

The Application of Risk Assessment Methodology in the Republic of Belarus

The application and accomplishment of risk assessment methodology in the Republic of Belarus is performed in the following directions:

- the choice of technical regulation objects,
- the development and application of technical regulations,
- the development and application of standards,
- the choice of forms (schemes) of conformation of compliance with the requirements of technical regulations,
- the choice of rules and procedures of conformity assessment, including market surveillance, accreditation, testing,
- the exchange of information on hazardous products.

The choice of technical regulation objects, the development and application of technical regulations, setting technical requirements in technical regulations

The Republic of Belarus takes actions to establish scientific foundations for the analysis and assessment of risk of hazardous factors, so that requirements of specific technical regulations and standards are based on them. These requirements concern not only the goods but also their security, production, exploitation (use), storage, transportation, sale and utilization, or rendering services affecting hazardous goods. The developer of a technical regulation determines, based on the product risk assessment methodology, both essential and specific requirements. The methodology of transformation and interpretation of essential technical requirements through related standards (i.e. harmonized standards) is especially important. It would be desirable to solve some of the issues arising at this stage in the framework of WP.6.

Product specific risk and the degree of state intervention are determining factors when setting requirements and classifying technical regulations into groups. The first experience of technical regulation rules has demonstrated that it is reasonable to decide in favor of three basic ways of stating technical requirements in technical regulations:

- ones containing specific technical requirements (specific safety requirements),
- ones containing essential technical requirements (essential safety requirements),
- ones containing technical requirements referring to specific standards and/or technical codes.

Depending on the way of stating specific technical requirements technical regulations are classified into ordering (for regulation objects for which new risks can appear at subsequent stages of life-cycle) and ones containing exploitation safety requirements (for regulation objects for which risks get removed at the development stage and do not appear later in the life-cycle).

In applying technical regulations for ensuring compliance with their requirements

If interrelated standards do not exist or have not been applied by the manufacturer, conformity assessment is performed with respect to the essential requirements of technical regulations. At the same time, the description of decisions taken and risk assessment confirming compliance with essential requirements of technical regulations has to be presented. The body stating that the product in question is compliant with requirements must have enough technical competence that allows (if necessary) to assist the manufacturer in

carrying out risk assessment (if related standards have not been used) and analyzing manufacturer's explanatory note (this note lists technical decisions and risk assessment actions taken, which confirm compliance with the essential requirements of technical regulations, if related standards have not been applied). Technical documentation should reflect risks related to the mission of specific assessed product in question.

In choosing and applying state standards

Risk assessment is carried out when technical requirements are set in specific standards, including the ones interrelated with technical regulations in standards. The technical requirements set should ensure the removal of any possible hazard or the reduction of risk level.

In choosing forms (schemes) of conformation of compliance with the requirements of technical regulations

In choosing rules and procedures of conformity assessment

When choosing forms (schemes) of confirmation of compliance it is recommended to consider a number of basic factors, including the cumulative risk from a wrong confirmation of compliance and hazard from the usage of goods that is confirmed to be compliant. At the same time the objective character of the assessment (characterized by the independence of procedure executors) should be considered.

Methodological documents

Creating a technical regulation and standardization system based on the methodology of analysis, risk assessment and management, requires forming a terminology, developing and introducing methods of analysis of hazards and quantitative methods of risk assessment based on international standards, training professionals and grading experts in the sphere of risk assessment, as well as working out relevant documents. "Recommendations on Developing Technical Regulations" and "Methodological Recommendation: Risk Analysis Based Assessment of Machinery Product Safety" have been developed in Belarus. Besides that, in the framework of technical regulation and standardization system of Republic of Belarus fundamental technical codes of settled practices have been developed. These codes set the rules of development, structure, exposition, legalization and content of working out technical regulations, taking into consideration risk analysis and assessment. These documents take into account international experience and at the same time are based on the experience accumulated through Belarusian System of Technical Regulation and Standardization.

Working out the Complex of State Standards in Risk Management

Working out state standards in risk management and its harmonization with international and European standards provides a base for these activities. At the moment, 9 state standards as well as 4 projects of standards in risk analysis and assessment and reliability spheres have been developed in Republic of Belarus. Among existing standards there are standards determining terms and definitions in risk management sphere, the rules of introducing safety aspects into standards, the procedure of identifying hazards related to medical goods, series of standards in reliability management and programs of increasing reliability. The fundamental standard in reliability management systems is at the stage of final formulation.

In exchanging information on hazardous products

For protecting the market and consumers activities aimed at creating the unified system of accumulation and exchange of information on products posing threat for human life and health (analogous to European RAPEX system) are performed in Republic of Belarus. Currently, the concept of the project of Law of Republic of Belarus “On Product Safety” (guaranteeing the creation and functioning rules of the Unified System) is being worked out.

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