NEEDS OF COUNTRIES WITH ECONOMIES IN TRANSITION IN CONFORMITY ASSESSMENT
- Technical legislation
- Technical regulations
- Standardization
- Conformity attestation
- Accreditation
- Market surveillance
- Liability
LEGISLATIVE FRAMEWORK

Laws of the Republic of Belarus

On technical regulation and standardization

of January 5, 2004

On conformity assessment to the requirements of technical
normative legal acts in technical regulation and standardization

of January 5, 2004

On assuring of uniformity of measurements

of July 20, 2006

BASED ON
WTO Agreements for TBT and SPS,
Code of Good Practice for development, acceptance and implementation of standards in compliance with the principles of New and Global Approaches to technical regulation in EC,
OIML documents
CONCEPT of TECHNICAL REGULATION and STANDARDIZATION in the REPUBLIC of BELARUS

Council of Ministers

Technical regulation

Essential safety requirements are OBLIGATORY

Order

For development of interconnected governmental standards

Principle of conformity presumption

Gosstandart

Interconnected governmental standards

STB

GOST

Are used on voluntary basis

Market surveillance

Information Index of TNLA

Manufacturer

Conformity attestation

Conformity declaration

Certification

CE-marking

CONCEPT of TECHNICAL REGULATION and STANDARDIZATION in the REPUBLIC of BELARUS
PROBLEMS in LEGISLATION

Development in the Republic of Belarus of horizontal legislation within technical regulation, concerning the issues of:

- **General safety of products**
  based on Directive 2001/95/EC

- **Liability for output of defective products**
  based on Directive 85/374/EEC
Draft Law of the Republic of Belarus
«On general safety of products»

Establishment of:

- general safety requirements
- obligations of a manufacturer and a distributor
- rights of surveillance authorities
- requirements to exchange of information of dangerous products, assurance of availability of information of dangerous products
- Decision making on danger of products

Rising at the legislative level of liability of the manufacturer (seller) for conformity of products to obligatory requirements and impartiality in taking of conformity declaration

Division of liability within conformity assessment
CLASSIFICATION OF PRODUCTS

SAFETY

--- complex technical property of products

On the basis of its scope of use

Is determined

by a complex of simple indices for individual group (type) of products

Which are to be
 • established in the process of products development
 • provided in the process of manufacturing
 • supported on the following stages of the products life-cycle

ESTABLISHMENT of general and specific SAFETY REQUIREMENTS to different groups (types) of products (objects of technical regulation)

RISK

COMBINATION of negative event and its consequences

AFTER HAVING ESTABLISHED ACCEPTABLE LEVEL OF RISK, we need to pass from evaluation of negative events to specific safety requirements for products and processes of its securing and maintenance
- Assurance of guarantees of products’ quality
- Defining of liability for damage impaired by defective products
- Establishing of indemnity obligation
- Mandatory insurance of liability for products’ quality
Choice of technical regulation objects on basis of risk analysis

with regard to analysis of statistics of cases of illnesses, their causes and consequences, as well as personal injury, property damage and environment damage accidents.
Technical regulations that contain specific safety requirements

Mandatory technical regulations

New risks appear at the following stages of products life-cycle

Technical regulations, containing operational safety requirements

Risks are reducing (eliminating) at the stage of development, new risks do not appear at the following stages

Problems:
Formation of risk analysis methodology for the purpose of comprehensive description of technical regulation safety requirements
PROBLEMS in DEVELOPMENT of TECHNICAL REGULATIONS

Harmonization of the developed technical regulations with the International and European requirements

Concentration in technical regulations of all the safety requirements concerning this object of regulation

Incl. sanitary, veterinary and phytosanitary requirements

Step-by-step exclusion of duplication of conformity attestation in different obligatory systems

Removal of duplication and contradictions between documents of different authorities – Ministry of Health, Ministry of Emergency Situations, Ministry of Architecture and Civil Engineering

Difficulties for manufacturers and importers
STANDARDIZATION

Full member

International Organization for Standardization
International Electrotechnical Commission

Affiliated member

European Committee for Standardization
European Committee for Electrotechnical Standardization

Level of harmonization of the adopted standards: about 70%

Main problem: is the translation of international and regional standards into the Russian language
REALIZATION of TECHNICAL REGULATION REQUIREMENTS

SIGNIFICANT TECHNICAL REGULATION REQUIREMENTS

Requirement 1

Requirement 2

...

Requirement i

SPECIFIC STANDARDS REQUIREMENTS

Requirement 1.1

Requirement 1.2

...

Requirement 1.n

Requirement 2.1

Requirement 2.2

...

Requirement 2.n

Requirement i.1

Requirement i.2

...

Requirement i.n

Problem:

Evaluation of sufficiency of the requirements establishing in standards in order to ensure the presumption of conformity
SELECTION OF CONFORMITY ATTESTATION PROCEDURES

Risk

Zero  Statement of compliance  Testing  Product certification  Quality management system assessment  Conformity attestation
APPROACH to CONFORMITY ATTESTATION

Choice of adequate measures for conformity attestation

Problems:

Development of the horizontal document, establishing (subject to risk analysis) general schemes of conformity attestation for all the objects of technical regulation for further use of them in the specified technical regulations

Use of EC modular approach in practice is awkwardly. This model may be used where there are clear recommendations for choice of the specific module

| Strengthening of liability of economic operators at all stages of products’ circulation |
| Liability insurance of economic operators |
| Transition to market surveillance |
Questions:

Development of risk analysis methodology in case of non-use or absence of standards, providing the adequate presumption of conformity to essential requirements of technical regulation

General requirements to technical documentation execution during conformity attestation to essential requirements of technical regulation on the basis of risk analysis
CONFORMITY ATTESTATION

Recognition of the results of conformity attestation

Signing of bilateral and multilateral agreements on recognition of test results

Trade facilitation
Access of safe products to market
Reduction of excess load on business
Phased transition from pre-market surveillance to market surveillance

Requirements for the system of exchange of information of dangerous products which is similar to the RAPEX European system

Creation of system for analysis and record of personal injury, property damage and environment damage accidents
THANK YOU FOR YOUR ATTENTION!