SINGLE REGULATION OF THE EAEU MARKET

Valery Koreshkov
Member of the Board, Minister for Technical regulation
Eurasian Economic Commission
Establishment of optimal requirements for ensuring the necessary safety level

Elimination of unnecessary regulation and reducing the burden on business

2011-2017

44 EAEU TRs adopted
36 EAEU TRs came into force
15 EAEU TR drafts and
draft amendments to EAEU TRs under development

List of standards to EAEU TRs:
approved to 36 EAEU TRs
not required to 2 EAEU TRs under development to 6 EAEU TR

Set of documents ensuring the establishment of requirements:

- Procedure for maintenance of the common list of products
- Plan of development and making amendments to EAEU TR
- Rules for development, adoption, amending and cancelation of EAEU TR
- Procedure for development, adoption, amendments for list of standards
- Recommendations to content and typical structure of EAEU TR
- Standard conformity assessments schemes
- Common Form of conformity assessment documents
- Unified rules for formation and maintenance of registers
- Rules for import of products

International requirements of WTO, CODEX Alimentarius, ISO, IEC, GHS, OECD, EU regulations and directives taken into account developing EAEU TRs
Technical regulation development

2016 г.
01.09.2017
Fish and fishery products

01.01.2018
Liquefied petroleum gases
IMDG Code (the International Maritime Dangerous Goods)

01.03.2018
Restrictions of dangerous substances in electrotechnics
Directive 2011/65/EU

18.04.2018
Attractions
EN 13814-2004

02.06.2021
Mineral fertilizers
Regulation EU №2003/2003

2017
17.11.2018
Equipment for children’s playgrounds
EN 1176-1, 1176-2, 1176-3, 1176-5, 1176-7

01.01.2019
Prepackaged drinking water
Directives 2009/54/EU, 2003/40/EU, 98/83/EU

01.01.2020
Equipment for fire safety and fire fighting

02.06.2021
Chemical products
GHS (Globally Harmonized System of Classification and Labeling of Chemicals)

Flammable natural gas prepared for transportation

Oil prepared for transportation

DRAFTS
Standards are the main mechanism that increases effectiveness of implementation of unified technical regulations

APPROVED lists of standards

APPROVED development programs of intergovernmental standards to:

- EAEU TRs: 36
- EAEU TRs: 32

Priority for inclusion of standards developed on the basis of international and regional requirements

On the basis of UNECE documents:
- Wheeled vehicles, agricultural machinery: 10
- Products for children and adolescents, toys, machinery and equipment, fuel, personal protective equipment, food products: 192

On the basis of IEC documents:
- Electrotechnics, toys, machinery and equipment, equipment for work in explosive environments: 211

On the basis of EN documents:
- Packaging, products for children and adolescents, toys, perfumes and cosmetics, machinery and equipment, fuel, light industry products, personal protective equipment, electrotechnics, food products: 272

On the basis of ISO documents:
- Updated: 3
- In the process of updating: 13
- Amended: 2
- Approved: 36
Safety of wheeled vehicles

23 UNECE Rules
- Environmental safety: 14
- Active safety: 3
- Passive safety: 3
- Other safety requirements, incl. to components: 3

112 UNECE Rules
- Environmental safety: 67
- Active safety: 16
- Passive safety: 22
- Other safety requirements, incl. to components: 7
Systems of vehicle electronic passports, passports for self-propelled machines and other machines

Agreement on Introduction of Single Forms of Vehicle Passports (Carriage Frame Passports) and Self-Propelled Machines Passports, and Creation of the System of Electronic Passports, signed on August 15, 2014

Administrator of the systems of vehicle electronic passports (carriage frame passports), passports for self-propelled machines and other machines – JSC “Electronic passport"


- Environment
- Insurance, Road accidents registration
- Economy, analytics
- Utilization
- Maintenance, inspection, repair
- Parking, passes, authorizations
- Whole Vehicle Type Approval (WVTA)

EEC The EURASIAN Economic Commission
Conformity Assessment

TREATY ON THE EURASIAN ECONOMIC UNION
uniformity of rules and procedures of conformity assessment

common rules, schemes and procedures of conformity assessment:

**STANDARD SCHEMES**

of conformity assessment

**DEVELOPED**: on the basis of laws of EAEU Member States using international practice ISO/IEC 17067:2013 and approaches adopted in the EU DECISION № 768/2008/EC

**ESTABLISH**: uniformity and equivalence of conformity assessment procedures

**FACILITATES**: reducing technical barriers through confidence in applied conformity assessment procedures.

**common documents of conformity assessment**

**common forms of certificates of conformity and declarations of conformity**

**common form of certificate of state registration of products**

Common mark of circulation of products on the EAEU market:

**Eurasian Conformity**
State control (surveillance) over compliance with requirements of the Union’s Technical regulations is carried out by order established in legislation of the Member-States.

On principles and approaches to implementation of state control (surveillance) over compliance with requirements of technical regulations of the Eurasian Economic Union in order to harmonize legislation of EAEU Member-States in this sphere.

Agreement

- Treaty on the Eurasian Economic Union (Section X, Article 53, cl. 4)
- Directives
- Regulations
- Standards

Directives
- № 2001/95/EU
- № 89/686/EEC
- № 93/15/EEC
- № 765/2008
- ISO 31000
- GOST R 51901-1-2002

Development of documents on the basis of international norms and best practices

- ICSMS
- RAPEX

Alerting system for unsafe products

- Procedure for cooperation between state control (surveillance) bodies of the Union Member-States
- Procedure for cooperation between state control (surveillance) bodies and customs authorities of the Union Member-States
- General principles and approaches to withdrawal and recall of products
- Appliance of the risk-oriented approach in the organization of state control (surveillance) over compliance with requirements of technical regulations of the Union

State control (surveillance) procedures
Creation of the system for information exchange and cooperation

Principles and approaches for creating a system of traceability of products that ensures their legality and security

Organizing interaction of state control bodies of the Member States at all stages of the product life cycle

Responsibility of interaction between authorized bodies

Creating of mechanisms for settling disputes (disagreements) on the results of state control in Member States

Information exchange in identifying products that do not comply with the requirements of technical regulations

Mutual consultations and negotiations on disputable issues
Regulation of the common market of medicines

Treaty on the Eurasian Economic Union of May 29, 2014
Agreement on Common Principles and Rules of Medicinal Products Circulation in the EAEU of December 23, 2014

- Marketing authorization and assessment rules
- Labelling requirements
- Requirements to instruction
- OTC Criteria
- Dosage Form Nomenclature
- Drug Registry and Information Databases
- Drug Expert Committee
- International catalogue of notions and definitions
- Concept of harmonization of pharmacopoeas
- GCP rules
- GLP rules
- Bioequivalence rules
- Research rules for biological medicines
- GMP rules
- GDP rules
- Certification and the register of certified qualified personnel
- Quality system of pharmaceutical inspectorates (QSPI)
- Rules and procedure of pharmaceutical inspections
- Register of inspectors
- Identification of out of specification medicines
- GVP rules

Developed on the basis of international norms and best practices of OECD, Council of Europe (EDQM), WHO, ICH, PIC/S

2017-2019 – development of “third level” acts

in the field of manufacturing of medicines; requirements for plant and homeopathic medicinal products; nonclinical and clinical study; specific issues of circulation of medicines
<table>
<thead>
<tr>
<th>Type of practice</th>
<th>Medicines</th>
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<tbody>
<tr>
<td>Good Laboratory Practice (GLP)</td>
<td>Decision of the EEC Council of November 3, 2016, № 81</td>
</tr>
<tr>
<td>Good Clinical Practice (GCP)</td>
<td>Decision of the EEC Council of November 3, 2016, № 79</td>
</tr>
<tr>
<td>Good Manufacturing Practice (GMP)</td>
<td>Decision of the EEC Council of November 3, 2016, № 77</td>
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<td></td>
<td>*Comes into force on January 1, 2021</td>
</tr>
<tr>
<td>Good Distribution Practice (GDP)</td>
<td>Decision of the EEC Council of November 3, 2016, № 80</td>
</tr>
<tr>
<td></td>
<td>Comes into force on April 26, 2018</td>
</tr>
<tr>
<td>Good Pharmacovigilance Practice (GVP)</td>
<td>Decision of the EEC Council of November 3, 2016, № 87</td>
</tr>
</tbody>
</table>

Developed on the basis of best international practices

OECD, ICH, EMA
Good Laboratory Practice

EEC
The EURASIAN Economic Commission
EAEU GLP

Regulates the nonclinical stage of MD development

On the basis of the OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring:

- Principles of Good Laboratory Practice,
- Guidelines for procedures for monitoring of compliance with the GLP principles
- Guidelines for conducting inspections of investigational plant and studies audits
- The application of GLP principles to computerized systems
- Quality assurance (QA) in accordance with the GLP principles,
- Applying the GLP principles to short-term studies
- The role and responsibilities of the research manager in accordance with the GLP principles,
- The role and responsibilities of the research sponsor in accordance with the GLP principles
- Organization and management of studies conducted at several investigational plants
- The application of GLP principles to in vitro studies,
- Organization and maintaining of archives.
Pharmacopoeia of the EAEU

Pharmacopoeia Committee of the Union

Was created for the purpose of consideration of general and private pharmacopoeia monographs of the EAEU including veterinary drugs:

- development of the model for harmonization of Member States pharmacopoeias;
- determination of the list of pharmacopoeia standards of the EAEU Pharmacopoeia;
- Development of draft EAEU Pharmacopoeia for the EEC consideration;
- determination of the types and mechanisms of harmonization of requirements of pharmacopoeia monographs;
- drafting guidelines for the development and harmonization of pharmacopoeia monographs;

Information about the Pharmacopoeia of the Union and the Pharmacopoeia Committee of the Union are included in the INDEX OF WORLD PHARMACOPOEIAS and PHARMACOPOEIAL AUTHORITIES WHO.
Regulation of the single market of medical devices

Treaty on the Eurasian Economic Union of May 29, 2014
Agreement on Common Principles and Rules of Circulation of Medical Devices in the EAEU of December 23, 2014

- The rules of MA and assessment
- General requirements for safety, labeling and efficacy
- Registers and informational bases
- Rules for technical tests of MD
- Nomenclature of Medical Devices
- Classification of MD according to the degree of risk
- Special certification mark for MD
- Rules for safety, efficacy and quality monitoring
- List of standards for safety assessment and rules for its formation
- Rules for clinical and laboratory studies
- List of MDs classified as measuring instruments

2017-2019: development of “third level” acts criteria and classification; issues of inspection; assessment of safety, efficacy, quality; document on the structure of the MA dossier
Architecture of information systems in the sphere of circulation of medicines and medical devices

Stakeholders

- Manufacturers
- Authorized organizations
- Commission staff and authorized bodies
- Consumers

INTEGRATIONAL SEGMENT OF THE COMMISSION

INTEGRATED SYSTEM

National system of AB of the Member State

Applicants

Receiving information

Provision of information
Risk assessment in the EAEU to ensure safety of products

- Treaty on the Eurasian Economic Union of May 29, 2014
- Common sanitary-epidemiological and hygienic requirements for products subject to sanitary-and-epidemiological surveillance
- Decision "On the equivalence of sanitary, veterinary and phytosanitary measures and carrying out risk assessment"
- Agreement of the Customs Union Member States on elimination of technical barriers to mutual trade with a number of other states

Products put into circulation in the territory of the Union should be safe

Safety - there is no unacceptable risk associated with the possibility of causing harm and / or damage

The risk to life and health is a criterion for the proper level of sanitary and phytosanitary protection of the population

Risk should be taken into account when substantiating product safety

✅ There has been developed methodology of risk assessment for the health of the population under the influence of chemical, physical and biological factors, for the determination of safety indicators of products (goods), based on harmonized principles of risk assessment and relevant scientific data. It develops and complements existing approaches.

The methodology was included in the OECD report on consumer product safety as one of the world's practices.

Application of the human health risk assessment methodology

An estimation of health risk in the Republic of Belarus was carried out regarding potential excessive intake of iodine with mass food products.

The absence of unacceptable risks for the humans has been proved.

In the Republic of Belarus, an assessment of the validity of the content of nitrites in food, was carried out according to the criteria for the health risk of individuals with high levels of consumption of sausage products.

In aggravated consumption scenarios, unacceptable health risks are established. Recommendations for dietary regimens for risk groups have been developed.

In the Russian Federation, the content of ractopamine in foods is not allowed. Similar standards exist in China and the EU countries (more than 60 countries).

It has been discovered that when taking ractopamine with food products at the level of residual amounts, recommended by the Codex Alimentarius Commission, with actual consumption, it will lead to an unacceptable life-threatening risk of cardiovascular disease (Risk = 0.47) and a decrease in the projected life expectancy of the Russian Federation.

Коломиец Н.Д. и соавт. // «Гигиена и санитария» 2016, T 95, № 5  
Kolomiets N.D. // "Hygiene and sanitation" 2016, V. 95, № 5

E.V. Fedorenko // "Analysis of Risk to Health", 2015, No. 3

Onischenko G.G., Popova A.Yu., Tupelian etc., Newsletter of the Russian Academy of Medical Sciences, 2013, No. 6
To date, the following steps have been completed

- Harmonized principles for the determination of food safety have been identified
- Common requirements to the initial information for establishing hygienic standards (MRLs of chemical contaminants and biological agents in food products)

Gradual steps are being considered (taking into account the EU experience) to create systems of international independent audit to ensure arbitration, objective resolution of conflicts in the field of product surveillance and simultaneous growth of the authority of the EEC as a coordinating supranational body.

Creation of a single information base containing results of the systems of national control of product safety, based on the history of violations, the creation of a bank of "risk profiles" of products, risk factors, technologies and manufacturing countries, and subsequently – individuals manufacturers.
Regulatory documents in the field of quarantine phytosanitary measures

Prepared on the basis of international standards, best practices and scientific evidence

The IPPC, WTO-SPS, IPPC international standards

Treaty on the EAEU of May 29, 2014
(p. 3, Article 59 and p.18-20,24 of the Annex No. 12)

9 acts of the Commission:
(8 Council's Decisions, 1 Board’s Decision)

8 COMMON DOCUMENTS
The list of regulated products
◇ The unified list of quarantine objects of the Union ◇ The unified quarantine phytosanitary requirements
◇ The unified rules and regulations for ensuring quarantine of plants
◇ The procedure for laboratory support of phytosanitary measures
◇ The procedure for carrying out phytosanitary control
◇ The requirements for phytosanitary control posts ◇ The Procedure for interaction of the competent authorities for introduction of temporary SPS measures
Regulatory documents in the sphere of veterinary and sanitary measures

Developed on the basis of international standards and best practices and scientific justification

The OIE Terrestrial and Aquatic Animal Health Codes, the WTO Agreement on SPS measures, the OIE international standards

Treaty on the EAEU of May 29, 2017
(Article 58 and Annex N12)

14 COMMON ACTS

- the common list of products subject to veterinary surveillance (control)
- the common veterinary requirements to products subject to veterinary surveillance (control)
- the common veterinary (veterinary-sanitary) requirements for facilities subject to veterinary control;
- the common procedure of veterinary control on the customs border of the Union and custom territory of the Union
- the common procedure of joint inspections of objects subject to veterinary control
- the common forms of veterinary certificates
- the order of interaction of Member -States in animal diseases control
- the rules on laboratory studies in the implementation of the veterinary control (surveillance);
- position on coordinated approaches for the identification, registration and traceability of animals and animal products;
- the rules of the Union regulating the circulation of veterinary medicinal, diagnostic, disinfection, dissection and desacarisation products and feed additives within the customs territory of the Union (4 acts);
- the procedure of interaction of the authorized bodies of Member -States for introduction of the temporary SPS measures;
Cooperation of Eurasian Economic Commission with:

- **MoU of cooperation**
- **MoU of Understanding**
- **Observer status**

**Application of Interstate Standards for implementation of requirements of the EAEU technical regulations** (EEC Board Decision of 18.10.2016, № 161)

**Roadmap for cooperation on technical regulation and standardization** (Draft)

**Roadmap for cooperation on technical regulation and standardization** (Draft)


**Programme of cooperation for 2016-2020** (Directive of the EEC Board of 06.12.2016, No. 198)

**Prospects for 2018**

- **MoU of Understanding between EEC and ISO**
- **Agreement between EEC and EDQM**
- **Getting an observer status with ICH**
- **MoU between EEC and ASTM**
Information cooperation

**Common registers:**
- Certificates of conformity and declarations of conformity;
- Certification bodies and testing laboratories;
- Authorized bodies and organizations, carrying out registration of electronic passports of vehicles.

**Under development:**
- Whole Vehicle Type Approval (WVTA,)
- Individual vehicle safety certificate;
- RAPEX;
- Exchange of information in the field of ensuring the uniformity of measurements.
Thank you for attention!

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