

## Part 3. Biosafety

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### DEVELOPMENT DIRECTIONS OF LABORATORY INFRASTRUCTURE SUPPLY IN AGRICULTURAL PRODUCTION

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**Summary.** The results of the Ukrainian Laboratory of Quality and Safety of Agricultural Products testing activity analysis was carried out. The normative documents on the accreditation of laboratories and international recommendations concerning the rational use of standardized biological material in the testing activity are analyzed. The optimizing expediency of biological material collections functioning in scientific institutions is substantiated. The conducted analysis testifies the creation expediency of the national bioresource center, which unites (informationally) all functioning collections of biological material in order to increase the efficiency of their innovative potential. Not a high level of competitiveness of domestic agricultural products on the world market indicates the need not to ensure proper control of the quality and safety of not only finished products, but also all technological processes in its production. Ukrainian Laboratory of Quality and Safety of Agricultural Products of the National University of Life and Environmental Sciences is accredited in accordance with the requirements of ISO/IEC 17025 for defining more than 370 indicators of quality and safety. Selection of samples (water, soil, grain, seeds, forage, fertilizers, pesticides, biological preparations, eggs, oils and fats, crop production, livestock, food products and food additives, etc.) for testing, conducting analytical studies and obtaining results are carried out accordingly, the documents regulating the order of work. They analyzed the results obtained in 2014–2017, as well as data on accreditation requirements and the technical competence of laboratories. An important direction in improving the efficiency of laboratory support for the production of agrarian sector of the economy is the organization of the proper functioning of biological resource centers. The scope of accreditation of the Ukrainian Laboratory of Quality and Safety of Agricultural Products involves the use of a range of standardized biological material. That is, the actual task is to create a unit to maintain a collection of biological materials used in experimental and scientific activities. The results of the analysis testify to the expediency of creating a nationwide bioresource center that will unite (informationally) all functioning collections of biological material with the aim of increasing the efficiency of using their innovative potential.

**Keywords:** agricultural products, biological material, collections, normative documents

**Introduction.** Agricultural production is one of the most important sectors of the economy in our country, which ensures food security. Food security of citizens is one of the main governmental components of economic security (Ushkalov et al., 2016). Ukraine has significant resource potential for the agrarian sector developing and improving the efficiency of agricultural production. However, quite often there is an unfair business activity in the production and sale of counterfeit and/or counterfeit products in the consumer market. This applies both to food and raw materials for their manufacture, and to the protection of plants, fertilizers, seeds, etc. (Ushkalov, Samkova and Danchuk, 2017). That is, the low level of competitiveness of domestic products of the agrarian sector in the world market indicates the need to ensure proper the quality and safety control not only for finished products, but also for all technological processes in its production. An effective mechanism for agro-industrial products controlling is monitoring of quality and safety

indicators not only for finished products but also for all components involved in its production (soil and water as the main resources for agricultural production, plant protection products, mineral and organic fertilizers, seeds of agricultural cultures, etc.) (Borg, 2014).

That is, at the time of demand, the role of proper/efficient laboratory support of production in the agrarian sector increases. Given the importance of export-oriented goods production, the role of accredited laboratories also increases. The presence of accreditation testifies to the official recognition of the laboratory ability to meet the requirements of customers in the field of testing, measurement or research. Accreditation takes into account: technical equipment and competence of the laboratory, that is, the minimum required level of equipment for testing and research in a certain field of activity, competence of staff (requirements for the composition, number and qualification of laboratory staff); the functioning of the quality system (rules and

standards for the implementation of the basic processes of the laboratory), through which it is possible to guarantee stable work and obtaining reliable results of research, testing or inspections (EP and CEU, 2002; VRU, 2001).

**The purpose of the work** is to determine the directions of infrastructure development for the laboratory support of the export-oriented agro-industrial goods production.

**Materials and methods.** The analysis of the results obtained in 2014–2017 in the Ukrainian Laboratory of Quality and Safety of Agricultural Products (ULQSAP) of the National University of Life and Environmental Sciences (accredited in accordance with the requirements of ISO/IEC 17025 for determination of more than 370 quality and safety indicators). Selection of samples (water, soil, grain, seeds, forage, fertilizers, pesticides, biological preparations, eggs, oils and fats, crop production, livestock, food products and food additives, etc.) for testing, conducting analytical studies and obtaining results are carried out accordingly to the documents regulating the order of work. Data analysis was carried out on the requirements for accreditation and technical competence of laboratories, as well as the use of standardized materials used in the conduct of research.

**Results and discussions.** The results of the analysis indicate that accreditation is required for those laboratories which performance should be recognized by other market participants or the professional community (NAAU, 2016). These laboratories include test laboratories — institutions that work with different types of products, materials and environments. Their purpose is to conduct samples testing (products, materials or environmental elements) for compliance with the parameters set in the regulatory documents. Analytical laboratories are solving research tasks. Accreditation of analytical laboratories allows ensuring the reliability of the elemental composition determination of the samples under study. This is necessary to recognize the results of research by other participants in economic activity. The scope of the laboratory accreditation may vary, depending on the purpose of its creation.

It must be taken into account that not every laboratory needs accreditation to perform the tasks. In certain cases, when there is no need to recognize the results of laboratories from other participants in the economic activity, the accreditation of the laboratory may not be carried out. In particular, training laboratories (at educational institutions) or laboratories that solve highly specialized tasks (scientific laboratories).

The features of the ULQSAP of agrarian and industrial complex activities are simultaneously of research and testing laboratories of the university accredited in accordance with the requirements of ISO/IEC 17025 and confirming their competence by participating in the laboratory comparisons of results organized by domestic and international coordinators. That is, a certain range of

researches carried out in the laboratory does not require compulsory accreditation, namely — scientific research projects (in the ULQSAP of the agrarian and industrial complex, in the average year, 3–5 scientific research projects by state order, 6–15 scientific research projects under economic contracts and 2–3 initiative scientific themes).

At the same time, it should be noted that both the testing activity and the execution of scientific research require the availability of standards. With regard to standards for chromatographic (gas, liquid) and spectral (emission, absorption and mass spectrometric) studies, the necessary analytical standards are developed and provided by companies such as Sigma-Aldrich, Romer Labs, etc. In particular, the analytical standards of mycotoxins, pesticides, heavy metals, alcohols, etc. are used in the ULQSAP. The market for biological standards is also rich in offers (National Institute of Biological Standards and Control (NIBSC), LGC Ltd, OIE reference laboratory, and others). For example, in Ukraine — in the State Research and Control Institute of Biotechnology and Strains of Microorganisms — it is developed, manufactured and delivered to interested microorganism test culture organizations (<https://drive.google.com/file/d/0B-9dlmwAZcW7WkhGSm1JT'TVIMkE/view>).

Standard test strains of microorganisms are used in accredited laboratories to confirm the ability of nutrient media and differential diagnostic tests to ensure the growth of bacteria and/or fungi in the research, manufacture of biologics and control of their quality, etc.

The availability of standard biological materials is a prerequisite for the survival of cellular biotechnology, genetic engineering, microbiology — biotechnology in the broadest sense of the word. In accordance with modern scientific concepts, the term 'biological material' means any material containing genetic information and able to self-reproduction or reproduction in the biological system (Holovko et al., 2007).

Nowadays the numbers of international organizations are trying to promote economic growth and disseminate the positive experience of socio-economic policy. For example, the Organization for Economic Co-operation and Development (OECD) is an international organization that brings together 35 economically developed countries of the world (USA, Germany, France, Australia, Canada, Switzerland, Norway, South Korea, Japan, etc.). In order to meet the current requirements for the further development of life sciences and biotechnologies, in particular to increase the efficiency of analytical research, the OECD in 2001 proposed a new concept for storage and supply of high quality biological materials and information about them, namely the creation of biological resource centers (BRCs) (OECD, 2001). BRCs should provide the scientific infrastructure with the relevant standard bioresources in order to better realize the benefits of biotechnology. As a result of

consultations in 2007, recommendations for the quality management system of BRC collections were developed. The OECD Biosafety Good Practice Handbook (2007) for BRCs describes methods and protocols for safe handling and handling of biological materials. BRCs should ensure the proper storage, maintenance and exchange of biological resources (OECD, 2004, 2007). Microbial resource centers are institutions that can protect, maintain and distribute authenticated microbial strains, their genomic DNA and related materials. In addition to taxonomy, the use of deposited strains allows for scientific research at a higher methodological level, which leads to a significant improvement in the results (Overmann, 2015).

Collections of microorganisms in Ukraine are functioned and used in scientific researches, the results of which are used in applied biotechnology, pharmacology, veterinary medicine, agronomy, health care, ecology, etc. Thus, in the National Center for Microorganism Strains, the State Research and Control Institute of Biotechnology and Strains of Microorganisms maintain active strains of microorganisms and cell cultures to meet the needs of veterinary medicine (used for the production and control of veterinary immunobiological drugs in Ukraine) (Holovko et al., 2007).

However, the needs of the modern market of 'biological standards' are not limited by test strains of microorganisms. For example, in the testing activity of the ULQSAP, the use/planning of the use of laboratory cultures of Algae (*Desmodesmus subspicatus*, *Phaeodactylum tricornerutum*, *Selenastrum gracile*, *Chlorella vulgaris*, *Spirulina (Arthrospira) platensis*), Infusoria (*Tetrahymena pyriformis*, *Colpoda steinii*), Daphnia (*Daphnia magna*, *Ceriodaphnia dubia*), fish (*Poecilia reticulata*, *Carassius*), earthworms (*Eisenia fetida*), entomophages, particularly *Trichogramma*, *Gabrobracon*, *Dibrachus*, *Ascogaster*, *Phytoseiidae*, cereal moth (*Sitotroga cerealella*), mill moth (*Ephesia kuehniella*), bees (*Apis mellifera*), and radish (*Raphanus sativus*). In addition, according to the results of testing, it is possible to create a collection of cultures-phytopathogens, micromycetes, soil microorganisms of certain ecological trophic groups (ammonifiers, amyolytic, pedotropic, oligotrophic, actinomycetes, etc.), DNA of genetically modified plants, etc.

That is, the modern interpretation of the concept of 'biological resources' raises the task of expanding the biological resource base and the development of biotechnology, in accordance with the recommendations of the OECD. In other words, at the time the issue is to ensure the unified management of collections in relation to the storage and circulation of biological materials used in economic activities, in particular testing. Centers of biological resources should become an element of the scientific infrastructure for the implementation of scientific achievements in biotechnology.

It is important to emphasize the fact that bioresources centers should be authorized not only to identify, collect, control quality, classification, registration, storage, reproduction, distribution of storage facilities, but also the merging of existing collections of different biomaterials into a single information network, training and training of relevant expert staff necessary to ensure the effective functioning of such centers. Biological collection is a systematic storage of any type biological material samples set. On this basis, it is possible to distinguish several types of biological collections depending on the types of biological material and storage methods stored in them (Kamenski, 2016):

— cryopreservation, in which the material is stored in a frozen (and lyophilized) form, including nucleic acids;

— materials of zoological museums and herbaria, such collections can be used both for the study of biodiversity, as it is a valuable source of DNA;

— computer databases (collections of biological information) containing information on the primary, secondary and tertiary structure of biological molecules, such as GenBank (nucleotide sequences of genomes of different organisms, <http://www.ncbi.nlm.nih.gov/genbank>) and Protein Data Bank (tertiary protein structures, <http://www.rcsb.org>).

The functional purpose of the collection of biomaterials may be:

— research, in cases where samples are stored in research laboratories and are necessary for their daily activities. Types of samples in such collections can be very different - from individual biological molecules to whole organisms;

— commercial, whose funds are for sale (sex cells, blood cells, etc.). For example, the Animal Blood Bank was created at the Faculty of Veterinary Medicine of NULES of Ukraine;

— government collections that are collected and maintained in the interests of the state. First of all, this category includes collections whose purpose is to preserve biodiversity (zoos, botanical gardens, etc.). In addition, these collections are designed to regulate the effective use of biological resources. In the US, the Natural Product Repository has been created in the National Institutes of Health, in Russia, the status of the national bioresource center is provided by the All-Russian Collection of Industrial Microorganisms. In other countries, work is under way to build and maintain the functioning of biological resource centers.

It should be noted that the functioning of biomaterial collections is considered at the OECD level as one of the key issues of national biosafety, since, for example, in the context of a 'crisis', the absence of its own collection of producer cells for industrial biotechnology (veterinary, agricultural) can have a negative impact on livestock farming and crop production respectively.

An example of a crisis situation can be the period of the former USSR collapse, and the crisis in veterinary biotechnology due to the lack of production strains and technologies for the production of animal protection means.

As to the current state of microorganism collections functioning in Ukraine, the following should be noted. In accordance with the Resolution of the Cabinet of Ministers of Ukraine No. 705 from 12.10.1994 'On the state system for the depositing of strains of microorganisms' by the state, three depositaries (collections) have been designated by the state for the purpose of ensuring the legal protection of strains of microorganisms and creating conditions for their timely wide use for biotechnological productions and scientific purposes:

— the Institute of Microbiology and Virology of the National Academy of Sciences responsible for the storage of non-pathogenic microorganisms;

— Kiev Research Institute of Epidemiology and Infectious Diseases of the Ministry of Health of Ukraine has been designated for the storage of microorganisms pathogenic to humans;

— for the storage of microorganisms pathogenic to animals responsible the Kyiv branch of the State Scientific-Research Control Institute for Veterinary Medicines and Feed Additives (now the State Research and Control Institute of Biotechnology and Strains of Microorganisms) has been identified.

Accordingly, research collections of microorganisms /other biomaterials were maintained in accordance with research institutes and faculties of educational institutions of biological, medical, veterinary and agricultural profile. Despite the invariable significant research and innovation potential of collections, its use requires additional impetus. One of the factors hindering their development is the isolation of existing collections, the ignorance of the scientific community about the availability and characteristics of the samples that are stored in. World experience shows that this problem can be solved by creating a single information system that would provide communication between collections and potential users. To this end, it is necessary to keep records in existing collections and to create a single electronic database of storage facilities, standardization of requirements for their storage and ways to ensure their availability.

The main deterrent to the functioning of collections is the lack of targeted funding. At this time in Ukraine, it is

almost impossible to find a source of material support for the proper maintenance of collections. However, attempts at financial and regulatory provision of collections for veterinary bio-industry in previous years were. For example, in 2006–2009 the financial support of research collections of strains for veterinary biotechnology in the National Scientific Center 'Institute of Experimental and Clinical Veterinary Medicine', Institute of Veterinary Medicine of NAAS, Institute for Epizootology of NAAS, Yuriev Institute of Plant Production of NAAS, Institute of Agricultural Microbiology and Agro-Industrial Production of NAAS, and some higher educational institutions provided by the State Committee for Veterinary Medicine through the State Scientific Control Institute of Biotechnology and Strains of Microorganisms, through the ordering of targeted research work on the study of biological properties in microorganisms that have been kept for a long time, the selection and identification of new topical strains of pathogens of animal diseases, etc.

Another problem that is critical for the development of collections is regulation of the circulation of biological resources, especially cross-border. The conducted analysis shows the expediency of creating a nationwide bioresource center, which will unite (first of all informationally) all functioning collections of biological materials in order to increase the efficiency of their innovative potential. To do this it is needed to provide:

— revision of the bioresources collections status that are functioning at this time;

— creation of a single database containing information on all collections of biomaterials (formation of information and analytical systems);

— development of effective measures to regulate the activities of collections and related fields of science and technology;

— formation of a scientific research state program in biomaterial collections;

— integration of national bioresources centers into the global bioresource information space.

#### **Conclusions and perspectives of further research.**

An important direction in improving the laboratory support efficiency of production activities in the economy agrarian sector is the organization of the proper functioning of biological resource centers. The scope of ULQSAP accreditation involves the use of a range of standardized biological material. That is, the actual task is to create a unit to support a collection of biological materials used in experimental and scientific activities.

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