

# URGENT ASPECTS OF RISK ANALYSIS

---

UDK 006.88;613.2-4

## LEGAL ASPECTS OF PRODUCT RISK ASSESSMENT: INTERNATIONAL EXPERIENCE AND THE PRACTICE OF THE CUSTOMS UNION

**N.V. Zaitseva, I.V. May**

Federal Scientific Center for Medical and Preventive Health Risk Management Technologies,  
82 Monastyrskaya st., Perm, 614045, Russian Federation

---

*The analysis of the legal framework of technical regulation and product safety systems used by the EU, the US and a number of international organizations shows that the legally formalized instrument for substantiating product safety standards is the methodology of product risk assessment. However, normative legal acts of the Customs Union require further development and improvement in terms of product risk assessment, internal harmonization and adjustment to the provisions of international documents. The improvement of the legal framework will stimulate the development of all aspects of scientific and organizational support for product risk assessment: development and implementation of risk assessment methodology, development of a health risk criteria system, improvement of product conformity assessment methods, and development of a risk monitoring system.*

**Key words:** *Legal framework, products, safety, risk assessment, Customs Union.*

---

Following the present-day intensive development of industries and the expansion of global markets, there emerge new chemical substances directly contacting with humans [2,6,7,9,20], various biological agents [10,18,21], and threats of secondary and tertiary contamination of consumer goods [1,17]. Among the new potential hazards are the nanomaterials and products containing nano-particles with poorly researched hygienic characteristics [13]. Cases of health harm caused by products are registered on a regular basis. Public health suffers, and producers bear losses when their goods are withdrawn from markets.

There is a general understanding that it is necessary to apply more advanced and more adequate methods and instruments of consumer health protection, and to improve the system of technical regulation and product safety [22]. One of such generally accepted instruments is the health risk assessment methodology, which was adopted first

in the USA and later in other countries as a modern management paradigm, and which is at present an integral part of safety arrangements and an instrument for the justification of administrative measures in the sphere of health protection and consumer rights [11, 21]. The results of risk assessment and scientific evidence of product safety are often the key reasons for granting a certain product access to the market [21, 22, 25].

The integration of the Customs Union and the Common Economic Space member states into global trade systems requires that their national legal frameworks and alliance legislative acts be adjusted with the corresponding international documents. It is also necessary that these countries adopt the requirements of the global markets and adapt those requirements to their national conditions.

Historically, the systems of sanitary and epidemiological control in Russia, Belarus, Kazakhstan, Ukraine and Kyrgyzstan were not based on risk assessment methodologies. However, over the

---

© Zaitseva N.V., May I.V., 2013

Zaitseva Nina Vladimirovna – Professor, DSc in Medicine, Fellow of the Russian Academy of Medical Sciences, Director (e-mail: [znv@fcrisk.ru](mailto:znv@fcrisk.ru); tel.: 8 (342) 237-25-34).

May Irina Vladislavovna – Professor, DSc in Biology, Deputy Director (e-mail: [may@fcrisk.ru](mailto:may@fcrisk.ru); tel.: 8 (342) 237-25-47).

past few years, the Russian Federal Service for Consumer Rights and Human Welfare, Health Ministries of Belarus and Kazakhstan have taken a series of steps towards the harmonization of their national standards with international norms, at the same time preserving their own best practices and achievements in this field [4,5,12,15]. The main aim of their on-going work on the improvement of the standards of hygienic safety of products is human health protection.

In order to incorporate risk assessment procedures into the product safety provision system, it is necessary to provide it with legal support at all stages of the product life cycle, to develop and adopt adequate forms of conformity assessment, formulate the requirements for the network of competent and independent test laboratories, certification agencies and experts that are entitled to verify health assessment results, issue certificates of conformity and register uniform Declarations of Conformity of the Customs Union.

Therefore, the aim of this research is to compare the concepts, methods, criteria and other aspects of health risk assessment used by the EU, the USA, the Customs Union (CU), other countries and international organizations, to guarantee product safety and protect consumer rights.

We have compared over 50 legislative acts and about 80 regulatory documents of the EU, the USA, Customs Union member states, Ukraine, Kyrgyzstan, and international organizations, such as World Health Organization and World Trade Organization.

The analysis showed that in terms of technical regulations and product safety measures, the legal frameworks of the EU, the USA and international organizations (mainly WHO) all have very similar definitions of the concepts of 'safety' and 'risk to life and health'. In many pieces of legislation, the concepts 'safety' and 'risk' are related to each other.

For instance, Directive 2001/95/EC on General Product Safety, EU Regulation No.178/2002 on General Principles of Food Law, Directive 2009/48/EC on Toy Safety, the US H.R. 4040 Consumer Product Safety Improvement Act and a number of other acts define safety as the absence of unacceptable risk. Some variations induced by the nature of the subject matter of different legislative acts do not change the essence of the definition of 'safety', which is regarded in terms of the assessment of risk to human life and health.

The definition of 'risk' is rather similar in many legislative acts of the EU, the USA and WTO, with minor differences in the wording. The most typical definition is given in EU Regulation 178/2002: "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard" (Article 3.9). In WHO recommendations, risk is defined as "the probability that some adverse effect for the organism or the population will result from a given exposure to an agent" [23]. In this definition, it is important that the adverse effect may expand on the population in general, which enlarges the sphere of health risk assessment.

The legislative frameworks of the European Union and the USA contain a number of concepts that are of paramount importance for the organization and unification of risk assessment procedures used for product safety evaluation. For instance, in EU Regulation 178/2002 risk analysis is defined as a "process consisting of three interconnected elements: risk assessment, risk management and risk communication" (Article 3.10). The same document defines risk assessment as "a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization (Article 3.11). It is secured in legislation that the term 'risk management' means "the process, distinct from risk

<sup>1</sup> The assessment of the risk to life and health presented by consumer products was first conducted on food additives in the USA in the mid-1950s by the Federal Drug and Food Enforcement Administration. They proposed the concept of a safe level of food additives or contaminants based on NOAEL (No-observed-adverse-effect level, mg/kg per day). This level was calculated through animal testing using the most sensitive toxic substances indicator and a number of safety factors, to determine an acceptable daily consumption level for humans. This approach was accepted by the United Expert Committee for Food Additives of the Organization for Food Products and Agriculture and the World Health Organization, and formalized at the Joint Meeting on Pesticide Residues in 1961.

<sup>2</sup> Here and elsewhere, we mean the risk to the health and life of consumers or other people (for example, baby minders)

<sup>3</sup> Directive 2001/95/EC of the European Parliament and Council as of December 3, 2001, on general product safety

<sup>4</sup> Regulation 178/2002 of the European Parliament and Council as of December 28, 2002, laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety// OJ 2002.L31/1.

assessment, weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors and, if need be, selecting appropriate prevention and control options (Article 3.12 of the EU Regulation 178/2002).

'Risk communication' is defined as "the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decision (Article 3.13).

EU legislative acts formalize the key role of risk assessment in the system of product safety provision. Directive 2001/95/EC, which is the source of "horizontal legislation" and establishes general requirements to all producers as well as the responsibility of states in controlling the EU market, stipulates that health risks are indices against which safety standards of individual factors are set and the general safety of product is evaluated (Article 2b).

EU Regulation 655/2004 of April 7, 2004 sets the standard of nitrate concentration in products referring to the findings of the Scientific Committee on the assessment of oncogenic risks of nitrosamines induced by the level of nitrates in food.

For instance, EU Regulation 1925/2006 of December 20, 2006 stipulates that the upper safe levels of food additives are adopted as a norm following the results of "risk assessment based on generally acceptable scientific data, taking into account the varying degrees of sensitivity of different groups of customers" (Article 6.3a). It also has a provision that, if necessary, the upper safe levels of additives may be set at a higher level based on the findings of scientific risk assessment.

A number of US legal acts also stipulate the mandatory nature of risk assessment for the adoption of safety standards: Federal Food, Drug and Cosmetic Act, Federal Hazardous Substances Act,

etc. Since 1998, all US federal agencies have been obliged to annually notify the Office of Management and Budget of newly developed governmental standards and the transformation of previously adopted governmental standards developed on consensus basis.

In summary, risk assessment is codified as part of the procedure of adopting safety norms (standards) in the European Union, the USA and a number of other countries.

Furthermore, Directive 2001/95/EC specifies that "conformity of a product with the criteria designed to ensure the general safety requirement... shall not bar the competent authorities... from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous" (Article 3.4). It is therefore acknowledged that in actual practice a product may turn out to be unsafe for the life and health of the consumer, even though it meets all conformity standards.

The general responsibility for assessing the risk of products at the stage of design and production is placed on the producer (Directive 2001/95/EC, Article 3.1). More specifically, the responsibilities of producers, importers, distributors in terms of health risk assessment, the openness of the findings and risk communication are set forth in EU Directive 2009/48/EC on toy safety, 89/686/EEC on personal protective equipment, 2006/42/EC, 89/392/EEC and 98/37/EU on machines and mechanisms, 90/385/EEC on implanted medical devices, EU Regulation №1907/2006 on chemical substances (REACH), and a number of others. In particular, REACH holds the producer fully responsible for produced or imported chemical substances, for conducting the risk assessment of chemical products in circulation, for risk management and risk communication, and for stimulating innovation and developing alternative methods of the evaluation of the hazards presented by chemical substances (including risks to hu-

<sup>5</sup> Directive 2009/48/EC of the European Parliament and Council as of June 18, 2009, on toy safety// OJ2009. № L170/1.

<sup>6</sup> US H.R. 4040 Consumer Product Safety Improvement Act as of August 14, 2008 (CPSIA 2008)

<sup>7</sup> Regulation 655/2004/EC of 7 April 2004 amending Regulation (EC) No 466/2001 as regards nitrate in foods for infants and young children // Official Journal of the European Union No. L104/48, 2004. (2004 TO 2004.5)

<sup>8</sup> Regulation 1925/2006 of the European Parliament and of The Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods // OJL. 2006. № L404/26.

<sup>9</sup> U.S.C. United States Code, 2010 Edition Title 21 – Federal Food, Drug, And Cosmetic Act From the U.S. Government Printing Office, (FSMA).

<sup>10</sup> USA. Federal Hazardous Substances Act. (Codified at 15 U.S.C. §1261–1278).

<sup>11</sup> OMB Circular A-119 Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities, FR. Vol. 63, № 33.

man life and health). Moreover, this Regulation specifies that risk assessment must be performed with account for different ways in which a given substance may be used by all consumers in the supply chain.

Directive 2001/95/EC prescribes mandatory “establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks” (Article 9.1a), “follow-up and updating of scientific and technical knowledge concerning the safety of products” (Article 9.1b), and the exchange of information on risk assessment, dangerous products, test methods and results (Article 10.2b), particularly through RAPEX and RASFF.

Developing the provisions of this Directive, Decision No.768/2008/EC holds the producer responsible for preparing the documentation for the product in such a way that it would permit evaluating the conformity of the product with regulatory requirements and include appropriate analysis of one or several risks. The document envisages (among others) a number of procedures for product conformity assessment and suggests a number of modules from which the legislator may choose the procedure which best suits the level of the emerging risk. All the modules (A – H) contain requirements for health risk assessment.

The type of product that is given the most comprehensive coverage in EU legislation in terms of risk assessment is food products. Regulation No. 178/2002 specifies special requirements to product risk evaluation and mechanisms of the exchange of information on dangerous products and health risks. The document emphasizes that “in order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data” (Preamble, 16-18). It should be noted that Regulation 178/2002 warns EU Member States against discrepancies in

methods and criteria of product safety evaluation (and therefore, risk assessment) that may result from lack of harmonization between national and EU legislations.

The National Technology Transfer and Advancement Act and Risk Assessment and Cost Benefit Act (RACBA), which are the central regulatory acts in the USA that regulate product standardization issues, contain chapters devoted to risk assessment and risk minimization. For instance, RACBA requires that the report of a product's potential hazard to health, life or the environment should be prepared prior to any other documents. Such report must contain relevant information about laboratory and epidemiological investigations and proof of either presence or absence of dependence between the risk to health and life, and potential activity.

Practically all legislative acts of the EU, the USA, Australia and a number of other countries emphasize the importance of scientific support in risk assessment and of substantiation of product safety criteria, as well as the necessity to provide open access to all information concerning the danger (safety) of products. A number of legislative acts establish a direct link between those criteria and the findings of scientific investigations, especially risk assessment. For instance, European Commission Regulation 2073/2005 makes a direct reference to the Opinions of the Scientific Committee on Veterinary measures concerning public health. The document contains the major conclusions and recommendations of scientists, with reference to the results of health risk assessment and the opinion of BIONAZ group.

Significantly, the American and EU legislations develop the methodology of risk assessment by formalizing the principles of ‘precaution’ and ‘transparency’. The ‘precaution’ principle is applied in individual cases when the available information indicates the possibility of adverse effect on health, but no scientific evidence is available yet. The ‘transparency’

<sup>12</sup> Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC) // OJ L 399, 1989).

<sup>13</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006, on machinery, and amending Directive 95/16/EC

<sup>14</sup> Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery

<sup>15</sup> Directive 98/37/EC of 22 June 1998 on the approximation of the laws of the Member States relating to machinery.

<sup>16</sup> Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices

<sup>17</sup> Regulation (EC) No №1907/2006 of the European Parliament and of the council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

<sup>18</sup> RAPEX: Rapid Exchange of Information System

<sup>19</sup> RASFF: Rapid Alert System for Food and Feed

<sup>20</sup> Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products// OJ L 218/82, 2008.

principle presupposes that if there are reasonable grounds for believing that a product may present a hazard to human health, the state agencies must take the appropriate measures to inform the population, with regard for the character, severity and scale of risk.

However, the legislative acts of the EU, the USA and other countries practically do not provide sufficient coverage of a number of aspects which nevertheless require definition and specialization. Among such aspects are the criteria of risk acceptability, classification of hazards and risk characteristics. There is insufficient coverage of the assessment of risk caused by a combination of factors that are simultaneously present in the product and are able to cause related effects. No answers are given to the question as to whether it is necessary to assess the risks associated with long service life of products with hazard factors if the standards are established for single use.

There are scientific discussions concerning practically all of the above mentioned issues, and decisions are being made to conduct special studies.

The legislative acts of the Customs Union and the Common Economic Space (CU and CES) and of their member states make heavy use of the term "risk to health and life" in the context of product safety. In the framework document on technical regulation of CU and CES "Agreement on Coordinated Policies in the Sphere of Technical Regulation, Sanitary and Phytosanitary Measures", the terms are fully harmonized with the internationally

accepted definitions.

The Decision of the Customs Union Commission "On the Equivalence of Sanitary, Veterinary and Phytosanitary Measures and Risk Assessment" declares that among the information the Parties should exchange should be references to corresponding international standards or product risk assessment.

The agreement of Customs Union member states on removing technical barriers in mutual trade with CIS member countries envisages that the Parties should strive for obtaining further information on the presence of threat to life or health of people, animals and plants which is necessary for more objective risk assessment.

The Agreement on Sanitary and Phytosanitary Measures in the Customs Union formalizes the provision that risk to life and health is regarded as a criterion of the appropriate level of sanitary and phytosanitary protection of the population and shall be evaluated with account for methods developed and used by relevant international organizations.

Health risk assessment is covered in the "Unified Sanitary, Epidemiological and Hygienic Requirements to Products Subject to Sanitary and Epidemiological Control". The document specifies the necessity to substantiate the safety of pesticides and other agrochemicals, electric devices, machinery, instruments, etc., i.e. products with radiation concerns, as well as medical products, individual protective devices, etc.

Thus, a number of "top level" legislative acts

<sup>21</sup> Internal production control and supervised product checks; B) EC-type examination; C) Conformity to type based on internal production control; D) conformity to type based on quality assurance of the production process; E) Conformity to type based on product quality assurance; F) Conformity to type based on product verification; G) conformity based on unit verification; H) conformity based on full quality assurance

<sup>22</sup> National Technology Transfer and Advancement Act., 15 U.S.A. §3701 et seq., 1996

<sup>23</sup> Risk Assessment and Cost Benefit Act (RACBA), 23.02.1995 H.R.1022

<sup>24</sup> Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

<sup>25</sup> Of January 25 2008 with amendments of 19 May 2011

<sup>26</sup> Of 18 October No 825

<sup>27</sup> Agreement of the Customs Union member states on removing technical barriers in mutual trade with CIS member countries of 17 December 2012

<sup>28</sup> Decision of the Interstate Council of the Eurasian Economic Community of 21 May 2010 No 39

<sup>29</sup> Decision of the Customs Union Commission of May 28 2010 N 299

<sup>30</sup> As benchmark definition, it adopts the definition given in ISO/IEC Guide 2:2004 "Standardization and joint activities. A General Dictionary": "Safety is the condition that presents no unacceptable risk to public life or health..."

This definition laconically summarises the generally accepted terminology of European and American legislation.

<sup>31</sup> As benchmark definition, it adopts the definition given in ISO/IEC Guide 2:2004 "Standardization and joint activities. A General Dictionary": "Risk is the combination of the probability of harm and the severity of harm". This definition laconically summarises the generally accepted terminology of European and American legislation.

<sup>32</sup> Decision of the Customs Union Commission of May 18.10.2011 N 823

<sup>33</sup> Of 9 December 2011 N 021/2011

of the Customs Union and the Common Economic Space fully conform with international documents:

- regard risk to life and health as a criterion of product safety;
- stipulate that health risk assessment should be taken as the basis of sanitary measures;
- provide for the development and application of normative and methodological documents on risk

assessment to substantiate sanitary and phytosanitary measures within the Common Economic Space;

- declare that the regulatory acts concerning health risk assessment should be harmonized with international norms, requirements and standards.

Table 1

Definition of ‘safety’ in CU and CES documents and its conformity with EU terminology

Definition	Customs Union document	Conformity with the EU definition <sup>30</sup>
Safety of food products is the condition of a given food product that presents no unacceptable risk to the health of people and future generations	On the Safety of Food Products CU TR 021/2011	Conformity given the specific character of the subject of regulation
Biological safety is the condition of the product that presents no unacceptable risk to the life or health of the user (consumer) caused by inconformity of its biological, toxicological, physical and physico-chemical properties to set requirements.	On the Safety of Consumer Industry Products	Incomplete conformity: no provision for risk when product conforms with standards
Mechanical safety is a complex of quantitative indices of mechanical properties and constructive characteristics of the product that provides for the reduction of risk to the user's life or health.	CU TR 017/2011	Non-conformity: no distinction between the concepts of risk, hazard (threat), and risk management
Chemical safety is the condition of the product that presents no unacceptable risk to the life or health of the user (consumer) caused by excessive concentration of hazardous chemical substances in the product.	On the Safety of Products for Children and Adolescents	Incomplete conformity: no provision for risk when product conforms with standards
Chemical safety is the condition of furniture that presents no unacceptable risk to consumer's health and life arising from increased concentration of harmful chemical substances in the indoor air.	On the Safety of Furniture CU TR 025/2012	Incomplete conformity: no provision for risk when product conforms with standards
Product safety is the absence of unacceptable risk of harm to human life or the environment including wildlife and plantlife, with regard for the probability of the actualization of the hazard and the severity of its consequences.	On Requirements to Lubricates, Oils and Special Liquids CU TR 030/2012	Conformity
Safety of perfume and beauty products is a combination of properties and characteristics of perfume and beauty products that guarantee the absence of harmful effect of the product on the consumer.	On Safety of Perfume and Beauty Products CU TR 009/2011	Incomplete conformity: no health risk assessment involved

Table 2

## The definition of the term ‘risk’ in CU and CES and its conformity with EU terminology

Definition	Document	Conformity with the EU terminology <sup>31</sup>
Risk is the degree of the potential hazard of pesticides to human health and human habitat in concrete conditions of use.	Agreement on the Application of Sanitary Measures in the Customs Union	Incomplete conformity: no distinction between “risk” and “hazard” (“danger”)
Risk is the combination of the probability of harm and the consequences of this harm for human life and health, property, the environment, health and life of wildlife and plantlife.	On the Safety of Products for Children and Adolescents CU TR 007/2011	Conformity given the specific character of the subject of regulation
Risk is the combination of the probability and severity of health harm that may be caused in a dangerous situation	On the Safety of Machinery and Equipment CU TR 010/2011	Conformity given the specific character of the subject of regulation

Technical regulations of the Customs Union generally take into account the general provisions of the inter-state Agreements of the Customs Union. However, on comparing the definitions of ‘safety’ and ‘risk’ in the Technical Regulations of the CU and CES with those used in the European legislation, it becomes clear that the CU documents need further development and improvement in terms of risk assessment terminology, and should be harmonized with the internationally accepted terminology (see Tables 1 and 2).

The most correct and full coverage of risk assessment issues is given in the CU Technical Regulation 010/2011 On the Safety of Machinery and Equipment. This regulation, in accord with the EU approaches, stipulates that at the stage of product design, it is necessary to consider and identify all possible hazards that may emerge during the product life cycle.

It is pointed out that it is necessary to prepare a special document containing the substantiation of product safety featuring risk analysis, and information from design, service and technical documentation on the minimal measures to guarantee safety. This document must be updated by including the results of risk assessment at the operational stage and after heavy overhaul. At the stage of designing the machine or equipment, an acceptable level of risk should be established. The list of standards required for mandatory and voluntary application and execution of the CU Technical Regulation 010/2011 contains the National Standards (GOST) establishing the methods and criteria of health risk assessment (e.g. GOST EN 1050-2002 “Safety of Machinery. Principles of Risk Assessment and Evaluation”, GOST 31217-2003 626-1:1994 “Safety of Machin-

ery. Reduction of Health Risk of Harmful Substances Emitted by Machinery in Operation”, etc.).

A number of risk assessment aspects are covered in the Technical Regulation “On the Safety of Food Products” (CU TR 021/2011), which defines product safety as the absence of unacceptable risk associated with an adverse effect on humans and future generations. However, the Customs Union document does not provide such comprehensive coverage of the role and the procedure of health risk assessment, the importance of scientific support, the issue of institutionalization and a number of other issues as its European counterpart (Regulation 178/2002). Table 3 presents a comparative analysis of the provisions in these two documents.

Consequently, given the highly specific character of the Technical Regulation CU TR 021/2011, it is by far less flexible regarding the general product safety indices. The list of standards attached to the Technical Regulation does not contain risk assessment methodologies, providing instead just the set requirements and norms. As a result, there is no legislative regulation for the situation when substances with new parameters and characteristics are used in production, or when there emerge incidents that were not foreseen at the stage of product design.

Many aspects of risk assessment are covered in the CU Technical Regulation 008/2011 on the Safety of Toys. The Regulation provides a corrective definition of risk, identifies possible types of risk and stipulates the obligation for the producer or importer to submit a set of documents to the certification authority, including a document on risk assessment proving the compliance of the product with safety requirements. However, obliging the producer to perform

the assessment of the risk to the consumer’s health, the CU Technical Regulation, unlike the analogous EU Directive 2009/48/EC, does not provide for risk assessment in the case of product use for purposes other than those specified, does not stimulate the producer to produce toys with reduced risks, and does not cover the cases when the producer is unable to assess the risks of its product. The attached list of

standards does not include documents on the procedure or methodology of risk assessment.

Similar problems concerning the assessment of risk to health are characteristic of other CU Technical Regulations: CU Technical Regulation 007/2011 on the Safety of Products for Children and Adolescents<sup>35</sup>.

Table 3

Comparative analysis of health risk assessment aspects for food products

Regulation (EU) No.178/2002 laying down the general principles and requirements of food law...	CU TR 021/2011 “On Food Products Safety”
6.1 In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis...	No direct analogy
Article 10. ... where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.	Article 39. The labeling of food products should meet the labeling requirements of Food Safety Technical Regulation, and (or) the appropriate requirements of Technical Regulations.
Preamble (17). ... the three interconnected components of risk analysis – risk assessment, risk management and risk communication – provide a systematic methodology for the determination ... actions to protect health.	No analogy
Preamble (18). In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data”.	No analogy
Preamble (21). In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures...	No analogy
Preamble (32). The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.	Article 2. The aim of this Technical Regulation is to protect the human life and health and to prevent the actions that misinform and mislead the product buyers (consumers)
Preamble (33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority... should reinforce the present system of scientific and technical support... Preamble (35). The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.	No analogy

<sup>34</sup> Decision of the Customs Union Commission of 23 September 2011 N 798

<sup>35</sup> Decision of the Customs Union Commission of 23 September 2011 N 797

<sup>36</sup> Decision of the Customs Union Commission of 23 September 2011 N 799

<sup>37</sup> Decision of the Customs Union Commission of 9 December 2011 N 874

<sup>38</sup> Decision of the Customs Union Commission of 9 December 2011 N 882

<sup>39</sup> Decision of the Customs Union Commission of 9 December 2011 N 883



Technical Regulations on perfume and beauty products (CU TR 009/2011) , on grain (CU TR 015/2011) , on juice products (CU TR 023/2012) [160] and fat-and-oil products (CU TR 024/2012) , and the draft technical regulations that are currently being prepared (on meat and meat products, on fish and fish products, etc.) contain no requirements of health risk assessment at all. Those documents treat safety as the condition of the product provided by meeting the set standards. This interpretation does not contradict the general definition of safety, provided that the safety standards are substantiated by risk criteria.

At present, there are hundreds of safety standards for products circulating within the Common Economic Space that cover each group of products and each danger factor (chemical, microbiological, different types of physical impact). Practically all safety indices have been transferred to the legislation of the Customs Union from the legal frameworks of the Russian Federation, Belarus and Kazakhstan. Due to the specific character of sanitary and epidemiological regulation of these countries, many standards were established without consideration for health risk (in the context of the international regulatory framework) and must be analyzed with respect for new approaches and criteria.

At the same time, the acts adopted in the Customs Union envisage the development of the legal framework in the direction of their harmonization with international norms, requirements and standards.

Therefore, the development of the legal framework of the Customs Union presupposes the inclusion in legislation of a number of provisions formalizing the role, procedure and content of assessment of risk to consumers' life and health as a standard methodology stimulating producers to enhance the safety of their products.

The improvement of the legal framework will create an incentive for the development of all aspects of scientific, methodological and organizational support to product risk assessment: design and implementation of risk assessment methodologies, development of a system of criteria of the risk of health harm of different degrees, and a system of risk monitoring of products circulating in the market. This should lead to a general improvement in the safety standard of products and a reduction in the risk to the health of the population of the Customs Union member states and of other market partners.

## References

1. Arshakuni V.L. Ocenka riska po nakoplenym znachenijam kontroliruemogo parametra [Risk assessment according to the accumulated values of the controlled parameter]. *Sertifikacija*, 2012, no. 2, pp. 12–13.
2. Vasilovskij A.M. Riski dlja zdorov'ja naselenija Krasnojarskogo kraja, obuslovlennye potreblenijem produktov pitaniya, kontaminirovannyh tjazhelymi metallami [Health risks in the Krasnoyarsk region population caused by the consumption of foods contaminated with heavy metals]. *Voprosy pitaniya*, 2009, vol. 78, no. 1, pp. 63–69.
3. Edelev D.A., Kantere V.M., Matison V.A. Ocenka riskov – vazhnejshij jelement risk-menedzhmenta pishhevoj produkcii [Risk assessment is the most important element of risk management of food products]. *Pishhevaja promyshlennost'*, 2011, no. 9, pp. 14–16.
4. Zajceva N.V., Maj I.V., Shur P.Z. Aktual'nye problemy sostojanija sredej obitaniya i zdorov'ja naselenija stran Sodruzhestva Nezavisimyh Gosudarstv [Proceedings of the Samara Scientific Center of the Russian Academy of Sciences]. *Izvestija Samarskogo nauchnogo centra Rossijskoj akademii nauk*, 2012, vol. 14, no. 5–2, pp. 527–533.
5. Zajceva N.V., Shur P.Z. Konceptija riska v sisteme meroprijatij po obespečeniju sanitarno-jepidemiologičeskogo blagopoluchija [The concept of risk in the system of measures to ensure the sanitary and epidemiological welfare]. *Gigiena i sanitarija*, 2002, no 6, pp. 19.
6. Naumenko T.E., Rybak V.A., Gricenko T.D., Shevchuk L.M., Pshegroda A.E., Gan'kin A.N. Zakonodatel'noe obespečenie ocenki riska vozdeystvija na zdorov'e naselenija kachestva atmosfernogo vozduha v respublike Belarus' [The legislative basis for assessing the risk of the impact of ambient air quality on human health in the Republic of Belarus]. *Analiz riska zdorov'ju*, 2013, no. 1, pp. 30–35.
7. Kamaliev L.A. Opasnye dlja zhizni ili zdorov'ja potrebitelej lekarstvennye sredstva i spirtsoderzhashhaja produkcija [Pharmaceuticals and alcohol-containing products hazardous to consumer life and health]. *Aktual'nye problemy jekonomiki i prava*, 2011, no. 1, pp. 237–239.
8. Kurljandskij B.A., Hamidulina H.H., Zamkova I.V. Analiz itogov gosudarstvennoj registracii potencial'no opasnyh himičeskikh veshhestv v Rossijskoj Federacii za 2005 g. [The analysis of the results of state registration of potentially hazardous chemical substances in the Russian Federation in 2005]. *Toksikologičeskij vestnik*, 2006, no. 2, pp. 2–4.

9. Kuchinskaja L.V. Opyt kontrolja i nadzora za potrebitel'skim rynkom stran-uchastnic Evropejskogo sojuza [The experience of control and surveillance of consumer market in the European Union member countries]. *Vestnik Rossijskoj tamozhennoj akademii*, 2010, no. 3, pp. 38–45.
10. Ljashenko O.V., Il'in V.P., Savchenkov M.F. Svinec v produktah pitaniya kak faktor riska dlja zdorov'ja detej [Lead in foods as a child's health risk factor]. *Voprosy detskoj dietologii*, 2005, vol. 3, no. 3, pp. 13–15.
11. O zaprete vvoza i oborota syryh ovoshhej, proizvedennyh v Germanii i Ispanii: press-reliz Federal'noj sluzhby po nadzoru v sfere zashhity prav potrebitelej i blagopoluchija cheloveka [On the ban on the import and sale of fresh vegetables produced in Germany and Spain: a press release of the Federal Service on Customers' Rights Protection and Human Well-Being Surveillance], available at: [http://rospotrebnadzor.ru/c/journal/view\\_article\\_content?groupId=10156&articleId=489934&version=11](http://rospotrebnadzor.ru/c/journal/view_article_content?groupId=10156&articleId=489934&version=11).
12. Onishhenko G.G. Ocenka i upravlenie riskami dlja zdorov'ja kak jeffektivnyj instrument reshenija zadach obespechenija sanitarno-jepidemiologicheskogo blagopoluchija naselenija Rossijskoj Federacii [Health risk assessment and management as an effective tool to solve issues to ensure the health and epidemiological well-being of the Russian Federation population]. *Analiz riska zdorov'ju*, 2013, no. 1, pp. 4–14.
13. Zajceva N.V., Shur P.Z., Atiskova N.G., Kir'janov D.A., Kamaltdinov M.R. Ocenka bezopasnosti dopustimyh urovnej sodержaniya L. Monocytogenes v pishhevyyh produktah po kriterijam riska zdorov'ju naselenija [Safety assessment of the maximum permitted levels of L. Monocytogenes in food according to health risk criteria]. *Analiz riska zdorov'ju*, 2013, no. 2, pp. 4–13.
14. Onishhenko G.G., Tutel'jan V.A., Gmoshinskij I.V., Hotimchenko S.A. Razvitie sistemy bezopasnosti i kontrolja nanomaterialov i nanotehnologij v rossijskoj Federacii [The development of the system for nanomaterials and nanotechnology safety and control of in the Russian Federation]. *Gigiena i sanitarija*, 2013, no. 1, pp. 4–11.
15. Rakitskij V.N. Nauchnye dostizhenija otechestvennoj gigieny i toksikologii pesticidov [Scientific achievements of Russian hygiene and the toxicology of pesticides]. *Zdravoohranenie Rossijskoj Federacii*, 2008, no. 1, pp. 14–15.
16. Sazhinov G.Ju., Krasil'nikova E.A. Risk kak obobshhennyj kriterij kachestva i bezopasnosti proizvodstva produkcii detskogo pitaniya [Risk as a generalized criterion of the quality and safety of children food production]. *Voprosy detskoj dietologii*, 2006, vol. 4, no. 2, pp. 30–33.
17. Hamidulina H.H., Zamkova I.V., Kasatkina T.A. Novye svedeniya o toksichnosti i opasnosti himicheskikh i biologicheskikh veshhestv [An update in the toxicity and hazards of chemical and biological substances]. *Toksikologicheskij vestnik*, 2006, no. 1, pp. 42–43.
18. Shumilova I.Sh. Analiz i ocenka riskov pri proizvodstve konditerskih izdelij [Risk analysis and assessment in confectionery manufacturing]. *Konditerskoe proizvodstvo*, 2011, no. 4, pp. 10–13.
19. Acosta O., Chaparro A. Genetically modified food crops and public health. *Acta Biologica Colombiana*, 2010, vol. 13, no. 3, pp. 3–26.
20. Eriksson J., Öborn I., Olsson I.-M., Oskarsson A., Skerfving S. Cadmium in food production systems: a health risk for sensitive population groups. *Ambio*, 2005, vol. 34, no. 4–5, pp. 344–351.
21. Cardwell K.F., Henry S.H. Risk of exposure to and mitigation of effect of aflatoxin on human health: a west African example. *Journal of Toxicology – Toxin Reviews*, 2004, vol. 23, no. 2–3, pp. 217–247.
22. Phillips Ia., Casewell M., Cox T., De Groot B., Friis Ch., Jones R., Nightingale Ch., Preston R., Waddell J. Does the use of antibiotics in food pose a risk to human health? A critical review of publishing data. *Journal of Antimicrobial Chemotherapy*, 2004, vol. 53, no. 1, pp. 28.
23. Attias L., Boccardi P., Boeije G., Brooke D., De Bruijn J., Comber M., Dolan B., Fischer S., Heinemeyer G., Koch V., Lijzen J., Müller B., Murray-Smith R., Rikken M., Tadeo J., Vermeire T. European Union System for the evaluation of substances: the second version. *Chemosphere*, 2005, vol. 59, no. 4, pp. 473–485.
24. IPCS risk assessment terminology. WHO. Geneva, 2004, 117 p.
25. Schoffro M.J. The coffee controversy. *Total Health*. 1996, vol. 18, no. 3, pp. 48–49.