Specific measures for contained use of living modified organisms that effectively limit their contact with and impact on the external environment. Republic of Belarus.

In the Republic of Belarus Practical Guidance on specific measures for contained use of living modified organisms has not been developed. At the same time, specific measures for contained use of living modified organisms that effectively limit their contact with and impact on the external environment are defined in the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" of January 9, 2006 and by-laws to it.

The Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" establishes fundamental legal principles and the institutional basis to ensure safety in genetic engineering activity for contained use of living modified organisms.

It defines the term "self-contained system":

"self-contained system" means a system where operations related to genetically engineered organisms are undertaken, fitted with special equipment and devices for eliminating a contact of genetically engineered organisms with the environment and impact on it.

Article 13 of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" defines risk levels of genetic engineering activity:

"risk level I" means work with non-pathogenic genetically engineered organisms;

"risk level II" means work with potentially pathogenic genetically engineered organisms;

"risk level III" means work with pathogenic genetically engineered organisms capable of causing dangerous infectious diseases and spreading infection and against which effective measures of prophylaxis and treatment exist;

"risk level IV" means work with pathogenic genetically engineered organisms which are pathogens of particularly dangerous infectious diseases having the ability to spread quickly and against which effective measures of prophylaxis and treatment are unknown.

The Law "On Safety in Genetic Engineering Activity" determines that accreditation must be carried out for a self-contained system to perform works of risk levels II, III and IV in genetic engineering activity. The Law determines that genetic engineering activities of risk levels II, III and IV are carried out exclusively by State legal entities.

The Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 50 establishes "Safety Requirements for Self-Contained Systems to Carry out

Works of Risk Level I in Genetic Engineering Activity".

The Resolution determines:

works of risk level I of genetic engineering activity in self-contained systems shall be carried out in isolated units (premises), excluding release of genetically engineered organisms into the environment. Premises used for works with genetically engineered plants shall be located at a distance of no less than 300 meters from nurseries, greenhouses and fields for growing of related plant species that belong to the same taxonomic plant genus with those used in works;

waste products of genetically engineered organisms generated as a result of works shall be deactivated by the method excluding preservation of viable spores, pollen, fruits or seeds. Waste products of genetically engineered microorganisms shall be deactivated in accordance with the procedure established by the Instruction "On Rules and Methods for Deactivation of Waste Products of Medicinal Agents, Healthcare Products and Medical Equipment" approved by the Resolution of the Ministry of Health of November 22, 2002 No. 81;

legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I of genetic engineering activity shall:

ensure execution of works in accordance with the instruction on work safety established by legal entities and individual entrepreneurs engaged in genetic engineering activity of risk level I on agreement with the competent territorial body of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus;

instruct employees engaged in the activity on work safety procedures.

Safety Requirements for Self-Contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity are established by the Resolution of the Ministry of Health of the Republic of Belarus of August 25, 2006 No. 65.

Main safety requirements for self-contained systems to carry out works of risk levels II, III and IV in genetic engineering activity are as follows:

a Certificate of Accreditation to ascertain that execution of works of risk levels II, III and IV in genetic engineering activity is allowed in this self-contained system of the organization issued in accordance with the Instruction "On Accreditation Procedures for Self-Contained Systems to Carry out Works of Risk Levels II, III and IV in Genetic Engineering Activity" established by this Resolution;

availability with organization employees of a permit for carrying out works of risk levels II, III and IV in genetic engineering activity;

arrangement of work in organization laboratories in accordance with sanitary norms and regulations and hygienic standards.

Organization employees are allowed to perform works of risk levels II, III and IV in genetic engineering activity, provided that:

they have higher and (or) secondary medical, biological, veterinary education;

they have been instructed on the compliance with biological safety requirements by the Lab Supervisor. The fact that they have passed safety induction shall be confirmed by a signature of the Lab Supervisor in the Registration Log of staff workplace briefing (Tool Box Talk) in line with Annex I. The follow-up briefing shall be carried out at least twice a year.

Admission of employees to perform works of risk levels II, III and IV of genetic engineering activity, as well as engineering and technical personnel to maintain laboratory equipment shall be made by order of the Head of an organization following a decision of the Compliance Committee on Biosafety Requirements and Anti-epidemic Regime established within an organization and endowed with powers to:

exercise control over compliance with safety requirements for self-contained systems by an organization when carrying out works of risk levels II, III and IV of genetic engineering activity;

take measures to carry out activities aimed at prevention of emergency situations and liquidation of their consequences in the implementation of genetic engineering activity;

take decisions on admission of organization employees to works of risk levels II, III and IV of genetic engineering activity and maintenance of laboratory equipment;

exercise control over staff training on works with genetically engineered organisms, their fulfillment of sanitary-epidemic and personal hygiene requirements.

Personal composition and operation procedures for Compliance Committee on Biosafety Requirements and Anti-epidemic Regime of an organization shall be established by statutes and approved by Head of an organization.

Organization staff members shall undergo periodic medical examination in accordance with the Procedures of Compulsory Medical Examination for Employees established by the Resolution of the Ministry of Health of the Republic of Belarus of August 8, 2000 No. 33.

In order to prevent unauthorized intrusion into the territory of an organization, its territory should be fenced; laboratory facilities are subject to 24-hour security.

Laboratories should be located in a separate building or isolated part of the building with a separate entrance. The Lab entrance door should be equipped with a locking device, a sign indicating laboratory name and (or) number and the sign “Biological Hazard” should be placed at its front in line with Annex II.

Requirements to the laboratory space planning, its facilities, interior furnishing, water supply facilities, canalization, laboratory equipment and furniture, the operation of supply and exhaust ventilation systems and other technical requirements shall be established in accordance with sanitary norms, rules and hygienic standards.

Laboratory premises should be separated into the “infectious” area to carry out genetic engineering activity and the “clean” area, which is not used for genetic engineering activity.

Biological safety cabinets of classes II and III are used in the laboratory premises of the “infectious” area. The following main types of genetic engineering activity are carried out there:

studies in animal (infection, autopsy);

infected animal management;

centrifugation of genetically engineered organisms, drying, disintegration and other operations with probable aerosol formation;

infection of cell cultures and chicken embryos;

making suspensions;

work on keeping collection strains and other.

All types of genetic engineering activity shall be carried out in accordance with sanitary norms, rules and hygienic standards.

When works are being carried out, the doors of cabinet and pre-cabinet laboratory premises should be closed; exit from side premises is prohibited. Cabinet premises should be equipped with alarm systems for emergencies.

When carrying out genetic engineering activity, at least two specialists shall be present in the laboratory premises of the “infectious” area, one of them is either a medical specialist or a research scientist. The continuous work time with genetically engineered organisms of risk levels II, III and IV shall not exceed 4 hours with 30-60-minute breaks to follow.

Calling out of employees from the “infectious” area of laboratory premises during works is not allowed.

Permission to visit laboratories by engineering and technical personnel, non-permanent laboratory staff, shall be issued by the Lab Supervisor. A visit to the laboratory is carried out when the laboratory work has been finished and current disinfection is being performed. Engineering and technical personnel are accompanied by either a medical specialist or a research scientist of the laboratory and their visit is registered in the Laboratory Visit Log.

Laboratory visit authorization forms and the Laboratory Visit Log are subject to approval by Head of an organization.

As soon as all woks have been finished, the laboratory should be locked and sealed. If there are collection microorganism cultures, their storage facilities should be additionally sealed.

Genetically engineered organisms should be kept in the “infectious” area of laboratory facilities in the sealed refrigerator destined for assay storing. Inoculated medium (plating) should be placed into thermostats, refrigerators and cabinet units pursuant to corresponding methods. Isolated cultures of genetically engineered organisms and collection strains should be stored in the separate dedicated refrigerator, also sealed.

An inventory sheet shall be compiled for the stored genetically engineered organisms. It includes:

name of a genetically engineered organism;

number and date of issue of the Registration Certificate for a genetically engineered organism, issued according to the form of Annex X to the Instruction “On Accounting Procedures by State Legal Entities of Developed, Imported into

the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms";

data on transport, storage, use and deactivation of a genetically engineered organism.

Capacities, containing genetically engineered organisms, should have clear indelible endorsements or firmly glued labels with name of a genetically engineered organism, a strain number and lyophilisation date.

Organizations should use genetically engineered organisms for scientific research, vaccine development and immunobiological medicinal products.

Organizations should keep a record of genetically engineered organisms in accordance with the Instruction "On Accounting Procedures by State Legal Entities of Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory Potentially Pathogenic and Pathogenic Genetically Engineered Organisms". Head of an organization shall hold responsibility for compliance with safety requirements for self-contained systems to carry out works of risk levels II, III and IV of genetic engineering activity in the organization.

Further details of work procedures in self-contained systems, preventing the entry of such organisms into the environment, responsible organizations that ensure safety of such activities and their relationships, as well as the developed forms can be found in the Para 1.3. "Work in Self-contained Systems" of the Final Desk Study (Belarus) of the Secretariat of the Convention on Biological Diversity project "Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level" (JBF2015-2016 BS-1) – 2016. – P. 48-56.

Galina Mozgova,
BCH NFP,
Head of the National Coordination Biosafety Centre,
Institute of Genetics and Cytology
National Academy of Sciences of Belarus