KAPITEL 1 / *CHAPTER 1* [1]
HARMONIZATION OF MANAGEMENT ELEMENTS: SYSTEMATIC APPROACH, AUDIT, ACCREDITATION, STANDARDIZATION AND CERTIFICATION

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Introduction

Certification systems operate at the national, regional and international levels. There is also a distinction between state (governmental) and non-state (non-governmental) certification systems. Product certification can be carried out by a separate enterprise (self-certification), which at the same time produces certified products with confirmation of their compliance with the requirements of certain national or international standards.

National certification is more common, according to which enterprises of one or another branch of industry produce products in accordance with the requirements of specified national and (or) international standards. The system of national certification involves, as a rule, the establishment at the state level of bodies that supervise the quality of manufactured products (the so-called certification with the participation of a third party), as well as participation in the system of research laboratories and laboratories of metrological safety.

In some countries, national certification activities have been going on for many years. The emergence of certification in these countries was aimed at protecting their own market from low-quality goods that do not meet the requirements of the standards. A positive result of activities in this field of national certification is the development of research and measurement tools, their metrological support, the theory and practice of product quality control, and, in particular, the creation of national research centers using the latest achievements of science and technology.

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1.1. Product certification procedure

The procedure for product certification involves various stages. Submission and consideration of an application (in accordance with the established procedure) for product certification. If there are several accredited bodies for the certification of a specific type of product, the applicant has the right to apply to any of them. The certification body reviews the application for no longer than one month and notifies the applicant of its decision.

The analysis of the provided documentation is carried out in order to verify its compliance with the established requirements:

- availability of regulatory documents for products;
- availability of a document confirming the origin of the products;
- availability of the manufacturer's document on guarantees and product compliance with current requirements;
- availability of a document confirming the size of the batch and the date of production;
- availability of the opinion of relevant controlling organizations (Ministry of Health, state inspections of veterinary medicine or plant quarantine, state bodies for labor protection supervision);
- authenticity, correctness of filling out and validity period of documentation;
- adequacy of requirements for marking and labeling of products. Making a decision on an application with an indication of the certification scheme (model). Product certification schemes depend on the series of products:

a) for a single product, only tests are carried out for each product and a certificate of conformity is issued for each product;

b) production certification is carried out for the batch of products (if decided by the certification body and the applicant); tests on samples selected in the quantity and order established by the certification body; technical supervision of production (if there is an agreement between the applicant and the certification body regarding production attestation) and a certificate of conformity is issued for the batch of products indicating

the size of the certified batch; c) for mass-produced products, there are three ways:

- a production survey is conducted; tests on samples selected in the quantity and order established by the certification body; technical supervision of production in the order determined by the certification body, and a certificate is issued with a validity period established by the license agreement (up to one year);

- certification of production is carried out; tests on samples selected in the quantity and order established by the certification body; technical supervision of production; a certificate is issued with a term of validity established by the license agreement, taking into account the validity of the production certificate (up to two years);

- certification of the production quality system is being carried out; tests on samples selected in the quantity and order established by the certification body; technical supervision of production and a certificate is issued with a validity period established by the license agreement, taking into account the validity period of the quality system certificate (up to three years).

The inspection of production is carried out with the aim of establishing compliance of the actual state of production with the requirements of the documentation, confirming the ability of the enterprise to manufacture products in accordance with the current requirements of regulatory documents, providing recommendations on the periodicity and forms of conducting technical supervision of the production of certified products. During the inspection of production, an examination of normative, technical and technological documentation is carried out, i.e.:

- verification of conformity of indicators and characteristics of products;

- assessment of the adequacy of control operations and tests;

- evaluation of the input control system of raw materials and materials;

- verification of compliance with the accuracy indicators of measuring equipment;

- verification of the availability of the metrological support system. Based on the results, an examination report is drawn up.

Production certification, if it is provided for by the certification scheme, is carried out in order to assess the technical capabilities of the manufacturing enterprise to

ensure stable production of products that meet the requirements of regulatory documents, and to provide appropriate recommendations regarding the frequency of tests, the number of samples to be tested, methods and rules for their selection. The order of these works is established in DSTU 3414. The results of the attestation must be formalized in the production certificate and sent to the applicant.

Testing of products for the purpose of certification is conducted by a testing laboratory (center), which is accredited for the right to conduct the types of tests provided for by regulatory documents. The applicant provides samples (samples) of products and technical documentation for them. The number of samples and selection rules are established by the certification body. In case of positive results, the test reports are sent to the certification body, copies to the applicant, but in case of negative results for at least one indicator, the tests are stopped. Retests are conducted after submitting a new application. Tested product samples remain the property of the applicant. The procedure for write-off, disposal, return and storage of samples is regulated by the body's documentation.

Issuance of a certificate of conformity. The certificate of conformity is issued exclusively by the certification body for a single product, a batch of products and for products that are produced in series during the term established by the license agreement, with the right to mark each product unit with a mark of conformity . In the presence of protocols with positive test results, a quality system certificate or a production certificate, depending on the established certification scheme, the certification body issues a certificate of conformity, registers it in the UkrSEPRO Register in accordance with DSTU 3415-96 and issues it to the applicant. The choice of the form of the certificate of conformity depends on the degree of confirmation of the requirements of regulatory documents. The decision to recognize foreign certificates of conformity for imported products is taken by the certification body based on DSTU 3417-96 and documented in the recognition certificate.

Technical supervision of certified products during their production is carried out by the body that issued the certificate, or the body for the certification of quality systems, or territorial centers of standardization, metrology and certification. Based on

the results of supervision, the certification body may suspend the validity of the certificate of conformity in the following cases:

- violation of the requirements set for products during mandatory certification;
- violation of requirements for manufacturing technology, acceptance rules, control and testing methods;
- changes in regulatory documents and design, completeness or manufacturing technology.

The validity of the certificate of conformity ceases from the moment of removal from the register in accordance with DSTU 3415-96. State Standard, on the basis of the register, issues directories containing information on certified products. In case of disagreement, the applicant can submit a written appeal, which is considered by the appeal commission.

1.2. Certification of production and the procedure for its implementation

Certification of production is carried out in order to assess the technical capabilities of the enterprise that manufactures products, to ensure stable production of products that meet the requirements of regulatory documents. Before the start of attestation, the enterprise must have documents on the organization of quality control, the organization of control over production, the quality control system, means of measurement, control and testing of equipment, the procedure for forming and marking batches of products, the procedure for registering control results.

An enterprise that wants to certify production must appoint a chief controller and his deputy. The chief controller carries out technical control and quality control of certified products. He must have all the appropriate powers and be independent from the management directly responsible for the production of products.

The procedure for carrying out work on certification of production involves the following stages:

- submission of an application (if the certification is introduced at the initiative of

the enterprise) to the certification body together with two copies of the instructions for certification of technical capabilities and information on production;

- the preliminary assessment is performed by a committee of product certification experts within the agreed time frame. The composition of the commission is approved by the certification body. The preliminary assessment includes an examination of the raw materials provided by the enterprise and drawing up a conclusion on the readiness of the enterprise to introduce production certification;

- compilation of the program and methodology of attestation by the committee of experts who conducted the preliminary assessment (includes the object of inspection, inspection procedures and decision-making rules);

- inspection of production and attestation of its technical capabilities. The primary task of the production inspection is to assess the compliance of the information provided in the source materials with the actual state directly at the enterprise, as well as conducting the necessary tests to certify the technical capabilities of the production. It is carried out by a committee of experts, which includes experts who performed a preliminary assessment and a specialist in technology conformity assessment. Based on the results of the inspection, the commission prepares a report within a month containing an analysis of the inspection results and substantiated conclusions. On the basis of positive conclusions, the certification body issues a production certificate, registers it in the register and issues it to the enterprise (validity period does not exceed three years);

- technical supervision of the certified production is carried out by the certification body during the validity period of the certificate (territorial centers of standardization and metrology are also involved).

In order to extend the validity of the production certificate, the enterprise sends the relevant materials to the certification body no later than three months before the expiration date. The validity of the production certificate is suspended in the following cases:

- if inconsistency of the released products with the quality level is found;

- if changes were made to the design or technology, which led to a decrease in

quality;

- the validity period of the certificate has expired, and the company has not sent materials for its extension;

- during the performance of technical supervision, non-compliance of production with technical capabilities was revealed.

If the production does not agree with the conclusions of the commission, it can appeal to the council of the certification body.

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1.3. Certification of quality systems and its procedure

Certification of quality systems for the manufacturer of certain products is carried out with the aim of certifying the compliance of quality systems with the requirements of DSTU ISO 9001-2001 and DSTU 180 9004-2001 and ensuring confidence that the manufacturer is able to constantly produce products that meet the requirements of regulatory documents, products of unsatisfactory quality are detected in a timely manner , and the manufacturer takes measures to prevent the manufacture of such products on a permanent basis.

The manufacturer first of all submits a corresponding application to the accredited certification body. This body examines the application and sends the applicant enterprise a survey questionnaire for conducting a preliminary examination of the quality system of the applicant enterprise and a list of raw materials that the enterprise must submit to the certification body for conducting a preliminary assessment of the quality system and the state of production.

Certification of quality systems consists of the following stages:

- a preliminary (in-person) assessment of the quality system is carried out in order to determine the expediency of continuing work on the certification of the enterprise's quality system and developing an inspection program. They are carried out by a commission of specialists formed by the chief auditor appointed by the certification body. The commission analyzes these materials received from the enterprise and prepares a written opinion on the expediency (improperty) of conducting a final inspection and assessment of quality systems. In the case of a positive decision, the applicant is sent a conclusion and a draft of the business contract for final verification.

- the final inspection and evaluation of the quality system is carried out by the commission that conducted the preliminary evaluation, or another commission that necessarily includes the experts that conducted the preliminary evaluation. The commission develops a program (plan) for the final inspection of the quality system; the program, methods of checking and assessing the state of production and prepares the necessary documents.

The inspection program (plan) includes: purpose and field of inspection; date and place of inspection; the list of documents for compliance with which the check is carried out; the list of structural divisions under inspection; the names of elements of the quality and production systems that are subject to inspection; distribution of responsibilities among commission members; sources; approximate terms of implementation; requirements for ensuring the confidentiality of information; the list of organizations and persons to whom the inspection report is submitted.

The inspection includes the following procedures: a preliminary meeting; examination; final meeting; preparation of the inspection report. Based on the results of the preliminary meeting, the chief expert draws up and signs the corresponding protocol, as well as the division of duties between the auditors. During the inspection, the necessary data on the quality system are collected by means of surveys, study of documents and carrying out observations on the inspected sites. The survey includes work on the assessment of the state of production, analysis of actual material and preparation of preliminary conclusions for the final meeting. The main purpose of the final meeting is to provide the management of the enterprise with comments based on the results of the inspection and evaluation, as well as to make preliminary conclusions regarding the possibility (impossibility) of providing a certificate of compliance of the enterprise's quality system with the requirements of regulatory documents. The inspection report is prepared by a commission headed by the chief auditor. The deadline for preparing the report is one month after the final meeting.

Issuance of inspection results. As a result of the inspection, the following options are possible.

Option 1. The system sufficiently meets the requirements of normative documents on quality systems. The certification body issues a certificate of the established model, registers it in the register in accordance with DSTU 3415-96, and its validity period is no more than three years.

Option 2. The system generally meets the requirements of normative documents on quality systems, but minor inconsistencies have been detected in relation to individual elements of the system, which can be eliminated fairly quickly. The

enterprise is obliged to eliminate the remarks and submit a new application within the time limit set by the certification body, and the certification work will be carried out according to the full or simplified (inspection of individual elements) scheme.

Option 3. The system has serious inconsistencies that can be eliminated only as a result of refinement over a long period of time. The assessment of the quality system is repeated according to the complete scheme.

The decision on the recognition of foreign certificates is made by the certification body in accordance with DSTU 3417-96.

Technical supervision of certified quality systems during the entire period of validity of the certificate is carried out by the certification body with the involvement of territorial centers for standardization and metrology. Based on the results of technical supervision, the certification body may terminate or cancel the validity of the certificate in the following cases:

- detection of non-compliance of the quality system with the requirements of the standards;

- existence of substantiated claims of consumers of this product;

- if improper use of the certificate is detected;

- if a violation of the rules or procedures established by the certification body is found.

The certification body cancels the certificate of conformity to the quality system if:

- the results of technical supervision indicate the fundamental non-compliance of the quality system with the current requirements;

- in the event of a change in the certification rules, the manufacturer cannot ensure compliance with the requirements;

- the manufacturer has not fulfilled financial obligations to the certification body;

- there is an official request from the manufacturer. If the applicant wishes to contest the decision on his application for certification, he must submit a written appeal no later than one month after receiving the notice.

1.4. Conformity assessment accreditation

The legal, organizational and economic principles of accreditation of conformity assessment bodies in Ukraine are determined by the Law of Ukraine "On Accreditation of Conformity Assessment Bodies", which entered into force on May 17, 2001. In accordance with this law, the following conformity assessment bodies may be accredited:

- testing and calibration laboratories;
- bodies for certification of products, processes and services;
- bodies for certification of quality systems, quality management systems, environmental management systems;
- personnel certification bodies;
- control bodies.

Requirements for product certification bodies and their accreditation procedure. An organization can be accredited as a certification body if it is independent of the developer, supplier, consumer and has such a level of competence that enables it to carry out certification in the declared field of accreditation. For this, the organization must have an appropriate organizational structure; administrative and legal rights for certification management; competent staff; fund of regulatory documents; a system of mutual relations with manufacturers and suppliers of certified products; contractual obligations with accredited testing laboratories; the statute defining its activities; regulations on the certification body and other regulatory documents; work experience in certification.

Accreditation of a certification body is an official recognition of its right to certify products for compliance with the requirements of regulatory documents in the field of its accreditation. Accreditation is carried out by the national accreditation body. Accreditation of the certification body involves the following main stages:

- submission of an application and examination of documents, based on the results of which an expert opinion is drawn up with an assessment of the compliance of the certification body with the established requirements;

- verification of the certification body is carried out by a commission of competent specialists; compliance of the actual state with the submitted documents and the ability to perform the declared functions are established; an act is drawn up based on the results obtained;

- the national accreditation body deals with the examination of the inspection results. In case of violation of the terms of accreditation, a decision is made to terminate or cancel the accreditation certificate.

Requirements for quality system certification bodies and their accreditation procedure. Quality system certification bodies, according to DSTU 3420-96, are created on the basis of organizations that have the status of a legal entity and can be recognized as a third party, that is, independent of the customer and other parties interested in this. The requirements for a quality system certification body are the same as for a product certification body. Accreditation of the quality system certification body is an official recognition of its legality to carry out quality system certification (attestation of production) for compliance with the requirements of regulatory documents. Accreditation of a quality system certification body (as well as a product certification body) consists of the following main stages: application submission and examination of documents;

verification of the certification body, consideration of the results of the verification; registration and issuance of an accreditation certificate.

Requirements for testing laboratories and their accreditation procedure. Accreditation of a testing laboratory is an official recognition of the technical competence and independence of the laboratory from developers, manufacturers and consumers of products, or only its technical competence in conducting tests in accordance with the requirements of standards or other regulatory documents. The testing laboratory must have: legal status, organizational structure, administrative subordination, financial status and employee remuneration system, which indicates its independence.

The testing laboratory must be technically competent, the laboratory staff must have high professional training, qualifications and experience in conducting tests in the

field of accreditation; own the necessary equipment and measuring equipment (all of them must be certified and authenticated); have documentation on test methods and other procedures; have premises that meet the established requirements.

Accreditation involves the following stages: application for accreditation; examination of submitted documents; inspection of the testing laboratory; making a decision on accreditation based on the results of the inspection; design, registration and issuance of an accreditation certificate.

Requirements for auditors and their accreditation procedure. Auditors can be specialists in various fields of activity who meet the requirements of DSTU 3418-96 and are certified by the commission appointed by the National Accreditation Body. Auditors in the UkrSEPRO certification system carry out activities in such areas as certification of products and services, certification of quality systems, attestation of production facilities, accreditation of testing laboratories. The auditor must be administratively and financially independent from producers and consumers of products and must have a special education in those fields of knowledge that correspond to the areas of activity, as well as practical experience in the field of activity for at least two years.

The auditor must have mandatory knowledge of the following issues:

- state and international standards, other normative documents, in accordance with which certification and accreditation are carried out;
- economic and legal bases of certification and accreditation;
- organization, procedure and content of certification and accreditation work;
- practice of certification and accreditation in the country and abroad. Attestation of auditors is carried out by a commission appointed by the national accreditation body in two stages:
- verification and assessment of theoretical knowledge (through conversation or written work);
- internship in a certain field of activity to assess practical skills and compliance with the requirements of DSTU 3418-96.

In the case of a positive assessment of theoretical knowledge, the auditor is issued

a certificate and a referral to an internship, which involves participation in:

- in product certification (at least three works on certification and two works on accreditation of the body);

- in the certification of quality systems and attestation of production (at least three times);

- in the accreditation of testing laboratories (at least three times).

A candidate who has passed both stages receives an auditor's certificate (for no more than three years), which is registered in the register of the UkrSEPRO certification system.

1.5. Mutual recognition of certification results in the countries of the European community

Policy of the European Community on Conformity Assessment. In 1988, a symposium of Western European countries on certification and testing was held in Brussels, at which recommendations were developed for the creation of uniform certification and testing principles for the European Commonwealth (later the European Union, EU). The EU Commission has prepared a resolution on issues of an integrated approach to technical conditions, testing and certification:

- enterprises of EU countries are invited to implement quality management systems based on EM 29001, EM 29002, EM 29003 standards;

- uniform criteria for assessing the competence and independence of testing laboratories, accreditation and certification bodies for EU countries are approved.

In the EU countries, there were significant differences in the procedures for confirming the safety of products — it could be both a statement and a third-party certification. But in 1985, the Directive of the Council of the EU on technical harmonization was adopted, which delineates the role of basic requirements and standards. Compliance with basic requirements is defined as mandatory, in contrast to the requirements of standards. If the standard is harmonized, then the products

manufactured according to it are considered to meet the basic requirements; if the standard is not harmonized, then confirmation of conformity by a third party is necessary.

A comprehensive approach to mutual recognition of certification results. A comprehensive approach brings the transition to mutual recognition of certification results closer under the condition of competence, high technical equipment and openness. The "Certificate" data bank created by the EU Commission contains information about all certification systems, test methods, laboratories and test centers, etc., existing in Europe. A comprehensive approach involves:

- increased attention to the accreditation of testing laboratories in EU member states;

- a new legal procedure for certification and testing, according to which it is not allowed to include one mandatory method of certification of a specific product in EU legal norms. Safety parameters and several methods of their confirmation should be defined. The intervention of state bodies in the activities of independent centers is limited, except in cases of extreme necessity;

- assessment of conformity of product development (design, prototype, production); type of control (documentation check, prototype test, quality system check); control body (manufacturer, independent organization, third party).

In 1989, the EU adopted the Global Concept of Harmonization of Conformity Assessment Rules. According to the Directive, conformity can be assessed by the manufacturer himself, as a result of which he confirms the conformity of the product with the established requirements of the Directive by means of a declaration and certifies this by marking the product with a mark (Fig. 1). Fig. 1. Mark of compliance with the EU Directive The new Directives differ from the old ones in that they:

- contain harmonized safety requirements specified for a certain stage of the product life cycle: design, manufacture, implementation, operation;

- differ in structure — they have legal and technical parts, the principles of the conformity assessment system and references to standards are given;

- unlike the "old" ones, they do not have a branch character.

1.6. European Organization for Testing and Certification

In 1990, on the basis of a Memorandum of Understanding, the EU Commission, the Secretariat of the European Free Trade Association (EFTA), the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELES) formed the European Organization for Testing and Certification (ETC), which in In 1993, it received the status of an international independent non-commercial association.

The main task of the EFSA is to establish mutual understanding and mutual trust between European organizations in member countries that are engaged in conformity assessment, to ensure the free movement of goods and services and fair competition. EOBS aims to create conditions that would guarantee all interested parties that products, services and technological processes that have passed tests or certification do not need to be re-checked for those results that should be accepted by different parties or different European countries.

EOVS provides valid and associative membership. Active members (with the right to vote) are divided into European and national. A national member is a body that has the right to represent all interested EU and EFTA member states. A European member is any group that unites at least five EU and EFTA member states and also represents cross-sectoral interests. Any European non-profit organization without the right to vote in the EOBS has the right to be an associate member.

EOBC carries out both external relations (conclusion of agreements on mutual recognition of test results and certification with countries that are not members of the EU), and promotes the conclusion of similar agreements based on the European standards of the EN 45000 series within the EU through the forces of industry committees. Seven European standards of the EN 45000 series relate to testing, certification and accreditation of test centers:

- EN 45001 and EN 45002 — contain criteria for evaluating the activity of testing laboratories;

- EN 45003 — contain assessment criteria of bodies for accreditation of testing

laboratories;

- EN 45011 — EN 45014 — contain requirements for the work of certification centers, bodies for certification of quality systems and personnel. At the level of government in EU countries, only those centers that organize their activities in full compliance with the European norms of the 45000 series are officially recognized.

In 1979, the ISO/TC 176 Technical Committee "Quality Management and Quality Assurance" was created with the aim of creating a unified approach to solving problems of product and service quality assurance, building a quality system. The ISO/TC 176 Technical Committee performs the main work of creating international standards for quality systems (a series of international standards for quality systems has been developed and issued). International standards for quality systems, which are developed by the ISO/TC 176 Technical Committee, are related to guidelines for the construction, selection and application of quality systems, and verification of their effectiveness. The technical committee ISO/TK176 works according to the general rules of procedure of working technical bodies I80. The ISO/TC 176 secretariat is managed by the Canadian Standards Council. At the beginning of 2006, ISO/TC 176 included 76 participating countries (R-members) and 21 observer countries (O-members), as well as a number of associated international organizations. Technical committee ISO/TC 176 cooperates with many ISO committees and other international organizations, special attention is paid to joint work with ISO/TC 207 on the adaptation of quality system standards in the field of environmental management.

1.7. EU basic structures for food products

European legislation in the food industry is represented by EU institutions. The institutional system is unique in world practice. Institutional triangle:

- The European Commission;

– European Parliament;

- Council of the European Union.

The European Court, the Court of Auditors, the European Commission represents the interests of the Commonwealth, has the right of legislative initiative and ensures consumer health protection. Key participants: state officials, heads of departments, commissioners. The European Parliament is a representative of European citizens, elected since 1979. Committee and Plenary meetings in Strasbourg and Brussels. The role of a critic of legislation (addition and adoption of legislation) Council of the European Union. Representation of the Governments of member states. Majority voting (measured by the number of states). The role of the chairman (stimulation of the legislative process and the process of political decision-making, organization and chairing of all meetings, development of compromises, rotation every 6 months). Key participants: Council Secretariat, Permanent Representatives (UKREP), Government officials of Member States.

Food legislation. Legal and administrative regulations for food products in general and food safety in particular, at the level of the community or individual state. Food legislation applies to all stages of production, processing and sale of food products, as well as fodder, which is made for feeding animals - raw materials for obtaining food products.

Food products are all products intended for human consumption in a processed, partially processed, or unprocessed state. Food products are not feed products;

- Live animals (if they have not been prepared for human consumption);
- Plants for harvesting;
- Medicines;
- Cosmetic products;
- Tobacco and tobacco products
- Narcotics and psychotropic substances;
- Industrial waste and polluting impurities.

The European Food Safety Agency is an independent scientific body of reference in risk assessment, it is:

- Scientific Committee and permanent public discussions;
- Consultations in the case of drafting legislation or a request from the

commission;

- Provision of scientific opinion and technical support;

- Data collection; identification of extraordinary risks;

- Information for the general public and interested parties, consumer confidence, transparency in the creation of policies and legislation.

The general principles of the EU Law on Food Products are as follows:

- High level of protection: life and health of people (as well as animals, as one of the main chains in population nutrition);

- Rights to safe food products; accurate and reliable information;

- Taking into account the protection of the health of animals and plants; • Environment;

- Free circulation of food products and feed in the middle of the EU;

- Legal instruments.

The regulations must be implemented in each member state exactly as stated in the EU publication. Apply in case of conflicts with national rules:

• Complete;

• Specialized:

• Narrowly focused;

• Do not require local legislation;

• Cannot be changed by the national Parliament;

• May not be changed by national legislation.

Directives are a goal that member states should strive for, leaving it up to each state to develop its own legislative framework that will be aimed at fulfilling the set goals. Allow Member States to adopt forms and methods of implementation (eg Laws and Regulations). Lack of legal force before adoption into national legislation.

Decisions are legally interconnected documents that are not applicable to the entire European Union, but only to a part of it, for example, to a person, company or one state.

Recommendations are not binding, but are taken into account when interpreting local legislation. The communications of the Commission provide guidance for action

on the policy being implemented. Act on the principle of Mutual Recognition. Any product imported from a member state must be authorized for use on the territory of another member state, if it is legally produced and placed on the market of that state. The principles are developed in accordance with Art. 28 of the Agreement (Free circulation of goods). The internal market involves the removal of customs duties between EU member states, quantitative restrictions between EU member states and other obstacles to trade in goods, services, labor and capital (the main task of DG MARKT), common rules of competition, common policy in the field of foreign trade.

Fundamental freedoms:

• Free movement of goods, individuals (employees and small entrepreneurs), services and capital.

• Free movement as a general rule: EU member states should not apply restrictions to internal trade (within the EU).

• The need for cross-border cooperation.

• Exceptions are defined in the EU Treaty and case law.

• Citizens/commercial entities can rely on these provisions by applying to the courts in their countries and to the European courts.

Community rules should be enforced at the level of national courts:

– Direct application of EU law;

– Interpretation of national legislation in the light of EU law.

– At the level of the European Commission: filing a protest, which leads to the application of the infringement review procedure by an EU member state. The principle of mutual recognition. Member States may not rely on the exceptions clauses contained in the Agreement to justify restrictions on free movement in cases where the requirements of the country of origin so require.

The country of origin is responsible for setting and monitoring requirements, and the host country is responsible for ensuring free movement, which depends on mutual trust between member countries regarding controls in the country of origin.

Exceptions to the article on mutual recognition:

• Direct limitations of the terms of the Agreement, Art. 30 of the EC Agreement;

• Official morality;

• State policy;

• State security;

• Protection of health and life of people, animals or plants;

• Protection of national property that has artistic, historical or archaeological value.

General provisions of the law on food products:

• Provides a basis for ensuring a consistent approach in the development of legislation on food products.

• Gives definitions, principles and defines responsibilities covering all stages of production and distribution of food and animal feed.

Due to the fact that food contamination has been one of the main problems of nutrition in recent years, it also represents a general basis for those areas that are not covered by specific harmonized rules.

The old approach:

• A very detailed description of product characteristics; • Difficult to install and perform;

• Impermeable to innovations;

• Member countries decide on the issuance of a certificate of conformity.

A new approach:

• Considers in the light of the principle of mutual recognition;

• Considers only mandatory essential requirements.

Technical characteristics are established through European standardization organizations (CEN, Cenelec, ETSI). Flexible and technologically neutral (CE marking), the SPS agreement encourages governments to implement SPS activities that are consistent with international standards, guidelines and recommendations. This process is often called "harmonization". The WTO does not and will not develop such standards. It establishes the basic rules for the use of risk analysis. The WTO is not a food safety organization, but an international trade organization.

In this case, the WTO should adopt the basic requirements of the FAO and the

WTO regarding food safety.

Protection of consumers' health is possible only if the risks are known. Thus, the risk analysis consists of:

• Risk assessments;

• Risk management;

• Dissemination of information regarding the presence of risk.

Food safety risk assessment has the following steps:

• Definition of danger;

• Characteristics of the danger;

• Expectancy assessment.

Characteristics of risk. The Codex Alimentarius Commission (CCA) is the organization that sets the standards of the WTO/SFC Food Agreement. This Commission was established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop standards, guidelines and other texts for food (for example, rules of the Joint Program on Food Standards of FAO and WHO).

1.8. Commission of the Organization for Food and Agriculture

Codex Alimentarius. The Codex Alimentarius Commission is a joint Commission of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) at the United Nations. Founded in 1961. The task is to protect the health of consumers all over the world, to ensure fair trade practices in the international trade of food products. Codex standards are the basis on which member countries of the Codex Alimentarius Commission should harmonize their provisions of the Food Codex, contain recommendations in the form of procedural rules (codes of practice), guidelines and other recommended measures aimed at fulfilling the goals of Codex Alimentarius.

To S.A. - includes all member countries and associate members of FAO and WTO. Standards for individual products – 202 standards. Methodological guidelines

and technical norms and rules relating to individual products – 38, general standards and methodological guidelines relating to the labeling of food products – 7; general technical norms, rules and methodological guidelines related to the hygiene of food products - 5; methodological guidelines related to risk assessment for the safety of food products - 5; standards, technical norms, rules and methodological guidelines concerning polluting impurities in food products - 14; standards, methodological guidelines and other recommendations related to sampling, analysis and certification procedures - 22.

Standards on the maximum permissible content of pesticide residues - 2597 standards, covering 213 pesticides. Provisions related to food additives - 683, covering 222 food additives. The maximum permissible content of residues of veterinary drugs in food products is 377, including 44 veterinary drugs.

Code standards - contain requirements for measures that must guarantee the consumer:

- safe,
- unadulterated,
- properly labeled food product.

They are developed according to a clearly defined scheme, which is divided into the following sections: name of the standard, scope, description of the food product, essential factors of composition and quality, auxiliary substances, pollutants, hygiene, weights and measures, labeling and methods of analysis and sampling.

WHO provides the scientific basis for the work of the Codex Alimentarius Commission on the development of international standards and provides advice to member countries of FAO and WHO on the development of their national food safety standards and measures.

The most important standards for food products in the EU. There are several ways to distinguish between standards or systems, such as:

- according to the orientation of the requirements (system or product standard),
- by depth of application (horizontal or vertical standard).

Global Food Safety Initiative (Global Food Safety Initiative - GFSI (May 2000))

The goals of this initiative: strengthening consumer confidence in food products, development and implementation of an international early warning system, implementation of a worldwide comparison program for food safety standards, development cooperation between the global food industry and state, as well as supra-state institutions and supervisory bodies. Standards for food products in the EU and the scope of application: regional, national or international.

Today, the following standards are recognized:

- "BRC Technical Standard",

- "Dutch HACCP Standard" (Dutch HACCP standard),

- "International Standard for Auditing Food Suppliers" (international standard for auditing food suppliers), - international standard for food products (IFS),

- "SQF 2000 Standard" (food safety and quality standard).

BRITISH RETAIL CONSORTIUM Global Standard – Food. The British Retail Consortium (BRC) technical standard was developed in 1998 as a general standard for English retail businesses. Among its participants are such world-famous chains as Tesco, Marks & Spencer, Sainsbury's, etc. (a total of 80-90% of British retail enterprises). This standard was intended to evaluate those manufacturers whose products were sold by supermarkets under their own brand.

The standard proved so successful that in 2003 the Consortium published a packaging standard, a non-food safety standard, a storage and distribution standard and then, in collaboration with the British Food and Drink Federation, a standard to ensure the production of genetically modified food - modified organisms.

Global Standard for Packaging and Packaging Materials, 3rd edition, 4th January 2008 (Global Standard for Packaging and Packaging Materials, 3rd edition, 4th January 2008)

BRC Global Standard – Consumer Products, October 2006 (BRC Flobal Standard – Consumer Products, October 2006)

BRC Global Standard – Storage and Distribution, August 2006 (BRC Global Standard – Storage and Distribution, August 2006)

Technical Standard for the Supply of Identity Preserved Non-Genetically

Modified Food Ingredients and Product (Technical Standard for the Supply of Identity Preserved Non-Genetically Modified Food Ingredients and Product) The BRC technical standard was revised and renamed "BRC Global Standard - Food Products".

In the future, the standard became indispensable for all organizations of the retail trade industry; On January 4, 2008, a new, 5th edition of the Standard was published.

Provisions of the standard. The standard is divided into 6 sections:

- HACCP system;
- Quality management system;
- Standards regarding the working environment;
- Product management;
- Process management;
- Personnel.

The first section requires the application of the HACCP system. The requirements are fully compatible with the seven HACCP principles defined by the Codex Alimentarius. However, the BRC Standard does not require all five previous steps defined in Codex to be followed; yes, the BRC requires the establishment of a HACCP group, but does not require a formalized description of the product and its intended use.

The second section deals with the quality management system, including issues such as management commitment, internal audits, resource management, as well as some aspects of traceability, non-conformance management, etc.

The other four sections establish operational requirements for quality management and general good manufacturing practice (GMP).

However, the implementation of these general GMPs does not relieve the company of the need to implement the specific and formalized GMP plan required in the first section. Prevalence. Until now, in many countries, the standard is associated with the best practice in the food industry. The application of the standard outside the UK has made it global, and not only for evaluating suppliers, but also as a basis for food production and inspection planning. The majority of retail chains in the UK and the Nordic countries work only with those suppliers who have a certificate of compliance with the BRC Global Standard. Since these networks are present in

significant numbers in other countries, or have suppliers abroad, the standard has spread almost all over the world.

Although the number of certified companies is not known, some idea of their number and geography can be given by the number of bodies carrying out certification for compliance with the BRC standard: more than 100 in 23 countries (Australia, Belgium, Denmark, Finland, France, Germany, Greece, the Netherlands, Ireland, Italy, New Zealand, Norway, Poland, Great Britain, the United States of America, etc.).

EFSIS standard. The International Food Standard (IFS) was created in 2002 by the German association HDE (Hauptverband des Deutschen Einzelhandels). In 2003, French retailers and wholesalers from the Federation of Traders and Distributors (FCD) joined the IFS Working Group; both associations jointly developed the current version of the standard.

Scope and objectives. IFS is a food safety and quality management standard based on the HACCP concept and intended for manufacturers of any food product, excluding primary products, e.g. fruit and vegetable growing (as well as the BRC Global Standard - Foodstuffs).

Like the BRC, the IFS standard was originally intended for manufacturers of supermarket branded food products and aimed to ensure safety at all stages of production.

Certification issue. The fourth edition of the IFS standard was published in January 2004. The IFS program provides two levels of certification:

- "basic level" is considered the minimum set of requirements for the food industry;

- "higher level" is considered as the highest standard in the food industry.

Breaking down the standard into steps allows for gradual and more flexible implementation and continuous improvement. The criteria are divided into two different levels corresponding to two different levels of certification:

- "basic level criteria" include 230 items;

- "higher level criteria" include an additional 60 points.

In addition, 46 recommendations are formulated for companies wishing to

demonstrate best practice in the industry. Each criterion is assigned a certain number of points, which reflects the degree of compliance and the level of the criterion.

A certificate (of basic or higher level) is issued depending on the number of points obtained. Such a system is flexible, because the company is not forced to demonstrate effective compliance with each clause of the standard. Instead, it is only required to submit a corrective action plan for the nonconformities.

The requirements of the IFS standard cover 5 topics:

- Management of the quality system (HACCP system, quality guidelines, etc.).
- Management responsibility (checks of quality and production systems, etc.).
- Resource management (human resources, hygiene, household facilities, etc.).
- Production processes (product development, production equipment, traceability, etc.).
- Measurement, analysis, improvement (control measures, product recall, etc.).

The first two topics are directly related to HACCP and quality assurance. Implementation of the HACCP system is mandatory, and reference is made to the relevant Codex Alimentarius document on HACCP principles. However, the requirements of the "basic level", although fully repeating the seven principles of HACCP, do not include some preparatory steps, in particular, the requirement to check the block diagram of the technological process on site. "Higher level" is completely identical to Codex Alimentarius requirements for HACCP. The other three topics relate to requirements for general good manufacturing practice and quality management. CAC/RCP 1-1969 (Rev.4-2003). Recommended international code of rules "General principles of food hygiene". Prevalence. According to IFS, almost all German and French retail chains (including some of the global players such as Metro, Carrefour and Auchan require IFS compliance certification. At the same time, some retailers do not support the IFS standard (for example, Leclerc , which is not part of the FCD association.

At the moment, IFS-supporting retail chains require IFS certification only from those companies whose products are sold under the supermarket brand. However, according to the developers of the standard, many other supplier companies also

conduct IFS compliance audits themselves and require the same from their suppliers and subcontractors.

Thus, whether to start implementing an international food safety management standard, and which standard to choose, is a question that each company can decide at its own discretion.

EUREPGAP/GLOBALGAP. The developing organization is the Association of European Retailers of Agricultural Products (EUREP) was created in 1997 by large European retail chains, a little later large companies of suppliers and manufacturers of agricultural products joined it; associated participants are also involved in the work of the association - manufacturers of agrochemicals, certification bodies, consulting firms, etc.

Each certification program is developed by a separate committee, which consists of 50% representatives of retail chains and 50% - manufacturers. The secretariat of all certification programs is located on the basis of FoodPLUS, a non-profit organization that is the legal owner of all regulatory documents.

Scope and objectives. The EUREP association has developed several certification programs, collectively known as EurepGAP and recently renamed GlobalGAP (GAP stands for "Good Agricultural Practices"), and are designed to promote good and best agricultural practices in order to restore consumer confidence in food safety, ensure welfare animals, environmental protection and labor protection.

Unlike other international food safety standards, GlobalGAP standards are designed exclusively for non-processed agricultural products and are therefore intended for use by farmers, not processing companies.

At the same time, these standards, stimulating the minimal use of agrochemicals and medicines, cover more issues than just food safety - they also cover occupational safety, environmental protection issues, and animal welfare.

Certification issue. Today, GlobalGAP is the only integrated standard with the possibility of applying its individual modules to different groups of goods - from the production of plant products, animal husbandry to the production of compound feed.

The certificate can be granted both to an individual manufacturer and to a group

of manufacturers - in this case, such a group of manufacturers must have a quality management system, including a written instruction on the application of the standard) and an internal audit procedure, which provides for the inspection of each member of the group at least once a year. Identified inconsistencies during certification or surveillance audits may lead to the revocation of the certificate not of an individual manufacturer, but of the entire group. Certificates are issued for three years, with an annual supervisory audit.

GlobalGAP standards allow, after carrying out an equivalence procedure, recognition of other good agricultural practice standards implemented by producer groups as meeting the requirements of GlobalGAP. The certification program includes a certain number of control points, compliance with which can be "significant", "minor" and "recommended". To be certified, a producer must meet all relevant "major" critical points and 90% (95% in the case of fruit and vegetables) of relevant "minor" critical points. If, after certification, the manufacturer violates the requirements of the standard, sanctions are introduced - warning, suspension, revocation of the certificate).

International Food Standard (IFS), version 4. International Food Standard (IFS), version 4. The objectives of the standard are:

- creation of a single evaluation basis for all manufacturers of own brands,
- unification of wording and auditing,
- mutual recognition of the conducted audit, - high transparency within the entire supply chain,
- determination of substantive requirements, progress and evaluation of the audit,
- determination of the specifics of the requirements for organizations conducting certification.

The food standard offers:

- an effective and transparent tool for the audit of manufacturers,
- the same basis for evaluation for everyone,
- unified wording and auditing and greater transparency.

After its introduction in 2002/2003, IFS gained significant recognition and began

to spread rapidly around the world. It is a prerequisite for establishing close supplier relations. So, around the world, approximately 3,187 companies have been audited according to version 4 of the IFS standard.

SQF 2000 is the standard of the SGS group (Societe Generale de Surveillance) with the SQF (Safe Quality Food) certificate. It is based on a food safety support system, as well as a quality management system. Scope - covers all economic participants in the food chain.

ISO 22000:2005. The International Organization for Standardization developed ISO 22000 to respond to the growing requirements for certification in the food chain. This standard was created for the entire food processing chain, in particular:

— for agricultural production;

— for the packaging industry;

— manufacturers of technologies for food products. The basis of the standard is the HACCP system.

The ISO 22000 standard has the following objectives:

• Compliance with HACCP principles;

• Harmonization of voluntary international standards;

• Providing an audit standard that can be used for either internal audits, self-certification, or third-party certification.

The structure is close to ISO 9001 and ISO 14001. To ensure the spread of information about HACCP concepts at the international level. ISO 22000:2005 establishes requirements for a food safety management system that combines the following commonly known key elements:

- interactive information; - system management;

- prerequisite programs;

- HACCP principles.

Interactive information. In order to provide effective interactive information, each organization must first of all define its place and role in the food chain.

The standard requires that the food safety management system (FMS) covers both external and internal reporting. Information along the entire food chain is essential to

ensure the identification and adequate management of all relevant food hazards at each stage within the food chain, in particular to provide information on aspects of an organization's food safety that may be relevant to other organizations in the food chain.

Resolutions of the European Parliament:

• White book on food safety; • Regulation of the European Parliament and Council 178/2002/EC of January 28, 2002;

• Resolution of the European Parliament No. 852/2004 of April 29, 2004;

• Resolution of the European Parliament No. 853/2004 of April 29, 2004;

• Regulation of the European Parliament and Council 854/2004/EC of April 29, 2004;

• Directive (EC) No. 852/2004; Directive (EC) No. 852/2004 of the European Parliament and of the Council of April 29, 2004 on the hygiene of foodstuffs is based on the previous Directive 93/43/EC of the Council on the hygiene of foodstuffs of June 14, 1993. It describes the basic rules of food hygiene for all enterprises of the entire food chain, including primary production.

1.9. Laws of Ukraine regulating the quality and safety of food products

The main Laws of Ukraine regulating the quality and safety of food products:

- Law of Ukraine "On the safety and quality of food products" (Document 771/97-vr, last edition dated 06.14.2007 based on 1104-16, valid);

- Law of Ukraine "On Protection of Consumer Rights" (Document 1023-12, last edition dated 01.13.2006 based on 3161-15, valid);

- Law of Ukraine "On Ensuring Sanitary and Epidemiological Welfare of the Population" (Document 4004-12, last edition dated 05.22.2008 based on v010p710-08, valid).

- Law of Ukraine "On Milk and Dairy Products" (issued on June 29, 2004 No. 1870-IV, in force);

- Law of Ukraine "On fish, other water resources and food products from them"

(issued on February 6, 2003 No. 486 IV, in force);

- Law of Ukraine "On Children's Nutrition" (from 14.09.2006 No. 142 – V, valid);

- Order of the Ministry of Health of Ukraine No. 222 dated 07/23/1996 No. 715/1740 "On the approval of sanitary rules and norms regarding the use of food additives";

- Order of the Ministry of Health of Ukraine "On the approval of state sanitary rules and regulations for enterprises and vessels producing products from fish and other aquatic living resources" dated May 6, 2003 No. 197;

- Draft Law of Ukraine "On Meat and Meat Products" (Decree of the Verkhovna Rada of Ukraine "On adoption as a basis of the draft Law of Ukraine "On Meat and Meat Products" dated November 2, 2005 No. 3044-IV);

- Law of Ukraine "On Withdrawal from Circulation, Processing, Disposal, Destruction or Further Use of Low-Quality and Dangerous Products" (Document 1393-14, latest edition dated 06.11.2003 based on 762-15, valid);

- The Law of Ukraine "On the responsibility of the supplier for the production and sale of low-quality and dangerous products".

National Commission of Ukraine Codex Alimentarius. The main tasks of the NCCA are: analysis of international and domestic legislation and development of proposals for improving legislation in the field of food safety and quality; harmonization of domestic legislation with international legislation in the specified area; promoting the introduction of new technologies, international standards, domestic technical regulations and international sanitary measures in the field of food production and new methods of their research.

1.10. "Horizontal" and "vertical" committees on general issues of food legislation

"Horizontal" committees on general issues of food legislation:

- Secretariat and department for organizing the work of the Central Committee and Committees;

- Committee of general principles and rules with an executive committee - on issues of food legislation and documentation, toxicological and hygienic regulation, science and education in the field of food hygiene, monitoring of food safety and nutritional status of the population, protection of consumer rights, international cooperation - the same reference body on issues of sanitary and phytosanitary measures;

- Committee on residual amounts of pesticides, veterinary drugs, food additives and other food contaminants;

- Committee on food hygiene and principles of HACCP, import and export products, systems and inspections and control of nutrition principles;

"Vertical" committees on specific groups of food products:

- Committee on plant-based products (cereals, fruits, vegetables and their products (including cocoa products, confectionery, juices, sugars, vegetable protein and others);

- Committee on issues of products of animal origin (fish and fish products, meat and meat products, milk and milk products, and others);

- Committee on fats and oils;

- Committee on drinking water, natural mineral waters and beverages; Committee on auxiliary means of substances and materials for the production and circulation of food products;

- Committee on nutrients and products for special dietary purpose;

- Committee on methods of analysis and sampling.

Conclusions

Special normative acts in the field of quality management are the normative acts of the State Standard of Ukraine, which regulate important issues of development, implementation and functioning of product quality management systems, conducting legal examination of normative documents. Therefore, the current legislation of Ukraine constitutes a strong regulatory framework at all levels of national economy

management. However, the legislation still does not fully meet social requirements. The current legislation of Ukraine provides for the responsibility of enterprises, associations, organizations, as well as officials and other workers for violations in the field of quality of products, services and contractual obligations. Types of legal liability of enterprises:

- civil law is liability based on the principle of full compensation for damages caused by an offense; - administrative and legal;

- financial and legal.

Types of personal liability of workers:

- administrative (regulated by the Civil Code of Ukraine, the Code of Ukraine on Administrative Offenses);

- material (the obligation of workers and employees to compensate for property damage caused by their fault) is limited (the amount of compensation does not exceed the limit established by law) or full (the compensation is made in full). It is regulated by the Code of Labor Laws and the provision on material responsibility.

- disciplinary (for violation of rules and regulations regarding product quality: remark, reprimand, severe reprimand, transfer to a lower salary or a lower position for a period of up to three months, dismissal);

- criminal (provided for repeated release or release in large quantities of low-quality, non-standard and incomplete products. Regulated by the Criminal Code of Ukraine