Chapter 12. International trade, standards and regulations

Learning objective: to show why the World Trade Organization (WTO) devotes significant attention to good standardization and regulatory practices so that standards, regulatory and conformity assessment procedure requirements don't become technical barriers to trade (examples will be provided of standards-related conflicts at WTO and the WTO position on such issues).

Issues for consideration:

- National standards policies and specifics of national regulatory regimes (EU - New Approach; USA; Russian Federation, etc.).
- Entering foreign markets (standardization, regulatory and conformity assessment requirements). National and foreign certificates of conformity (alignment of regulatory and compliance regimes, recognition of foreign certificates, issues of competence and of confidence in national laboratories abroad and in their tests/certificates, etc.).
- WTO and principles of good standardization, regulatory and conformity assessment practices (technical barriers to trade, international standards in the WTO context, international competition and standards, mutual recognition agreements (MRAs), trade facilitation, etc.). Examples of standards-related conflicts at WTO and the WTO position on such issues.
- International accreditation and confidence building (regional and international cooperation on accreditation).
- Harmonization and alignment of standards, regulations, conformity assessment procedures.

This thematic section of the model program on technical rate-setting and conformity assessment procedure is devoted to the influence of WTO's decisions on aspects of technical regulations in international trade such as the technical regulating, standardization, conformity assessment, accreditation.

By methodology this chapter is built in the form of questions and answers. The author considers this form as most clear and allowing to have a well-structured text.

I. Brief background of WTO and its requirements on technical regulating

1. What is World Trade Organization, who are its members and by which main documents it is guided in its activities?

The WTO is an international entity engaged in establishing and monitoring of the rules in international trade. WTO members are countries that are represented by their respective governments and their authorized representatives, as well as separate customs territories, including a number of countries, and that are working under the same rules regarding access to the market of this customs territory and their authorized representatives.

The WTO tasks include the development of trade between countries through the establishment of fair and equitable conditions of competition, lowering tariffs and reduce other barriers in trade with the help of a reached basic agreements (their total number- 18), and numerous other documents regulating the specific matters of trade in goods and services (agreements, decisions, interpretations).

2. When and on the basis of what organization was WTO created ?

By the end of World War II, leaders of the major countries of the world, being shocked by the devastating effects of two World Wars, came to the undeniable conclusion that the alternative to war should be a system of international organizations that exist to solve via the collective intelligence political, trade and economic problems between the countries. In 1945, among other similar organizations, by United States suggested to create an International Trade Organization. These steps were completed by preparing in 1947 the text of the General Agreement on Tariffs and Trade (GATT).The agreement was signed by representatives of 27 countries, mainly Western Europe and North America. The main purpose of the establishment of the GATT was the creation of international trade rules and mechanisms of negotiation to discuss the most pressing issues related to the escalation of trade disputes with their potential transition in the beginning to the "trade wars", and then to the actual armed conflict. GATT came into effect on January 1, 1948. It served as the basis for eight very important rounds of international negotiations on the liberalization of international trade, on reducing the levels of tariffs, on the development of numerous agreements and other documents supplementing the GATT. The number of participants in the GATT also grew rapidly.

In 1994, at the end of the so-called Uruguay Negotiation Round of GATT members (1986-1994) it was decided to establish the WTO as the successor of the GATT. The WTO officially became operational on January 1, 1995. The main reasons for the decision to change the status and rename the community of the member countries of GATT were the following factors. Firstly, the GATT was not formalized as an organization with a permanent headquarters, with the presence of permanent staff. Meetings of GATT were conducted as required in various places on the initiative of its members. The requirement for compliance with the basic agreements of GATT was not binding: it allowed its non-execution or execution with reservations. The increased role of the GATT, the augmentation in the number of its members and a drastic volume increase of the technical and procedural work has led to the need for structuration it as a permanent organization, as well as the need to commit the rigid obligations compliance with the arrangements reached in the Agreements up to their legislative consolidation into legal instruments of members. Secondly, the solvable problems also have expanded dramatically. Apart from the tangible goods GATT became involved in trade problems and intangible products via works and services. Third, apart from the tariff and non-tariff customs regulations GATT more and in ever-increasing extent become engaged also in regulatory issues of non-customs barriers (in the first place - technical), which create obstacles to fair competition in international markets, as well as the trade aspects of copyright protection and intellectual property. The WTO Secretariat is located in Geneva.

In 2014 the WTO has 159 members, and their number continues to grow. Although it would seem, that there is no need for every country to join the WTO, but the existing system of trade gives certain advantages for WTO members. And not by chance that the proportion of WTO member countries in world volume of goods is constantly increasing and now stands at about 98%.

3. What are the basic functioning principles of WTO that have an impact on the problems of standardization?

In accordance with the fundamental documents of the WTO its activities are based on a number of very important principles. Among them we will comment on only those that are relevant to the subject of this section.

1) Organization and maintenance of fair competition through the negotiating process and execution of arrangements, decisions and agreements

The cornerstone of the WTO activity is the solution of all the procedural, legal and terminological issues through negotiations, often very difficult and time-consuming. Achieved with such difficulty arrangements are fixed in the form of documents of different status, and after their adoption member countries must comply with them. Of course, these documents are not permanent and can be changed or even cancelled, but again only via the negotiation process and voting.

2) Liberalization of international trade – steady reduction of justified barriers and removing of unnecessary barriers to trade.

As justified barriers are considered those customs barriers that are imposed by states in the implementation of their sovereign rights to protect economic space and economic interests. Among these barriers the most important are tariff restrictions (customs import and export duties) on import or export of various product groups. Also take place non-tariff measures. Such as the introduction of physical quotas for individual countries, the overall upper restrictions on the import, prior import permission, licensing, export subsidies, using of dumping and etc. It should be noted that the WTO considers the non-tariff measures of customs regulations as contradictory to the rules of fair market competition, and since 2005 requires a complete cessation of their use.

GATT and the WTO during their existence have achieved very significant progress. To cite just two examples. The average level of import duties in world trade fell by dozens of times and now amounts to several percent. More than half of the full nomenclature of goods is traded without imposing a duty. The trend towards further liberalization is continues at the moment.

Unnecessary barriers include barriers, which under certain conditions can be completely removed without a damage to the sovereignty of the WTO member countries. The most significant for them are technical barriers.

3) Reflection of the core requirements of the WTO Agreements in the national legislation of member countries.

The very important requirement in line with the international legal is the principle of the priority of international treaties over national law. This requirement, in fact, means that the country which declared its intention to join the WTO, should carefully study the basic requirements of the WTO Agreements, and then reflect their essence in their domestic legislation and, if necessary, to change existing laws or to developing them again.

4. What are technical barriers and why the WTO is fighting with them?

In international trade a very important principle governs - any product that is moved from one country to another must meet the requirements of the importing country. All requirements for the product are traditionally divided into mandatory, voluntary for the application and those usually assumed (without their documentary formalization).The composition of the mandatory requirements is established by the legislation of the country and that's why compliance with it is verified both for domestically manufactured goods and for imported. If there is a difference between mandatory requirements in the country of origin and the importing country, the manufacturer of the goods faces the following problems. The first – to scrutinize these requirements to the product, existing in the country of importation, it is necessary to hold an information search and analysis of its results. The second - adapt its products to the mandatory requirements of the importing country. The third - when exporting its products to various countries to create a variety of modifications of production to meet the requirements of different markets, which is due, firstly, to the

breaking of seriality (it is clear that it leads to the increase in cost, because it is one thing to make hundreds of identical products and ten parties of ten different), and secondly, to the establishment and tracking of logistics supply chain. The fourth - confirm on entry the compliance of its products with mandatory requirements of the country (sanitary, phytosanitary, environmental, technical etc.) through the procedure stipulated by the legislation of the country of obligatory conformity assessment procedures, such as research (testing), state registration, state control (surveillance), certification of conformity, declaration of conformity, inspections and so on to obtain the relevant documents for conformity assessment.

All these factors make exports very difficult because of financial and time-consuming costs; that's why the technical barriers can be comparable by significance with the tariff and other customs barriers, and often present either the insurmountable problems for imports or leads to long delays.

Historically, technical barriers appeared for the following reasons.

Each country was developing standards and technical regulations for the needs of industry and society at the national level, which not always took into account international practice. As a result the requirements for the same products could be and often actually varied in different countries. With the growth of international trade these differences have become a real problem for the manufacturing industries, especially in the major exporting countries. On the other hand, local industries quickly realized that these differences might protect them from competitive imports and therefore supported it. In general for the imported products it became harder and harder meet many diverse requirements.

Participants of multilateral trade negotiations quickly realized this. At the end, decisions worked out on these problems have been transformed in the TBT Agreement.

The agreement is intended to ensure that technical regulations and standards, as well as testing and certification procedures do not create unnecessary obstacles to trade. At the same time the mandatory requirements of regulations primarily should be based on specially developed for this purpose uniform standards. In the absence of such standards or in justified cases even if they exist in the country and now have the right to establish the required levels of protection that they consider appropriate, for example, to protect the lives and health of people, animals, plants or the environment. The agreement does not prohibit countries under certain conditions to take evidence-based reasonable measures that are necessary to ensure such protection levels, notifying in advance other market participants.

5. How exactly is solving the problem of technical barriers in the WTO?

In 1995 with the creation of the WTO came into force, among other agreements, two very important agreements, which are directly relevant to the subject of our section, namely the Agreement on Technical Barriers to Trade (TBT Agreement) and the Sanitary and Phytosanitary Agreement (SPS Agreement).These agreements help to ensure that national regulations and conformity assessment procedures to their requirements will not create unnecessary barriers to trade. Let’s consider the basic conceptual ideas of the TBT Agreement. Similar ideas are laid down in the SPS Agreement.

1) To eliminate in reasonably short time the difference in mandatory requirements for the same goods in different countries-members of the WTO, the TBT Agreement obliges them to pass on in this area to the unified international standards developed by international standardization organizations on a priority basis and taking into account the mandatory requirements.

In its turn, the SPS Agreement requires WTO members that their national measures to protect their territories with the aspects of the Agreement also will be based on international standards

and other documents, which are developed and agreed upon in international organizations such as the International Organization for Standardization in respect of technical regulations and the Codex Alimentarius Commission, the International Office of Epizootics and the International Plant Protection Convention in respect of sanitary and phytosanitary measures.

2) To eliminate the difference in procedures of the compliance WTO member states are obliged to pass on to united international documents on the procedures mainly developed by the ISO Committee on conformity assessment (CASCO) (see below).

3) Exactly on the basis of the above-mentioned international documents member countries shall develop:

- technical regulations establishing requirements for products, processes and production methods, compliance with which are compulsory (in this context as technical regulations are also considered legal documents such as laws, provisions and orders of government and governmental bodies, other legal acts concerning the scope of the TBT and SPS Agreements);
- standards and rules adopted by a recognized body that set the rules, guidance or requirements for products features or related processes and production methods, compliance with which is not mandatory;
- conformity assessment procedures.

4) Mass increasing compliance with the first two ideas of methodological unity ("requirements uniformity", "uniformity of decision-making procedures of conformity") created the basis for the gradual development of bilateral, multilateral, regional, and at the last step of international agreements on mutual recognition of conformity assessment documents in different countries between them. In the customs clearance area remain only procedures of collection of established import and export duties. The end result of the development of this approach should be a significant simplification of customs clearance procedures for goods carried from country to country thanks to mass transfer to the electronic exchange of confirming compliance documents and to electronic forms of payment of the required customs duties and thanks to sharp reduction in time and in financial cost of inspection of goods and implementation of export-import operations. In many ways, it has been already realized.

II. Standardization and technical regulation

6. Which are the principal international standardization organizations that are setting requirements ?

To recall that the most reputable non-governmental international organizations in the field of technical standardization are the International Organization for Standardization - ISO, International Electrotechnical Commission - IEC and the International Telecommunication Union - ITU. All three organizations are based in Geneva.

ISO was established in 1947 and is a Worldwide Federation of national standards bodies of more than 140 countries, about 100 of which are developing countries. ISO has published a very large number of standards relating to many types of products that do not fall into the scope of IEC activity and in the telecommunications sector, which is serviced by the International Telecommunication Union (ITU) (see below). ISO has also published a series of standards on management systems such as ISO 9000, ISO 14000, ISO 22000 and others. Website: www.iso.org.The structure of ISO also includes a very important Committee on Conformity Assessment (CASCO), under whose auspices are developed and continue to be developed standards on requirements for certification bodies, on testing and calibration laboratories, on the accreditation bodies, etc.

IEC was founded in 1906. The membership is realized through national committees IEC. Currently it counts more than 50 countries, only a small part of which are developing countries. IEC has published more than 12,000 standards in the field of electrical engineering, including electronics, magnetic equipment, electromagnetic technology, electroacoustics, energy production and distribution. Website: www.iec.ch.

ITU is the oldest intergovernmental body founded in 1865 as the International Telegraph Union, which changed its name to the present in 1934. Members are experts from government departments responsible for regulations on communications and telecommunications at the national level, industrial, scientific and manufacturing companies, broadcast authorities, regional and international organizations. It has more than 190 member states and more than 650 sector members (from the industry).ITU has published a wide range of ITU-T Recommendations, which are usually implemented, because they guarantee the ensuring of the global communicational networks coordination and provision of technical services. Website: www.itu.int.

In the area of food and health protection the work of the following international bodies is particularly important for trade, as it is recognized in the SPS Agreement:

- Codex Alimentarius Commission. Founded by the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to coordinate all work relating to food standards which is undertaken by international governmental and non-governmental organizations, to prepare and publish such standards. Composed of members from over 160 countries, representing about 95% of the population. Website: www.codexalimentarius.net.
- World Organization for Animal Health (OIE). It is an intergovernmental organization with about 160 members. It informs the Governments about the occurrence of diseases and ways of its controlling. It also harmonizes regulations and standards for trade in animals and in animal origin products. Website: www.oie.int.
- International Plant Protection Convention (IPPC).Multilateral treaty implemented by FAO. Convention is managed by the IPPC Secretariat, which is located in the FAO Plant Protection Service. Parties of the treaty are 116 governments. IPPC plays an important role in the trade as a source of international standards for phytosanitary measures. Website: www.fao / org / ag / agp / pq / en / ippct.htm.

7. Which are the basic requirements of the TBT Agreement on the use and maintenance of technical regulations?

First, members of the WTO should ensure that the access procedures to their market for products imported from another member state of WTO, correspond to similar procedures for products originating from this country or from any other member of the WTO.

Second, the WTO members shall need to introduce technical regulations that create unnecessary obstacles to international trade. They are requested to introduce regulations with minimum set of aspects, namely on aspects such as technological safety (in particular, the protection of property of legal entities and individuals, state and municipal property), the prevention of fraudulent activity (in Russia in the Federal Law № 184-FZ "On technical regulation" is used a definition – prevent actions that are misleading purchasers, including consumers), protection of human health or safety, protection of life or safety of the animals and plants; environmental protection).

The WTO members must be able to demonstrate the justification of such measures whenever another member requests. The agreement doesn't specify in detail what shouldn't be covered by technical regulations, stipulating clearly only one of these aspects - the consumer characteristics of goods. By default the countries don't have to extend the effect of regulations

to all other aspects that are not included in the above list, including the technical indicators on the interchangeability and compatibility. But in reality many countries go beyond this list. In Russia, for example, directly in the basic list are included: ensuring of energy efficiency and resource conservation (as an important aspect for the country's economy). Developed countries, Russia also, include in the scope of a regulation, as a rule, the electromagnetic compatibility of technical means in terms of ensuring the safety of the devices and equipment, ensuring the uniformity of measurements as a basis for obtaining reliable information about the required product characteristics and ensuring uniformity of labeling as an attribute of the rights of consumers to information about products and the rules for their safe use.

Third, members of the BTO should take measures on mutual agreeing and harmonization of technical regulations as far as it is possible. International standards should be used as a basis for technical regulations and therefore members of the WTO are convinced to take an active part in the development of such standards. If the technical regulation may have a significant effect on trade of other Member States and relevant international standard does not exist or the technical regulations is not based on the international standard, the WTO Member shall notify other members at early stages of a regulation development. But in any case the WTO member is obliged to give advance notice to other WTO members on the planned regulations development to ensure that the comments of stakeholders can be taken into account and the additions and changes to the technical regulations were introduced before its publication.

Fourth, technical regulations shall include a description of all necessary procedures of conformity assessment of the regulated area set via mandatory requirements.

Obviously, when there is an urgent problem relating to a threat to safety, health, environment or national security, a member of WTO can immediately introduce such measures under the condition that their reasonable explanation will be communicated to the public, explained to the WTO Secretariat and may subsequently be justified.

Because the WTO is a community of states, to ensure that technical regulations have legal legitimacy in international trade also, they need to be introduced by national government or governmental bodies, authorized by special legislation. Of course, it is acceptable the case of legal acceptance of such documents in a parliament as a higher legal form. (In Russia according to the law "On technical regulation" technical regulations may be adopted by the federal law, presidential decree, Decree of the Government of the Russian Federation, normative legal acts of the federal executive body on technical regulation, as well as through an international treaty of the Russian Federation, for example, the agreement on the establishment of the Customs Union, which provided for establishing common technical regulations operational on the territories of all members of the Customs Union).

Adopted technical regulations shall be published in such a way as to be able to be read by any interested party, as well as enter into force after its adoption after a reasonable period (not less than six months) to enable both domestic producers and exporting countries to adapt the characteristics of their products and their production methods to the document (this rule can be waived only in case of force majeure).

Technical regulations under the TBT Agreement establish mandatory requirements, mainly with respect to industrial goods, raw materials and agricultural products.

8. Which requirements the TBT Agreement imposes on conformity assessment procedures?

The TBT Agreement formulates a set of clear requirements that must be met by the WTO members while defining conformity assessment procedures (certification, declaration,

control and surveillance, testing) to met requirements of regulations or standards that are given below. The main requirements of the TBT Agreement to the conformity assessment procedures:

- Equitable access to the procedures for all WTO member countries.
- The procedures should not create unnecessary obstacles to trade.
- Payment for services should be the same both for import and for domestic products.
- Founded on requirements of international standards, guidelines and recommendations.
- WTO assistance in preparation of international documents.

All accepted conformity assessment procedures should be immediately released to allow other WTO members to get acquainted with it, and should be given sufficient time for the implementation of new or revised conformity assessment procedures to give a chance for both domestic producers and exporting countries to adapt to it .

9. For what purposes and how to apply the SPS Agreement?

The SPS Agreement applies to sanitary and phytosanitary measures, which can directly or indirectly influence international trade. Sanitary measures deal with human and animal health (including the veterinary measures also) and phytosanitary measures are related to plant health. The agreement includes the protection of fish and wild fauna, forests and wild flora, but excludes the protection of the environment.

The most important provisions of the SPS Agreement:

- discrimination between members of WTO isn't allowed
- Members are encouraged to create SPS that are harmonized with international standards, guidelines and recommendations
- Members must in the course of negotiations reach the equivalence in using SPS
- Members should create their SPS based on the assessment of the actually existing risks using international risk assessment techniques.
- Members are required to notify other members about the changes in their SPS, as well as to ensure transparency should establish appropriate public information centers.
- Members should recognize the territories, which are declared free from pests and diseases by other Member States, and to observe the status of these territories and the conditions of inspections.

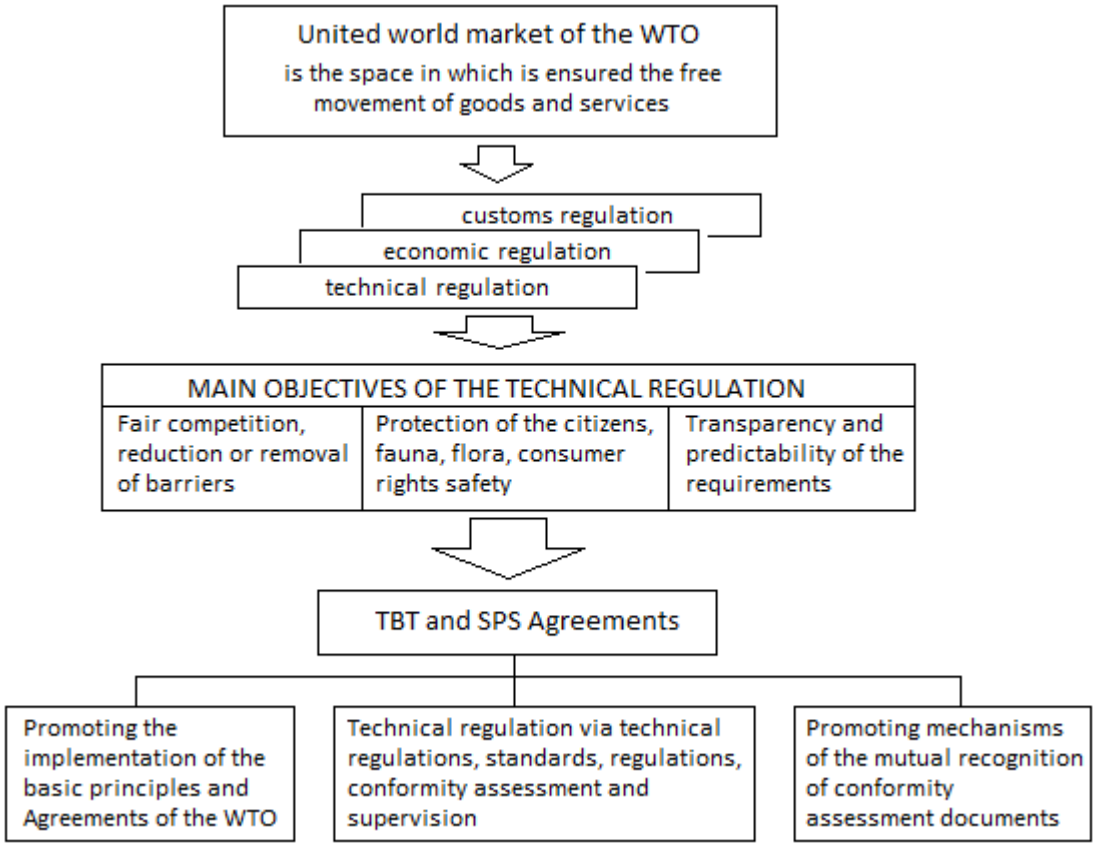
Procedures for monitoring, inspection and approval shall be based on the requirements set out in Annex C of the SPS Agreement.

10. How do the economies of WTO Members benefit from TBT and SPS Agreements?

By preparation and signing of these Agreements WTO members actually agree by consensus on the rules and regulations that must be applied on a multilateral basis (see pic. 12.1).They don't lose their sovereignty, when make a decision together with its partners on these rules, but at the same time receive a number of benefits from this approach:

- availability of information on mandatory and voluntary requirements for products and services on export markets;
- availability of information on conformity assessment procedures on export markets;
- availability of information on mandatory and voluntary requirements for products and services on export markets;

- availability of information on conformity assessment procedures on export markets;
- confidence in the official legal status and legitimacy of technical regulations;
- possibility of mutual recognition of conformity assessment procedures between the member countries of the WTO;
- availability of information about the requirements in export markets related to security of people, animals and plants;
- availability of information on the applicable in export markets sanitary, veterinary, phytosanitary and quarantine measures and required conformity assessment documents;
- confidence in the harmonization of sanitary, veterinary, phytosanitary and quarantine requirements and their control measures based on international documents and their equivalence in different countries;
- confidence in the uniformity of the conformity assessment procedures for imported and manufactured products, its reasonable sufficiency and non-discriminatory;
- possibility of mutual recognition of conformity assessment procedures between the member countries of the WTO;
- confidence in the official legal status and legitimacy of technical regulations.



Picture 12.1 – Technical regulation and the WTO

11. What are the technical regulations, standards and rules on the definitions from the different sources?

Recall some terms. According to the international ISO/IEC Guide 2:2004 “Standardization and related activities -- General vocabulary”

«**regulation** - document providing binding legislative rules, that is adopted by an authority»;

«**technical regulation** - regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice»;

«**standard**- document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context».(In this definition there is no statement that the standard is a document is exclusively voluntary application, so this term allows that the standards can be either voluntary or mandatory, depending on the decisions of the relevant national standardization systems in different countries);

«**code of practice** - document that recommends practices or procedures for the design, manufacture, installation, maintenance or utilization of equipment, structures or products».

In the annex 1 of the TBT Agreement to implement the objectives of the Agreement are given similar, but slightly different definitions:

«**technical regulation** - document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method».

«**standard** - document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method». It can be seen immediately obvious difference from the above given definition of a standard - the standards applied for the purposes of technical regulation can be only purely voluntary.

12. What is the main purpose of technical regulations and what are the main requirements for them?

Product satisfying the consumer, in any case, should be safe for his health and does not harm the environment. Therefore the technical characteristics of the product and its price, as a rule, are the criteria based on which the customer decides to buy, and the corresponding security is considered by a consumer for granted. However in the real competitive world for products the more important criterion often is the cost of production, so that they tend to reduce it to get a bigger share of the profits in the market, even at the expense of the safety of products or a potential harm to the environment.

Individual consumer rarely has the means to identify the aspects of product safety at time of purchasing and is obliges to appeal to authorities for a protection from such deficiencies. Consequently, the authorities have not only the right, but also must intervene in the affairs of the market. This intervention in order to introduce mandatory compliance of technical specifications of the product and mandatory procedures for assessing compliance with these requirements, while maintaining the voluntary for use requirements and voluntary conformity assessment procedures takes the form of a legislation called "technical regulation".

Governments or legislative bodies of different countries are developing different approaches on the use of technical regulations. In this area they can concern technical regulations and product standards or conformity assessment, or both. They can focus only on

consumer protection (safety, hygiene, health care, protection from fraud), or regulatory objectives can be wider: in the food sector, for example, along with standards for security requirements there are mandatory standards for safety management system of production.

Whatever the actual practice of formation of technical legislation in the country, development of regulations must meet the previously marked requirements set out in the TBT Agreement:

- public discussion and openness
- legal legitimacy
- transparency(information accessibility)
- argumentation
- effectiveness and expediency
- complexity
- non-discriminatory
- based on international standards and other international documents
- focus on the development.

The government can implement these requirements by different ways, and also may in any way bind the standards to technical regulations, may enter into any agreement on these issues with other countries.

In the Russian Federation an access to the adopted technical regulations is provided free of charge to any person on the websites of government organizations and in relevant public information systems.

13. Which specific requirements for a product are regulated by technical regulations?

Technical regulations can cover a wide range of product properties. The basic definition of a technical regulation given in the TBT Agreement gives some guidelines for those elements that can be used in general as part of the technical regulations.

Product characteristics

Characteristics of the production indicators of safety may include:

- requirements directly on functionality and operational characteristics, ensuring the safety of the relevant products;
- implementation requirements. There are many examples of such implementation criteria. In the field of vehicle safety usual safety criteria include requirements for the brake system, contained for example in the rules of the UN Economic Commission for Europe (UNECE) on homologation for road vehicles;
  Homologation - improvement of the object, improving the technical specifications for the purpose of conformity with any standards or requirements, obtaining agreement from the official organization.
- Requirements on design. Vessels for operation under high pressure are a good example of this type of requirements. Almost all technical regulations relating to the high pressure vessels, require that these vessels were structurally designed in accordance with certain technical conditions similar to those included in the design standards of the American Society of Mechanical Engineers (ASME) or in the relevant European standards (EN) for designing vessels;

- requirements for materials are given rarely and only in cases when without it it's difficult to define specific criteria. An example of this type of technical terms is using alloy based brass with a copper content of more than 84% for manufacturing faucets in areas requiring dezincification;
- size requirements are often fixed if compatibility is very important to ensure safety. Plugs and outlets are a good example.

Production processes

Production processes are often a subject of technical regulations, if the conformity of production to safety requirements and health safety is fundamentally determined by them. A good example is the food industry. The obligatoriness of using the HACCP methodology (Hazard Analysis Critical Control Point) imposed by many countries, requires in particular the establishment of critical control points, according to which should be made monitoring during processing shall be made to ensure that sanitary and other safety requirements for food meet the establishing requirements.

Packing

Packaging requirements cover not only the requirements, which ensure that the products arrive at their destination intact, but also mandatory requirements relating to safety and environmental protection. These requirements are established in accordance with a wide range of national standards and international rules.

Marking

A large number of mandatory requirements are shown in regulations for the labeling of products. This is related, primarily, with the right of consumers to information about the product. Each country has its own requirements for the labeling. One example of informing consumers about the carried out conformity assessment procedures is the CE marking of the European Union, indicating that this product meets the requirements of the New Approach Directives.

14. What models of technical regulations are currently applied?

It should be noted that the mandatory designation in regulations of all specific requirements regulations to ensure the safety of products (including design, manufacturing, materials, etc.) was used, for example, in the EU only until 1985 and in the Russian regulations - since the entry into force of the law "On technical regulation" in 2003 and up to 2007. After the conversion since 1985 of the EU to New Approach concept and development of the EU Directives and of national technical regulations of EU member states and the transition of Russia to a similar model in 2007 after the introduction to the law of relevant changes on specifying in regulations the specific requirements for design, manufacturing, materials shouldn't be performed except for rare justified cases. The same approach was immediately adopted by the Commission of the Customs Union to develop technical regulations of the Customs Union and the of Eurasian Economic Community.

The New Approach model provides a two-level meeting of technical regulations’ requirements: regulations contain only the most essential requirements and the specification of these requirements and the methods of their implementation are contained in the standards and rules that serve as the evidence base to demonstrate compliance with the technical

regulations requirements (corresponding lists of standards are specially selected by the time of entering regulations into force).

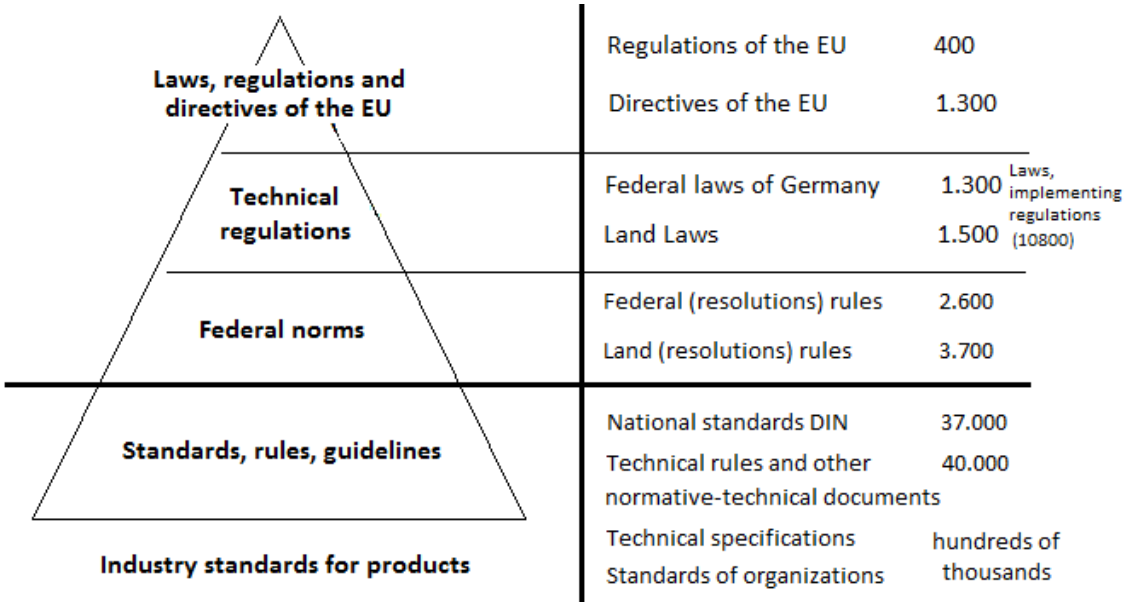
In the EU to the standards serving as the evidence base to demonstrate compliance with the requirements of technical regulations, is applied a very important requirement of its harmonization with the content of regulations. These standards are developed (or updated) in parallel with the development of regulations or with a delay not exceeding the interval between the approval of the relevant regulation and its entry into force, in such a way that the content of the standards by the time the regulations will come into force, shall fully take into account the regulations requirements and allow to shift the focus upon confirmation of product conformity with regulations requirement on demonstration of compliance with the requirements of such harmonized standards. Moreover, EU legislation sets out the responsibilities of developers of such harmonized standards regarding compliance issues. The hallmark of such standards is the presence of a special article "presumption of conformity", which states, in relation to which EU Directives and (or) specific national technical regulations (or any part thereof), this standard provides automatic compliance with requirements, and that standard developer is responsible for this compliance. This approach can significantly facilitate the conformity assessment procedure for producers and exporters of products at the expense of the inspection and test not on the requirements of regulations directly, but on requirements of clear, transparent, detailed harmonized standards. To respond quickly to possible changes of technical regulations, as well as to take into account technical progress in constructive solutions, technologies of manufacturing and test procedures of relevant products, lists of harmonized standards under specific regulations are updated and reissued annually. Application of harmonized standards is voluntary, and for the purposes conformity assessment other documents can also be used. To ensure priority in using harmonized standards in the EU in 1989 was adopted a Global Approach to conformity assessment, discussed below.

This thoughtful approach isn't used in the system of technical regulation of the Customs Union and the Russian Federation yet.

In the Customs Union because of the accumulated perennial backlog of standardization compared with the dynamic development of technical progress, the lists of standards used for the purposes of conformity assessment with the relevant technical regulations, very often include "suitable" standards, which do not really provide the required harmonization, because they are adopted before the development of regulations. To talk about automatic matching in such cases can be problematic. Moreover, not for all types of products covered by a modern technical regulation are available even just “suitable” standards, which results in such cases in the need to assess conformity assessment procedures directly from the point of meting requirements under regulations and thereby creates a significant methodological difficulties both for the manufacturers of such products and for conformity assessment bodies. Of course, accelerated efforts to remedy this situation are taking place at the moment.

The documental hierarchy of two-level model at the examples of Russia and Germany are shown in Pictures. 12.2 and 12.3.

Picture 12.2 - The hierarchy of regulatory documents in Russia



Picture 12.3 - The hierarchy of regulatory documents in Germany

Adopting of technical regulation model is a sovereign right of a country, and therefore in the world can be found many examples of conserving direct regulation concept. Incidentally, in the European Union and in the Russian Federation remain in force a number of the regulations (established under previous regulatory model), which entered into force before the adoption of the two-level model.

15. Is the quality management system a compliance requirement with technical regulations?

The answer to this question can vary in different countries as well as the requirements of their technical regulations.

In principle, the quality management system (QMS) shall require the conformity of products to mandatory requirements, including the requirements of the technical regulations. Technical regulations relate to the characteristics of products, but their compliance with these characteristics can confirm with certainty only if the manufacturing process is also under control. An inverse statement that regulations should require the presence of QMS at manufacturer, is incorrect, but many developers of regulations require the conformity with certain management systems as one of the conditions of conformity of their products with technical regulations.

In some areas, such as medical equipment, the conformity to quality management system is very important. In the US, for example, the absence of manufacturer's quality management system can result in huge fines and indirect costs. Food and Drug Administration (FDA) in the US a few years ago arranged the requirements for quality management systems of medical equipment into a so-called regulations of Quality System (QS). This regulation served as the basis for the revision of the methodology of "Good Manufacturing Practice» (GMP) for medical equipment. QS regulation has resulted in including the concept of quality management systems according to ISO 9001 in the GMP, on the basis of what was developed the standard ISO 13485: 2003 (in Russian it is a similar standard GOST ISO 13485-2004). Japan's approach to the management of the design and manufacturing of medical equipment is similar to the FDA approach. Into many regulations of Japan also were included the requirements of ISO 9001.

The EU is one of the trade zones, where the requirements for quality management are clearly stated. The resolution of the Council of Europe of December 21, 1989 states that quality management is an integral part of the process of creating trust in the conformity assessment of products covered by the EU Directives. This is followed by the definition of the various modules (the modules will be discussed below), which must be used to ensure the required level of confidence. Some modules require the manufacturer to use the QMS that meets a specific set of requirements of ISO 9001.

Sometimes there is a misunderstanding that the application of ISO 9001 is an indispensable prerequisite for trade with the EU countries. That’s wrong. If the exported products falls under the New Approach and relevant EU directives and technical regulations of the EU member states (since 1985) and under the Global Approach to the conformity assessment in the EU (since 1989), then the manufacturer has the choice between different options to meet these requirements. But if the module selected by the manufacturer requires the QMS, the conformity with ISO 9001 gives a presumption of conformity under the condition that such system takes into account the special requirements for the products for which it is intended. The conformity of the module in general doesn't require the certified QMS, although such certification facilitates the proof of compliance.

16. What are the goals of standardization and the purpose of key documents in the field of standardization?

For the sphere of technical regulation related to the implementation of requirements of the TBT Agreement, the main goals of standardization can be selected:

- increasing the level of life and health safety of citizens, property of individuals and of legal entities, state and municipal property, increasing environmental safety and security of the life and health of animals and plants;

- ensuring the competitiveness and quality of products (works, services), resource management, interchangeability of technical means, technical and information compatibility, compatibility of test results and of measurement, analysis of the characteristics of products (works, services), voluntary conformity assessment of products (works, services) ;
- promotion of compliance with technical regulations (see the answer for the next question below);
- establishing coding of technical-economic and social information classification systems, quality assurance of products (works, services).

The structure of the documents in the field of standardization taking as an example the national standardization system in the Russian Federation is the following:

1. National standards
2. Preliminary national standards
3. Standards of the organizations
4. Codes of practice
5. Rules of standardization, norms and recommendations on standardization
6. International and regional standards, regional codes of practice, standards and codes of practice of foreign countries, registered in the Federal Information Fund
7. Properly attested translations into Russian of international standards, regional standards and codes of practice, standards and codes of practice of foreign countries, adopted by the national standardization body

For the purposes of conformity assessment with technical regulations are used documents under the positions 1, 4, 6 and 7 of the above list of documents.

Development and approval of national standards developing programs is implemented by a national standards body - the Federal Agency for Technical Regulation and Metrology (Rosstandart).The developer of the national standard can be any person. The developer must provide access to the standard draft to all stockholders for review and clearance comments. Modified on the basis of their comments a standard draft is then sent for examination to the technical committee on standardization according to its specialization. In Russia there are more than 400 technical committees. The standard is adopted by Rosstandart upon presentation by the technical committee.

The development and approval of codes of practice is made by the federal executive authorities within their competence. The project of code of practice must be placed in the public information system not later than sixty days before the date of its adoption.

Access to the national standardization documents should be free to any person except cases when by the license contract or international agreements such access is provided on a compensatory basis or is restricted. In such cases the national body on standardization must publish in the free public information system the data on the payment conditions for provision of relevant documents and (or) the rules for their distribution.

17. What is the link between technical regulations, standards and codes of practice?

Between the standards and codes of practice(that in the sphere of technical regulation are voluntary), and mandatory technical regulations is a close relationship, as the latter use standards and codes of practice as a basis for specifying their requirements and for certifying compliance.

In any case, all the above definitions and principles of technical regulation leads to important conclusions.

First, the mandatory character of technical regulations means that you must verify that imported products comply with these regulations or such imports will be denied. At the same time regulations must cover two equivalent aspects, namely:

- characteristics of the products to which it must necessarily conform;
- administrative conformity assessment procedures that must be performed to ensure the verification of mandatory features.

Second, standards are voluntary for use and can be developed by different bodies, both public and community. Governments of the WTO member countries must ensure that these bodies develop standards in accordance with the requirements of Annex 3 to the TBT Agreement "Code of established practice for the preparation, adoption and application of standards."

There's another very important issue. The TBT Agreement in the Article 2 articulates that the characteristics of products, established by the technical regulations must be based on international standards, specially developed on these issues. The phrase "based on" can be interpreted in different ways, and it is what really takes place in actual use in various countries:

- Direct reference to a standard in a technical regulation.
- Application of the standard content as a basis for technical regulation text. In such situation the text of the standard will be simply included in the text of the regulation. The regulation in such case will not refer either directly or indirectly to this standard.
- Application of the standard according to the rule "is considered as satisfying requirements." In this case national regulations prescribes in a single publication a number of standards that can be used to confirm their compliance with the requirements (it will be considered as meeting requirements of a regulations). This is the methodology of application of standards in the EU.
- Presentation of requirements based primarily on international standards with the necessary clarifications and amendments directly in the regulation without any reference to these standards and other documents - "direct regulation".

Legislation of the country, its history and, sometimes, its legislator’s preferences determine the choice of a particular solution. There is no unified international position on this issue.

In particular, the Russian law "On technical regulation" doesn't provide possibility of a direct reference to standards in technical regulations, and doesn't use the inclusion of fragments of texts of standards in its contents. Before the introduction in 2007 of significant changes in the law, in contained the legal form of "direct regulation". Now in Russia and the Customs Union as well as in the EU is used the principle of application of standards and codes of practice as an evidence of conformity with technical regulations. According to the new approach the developer of the technical regulation shall during the time interval between the development of regulations and its entry into force prepare and ensure the approval of two lists:

- list of documents in the field of standardization, containing rules and methods of inspection (tests) and measurements (including the rules of sampling) required for the application and enforcement of adopted technical regulations and for conformity assessment, approved by the Government of the Russian Federation or the federal executive body on technical regulation (if it was the developer of the regulation);

- list of documents in the field of standardization to be used on a voluntary basis to ensure the compliance with the adopted technical regulation (endorsed by the national standardization body).

  Both of these lists may also include the documents from the previously mentioned list (items 6 and 7). Both lists should be published in advance in the public information systems.

18. Are technical regulations in different countries equal and constitute they barriers to trade?

To the first question can be given a short answer - "no". Despite the obvious goal set in the TBT Agreement to harmonize technical regulations, even members of the WTO are close (but not yet implemented) to the final fulfillment of this task. The situation in countries that are not members of the WTO is even worse.

After the adoption of the TBT Agreement its fulfillment in different countries was monitored with an interval of three years. As it has already shown in the reviews of the Agreement implementing, technical regulations still remain barriers to trade. Although barriers sharply decreased, there is still "underdone" work, especially in developing countries due to lack of knowledge, of infrastructure and finance to meet the requirements of international standards (the basis of what are, generally, constitute standards of the developed countries). Also in accordance with a differentiated approach of the WTO to different categories of countries, the Agreement provided an opportunity for developing countries to derogate from some provisions of the Agreement and international standards regarding products requirements (decisions are taken at the request of developing countries by the Committee on Technical Barriers to Trade). However, the Committee gradually makes more strict the application of such derogation.

19. Where can be found an information on technical regulations and standards?

The TBT Agreement requires each WTO member to create at least one national informational center on applicable in a given country regulations and standards, and to notify about it the WTO Secretariat in Geneva. The Secretariat will make this information available on the international level. It is permitted the creation of several centers, but with clear specification which information is in which center to answer to requests on the applicable regulations and standards on products from other countries.

Any informational center is responsible for providing adequate answers to the questions on national technical regulations or standards.

In accordance with the TBT Agreement countries must publish notices about the proposals to develop new technical regulations or changes to existing regulations, before the final version is published. The purpose of the notice is to provide opportunities for stakeholders to discuss and provide comments on the draft regulation, suggest amendments and changes (to do it WTO members have at least 60 days from the date of publication of the notice).

Notifications are sent to the WTO Secretariat, which distributes them within all members and places on the WTO website (from which it can be downloaded for free). Notifications come to diplomatic missions in Geneva, after it they are sent to the national information services. Individual enterprises or industry associations can communicate with their national information service during the required time to allow their governments to protect their interests, responding to notices WTO.

In Russia this function (even before the joining to the WTO) was assigned to information service RIP WTO (TBT / SPS) FSUE "Standartinform" of the Russian Federal Agency for Technical Regulation and Metrology (Rosstandart), tel. (495) 290-38-41, fax (495) 230-25-98, site www.gostinfo.ru, E-mail: info@gostinfo.ru.

In any country, including in Russia, you can ask a similar service to send a request for information to its partner in the country into which one wishes to export products. You can also address a request directly to the information service of another country. While looking for necessary information, can be of help brief notices on developing or revising in other WTO member countries of technical regulations, that are regularly published in their official publications.

In Russia, it is a monthly journal "Bulletin of Technical Regulation" published by Rosstandart. Many technical regulations of Russia and of Customs Union are regularly published in this edition. Also published brief notices of the developing or revising in other WTO member countries of technical regulations. Besides it the texts of technical regulations of the Russian Federation are published on the open official website of Rosstandart, and the texts of regulations of the Customs Union are required to be published, respectively, on its official website. Of course, the texts of regulations both from Russia and the Customs Union can be found in the information systems of the "Guarantor", "Consultant Plus", "Techexpert", in open public information systems «Yandex», «Google» and others.

Now about standards. In accordance with the TBT Agreement it is advisable that the work on standardization has open public character, what would allow all stockholders to convey their point of view to the developers of standards even before their adoption. In Russia the working program of standardization and more detailed information on forthcoming national standards, and in some cases regional, European and international standards can be found in the official publication of Rosstandart "World of standards". There also published a short information on standards developed in ISO technical committees.

But the minimum requirement is that standards must be published immediately before their entry into force, so that stakeholders can get acquainted with them.

The information on standards apart from the national resource centers is available in national standards bodies on standardization in the country of your interest, which usually have similar information centers. Any national standards body has a library of all national standards and often contains a number of national standards of other countries, of regional and international standards.

According to the Federal Law "On Technical Regulation" national body on standardization provides in public information systems an access at no cost to documents in the field of standardization (as a result of using which on a voluntary basis is ensured the compliance with accepted technical regulations), as well as documents containing the rules and methods of inspection (tests) and measurements (including the rules of sampling) required for the application and enforcement of adopted technical regulations and conformity assessment. If for standards the license agreements with the foreign owners or international agreements and other rules of international law provided for the compensation of an access and (or) the inadmissibility of open access, then an information must be published on the amount of payment for the provision of relevant documents.

Copies of international standards and the standards of other countries are generally not available for free, but there are some exceptions. Codex Alimentarius standards, for example, can be downloaded free of charge from the site www / codexalimentarius.net. The price of a standard copy depends strongly dependent on the size of the text. But in any case, this price must have a tariff calculated character and compensation of expenses for making and transmiting copies shall be the same for all customers.

If you wish to receive unofficial publications of foreign standards not directly from their standardization bodies, you can use the Internet. Many commercial publishers prepare electronic catalogues of standards. Others, including national bodies on standardization, offer a complete library of standards. However, these libraries are quite expensive.

20. Which work is carried out to ensure the equivalence of technical regulations and standards of different countries?

The TBT Agreement requires that WTO members positively accept the application of technical regulations by other members (that are equivalent to their own), even if these regulations differ, on condition that the objectives of their own regulations are adequately met by the regulations of other countries. What does it mean?

Characteristics of production are the most important element of technical regulations. They are often based on the standards, and the TBT Agreement clearly requires the use of international standards as the basis for technical regulations. However, relevant international standards in some cases don't exist and then as a basis for technical regulations are used national standards. But national standards in different countries are quite different. Therefore, in the absence of an international standard in trade we have to use recognition procedures of an equivalence of technical regulations that are based on different national standards. This often happens in reality. These examples show that standards or regulations, although not identical, may be equivalent in achieving the desired result.

III. Conformity assessment

21. Which main forms of conformity assessment are used in international trade?

Forms of conformity assessment in international trade are testing, certification of conformity, declaration of conformity, expertise, state control (surveillance), acceptance and dispatching inspections. Certification and declaration of conformity (as procedures that are finalized with an issuance of an official document ascertaining compliance) are often combined into the term "conformity assessment". To ensure confidence in the results of the activities of testing laboratories and of certification bodies is very widely used a procedure of accreditation, confirming their independence and competence. This section covers only the most common forms of conformity assessment, namely testing, certification and declaration of conformity, as well as touching upon accreditation issues.

22. Why tests are so important for international trade?

According to the international ISO/IEC Guide 2:2004 “Standardization and related activities -- General vocabulary”: "**testing** -technical operation, consisting in determining one or more characteristics of the product, work (process) or services in accordance with established procedure."

The close definition is given in the international standard ISO/IEC 17000:2004 «Conformity assessment. Vocabulary and general principles» and in the similar interstate standard GOST ISO/IEC 17000-2012: «**testing** – determination of one or more characteristics of an object of conformity assessment according to a procedure (established method of the implementation of activities)».

The tests can generally include determination of the chemical composition, microbiological indicators, mechanical and physical characteristics of the material or design, evaluation of electrical safety, size, lack of defects, etc.

The test procedure is the most important type of conformity assessment, as only the tests give the actual data for all other forms of conformity assessment. Quite often test reports are directly used for decision-making in international trade without involving other forms of conformity assessment.

Tests are conducted in a laboratory, usually prior to delivery to the consumer. Tests can be carried out on the spot after delivery and installation.

The WTO always believed that insufficient level of direct recognition of test results of foreign testing laboratories is one of the most serious obstacles to free trade. Regulators and purchasers of foreign products still require, in some cases testing at the point of entry by "their" designated laboratories - even when adequate testing has been already completed in the country of production. (As regulators in this case are considered legislative bodies, government ministries and agencies, public authorities on control (surveillance), customs, inspection, etc., which define and implement procedures of access of goods and services to the markets of their country through setting and verifying compliance with the established in the country mandatory requirements).

This policy relates to technical barriers, because it increases the cost through repetitive tests and time delays. If the test is carried out at the place of production competently and in accordance with the requirements of a consumer or of an import market, there is no technical reason for the repeated testing of the product (if the transportation conditions couldn't cause damage to it). The prudent manufacturer always checks himself that a nonconforming product is not shipped, and that the product has been manufactured and tested in accordance with the requirements of the foreign market before the shipment. Any delay in entry into the foreign market reduces the competitive advantages of products due to increase of their cost (for example, due to repeated tests) and delays in payments to their internal suppliers.

Because manufactured goods become more technically complicated, and market requirements more stringent, tests are becoming the most important part of trade procedures. The movement to free trade calls for greater recognition of the tests conducted in the country of origin, but it can only happen if the end user will trust the competence of laboratories performing the tests. To be fair it should be noted that in sphere of recognition of test results now very significant progress was achieved, as well as for the recognition of certificates and other documents of confirming compliance. Especially great contribution to these processes brings International Accreditation Forum (IAF) (see below).

23. Where can be carried out the testing of products in order to confirm their compliance with the requirements of standards or of technical regulations?

This question actually involves two problems. The first concerns the manufacturer, who is looking for confirmation of compliance of its products with the requirements of the consumer, and the second is related to the obligation to provide proof of compliance to the regulatory body. For each of these problems it's important that the laboratory was a competent and independent in the performance of the required tests that is confirmed usually by its accreditation to the requirements of the international standard ISO / IEC 17025: 2005 (similar to an interstate standard GOST ISO / IEC 17025-2009) "General requirements for the competence of testing and calibration laboratories ".

Customer requirements are usually defined in the standards, specifications or contract for purchase, but the requirements of the relevant regulations are not always clearly defined or easily accessible. Manufacturers trying to bring goods to a new market and hesitant in respect of any claims, should contact the National information service on Technical Barriers on Trade in the importing country. The manufacturer must also ascertain that he understood regulatory requirements of the market properly. Independently of whether the test report is

accepted by the authorities of the importing country, it's advisable to make sure (before the delivery) that your product meets all requirements. This is done in order to reduce the costs of re-testing and the cost of goods shipped, the imports of which was banned.

Another problem is that the manufacturers don't always understand that the task of the experts that are organizing tests includes a clear knowledge of and compliance with the requirements of a particular importing market. Tests performed to satisfy the domestic market are often not enough or they don't fit at all.

The accreditation bodies shall also consider these questions when evaluating of laboratory that wants to serve for the export industries. When a manufacturer relies on accreditation while selecting laboratories, this laboratory should demonstrate its competence with respect to the importing market.

Where the results of product testing are required to be shown to regulatory authorities to confirm permission to access to the market, it's necessary that these bodies recognize laboratory that conducted the test. Often it can be a laboratory, which is one of the designated by this authority. Sometimes regulators accept data from any recognized laboratory; but there is a tendency of accepting the results only from laboratories accredited according to international rules. In Russia and in the Customs Union it is an indispensable demand, checked by the appropriate customs authorities. In any case the manufacturer must make inquiries with regulatory authorities of the importing market in relation to its policy of recognition of test results of domestic and foreign laboratories.

All national bodies on accreditation of laboratories maintain registers (lists) of laboratories, with the addresses and other contact information, description of the sphere of testing and measuring ranges.

Increasing role in the mutual recognition of the results of tests carried out by laboratories in different countries, is played the International Laboratory Accreditation Cooperation (ILAC). This organization includes bodies on accreditation of testing laboratories, which have signed the corresponding agreement. Russia is now an associate member of ILAC and conducts the necessary procedures for joining the organization as a full member.

24. Will the test report be recognized abroad?

On this question there's no clear answer in today's environment, since it depends on the decision of the regulatory authority of the country of importation. The answer to that the manufacturer must obtain before beginning to search for an access to a specific market. Regulatory authorities in different countries with regard to the recognition of test reports can act as follows:

- accept any test protocol;
- accept a test report from a laboratory that has a good reputation from the point of view of the regulatory authority;
- accept a test report from the laboratory accredited by the national accreditation body of the importing market;
- if between accreditation bodies exists an agreement on mutual recognition of accreditation results, accept a test report from a laboratory accredited by one of the participating agencies of this agreement;
- accept test reports from only those laboratories which are chosen by a regulatory authority;
- accept test reports from only one laboratory which is subordinate to the corresponding regulatory body.

In all described cases, except the last one, accepting authority will usually require that the test laboratory was accredited. With the spread of the Agreement on mutual recognition between accreditation bodies of laboratories the existing barriers are rapidly being eliminated.

25. What is certification?

Certification is the most common type of conformity assessment, as is defined in the ISO/IEC GUIDE 2:2004 «Standardization and related activities — General vocabulary» as «procedure whereby a third party documentally certifies that the product, work (process) or service conforms to specified requirements».

Close definition gives an interstate standard GOST ISO / IEC 17000-2012:

Certification - "third-party conformity assessment relating to products, processes, systems or personnel."

Requirements for an object of a certification may be contained in technical regulations, standards and other recognized documents. Product certification involves issuing by certification authority (by a third party independent of the consumer, seller and buyer) the certificate of conformity and (or) the right to use the mark of conformity to demonstrate that the product performs a specific set of requirements as set in the technical regulation, standard or another normative document. Mark of conformity is usually placed on the product or its packaging.

Product certification generally confirms that:

- products meet all or specified part of the requirements of documents mentioned in the certificates;
- products have been tested and verified against the certified indicators;
- production is conducted under the supervision of the certification body;
- if consumers discover that products having mark do not meet the stated requirements, they may contact the certification body with the appeal.

Products certification bodies use a variety of assessment methods for decision making about issuing the certificate. Among the widespread methods used in arranging various schemes (options for set procedures) certification, are the following:

- testing of type samples of products, selected according to established procedures;
- assessment of the production conditions (in Russia it's carried out in form of production analysis or certification of quality management systems);
- conducting inspection control, during which are tested control samples taken at the plant, and is checked the status of production.

The need of product certification arises for the following reasons:

- sellers are concerned about maintaining their reputation, expand their markets, increase the competitiveness of their products, promote new products;
- buyers(retail buyers, wholesalers, manufacturers, government supply agents, importers) want to get a guarantee of a quality of products they purchase;
- legislative bodies in order to protect consumer health and safety require that products must pass the mandatory certification to requirements established by the specified government decisions under regulations (usually technical regulations) and have a certification mark.

For example:

- products noted in the EU New Approach Directives, require for their circulation in the EU markets to have a CE marking;
- products that meet the requirements of technical regulations of the Customs Union or Russian Federation, shall be marked accordingly by a compliance mark for the market of the Russian Federation or by the united mark for the market of the Customs Union.

Certification of products as a form of conformity assessment is most acceptable for the majority of buyers, importers and regulatory authorities. Mandatory certification of products is carried out only by bodies accredited by national bodies on accreditation. Voluntary certification of products may be performed by an accredited certification body or any other person, who takes on functions of the certification body. In many countries, voluntary certification is carried out by trade or industry associations or private certification bodies. Voluntary certification systems can include the use of appropriate compliance sign as reuired by such systems.

International Standard ISO/IEC 17065:2012 (similar to a Russian national standard GOST R ISO / IEC 17065-2012) "Conformity assessment. Requirements for bodies on certification of products, processes and services" establishes requirements for independence and technical competence to ensure reliable operation of bodies on certification. The use of this document will help certification bodies to receive national and international recognition, thus fulfilling the requirements of conformity assessment of WTO's TBT Agreement and contributing to international trade.

The purpose of quality management system (QMS) certification is a demonstration of the possibilities of company's producing or delivering products that meet customer requirements and applicable to these products mandatory requirements. QMS certification doesn't apply to any particular product, but relates to the management of the manufacturing company as a whole.

Applicable criteria of QMS certification are based on commonly accepted international standards ISO 9000 and their modifications for major industries characteristics.

Bodies on QMS certification must meet the requirements of the international standard ISO / IEC 17021: 2011 (similar to Russian national standard GOST R ISO / IEC 17021-2012) "Conformity assessment. Requirements for bodies providing audit and certification of management systems." Upon the conclusion of the certification, the authority issues a certificate of conformity, which establishes the scope of certification and applicable standard for QMS. Sign of the body (or of the Certification System) is put on the letterhead of the company, brochures, documents with information about products, etc. that are used by the certified company. Thus neither labeling nor other attributes in the shipping documentation or on the product, no advertising or any other means of publication shall not create the impression that a product (or service) is also certified.

In some cases, as noted above, the requirement of QMS presence in the organization is used as one of the requirements for mandatory certification of products. This approach is used in a number of EU Directives and in technical regulations of the Customs Union and of Russian Federation.

26. What are the selection criteria for certification bodies?

In certification and accreditation of certification bodies are engaged the following bodies:

- Concrete certification bodies of products and management systems. After the accreditation this authorities are empowered to use the certification mark on products or logo of QMS certification body in an order established in this country.

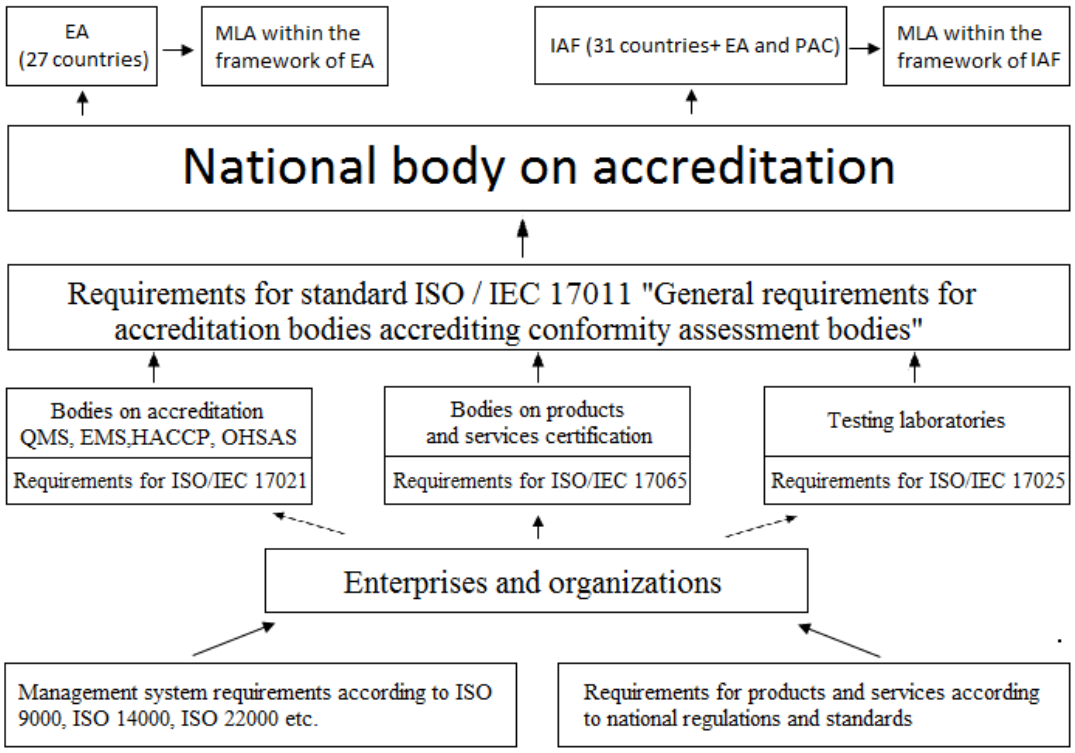
- Major national organization on certification. Are included: organizations working mainly on QMS certification at both the national and international level (such as DetNorskeVeritas, (Lloyd's Register, KPMG, TÜV CERT, BV etc.).
- National bodies on accreditation. These bodies assess the competence of various bodies on certification at the national level.

Examples:

- China National Accreditation Council for Registrars (CNACR);
- Registrar Accreditation Board (RAB), USA;
- United Kingdom Accreditation Service (UKAS), Great Britain;
- Federal Service on Accreditation (Rosaccreditation), Russia;
- European co-operation for Accreditation (EA), includes EU countries;
- International Accreditation Forum (IAF), includes EU countries, Pacific community (PAC) countries and any other individually acceding countries, the number of which is increasing.

The last two organizations carry out cooperation between bodies on accreditation operating in the field of conformity assessment. Exactly these organizations provide a mechanism for mutual recognition of national accreditation systems at European or global level and documents issued by accredited by them bodies on certification, ensuring the free movement of certified goods across borders without repetition of conformity assessment procedures.

Constructive solution of mutual recognition requires the implementation, as a minimum, the following assumptions. First, is required the existence in the respective countries of an unified national system on accreditation of the conformity assessment bodies. Second, these systems must operate under the rules established in international standards. Basic standards in this sphere is the standard ISO / IEC 17011: 2004 (equivalent interstate standard GOST R ISO / IEC 17011-2009) "General requirements for accreditation bodies accrediting conformity assessment bodies." Third, should be carried out the procedure of mutual verifying of uniform rules of compliance and is ascertained their specific performance (pic. 12.4).



Picture 12.4 – Relationship of assessment conformity participants

Currently the national accreditation system of the Russian Federation is still not a member of either EA or IAF, but after entering from 01.07.2014 in force the law of the Russian Federation "On accreditation in the national accreditation system" Russia has started negotiations about joining these organizations.

Choosing a certification body of quality management system

Organization that is preparing for certification of an QMS, should consider the following criteria for the selection by the certification body:

- Reputation, image and market experience.
- Whether the certification body is accredited by a national accreditation body.
- If the certification body for certification is accredited in your area of business (certification bodies are accredited by areas of activity).
- The proximity of the certification body (long distances may involve significant costs on the interaction with the certification body, as well as travel expenses of auditors during the certification and inspection checks).
- The validity of issued certificates, costs of certification and of inspection control, currency of payment.
- If the certification is carried out at the insistence of the foreign partners, it is necessary to consider and take into account their views in regard to the selection of the certification body.

Selecting a body on product certification

Selection of bodies on product certification is generally less diverse, as they tend to become isolated in their activities within the national boundaries. If the product certification

is a requirement of regulatory body and is carried out not only for internal purposes, but also for exports, is desirable to limit the selection of the certification body by those bodies that are recognized as trading partners.

If you still have the choice of product certification bodies, the proposed selection criteria can include criteria listed above with regard to choice-making of the QMS certification bodies.

Mutual recognition between certification bodies

Various groups have a particular interest in the mutual recognition of QMS certification bodies. The biggest of these groups - International Certification Network (IQNet). IQNet certificate is based on regular equivalent assessments and on constant global collaboration between members of IQNet, which signed a multilateral MLA agreement. In accordance with this agreement, the participants recognize the certificates ISO 9001 and ISO 14001 issued by all other members of the IQNet as equivalent to their own.

27. What verification form is required for conformity assessment with technical regulations?

Approach to this question varies greatly in different countries, moreover, varies even within the same country for different products or by different regulators. This issue is the one of main subjects of the debate at WTO.

Ideally, technical regulations should clearly present claims for conformity assessment, which must be performed. For these purposes regulatory bodies set in the texts of regulations the requirements for methods of compliance assessment with their requirements. Most often the following set of methods is used:

- Testing at independent laboratories or laboratories recognized by the government;
- Product certification in the certification body approved by the regulatory body (for example, in the Customs Union there're bodies listed in the corresponding Single Register of Customs Union);
- Supplier's declaration of conformity (see below).

28. Will the certificate be recognized in another country?

The answer to this question, so important for each exporter, depends on many factors. Generally speaking, the acceptability of a product certification is traditionally limited by national or regional (eg, within the Customs Union) level. It rarely happens that the product certification systems are international and achieve universal acceptance; although there are examples of such systems.

Some certification systems, although operating at a regional level, are widely used around the world. The most well-known, already mentioned, is the EU system of marking with mark CE for certain types of dangerous products, for which the requirements are set in the EU Directives of the New Approach.

With an QMS certification the picture is a little better. Multinational certification organization (firms with national and regional branches) and their entering in the Certification Network IQNet have made certification by these organizations widespread; but even their certificates aren't universally recognized at an international level.

There are various possibilities of recognition of your products’s certification. It's necessary to determine whether there is a presence of any of the below-described issues:

- Mutual recognition agreement

In the course of trade negotiations between countries and trading blocs agreements on mutual recognition of certification systems may be signed by the parties of governments involved in the negotiations. Under these agreements regulators in one of the countries recognize products certified in accordance with the recognized system in another country (member of the agreement). These agreements are based on a checking of full equivalence of consent (the simplest and most effective option) or on the recognition of conformity assessment procedures (require a longer and more thorough inspections of recognition possibility).

One example of such agreements is the agreement between the member countries of the CIS on mutual recognition of certificates of compulsory product certification. But in this case the certificate of the exporting country is reissued according to certain rules by the accredited certification bodies of the importing country as a national certificate.

Significantly closer agreement on mutual recognition was formed in the Customs Union, according to the rules of which the products, for which are elaborated common Customs Union mandatory requirements (there is an appropriate approved list of the products), are issued certificates of conformity in a single form (having direct circulation in all member states Customs Union).

- Agreement in the field of accreditation

Discussed above organizations European Co-operation for Accreditation (EA) and the International Accreditation Forum (IAF) are the most well-known international networks of accreditation bodies. EA and IAF increasingly ensure that certification bodies, accredited by bodies, which have joined them, received international recognition.

- Unilaterally recognition

The government or the regulatory body may unilaterally recognize the results of foreign conformity assessment. Conformity assessment body may be accredited abroad in recognized regional or international accreditation systems. A number of regulators accept the results of tests of foreign organizations. It's difficult to give a special widely known example, because such recognition isn't advertised usually.

29. What is the supplier's declaration of conformity and in what situations is it used?

According to the international standard ISO/IEC 17000: 2004 «Conformity assessment. Vocabulary and general principles», as well as interstate standards GOST ISO/IEC 17000-2012 «Conformity Assessment. Vocabulary and general principles» «**declaration (declaration of conformity)** - confirmation of conformity by the first party.» In the international standard ISO / IEC 17050-1: 2004 "Conformity assessment. Supplier's declaration of conformity. Chapter 1. General requirements» and comparable national standard GOST R ISO/IEC 17050-1-2009 is used slightly modified concept: "**supplier's declaration of conformity**", because as the first party in these standards is supplier of products, even though these same standards allow also the application of the summary form of the "**declaration of conformity**".

The purpose of the declaration is the assurance that a particular object meets the requirements set out in the declaration, with a clear indication of the person responsible for this conformity.

Functions of the supplier (applicant) can be performed by the manufacturer, seller, importer, assembly or a service organization. Suppliers are responsible for their declaration, which must be based on the inspections and tests carried out by the supplier, or on the assessment through a third party.

The declaration of conformity is a widely used conformity assessment procedure both in the EU, in Russia and in the Customs Union.

In the supplier declaration procedure adopted in the Russian Federation and in the Customs Union, it is required that in the declaration must be provided an information that allows to correlate the declaration with the conformity assessment results, on which is based this declaration. Such information can be:

- name and address of the involved third party body (testing laboratories, product certification body, QMS certification body);
- reference to the report on conformity assessment and their coordinates and dates (test reports, certificates of conformity, documents of control (supervision);
- reference to documents on accreditation by involved conformity assessment bodies (accreditation certificate);
- reference to supporting documentation of the applicant (eg, engineering and other technical documentation, results of the risk analysis, experimental studies and tests, etc.);
- reference to any other additional information regarding the available certificates, registration certificates or marks of conformity.

But to make supplier's declaration effective, the precondition is a well-functioning surveillance system on the markets and organized legal system, which would deal with the protection of the consumer and use harsh measures of responsibility for the quality of products. For these reasons, a system declaration of compliance shall be maintained by:

- adequate surveillance on the market;
- significant penalties for misrepresentation and false declarations;
- relevant regulatory environment;
- relevant regime of responsibility for the quality of products.

Supplier's declaration of conformity is the most “gentle” trade approach, but it can be used only on markets that have developed legal structure of a responsibility for the quality of products, clearly defined sanctions for non-compliance and effective market surveillance mechanisms. We can also say that the declaration that is based only on the own evidence of the supplier, isn't adequate to the purposes of regulation in those countries that don't have the legal and administrative infrastructure in order to make it effective. This is true for Russia also, because the rigidity of surveillance and the certainty of punishment for not objective declaration are still extremely weak.

30. What is the EU Global approach to conformity assessment?

Currently in the EU, as was mentioned above, is in operation the New Approach to technical regulations. To recall that it's based on the following principles:

- introduced by the EU Directives mandatory requirements are limited only to main essential requirements that products must be met for admission to the EU market. These requirements are included in the Directives under product groups;
- technical characteristics that implement these basic requirements are established in the harmonized standards, as indicated under presumption of conformity, which used in the development of the standard;
- since the implementation of the harmonized standards is voluntary, producers can apply technical documents that differ from the harmonized standards.

New Approach includes, among other areas: mechanisms and machines, gas appliances, medical equipment, building materials, electrical equipment, and others. In total by now there are 23 New Approach Directives at EU. New Approach isn't applicable, in particular, to food, chemicals and pharmaceutical products for which are applicable technical regulations, developed earlier and that are containing detail mandatory compliance product requirements.

The Global Approach to conformity confirmation was presented in 1989 and later was repeatedly specified. It's based on a modular principle of formation of the conformity assessment procedures, appointment of registered (notified) bodies and application of the CE mark.

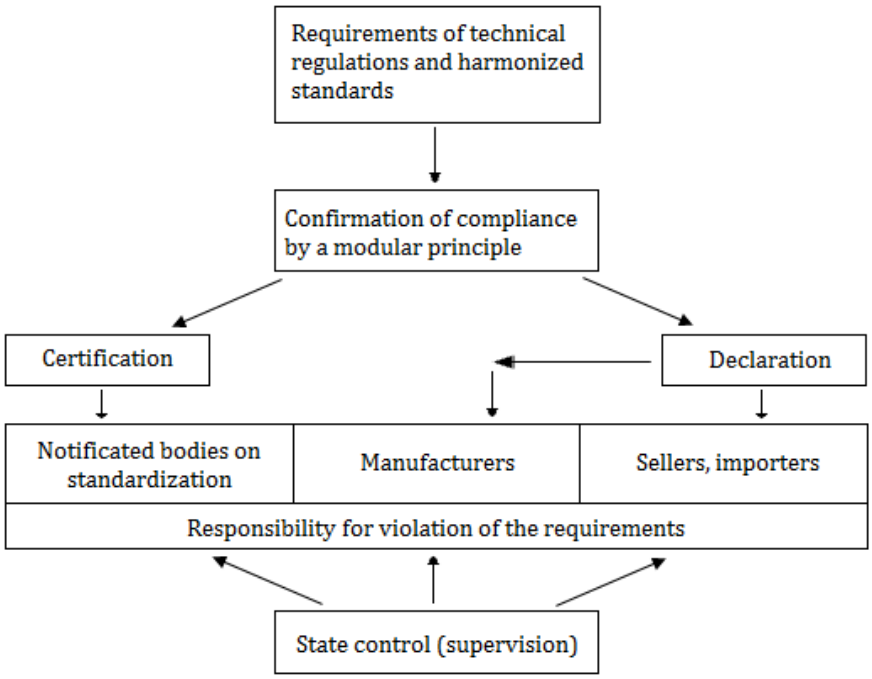
Modular approach uses 7 core modules from which (on the basis of certain rules) their combination is formed for the use in conformity assessment of various types of products with regard to the degree of danger, production volumes, production stages and a number of other factors. In case of mandatory conformity assessment of products to specific requirements of the EU Directives, the combinations of models for different situations under Directive are suggested by developers with a choice for applicants. One important circumstance should be noted. If for some products it is possible to use the most simple and widely used module A, which consists in declaring the conformity of products based on the manufacturer's own evidence and on independent internal control of production, the choice of this module is possible only if the manufacturer uses in production harmonized standards. If he uses other documents, such as their own technical conditions or standards of the organization, he is obliged to use other combinations of modules that provide the mandatory involvement of a third party (usually to conduct tests in an independent accredited laboratory or to certify its products or its QMS against a various set of the requirements under ISO 9001), that involves significant additional costs. Thereby manufacturer is economically forced to use exactly the harmonized standards, although their use is voluntary. Unfortunately, this elegant mechanism isn't incorporated in the confirmation of conformity with the technical regulations of the Customs Union and the Russian Federation, and the manufacturer can choose the most simple form the proposed in the regulations scheme of conformity, even if he doesn't apply the recommended standards.

Notification - it's also a very important thoughtful procedure which constitutes that when enacting any new EU Directive or introducing significant changes into it, the appropriate state authority analyzes the existing list of accredited certification bodies and authorizes (notifies) only some of them to do work on conformity to requirements of the Directive, in terms of its scope of accreditation and professional reputation.

Such a mechanism, unfortunately, has not been included in the confirmation of conformity with the technical regulations of the Customs Union and the Russian Federation yet, and the certification bodies of the Russian Federation should be re-accredited to conduct work on conformity confirmation with the requirements of the regulations, even if previously these products and the standards used for conformity confirmation, were included in their scope of accreditation. However, at the level of the Customs Union the procedure is used that is close to the EU authorization procedure.

After passing through the conformity confirmation procedures the applicant obtains the right to label his products with CE mark. The process on correctness (and full scope) respecting by the applicant of the conformity assessment procedures provided in the EU Directives and of the objectivity of the declarations of conformity, of the correctness on CE labeling is under strict control at EU states by relevant public authorities (that are having the to impose on violators very significant penalties).

The basic conceptual essence of the Global Approach regarding conformity assessment is reflected in the picture 12.5.



Picture 12.5 – Global approach to conformity assessment of technical regulations adoption

In this section we have considered issues such as the impact of the World Trade Organization decisions on such aspects of technical regulation in international trade as a technical regulation, standardization, conformity assessment, accreditation.

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Test

1. What is the main goal of the WTO's establishment:

   a) establishment of competitive advantages in international trade for founding countries
   b) development of international trade via creating conditions of fair competition and the reduction or removal of existing barriers to trade
   c) support of protectionist policy in the most economically developed countries and monopolization of international trade by them

2. What caused the existence of technical barriers to international trade:

   a) difference between requirements in various countries to the characteristics of products and conformity assessment procedures
   b) difference in the composition and legal status of normative documents in different countries
   c) differences in national customs legislation

3. Technical regulation is:

   a) document containing technical requirements adopted by a national body on standardization
   b) document adopted by the developer of products and containing requirements for it
   c) document containing mandatory requirements for products and conformity assessment procedures for these requirements adopted by the authority

4. Documents related to standardization:

   a) are being developed once and forever
   b) are periodically updated to maintain their relevance to the needs
   c) are checked at least once every five years

5. Standard in the field of technical regulation is:

   a) document that establishes the mandatory requirements for products, processes, services and works
   b) document establishing the voluntary requirements for application to products, processes, services and works
   c) document establishing both mandatory and voluntary requirements for application to products, processes, services and works

6. Certification is:

   a) form of product or services conformity assessment by a first-party (manufacturers, sellers, importers, services executor)

b) form of product or services conformity assessment by a second-party (customer, buyer, service customer)
c) form of product or services conformity assessment by a third-party that is an organization independent of the manufacturer, seller, importer, services executor

7. Declaration of conformity is:

a) form of product conformity assessment by a first-party (manufacturers, sellers, importers)
b) form of product or services conformity assessment by a second-party (customer, buyer)
c) form of product or services conformity assessment by a third-party that is an organization independent of the manufacturer, seller, importer

8. What type of certification is subjected an importing potentially dangerous product on entry:

a) mandatory certification
b) voluntary certification

9. Specify provisions that are mandatory to establish in normative documents for the products, which must be certified:

a) requirements against which is going the certification
b) methods of controls for compliance with specified requirements
c) traffic regulations
d) drawing up rules of accompanying documentation

10. By which international standard are established requirements for product certification bodies:

a) ISO/IEC 17011:2004
b) ISO/IEC 17021:2011
c) ISO/IEC 17025:2005
d) ISO/IEC 17065:2012

11. By which international standard are established requirements for testing laboratories:

a) ISO/IEC 17011:2004
b) ISO/IEC 17021:2011
c) ISO/IEC 17025:2005
d) ISO/IEC 17065:2012

12. Distinctive features of the EU's New approach to the establishment of mandatory requirements to products:

a) establishment of all mandatory requirements to products in the EU Directives and national technical regulations of the EU countries

b) establishment in the EU Directives and national technical regulations of the EU countries only the most essential requirements with specification of these requirements in the harmonized standards
c) establishment of mandatory requirements directly in the standards

13. Distinctive features of the EU Global approach to mandatory conformity of EU New Approach:

a) application of set of not connected with each other schemes of product compliance with mandatory requirements at the option of the applicant and by using for it any existing standards and other normative and technical documents
b) application of a modular principle of compliance with the impact of priority to using of harmonized standards, which allows the applicant to choose less expensive modules

14. Which international organization ensures the mutual recognition of testing results was made by laboratories in different countries:

a) ILAC
b) UKAS
c) IQNet

15. What are the main criteria of assent equivalence when deciding on the mutual recognition of conformity assessment bodies in different countries:

a) regulatory requirements for products and conformity assessment procedures in general are different, but mutually verifiable and comparable
b) regulatory requirements for products and conformity assessment procedures are identical

16. Prerequisites necessary to ensure recognition of accreditation systems and issued by them confirm compliance documents:

a) presence in the country more independent accreditation systems operating according to the rules set out in the legislation of the country and national standards
b) presence in the country of a single national accreditation system operating by the rules established in international standards