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INTERNATIONAL STANDARDS OF LEGISLATIVE REGULATION OF NANOTECHNOLOGIES: LEGAL ASPECT

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Анотація. Інтенсивний розвиток нанотехнологій у сучасному світі зумовлений можливістю отримання значних ефектів та результатів у довгостроковій перспективі без надзвичайних витрат природних ресурсів та великого потенціалу впливу на економічну систему суспільства. Активізація розробки та реалізації державної політики прискореної наноіндустріалізації економіки в багатьох країнах на основі широкомасштабного фінансування ініціатив, стратегій, різноманітних цільових програм створення національної наноіндустрії стала відображенням жорсткої конкуренції за першість у цій сфері на міжнародному рівні. рівень. Розвиток нанотехнологій створює передумови для зміцнення конкурентних позицій, забезпечення інноваційної модернізації та національної безпеки України, підвищення темпів економічного зростання. Станом на сьогодні в Україні поступово посилюється увага вчених до розвитку та поширення нанотехнологій, становлення наноіндустрії, формування та розширення світового ринку продукції, що виробляється в цій галузі. Тим не менш, правові аспекти становлення нанотехнологій в Україні, формування перспектив розвитку підходів до державного управління та функціонування особливої системи органів державної влади залишаються абсолютно недослідженими. Існують окремі наукові розробки О. Печерського, О. Синеокого, Я. Тринева. Це створює ситуацію, коли одна з найважливіших сфер розвитку сучасного світу виходить за межі законодавчого регулювання та державного контролю. Окрім відсутності належної теоретичної бази для розвитку наноіндустрії, зазначається, що в Україні немає спеціального закону в цій сфері. Враховуючи всю систему джерел вітчизняного права, законодавчим актом 2009 року «Концепція Державної цільової науково-технічної програми «Нанотехнології та наноматеріали» на 2010-2014 роки, затвердженою постановою Кабінету Міністрів України від 2 квітня, 2009 р. № 331-с. залишається прийнятим і чинним.

У цій науковій статті автори аналізують світові тенденції розвитку нанотехнологій, їх законодавче закріплення та державне регулювання, окреслюють основні недоліки вітчизняної нормативно-правової бази та визначають перспективи та вектори розвитку галузі.

Ключові слова: державне управління, законодавство у сфері нанотехнологій, нанотехнології, наноматеріали, світові стандарти.

Annotation. Intensive development of nanotechnologies in the modern world is due to the possibility of obtaining significant effects and results in the long run without the extraordinary cost of natural resources and the great potential for impact on the economic system of society. Intensification of development and implementation of the state policy of accelerated nanoindustrialization of economy in many countries based on large-scale financing of initiatives, strategies, various target programs of creation of the national nanoindustry became reflection of fierce competition for supremacy in this sphere at the international level. The development of nanotechnologies creates preconditions for strengthening competitive positions, ensuring innovative modernization and national security of Ukraine, increasing the rate of economic growth. As of today, the attention of scientists to the development and dissemination of nanotechnology, the formation of the nanoindustry, the formation and expansion of the world market for products manufactured in this field is gradually increasing in Ukraine. Nevertheless, the legal aspects of the formation of nanotechnology in Ukraine, the formation of prospects for the development of approaches to public administration and the functioning of a special system of public authorities remain completely unexplored. There are isolated scientific developments of O. Pecherskyi, O. Synieokyi, Ya. Tryneva. This creates a situation when one of the most important areas of development of the modern world is outside the scope of legislative regulation and state control. In addition to the lack of a proper theoretical basis for the development of nanoindustries, it is noted that there is no special law in this area in Ukraine. Taking into account the whole system of sources of domestic law, the legislative act of 2009 “The Concept of the State Targeted Scientific and Technical Program “Nanotechnologies and Nanomaterials” for 2010-2014, approved by the Cabinet of Ministers of Ukraine dated April 2, 2009 № 331-p. remains adopted and valid.

In this scientific article, the authors analyse global trends in nanotechnology, their legislative consolidation and government regulation, outline the main shortcomings of the domestic regulatory framework and identify prospects and vectors for the development of the field.

Keywords: public administration, legislation in the field of nanotechnologies, nanotechnologies, nanomaterials, world standards.

Introduction

The development of nanotechnology is based on the integration of a number of disciplines: chemistry, physics, mechanics, biology, electronics, materials science, etc. In modern society, nanotechnology is changing the model of functioning of all sectors of the economy and social life, as well as forming new directions for the development of the economic environment and markets. Some researchers argue that nanotechnology is not a separate branch of the world economy, but is intended to modernize the existing boundaries of the world economy and reform sectors of the economy. For the first time, a wide-ranging discussion among various representatives of science, politics and business on this topic took place at the US National Science Foundation in 2000. Theme of the event: “Social significance of nanoscience and nanotechnology”. During the discussion it was concluded that nanotechnology is interdisciplinary in nature and provides for the possibility of integration and combination of natural sciences such as biology, chemistry, physics and humanities (economics, law, sociology, psychology, ethics).

The field of nanotechnology development is the most relevant in the modern world. According to official data, the total amount of funding (public investment) in the nanoindustry in the United States last year was around \$ 1.5 billion. In total, over the years of development in this area, the United States has

invested \$ 29 billion. Japan annually invests \$ 0.9 billion in the development of nanotechnology since 2001. Germany allocates € 0.5 billion annually from the state budget. Patenting in the field of nanotechnology, in order to protect intellectual property rights, is enormous. Thus, China has more than 65 thousand patents, the United States – 28 thousand patents, South Korea – 17, Japan – 10.

The first scientific research on the prospects of nanotechnology research was made by the American scientist R. Feynman in 1959, whose research was made at the molecular level. However, the first official mention of the term “nanotechnology” is found in the works of Japanese physicist N. Taniguchi. Thus, in 1974 he used this term at a conference of the Japanese Society for Precision Engineering, denoting the phenomenon under which it was offered to understand the production technology using which the ultra-thin size of about 1 nanometer or 1 billionth of a meter is obtained. The measurement in the size of a “nanometer” was the basis for the name of this area.

Results

As an independent field of science, nanotechnology began to develop in the early 1980s by the American researcher K. Drexler in the laboratory of artificial intelligence, who first published a book based on his dissertation research “Nanosystems. Molecular engineering, production and calculation”.

Over the years, more and more attention has been paid to nanotechnology. World leaders in the development of the industry have adopted official documents that consolidate the understanding of the category of “nanotechnology” (Table 1 shows the most famous documents).

Table 1

The content of the category “nanotechnology” in accordance with the provisions of official documents of general international importance.

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| 1. | US National Nanotechnology Initiative (2001) The content of nanotechnology includes work at the molecular level to create larger structures within a fundamentally new molecular organization. Nanotechnologies are related to materials and systems, the components and structures of which demonstrate new, modernized and improved chemical, physical, biological characteristics [1]. |
| 2. | The second plan of general importance in the development of science and technology in Japan (2001-2005) Nanotechnology is understood as an interdisciplinary branch of science and technology that includes information technology, life and environmental science, materials science, etc. Nanotechnology exists for the actual control of atoms and molecules on a large scale – nanometers, which makes it possible to distinguish new functions and new materials that are manifested at the level of nanometers. |
| 3. | Report of the Royal Academy of Engineering of Great Britain (2004) Nanotechnology involves the study of objects and phenomena at the level of atoms, molecules and the macromolecular level, the characteristics of which differ significantly from the properties of their macro-analogues. The possibility of design, production, application of structures, systems and devices, the characteristics of which are determined by their shape and size at the nanoscale [2]. |
| 4. | International Organization for Standardization Work Plan (2007) Nanotechnology involves an understanding of the management of matter and processes on a nanoscale, where phenomena associated with extremely small sizes usually open up new possibilities for practical use. Nanotechnology involves the study of the characteristics of materials that appear on the nanoscale and different from the properties of individual atoms, molecules and bulk substances, in order to create improved materials, systems, devices that are based on these new properties. |
| 5. | Seventh EU Framework Program (2007-2013) Nanotechnology as a field involves gaining new knowledge about phenomena whose properties depend on size and interface; management of material properties at the nanoscale to obtain new opportunities for their practical application and industrial development; nanomotors; machines and |

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| | systems; methods and tools for description and manipulation at the nanoscale; integration of technologies at the nanoscale; research of new concepts and approaches for practical application in various fields, including integration and convergence with new technologies [3]. |
| 6. | Patent information of the European Patent Office (2011) Nanotechnology means an object whose controlled geometric size of at least one of the functional components in one or more dimensions does not exceed 100 nanometers, while maintaining their level of physical, chemical and biological effects. Nanotechnologies are also related to the production and methods of controlled analysis, manipulation, processing, production or measurement with an accuracy of less than 100 nanometers [4]. |

Source: created by the authors.

Analysing the provisions listed in Table 1, we note that in the process of implementing nanotechnology priorities there are new problems for Europe related to legal, social, ethical and other aspects of this area of activity. Therefore, having examined EU legislation to determine the suitability of existing rules for the potential risks of nanomaterials, the European Commission found that the term “nanomaterials” is not specifically mentioned in any EU legislation [5]. In its resolution on the legal aspects of nanomaterials, the European Parliament called, inter alia, for the introduction of a scientific definition of nanomaterials in EU legislation [6; 7].

In the process of presenting the study “Principles of definitions of nanomaterials for regulatory purposes”, the representatives of the Joint Research Centre of the European Commission concluded that the nanomaterial is a natural, manufactured and related (by-product) material which contains particles (in the free state, in aggregate or agglomerate), at least 50% of which (in numerical size distribution) have one or more external dimensions in the range from 1 nm to 100 nm. In some cases, when it is justified by considerations of environmental protection, health and safety, competitiveness, the limit of 50% set for the size distribution may be replaced by an interval of 1 to 50% [7].

The definition of nanomaterials should take into account the proportion of nanomaterials, as well as fully comply with current EU legislation and be consistent with other regulatory approaches and global trends.

An important place in the development of public administration and the construction of the legal framework for regulating this area is occupied by the EU program – “Horizon 2020”. The aim of the program is to increase the overall competitiveness and sustainable development of Europe. In the issue of increasing the competitiveness of economies, the leading place is determined by nanomaterials [7].

Analysing the situation in Ukraine, we fully agree with the position of O. B. Salikhov, who notes that one of the prerequisites for the future competitiveness of Ukrainian industry, and consequently the development of the economy and social welfare is the development of domestic scientific and technological potential in the field of nanotechnology and its comprehensive use. At the same time, state policy in the field of nanotechnology will help solve not only national but also global problems related to limited access to environmentally friendly energy, food and clean water; an effective health care system; climate change and environmental protection.

The development of nanotechnology is the subject of research by many scientific institutions in Ukraine, in particular:

- R. E. Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology, National Academy of Sciences of Ukraine;
- Institute of Applied Problems of Physics and Biophysics, National Academy of Sciences of Ukraine;
- V. Bakul Institute for Superhard Materials;
- Department of Nuclear Physics and Energy of the Educational and Scientific Centre “Physical and Chemical Materials Science” of Taras Shevchenko National University of Kyiv and the National Academy of Sciences of Ukraine;

- Verkin Institute for Low Temperature Physics and Engineering;
- Chuiko Institute of Surface Chemistry of NAS of Ukraine, etc. [7].

However, even given the interest of the research community in the study of nanomaterials as a chemical, physical, biological phenomenon, Ukraine, represented by government agencies, ignores the need and relevance of effective government regulation in this area. As of today, there is only one normative-legal one in the domestic legislation that is directly related to nanotechnologies – the Concept of the State Targeted Scientific and Technical Program “Nanotechnologies and Nanomaterials” for 2010-2014, approved by the Cabinet of Ministers of Ukraine dated April 2, 2009 № 331-p. This Concept officially defines that nanotechnologies are interdisciplinary technologies that are designed for objects smaller than one micron in size and allow research, manipulation and processing of substances in the size range from 0.1 to 100 nanometers (1 nanometer – one billionth meters). The expediency of using nanomaterials, which are manufactured using nanotechnology, is due to the fact that in such sizes of objects the substance has properties that are not inherent in its macroquantity [8].

In the next ten years, the development of nanotechnology and the production of new nanomaterials will be one of the main drivers of stimulating significant changes in industries such as mechanical engineering, optoelectronics, microelectronics, automotive industry, as well as agriculture, medicine and ecology [8].

In 2014, drafts of the Law of Ukraine “On High (Progressive) Technologies” and the Law of Ukraine “On Nanotechnologies and Nanomaterials” were prepared. However, the situation on the territory of the ATO (Anti-Terrorist Operation) in Ukraine actually annulled the legislative initiative in this area and slowed down the prospects for the development of legal relations. This trend is not entirely clear, because the Concept of the State Targeted Scientific and Technical Program “Nanotechnologies and Nanomaterials” for 2010-2014 focuses in 2009 on the fact that the main problem to be solved is the recognition of the strategic importance of development and implementation of nanotechnologies and nanomaterials at the state level and overcoming Ukraine’s lag in scientific and methodological support for coordination of research and development, formation and development of technological base, meeting the need for specially trained personnel providing appropriate financial support. In addition, we note that the Concept itself has a functional focus for 2010-2014. We believe that today it cannot be assessed as a document that can fully ensure the interests of public administration in the field of nanotechnology, even given the time limits of its action [8].

Investigating the legislative basis for the regulation of nanotechnology in Ukraine O. V. Pechersky in his work “Problems of legal regulation of relations in the field of nanotechnology in Ukraine” argues that the legislative base for the development of nanotechnologies in Ukraine includes such legislative acts as the Law of Ukraine “On Scientific and Scientific-Technical Activity” and the Law of Ukraine “On Priority Areas of Innovative Activity in Ukraine”. We note that these normative legal acts do not have a direct reference to the categories of “nanotechnology”, “nanomaterials”, “nanoindustry” [9]. All provisions of these laws are declarative and conceptual in nature and do not create an effective legal framework for regulating this area and the emerging legal relationship. By the way, the researcher O. V. Pechersky makes a reasonable comparison made by Prof. Ya. O. Trynova about the fact that the current situation with the development of nanotechnology resembles the use of the positive potential of radiation in the early twentieth century [10]. Agreeing with the above positions O. A. Tkachova in her dissertation “Economic assessment of prospects for the development of nanotechnology” that in Ukraine the legal basis for the development of nanotechnology and government regulation rejected the positive effect of nanotechnology and moved the field to a “dead” zone [11].

Conclusions

Given all the above, we note that today the authorities in Ukraine can no longer ignore global trends and importance for the economy, state competitiveness and improving the socio-economic well-being of the population, the need for state regulation of nanotechnology. Since the National Nanotechnology

Initiative was launched in the United States in 2000 and a real nanotechnology “boom” has begun, more than \$ 80 billion public and private investments have been made in the global nanoindustry. Several thousand types of nanoproducts have been created in the United States, and dozens of development strategies and programs have been adopted at both the national and international levels. Ukraine can also follow a path that will ensure its stability and significance on the world stage.

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