enabling technologies in the EU", COM(2009) 512 of 30.09.2009; basic uses of nanotechnology are: advanced materials (construction, thermal insulation, aerogels, motor and military industry materials); energy

pose a threat, especially increased reactivity and mobility, and consequently toxicity, having an atypical effect on the physiology of humans and other species⁴. The research problem is the unknown in the scientific knowledge with regard to the possible risks to human health and the environment, associated with the use of nanotechnology and in consequence the requirement for appropriate approach by the authorities (EU institutions and bodies and national authorities) to legal regulations in this area; the precautionary principle is an attempt to balance the objectives: to provide the public with the safe use of innovative applications of nanotechnology and not to disturb the development of this pioneering technology.

THE PRECAUTIONARY PRINCIPLE AND REGULATORY REQUIREMENTS IN THE FIELD OF NANOTECHNOLOGY

The precautionary principle is well-established in the EU law on environmental protection⁵(Art. 191 of the Treaty on the Functioning of the European Union⁶). This principle was included in international, regional and national instruments of the environmental protection law and policy⁷. The precautionary principle is applied in other sectors in order to ensure the protection of the human health. It also includes the most important elements of consumer protection policy. Its legally binding nature was established by the case-law of the EU Court of Justice⁸. On the other hand, the first literal presence of the precautionary principle is the „Communication of the European Commission regarding the application of the precautionary principle”⁹, according to which this principle may be referred to if there are justified concerns that potential risks may affect the environment or human health, animals or plants, while the available data prevents a detailed risk

technology (generation of energy from renewable sources: solar batteries and fuel cells as well as storage and energy saving); electronics (semiconductors, mass memories, nanoelectromechanical systems); IT technologies (data recording, processing and transmission systems, multi-functional telecommunications devices, quantum computers); optics and optoelectronics (lasers, displays, laser diodes, optical equipment with functional coatings); pharmacy (drugs stabilized with nanoparticles, materials for dressings, nanocapsules); diagnostics and medical equipment (lab-on-chip devices - integrated mini laboratory systems, drug dosing systems, high resolution imaging, diagnostics, prostheses and implants); cosmetics (UV filters, creams, personal hygiene products); packaging (increasing shelf-life, biodegradable, packaging recycling); food production (sensors that monitor food shelf life, food remaining inactive in the body and released along with the supply of nutrients only after reaching specific cells, food additives); textile and sporting goods (functional textile materials, equipment and sports consumables); reduction of pollutant emissions (pollution removal and neutralization, detection of contamination, ecological production and energy, waste treatment) and water treatment (membranes for water filtration, desalination technologies) - R. Wawrzyński, W. Karsznia, *Zastosowania nanotechnologii*, [in:] *Nanonauki i nanotechnologie. Stan i perspektywy rozwoju*, ed. A. Mazurkiewicz, Radom 2007, p. 262, 279 and 285.

⁴ Resolution of the European Parliament „Regulatory aspects of nanomaterials”, Journal of Laws C 184 of 08.07.2010, p. 82.

⁵ S. Heselhaus, *Nanomaterials and the Precautionary Principle in the EU*, “Journal of Consumer Policy” 2010, no 1 (33), p. 106.

⁶ Journal of Laws C 326 of 26.10.2012, p. 47.

⁷ S. Ngarize, K. E. Makuch, R. Pereira, *The Case for Regulating Nanotechnologies: International, European and National Perspectives*, “Review of European Community & International Environmental Law” 2013, no. 2 (22), p. 132.

⁸ S. Heselhaus, *Nanomaterials...*, p. 96 and 106.

⁹ COM(2000) 1 of 02.02.2000.

assessment. The precautionary principle means, therefore, that the lack of full scientific certainty should not be used as a reason justifying the postponement of the implementation of measures to prevent damage in legally protected interests in a situation where there is a threat of serious or irreparable damage. Risk must be prevented from becoming a reality. However, legal actions are only allowed if a full risk assessment is carried out based on the most reliable available scientific data¹⁰. The risk assessment must precede the risk management phase, during which a decision should be taken on the introduction of appropriate measures. After such an assessment, if it is impossible to conclusively state the existence or degree of alleged risk due to insufficient, convincing or accurate results of the tests carried out, but there is a probable occurrence of harmful influence on public health if the risk materializes, the precautionary principle justifies the introduction of restrictive measures¹¹. The mere possibility of risk allows the authorities (EU institutions and bodies and national authorities) to intervene. This in turn means that the authorities can intervene faster and do not have to wait for the evidence of the actual threat¹².

The Communication from the European Commission „Regulatory aspects of nanomaterials”¹³ states that in situations where the full scale of risks is not known, but the concerns are so great that risk management measures are considered essential - as is currently the case for nanomaterials - these measures must be based on the precautionary principle. Referring to this principle does not necessarily mean taking instruments that have legal effects; a wide range of activities and measures is available, such as legally binding measures, launching research projects or recommendations. Measures which follow the precautionary principle must be based on general principles of risk management, i.e. they must be proportionate, non-discriminatory and consistent and based on an analysis of the benefits and costs of an action or omission, and take into account the development of scientific knowledge. Preventive measures must, however, be based on more than just a hypothesis or purely theoretical assessment - there must be „reasonable grounds for concern”¹⁴. Reflections on the application of the precautionary principle in the context of nanotechnology lead to the explicit conclusion that there is a lack of full scientific certainty regarding the potential risks to human health and the environment. The knowledge base on nanotechnology is still very limited and the authorities are still working on defining a basic framework for future legislation¹⁵. In the management of the process leading to the decision on the measures implemented in relation to specific cases of nanomaterials, the principle of proportionality plays a key

¹⁰ S. Mielke, *Regulating in Thin Air: Nanotechnology Regulation in the European Union*, “Review of European Community & International Environmental Law” 2013, no. 2 (22), p. 147.

¹¹ S. Heselhaus, *Nanomaterials...*, pp. 101-102.

¹² C. Calliess, H. Stockhaus, *Precautionary Principle and Nanomaterials: REACH Revisited*, “JEEPL” 2012, no. 2 (9), p. 116.

¹³ COM(2008) 366 of 17.06.2008.

¹⁴ S. Ngarize, K. E. Makuch, R. Pereira, *The Case...*, p. 132.

¹⁵ S. Mielke, *Regulating...*, pp. 147-148.

role. It is the main driving force especially in very competitive industries, i.e. nanomaterials, for which some of the wide range of legal instruments used under the precautionary principle are selected¹⁶. Measures applied according to the precautionary principle – on the basis of the „Communication of the European Commission regarding the application of the precautionary principle” – should be proportional to the necessary level of protection, i.e. include less restrictive alternatives that allow achieving an equivalent level of protection, i.e. appropriate handling, reduced exposure, tightening control, adoption of temporary restrictions, recommendations on the population at risk, etc.

The legislator’s task is to define the limitations of the precautionary principle by establishing clear barriers to its application and its consequences. Such barriers should result from the principle of proportionality, determined individually for each sector covered by legal regulations and based on indisputable scientific evidence. In the case of nanotechnology, the lack of scientific evidence regarding its potential risk would expose preventive provisions to a certain degree of freedom and potential political influence, jeopardizing the predictability of legal solutions¹⁷. The successive acquisition of data on risk assessment and risk management in nanotechnology is the foundation for precise, unequivocal legislation in this area. Establishing a moratorium, i.e. a temporary suspension of the use of nanotechnology – due to the potential risk – should not be taken into account. It would deprive the public of the possibility of using diverse, innovative applications of nanotechnology.

The precautionary principle is an attempt to avoid certain problems that, if not avoided, could result in unmanageable consequences due to their serious or irreversible nature. In doubtful situations, instead of waiting for scientific evidence proving the suspected effects to take compensatory measures, the precautionary principle proposes to avoid taking any action that may be harmful or to exercise appropriate caution until the consequences are confirmed¹⁸. On the other hand, it is difficult to share the view that applying the precautionary principle as the basis for legal regulations concerning nanotechnology or other new technologies seems to be an unnecessary, exaggerated response from the authorities, for which the society must pay a significant price. This price is a potential loss of public access to important, useful applications of new technologies. Legal regulations based on the precautionary principle can drastically inhibit the development of new technologies, including nanotechnology. The precautionary principle seems to force the authorities to use a desperate legal regulation strategy, determined to give up or significantly delay the social benefits of innovation in the name of implementing a more conservative response to significant but doubtful social threats¹⁹. On the contrary, it should be possible to advance the work on innova-

¹⁶ S. Heselhaus, *Nanomaterials...*, p. 106.

¹⁷ S. Mielke, *Regulating...*, p. 152.

¹⁸ I.L. Herrarte, A.A. Cela, *The Precautionary Principle: Regulation Needed to Confront the Risks Associated with Nanotechnology*, [in:] *Innovation: Economic, Social and Cultural Aspects*, ed. M.G. Uranga, J.C.M. de Bustos, Reno 2011, p. 46.

¹⁹ J.H. Matsuura, *Nanotechnology Regulation and Policy Worldwide*, Norwood 2006, p. 93-94.

tive nanotechnology products together with ensuring the safety of their use.

CONCLUSION

It is emphasized that a system for the approval of nanomaterials is required to introduce them on the market²⁰. Risk management can lead to a total ban on the sale of products, the use of processes, etc. or to the mechanism of prior approval. In the latter case, the European Commission indicates that the change requiring proof is the result of the precautionary principle enforcing the industry to provide the scientific evidence necessary to carry out an in-depth risk assessment. The European Commission therefore calls on the public sector to provide assistance in the field of research²¹. The precautionary principle may serve to shift the burden of evidence by creating a „challengeable presumption of danger”. If there are reasonable grounds for concern, the entity responsible for the risk should be to refute the alleged cause and effect relationship and to demonstrate that the concerns raised are unfounded. For this purpose, the entity responsible for the risk is not obliged to prove the harmlessness of the substance or product, but must provide facts that show that it is unlikely that the revealed reasons for concern appeared²². The precautionary principle does not necessarily mean giving up the use of certain technologies, in many cases, caution would be limited to indirect measures, i.e.: promoting more in-depth research to gain a better understanding of the degree of risk involved, imposing an obligation to include customer information labels, strict product monitoring and their activities, encouraging the search for alternative solutions safer for the public²³. The requirement of separate approval of nanomaterials before they are placed on the market has so far been established for their use in the manufacture of the most significant products for the protection of consumers – food, food packaging and biocides; cosmetics are also subject to the obligation to report the use of nanomaterials in the production process. In addition, food, biocidal products and cosmetic products that contain nanomaterials must be labelled with the indication on the label of any ingredients present in the form of nanomaterials together with the word ‘nano’ in brackets after the name of those ingredients²⁴. With regard to medical

²⁰ I.L. Herrarte, A.A. Cela, *The Precautionary Principle...*, p. 54.

²¹ S. Heselhaus, *Nanomaterials...*, pp. 103-104.

²² C. Calliess, H. Stockhaus, *Precautionary Principle...*, pp. 117-118.

²³ I.L. Herrarte, A. A. Cela, *The Precautionary Principle...*, p. 49.

²⁴ Art. 10 section 1 and 3 as well as Art. 12 section 1 of Regulation no. 2015/2283 / EU of the European Parliament and of the Council on novel foods, amending Regulation (EU) no. 1169/2011 of the European Parliament and of the Council repealing Regulation (EC) no. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) no. 1852/2001 (OJ L 327, 11.12.2015, p. 1.), which has been in force since 01.01.2018; Art. 9 section 4 of Regulation no. 609/2013/UE of the European Parliament and Council on foods intended for infants and young children and foods for special medical purposes and foodstuffs replacing a full-day diet, for weight control and repealing Council Directive 92/52 / EEC, Commission Directives 96/8 / EC, 1999/21 / EC, 2006/125 / EC and 2006/141 / EC, Directive 2009/39 / EC of the European Parliament and of the Council and Commission Regulations 41/2009 / WE and 953/2009 / EC (Journal of Laws L 181, 29.06.2013, p. 35, as amended); Art. 18 section 3 of Regulation 1169/2011 / EU of the European Parliament and of the Council on the provision of food information to consumers (Journal of Laws L 304, 22.11.2011, p. 18, as amended); Art. 12 of Regulation 1333/2008 / EC of the European Parliament and of the Council on food additives (Journal of Laws L 354, 31.12.2008, p. 16,

products, there is a requirement to design and manufacture them in such a way as to reduce as far as possible the risks associated with the size and properties of particles that may be released into the patient's or user's body (unless they come into contact only with intact skin) and special attention should be paid to nanomaterials; medical products containing or consisting of a nanomaterial belong to: Class III – if they pose a high or medium risk of internal exposure; class IIb – if they pose a low risk of internal exposure or class IIa – if they pose a negligible risk of internal exposure²⁵. In this way, they are subject to more rigorous, meticulous conformity assessment procedures to minimize the risk and highlight the benefits of their use. In relation to other products intended for consumers, work is currently underway at the EU level to establish similar provisions²⁶, to strengthen the safety of using nanotechnology. The Polish legal system has not yet introduced provisions referring literally to nanomaterials, so the same legal regulations concern nanomaterials and substances in conventional forms. Proper monitoring of products containing nanomaterials and their activities is conditional, in addition to introducing the requirement to validate nanomaterials that are also included in consumer products, to improve the scientific knowledge on detection and testing of nanomaterials. In addition, it would be advisable to create a register of products containing nanomaterials²⁷, to obtain information on the amount, applications and properties of nanomaterials, also facilitating the monitoring of such products.

Bibliography

- Azoulay D., Buonsante V., *Regulation of Nanomaterials in the EU: Proposed Measures to Fill in the Gap*, "StoffRecht" 2014, no. 3.
- Calliess C., Stockhaus H., *Precautionary Principle and Nanomaterials: REACH Revisited*, "JEEPL" 2012, no. 2 (9).
- Herrarte I. L., Cela A.A., *The Precautionary Principle: Regulation Needed to Confront the Risks Associated with Nanotechnology*, [in:] *Innovation: Economic, Social and Cultural Aspects*, ed. M.G. Uranga, J.C.M. de Bustos, Reno 2011.

as amended); Art. 9 section 2, Art. 13 section 4 letter b and Art. 14 section 3 letter b of Commission Regulation 10/2011 / EU on plastic materials and articles intended for contact with food (Journal of Laws L 12, 15.01.2011, p. 1, as amended); Art. 5 section 2 letter c of the Commission Regulation No. 450/2009 / EC on active and intelligent materials and articles intended for contact with food (Journal of Laws L 135, 30.05.2009, p. 3, as amended); Art. 4 section 4, Art. 19 section 1 letter f, Art. 58 section 3 letter d and Art. 69 section 2 letter b of Regulation 528/2012 / EU of the European Parliament and of the Council regarding the making available on the market and use of biocidal products (Journal of Laws L 167, 27.06.2012, p. 1, as amended) and Art. 13 section 1, Art. 16 section 3 and Art. 19 section 1 of the Regulation No. 1223/2009 / EC of the European Parliament and of the Council concerning cosmetics (Journal of Laws L 342, 22.12.2009, p. 59, as amended).

²⁵ Annex I, Chapter II, Section 10.6. and Annex VIII, Chapter III, Section 7.6. Rule 19 of Regulation 2017/745 / EU of the European Parliament and of the Council on medical products, amending Directive 2001/83 / EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385 / EWG and 93/42 / EEC (Journal of Laws L 117, 05/05/2017, p. 1), which will be in force from 26.05.2020.

²⁶ European Commission Communication "Second regulatory review on nanomaterials", COM (2012) 572, 03/10/2012.

²⁷ Szerzej D. Azoulay, V. Buonsante, *Regulation of Nanomaterials in the EU: Proposed Measures to Fill in the Gap*, "StoffRecht" 2014, no. 3, pp. 119-120.

Heselhaus S., *Nanomaterials and the Precautionary Principle in the EU*, "Journal of Consumer Policy" 2010, no. 1 (33).

Kelsall R., Hamley I. W., Geoghegan M., *Nanotechnology*, Warszawa 2012.

Matsuura J. H., *Nanotechnology Regulation and Policy Worldwide*, Norwood 2006.

Mielke S., *Regulating in Thin Air: Nanotechnology Regulation in the European Union*, "Review of European Community & International Environmental Law" 2013, no. 2 (22).

Ngarize S., Makuch K. E., Pereira R., *The Case for Regulating Nanotechnologies: International, European and National Perspectives*, "Review of European Community & International Environmental Law" 2013, no. 2 (22).

Wawrzyński R., Karsznia W., *Zastosowania nanotechnologii*, [in:] *Nanonauki i nanotechnologie. Stan i perspektywy rozwoju*, ed. A. Mazurkiewicz, Radom 2007.

Summary: The purpose of this article is to characterize and comment on EU nanotechnology regulation in the context of the precautionary principle. Nanotechnology involves the design, creation and use of materials having at least one dimension in the range of 1 nanometer (10^{-9} m) to 100 nanometers (10^{-7} m). Nanotechnology, thanks to numerous innovative applications, contributes to the realization of social challenges. Its use, however, involves scientific uncertainty regarding the impact of nanomaterials on human health and the environment. The Commission's Communication "Regulatory Aspects of Nanomaterials" states that in situations where the full scale of threats is not known, but the concerns are so great that risk management measures are considered indispensable (as is currently in relation to nanomaterials), these measures must be based on the precautionary principle. Precautionary measures should be proportionate to the level of protection needed to ensure the safety of nanotechnology and the absence of restrictions on the development of this innovative technology.

Key words: nanotechnology, the precautionary principle, safety

ZASADA OSTROŻNOŚCI JAKO PODSTAWA UREGULOWAŃ PRAWNYCH W OBSZARZE NANOTECHNOLOGII

Streszczenie: Cel artykułu stanowi charakterystyka i komentowanie uregulowań prawnych UE w obszarze nanotechnologii w kontekście zasady ostrożności. Nanotechnologia obejmuje projektowanie, tworzenie oraz użytkowanie materiałów posiadających przynajmniej jeden wymiar w zakresie od 1 nanometra (10^{-9} m) do 100 nanometrów (10^{-7} m). Nanotechnologia, dzięki licznym nowatorskim zastosowaniom, przyczynia się do urzeczywistniania wyzwań społecznych. Jej wykorzystywanie wiąże się jednak z niepewnością naukową w odniesieniu do wpływu nanomateriałów na zdrowie ludzkie i środowisko. Komunikat Komisji Europejskiej „Aspekty regulacyjne nanomateriałów” stanowi, iż w sytuacjach, w których nie jest znana pełna skala zagrożeń, ale obawy są na tyle duże, że środki zarządzania ryzykiem uznaje się za nieodzowne (tak jak ma to miejsce aktualnie odnośnie do nanomateriałów), środki te muszą bazować na zasadzie ostrożności. Środki stosowane w oparciu o zasadę ostrożności powinny być proporcjonalne do niezbędnego poziomu ochrony w celu zapewnienia bezpieczeństwa stosowania nanotechnologii i niestwarzania ograniczeń w rozwoju tej innowacyjnej technologii.

Słowa kluczowe: nanotechnologia, zasada ostrożności, bezpieczeństwo