Legal issues of the environmental safety regulation in the sphere of nanotechnology in Russian Federation

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Abstract. Nowadays one of the principal innovative spheres in Russia is considered to be a rapid development of nanotechnology and nanomaterials and implementation its products into almost all fields of social and industrial life. Nevertheless, despite the pointed advantages an appearance of nano products has set not only a positive example of the scientific progress development and dynamics, but also a potential threat of possible risks for the environment and people’s health in the case of its massive use when there is a lack of research about its impacts. In Russian Federation the problem of nanosafety regulation is extremely actual. A number of international documents have noted a lack of legal regulation in the sphere of nanotechnologies in Russian Federation. Thus, according to the strategic EU program, it’s mentioned that in 2009 on an annual meeting of OECD Tour de Table Meeting in Paris (November, 2007) Russia took responsibility to develop a long term program of nanoindustry development by 2015 (Nanotechnology Action Plan for Russia-2015). The key role should be dedicated to the nanosafety aspects and potential risk assessment of nanomaterials for environment and humans’ health. Unfortunately, until now Russia did not provide this document for discussion at the international level by the partners of nanoconsortium. Indeed, from 2007 until nowadays in Russian Federation there are no a single federal act of legislation (federal’nyi zakon), establishing the state foundations of regulation of nanosafety. The only one Federal Legal Act in the described sphere is the Federalniy Zakon from 19 July 2007 «About the Russian corporation of nanotechnologies», which has established the principles of organization, activites, functions and termination of Rosnanotech. However, there are no articles dedicated to the environmental safety provision in regards of nano products applications. Also there is no complex federal act consolidating legal status of action in the field of development and application of nanoproducts, inspite of fact, that these relationships have a significant financial segment. Thus, according to the Federal Act from December 13, 2010 «About federal budget for 2011 year and the period of 2012 and 2013 years” the expenses for realisation of program «The infrastructure development of nano industry in Russian Federation for 2008-2011» were 250 milliard of Russian rubbles. The profound analyses of the current legal systems has demonstrated that nowadays the main legal regulation in nano sphere consist of some range of frame documents (accentuated by the author). Thereby, one of the most dynamic and developed field of innovative activities in Russian Federation – nanotechnology - is left out of environmental and legal area of protection and that is might lead to the raising level of ecological risks at the stage of creation and application nano products to the environment and humans’ health. During the analyses of annual norms of the Report OECD « Nano technologies: the Environment, health and safety» the conclusion is following –
Russia has an extremely low degree of conceptual realization of the program in the sphere of forming the policy connected with nanotechnology and its impact on the environment and also a lack of implementations of norms into the national legal systems in terms of the assessment criteria of nano safety EHS (Environmental, Health and Safety) and ELSI (Ethical, Legal and Social Issues). To the great regret, there is no independent and precise legal act about the ways to create and apply nano products with the certain definitions and principles and, more importantly, with the level of legal obligations and responsibility. This gap is not possible to fill by just altering and editing the existed legal acts due to the lack of the state Russian regulation. Thus, one of the most dynamic fields of innovative activities – nano technologies – is practically out of the regulation. It might lead to an increase of ecological risks’ level in the process of creation and application of nano products to the environment and health of people. As a result, implementation of international legal recommendations in the field of safety regulation of nanotechnology is quite crucial for Russian Federation.

Like any other state, Russian Federation has its own legal system. It consists of accurately consolidated hierarchy based upon a legal validity of documents. Due to that in the theory of Russian Law, there are two principal kinds of legal documents: legislative acts and subordinate acts. The foundation of legislative acts is the Constitution of Russian Federation, dated from 12 December, 1993. It regulates common provisions of all specific areas of law: it also includes the environmental law, where the main norms for guaranteeing of nanotechnology nanomaterial’s safety had been set. The Constitution of Russian Federation has got the highest legal power and not a single legal act can violate its clauses. The key provision of the Constitution, which regulates issues about nanotechnology safety, is article 42. It vests a right of every citizen for a favorable environment, reliable information about its state and compensation for a harm, that have been caused to life, health and property of a citizen by any kinds of unsafe activities.

For more comprehensive and detailed implementation of Constitution’s provisions in Russian Federation there is a legal possibility of creating federal constitutional acts and federal acts which will formulate a principal mechanism of state politics realization in the economic, social, political and other spheres. Particularly, for the basic regulation in the sphere of environmental safety realization federal acts are issued – The Federal Act “About Environmental safety”, The Federal Act “About Atomic Energy”, The Federal Act “About Waste”, The Federal Act “About Environmental Impact Assessment”, The Federal Act “About Regulation of Genetically Engineered Activities” and etc.

The Constitution of Russian Federation, the federal constitutional acts and federal acts is the sphere of the regulation, which is the principal because it forms the basic postulates of any activity in Russian Federation. The foundation of subordinate acts of the ordinances of the President of Russian Federation and decrees of the Government of Russian Federation, which are being issued following the federal legislation and also supervision and audit for the observance of federal acts. A separate niche in the system of subordinate regulation occupy official acts of suitable departments, for instance, by the Department of public health and social development, its divisions, agents and services. An essential place in the system of official acts of departments in the sphere of nanosafety has the Federal service on customers’ rights protection and human well-being surveillance (in Russian - Rospotrebnadzor), led by the Main Sanitary Inspector of
Russian Federation. Precisely that organization guaranties the main regulation of relations in the sphere of development and application of nanotechnologies [1].

In Russian Federation it is compulsory to register new legal acts, connected with civil, political, socio-economic and ecological rights and responsibilities of citizens and also their implementation guaranties, secured in the Constitution of Russian Federation and other subordinate acts. It is considered to be a supplementary guaranty of fulfillment those kinds of acts. It is also legal evidence that these acts don’t contradict Constitution of Russian Federation.

Acts, issued by Rospotrebnadzor don’t have to be obligatory registered in the Ministry of Justice of Russian Federation and are approved by the Main Sanitary Inspector of Russian Federation. In the sphere of relations, which regulate the principles of nanosafety in Russian Federation Rospotrebnadzor issues resolutions, methodical instructions and letters. Traditionally, these acts belong to the system of normative-technical documents, which have a subsidiary and voluntary characteristic.

It was a little excursus into the theory of regulation in Russian Federation, conducted in order to orientate in the system of legal regulation of relations, connected with specifics of guaranteeing nanotechnology’s environmental safety in Russian Federation.

A rise of considerable amount of subsidiary documents has become a first step on a way of politico-legislative creation in the sphere of development and implementation nanotechnologies.

The foundation of the process has been approved by the President of Russian Federation The basics of politics in Russian Federation in the area of science development and technologies for the period until 2010 and further prospect from 30 March 2002. According to that, the environmental priorities while developing and implementing of nanotechnologies should be the main tasks of Russian scientific policy. It is connected with the requirements of environmental legislation in Russian Federation in the sphere of realization of any kinds of industrial activity. Hence, the President of Russian Federation has announced that a development of legal acts in the sphere of safety provision ought to become a primary target. Furthermore, a Program for coordination of activity in the sphere of nanotechnologies and nanomaterials in Russian Federation has been appeared, approved by the Direction of the Government of Russian Federation July 25, 2006 has been announced that one of the main tasks was an increase of a level for environmental safety and an improvement of habitat with a use of nanosystematic technology for the environmental monitoring.

An annual Message from the President V.V. Putin to the Federal Committee of Russian Federation from April 26, 2007 declared and first revealed an importance of regulation in the sphere of nanotechnology. On the basis of that document it had been offered to develop a complex of necessary documents. A rapid fulfillment of suitable activities in the sphere of nanoindustry development is one of strategic national priorities of Russian Federation. It would have been logical to suppose that the mentioned initiative could find its objective expression in activities of appropriate authorities, which were willing to prepare a draft of legislative acts about a procedure of activities in nanotechnologies areas. Those authorities could develop a basis for preparation and approval of subordinate regulatory acts.

Up until now in Russian Federation there is no federal legislative act about procedure of nanotechnologies’ development and application, which could have contained all necessary terminology; the major principles and kinds of activities in the sphere of nanotechnology and also a liability for violation of norms and requirements in the field of environmental safety. In
addition, there are even no technical regulations while a practical activity in the current field has been actively in progress [2].

In the theory of Russian law this situation is called “legal gap”, which could not have been resolved by altering already existed regulations because in Russian Federation there are no suitable acts with allied legal characteristic and an object of legal regulation.

It is worth noting highlighting, that in the significant majorities of industrial areas of Russian Federation such acts exist. For instance, the federal acts “About Atomic Energy”, “About Waste”, “About Regulation of Genetically Engineered Activities”, “About Radioactive Waste”, “About Destruction of Chemical Weapon” and so on. According to the mentioned acts a set of subordinate regularity acts have been issued, which provide a mechanism of their implementation (decrees, resolutions, directions and etc.).

Among the main subsidiary acts in the sphere of nanoregulation in Russian Federation two programs have to be mentioned particular – The Program of nanoindustry’s development in Russian Federation until 2015 (January 17, 2008) and The Strategy of nanoindustry’s development in Russian Federation (April 24, 2007). These documents regulate an activity for analysis potential threats related to a development and technical provision of nanoindustry. A special attention had been drawn to the following areas:

- A system of technical regulations;
- Guarantee of nanotechnologies’ safety and its products;
- An insurance of risks in the sphere of nanotechnologies.

Nowadays the mentioned area of relations is on a stage of dynamic development.

A system of nanosafety regulation can be divided into two principle categories: 1) legislative sphere; 2) subordinate (by-law) sphere [3].

**I. Legislative nanosafety regulation in Russian Federation.**

Nevertheless, there are federal acts which, in any event, regulate a field of nanoactivity. One if the example is The Federal Act from July 19, 2007 “About Russian nanotechnologies’ corporation” (Rosnanotech) – the only act in the mentioned sphere. It has been set, that Rosnanotech is the main specially authorized body in the established area and acts towards assistance of nanotechnologies politics and nanoindustry realization [4]. Nevertheless, in the text of this act there is a lack of regulation about guaranteeing of nanosafety; only organizational and financial support of nanoprojects has been mentioned. In addition, the article 3 of this law clarifies that Rosnanotech has the principle authority in the sphere of state politics implementation of prospective nanotechnologies and nanoindustry. Among aims, tasks and functions of Rosnanotech there is no mentioning about a participation in the nanosafety regulation, but the main subject of its activities is an organizational and financial support of nanoprojects [5].

Besides the above-listed law, in the sphere of nanotechnologies nowadays in Russian Federation there are legislative acts which have only an indirect connection to provide nanosafety, for instance:

- The Federal Act from 30 March 1999 N 52-ФЗ “About Sanitarian and Epidemiological Well-being of Inhabitants”;
- The Federal Act from 26 June 2008 N 102-ФЗ “About Proving of Measurements Unity”;
The Federal Act from 18 July 1999 N 183-ФЗ “About an Export Control”; The Federal Act from 27 December 2002 N 184-ФЗ “About Technical Regulation”; The Federal Act from 10 January 2002 N 7-ФЗ “About Environmental Protection”; The Federal Act from 21 November 2011 N 323-ФЗ “About Health Protection in Russian Federation” and etc [6].

Due to that, it became evident that these acts have only a common connection to provide nanosafety in Russian Federation. Thus, relations in the sphere of nanotechnology have no independent legislative regulation.

II. Subordinate (by-law) nanosafety regulation in Russian Federation.

The existed legal vacuum has been actively filled with a lot of subordinate acts issued by suitable departments. Thus, according to the Order of Public Health Ministry of Russian Federation (August 5, 2009) a Working Group has been created in order to organise a development of subordinate and methodical documents covering questions of nanomaterials’ and nanotechnologies’ safety and methods of Nanosafety Risk Assessment.

The precise due dates for issuing and approving three categories of documents have been set. The covered areas were:

- medico-sanitary provision of nanoindustry safety;
- development of requirements applied to products of nanoindustry, its processes designing, production and its market turnover and utilisation;
- priorities and issue of recommendations to provide an environmental protection and health of employees engaged in nano technological factories and also inhabitants of areas close to those industries.

It is stated that the Working Group under the Public Health Ministry and Social Development in Russian Federation must prepare suggestions for the principle federal legislation and subsidiary acts in the nanosafety regulation. Unfortunately, in the context of this Order there are no exact dates and up until now not all mentioned categories of documents have been prepared.

Currently in Russian Federation all acts about nanosafety are being regulated by the means of normative technical acts, authorized in the form of resolutions, methodical instructions (in Russian - МУ) and methodical recommendations (in Russian - МР), approved by The Main Sanitarian Inspector of Russian Federation.

The main document in the field of nanosafety is The Concept of toxicological researches, methodology of risk assessment, methods of an identification of quantitative detection of nanomaterials (October 31, 2007). It is very important that the document has been registered by the Ministry of Justice of Russian Federation. As it was stated before, it indicates of high importance and highlights that this act is connected with the constitutional rights of citizens in the sphere of nanosafety and its guaranteeing.
Due to the fact that it is one of the most influences and essential documents in the field of nanosafety, it is worth listing its key parts:

✓ The characteristics new properties and behavior of nanomaterials in the environment and biological objects;
✓ The particularity of Risk Assessment on the stage of manufacturing and use of nanomaterials; the existed methodology of risk assessment nowadays cannot be completely applied to nanomaterials because it is based upon a full toxicological assessment of a specific substance or its combination and detection of “dose-effect”. In this regards it is necessary for every individual nanomaterial to be comprehensibly studied in the toxicological aspect with an identification of allowed twenty-four-hour dose or conditionally bearable (monthly) inflow. It is also necessary to create data resources for biosafety of nanomaterials. Until now those resources are not enough in Russian Federation.
✓ The analysis of data about safety of manufacturing and use of nanomaterials;
✓ The procedure for supervision and toxicological research of nanomaterials. A development and maintaining of nanoparticles and nanomaterials register (in accordance with the Federal Register of potential hazardous chemical and biological substances) has to be fulfilled by Rospotrebnadzor.

The next key acts issued by Rospotrebnadzor in the field of nanosafety is The Assessment on nanomaterials’ safety (October 12, 2007), published in the form of methodical recommendations. The mentioned document establishes an Algorithm of identification of high level of a potential danger for nanomaterials towards a health of human being.

There are three levels of potential danger of nanomaterials:

1. Low level of potential danger (low priority). A suitable nanomaterial has to be assessed according existed indicators of its components in traditional form. An extra research of specific biological effect of nanomaterials is not needed.
2. Medium level of potential danger (medium priority). A suitable common toxicological assessment is needed and when it is necessary, some kinds of extra researches have to be conducted.
3. High level of potential danger (high priority). A comprehensive complex of researches have to be conducted on the subject of nano materials’ penetration through biological membranes and tissues of organisms plus a common toxicological assessment which includes studies contained a test of genotoxicity.

The Assessment of Nanomaterials’ Safety consists of a list of methods for studying the main physical, chemical and molecular-biological characteristics of nanomaterials and also approximate schemes for organizing of experiments to conduct a research about general toxic effects of nanomaterials.

For the purpose of The Assessment of Nanomaterials’ Safety it recommendable to apply The Procedure of Medico-Biological Assessment of nanomaterials’ impact engaging laboratory animals according to their morphological attributes and metabolic parameters (October 17, 2011).
Except all above-listed documents nowadays in Russian Federation there more than 30 approved methodical acts of Rospotrebnadzor in the sphere of nanosafety regulation, which have a departmental and not compulsory power. The vast majority of those acts have been issued within a timeframe of 2010-2011.

It is worth mentioning that there is a Policy of nanotechnologies’ Classification and its products according to level of potential harm (December, 17, 2010). Thereby, in Russian Federation the regulation of nanosafety has been fulfilled most purely on a subordinate (by-law) - “lowest” departmental level. It proves that the essential statutory provisions in the field of nanoregulation don’t have an imperative legislative binding. Currently this is one of the key challenges in Russian Federation in the sphere of nanorelations’ regulations. A situation might be resolved by a issuing a separate federal legislative act which will become a “catalyst” of other sub-laws creation.

References:

[1] See full source: State Internet portal of Russian Federal service on customers’ rights protection and human well-being surveillance, http://rospotrebnadzor.ru/news [access 15/11/12].

[2] See full source: State Internet portal «Nanotechnologies and nanomaterials», http://www.portalnano.ru/toplevel/?id=2 [access 15/11/12].

[3] See full: Belokrylova E. A. The specifics of formulating a state politics in Russian Federation in the sphere of legal provision of environmental safety on the stage of nanotechnologies development and application. Law&Policy. №5. 2011. 10 p.

[4] See full source: Ekaterina A. Belokrylova. Some legal problems of environmental safety of nanotechnology and nanomaterials in the Russian Federation, Vestnik Udmurtskogo Universiteta, N4, 2012 http://vestnik.udsu.ru/2012/2012-024/vuu_12_024_14.pdf [access 15/11/12].

[5] See full source: Ekaterina A. Belokrylova. The Legal Problems of Nanotechnology Environmental Safety Provision in the Russian Federation: The Foreign Country’s Experience, Nanotechnology Law&Business, http://www.nanolabweb.com/index.cfm/action/main.default.viewArticle/articleID/370/CFID/5073669/CFTOKEN/44254839/index.html [access 15/11/12].

[6] See Full source: Russian Legal Internet portal Garant, http://www.garant.ru/ [access 15/11/12].