

## Quality and Safety of Products and Services as Constituents of the Right to Health Protection in the Russian Federation

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**Abstract:** The present article is concerned with the problem of legal support of quality and safety of products and services in the Russian Federation. The authors believe that the creation of a specialized system of legal regulation, which is able to provide the quality and safety of products and services, is the basis for the entire legal mechanism of ensuring the right to health protection. The analysis focuses on the essential characteristics of fundamental concepts: products, service, quality, safety. For that purpose, we have studied some normative documents that contain the definitions of these concepts. According to the authors, it is the imperfections of these normative definitions that do not allow building a clear system of criteria of quality and safety of products and services, which, in turn, does not contribute to the implementation of the constitutional right to health protection.

**Key words:** Right to health protection • Product quality • Quality of services • Safety of products (goods) • Criteria of quality and safety • Technical regulation • Standards • Technical regulations

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### INTRODUCTION

In Russia, the right to health protection is enshrined in the law at the constitutional level, (article 41 of the Constitution of the Russian Federation). In terms of its practical implementation, this is faced with several challenges, one of which is the quality and safety of produced and consumed products and services. This problem, in addition to its direct relevance to health of citizens, has a pronounced legal significance because legal support of safety and quality of any products, including made-for-sale items, i.e. goods, works, services is the basis for the whole legal mechanism of ensuring the right to health. Thus, the Russian legislator faces a task of creating a specialized system of legal regulation, which is able to provide the quality and safety of goods and works (services) [1].

In the present context, it is not so simple to do this: there are difficulties associated with the emergence of new groups of products, the necessity of their classification, the emergence of goods, which cannot be attributed to items directly satisfying human needs, etc. The same can

be said about services: in recent years their number and broad variety has significantly increased, which requires consideration of the important features of many of them in legal terms. Moreover there are some conceptual discrepancies and incompleteness in the existing legislation [2].

Hence the need for scientific support of the process of forming a legal system of ensuring quality and safety of products and services being in the trade turnover significantly increases. The role of legal science should be in a deep understanding of the subject of legal regulation, development of theoretical structures, ensuring the unity of conceptual tools. Therefore identifying the essential characteristics of categories underlying a legal mechanism which guarantees quality and safety of products and services is of paramount importance for creating the one [3-25].

Being ahead of time we should note that today's market which as it does exists in almost all spheres of relations with economic background (information market, market for land, software market, labor market and others), type of goods, in our opinion, could serve as the most

universal category, because it could include the greatest number of objects of legal regulation (including objects without tangible physical form) and could be the starting point to form a mechanism of ensuring quality and safety of these objects. In addition, those or other works, as well as services in the present context could be a product after all since they, as made-for-sale items, are also offered and sold in the market. We can justifiably speak of the existence of various markets of educational, medical and other services. And these kinds of markets are characterized by all necessary attributes: demand, supply, market conditions, marketing vehicle, etc. However, the Russian legislation has firmly associated the notion of product with the concept of "item of property" (section 454 of the Civil Code of the Russian Federation, GOST P 51303-99). Therefore today in the Russian legal field it is impossible to combine manufactured products and rendered services (works) within the concept of "product".

At the present time the Russian legislation singles out the following items about which we can talk in terms of quality and safety. These are products, goods, food products, alimentary raw materials, services, medical assistance and many others. Taking into account the fact that some of them are related to items of material production (i.e. they are the result of activities that have a tangible physical form), while the others are definite steps in someone else's interests which do not imply the materialized result it seems quite logical to use the concept of "product" as a unifying concept for the items of material production and for nonmaterial items – the concept of "service" [26-40].

Federal Law of December 27, 2002 No.184-FZ "On technical regulation" (section 2) gives the following normative definition of "product". It is the result of activities presented in tangible physical form and intended for further use in economic and other purposes.

With regard to the normative definition of "service", the Russian legislation contains definitions that are functionally designed for specific areas: medical service, public and municipal service, etc. Perhaps the exception is the definition contained in the Federal Law of July 24, 2009 No. 212-FZ "On insurance contributions to Pension Fund of the Russian Federation, Social Insurance Fund of the Russian Federation, Federal Compulsory Medical Insurance Fund", which could be regarded as a general definition. Section 2 of this Federal Law defines a service as "the activity, the results of which have no monetary value, which is marketed and consumed in the process of implementation of this activity".

The above mentioned and other definitions allow us to select the characteristics of a service as a legal phenomenon, among which the main ones will be the following:

- They (services) are actions (activities);
- These are actions taken in favour of the customer (consumer) of a service;
- For proper performance of a service the availability of result according to general principles is optional.

Despite the existing difference of opinions in the Russian legal literature over the third above mentioned characteristic on the whole we can say that the "divide" between "products" and "service" is traced through all main elements of these concepts.

The existing difference of the above concepts makes it logical to assume that the criteria of quality and safety will also differ from each other. Moreover, the very concepts of "quality" and "safety" are often used interchangeably (qualitative means safe; safe means qualitative). In fact they are far from being equal and the quality of products (services) and their safety have not always had the same legal status in Russia as objects of legal regulation.

Despite the obvious importance of product safety for life and health of citizens, for a long time the concept of "safety" in relation to the products has not been independent. It was part of a comprehensive concept of "quality of products (goods) and this incorporation was very necessary being taken for granted. In Russia until the beginning of the 90-s of XX century product safety, as such, had not been the object of legal regulation in any normative act. This regulation was carried out through the establishment of national standards, which only covered consumer product requirements, i.e. requirements that characterize primarily its quality. The state certification of products introduced in the Soviet period aimed at improving the quality of products. There was established administrative and criminal liability for the production of poor quality products or the products not meeting the standards or technical specifications.

Please note that the most important products in the context of ensuring the right to health protection, such as medicines and food products did not go through the procedures of the state certification of quality. However, this only indicates that, in principle, the state prohibited any deviations from the requirements of accepted standards for quality in the production of these products. Simply put, the manufacturer in this case could not

deviate from the requirements of standards even in the direction of quality improvement. In order to do this it was necessary to change the requirements of standards that could be performed only by relevant state authorities.

We think that the opinion of L.E. Chapkevich concerning the safety of manufactured products and their trade turnover is quite justified. The idea is that the safety of manufactured and imported products was presumed by the Soviet state.

With the beginning of market reforms the category of safety becomes independent. It was at this time in the Russian legislation when there appeared the term "safety of products (goods)".

Until putting the Federal Law "On technical regulation" into execution the criteria of quality and safety of products had had equal importance for the emergence of the administrative responsibility in case of violations. This cannot be said about the responsibility as required by the criminal law; this responsibility from July 01, 1993 has been imposed only for the production or sale of goods which do not meet safety requirements. This approach is followed in the current Russian Criminal Code.

The above-mentioned Federal Law "On technical regulation" fundamentally changed government priorities in ensuring the quality and safety of products. It transferred the emphasis of legal regulation in the direction of ensuring product safety. It is the safety requirements that are considered by this law as binding and, accordingly, they are subject to state control. As for the quality of products, we cannot say that they remained outside the scope of legal regulation, but most of qualitative characteristics, which had been the object of state regulation and control, are currently being settled at the manufacturer's sole discretion. The exception is, perhaps, medications and some food products.

In ensuring the quality and safety of products (services) the Russian legislator chose the way of developing technical regulations which are compulsorily to be followed and national standards of a voluntary nature. In this case the constitutional right to health protection is implemented by the mandatory requirements contained in technical regulations and aimed at ensuring the safety of life and health of citizens.

However, according to the Federal Law "On technical regulation" the above mentioned requirements are binding only for the category of "product". With the adoption of the Law the requirements to works and services began to be voluntary. In addition, technical regulations contain only minimum (emphasis added) essential requirements,

i.e. not allowing the possibilities of their reduction due to occurrence of real danger for life and health of citizens in such a case.

It is fair to say that following these requirements does not always exclude the possibility (emphasis added) of occurrence of such hazards under certain conditions (we are talking about the usage of products in certain climatic conditions; peculiarities of transportation, storage, etc).

We should also note that in fact, the mandatory requirements contained in technical regulations are not related to product quality. They are entirely focused on safety (part 1 of section 7 of the Federal Law "On technical regulation"). The only exceptions are the rules applicable to "prevention of actions misleading purchasers, including consumers" (paragraph 4, part 1, section 6 of the Federal Law "On technical regulation"), i.e. provisions aimed against the manufacture of counterfeit products.

The above said allows us to conclude that the implementation of the constitutional right to health protection in the sphere of production and products turnover cannot be realized only by the mandatory requirements of technical regulations to the full extent. And it is not even about the fact that today in Russia there have been adopted only several technical regulations for food products: milk and milk products, juices and juice products; butter and oil and fat products; tobacco products. And with the introduction of technical regulations of the Customs Union, the Russian technical regulations (in particular, on food production) were discontinued. But it is much more important that underestimating the indicators of production quality by the Russian legislator which manifested itself in the lack of legal regulation of its criteria directly affects the quality of life and health of Russian citizens.

Federal Law of December 27, 2002. No. 184-FZ "On technical regulation", which is the main in the sphere of technical regulation does not mention the concept of "quality" among the basic concepts. In addition to that, the norms of this Federal Law come into contradiction with the Constitution of the Russian Federation. They give the right to develop national standards (i.e. the documents establishing quality requirements) to any person (part 2 of section 16 of the Federal Law "On technical regulation"). It is to be recalled that item "p" of article 71 of the Constitution of the Russian Federation considers standards to be within the jurisdiction of the Russian Federation. Thus, the provisions of the Federal Law "On technical regulation" provide an opportunity for producers (and they are, first of all, party in interest) to

determine quality criteria for their products. Of course, in this situation manufacturers of the goods in the process of manufacture will be guided primarily by their own commercial interests who can be very far from the interests of the consumer.

Obviously, the solution to these problems is scope of activity for the Russian legislator, which should eliminate the existing contradictions and highlight key points in the legal regulation of questions of quality and safety of products and services taking into account the need for their harmonization [40-49].

Moreover, these problems are caused by the drawbacks of scientific and theoretical support of the process of creating the system of quality and safety of products and services. We spoke about this in the beginning of our paper.

First of all, it is connected with absence of a unified opinion on the content of such notions as "quality" and "safety" and, as a consequence, lack of clear fixed criteria of quality and safety in relation to specific types of products.

Part of the Russian legal scholars determines the product quality by means of the term "property". In particular, V.S. Belykh believes that the quality of products (works, services) is a set of technical, economic and other socially useful properties of products (works, services) arising at all stages of its life cycle and adopted in normative and technical documentation and stipulated by contracts. In the absence of such contracts stipulated by legislative acts; the quality of products is characterized by the ability to meet certain social needs with optimal costs per unit of its value".

There are scientists who determine the quality as the conformity of products' properties with the requirements of normative documents and agreements. For example, M.B. Emelyanova believes that "product quality" means the degree of conformity of product properties with the level of requirements established by standards, specifications or samples and in case of absence of the mentioned normative documents or in agreeing on higher or more detailed requirements with a supply contract.

The difference of doctrinal standpoints caused the lack of a uniform definition of "product quality" in the Russian legislation. Mostly, normative sources determine the quality of products through compliance with state standards, or as a set of consumer properties (characteristics) of products. For example, the Federal Law of April 12, 2010 No.61-FZ "On circulation of medicines" sees medicines' quality as "the conformity of the

medicinal product with the requirements of certified pharmacopeial description (a document approved by the authorized federal body of the executive power). It contains a list of the quality criteria of the medicinal product or in case of absence of such description there should be normative documentation or normative document". The Federal Law of January 2, 2000 No. 29-FZ "On quality and safety of food products" sees food products' quality as "a set of characteristics of food products which are capable to satisfy human needs in food under normal conditions of their use". As you can see, the last definition directly links the category of quality with satisfaction of social needs which, in our opinion, is quite justified, because the quality is always determined by the need for which the product has been created". Moreover, "the very existence of the category of quality of products (works, services) is due to the presence of various needs in society".

Thus, the lack of unity in views on the essential characteristics of the category of "quality" as among scientists and among legislators does not allow to properly formulate its normative criteria which, of course, is not conducive to the implementation of the Russian citizens' constitutional right to health protection in the sphere of production and products turnover.

As for the criteria of quality of services, their formation is one of the most complicated problems of lawmaking and law enforcement activity.

Attempts to apply approaches to defining product quality in the field of services often fail due to the earlier noted differences of these legal concepts. For legal formalization of "quality of service" the most complex circumstances are the following: creative character of services as a type of activity; direct consumer evaluation; using services often occurs at the moment of their rendering; considerable variation of individual consumer needs. Despite this in recent years the evaluation criteria of quality of services have repeatedly been the subject of research by Russian scientists.

However, there have been mostly developed the specific quality criteria of a particular type of services – informational, legal, medical etc. There have not been made any fundamental theoretical researches. Therefore, at the present moment there exists only one normative definition of the quality of services. We can find it in GOST 30335-95/ GOST P. 50646-94 in which the quality of services is the "the whole range of characteristics of services that determine their ability to satisfy stated or implied needs of consumers".

We should note that this definition actually repeats the definitions of Russian and international quality standards of product quality. Once again it confirms the previously expressed thought about the existing practice of mechanical transfer of approaches in determining the quality of products to determining the quality of services. Moreover, this tendency is typical not only for Russia.

The example of the above said idea may be a standard 15467-79 "Product quality control. Basic concepts. Terms and definitions" in which the product quality is "a set of properties of products determining its suitability to satisfy certain needs in accordance with their purpose" or international standard ISO 8402-86 in which "quality is a set of features and characteristics of products or services that give them the ability to meet conditioned or implied needs".

It is easy to notice that in the definition of GOST 30335-95 / GOST R 50646-94 and in the two following definitions the main (and the only) criterion of quality of services and products is their ability (suitability) to satisfy stated (conditioned) or implied needs. Moreover, in the international standard ISO 8402 products and service are combined in one definition which once again underlines the fact that the developers of these standards consider them as absolutely equivalent objects of legal regulation to which, accordingly we could apply the same evaluation quality criteria.

The last fact offers the greatest objections and, first of all, due to initial subjectivity of expectations of services' consumers. In our opinion, person's perception, individual sensations of a particular customer are too amorphous entities to become a full-fledged legal criterion of estimating the quality of provided services.

Thus, if in respect of product quality we can talk about some uncertainties in the normative provision of its criteria then in respect of the quality of services, in our opinion, the conceptual approach to defining its criteria through matching expectations (needs) of the consumer is wrong in itself.

As for the constituent of the right to health protection designated as product safety we can say that despite accepting mandatory technical regulations being focused upon safety clarity in defining its criteria has not become less. In our opinion, it is connected with the drawbacks of normative formulations of the very concept of "safety" which is applicable to products as a whole and to its various types.

If we analyze the meaning of the Federal Law of December 27, 2002 No. 184-FZ "On technical regulation" and the Federal Law of January 2, 2000 No. 29-FZ "On quality and safety of food products" we can say that none of the definitions included therein considers safety as a characteristic inherent in the concept of product itself. Instead, the legislator uses a very general notion of "condition" which as defined by the Federal Law "On technical regulation" does not relate to product: "product safety... is a condition in which there is no unacceptable risk of harm to life or health of citizens, property of physical or legal persons, state or municipal property, environment, life or health of animals and plants" and in the definition of the Federal Law "On quality and safety of food products" the lawmaker puts the concept of "safety" beyond the boundaries of objective phenomena avoiding its subject (emphasis added) content and defining the concept of food safety as "the state of certainty that food products under normal conditions of their use are not harmful and are not dangerous for the health of present and future generations". Obviously, the state of certainty is a measure that cannot be inherent in the product as it mostly lies in mental sphere. In addition, a sense of certainty can be influenced from outside and it is not always caused by objective factors. It seems that there is no need to prove the significance of this circumstance for the resolution of dilemma: is product safe or not?

As a characteristic of the product itself the notion of "safety" appears in the text of the Federal Law of April 12, 2010 No. 61-FZ "On circulation of drugs": "medicinal product safety is the characteristic of the medicinal product based on the comparative analysis of efficiency and risk of injury to health" (section 4 of the above mentioned Federal Law). However, in our opinion, this formulation is not definite because it does not disclose adequately the meaning of the term. The same claim can be presented to the definition of safety of the goods given in the Law of the Russian Federation of February 7, 1992 No. 2300-1 "On protection of consumer rights": "safety of the goods is the goods safety for life, health, property of consumers and the environment under normal conditions of their use, storage, transportation and disposal".

Thus, in modern Russia the solution of practical issues in realization of the right to health protection in the sphere of ensuring the quality and safety of products and services faces a number of serious problems, one of which

is the uncertainty of legitimization of the very concepts of quality and safety. Inconsistency, the variability of interpretation, the abstractness of existing definitions does not create opportunities for the development of clear criteria necessary for an objective assessment of the quality and safety of manufactured products.

Along with that, under the conditions of Russian reality a disparity in the legal regulation of questions of quality and safety, which found its expression in the loss of a quality criterion as binding regulatory requirement for products, poses a serious problem for realization of the right to health protection.

In the circumstances, taking into account the current Russian legal traditions and mentality of the Russian manufacturer, the rights of Russian citizens in the field of health protection cannot be fully guaranteed.

The way out of this situation, we believe, lies in the area of further improvement of legal framework of relations regulation in the sphere of ensuring the quality and safety of products and services. It is necessary to harmonize the legislative approaches to fixing mandatory requirements to products, providing these requirements not only with safety criteria, but also with quality criteria. Thus, the starting point in this process should be the development of unified normative definitions, which would state the concepts of quality and safety of products and services and allow in its turn to determine the criteria of quality and safety for products and services of various kinds.

The solution of this problem is a pressing task for the Russian legal science.

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