APPLICATION OF RISK ASSESSMENT METHODOLOGY IN THE REPUBLIC OF BELARUS

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APPLICATION AND IMPROVEMENT OF RISK ASSESSMENT METHODOLOGY IN THE REPUBLIC OF BELARUS

DIRECTIONS

- when selecting technical regulation objects
- when developing and applying technical regulations
- when developing and applying standards
- when selecting forms (schemes) of product conformity attestation to technical regulation requirements
- when selecting rules and procedures of conformity attestation including market surveillance, accreditation, tests
- when carrying out state surveillance over compliance with technical regulation requirements
- when exchanging the hazardous products information
Development of scientific basis for risk analysis and assessment of hazardous factors

Requirements setting in specific technical regulations and standards
  - to the products itself
  - to processes of product development, production, operation (use), storage, transportation, realization and utilization, related to product safety, or provision of services
Making-up technical requirements in technical regulation

Main principles to be followed when making-up requirements in technical regulations

- determination of the level of the requirements non-conformity permissible risk
- harmonization of the requirements with the relative international documents and agreements
- definition of the form of the requirements presentation
- established requirements shall be relative to all the stages of the products life cycle and to all conditions of their use
These decisions may be taken as a part of the larger process for risk management by comparison of the risk analysis results with the permissible risk criteria.
Making-up technical requirements in technical regulation

**IN TECHNICAL REGULATION**

- It should be exactly determined the necessary safety level, which the manufacturer shall provide for protection of public interest.
- All the kinds of risk, protection of which is to be foreseen are established.
  - It concerns safety of products, safety of personnel, customers, etc.

In line with this it’s necessary to determine clearly the requirements to products, in order the conformity attestation bodies could properly assess conformity of this products against established requirements.
STAGES OF RISK ANALYSIS AND ASSESSMENT

1. Determination of **products scope**
   including intended use and all types of possible predictable improper use of products

2. Carrying out the **hazard identification**, related to the technical regulation object
   and arising at all stages of life cycle and under all conditions of product use, including assembling, operation, repair and utilization etc.

3. Determination of **risk magnitude**, arising as a result of **defined hazard**
   including risk quantification

4. Comparison of risk with accepted level

5. Risk management, risk mitigation measures to the accepted level

**Permissible risk**
is an optimal balance between

- safety
- Requirements which they should met
  - products
  - process
  - service
- factors
  - profitability for users
  - costs efficiency
  - traditions, etc.
KEY METHODS OF TECHNICAL REQUIREMENTS PRESENTATION IN TECHNICAL REGULATIONS

✓ specific technical requirements

✓ essential technical requirements

✓ technical requirements, presented in the form of references to specific standards

TECHNICAL REGULATIONS

depending on the way of setting out the specific technical requirements

• Directive technical regulations

☐ for technical regulation objects, which can have new risks arising during further stages of products life cycle

• Technical regulations, containing operation safety requirements

☐ for technical regulation objects, which have risks that are reduced (eliminated) at the development stage, and new risks don't arise at further stages
IMPLEMENTATION OF TECHNICAL REGULATIONS
ESSENTIAL REQUIREMENTS

INTERRELATED STANDARDS
WHERE NOT APPLIED BY MANUFACTURER OR ARE ABSENT

รวดrous Posey an sefleclleco to
directly essential requirements of technical regulation

Definition of decision made and risk assessment,
confirming the implementation of essential requirements of technical regulation

AUTHORIZED BODY
• Rendering of help to the manufacturer in carrying out risk assessment
• Carrying out the analysis of notes, prepared by manufacturer, containing risk assessment, and confirming the implementation of essential requirements of technical regulation

TECHNICAL DOCUMENTATION
• risks, connected with specific products under assessment, should be reflected
CONFORMITY ASSESSMENT RULES AND PROCEDURES

KEY FACTORS, INFLUENCING THE SELECTION OF FORMS (SCHEMES) OF CONFORMITY ATTESTATION

- **products complexity** simple, of medium complexity and complex
- **degree of potential hazard for products** low, medium, high
- **sensitiveness degree** of safety indicators, administered by technical regulation, to the change of production and (or) operational factors
- **risk degree** in scores
- **applicant status** manufacturer or seller

WITH RESPECT TO

- **total risk from misleading conformity attestation**
- **damage from application of products, which have passed conformity attestation**
- **assessment objectivity, which is characterized by the degree of executive procedure independency (the first and the third party)**
Making-up technical requirements in technical regulation

Use of conformity declaration **does not depend** on the extent of potential danger of products

Harm-doing risk at using the products for human-beings and environment is connected only with the content of evidential base.

Content of the evidential base should be more meaningful, than for less dangerous products.

In both cases conformity attestation procedures are completed by the manufacturer’s acceptance of declaration of conformity, particularly after voluntary third party certification.

By this he assumes before authorities responsibility that he met all the technical regulation requirements and attested them properly.
GUIDANCE DOCUMENTS

«Technical regulations development recommendations»
are based on the provisions of the Law of the Republic of Belarus «On technical regulation and standardization», the WTO Agreement on Technical Barriers to Trade, UNECE Recommendations and good technical regulation practice of APEC and EC member-states.

«Methodological recommendations. Safety assessment of engineering products on the basis of risk analysis»

basic concepts, principles of risk assessment and determination, key methods of risk assessment

provisions on engineering products safety assessment, definition of hazards, associated with these products, and the strategy of safety measures selection

Fundamental technical codes of good practice (TCP)
TCP 1.0-2004, TCP 1.10-2007

development rules of technical regulations, and rules of their composition, presentation, preparation and maintenance

TCP Project

development and presentation rules of standards interrelated with technical regulation, rules of its drawing up and the form of the list of standards interrelated with technical regulation.
## SET OF STANDARDS ON RISK MANAGEMENT

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## PROJECTS

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Establishment of Uniform system of collection and exchange of information, about products, posing hazard to life and health similar to the RAPEX European system

REQUIRES DEVELOPMENT OF

The Law of the Republic of Belarus «On products safety»

- Operation rules of the Uniform information system
- Requirements to the provision of information about cases of products non-conformity to the safety requirements
- Requirements to the hazardous products information exchange

The provision, establishing the operation order of the Uniform information system

System structures
UNIFORM INFORMATION SYSTEM

- Information about products, posing hazard to life and health

- Information about manufacturers, importers (sellers), distributors, delivering products, posing hazard to life and health

- Information about accounting and analysis of cases of harm causing to man’s life, health and heredity, property, and environment as a result of non-compliance with technical regulations and standards requirements

INFORMATION SOURCE

- Results of the state control (surveillance) of the state administration bodies

- Information from manufacturers

- Information from importers (sellers), distributors