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UNIFIED TECHNICAL REGULATION

A unified system of technical regulation in the EAEU is a core element of the safety of products throughout their life cycle. The system itself has been developed so that to remove technical barriers to mutual trade, to protect the domestic market from unsafe products, and to improve the quality and competitiveness of goods manufactured.

48 regulations have been adopted in the EAEU, 43 of which came into force
ENSURING GENERAL SAFETY OF PRODUCTS IN THE EAEU MARKET

THE RULES AND PROCEDURE FOR ENSURING SAFETY AND CIRCULATION OF PRODUCTS, THE REQUIREMENTS FOR WHICH ARE NOT ESTABLISHED BY THE EAEU TECHNICAL REGULATIONS

Signed on February 3, 2020

Based on Directive 2001/95/EC on general safety of products

Mandatory requirements for products in the EAEU TR

I. National mandatory requirements of the Member States

II. There are no mandatory requirements in the national legislation

Monitoring of the safety of products in the EAEU Member States, including collection and analysis of information about any cases of harm.

Ensuring the exchange of information about unsafe products between the EAEU Member States.

Technical regulation in the EAEU applies to three linked areas as well as include legal regulation in the following fields:

» establishment, application and implementation of mandatory requirements for products, production processes, installation, adjustment, operation, storage, transportation, sale and disposal;

» standardization and voluntary application of standards to comply with the mandatory requirements;

» conformity assessment of products to the requirements of the EAEU technical regulations.

Technical regulations are developed for products in the Single List only. Their preparation is an open procedure, so that any entrepreneur is welcome to send his proposals during the public discussion period.

THE EAEU LEGAL FRAMEWORK FOR TECHNICAL REGULATION

TREATY ON THE EURASIAN ECONOMIC UNION DATED MAY 29, 2014

Section X of the Treaty
“TECHNICAL REGULATION”

Protocol No. 9 ON TECHNICAL REGULATION

Protocol No. 10 ON IMPLEMENTING AN AGREED POLICY IN THE FIELD OF THE UNIFORMITY OF MEASUREMENTS

Protocol No. 11 ON THE ACCEPTANCE OF ACCREDITATION RESULTS OF CONFORMITY ASSESSMENT BODIES

COMMON REQUIREMENTS

» The Single List of products for which mandatory requirements are established (67 items)

» The EAEU technical regulations

» Common lists of standards to the EAEU’s TRs, including rules and methods of research (testing)

» Standard schemes of conformity assessment

» The Unified Register of Conformity Assessment Bodies and Testing Laboratories

COMMON PROCEDURES

» Application of legal units of measurement

» Standard forms of conformity assessment documents

» The Unified Register of Certification Bodies and Testing Laboratories

» Mutual recognition of the results of work to ensure the uniformity of measurements

13
TRs planned by the EAEU

27
amendments planned

43
EAEU TRs entered into force

48
EAEU TRs adopted

Removal of technical barriers to mutual trade

Possibility of cooperation and export development

Creation of conditions for the production of innovative goods
STANDARDIZATION

Standardization is a key element necessary for the efficient implementation of the technical regulation system. Interstate standards for technical regulations are necessary for the full implementation of the established requirements, ensuring a high technical level of manufactured products and increasing their competitiveness.

Each technical regulation is supported by lists of standards that allow for the compliance with its requirements and contain rules and methods of product conformity assessment.

MODERN STANDARDS AS THE BASIS FOR DEVELOPING MUTUAL TRADE WITH THIRD COUNTRIES

To date, the Lists of Standards (over 12,000 items) applicable to 42 EAEU technical regulations have been approved.

1,270 are based on ISO documents
- Perfumery products and cosmetics
- Personal protective equipment
- Toys
- Electrical engineering
- Machinery and equipment
- Consumer goods
- Fuel
- Food products
- Products for children and adolescents
- Packaging

315 are based on CEN/CENELEC documents
- Machinery and equipment
- Products for children and adolescents
- Toys
- Food products
- Personal protective equipment
- Fuel

915 are based on IEC documents
- Machinery and equipment
- Equipment for explosive environments
- Electromagnetic compatibility

143 are based on the UNECE documents
- Wheeled vehicles
- Agricultural machinery

TREATY ON THE EURASIAN ECONOMIC UNION DATED MAY 29, 2014

About 12,000 items out of them are GOSTs

42 EAEU TRs approved

The lists of standards include

The programs include

Programs of CIS GOST development for

Council of Heads of Standardization Bodies

Armenian National Institute of Standards
State Committee for Standardization of the Republic of Belarus
Committee for Technical Regulation and Metrology of the Republic of Kazakhstan
Standardization and Metrology Center of the Kyrgyz Republic
Federal Agency for Technical Regulation and Metrology of the Russian Federation

The Council’s Core Functions are as follows:
- Assistance to state (national) bodies in the elaboration and implementation of coordinated activities aimed at improving the standardization development within the EAEU.
- Definition of the strategy, areas and prospects of standardization development in the EAEU.
- Priority on the development (revision) of interstate standards, including those prepared on the basis of international and regional standards, and their inclusion in the lists of standards for the EAEU technical regulations.
- Development of efficient mechanisms for the implementation of coordinated activities in the field of standardization by the Member States, including advanced standardization to ensure the manufacturing of innovative and high-tech products across the Member States.
CONFORMANCE ASSESSMENT SYSTEM IN THE EAEU

As of October 8, 2020, the Unified Register of Conformity Assessment Documents contained information about 1,109,729 issued certificates of conformity and 6,302,412 registered declarations of conformity.

Conformity assessment means direct or indirect determination of compliance with requirements imposed on the object of technical regulation. One of the fundamental principles of technical regulation is the uniformity of rules and procedures for mandatory conformity assessment.

In the EAEU, the unity of the rules and procedures for conducting mandatory conformity assessment is ensured.

The assessment of manufactured products’ conformity with the Union’s technical regulations takes place before their release into circulation.

Release into circulation means delivery or import of products (including shipment from the manufacturer’s warehouse or without warehousing at all) for distribution in the Union as part of commercial activities carried out free of charge or for a fee.

Conformity assessment is carried out in the forms of registration, testing, conformity assessment, examination, and others. Forms, schemes and procedures for conformity assessment are established in the technical regulations of the EAEU on the basis of standard conformity assessment schemes approved by the Commission.

To date, 80% of the adopted technical regulations of the EEU envisages conformity assessment of products in the form of declaration.

Products that meet the requirements of the technical regulations and have passed the established conformity assessment procedures are marked with the common mark of circulation in the EAEU Market. The “EAC” abbreviation can be written in Cyrillic or Latin characters. It is placed on a light or contrasting background, and their color should be different from that of the color on the package. The mark must be square (with a side of at least 5 mm) and distinguishable throughout the lifespan of products.

EAC, common mark of circulation in the EAEU market. It stands for Eurasian Conformity

COMMON FORMS OF CONFORMITY ASSESSMENT DOCUMENTS
ENSURING COMPARABILITY AND TRACEABILITY OF TEST RESULTS

ACREDITATION IN THE EAEU

Accreditation is one of the main elements that build trust in the results of the work carried out by the conformity assessment bodies.

Accreditation of the conformity assessment bodies is carried out by the accreditation bodies of the member States, authorized in accordance with the legislation of the member States to carry out this activity.

Goals
- Building trust in the accredited conformity assessment bodies.
- Taking measures to prevent the issuance of unsubstantiated conformity assessment documents and increasing the level of responsibility of conformity assessment bodies.
- Conducting on an ongoing basis mutual comparative assessments of accreditation bodies in order to achieve the equivalence of the applied procedures.
- Development of mechanisms for maintaining the Unified Register of Conformity Assessment Bodies of the EAEU.
- Adoption of rules on accreditation based on international standards.
- Application of interstate standards in the field of accreditation.

Council of Heads of Accreditation Bodies

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<tr>
<th>Armenia</th>
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<th>Kazakhstan</th>
<th>Kyrgyzstan</th>
<th>Russia</th>
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<td>National Center of Accreditation, Committee for Technical Regulation and Metrology of the Republic of Kazakhstan</td>
<td>National Center of Accreditation of the Kyrgyz Republic</td>
<td>Federal Service for Accreditation of the Russian Federation</td>
<td>EEC</td>
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Over 850 accredited certification bodies and 2,500 test laboratories are included in the Unified Register of the EAEU
STATE CONTROL (SURVEILLANCE) IN THE EAEU

State control (surveillance) over compliance with the requirements of technical regulations of the EAEU is carried out according to the procedure established by legislation of the Union Member States, and is currently exercised by 27 authorized bodies. The key objective is to ensure the coordination of actions taken by the Union’s authorized state control bodies, aimed at preventing the release into circulation and circulation on the Union’s market of products that do not meet the requirements of technical regulations. Principles and approaches to harmonization of legislation of the Union States in the field of state control over compliance with the requirements of technical regulations of the EAEU are determined by the international treaty within the EAEU.

A pilot project is underway to create an information system, so that to facilitate faster decision-making in respect of the products that do not meet the requirements of the Union’s technical regulations. It is aimed at testing the coordination of actions taken by the EAEU Member States’ control bodies.

Key Functions of the Council of Heads of Accreditation Bodies of the EAEU Member States

» Definition of the strategy, areas and prospects of accreditation development.
» Formation of efficient mechanisms for the implementation of accreditation development areas.
» Decision-making on the results of mutual comparative assessment performed by the accreditation bodies and on the efficiency of corrective actions taken.

Unified Register of Conformity Assessment Bodies of the EAEU

The criteria for inclusion in the Unified Register of Conformity Assessment Bodies of the EAEU are established by the procedure approved by Decision No. 100 of the EEC Council dated December 5, 2018.

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COMMUN MARKETS FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

By the end of the transition periods — the end of 2025, the rules of production and authorization of medicinal products and medical devices on the EAEU territory should be fully unified. This will reduce administrative costs for manufacturers, and patients will have access to modern, safe, high-quality and effective medicinal products and medical devices.

The transition to common markets for medicinal products and medical devices is carried out in stages, thus helping entrepreneurs to better adapt to a new environment.

In the field of medicinal products circulation, all applicants have the right to choose between national or the Union’s rules of marketing authorization until December 31, 2020. At the same time, the master file of pharmaceuticals that have been authorized in line with national regulations should be brought into compliance with the EAEU regulations until December 31, 2025.

In the field of medicinal products circulation, the transition period will end on December 31, 2021, then authorization of medical devices will be carried out according to the Union’s guidelines only.

In 2020, the work continued on preparation of draft guidelines and requirements on circulation-specific issues, providing for common approaches within the framework of the EAEU in the field of production and research of pharmaceuticals; as well as new general and private monographs have been prepared for subsequent releases of the Pharmacopoeia of the EAEU.

The first part of Volume I of the EAEU’s Pharmacopoeia, which includes general pharmacopoeia monographs about general information on the application and methods of pharmacopoeial analysis, methods of biological and microbiological testing, reagents, devices and apparatus for quality analysis of both already marketed and new medicines that are still under development, is the most important document adopted in 2020. The Pharmacopoeia will be the backbone of a unified approach to assessing the quality of medicinal products in the EAEU. The document will come into effect on March 1, 2021.

Manufacturers of pharmaceuticals previously authorized in the EAEU common market have been given a 5-year transition period — until January 1, 2026 — to bring their regulatory documents on quality of medicinal products in line with the Pharmacopoeia of the EAEU.

First Results of the Single Market

As of December 2020

- More than 500 applications submitted under the unified rules of authorization of pharmaceuticals in the EAEU market, and more than 80 authorization certificates entered into the Unified Register of the Authorized Pharmaceuticals.
- More than 50 applications submitted for the authorization of medicinal products under the EAEU common rules.
- More than 200 applications submitted for pharmaceutical inspections, and more than 40 pharmaceutical inspections of medicinal product manufacturers completed with 35 GMP certificates of the EAEU issued.

MARKET OF MEDICINAL PRODUCTS AS PART OF AGREEMENT IMPLEMENTATION
Legal Framework in the Field of Medicines Market Regulation: Sublaw Documents

8 general documents
- Labeling requirements
- Requirements for patient’s package leaflet and SMPC
- Authorization and assessment rules
- Criteria for OTC pharmaceuticals
- Nomenclature of dosage forms
- Expert Committee on Medicinal Products
- Reference book of terms and definitions

65 REGULATIONS

26 decisions by the Commission’s Council

27 recommendations by the Commission’s Board

37 DOCUMENTS

Safety
- GLP guidelines
- GVP guidelines

Efficacy
- GCP guidelines
- Rules of bioequivalence
- Rules for conducting studies of biological medicinal products

Control and assurance of the quality of pharmaceuticals
- GMP Rules
- GDP Rules
- Certification and Register of Qualified Persons
- Pharmaceutical Inspectorate (PI) Quality System
- Rules and procedure of pharmaceutical inspections
- Register of Inspectors
- Pharmacopoeia Harmonization Concept
- Pharmacopoeial Committee
- Interaction to identify substandard medicinal products

Changes in the Regulatory Classification of Medicinal Products

PREVIOUSLY

- Original
- Immunobiological
- Generic

CURRENTLY

- Biological
- Chemical synthesis
- Grandma’s drugs

- Original
- Generic
- Hybrid
- Reference
- Biosimilar
  - essentially similar
  - adequately similar
- HIP pharmaceuticals
- Homeopathic pharmaceuticals
- Herbal pharmaceuticals
SPS MEASURES: GUARDING SAFETY AND HEALTH

SPS measures are mandatory sanitary, veterinary and phytosanitary measures and procedures.

Goals of SPS measures:

» protection of human life and health from risks arising from diseases borne by animals, plants or products thereof;

» protection of life and health of humans and animals from risks arising from additives, contaminants, toxins or pathogens in food, beverages, feeds and other products;

» protection of life and health of animals and plants from risks arising from penetration, rooting or spread of plant pests, agents of plant and animal diseases, weeds, vectors or pathogens of quarantine importance for the Member States;

» prevention or limitation of other damage caused by penetration, rooting or spread of plant pests, agents of plant and animal diseases, weeds, pathogens of quarantine importance for the Member States, including the cases of transmission or spread of diseases by animals and (or) plants via products, goods, materials or vehicles.

In terms of SPS measures, the EEC is working on such fundamental issues as development of regulatory acts to ensure sanitary and epidemiological well-being along with phytosanitary and veterinary and sanitary safety across the Union, scientific justification of SPS measures, weighted evaluation of relevant risks, proportionality compliance of restrictive measures, elimination of unreasonable administrative barriers in trade as well as raising the living standards of the population.

To ensure the safety of the goods imported, certain procedures to prevent pathogens and harmful substances are of key importance. These procedures are pre-market inspections, market control, or quarantine regime.

The ultimate goals of the EEC are to ensure the safety of food items and other goods, the health of humans, animals, and plants, and provide scientific justification and careful evaluation of risks in line with the proportionality of measures.

SPS measures include:

» all the relevant laws, decrees, rules, requirements, and procedures including, inter alia, end product requirements;

» processes and production methods;

» testing, inspection, certification and approval procedures;

» quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport;

» provisions on relevant statistical methods, sampling procedures and methods of risk assessment;

» packaging and labeling requirements directly related to food safety.

The Treaty on the Union defines the rules according to which the establishment and application of product safety requirements should be based on scientifically justified principles, and only to the extent necessary to protect human life and health. These principles should be implemented taking into account risk assessment.

The activities carried out by the EEC in terms of SPS measures contribute to removing barriers in the movement of goods and obtaining safe and quality goods and services. It directly depends on streamlining the requirements in this area and consumer rights protection techniques.

WITHIN THE EAEU, SPS MEASURES ARE REGULATED BY:

- General lists of products that fall under mandatory requirements
- Common requirements
- Single forms of documents confirming product safety
- Unified procedures for control and supervisory measures
**Phytosanitary Measures**

Requirements, rules and procedures, applied for the purposes of:

- protection of the Union’s customs territory from:
  - entry and spread of quarantine pests,
  - reduction of losses caused by them;
- elimination of obstacles to international trade in plant products (freights, plant materials, plant goods).

Pursuant to the List of plant products subject to phytosanitary suppression at the customs border of the Customs Union and in the customs territory of the Customs Union, approved by Decision No. 318 of the CU Commission dated June 18, 2010, 128 groups of goods shall be subject to phytosanitary suppression. 106 specific phytosanitary requirements have been developed and approved thereto. The Commission adopted 5 acts in terms of phytosanitary measures in 2020.

Since the adoption of the Common Phytosanitary Requirements (Decision No. 157 of the Eurasian Economic Commission’s Council dated November 30, 2016), about 50% of specific phytosanitary requirements for plant products and items at the customs border and the customs territory of the Eurasian Economic Union have been updated.

**Veterinary Measures**

Requirements and procedures, applied for the purposes of preventing the diseases of animals and protecting population from diseases that are common for animals and humans, due to the emerging risks, including in case of their transport or spread:

- by animals;
- with feed;
- with raw materials;
- with products of animal origin;
- by transportation vehicles that carry them within the Union’s customs territory.

In terms of applying veterinary measures, the Commission was granted powers in 14 areas of activity.

The Unified List of Goods Subject to Veterinary Control (Supervision) includes 110 groups of goods under 146 codes of the Commodity Nomenclature of Foreign Economic Activity of the Eurasian Economic Union (CN FEA of the EAEU). Controlled goods fall under the Uniform Veterinary Requirements Imposed on the Goods Subject to Veterinary Control (Supervision). The requirements include 46 chapters. The Requirements are being updated on an ongoing basis to comply with international standards, including by adopting new chapters. In 2020, the Commission adopted 8 regulations. 7 projects amending the Requirements are being developed, including 1 project for the approval of a new chapter.

47 forms of Unified Veterinary Certificates have been approved by the Commission for the import of controlled goods to the Union’s customs territory. 4 forms of veterinary certificates are applied to transport controlled goods between the Member States.

6 measures have been taken as part of the implementation of the Memorandum of Understanding between the Eurasian Economic Commission and the World Organization for Animal Health (OIE). Experts from the Department have participated in 2 events held under the auspices of the World Trade Organization.
19 groups of products (goods) are subject to the state sanitary and epidemiological surveilance (control) that includes state supervision of compliance with more than 25 technical regulations of the Customs Union (the Union).

More than 500,000 state registration certificates for goods have been issued for the goods that are subject to state registration as per the Commission’s acts.

In terms of sanitary measures in 2020, the Commission adopted 12 acts aimed for updating sanitary and epidemiological and hygienic requirements along with the list of controlled goods, approving the Rules for Implementing Common Processes in the Sphere of Information Support for Applying Sanitary Measures, and implementing risk assessment methods for the sanitary and epidemiological supervision and standardization of the amount of chemicals and biological agents in foods.

Since the very first days of the pandemic, the Council of Heads of Authorized Bodies in the Field of Sanitary and Epidemiological Welfare of the Population of the Eurasian Economic Union Member States (auxiliary body of the Eurasian Economic Union aimed at implementing an agreed and coordinated policy for sanitary and epidemiological welfare by the Union Member States) engaged in the activities to combat the spread of the new coronavirus infection (COVID-19) across the Union.

In 2020, 16 meetings of the Council of Heads of Authorized Bodies in the Field of Sanitary and Epidemiological Welfare of the Population of the EAEU Member States were held.

The Council of Heads Considered the Following Issues:

» Comprehensive Action Plan to Prevent the Spread of the Coronavirus Infection COVID-19 and Other Infectious Diseases;
» mutual informing on the epidemiological situation;
» steady cross-border supply of the Member States with necessary goods to combat COVID-19;
» coordination of preventive and anti-epidemic measures in the EAEU Member States;
» development and revision of the medical services and laboratory diagnostics algorithm in case of detected infection;
» retraining and training of medical personnel;
» vaccination;
» Russian Federation assistance to the Union’s Member States in providing equipment for laboratory diagnostics of coronavirus;
» organizational, methodological and practical assistance to the Union’s Member States;
» project “Traveling without COVID-19” aimed for creating an information system to reduce the spread of the new coronavirus infection upon cross-border movement of people during the pandemic (the EDB initiative).

KEY DOCUMENTS ADOPTED BY THE COMMISSION IN THE CONTEXT OF THE CORONAVIRUS PANDEMIC COVID-19

Order No. 6 of the Eurasian Intergovernmental Council dated April 10, 2020 “On measures taken within the Eurasian Economic Union aimed at ensuring economic stability amid developing COVID-19 coronavirus pandemic”

Order No. 16 of the Eurasian Intergovernmental Council dated July 17, 2020 “On a comprehensive action plan in the field of public health and sanitary and epidemiological welfare of the population to prevent spreading the COVID-19 coronavirus infection and other infectious diseases in the Member States of the Eurasian Economic Union”

Recommendation No. 11 of the EEC Board dated July 7, 2020 “On sanitary and epidemiological recommendations to manage “green channels (routes)” at the customs border of the Eurasian Economic Union and its customs territory in frame of the unfavorable epidemiological situation related to the spread of the coronavirus infection (COVID-19)”

Since it is currently important to develop common approaches to mitigating restrictive measures and resuming transport services and passenger traffic, Guidelines on Approaches to Resuming Railway Services in the Union’s Member States during Unfavorable Epidemiological Situation Caused by the Spread of the Coronavirus Infection (COVID-19) were developed.
CONSUMER PROTECTION

The EEC aims to provide an agreed policy of the EAEU Member States for equal conditions for citizens with respect to protecting their interests from unscrupulous practices of economic entities.

The agreed policy guarantees and protects consumer rights throughout the EAEU. It provides for:

- developing common rules and approaches to consumer rights protection in various economic sectors, including e-commerce, applied by all Member States;
- reducing the risks of dangerous goods in the Union’s common (single) market by establishing fruitful cooperation between the states;
- creating equal conditions to protect consumer rights throughout the Union;
- taking special measures to protect vulnerable consumers, including children;
- building consumer awareness mechanisms;
- converging national legislation on consumer rights protection.

Citizens of any Member State of the EAEU have the same consumer rights in other Member States as the citizens of these States. They are entitled to apply to state authorities and non-governmental organizations, including courts.

Learn where to report on violating consumer rights for goods, works and services.
Consumer Protection: Key Results in 2020

**AREAS**

- **MONITORING AND HARMONIZATION**
  - **ADOPTED:**
    - Recommendation No. 14 of the EEC Board dated September 15, 2020 on the information exchange between the Member States and the Commission in the field of consumer protection
  - **REVIEW:**
    - The composition of the EAEU Member States Advisory Committee on Consumer Protection Issues was updated (Disposition No. 173 of the EEC Board dated December 1, 2020)
  - **Two scientific researches in Consumer Protection area results were approved by the EEC (both works defended on October 30, 2020)**

- **DRAFT ACTS**
  - **PREPARED:**
    - On principles and criteria for good business practices regarding retail consumers (the Commission is to adopt this recommendation in January 2021)
    - On the Model Methodology for the Development of the EAEU Member State Program for Consumer Rights Protection (the Commission is to consider the recommendation in H1 2021)

- **STRATEGY 2025**
  - **AGREED UPON:**
    - Section 4.12 Consumer Rights Protection: 7 specific measures
      - Section 11: 2 measures to promote international cooperation (CIS, UNCTAD), including:
        - establishment of common approaches to consumer protection in e-commerce
        - further convergence of national consumer rights protection mechanisms and procedures
        - development of the Joint Action Program of the EAEU Member States aimed at protecting consumer rights and assuring quality of goods and services

- **INFORMING**
  - **OPERATES:**
    - Thematic section “Consumer Rights Protection” on the Union’s portal of open data