

Risk assessment and management techniques used by the *Gospotrestandart* of Ukraine

Due to Ukraine's entry to WTO and its integration to the EU the *Gospotrestandart* of the country, as well as its president and government need to guarantee a step-by-step switch from mandatory certification to the conformity assessment based on the requirements of technical regulations. This requirement is stated in a number of international and internal documents and is also stipulated by Ukrainian technical legislation.

According to WTO agreement on technical barriers to trade (TBT agreement), every country has the right of setting procedures of product conformity assessment based on its national interests and the need for guaranteeing the safe protection of human life and health and the environment. Obviously, the protection level must be scientifically justified and proportionate to the risk the product in question poses. EU experience in this sphere stipulates no regulation for low risk goods and declaration by the manufacturer (self-control, introduction of contemporary management methods and efficient market surveillance) for medium risk goods. As for high risk goods, they get exposed to, besides what has already been mentioned, product certification and quality management system assessment. This method is realized in the relevant decision of European Commission with respect to module approach and CE marking.

In Ukraine, state system of mandatory certification, UkrSEPRO, functions as per the *Decree on standardization and certification* and *Specification of products subject to mandatory certification*. This Specification has been reviewed several times, and various groups and types of goods have been removed from it.

By now, 27 technical regulations based on European directives of New and Global Approach have been accepted in Ukraine. They set mandatory safety requirements for certain kinds of goods (toys, low-voltage equipment, electromagnetic compatibility, vessels functioning under pressure, machines and mechanisms, means of personal defense, etc.).

As per the schedule approved by the Cabinet of Ministers of Ukraine, the implementation of these regulations is planned to take place starting from 2010. As it is implemented, the *Specification of products subject to mandatory certification* (to be called *the specification* further) will shrink.

Nowadays, the situation in Ukraine considerably differs from the one in Europe in terms of such indicators as the state of consumer market, production culture, compliance level, awareness and activeness of consumers. This, in turn, substantially complicates the process of applying technical regulations based on European approach.

According to the procedure currently introduced in Ukraine the measures on product market regulation are based on risk analysis.

In December 2007, the Law of Ukraine *On basic principles of state monitoring (control) in the sphere of economic activity* was passed. Following up, in December 2008 the Cabinet of Ministers of Ukraine accepted the Enactment *On confirming the specification of criteria of assessment of risk on products manufactured, imported and sold at the consumer market of*

Ukraine, as well as the periodicity of taking planned measures of state monitoring (control)(to be called The Enactment further).

The degree of risk to human life or health or environment is assessed based on such criteria as the number of cases of incompliance with requirements of technical regulations, standards, norms and rules discovered at the enterprise concerned, the degree of complexity and duration of the process of goods production, the possibility of non-purpose usage of products, etc.

Depending on the risk assessment criteria, economic agents are classified into high, medium and low level risk.

High level products are food and feed, goods with high degree of hazard (pesticides, explosives), medical equipment, goods for children, etc.

The premise of determining the basic risk assessment criteria are consultations with experts from CIS countries, meetings with associations of enterprises and manufacturers of Ukraine, discussions with local leaders of *Gospotrestandart* of Ukraine, as well as the representatives of state research institutions on standardization, metrology and consumer right protection, results of analysis of Ukrainian consumer market. These criteria are based on the results of analysis and monitoring of state control performed by local bodies of *Gospotrestandart* of Ukraine for 3 years.

The analysis regarding consumer products (such as food and feed, goods for children, products of oil processing, flammables, pyrotechnic products, household appliance, medical equipment, poisons) has shown that low quality goods were produced in 77% to 89% of the cases. For this reason, they have to be constantly kept under permanent control. It was decided that planned checks of economic agents' compliance with the requirements of standards, norms and rules should be performed yearly.

The percentage of products failing to match requirements of normative documents made up 30-50% of the whole volume of the goods produced (industrial production, goods of light and construction industry, chemicals, rubber and plastic goods, fire-prevention goods, metallic, mineral and non-metal machines and equipment) is classified to the middle risk group.

The implementation of The Enactment has allowed for improving the systemic and balance character, as well as the transparency of state control (monitoring) of production sold at the consumer market in Ukraine. There are opportunities for unified approach to planning state monitoring (control) measures. This approach implies a risk level based, proportional approach to economic subject.

The *Gospotrestandart* of Ukraine conducts permanent monitoring of results of state control. Based on the monitoring of state monitoring results in 2009 a package of changes to the enactment of Cabinet of Ministers has been prepared. This package stipulates assigned part of the high risk group to the medium risk group.

It should be mentioned that this procedure was accepted for a transitory period of market surveillance system reform, based on unregulated economic relations, imperfection of legislation, insufficient responsibility of the manufacturer for producing goods that are hazardous or do not match requirements set.

Running a policy aimed at step-by-step reforming and harmonization of the existent system of technical regulation with international and European norms, *Gospotrebandart* of Ukraine has worked out a number of legislative and normative acts the introduction of which will allow for creating in Ukraine a modern market surveillance system. These include the drafts of Laws of Ukraine *On state market surveillance*, *On basic product safety* and *On responsibility for defective goods*.

These laws in draft are harmonized with the following directives of European Parliament and Council of Europe, #2001/95/EC *On basic food safety* (issued on December 3, 2001), #85/374/EC *On the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products* (issued July 25, 1985). The provisions of European documents, namely Regulation (EC) #178/2002 of European Union and Council of Europe *On laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, as well as *Guidelines on execution of directives based on the principles of the New and Global approaches* have been taken into account.

The law in draft *On basic food safety* provides a new approach to risk assessment and management built on European practice stipulating the discovery of hazards associated with the use of certain goods, its properties and the assessment of its possible consequences. It will be the manufacturer who carries out risk assessment through the existing means of production and professional knowledge of specialists, in order to anticipate the probability of hazardous properties of the production, according to the methodology approved. The results of the assessment must become a component of technical documentation.

Mutual exchange of information and opinions on hazards and risks, risk related factors and risk perception is planned to involve people responsible for risk assessment and management, consumers, manufacturers, scientists and other interested parties. This will also include the explanation of risk assessment results and the reasoning of decisions taken with respect to risk management.