2021

Ministry of Natural Resources and Environmental Protection of the Republic of Belarus

United Nations Environment Programme

Global Environment Facility

National Coordination Biosafety Centre

Institute of Genetics and Cytology, NAS of Belarus

FOURTH NATIONAL REPORT ON THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY IN THE REPUBLIC OF BELARUS

SUPPORT TO PREPARATION OF THE FOURTH NATIONAL BIOSAFETY REPORTS TO THE CARTAGENA PROTOCOL ON BIOSAFETY - ASIA-PACIFIC, GRULAC, CENTRAL AND EASTERN EUROPE REGIONS

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UNEP-GEF Project
Support to Preparation of the Fourth National Biosafety Reports to the Cartagena Protocol on Biosafety - Asia-Pacific, Grulac, Central and Eastern Europe Regions

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Conservation of biological diversity and ensuring the safety in genetic engineering activities are the most important tasks of environmental protection and protection of human health in the Republic of Belarus. In 2002, the Republic of Belarus joined the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and effectively fulfills its obligations under this Protocol. The purpose of the Cartagena Protocol is articulated in the Article 1: « In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements».

This issue includes the Fourth National Biosafety Report Implementation of the Cartagena Protocol on Biosafety by the Republic of Belarus (2015-2021).

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Submission

10. Date of submission: 30/04/2021

11. Time period covered by this report: From 30/10/2015 to 01/04/2021

12. If your country is not a Party to the Cartagena Protocol on Biosafety (CPB), is there any national process in place towards becoming a Party?

- ☐ Yes
- ☐ No

13. **Here you may provide further details:**

The Republic of Belarus acceded to the Cartagena Protocol on Biosafety in 2002. In 2006, a regulatory legal framework, including the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" of January 9, 2006 No. 96-3 (hereinafter referred to as "the Law") and about 40 Regulations of the Government of the Republic of Belarus and Republican State Administration Bodies and other organizations, were developed.

Article 2 – General provisions

14. Has your country introduced the necessary national measures for the implementation of the Protocol?

- ☒ National measures are fully in place
- ☐ National measures are partially in place
- ☐ Only temporary measures have been introduced
- ☐ Only draft measures exist
- ☐ No measures have yet been taken

15. Which specific instruments are in place for the implementation of national biosafety measures?

- ☒ One or more national biosafety laws
- ☒ One or more national biosafety regulations
- ☒ One or more sets of biosafety guidelines
- ☒ Other laws, regulations or guidelines that indirectly apply to biosafety
- ☐ No instruments are in place

16. Has your country undertaken initiatives to mainstream biosafety into national biodiversity strategies and action plans, other policies, or legislation?

- ☒ Yes: The Strategic Plan for the implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of the Republic of Belarus approved by V. G. Tsalko, the Minister of Natural Resources and Environmental Protection of the Republic of Belarus, of December 26, 2012. In addition, work is currently underway to revise (update) the National Action Plan for the Conservation and Sustainable Use of Biological Diversity for 2021-2025, which will include the issues related to ensuring of biosafety.
- ☐ No
- ☐ Other: (Please specify)

17. Has your country established a mechanism for budget allocations for the operation of its national biosafety measures?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

18. Does your country have permanent staff to administer functions directly related to biosafety?

☒ Yes
☐ No

19. If you answered *Yes* to question 18, how many permanent staff members are in place whose functions are directly related to biosafety ?

☐ 1 to 4
☐ 5 to 9
☒ 10 or more

Is this number adequate: ☒ *Yes* ☐ *No*

20. **Here you may provide further details on the implementation of Article 2 in your country:**

The Law "On Safety in Genetic Engineering Activity" of January 9, 2006 No. 96-3 establishes the legal and institutional framework ensuring the safety of genetic engineering activity (GEA) and is aimed at protecting human health and the environment and fulfilling of international commitments in the field of safety in genetic engineering activity by the Republic of Belarus.

The Law establishes the legal and institutional framework in the following areas ensuring the GEA safety:

- contained use;
- release of genetically engineered organisms into the environment for testing;
- use of genetically engineered organisms for economic purposes;
- import into the Republic of Belarus, export from the territory of the Republic of Belarus and transit through its territory of genetically engineered organisms;
- storage and neutralization of genetically engineered organisms;
- responsibility for a violation of legislative requirements for the safety of genetic engineering activity.

Specially authorized republican bodies of state administration in the field of safety in genetic engineering activity have been identified, which are the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, the Ministry of Health of the Republic of Belarus, and the Ministry of Agriculture and Food of the Republic of Belarus.

With a view of timely informing of state institutions, non-government organizations (NGOs) and citizens about the measures undertaken in the country to ensure the safety in genetic engineering activity for the environment and human health, as well as maintaining constant liaison with the Secretariat of the Convention on Biological Diversity, the National Coordination Biosafety Centre (NCBC) has been established, the functions of which are assigned to the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus.

Alongside with that, to implement the functions in the field of genetic engineering activity, an Expert Board on Safety of Genetically Engineered Organisms, which includes the representatives of interested government authorities, scientific organizations and the public, has been established at the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus. The work of this Board allows, using the knowledge and experience of all the country's organizations competent in the safety of genetic engineering activity, making the decisions as follows:

on the admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for testing or use for economic purposes;

identify risk-management techniques when releasing genetically engineered organisms into the environment, as well as ecological and genetic monitoring techniques.

The review and analysis of the activities carried out in the Republic of Belarus in the field of biosafety in 2014-2016, as well as law enforcement practices related to the existing regulatory legal framework, determined the need to revise some provisions of the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity". In view of this, and in 2017-2018 in particular, the Law:

was harmonized with the norms of the following international treaties of the Republic of Belarus, as well as international legal acts that constitute the Law of the Eurasian Economic Union:

the Treaty on the Eurasian Economic Union of May 29, 2014;

Decision of the Customs Union Committee "On control over the movement of potentially pathogenic and pathogenic genetically engineered organisms, explosives, explosive devices and industrial-purpose explosive items" of October 14, 2010 No. 423;

the following was specified and supplemented with the main terms: "risk of possible harmful impacts", "genetic engineering activity", "neutralization of genetically engineered organisms";

a procedure and conditions for evaluating the risks of possible harmful impacts of genetically engineered organisms on human health and the environment were revised;

the relations associated with the following were specified:

non-pathogenic genetically engineered organisms;

import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms;

accountability and notification of the movement of genetically engineered organisms, etc.

A new version of the Law of December 18, 2018 No. 154-3 came into force on June 29, 2019. By that moment, in accordance with the Plan of Activities on Article 3 of the Law of the Republic of Belarus of December 18, 2018 "On Amendments and Additions to the Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" approved by M. I. Rusyi, the Deputy Prime Minister of the Republic of Belarus, on January 14, 2019 No. 06/140-71, 214-13/17, the Resolutions of the Council of Ministers of the Republic of Belarus, the Resolutions of the Republican Bodies of the State Administration and other organizations in the field of safety in genetic engineering activity had been harmonized.

Article 5 – Pharmaceuticals

21. Does your country regulate the transboundary movement, handling or use of living modified organisms (LMOs) which are pharmaceuticals to humans?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

22. **Here you may provide further details on the implementation of Article 5 in your country:**

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Article 6 – Transit and contained use

23. Does your country regulate the transit of LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

24. Does your country regulate the contained use of LMOs?

- ☒ Yes
- ☐ No

25. Has your country taken a decision concerning the import of LMOs for contained use?

☒ Yes

☐ No

26. **Here you may provide further details on the implementation of Article 6 in your country:**

In accordance with Article 18 of the Law, the transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed following the notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the owner of non-pathogenic genetically engineered organisms or by a person carrying out their transit through the territory of the Republic of Belarus in accordance with the procedure established by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 49.

Only public legal entities shall have the right to the import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms.

The import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms shall be carried out upon the permit on the import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms issued by the Ministry of Health of the Republic of Belarus in accordance with international legal acts constituting the Law of the Eurasian Economic Union, and according to the procedure "On some issues related to the procedure for the movement of certain kinds of goods through the State Border of the Republic of Belarus" established by the Resolution of the Council of Ministers of the Republic of Belarus of September 23, 2008 No. 1397.

Article 22 of the Law establishes that for the formation of the data bank for genetically engineered organisms, the specially authorized Republican bodies of the State Administration in the field of safety in genetically engineering activity shall submit related information to the National Coordination Biosafety Centre within 5 days from:

issuance of a permit on the import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms;

obtaining of notification of the transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms or their import into the Republic of Belarus for scientific research without the release into the environment to carry out trials.

The State Customs Committee of the Republic of Belarus shall submit within 5 days after the freight with genetically engineered organisms has crossed the customs border of the Eurasian Economic Union in the Republic of Belarus related information to the National Coordination Biosafety Centre.

Safety requirements for self-contained systems (contained use) in carrying out of works of risk level I of genetic engineering activity established by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 50 (as amended by the Resolution of May 31, 2019 No 12).

Safety requirements for self-contained systems in carrying out of works of risk levels II, III and IV of genetic engineering activity established by the Resolution of the Ministry of Health of the Republic of Belarus of August 25, 2006 No. 65.

Articles 7 to 10: Advance informed agreement (AIA) and intentional introduction of LMOs into the environment

27. Has your country established legal requirements for exporters under its jurisdiction to notify in writing the competent national authority of the Party of import prior to the intentional transboundary movement of an LMO that falls within the scope of the AIA procedure?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

28. When acting as the Party of export, has your country established legal requirements for the accuracy of information contained in the notification provided by the exporter?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No
- ☐ Not applicable (Party currently not exporting LMOs)

29. In the current reporting period, has your country received a notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

- ☐ Yes
- ☒ No

30. If you answered *Yes* to question 29, did the notification(s) contain complete information (at a minimum the information specified in Annex I to the Cartagena Protocol on Biosafety)?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

31. If you answered *Yes* to question 29, has your country acknowledged receipt of the notification(s) to the notifier within ninety days of receipt?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

32. If you answered *Yes* to question 29, has your country informed of its decision(s):

a. The notifier?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

b. The Biosafety Clearing-House (BCH)?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

33. In the current reporting period, has your country taken a decision in response to the notification(s) regarding intentional transboundary movements of LMOs for intentional introduction into the environment?

- ☐ Yes
- ☒ No

34. If you answered *Yes* to question 33, how many LMOs has your country approved for import for intentional introduction into the environment?

- ☐ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

35. If you answered *under question 34* that *LMOs were approved*, have all these LMOs actually been imported into your country?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

36. If you answered *Yes* to question 33, what percentage of your country's decisions fall into the following categories?

- [%] Approval of the import/use of the LMO(s) without conditions
- [%] Approval of the import/use of the LMO(s) with conditions
- [%] Prohibition of the import/use of the LMO(s)
- [%] Request for additional relevant information
- [%] Inform the notifier that the period for communicating the decision has been extended

37. If you answered *under question 36* that your country has taken a decision to *approve the import with conditions* or to *prohibit the import*, were the reasons provided?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

38. **Here you may provide further details on the implementation of Articles 7 to 10 in your country, including measures in case of lack of scientific certainty on potential adverse effects of LMOs for intentional introduction to the environment:**

During the reporting period, strong contacts were established between the National Coordination Biosafety Centre (NCBC) and the State Customs Committee of the Republic of Belarus (SCC), as well as its divisions that inspect goods of plant and animal origin, microorganisms during their movement across the border of the Eurasian Customs Union. NCBC carried out awareness-raising activities for the State Customs Committee on LMO and the goods containing LMO, which must be paid attention to when analyzing shipping documentation, as well as on the issues related to the laboratory detection and identification of LMOs.

In 2016-2017, NCBC developed an online training module for the employees of GMO detection laboratories and for the customs authorities. The module contains information on the movement of LMOs, detection and identification of LMOs and the labelling of goods in accordance with the Cartagena Protocol on Biosafety, Legislation of the Republic of Belarus on the Technical Regulations of the Customs Union.

On 28 November 2017, NCBC held an online webinar "Detection, identification and quantification of GMOs in food products, raw materials and seeds in the context of the legislation of the Republic of Belarus" for the employees of GMO detection laboratories and the customs authorities of the Republic of Belarus. The webinar was attended by the employees of the Customs Laboratory of the State Institute for

Advanced Training and Retraining of Customs Authorities of the Republic of Belarus, the laboratories of the Scientific and Practical Centre for Foodstuffs of the National Academy of Sciences of Belarus, the laboratories of Brest Regional Centre for Hygiene, Epidemiology and Public Health, Gomel Regional Centre for Hygiene, Epidemiology and Public Health, Mogilev Regional Centre for Hygiene, Epidemiology and Public Health and the Institute of Genetics and Cytology, NAS of Belarus.

In accordance with Article 18 of the Law, the import of non-pathogenic genetically engineered organisms into the Republic of Belarus for scientific research without releasing these organisms into the environment, transit through the territory of the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed upon notification of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus by the owner of non-pathogenic genetically engineered organisms or a person carrying out their transit through the territory of the Republic of Belarus according to the procedure established by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 49.

Import into the Republic of Belarus, export from the Republic of Belarus, and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms shall be realized upon a permit for the import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms issued by the Ministry of Health of the Republic of Belarus in accordance with international legal acts constituting the Law of the Eurasian Economic Union, and in accordance with the procedure established by the Resolution of the Council of Ministers of the Republic of Belarus "On some issues related to the procedure for the movement of certain types of goods across the State Border of the Republic of Belarus" of September 23, 2008 No. 1397.

In case of the import into the Republic of Belarus, transit through its territory of genetically engineered organisms in breach of the requirements set out by legislation, these genetically engineered organisms shall be subject to immediate reverse export from the Republic of Belarus by the owner of genetically engineered organisms or a person having imported them into the Republic of Belarus.

In addition, Article 19 of the Law provides that genetically engineered organisms shall be subject to neutralization in the cases as follows:

the release of genetically engineered organisms into the environment for testing was carried out without a permit for the release of non-pathogenic genetically engineered organisms into the environment;

genetically engineered organisms used for economic purposes by legal persons and individual entrepreneurs that do not have the State Registration Certificate for genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms, or its copy.

Neutralization of non-pathogenic genetically engineered organisms, including those classified as waste in accordance with legislation, shall be carried according to the procedure established by the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of May 31, 2019 No. 12.

Neutralization of potentially pathogenic and pathogenic genetically engineered organisms, including those classified as waste in accordance with legislation, shall be carried out according to the procedure established by the Resolution of the Ministry of Health of the Republic of Belarus of August 25, 2006 No. 65.

In case of a violation of safety regulations during the handling of genetically engineered organisms, liability shall be provided for by Article 15.4 of the Code of Administrative Offenses of the Republic of Belarus, as well as Article 278 of the Penal Code of the Republic of Belarus.

Article 11 – Procedure for living modified organisms intended for direct use as food or feed, or for processing (LMOs-FFP)

39. Does your country have law(s), regulation(s) or administrative measures for decision-making regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

- ☒ Yes
- ☐ No

40. Has your country established legal requirements for the accuracy of information to be provided by the applicant regarding the domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

41. In the current reporting period, how many decisions has your country taken regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

42. Does your country have law(s), regulation(s) or administrative measures for decision-making regarding the import of LMOs for direct use as food or feed, or for processing?

- ☒ Yes
- ☐ No

43. In the current reporting period, how many decisions has your country taken regarding the import of LMOs for direct use as food or feed, or for processing?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

44. **Here you may provide further details on the implementation of Article 11 in your country, including measures in case of lack of scientific certainty on potential adverse effects of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing:**

In the Republic of Belarus, there is a list of agricultural crops and products that are mandatory for screening on an ongoing basis with a view of detecting of genetically modified ingredients (the Resolution of the Ministry of Health of the Republic of Belarus and the Committee for Standardization, Metrology and Certification under the Council of Ministers of the Republic of Belarus "On approval of a list of industrial raw materials and food products subject to control for the presence of genetically modified ingredients" of June 8, 2005 No. 12/26). A list of products subject to mandatory control contains 25 names of soya and maize products. Appendix 2 to "Veterinary and sanitary regulations ensuring safety in the veterinary and sanitary relation of food and food additives" as amended by the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of February 5, 2018 No. 9 specifies the lines of soya and maize contained in food that have passed risk assessment in the EAEU territory allowing that the content of genetically modified organisms in them exceeds 0.9%. The list currently includes 9 soya and 11 maize lines that have undergone risk assessment in the Russian Federation. The list is being revised with the approval of GM lines destined for direct use as food or feed. Three GM plant lines developed in the Republic of Belarus destined directly for food or feed, and which may become the subject of movement passed during the reporting period only the first of two stages required to register a new LMO by the Ministry of Agriculture and Food of the Republic of Belarus – the state procedure for risk assessment before the first release into the environment for testing in experimental fields corresponding biosafety regulations. Forth GM line was not approved for large-scale release into the environment for growing by the Biosafety Expert Council at the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

An extensive network of GMO detection laboratories has been formed in the territory of the Republic of Belarus. As of 2021, 17 of such laboratories were accredited in the Republic in line with the State Committee for Standadization system, subordinate to the National Academy of Sciences of Belarus, the State Committee for Standadization, the Ministry of Agriculture and Food of the Republic of Belarus, and the Ministry of Health of the Republic of Belarus. Laboratories carry out the screening of authorized and the identification of unauthorized LMOs in the territory of the Republic of Belarus and EAEU destined for use as food and feed. The main normative documents are as follows: for LMOs destined for food purposes: Sanitary Regulations and Standards "Requirements for food raw materials and foodstuffs", the Hygienic Standard "Safety and harmlessness indicators of food raw materials and foodstuffs to humans" of June 21, 2013 No. 52; for feed: the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus "On approval of veterinary and sanitary regulations ensuring safety in the veterinary and sanitary relation of feed and feed additives" of February 10, 2011 No. 10.

Article 12 – Review of decision

45. Has your country established a mechanism for the review and change of a decision regarding an intentional transboundary movement of LMOs?

- ☐ Yes
- ☐ Yes, to some extent: (Please specify)
- ☒ No

46. In the current reporting period, has your country reviewed and/or changed a decision regarding an intentional transboundary movement of an LMO?

- ☐ Yes
- ☒ No

47. If you answered *Yes* to question 46, how many decisions were reviewed and/or changed?

- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

48. If you answered *Yes* to question 46, were any of the reviews triggered by a request from the Party of export or the notifier?

- ☐ Yes
- ☐ No

49. If you answered *Yes* to question 48, did your country provide a response within ninety days setting out the reasons for the decision?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

50. If you answered *Yes* to question 46, were any of the reviews initiated by your country as the Party of import?

- ☐ Yes
- ☐ No

51. If you answered *Yes* to question 50, did your country, within thirty days, set out the reasons for the decision and inform:

a. The notifier?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

b. The BCH?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

52. **Here you may provide further details on the implementation of Article 12 in your country:**

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Article 13 – Simplified procedure

53. Has your country established a mechanism for the application of the simplified procedure regarding an intentional transboundary movement of LMOs?

- ☐ Yes
- ☐ Yes, to some extent: (Please specify)
- ☒ No

54. In the current reporting period, has your country applied the simplified procedure?

- ☐ Yes
- ☒ No

55. If you answered *Yes* to question 54, for how many LMOs has your country applied the simplified procedure?

- ☐ None
- ☐ 1 to 5
- ☐ 5 or more

56. If you answered *Yes* to question 54, has your country informed the Parties through the BCH of the cases where the simplified procedure was applied?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

57. **Here you may provide further details on the implementation of Article 13 in your country:**

Article 14 – Bilateral, regional and multilateral agreements and arrangements

58. How many bilateral, regional or multilateral agreements or arrangements relevant to biosafety has your country established with other Parties/non-Parties?

- ☐ None
- ☒ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

59. If you answered *under question 58* that *agreements or arrangements were established*, please provide a brief description of their scope and objective:

In connection with the accession to the Customs Union, the Republic of Belarus has adopted the Technical Regulations of the Customs Union TR CU 021/2011 "On Food Safety" (available in the Belarus's profile on the BCH website) that shall apply to the countries of the Customs Union (interstate agreement within the framework of the Eurasian Economic Union, EAEU), including 0.9% for the labelling of GM-products for the purpose of the Technical Regulations.

The technical regulation of the Customs Union in the field of LMO handling, as well as the labelling rules for GM-products are similar to the Directives and Labelling Requirements of the European Union and comply with the requirements set out in Paragraph 1 of Article 14 of the Cartagena Protocol on Biosafety.

60. **Here you may provide further details on the implementation of Article 14 in your country:**

Article 20 of TR CU 021/2011 states that "Methods of research (trials/testing) and measurements of food products shall be established in the List of Standards containing rules and methods of research (trials/testing) and measurements, including sampling rules necessary for the application and fulfillment of the requirements of these Technical Regulations and the evaluation (confirmation) of the conformity of food products." For LMOs, this is the Resolution of the Chief State Sanitary Doctor of the Russian Federation of November 30, 2007 No. 80 "On supervision of the circulation of food products containing GMOs" (together with "MU 2.3.2.2306-07.23.2. Food products and food additives. Medicobiological assessment of safety of genetically modified organisms of plant origin. Methodical Guidelines", "MUK 4.2.2304-07. Control methods and microbiological factors. Food products and food additives. Methods for the identification and quantitative determination of genetically modified organisms of plant origin. Methodological Guidelines", "MUK 4.2.2305-07. 4.2. Control methods. Biological and microbiological factors. Food products and food additives. Determination of genetically engineered microorganisms and microorganisms with genetically modified analogs, in food products by real-time PCR and PCR with electrophoretic detection. Methodological Guidelines." This Resolution is available in the Belarus's profile on the BCH website.

The methodological base developed in the Customs Union is largely harmonized with the requirements of international organizations and the European Union and provides a level of protection not lower than that defined in the Cartagena Protocol on Biosafety.

Articles 15 & 16 – Risk assessment and risk management

61. Does the domestic regulatory framework of your country require risk assessments of LMOs to be conducted?

- ☒ Yes
- ☐ No

62. If you answered Yes to question 61, with regard to which LMOs does the requirement apply (select all that apply)?

- ☒ For imports of LMOs for intentional introduction into the environment
- ☒ For imports of LMOs intended for direct use as food or feed, or for processing
- ☒ For decisions regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movements for direct use as food or feed, or for processing
- ☐ For imports of LMOs for contained use
- ☐ Other: (Please specify)

63. Has your country established a mechanism to conduct risk assessments prior to taking decisions regarding LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

64. If you answered Yes to question 63, does the mechanism include procedures to identify and/or train national experts to conduct risk assessments?

- ☒ Yes
- ☐ No

Capacity-building in risk assessment or risk management

65. How many people in your country have been trained in risk assessment, risk management and monitoring of LMOs?

a. Risk assessment:

- ☐ None
- ☒ 1 to 9
- ☐ 10 to 49
- ☐ 50 to 99
- ☐ 100 or more

Is this number adequate: ☐ *Yes* ☐ *No*

b. Risk management:

- ☐ None
- ☒ 1 to 9
- ☐ 10 to 49
- ☐ 50 to 99
- ☐ 100 or more

Is this number adequate: ☒ *Yes* ☐ *No*

c. Monitoring:

- ☐ None
- ☒ 1 to 9
- ☐ 10 to 49
- ☐ 50 to 99
- ☐ 100 or more

Is this number adequate: ☐ *Yes* ☐ *No*

66. Is your country using training material and/or technical guidance for training in risk assessment and risk management of LMOs?

- ☒ Yes
- ☐ No

67. If you answered *Yes* to question 66, is your country using the "Manual on Risk Assessment of LMOs" (developed by the CBD Secretariat) for training in risk assessment?

- ☒ Yes
- ☐ No

68. If you answered *Yes* to question 66, is your country using the "Guidance on Risk Assessment of LMOs" (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for training in risk assessment?

- ☒ Yes
- ☐ No

69. Does your country have specific needs for further guidance on specific topics of risk assessment of LMOs?

- ☒ Yes: Risk assessment, including monitoring methodology and laboratory identification of the following LMOs: LMOs containing gene drives, living modified fish, LMOs developed by synthetic biology methods.
- ☐ No

70. Does your country have the capacity to detect, identify, assess the risk of and/or monitor LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health?

a. Detect:

- ☒ Yes
- ☐ No

b. Identify:

- ☒ Yes
- ☐ No

c. Assess the risk:

- [x] Yes
- [ ] No

d. Monitor:

- [x] Yes
- [ ] No

Conducting risk assessment or risk management

71. Has your country adopted or used any guidance documents for the purpose of conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers?

a. Risk assessment:

- [x] Yes
- [ ] No

b. Risk management:

- [x] Yes
- [ ] No

72. If you answered *Yes* to question 71, is your country using the "Guidance on Risk Assessment of LMOs" (developed by the Online Forum and the AHTEG on Risk Assessment and Risk Management) for conducting risk assessment or risk management, or for evaluating risk assessment reports submitted by notifiers?

- [x] Yes
- [ ] No

73. Has your country adopted common approaches or methodologies to risk assessment in coordination with other countries?

- [x] Yes
- [ ] No

74. Has your country cooperated with other Parties with a view to identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity?

- [ ] Yes
- [x] No

75. In the current reporting period, has your country conducted any kind of risk assessment of LMOs, including for contained use, field trials, commercial purposes, direct use as food, feed, or for processing?

- [x] Yes
- [ ] No

76. If you answered *Yes* to question 75, how many risk assessments were conducted?

- [x] 1 to 9
- [ ] 10 to 49
- [ ] 50 to 99
- [ ] More than 100

77. If you answered *Yes* to question 75, please indicate the scope of the risk assessments (select all that apply):

- [ ] LMOs for contained use (in accordance with Article 3)
- [x] LMOs for intentional introduction into the environment for experimental testing or field trials
- [ ] LMOs for intentional introduction into the environment for commercial purposes
- [ ] LMOs for direct use as food
- [ ] LMOs for direct use as feed
- [ ] LMOs for processing
- [x] Other: In 2018, a conclusion was received from the Expert Council on Safety of Genetically Engineered Organisms at the Ministry of Natural Resources and Environmental Protection (Expert Council) on the admissibility of release into the environment in the territory of a biotechnological scientific and experimental production for animal transgenesis – the Republican Unitary Enterprise "Scientific and Practical Centre of the National Academy of Sciences Belarus for Animal Breeding" (meeting safety requirements in accordance with legislation) – of a line of transgenic goats with an inserted gene construct responsible for the production of recombinant lactoferrin in the mammary gland. In accordance with the recommendations of the Expert Council, a herd of transgenic goats may only be kept in a controlled environment that prevents the exchange of genetic material with non-transgenic individuals; the final product (lactoferrin) may only be used for economic purposes; it is necessary to check the final product for the presence of the inserted new genetic sequence. All information has been posted on the BCH website in the Belarus's profile.

78. If you answered *Yes* to question 75, were risk assessments conducted for all decisions taken on LMOs for intentional introduction into the environment or on domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing?

- [x] Yes, always
- [ ] In some cases only
- [ ] No

79. Has your country established appropriate mechanisms, measures and strategies to regulate and manage risks identified in the risk assessment of LMOs?

- ☒ Yes
- ☐ No

80. Has your country taken appropriate measures to prevent unintentional transboundary movements of LMOs, including such measures as requiring a risk assessment to be carried out prior to the first release of a LMO?

- ☒ Yes
- ☐ No

81. Has your country taken measures to ensure that any LMO, whether imported or locally developed, undergoes an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

82. Has your country established a mechanism for monitoring potential effects of LMOs released into the environment?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

83. Does your country have the necessary infrastructure (e.g. laboratory facilities) for monitoring or managing LMOs?

- ☒ Yes
- ☐ No

84. **Here you may provide further details on the implementation of Articles 15 and 16 in your country:**

Additional information related to this section on legislative regulation is provided as an answer to question 115 of the 2nd National Report and question 97 of the 3rd National Report. On 29 June 2019, a new version of the Law "On Safety in Genetic Engineering Activity" of the Republic of Belarus of January 9, 2006 No. 96-3 and by-laws to it came into force and are posted on the NCBC website at: https://biosafety.igc.by/zakon-respubliki-belarus-o-bezopas/ and the BCH website at: http://bch.cbd.int/database/results?searchid=755167.

Article 17 – Unintentional transboundary movements and emergency measures

85. Has your country established measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations in case of a release under its jurisdiction that leads, or may lead, to an unintentional transboundary movement?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

86. In the current reporting period, how many releases of LMOs occurred under your country's jurisdiction that led, or may have led, to an unintentional transboundary movement?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

87. If you answered *under question 86* that a *release occurred*, has your country notified affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

88. Does your country have the capacity to take appropriate response measures in response to unintentional transboundary movements?

- ☒ Yes
- ☐ No

89. In the current reporting period, how many times has your country become aware of an unintentional transboundary movement into its territory?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

90. **Here you may provide further details on the implementation of Article 17 in your country:**

Additional information related to this section on legislative regulation is provided as an answer to question 115 of the 2nd National Report and question 97 of the 3rd National Report. On 29 June 2019, a new version of the Law "On Safety in Genetic Engineering Activity" of the Republic of Belarus of January 9, 2006 No. 96-3 and by-laws to it came into force. Up-to-date documents are posted on the NCBC website at: https://biosafety.igc.by/zakon-respubliki-belarus-o-bezopas/ and the BCH website at: http://bch.cbd.int/database/results?searchid=755167.

Article 18 – Handling, transport, packaging and identification

91. Has your country taken measures to require that *LMOs that are subject to transboundary movement* are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

92. Has your country taken measures to require that documentation accompanying LMOs-FFP, *in cases where the identity of the LMOs is not known,* clearly identifies that they *may contain LMOs* and are not intended for intentional introduction into the environment, as well as a contact point for further information?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

93. Has your country taken measures to require that documentation accompanying LMOs-FFP, *in cases where the identity of the LMOs is known*, clearly identifies that they *contain LMOs* and are not intended for intentional introduction into the environment, as well as a contact point for further information?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

94. If you answered *Yes* to question(s) 91, 92 and/or 93, what type of documentation accompanying LMOs does your country require?

- ☐ Documentation specific for LMOs
- ☒ As part of other documentation (not specific for LMOs)
- ☐ Other: (Please specify)

95. Has your country taken measures to require that documentation accompanying *LMOs that are destined for contained use* clearly identifies them as *LMOs* and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMO are consigned?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

96. If you answered *Yes* to question 95, what type of documentation does your country require for the identification of LMOs that are destined for contained use?

- ☐ Documentation specific for LMOs
- ☒ As part of other documentation (not specific for LMOs)
- ☐ Other: (Please specify)

97. Has your country taken measures to require that documentation accompanying *LMOs that are intended for intentional introduction into the environment of the Party of import*, clearly identifies them as *living modified organisms*; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter?

☐ Yes

☒ Yes, to some extent: In accordance with the Article 24 of the Law, information on the safety of genetically engineered organisms during their transportation must be contained on the packaging (container, another object destined for the location (keeping) of genetically engineered organisms) and include the following:

name of the genetically engineered organism;

number and date of issue of the State Registration Certificate for genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms (for genetically engineered organisms destined for economic use);

information concerning methods of transport, storage, use and neutralization of genetically engineered organisms;

name and location of a legal person or the surname, proper name, patronymic (if any) and place of residence (place of stay) of an individual entrepreneur that deliver genetically engineered organisms;

name and location of a legal person or the surname, proper name, patronymic (if any) and place of residence (place of stay) of an individual entrepreneur genetically engineered organisms are delivered to.

Transport of genetically engineered organisms shall be carried out in the case where accompanying documentation provided for by legislation in the field of the transport of goods, as well as international legal acts constituting the Law of the Eurasian Economic Union is available.

Information on the safety of genetically engineered organisms during their storage must be contained on the packaging (container, another object destined for the location (keeping) of genetically engineered organisms) and include the above information.

☐ No

98. If you answered *Yes* to question 97, what type of documentation does your country require for the identification of LMOs that are intended for intentional introduction into the environment?

☐ Documentation specific for LMOs

☒ As part of other documentation (not specific for LMOs)

☐ Other: (Please specify)

99. Does your country have available any guidance for the purpose of ensuring the safe handling, transport, and packaging of living modified organisms?

- ☒ Yes
- ☐ No

100. Does your country have the capacity to enforce the requirements of identification and documentation of LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

101. How many customs officers in your country have received training in the identification of LMOs?

- ☐ None
- ☒ 1 to 9
- ☐ 10 to 49
- ☐ 50 to 99
- ☐ 100 or more

Is this number adequate: ☐ *Yes* ☐ *No*

102. Has your country established procedures for the sampling and detection of LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

103. How many laboratory personnel in your country have received training in detection of LMOs?

- ☐ None
- ☐ 1 to 9
- ☒ 10 to 49
- ☐ 50 to 99
- ☐ 100 or more

Is this number adequate: ☐ *Yes* ☐ *No*

104. Does your country have reliable access to laboratory facilities for the detection of LMOs?

- ☒ Yes
- ☐ No

105. How many laboratories in your country are certified for LMO detection?

- ☐ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☒ 10 to 49
- ☐ 50 or more

106. If you answered under question 105 that certified laboratories exist in your country, how many of them are currently operating in the detection of LMOs?

- ☐ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☒ 10 to 49
- ☐ 50 or more

107. **Here you may provide further details on the implementation of Article 18 in your country:**

In accordance with Article 24 "Requirements for Information on the Safety of Genetically Engineered Organisms during their Transport and Storage"of the Law, information on the safety of genetically engineered organisms during their transport must be contained on the packaging (container, another object destined for the location (keeping) of genetically engineered organisms) and include the following:

name of the genetically engineered organism; number and date of issue of the State Registration Certificate for genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms (for genetically engineered organisms destined for economic use);

information concerning the methods of transport, storage, use and neutralization (disposal) of genetically engineered organisms; the name and location of a legal person or the surname, proper name, patronymic (if any) and place of residence (place of stay) of an individual entrepreneur that deliver genetically engineered organisms; the name and location of a legal person or the surname, proper name, patronymic (if any) and place of residence (place of stay) of an individual entrepreneur genetically engineered organisms are delivered to.

Transport of genetically engineered organisms shall be carried out upon availability of accompanying documentation provided for by legislation in the field of the transport of goods, as well as international legal acts constituting the Law of the Eurasian Economic Union. Information on the safety of genetically engineered organisms during storage must be contained on the packaging (container, another object destined for the location (keeping) of genetically engineered organisms) and include information specified in Paragraphs 2-4 of the Part 1 of this Article.

As of 2018, 17 GMO detection laboratories were accredited in line with the Committee for Standardization system (GOST ISO 17025) of the Republic of Belarus. Laboratories are involved in the detection of authorized and unauthorized LMOs in the territory of the Republic of Belarus and EAEU, the detection of GMOs in raw materials, food and feed. A full list of laboratories is available on the BCH website, Belarus's profile, at http://bch.cbd.int/database/record.shtml?documentid=113848 (ID 113848)

Article 19 – Competent national authorities and national focal points

108. In case your country has designated more than one competent national authority, has your country established a mechanism for the coordination of their actions prior to taking decisions regarding LMOs?

- ☒ Yes
- ☐ No
- ☐ Not applicable (no competent national authority was designated)
- ☐ Not applicable (only one competent national authority was designated)

109. Has your country established adequate institutional capacity to enable the competent national authority(ies) to perform the administrative functions required by the Cartagena Protocol on Biosafety?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

110. Has your country undertaken initiatives to strengthen collaboration among national focal points, competent national authority(ies) and other institutions on biosafety-related matters?

☒ Yes: By the order of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of July 19, 2019 No. 181-OD (the order in its edition of December 5, 2012 No. 412), the Provision on the Expert Council on Safety of Genetically Engineered Organisms at the Ministry of Natural Resources and Environmental Protection, as well as the composition of the Expert Council on Safety of Genetically Engineered Organisms at the Ministry of Natural Resources and Environmental Protection, were approved.

The Expert Council is a collegial advisory body and is formed from the officials of the specially authorized republican bodies of the state administration in the field of safety of genetic engineering activity, scientists and specialists.

The main tasks of the Expert Council include the adoption of recommendations for the admissibility (inadmissibility) of the release of genetically engineered organisms into the environment for testing or use for economic purposes.

Also, to each workshop, round table and other events on various issues related to the biosafety of genetic engineering activity, NCBC invites representatives of all interested departments and institutions. Issues of strengthened interdepartmental communication are discussed at the events.

☐ No

111. **Here you may provide further details on the implementation of Article 19 in your country:**

On September 18-20, 2019, the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus that performs NCBC functions jointly with the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus held a round table “Enhancing the CEE Collaboration And Know-How Transfer In Biotechnology And Biosecurity” within the framework of the International Technical Assistance project of the Central European Initiative.

The round table aimed at promoting of scientific cooperation and transferring of know-how in the Central and Eastern European countries in the field of modern biotechnology and biosafety, finding solutions to strengthen cooperation and building bridges between experienced, less experienced and the least experienced Central and Eastern European countries in the field of biotechnology and biosafety.

The round table was attended by the representatives of the scientific community and the employees of ministries and the National Academy of Sciences of Belarus, the International Center for Genetic Engineering and Biotechnology (ICGEB, Italy); the Joint Research Center of the European Commission (JRC, Italy); scientists and experts from the ministries of Central and Eastern Europe. The results of the round table are posted on the NCBC website at https://biosafety.igc.by/kruglyj-stol-ukreplenie-sotrudniche/ in the section “Conferences”.

Article 20 – Information sharing and the Biosafety Clearing-House (BCH)

112. Please provide an overview of the status of the mandatory information provided by your country to the BCH by specifying for each category of information whether it is available and whether it has been submitted to the BCH.

a. Existing legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20, paragraph 3 (a))

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

b. Legislation, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 5)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☒ Information available but only partially available in the BCH
- ☐ Information not available

c. Bilateral, multilateral and regional agreements and arrangements (Article 14, paragraph 2, and Article 20, paragraph 3 (b))

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

d. Contact details for competent national authorities (Article 19, paragraphs 2 and 3), national focal points (Article 19, paragraphs 1 and 3), and emergency contacts (Article 17, paragraph 3 (e))

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

e. Decisions by a Party regarding transit of LMOs (Article 6, paragraph 1)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

f. Decisions by a Party regarding import of LMOs for contained use (Article 6, paragraph 2)

- ☐ Information available and in the BCH
- ☒ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

g. Notifications regarding the release under your country's jurisdiction that leads, or may lead, to an unintentional transboundary movement of a LMO that is likely to have significant adverse effects on biological diversity (Article 17, paragraph 1)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

h. Information concerning cases of illegal transboundary movements of LMOs (Article 25, paragraph 3)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

i. Decisions regarding the importation of LMOs for intentional introduction into the environment (Article 10, paragraph 3)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

j. Information on the application of domestic regulations to specific imports of LMOs (Article 14, paragraph 4)

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

k. Decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11, paragraph 1)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

l. Decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11, paragraph 4) or in accordance with Annex III to the Protocol (Article 11, paragraph 6)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

m. Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11, paragraph 6)

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

n. Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12, paragraph 1)

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

o. Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13, paragraph 1 (a))

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

p. LMOs granted exemption status by each Party (Article 13, paragraph 1 (b))

- ☐ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☒ Information not available

q. Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20, paragraph 3 (c))

- ☒ Information available and in the BCH
- ☐ Information available but not in the BCH
- ☐ Information available but only partially available in the BCH
- ☐ Information not available

113. **Please provide a brief explanation if you answered that the information is available *but not in the BCH* or *only partially available in the BCH* to any item under question 112:**

In connection with the adoption in 2019 of a new edition of the Law "On Safety in Genetic Engineering Activity" and its by-laws, legislative and regulatory acts are being actualized on BCH and NCBC websites.

In the Republic of Belarus, the existing regulatory legal framework in the field of safety in genetic engineering activity fully meets the requirements of Article 6 of the Cartagena Protocol.

114. Has your country established a mechanism for strengthening the capacity of the BCH national focal point to perform its administrative functions?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

115. Has your country established a mechanism for the coordination among the BCH national focal point, the Cartagena Protocol national focal point, and the competent national authority(ies) for making information available to the BCH?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

116. Does your country use the information available in the BCH in its decision-making processes on LMOs?

- [x] Yes, always
- [ ] Yes, in some cases
- [ ] No
- [ ] Not applicable (no decisions were taken)

117. Has your country experienced difficulties accessing or using the BCH?

- [ ] Yes: (Please specify)
- [x] No

118. In the current reporting period, how many biosafety-related events (e.g. seminars, workshops, press conferences, educational events) has your country organized?

- [ ] None
- [ ] 1 to 4
- [ ] 5 to 9
- [ ] 10 to 24
- [x] 25 or more

119. In the current reporting period, how many biosafety-related publications has your country published?

- [ ] None
- [ ] 1 to 9
- [x] 10 to 49
- [ ] 50 to 99
- [ ] 100 or more

120. **Here you may provide further details on the implementation of Article 20 in your country:**

In connection with the adoption in 2019 of a new edition of the Law "On Safety in Genetic Engineering Activity" and by-laws to it, legislative and regulatory acts are being actualized on BCH and NCBC websites.

The task of ensuring the exchange of information on activities in the field of biosafety, as well as legislation in this area, with the Coordination Biosafety Centres of other countries and international organizations has been assigned to the National Coordination Biosafety Centre in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of June 19, 1998 No. 963.

In turn, the Regulations of the Government of the Republic of Belarus, including departmental regulatory legal acts, establish that in order to collect, analyze and systematize information on the legislation of the Republic of Belarus and scientific research related to biosafety issues on risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, testing of genetically engineered objects, the import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms, use of genetically engineered organisms and products based on them for economic purposes in the Republic of Belarus, the republican bodies of the state administration and other organizations shall be obliged to submit the above information to NCBC.

Article 21 – Confidential information

121. Has your country established procedures to protect confidential information received under the Protocol?

- [x] Yes
- [ ] Yes, to some extent: (Please specify)
- [ ] No

122. Does your country allow the notifier to identify information that is to be treated as confidential?

- [x] Yes, always
- [ ] In some cases only
- [ ] No

123. **Here you may provide further details on the implementation of Article 21 in your country:**

In accordance with clause 3 of the "Provision on the Procedure for the Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health and the Environment" approved by the Resolution of the Council of Ministers of the Republic of Belarus of June 12, 2019 No. 382, a stakeholder may provide justification, as required, for the need to consider risk assessment information as confidential that shall be used in accordance with legislation. In this case, a stakeholder shall provide two variants of risk assessment information. Such being the case, the variant containing confidential information shall be submitted in one hard copy with the indication "Contains confidential information", and its second variant – in electronic copy in which confidential information is replaced by the note "Confidential information".

For the purposes of this Provision, the following information can not be recognized as confidential:

name and postal address of an applicant;

taxonomic description of the recipient organism used to obtain genetically engineered organisms;

taxonomic description of the donor organism used to obtain genetically engineered organisms;

general description of the vector used and the technique of the transgenic construct insertion;

general description of all the genes inserted in genetically engineered organisms and their functions;

results of the tests carried out on genetically engineered organisms needed to assess the risk of possible harmful effects of genetically engineered organisms on human health and the state of the environment;

results of earlier risk assessments of possible harmful effects of genetically engineered organisms on human health and the state of the environment and decisions on the release of genetically engineered organisms into the environment made on their basis;

emergency plan.

Article 22 – Capacity-building

124. Does your country have predictable and reliable funding for building capacity for the effective implementation of the Protocol?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

125. Has your country received external support or benefited from collaborative activities with other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

126. If you answered *Yes* to question 125, how were these resources made available?

- ☒ Bilateral channels
- ☒ Regional channels
- ☐ Multilateral channels

127. Has your country provided support to other Parties in the development and/or strengthening of human resources and institutional capacities in biosafety?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

128. If you answered *Yes* to question 127, how were these resources made available?

- ☒ Bilateral channels
- ☒ Regional channels
- ☐ Multilateral channels

129. In the reporting period, has your country initiated a process to access funds from the Global Environment Facility (GEF) for building capacity in biosafety?

- ☒ Yes: In the Republic of Belarus, the BCH III project supported by UNEP-GEF was implemented in 2018-2019, and in 2019, an Agreement on the implementation of the 4th National Biosafety Report by the Republic of Belarus was signed.
- ☐ No

130. If you answered *Yes* to question 129, how would you characterize the process?

- ☐ Very easy
- ☐ Easy
- ☒ Average
- ☐ Difficult
- ☐ Very difficult

131. In the current reporting period, has your country undertaken activities for the development and/or strengthening of human resources and institutional capacities in biosafety?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

132. If you answered *Yes* to question 131, in which of the following areas were these activities undertaken (select all that apply)?

- ☒ Institutional capacity and human resources
- ☐ Integration of biosafety in cross-sectoral and sectoral legislation, policies and institutions (mainstreaming biosafety)
- ☒ Risk assessment and other scientific and technical expertise
- ☐ Risk management
- ☒ Public awareness, participation and education in biosafety
- ☒ Information exchange and data management, including participation in the Biosafety Clearing-House
- ☒ Scientific, technical and institutional collaboration at subregional, regional and international levels
- ☒ Technology transfer
- ☐ Identification of LMOs, including their detection
- ☐ Socioeconomic considerations
- ☐ Implementation of the documentation requirements under Article 18.2 of the Protocol
- ☐ Handling of confidential information
- ☐ Measures to address unintentional and/or illegal transboundary movements of LMOs
- ☐ Scientific biosafety research relating to LMOs
- ☐ Taking into account risks to human health
- ☐ Liability and redress
- ☐ Other: (Please specify)

133. In the current reporting period, has your country carried out a capacity-building needs assessment?

- ☒ Yes
- ☐ No

134. Does your country still have capacity-building needs?

- ☒ Yes
- ☐ No

135. If you answered Yes to question 134, which of the following areas still need capacity-building (select all that apply)?

- ☐ Institutional capacity and human resources
- ☒ Integration of biosafety in cross-sectoral and sectoral legislation, policies and institutions (mainstreaming biosafety)
- ☒ Risk assessment and other scientific and technical expertise
- ☒ Risk management
- ☒ Public awareness, participation and education in biosafety
- ☒ Information exchange and data management, including participation in the Biosafety Clearing-House
- ☒ Scientific, technical and institutional collaboration at subregional, regional and international levels
- ☒ Technology transfer
- ☒ Sampling, detection and identification of LMOs
- ☒ Socioeconomic considerations
- ☐ Implementation of the documentation requirements for handling, transport, packaging and identification
- ☐ Handling of confidential information
- ☒ Measures to address unintentional and/or illegal transboundary movements of LMOs
- ☒ Scientific biosafety research relating to LMOs
- ☒ Taking into account risks to human health
- ☒ Liability and redress
- ☐ Other: (Please specify)

136. Has your country developed a capacity-building strategy or action plan?

- ☐ Yes
- ☒ No

137. Does your country have in place a functional national mechanism for coordinating biosafety capacity-building initiatives?

- ☒ Yes
- ☐ No

138. **Here you may provide further details on the implementation of Article 22 in your country, including further details about your experience in accessing GEF funds**

In 2018-2019, the Republic of Belarus implemented the UNEP-GEF Project on Sustainable Capacity-building for Effective Participation in BCH.

The project aimed at enhancing access and sharing of information through BCH for the implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

This goal was achieved by means of full and reliable information collected on the implementation of the Provisions of the Cartagena Protocol on Biosafety in the Republic of Belarus, updating national data in BCH, in particular national contacts and existing laws and regulations, decisions and declarations, as well as risk assessment reports, and three training workshops to raise awareness of biosafety-related issues, as well as an elaborated sustainable development plan demonstrating how BCH potential will be sustainably maintained after the end of the activities on this Project.

Three training workshops on the BCH were held for related target groups (representatives of state administration bodies in the field of safety of genetic engineering activity, technical personnel of state bodies, employees of border and customs control, employees of GMO detection laboratories, GMO developers, representatives of higher educational institutions, including youth, representatives of the industrial sector, large food and feed companies, civil society and non-governmental organizations (NGOs), print and broadcast media). Implementation of the activities planned allowed strengthening the communication between national governing authorities in the field of biosafety and key stakeholders, BCH information providers, raised the awareness of stakeholders about the BCH structure, the procedure for collecting, registering and providing information on the Portal.

Article 23 – Public awareness and participation

139. Is biosafety public awareness, education and/or participation addressed in legislation or policy in your country?

☒ Yes

☐ Yes, to some extent: (Please specify)

☐ No

140. In the current reporting period, has your country cooperated with other States and international bodies in relation to public awareness, education and participation?

☒ Yes: In order to address the issues related to public awareness-raising, close cooperation is carried out with the Aarhus Center of the Republic of Belarus; National Focal Points for the Cartagena Protocol on Biosafety and the Biosafety Clearing-House participated in joint round tables on building public awareness, accessing information and public participation in relation to LMO/GMO issues organized by the Secretariat of the Aarhus Convention and the Secretariat of the Convention on Biological Diversity and the development of mechanisms for awareness-raising, enlightenment and public engagement in biosafety issues.

In 2017, the NCBC of the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus was approved by the Secretariat of the Convention on Biological Diversity as a regional partner and moderator of the official online forum for public education in the field of biosafety from the countries of Central and Eastern Europe.

☐ No

141. Has your country established a mechanism to ensure public access to information on LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

142. Does your country have in place a national communication strategy on biosafety?

- ☐ Yes: (Please specify)
- ☒ No

143. Does your country have any awareness and outreach programmes on biosafety?

- ☐ Yes: (Please specify)
- ☒ No

144. Does your country currently have a national biosafety website?

- ☒ Yes
- ☐ No

145. How many academic institutions in your country are offering biosafety education and training courses and programmes?

- ☐ None
- ☒ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

Is this number adequate: ☐ *Yes* ☐ *No*

146. How many educational materials and/or online modules on biosafety are available and accessible to the public in your country?

- ☐ None
- ☒ 1 to 4
- ☐ 5 to 9
- ☐ 10 to 24
- ☐ 25 to 99
- ☐ 100 or more

Is this number adequate: ☐ *Yes* ☐ *No*

147. Has your country established a mechanism to consult the public in the decision-making process regarding LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

148. Has your country informed the public about existing modalities for public participation in the decision-making process regarding LMOs?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

149. If you answered *Yes* to question 148, please indicate the modalities used to inform the public:

- ☒ National websites
- ☒ Newspapers
- ☐ Forums
- ☒ Mailing lists
- ☐ Public hearings
- ☒ Social media
- ☐ Other: (Please specify)

150. In the current reporting period, how many times has your country consulted the public in the decision-making process regarding LMOs?

- ☐ None (decisions taken without consultation)
- ☐ 1 to 4
- ☒ 5 or more
- ☐ Not applicable (no decisions were taken)

151. Has your country informed the public about the means to access the Biosafety Clearing-House?

- ☒ Yes
- ☐ No

152. **Here you may provide further details on the implementation of Article 23 in your country:**

During the reporting period, the Expert Board on Biosafety at the Ministry of Natural Resources and Environmental Protection carried out the risk assessment of 2 living modified organisms of plant origin and 1 – animal origin. Prior to the expert examinations, awareness-raising activities were carried out in the mass media and information was provided that according to legislation, interested legal persons and individuals may within 60 days from the date of posting information about the risk assessment on the information website of the National Coordination Biosafety Centre familiarize themselves with this information and submit their comments and proposals to the National Coordination Biosafety Centre, which, after the specified period, summarizes the received comments and suggestions and within 10 days submits them to the Expert Council for consideration.

During the reporting period, NCBC, when running special courses for students, holding workshops, appearing on radio and TV, brought to the attention of the public that information posted on the BCH website is available and it is possible to use it for training purposes. During 3 workshops (September 17-19, 2018; December 4-5, 2018; March 18-19, 2019) held in the framework of the UNEP-GEF Project "Sustainable Capacity-Building for Effective Participation in BCH", the structure of the BCH website and the materials posted on the website were presented, and it was explained how the BCH materials may be used to inform, educate, and make decisions in the field of biosafety.

Article 24 – Non-Parties

153. Has your country entered into any bilateral, regional, multilateral agreement with non-Parties regardi transboundary movements of LMOs?

- ☒ Yes
- ☐ No

154. In the current reporting period, has your country imported LMOs from a non-Party?

- ☐ Yes
- ☒ No

155. In the current reporting period, has your country exported LMOs to a non-Party?

- ☐ Yes
- ☒ No

156. If you answered Yes to question 154 and/or 155, were the transboundary movements of LMOs consistent with the objective of the Cartagena Protocol on Biosafety?

- ☐ Yes, always
- ☐ In some cases only
- ☐ No

157. **Here you may provide further details on the implementation of Article 24 in your country:**

Additional data is provided as an answer to question 188 of the 3rd National Report.

Article 25 – Illegal transboundary movements

158. Has your country adopted domestic measures aimed at preventing and/or penalizing transboundary movements of LMOs carried out in contravention of its domestic measures to implement the Cartagena Protocol?

- ☒ Yes
- ☐ Yes, to some extent: (Please specify)
- ☐ No

159. In the current reporting period, how many cases of illegal transboundary movements of LMOs has your country become aware of?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 or more

160. If you indicated *under question 159* that *your country became aware of cases of illegal transboundary movements*, has the origin of the LMO(s) been established?

- ☐ Yes
- ☐ Yes, some cases
- ☐ No

161. **Here you may provide further details on the implementation of Article 25 in your country:**

National legislation and the regulatory legal framework of the Republic of Belarus were developed in accordance with the requirements of the Cartagena Protocol. Article 5 of the Law stipulates measures to ensure safety, including, *inter alia*, measures that establish liability for a violation of legislative requirements in relation to the safety of genetic engineering activity. Article 26 of the Law determines that control (supervision) in the field of safety of genetic engineering activity shall be carried out in order to check compliance with the requirements of regulatory legal acts, including the requirements of technical normative legal acts mandatory for compliance, as well as to implement the measures insuring the safety of this activity.

In case of the import into the Republic of Belarus, transit through its territory of genetically engineered organisms in violation of legislative requirements, these genetically engineered organisms shall be subject to immediate reverse export from the Republic of Belarus by the owner of genetically engineered organisms or a person having realized their import into the Republic of Belarus.

For a violation of safety regulations during the handling of genetically engineered organisms, liability shall be stipulated by the Article 15.4 of the Code of Administrative Offenses of the Republic of Belarus, as well as the Article 278 of the Penal Code of the Republic of Belarus.

Article 26 – Socio-economic considerations

162. Does your country have any specific approaches or requirements that facilitate how socioeconomic considerations should be taken into account in LMO decision-making?

- ☐ Yes
- ☒ No

163. In the current reporting period, have socioeconomic considerations arising from the impact of LMOs been taken into account in decision-making?

- ☒ Yes, always
- ☐ In some cases only
- ☐ No
- ☐ Not applicable (no decisions were taken)

164. How many peer-reviewed published materials has your country used for the purpose of elaborating or determining national actions with regard to socioeconomic considerations?

- ☒ None
- ☐ 1 to 4
- ☐ 5 to 9
- ☐ 10 to 49
- ☐ 50 or more

Is this number adequate: ☐ *Yes* ☐ *No*

165. Has your country cooperated with other Parties on research and information exchange on any socioeconomic impacts of LMOs?

- ☒ Yes
- ☐ No

166. **Here you may provide further details on the implementation of Article 26 in your country:**

NCBC staff members participate in the online forum and the Ad Hoc Technical Expert Group on Socio-Economic Considerations. Socio-economic considerations were taken into account when a decision on the admissibility of the use of transgenic animals and plants was being made.

Article 28 – Financial mechanism and resources

167. In the current reporting period, how much funding (in the equivalent of US dollars) has your country mobilized to support implementation of the Cartagena Protocol beyond the regular national budgetary allocation?

- ☐ Nothing
- ☐ 1 to 4,999 USD
- ☒ 5,000 to 49,999 USD
- ☐ 50,000 to 99,999 USD
- ☐ 100,000 to 499,000 USD
- ☐ 500,000 USD or more

Article 33 – Monitoring and reporting

168. Does your country have in place a system to monitor and enforce the implementation of the Cartagena Protocol?

- ☒ Yes
- ☐ No

Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

Parties to the Cartagena Protocol that are not yet Party to the Supplementary Protocol are also invited to respond to the questions below

169. Is your country a Party to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress?

- ☐ Yes
- ☒ No

170. If you answered *No* to question 169, is there any national process in place towards becoming a Party to the Supplementary Protocol?

- ☐ Yes
- ☒ No

171. Has your country introduced the necessary measures for the implementation of the Supplementary Protocol?

- ☐ National measures are fully in place
- ☐ National measures are partially in place
- ☐ Only temporary measures have been introduced
- ☐ Only draft measures exist
- ☒ No measures have yet been taken

172. Which instruments are in place for the implementation of the Supplementary Protocol?

- ☐ One or more national laws: (Please specify)
- ☐ One or more national regulations: (Please specify)
- ☐ One or more sets of guidelines: (Please specify)
- ☒ No instruments are in place

173. Does your country have administrative or legal instruments that require response measures to be taken:

a. In case of damage resulting from LMOs?

- ☒ Yes
- ☐ No

b. In case there is sufficient likelihood that damage will result if response measures are not taken?

- ☒ Yes
- ☐ No

174. If you answered *Yes* to question 173a, do these instruments impose requirements on an operator (select all that apply)?

- ☒ Yes, the operator must inform the competent authority of the damage
- ☐ Yes, the operator must evaluate the damage
- ☒ Yes, the operator must take response measures
- ☐ Yes, other requirements: (Please specify)
- ☐ No

175. If you answered *Yes* to question 173a, do these instruments require the operator to take response measures to avoid damage?

- ☒ Yes
- ☐ No

176. If you answered *Yes* to question 173a or 173b, do these instruments provide for a definition of "operator"?

- ☐ Yes
- ☒ No

177. If you answered *Yes* to question 176, which of the following could be an 'operator' (select all that apply)?

- ☐ Permit holder
- ☐ Person who placed the LMO on the market
- ☐ Developer
- ☐ Producer
- ☐ Notifier
- ☐ Exporter
- ☐ Importer
- ☐ Carrier
- ☐ Supplier
- ☐ Other: (Please specify)

178. Has a competent authority been identified for carrying out the functions set out in the Supplementary Protocol?

- ☐ Yes: (Please specify)
- ☒ No

179. If you answered *Yes* to question 178, what measures may the competent authority take (select all that apply)?

- ☐ Identify the operator that caused the damage
- ☐ Evaluate the damage
- ☐ Determine response measures to be taken by operator
- ☐ Implement response measures
- ☐ Recover costs and expenses of the evaluation of the damage and the implementation of any response measures from the operator
- ☐ Other: (Please specify)

180. Does your country have measures in place to provide for financial security for damage resulting from LMOs?

- ☐ Yes
- ☒ No

181. If you answered *Yes* to question 180, what type of financial security measures are in place (select all that apply)?

- ☐ Requirement to provide evidence for secure source of funding
- ☐ Mandatory insurance
- ☐ Government schemes, including funds
- ☐ Other: (Please specify)

182. Does your country have rules and procedures on civil liability that address damage resulting from LMOs, or has such damage been recognized in court rulings (select all that apply)?

- ☒ Yes, in a civil liability instrument
- ☒ Yes, in court rulings
- ☐ Yes, in other instruments: (Please specify)
- ☐ No

183. Have there been any occurrences of damage resulting from LMOs in your country?

- ☐ Yes: (Please specify)
- ☒ No

184. If you answered *Yes* to question 183, have response measures been taken?

- ☐ Yes: (Please specify)
- ☐ No

185. Here you may provide further details on any activities undertaken in your country towards the implementation of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress:

_____

_____