BELARUS

National Coordination Biosafety Centre

BIOSAFETY OF GENETIC ENGINEERING ACTIVITY. DETECTION AND IDENTIFICATION OF GENETICALLY ENGINEERED ORGANISMS

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

United Nations Environment Programme

Global Ecilogical Fund

National Coordination Biosafety Centre

Institute of Genetics and Cytology, NAS of Belarus

BIOSAFETY OF GENETIC ENGINEERING ACTIVITY. DETECTION AND IDENTIFICATION OF GENETICALLY ENGINEERED ORGANISMS

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Biosafety of Genetic Engineering Activity. Detection and Identification of Genetically Engineered Organisms: 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” No. S1-32GFL-000644-14AC0003-11207-SB-015913.02.09, Certificate of Registration of Foreign Gratuitous Aid of May 13, 2022 No. 13-08/216 issued by the Department for Humanitarian Activities of the Office of the President of the Republic of Belarus; Authors: G. V. Mozgova, E. N. Makeyeva, A. N. Astrouskaya, V. S. Astapchyk, N. I. Drobat, T. V. Zhialiaznova, A. N. Kuzmich; under the editorship of G. V. Mozgova, E.N. Makeyeva. — Minsk: Pravo & Ekonomika. 2022. – 212 p. - ISBN 978-985-887-030-0.

Conservation of biological diversity and ensuring safety in genetic engineering activity are the most important tasks of environmental activity and the protection of human and animal health in the Republic of Belarus and aim to achieve progress in the implementation of the approach “One Health”. In 2002, the Republic of Belarus acceded to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and it effectively fulfills its commitments under the Protocol. The monograph deals with international and national legal regulation in the field of biosafety both in general sense and in relation to its key sphere ― GEO detection. Cutting-edge methodological approaches that allow effective GEO monitoring are deliberated, the issues related to the detection of new GEO generations are examined, databases and databanks and their role in assisting of laboratory GEO detection are considered. Issues that may in the near future have an important impact both on GEO detection and identification spheres and biosafety in general are touched upon. The monograph is destined for specialists who evaluate the quality of food, feed, and seed material, scientists, university professors, PhD students, Master’s students, students, as well as for everyone who is interested in the issues dealing with GEO development and ensuring of safety in genetic engineering activity.

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ISBN

CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
GEA	Genetic Engineering Activity
GEO	Genetically Engineered Organisms
GMI	Genetically Modified Ingredients
GMM	Genetically Modified Microorganisms
GMO	Genetically Modified Organisms
GEF	Global Environment Facility
ABS	Access to Genetic Resources and Benefit-sharing
DNA	deoxyribonucleic acid
EU	European Union
LMO	Living Modified Organisms
AIA	Advance Informed Agreement
CBD	Convention on Biological Diversity
CGE	Capillary Gel Electrophoresis
CPB	Cartagena Protocol on Biosafety
BCH	Biosafety Clearing-House
NCBC	National Coordination Biosafety Centre
ABS NCC	National Coordination Biosafety Centre on Access to Genetic Resources and Benefit-sharing
UN	United Nations
LAMP	loop-mediated isothermal amplification
PCR	polymerase chain reaction
RNA	ribonucleic acid
AHTEG	Ad Hoc Technical Expert Group
TNLA	technical normative legal acts
TR CU	Technical Regulations of the Customs Union
FAO	Food and Agriculture Organisation of the United Nations
DSI	digital sequence information on genetic resources
UNEP	United Nations Environment Programme

INTRODUCTION

It should be noted that genetically engineered organisms (GEO) are becoming an increasingly important genetic resource in terms of food, feed and seed material. During the period from 2007 to 2019, the total area of fields occupied by GEO increased by 89.7 million hectares, i.e. by 87.9% (Figure 1).

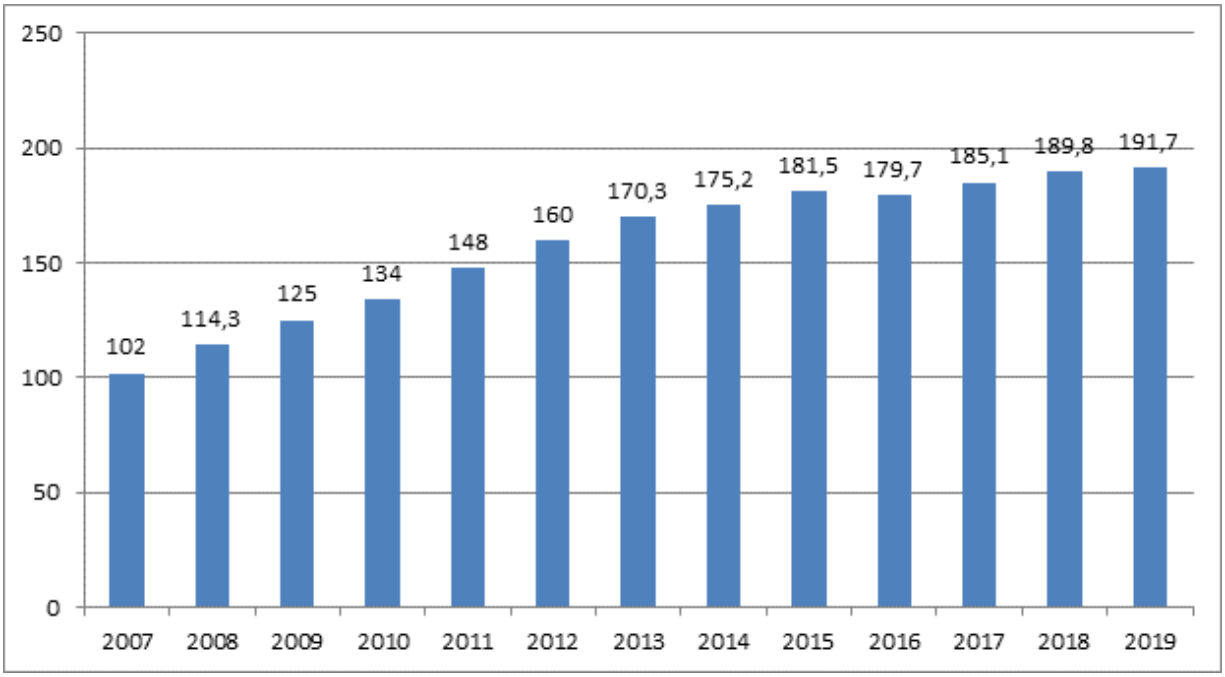


Figure 1 – Dynamics of GEO crops across the globe from 2007 to 2019, mln. ha [28]

Genetically engineered plant varieties are grown on over 191 mln. hectares in 29 countries (24 developing and 5 developed countries). Additionally, 42 countries, including 26 EU countries, import genetically engineered plants for food, feed and processing. Thus, 72 countries approve the production and use of genetically engineered plants [22].

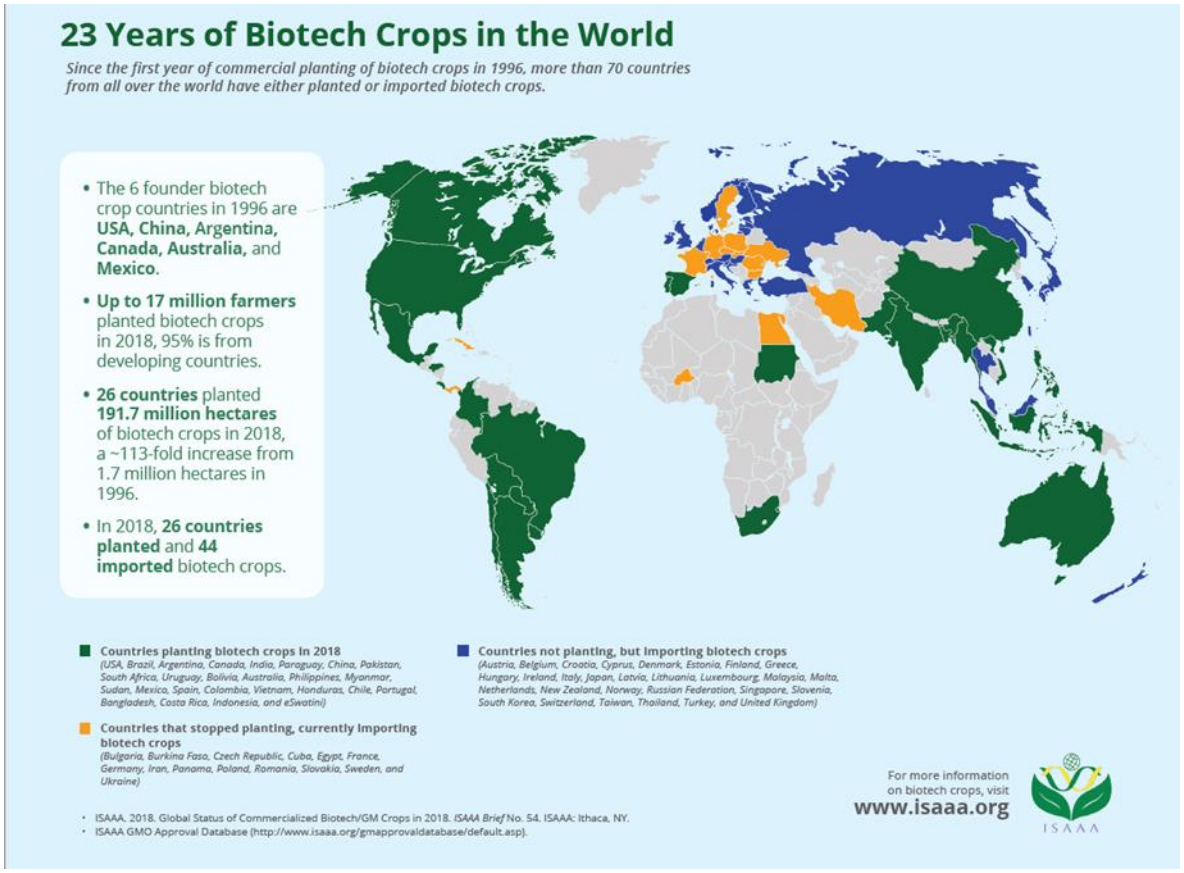


Figure 2 – Infographics of growing of biotech crops across the globe [22]

Modern biotechnologies, including genetic engineering, are useful tools that may be of great help in the areas of sustainable development of agriculture, forestry, food processing and medicine. At that, from the very beginning of the emergence of new biotechnologies, they came under close attention of the public and the scientific community, which led at the beginning of the 21st century to a wide discussion by various Parties and the development of international, regional and national legal mechanisms, rules and instruments aimed at their regulation, which are united under the general term “biosafety”. Biosafety is a term used to describe systems covering policy, regulation and management to control potential risks associated with the experimentation, production, and use and transboundary movement of GEO.

In 2003, the main international treaty in the field of the safe use of living modified organisms (synonymous with GEO) came into force ― the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. In addition, the issues related to the safe use of biotechnology have come under the close attention

of various international organizations, including the Food and Agriculture Organization of the United Nations (FAO). While the issue was evolving, many aspects of biosafety related to the environment, trade and food, as well as their impact on agriculture, were being considered by FAO bodies and at their meetings legal, political and technical aspects were discussed to ensure that relevant strategies in use in the field of agricultural biotechnology were in line with the commitments under the Cartagena Protocol [53].

Over the past 19 years following the accession to the Cartagena Protocol and with the support of the UN Environment Programme, the National Biosafety System was developed in the Republic of Belarus, including legislative and regulatory components for regulating of safety in genetic engineering activity [36]. Monitoring of GEOs is a key component in the implementation of the biosafety system in the country and it allows preventing the intentional and unintentional transboundary movement of unauthorized GEOs or the GEOs that have not undergone a risk assessment, detecting of GEOs in case of emergencies in laboratories or at the production facility, and in case of their illegal release to fields.

The idea of the need to publish a book on the biosafety of GEOs with a focus on the detection and identification came from the staff of the National Coordination Biosafety Center (NCBC) accredited within the Republican Center for Genomic Biotechnology in the field of detection, identification and quantification of GEOs during the implementation of the 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" (No. S1-32GFL-000644-14AC0003-11207-SB-015913.02.09). In the course of the analysis of the implementation of the system of biosafety of genetic engineering activity in the country, the NCBC noted the need of capacity building for GMO detection laboratories and highlighting the issues of both methodological and legal regulation of GEO detection and identification. The book deals with international and national legal regulation of the biosafety sphere both in a broad sense and in application to the detection of GEOs, modern methodological approaches that allow effective GEO monitoring, issues related to the detection of new GEO generations, databases and

databanks and their role in assisting of laboratory detection of GEOs. Issues that may in the near future have an important impact both on the field of detection and identification of GEO and the sphere of biosafety in general have been touched upon: the interplay between the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, as well as the role of digital sequence information on genetic resources and the issues related to the legal regulation of its use.

The book is published in line with NCBC commitments undertaken with regard to scientific support for biosafety, food and feed safety of the Action Programme for Nature and People aimed at strengthening the country's GEO detection and identification system and further developing of Standard Operating Procedures for GEO Screening and Identification that have not been authorized for release into the environment or for use in food, feed production or processing in Belarus [19].

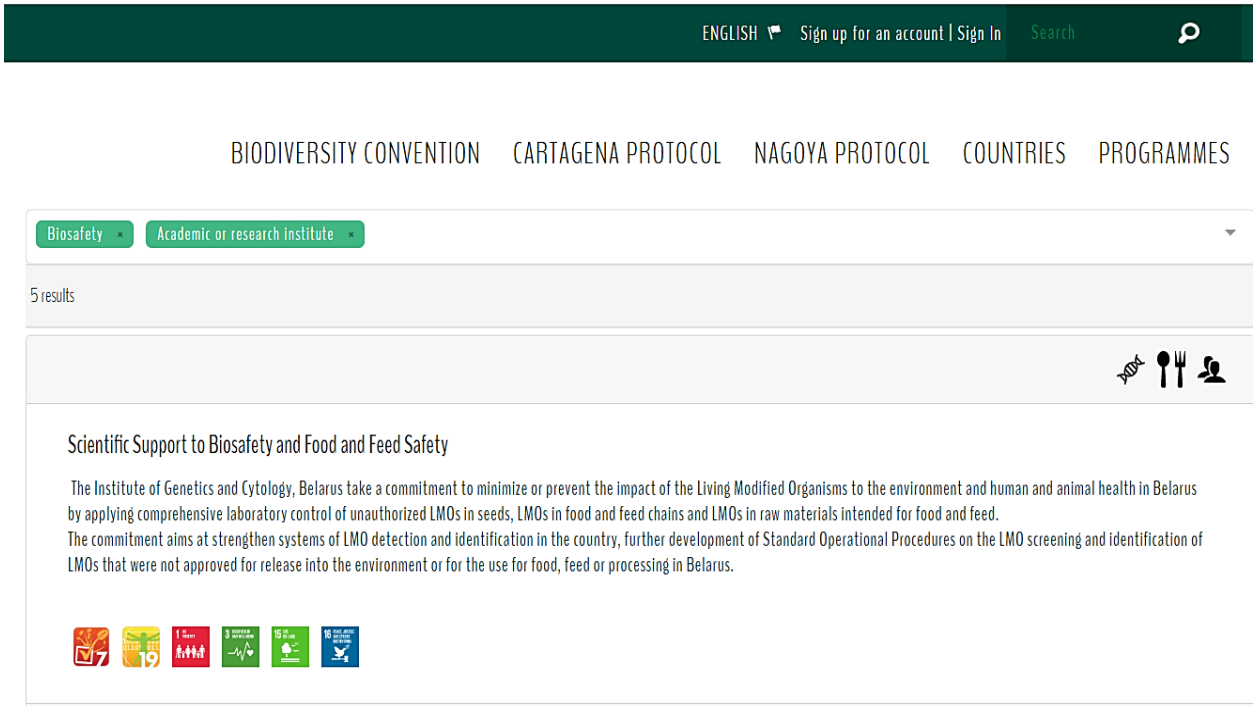
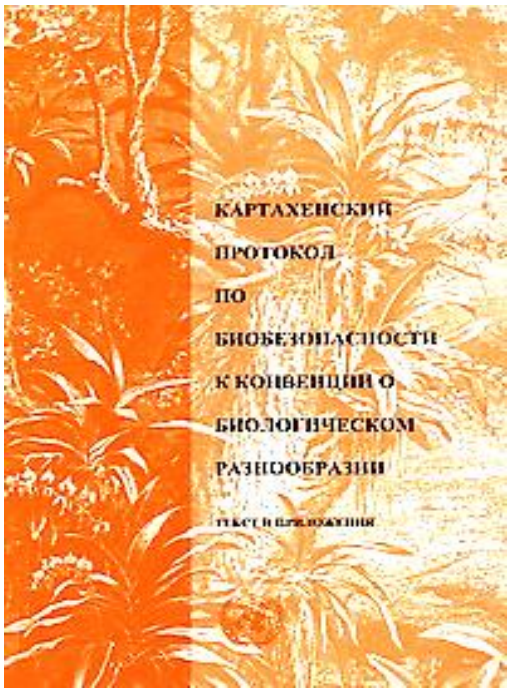


Figure 3 – Commitments undertaken by the NCBC “Scientific Support for Biosafety and Food and Feed Safety”

CHAPTER 1
INTERNATIONAL AND NATIONAL LEGISLATION IN THE FIELD OF BIOSAFETY, ACCESS TO LMOs AND BENEFIT-SHARING AND TRACEABILITY OF THE LMOs CIRCULATION

1.1 Cartagena Protocol on Biosafety



In 1992, the Republic of Belarus signed the Rio Declaration on Environment and Development, and in 1993, the country ratified the Convention on Biological Diversity, which entered into force on December 23, 1993 with currently 196 state Parties, including EU countries in general, and out of them 193 countries are UN member States [26; 102]. Considering a very short historical period of the use of genetically engineered organisms (GEOs), most countries shall be guided by Principle 15, or the Precautionary Principle of this Declaration, which states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

In accordance with the precautionary principle, the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity was finalized in 2000 and it entered into force on September 11, 2003 and the Republic of Belarus acceded to it on May 6, 2002 and undertook all the commitments required for its implementation [47]. The Cartagena Protocol is the most important treaty among the countries regulating interstate relations in the field of biosafety with its objective "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs)[1] resulting from modern

[1] Synonyms: genetically modified organisms (GMOs); genetically engineered organisms (GEOs)

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." To date, 173 UN member States are Parties to the CPB [15].

The Cartagena Protocol on Biosafety introduces a number of terms that fall under the scope of its regulation, including the terms "living modified organism", "living organism" and "modern biotechnology":

"Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

"Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

The Cartagena Protocol also defines the terms related to transboundary movement and the advance informed agreement (AIA) procedure:

"Export" means intentional transboundary movement from one Party to another Party;

"Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

"Import" means intentional transboundary movement into one Party from another Party;

"Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported.

The scope of the CPB shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account

risks to human health (Article 4, CPB). At the same time, the CPB shall not apply to the transboundary movement of living modified organisms, which are pharmaceuticals for humans, and that are regulated by other corresponding international agreements or organisations (Article 5, CPB).

The Parties to the CPB shall ensure that the development of any living modified organism, its handling, transport, use, transfer and release shall be undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. At that, "Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law" (Article 2, CPB).

As a key element of the Protocol, the term and mechanism of the advance informed agreement procedure was introduced in the CPB (AIA, Figure 4). The AIA procedure was developed to ensure that prior to the first import into the country of LMOs intended for intentional introduction into the environment the Party of import:

(a) has received notification of the intended import;

(b) has obtained full information on LMO and its intended use;

(c) has had a chance to conduct the assessment of risks associated with this particular LMO and decide whether to authorize its import or not [63].

The AIA procedure includes notification (Articles 8-9) and decision (Article 10) procedures.

The notification procedure:

(a) The Party of export, or the **exporter shall notify,** in writing, the Party of import of the intentional transboundary movement of LMO prior to its first delivery, including the detailed information on LMO and its intended use.

(b) The Party of import shall acknowledge receipt of this information within ninety days.

(c) Then, within two hundred and seventy days of the date of receipt of

notification, the Party of import shall make a decision and communicate to the notifier and the BCH about it: (a) approving the import; (b) prohibiting the import; (c) requesting additional relevant information; or (d) extending the decision for a defined period of time. Except in a case in which consent is unconditional, a Party of import shall set out the reasons on which it is based.

Decision procedure:

(a) A decision of the Party of import shall be based on **a risk assessment;**

b) The Parties may also pay regard to **socio-economic considerations,** while making a decision whether to authorize the LMO import or not;

c) The CPB provides the Parties with an opportunity to make decisions based on the **precautionary principle** in the case of no scientific certainty or insufficient scientific data and knowledge regarding the magnitude of possible adverse effects of LMOs.

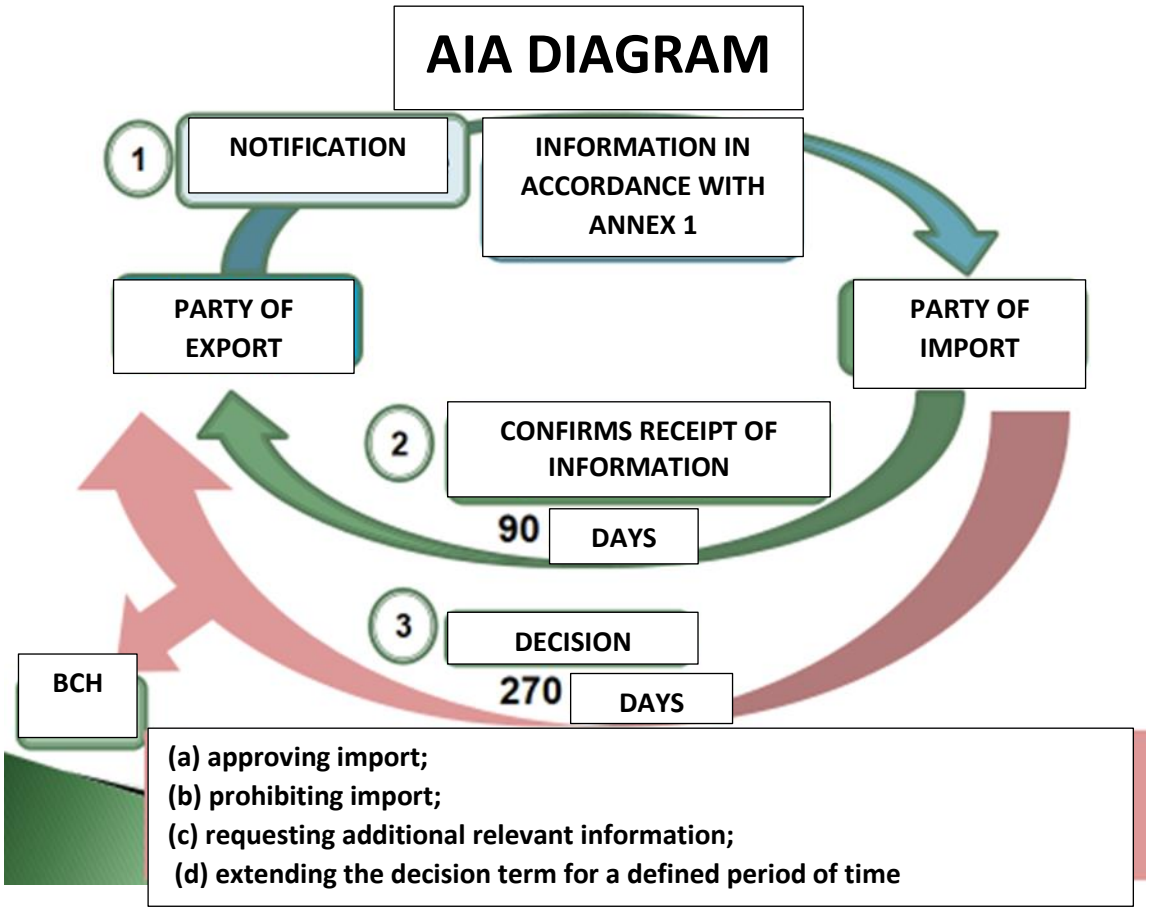


Figure 4 – AIA procedure

The AIA procedure shall not apply in relation to:

- LMOs **transit** (Article 6.1.);

- LMOs **destined for contained use** in the Party of import (Article 6.2.);
- LMOs destined for direct use as food or feed, or for processing (Article 7).

Nevertheless, the Parties shall have the right to regulate such transboundary movements at the national level. In this case, the Party must submit to the Biosafety Clearing-House (BCH) any decision it has taken regarding the transit through its territory of a particular LMO.

Article 13 describes the terms of the simplified procedure, which the Party of import may use in the transboundary movement of LMOs:

1. The Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of the Cartagena Protocol, discuss the simplified procedure in advance in the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications stipulated in subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

The decision procedure is described in Article 10. At that, decisions taken by the Party of import shall be in accordance with Article 15 “Risk Assessment”. Pursuant to this Article, risk assessments “shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking into account risks to human health.”

Annex I to the CPB establishes information required within the framework of notifications in accordance with Articles 8, 10 and 13. Such information includes, *inter alia*, a description of a nucleic acid or an introduced modification, the technique used, characteristics of LMOs obtained, and a risk assessment report in accordance with Annex III of the CPB.

In relation to the LMOs not destined for release into the environment, but destined for direct use as food, or feed, or for processing, the provisions of Article 11 of the CPB shall apply and in which it states "A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism, that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. This provision shall not apply to decisions regarding field trials". The information provided in Annex II includes, *inter alia*, a description of a genetic modification, the technique used, and characteristics of a living modified organism obtained as a result of its application, any unique identification data of a living modified organism and a risk assessment report in accordance with Annex III of the CPB.

Among the important issues to consider when conducting risk assessments in accordance with Annex III are the detection and identification of a living modified organism, as well as the proposed detection and identification techniques and their accuracy, sensitivity and reliability.

Article 16 "Risk Management" states that "The Parties shall establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms." At that, the Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17 “Unintentional Transboundary Movements and Emergency Measures” defines that “Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation” (Paragraph 1, Article 17). At that, any notification, arising from Paragraph 1 above, should, *inter alia,* include any available information about possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures. Additionally, pursuant to Article 11, “In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in Paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.”

Article 18 “Handling, Transport, Packaging and Identification” defines that “In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to international transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards”, and “The Conference of

the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies."

An important role in the implementation of the biosafety of LMOs is given to the Biosafety Clearing-House (the BCH) to the CPB, which is both the largest and most comprehensive biosafety database and Internet resource. BCH information is available to any user at https://bch.cbd.int.

Article 20 states that the Biosafety Clearing-House is established in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and assist Parties to implement the Cartagena Protocol, taking into account the special needs of developing country Parties, in particular the least developed and island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

The BCH shall facilitate access to information provided by the Parties related to the implementation of the CPB. It also provides access, where possible, to other international instruments providing for the exchange of information in the field of biosafety.

Each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under the Cartagena Protocol on Biosafety, and:

(a) Any existing laws, regulations and guidelines for implementation of the CPB, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified

organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on the implementation of the advance informed agreement procedure.

Thus, the CPB establishes rules for LMO management, a risk assessment, and LMO monitoring and traceability, facilitating control over the circulation of such organisms. The CPB also establishes the Biosafety Clearing-House, which is also a publicly available global database on LMOs. In more detail, the BCH is covered in section 2.2. At the same time, it is necessary to separately note the section “LMO Registry” on the BCH website. In this Register, country Parties to the CPB, on a mandatory basis, and country non-Parties to the CPB, on a voluntary basis, provide information on LMOs that may become the object of transboundary movement, including a description of the transgenic construct (all inserted genetic elements, including promoters, terminators, target gene/genes and selective gene/genes, as well as LMO detection and identification techniques).

Thus, it is obvious from the above that molecular methods used for the LMO detection are an important link in monitoring and controlling the traceability of the transboundary movement of authorized and unauthorized LMOs, identifying intentional and unintentional releases of LMOs in emergency situations, an integral tool for the implementation of Articles 8, 9, 11, 13, 16, 17, and 18 of the CPB.

1.2. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity and its Tie-in with the Cartagena Protocol on Biosafety and other International Treaties in Part of Access to LMOs

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (hereinafter referred to as "the Nagoya Protocol") was adopted at the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity on 29 October 2010, in Nagoya, Japan, and it entered into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification on 12 October 2014. This gave the green light to the first meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol in Pyeongchang (the Republic of Korea) concurrently with the twelfth meeting of the Conference of the Parties to the CBD on 13-17 October 2014 [27].

As of 8 April 2022, the Nagoya Protocol was ratified by 136 countries, including the Republic of Belarus [94].

The Nagoya Protocol significantly contributes to the implementation of the 3rd objective of the CBD by laying a solid foundation that offers greater legal certainty and transparency to the providers and users of genetic resources. The most important innovation of the Nagoya Protocol are specific commitments in furtherance of compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual commitments set out in mutually agreed terms.

The objective of this Protocol is framed in Article 1 "The fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by

appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components." [41].

Thus, the Nagoya Protocol aims to develop regulatory (legal) frameworks ensuring access to genetic resources, transferring of relevant technologies, as well as deriving benefits arising from the utilization of such resources and technologies establishing terms allowing to implement the provisions of Article 15 "Access to Genetic Resources", Article 16 "Access to and Transfer of Technology" and Article 19 "Handling of Biotechnology and Distribution of its Benefits" of the Convention on Biological Diversity (the CBD).

Recognizing the sovereign rights of States over their natural resources (Article 15) by the CBD, the authority to determine a legal regime for access to their genetic resources rests with the national governments and is subject to national legislation. At that, each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention. The genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 15 and 16, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired such genetic resources in accordance with the CBD and to the biotechnology referred to in Article 19 – those that are applied to the provided genetic resources [37].

The provisions that lay foundations for fair and equitable benefit-sharing are covered by Article 5 of the Nagoya Protocol "Fair and Equitable Benefit-sharing". They establish the requirements as follows:

1. Pursuant to Paragraphs 3 and 7, Article 15 of the CBD, the benefits arising from the utilization of genetic resources, as well as from subsequent uses and commercialization shall be fair and equitably shared with the Party providing such resources, which is the country of origin of such resources, or the Party that has

acquired genetic resources in accordance with CBD provisions. Such benefit-sharing shall be based on mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement Paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex to the Nagoya Protocol.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 6 of the Nagoya Protocol "Access to Genetic Resources" particularizes the key provisions of the CBD on access and establishes the following measures required to actualize such access:

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the provisions of the Convention, unless otherwise determined by the Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to Paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia:*

i) A dispute settlement clause;

ii) Terms on benefit-sharing, including in relation to intellectual property rights;

iii) Terms on subsequent third-party use, if any; and

iv) Terms on changes of intent, where applicable [41].

Article 8 “Special Considerations” is essential to ensure compliance with the Nagoya Protocol in complicated situations or *force majeure* that countries may face. Pursuant to this Article, in the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in

developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

In addition to the main objective specified in Article 1 "Objective", the provision formulated in Article 9 "Contribution to the Conservation and Sustainable Use" that states that "The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components" is instrumental for the whole Convention.

With the rapid development of modern biotechnology and the use of living modified plants and animals for food, the genetic resources of organisms modified using genetic engineering methods shall fall under the scope of the Nagoya Protocol.

Pursuant to Article 2 of the CBD:

"**Genetic resources**" means genetic material of actual or potential value;

"**Genetic material**" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Thus, LMOs refer to genetic resources and are a common point of synergy between the Nagoya and Cartagena Protocols.

Based on the definitions of the Nagoya Protocol, two objects may be considered to fall under its scope:

1) LMOs themselves as living objects that possess valuable genetic characteristics and represent the genetic resources of organisms modified using genetic engineering methods;

2) Technologies for the development and/or use of LMOs, including technologies the know-how of which is protected under intellectual property rights legislation.

In both cases, access to such objects may be provided with certain benefits:

- In-kind (non-monetary) – when jointly conducting scientific and other studies of biological properties; genetic, economic and other characteristics of LMOs;
- Monetary, including commercial ones, – when using both the LMOs themselves and the products derived from living modified plants, animals or when cultivating the strains of microorganisms, e.g. in the pharmaceutical or cosmetic industry.

In all cases, the main principle of the Nagoya Protocol must be observed: fair and equitable sharing of benefits between the provider of LMO genetic resources and their user.

In order to conserve LMO genetic resources, the following scientific approaches shall be used:

DNA-identification of objects;

Characterization of facilities with regard to their impact on the environment (risk assessment);

Preservation of valuable samples at low (-80^0C) and ultra-low (cryopreservation) temperatures;

In vitro storage (in the case of growth retardation);

Microclonal propagation.

The preamble to the Nagoya Protocol recognizes the interdependence of all countries on genetic resources for food and agriculture, as well as their special nature and weightiness for food security worldwide and sustainable agricultural development in the context of combating poverty and climate change, and recognizing the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as “the International Treaty on Plant Genetic Resources”) and the FAO Commission on Genetic Resources for Food and Agriculture (hereinafter referred to as “the FAO Commission on Genetic Resources”) in this regard.

The preamble to the Nagoya Protocol also refers to the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources and developed in coordination with the CBD.

It should be noted that the detection and identification of LMOs, including of synthetic biology objects, using high-resolution molecular genetics methods, is the key tool enabling to ensure the traceability of LMOs, both for the purposes of biological safety under the Cartagena Protocol, and for the purposes of traceability of LMOs as a genetic resource under the Nagoya Protocol, serving all three objectives of the Convention on Biological Diversity ─ the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources. Improving legal and economic frameworks to underpin large-scale monitoring, control over and supervision of the spread of LMOs, including the organisms obtained using modern biotechnologies and the products of modern biotechnologies, is defined in the Concept of the National Biosafety System approved by the Resolution of the Council of Ministers of the Republic of Belarus of March 22, 2022 No. 161 [44] as one of the priority measures for the protection of the people, animals and the environment from the impact of hazardous biological factors and the prevention of biological threats.

1.3. Legal Regulation of LMOs Handling in the Republic of Belarus

Pursuant to Paragraph 3 of Article 6 of the Law "On Normative Legal Acts" of the Republic of Belarus of July 17, 2018 No. 130-3, the Republic of Belarus recognizes priority of universally acknowledged principles of international law and ensures the compliance of legislation with them [46].

Pursuant to Article 17 of the Law "On the International Treaties of the Republic of Belarus" of July 23, 2008 No. 421-3, the consent of the Republic of Belarus to be bound by an international treaty may be expressed by signing an international treaty, exchanging of notes, letters or other documentation constituting an international

treaty; ratifying an international treaty, approving (adopting) an international treaty, and through the law of succession with respect to an international treaty [45].

The Republic of Belarus acceded to the Cartagena Protocol in accordance with the Law "On the Accession of the Republic of Belarus to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity" of the Republic of Belarus of May 6, 2002 No. 97-3 [47]. In accordance with this Law, the Council of Ministers of the Republic of Belarus orders to determine the Republican bodies of the State administration responsible for the implementation of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity: the Ministry of Natural Resources and Environmental Protection ― in terms of functions related to the release of living modified organisms into the environment; the Ministry of Agriculture and Food and the Ministry of Health ― in terms of functions related to the use of living modified organisms in economic activity. The Institute of Genetics and Cytology of the National Academy of Sciences of Belarus, which performs the functions of the National Coordination Biosafety Centre in accordance with the Resolution of the Council of Ministers of the Republic of Belarus "On the Establishment of the National Coordination Biosafety Centre" of June 19, 1998 No. 963 is determined to be responsible for liaison with the Secretariat of the Convention on Biological Diversity on biosafety issues. The Ministry of Natural Resources and Environmental Protection (hereinafter referred to as "the Ministry of Nature") is the National Coordination Centre for the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, the National Coordination Biosafety Centre of the Institute of Genetics and Cytology ― the National Focal Point for the Biosafety Clearing-House to the Cartagena Protocol on Biosafety [33].

The Republic of Belarus acceded to the Nagoya Protocol by adopting the Decree of the President of the Republic of Belarus "On the Accession of the Republic of Belarus to the International Treaty" of May 22, 2014 No. 235, which recognizes the Ministry of Nature as the authority responsible for the fulfillment of commitments assumed by the Republic of Belarus under the Nagoya Protocol, namely the Competent National Authority [48].

Pursuant to Article 26 of the Law “On International Treaties of the Republic of Belarus”, the International Treaties of the Republic of Belarus shall be subject to conscientious execution by the Republic of Belarus in accordance with the International Law. Legal provisions embodied in the International Treaties of the Republic of Belarus shall be subject to direct application, except for the cases where it follows from the International Treaty that the application of such provisions shall require the adoption (issuance) of a normative legal act, and have the force of that normative legal act, which expresses the consent of the Republic of Belarus to be bound by the relevant International Treaty [45].

Thus, the Cartagena and Nagoya Protocols to the CBD, the Republic of Belarus acceded to by adopting of respective legislative acts, shall have the force of these legislative acts in the Republic of Belarus.

With a view of the effective implementation of the Cartagena Protocol, the Law “On Safety in Genetic Engineering Activity” of the Republic of Belarus of January 9, 2006 No. 96-3 (hereinafter referred to as “the Law”) [29] was adopted and the National Biosafety System was developed.

The Law establishes the main legal and organizational measures; a system of measures was developed to monitor and control all areas of genetic engineering activity (GEA): implementation of works in self-contained systems (contained use), the release of genetically engineered organisms (GEO ― a synonym for LMO) into the environment for testing, use for economic purposes, import and export of GEOs into and from the Republic of Belarus, transit through its territory, transport, storage and neutralization. Article 1-1 of the Law determines that relations in the field of safety in genetic engineering activity shall be regulated by this Law and other legislative acts in the field of GEA safety, International Treaties of the Republic of Belarus, international legal acts constituting the Law of the Eurasian Economic Union. In that, if an International Treaty of the Republic of Belarus establishes other rules than those embodied in this Law, then the rules of the International Treaty shall apply.

The Law defines the following terms (Annex A):

“Genetically Engineered Organism” (genetically altered (modified,

transgenic organism) means a living organism containing a novel combination of genetic material obtained using genetic engineering;

"Genetic Engineering" means the technology of obtaining novel combinations of genetic material by means of manipulations with nucleic acid molecules carried out outside the cell and the transfer of designed gene constructs into a living organism, as a result of which their inclusion and activity in this organism and in its offspring are achieved.

Article 22 of the Law defines the functions of the National Coordination Biosafety Centre of the Institute of Genetics and Cytology, NAS of Belarus (NCBC), in the framework of information support in the field of GEA safety.

Article 13 of the Law establishes GEA Risk Levels:

Risk Level I ― work with non-pathogenic GEO;

Risk Level II ― work with potentially pathogenic GEO;

Risk Level III ― work with pathogenic GEO capable of causing dangerous infectious diseases and spreading of infection and for which effective prevention and treatment measures exist;

Risk Level IV ― work with pathogenic GEO that are the causative agents of particularly dangerous infectious diseases able to spread rapidly, and for which effective prevention and treatment measures are unknown.

Individual entrepreneurs shall have the right to carry out the GEA only of Risk Level I as provided. The GEA of Risk Levels II, III and IV shall be exercised by state legal entities exclusively.

The scope of competence of the Ministry of Health, the Ministry of Natural Resources and the Ministry of Agriculture and Food shall include state management and control (supervision) in the field of GEA safety, within the framework of which the problem of biosafety shall be considered, primarily in the context of the safe use of biotechnology when carrying out the works with GEO of various pathogenic degrees.

The Ministry of Nature shall, as the state authority responsible for the implementation of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety in the Republic of Belarus, fulfill the main functions related to the control

and supervision of non-pathogenic GEO (Risk Level I) from the moment of their development and release into the environment for testing prior to the transgenic movement of both the GEO developed in the country and the imported ones. The Ministry of Health shall establish the procedure for the works of Risk Levels II, III and IV. The Ministry of Agriculture and Food shall be accountable for the registration of GE plant varieties, GE microorganism strains and GE animal breeds.

GEO risk levels shall determine a procedure to follow for all GEO developers and the persons involved in GEO transport.

When carrying out GEA with non-pathogenic GEO in cases of works undertaken in self-contained systems (contained use) excluding the contact with the external environment, the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 50 shall apply (Table 1). The works of Risk Level I of genetic engineering activity in self-contained systems (hereinafter referred to as "the works") should be undertaken at self-contained facilities excluding the release of GEO into the environment. GEO waste generated as a result of works performed shall be neutralized in a way that excludes the preservation of viable spores, pollen, fruit or seeds, and microorganisms in accordance with the procedure established by legislation [57].

In cases where GEA is carried out by a legal person or an individual entrepreneur, a local legal act on the exercise of the production control in the field of GEA safety should be developed [58]. The Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 51 establishes that legal persons and individual entrepreneurs carrying out the GEA of Risk Level I shall maintain record of the non-pathogenic GEO developed, imported from the Republic of Belarus by filling in the registration sheet for non-pathogenic GEO according to the form of the Annex to this Resolution that shall be directed, within one week of the date it has been completed, to the Ministry of Nature. The Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus approves "The Instruction on the Procedure for Neutralizing of Non-pathogenic Genetically Engineered Organisms" of May 31,

2019 No. 12 (Table 1).

Pursuant to Article 15 of the Law, the release of potentially pathogenic and pathogenic GEO into the environment for testing shall not be allowed. The release of non-pathogenic GEO into the environment for testing shall be carried out, provided that there is a permit for the release of non-pathogenic GEO into the environment issued by the Ministry of Nature. A permit shall be issued with due regard to the recommendations of the Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus for the admissibility of the release of non-pathogenic genetically engineered organisms into the environment [59]. Testing of non-pathogenic GEO at their first release into the environment should be carried out in trial fields and at other facilities specially equipped to prevent possible adverse effects of these organisms on the environment and that comply with safety requirements established by the Ministry of Nature subject to coordination with the National Academy of Sciences of Belarus [60].

Pursuant to Article 16 of the Law, the use of potentially pathogenic and pathogenic GEO for economic purposes shall not be allowed. The use of non-pathogenic GEO for economic purposes shall be allowed only after their state registration with the Ministry of Agriculture and Food in accordance with the Resolution of the Council of Ministers of the Republic of Belarus of September 12, 2006 No. 1195 and the Resolution of the Ministry of Agriculture and Food of the Republic of Belarus of February 10, 2021 No. 8 (Table 1).

Pursuant to Article 20 of the Law, non-pathogenic GEO, at their first release into the environment for testing and in the case of state registration of GE plant varieties, GE animal breeds and strains of non-pathogenic GE microorganisms destined for use for economic purposes, shall be subject to a risk assessment of possible adverse effects on human health and the environment. Such risk assessment shall underlie a decision of the Expert Board on Safety of Genetically Engineered Organisms.

In order to perform a risk assessment, a legal person or an individual entrepreneur, who are the initiators of carrying it out, shall submit to one of nine

authorized organizations (Scientific Institutions and Republican Scientific and Practical Centres), pursuant to the Annex to the Resolution of the Council of Ministers of the Republic of Belarus of June 12, 2019 No. 382 [61], GEO samples, as well as materials containing information on GEO and measures for preventing of possible adverse effects of GEO on human health and the environment. Based on risk assessment results, an authorized organization shall issue a protocol including the findings on the admissibility (inadmissibility) of the GEO release into the environment for testing or use for economic purposes and provide it to the stakeholder. The protocol on the admissibility (inadmissibility) of the GEO release into the environment for testing or use for economic purposes shall be considered at a meeting of the Expert Board on Safety in Genetic Engineering Activity of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and a conclusion on the admissibility (inadmissibility) of the GEO release into the environment for testing or use for economic purposes shall be issued [61].

Authorized organizations carrying out a GEO risk assessment shall be guided by the instructions and methodological recommendations developed in the country for a GEO risk assessment and a risk to human health [39; 55], which are based on the Guidance on Risk Assessment of Living Modified Organisms of the Convention on Biological Diversity [80], recommendations and a set of international food standards adopted by the International Commission of the Food and Agriculture Organization of the United Nations and the World Health Organization (the Codex Alimentarius) [87-89; 95].

Since 2014, eleven risk assessments have been conducted of the GEOs of plant, animal and microbial origin developed by different Institutions of the Republic of Belarus [52]. Five GEOs, belonging to *Brassicaceae*, *Solanaceae* and *Bovidae* families, have obtained a positive conclusion for their release for the purposes of testing in trial fields that meet biosafety requirements. Four GEOs (transgenic goats with an inserted gene of recombinant lactoferrin and three microorganisms for the self-contained use) have been allowed for use in economic

activity. At that, an animal may be released only in the territory of the specially designated experimental farm [52].

In accordance with the legislation of the Republic of Belarus, the GEO release for field trials may be carried out only in specially designated and equipped fields. In accordance with the Law of the Republic of Belarus, three of such fields have been produced: at the experimental base of the State Scientific Institution "Institute of Genetics and Cytology, NAS of Belarus", at the Central Botanical Garden, NAS of Belarus, and at the Scientific and Practical Centre for Potato, Fruit and Vegetable Growing, NAS of Belarus [51]. The fields are in full compliance with the Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus "On Safety Requirements for Trial Fields and other Facilities Destined for Testing of Non-pathogenic Genetically Engineered Organisms at their First Release into the Environment" of August 29, 2006 No. 56 [59].

The release and use in economic activity of potentially pathogenic and pathogenic GEO shall not be allowed. In relation to such organisms, the GEA shall be regulated by the Resolution of the Ministry of Health of the Republic of Belarus of June 21, 2019 No. 61 [56] that establishes the instructions as follows:

The Instruction on Safety Requirements for Self-contained Systems in Carrying Out of Works of Risk Levels II, III and IV of Genetic Engineering Activity;

The Instruction on Safety Requirements during the Transport of Potentially Pathogenic and Pathogenic Genetically Engineered Organisms;

The Instruction on the Accountability by State Legal Entities of Potentially Pathogenic and Pathogenic Genetically Engineered Organisms Developed by them, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory.

The main safety requirements for self-contained systems (self-contained use) at carrying out of works of GEA Risk Levels II, III and IV shall be as follows:

A permit for carrying out of works with potentially pathogenic microorganisms and pathogenic biological agents;

An authorization document held by the employees of an organization for carrying out of works of GEA Risk Levels II, III and IV;

Organization of work in the laboratories of an organization in accordance with sanitary norms and rules.

The Instructions shall clearly establish all the requirements for premises, personnel, compliance with safety requirements when used in such self-contained systems, for the transport of potentially pathogenic or pathogenic GEO from one structural subdivision of an organization to another, for their transport outside the territory of the Republic of Belarus, to the Republic of Belarus and transit through its territory, the procedure for and formats of accounting by state legal persons of the potentially pathogenic and pathogenic GEO developed by them, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory. In order to ensure control over such GEO, it is also determined that the recipient organization shall direct copies of an act of opening the box packaging and a letter confirming the receipt of potentially pathogenic and pathogenic GEO to the State Institution "Republican Scientific and Practical Center for Epidemiology and Microbiology" for keeping track of the potentially pathogenic and pathogenic genetically engineered organisms developed in the Republic of Belarus, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory.

A list of regulatory normative legal acts is provided in Table 1.

Thus, the biosafety system effectively regulates all types of genetic engineering activity.

It should be noted, however, that at present there is a rapid development of such a new area of genetic engineering as synthetic biology, which includes organisms developed using genome editing techniques, including various areas of CRISPR-Cas genome editing, xenobiology, etc. By 2017, more than 25 thousand authors from 3.7 thousand organizations located in 79 countries had contributed to the study of synthetic biology [100]. Since 1980, 13 thousand articles on synthetic biology have been published [104]. Such organisms are

not similar to the previous generations of GEO – these are GEO with a rearranged metabolic system or fully synthesized genomes, life forms with unknown biochemistry, genetic code, synthesized *de novo*, etc. A number of such organisms are commercialized, some other of such organisms are under development, but there may be an active exchange among the laboratories. Methods of control, supervision, monitoring, detection and a risk assessment may differ significantly for the objects of synthetic biology. Therefore, in the near future it may be necessary to improve legislative mechanisms and other approaches to regulate such organisms.

A report submitted by the Ad Hoc Technical Expert Group on Synthetic Biology of the Convention on Biological Diversity in the run-up to the fourteenth Meeting of the Conference of the Parties to the Convention on Biological Diversity (Sharm el-Sheikh, Egypt, 17-29 November 2018) states that living organisms developed using synthetic biology tools, including engineered gene drives, are similar to living modified organisms (LMOs) as defined in the Cartagena Protocol on Biosafety [96]. The group also noted some synthetic biology organisms that are currently in the early stages of research (in particular, cell-free systems and organisms obtained using epigenetic engineering techniques) that may not fall under the term of LMO. At the same time, all organisms currently developed using synthetic biology techniques are recognized as living modified organisms (the GEO synonym, the term used in the Cartagena Protocol on Biosafety) [96].

Table 1 – A list of normative legal acts, regulating safety in genetic engineering activity

Name	**Registration Date**	**Source**
The Law "On Safety in Genetic Engineering Activity" of the Republic of Belarus of January 9, 2006 No. 96-3 *The Law establishes legal and institutional frameworks for ensuring safety in genetic engineering activity and is aimed at protecting human health and the environment, the fulfillment by the Republic of Belarus of international commitments in the field of safety in genetic engineering activity, including within the framework of fulfilling of commitments under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.* *The scope of this Law shall not apply to relations associated with the application of genetic engineering to a human, his/her organs and tissues, handling of medicines, food raw materials and food products, animal feeds obtained from genetically engineered organisms or their components. When carrying out of works with potentially pathogenic microorganisms and pathogenic biological agents that are genetically engineered organisms, the requirements of legislation in the field of sanitary and epidemiological welfare of the population shall apply, taking into account the specifics established by legislation in the field of safety in genetic engineering activity.* *To the relations arising in connection with the import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory and use of genetically engineered organisms that are the objects of export control, this Law shall apply in part not regulated by legislation in the field of export control.*	Registered with the National Register of Legal Acts of the Republic of Belarus of January 17, 2006 No. 2/1193	*https://biosafety.igc.by/wp-content/uploads/2021/01/04O-bezopasnosti-genno-inzhenernoj-deyatelnosti.pdf*
The Resolution "On Risk Assessment in Genetic Engineering Activity and Issuance of an Authorization Document" of the Council of Ministers of the Republic of Belarus of June 12, No. 382 *The Resolution establishes the Provision on the procedure for carrying out of a risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment; the Provision on the procedure for and terms of issuance of permits for the release of non-pathogenic genetically engineered organisms into the environment for testing; the Provision establishes a list of organizations authorized to carry out a risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment.*	Registered with the National Register of Legal Acts of the Republic of Belarus of June 13, 2019 No. 5/46619	https://biosafety.igc.by//wp-content/uploads/2021/01/08Postanovlenie-Sov-Mina-382-2.pdf
The Resolution "On the Procedure for Work with Non-pathogenic Genetically Engineered Organisms" of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of May 31, 2019 No. 12 *The Resolution establishes the instruction on the procedure for the neutralization of non-pathogenic genetically engineered organisms and introduces amendments to a number of Resolutions of the Ministry of Natural Resources and Environmental Protection.*	Registered with the National Register of Legal Acts of the Republic of Belarus of June 17, 2019 No. 8/34242	https://biosafety.igc.by//wp-content/uploads/2021/01/22Minprirody-12.pdf
The Resolution "On Safety Requirements for Self-contained Systems in Carrying out of Works of Risk Level I in Genetic Engineering Activity" of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 50. *The Resolution establishes safety requirements for self-contained systems when carrying out of works with non-pathogenic genetically engineered organisms.*	Registered with the National Register of Legal Acts of the Republic of Belarus of September 1, 2006 No. 8/14952	https://biosafety.igc.by//wp-content/uploads/2021/01/25Minprirody-50.pdf

Continuation of Table 1

The Resolution "On the Procedure for Developing and Approving of a Local Legal Act on Exercising the Production Control in the Field of Safety in Genetic Engineering Activity" of the Ministry of Natural Resources and Environmental Protection, the Ministry of Health and the Ministry of Agriculture and Food of April 3, 2014 No. 19/23/14. *The Resolution establishes the instruction on the procedure for the development and approval by a legal entity or an individual entrepreneur, exercising genetic engineering activity, of a local legal act on the exercise of the production control in the field of safety in genetic engineering activity.*	Registered with the National Register of Legal Acts of the Republic of Belarus of April 23, 2014 No. 8/28600	https://biosafety.igc.by//wp-content/uploads/2021/01/23Postanovlenie-MinPrirody-N-19-23-14.pdf
The Resolution "On the Procedure for Maintaining Record of Non-pathogenic Genetically Engineered Organisms by Legal Persons and Individual Entrepreneurs Developed by them and Exported from the Republic of Belarus" of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 17, 2006 No. 51. *The Resolution establishes the procedure for maintaining records of non-pathogenic genetically engineered organisms by legal persons and individual entrepreneurs developed by them and exported from the Republic of Belarus and approves a registration form for non-pathogenic genetically engineered organisms.*	Registered with the National Register of Legal Acts of the Republic of Belarus of September 1, 2006 No. 8/14953	https://biosafety.igc.by//wp-content/uploads/2021/01/26Minprirody-51.-Red.-12.-2019-g..pdf
The Order "On the Expert Board on Safety of Genetically Engineered Organisms" of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of July 19, 2019 No. 181-OD *The Order establishes the composition of an Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.*	-	https://biosafety.igc.by/wp-content/uploads/2021/04/exp_sovet.pdf
The Resolution "On Safety Requirements for Trial Fields and other Facilities Destined for Testing of Non-pathogenic Genetically Engineered Organisms at their First Release into the Environment" of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of August 29, 2006 No. 56 *The Resolution establishes safety requirements for trial fields and other facilities destined for testing of non-pathogenic genetically engineered organisms at their first release into the environment.*	Registered with the National Register of Legal Acts of the Republic of Belarus of September 11, 2006 No. 8/14993	https://biosafety.igc.by//wp-content/uploads/2021/01/27Minprirody-56.pdf
The Resolution "On Approving of the Procedure for the State Registration of Genetically Engineered Plant Varieties, Genetically Engineered Animal Breeds and Strains of Non-pathogenic Genetically Engineered Organisms" of the Council of Ministers of the Republic of Belarus of September 12, 2006 No. 1195 *The Resolution establishes the procedure for the State registration of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms.*	Registered with the National Register of Legal Acts of the Republic of Belarus of September 15, 2006 No. 5/22920	https://biosafety.igc.by//wp-content/uploads/2021/01/13Postanovlenie-SovMina-1195.pdf

Continuation of Table

The Resolution "On Establishing of the Form of the State Registration Certificate" of the Ministry of Agriculture and Food of the Republic of Belarus of February 10, 2021 No. 8 *The Resolution establishes the form of the State registration of genetically engineered plant varieties, genetically engineered animal breeds and strains of non-pathogenic genetically engineered microorganisms destined for use in economic activity.*	Registered with the National Register of Legal Acts of the Republic of Belarus of February 25, 2021 No. 8/36369	https://pravo.by/document/?guid=3961&p0=W22136369
The Resolution "On a Risk Assessment of Genetic Engineering Activity and Issuance of an Authorization Document" of the Council of Ministers of the Republic of Belarus of June 12, 2019 No. 382	Registered with the National Register of Legal Acts of the Republic of Belarus of June 15, 2019 No. 5/46619	https://biosafety.igc.by//wp-content/uploads/2021/01/08Postanovlenie-Sov-Mina-382-2.pdf.
The Law "On Introducing Additions to some Codes of the Republic of Belarus on the Issues of Establishing of Responsibility for a Violation of Legislation on Safety in Genetic Engineering Activity" of the Republic of Belarus of May 18, 2007 No. 231	Registered with the National Register of Legal Acts of the Republic of Belarus of January 3, 2007 No. 2/1291	https://biosafety.igc.by//wp-content/uploads/2021/01/06act-2007-N231-add-codexes.pdf

With a view of fulfilling commitments under the Nagoya Protocol by the Parties, certain organizations should be vested with corresponding powers and responsibilities.

Article 13 of the Nagoya Protocol "National Focal Points and Competent National Authorities" establishes institutional frameworks and functions they should perform. It establishes that each Party shall designate a national focal point, as well as one or several competent national authorities on access and benefit-sharing, each of them fulfilling the functions specified in the Article [41].

The Council of Ministers of the Republic of Belarus adopted the Resolution "On the Establishment of the National Coordination Centre on Access to Genetic Resources and Benefit-sharing" of October 1, 2014 No. 933. In accordance with the Resolution, the functions of the aforementioned National Coordination Centre were bestowed on the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" [49].

Since GEO are genetic resources, the provisions of the Nagoya Protocol shall apply when accessing them.

In order to implement access to genetic resources, the ABS NCC has developed the following procedure used for genetic resources in the Republic of Belarus, which may apply to GEO:

1. The provider of genetic resources and their potential user shall apply to the ABS NCC in any convenient way (phone, email and in person) and either in English or Russian fill in an application form for accessing genetic resources;

2. The ABS NCC shall apply to the Competent National Authority (the Ministry of Natural Resources and Environmental Protection) to obtain prior informed consent; the Ministry of Nature shall analyze the submitted information and make a decision whether to issue prior informed consent or reject its issuance;

3. When obtaining prior informed consent, the ABS NCC shall check whether mutually agreed terms have been concluded between the provider and user of genetic resources and are specified in the contract (cooperation agreement) and are in compliance with the Nagoya Protocol's requirements.

4. On signature of a contract (a cooperation agreement) containing mutually agreed terms, the ABS NCC shall apply to the Ministry of Nature for a permit for accessing genetic resources that serves as evidence of compliance with the Nagoya Protocol's requirements;

5. The information contained in a permit for accessing genetic resources issued by the Ministry of Nature shall be submitted by the ABS NCC to the Access and Benefit-sharing Clearing-House at https://absch.cbd.int/countries, which generates the Internationally Recognized Certificate of Compliance that confirms the legality of the genetic resource transfer [54].

However, for the full implementation of the Nagoya Protocol, it is necessary to develop a national regulatory framework in terms of ensuring access to genetic resources and sharing of benefits arising from their utilization by both the providers and users of those resources.

The Concept of the National Biosafety System approved by the Resolution of the Council of Ministers of the Republic of Belarus of March 22, 2022 No. 161 establishes, as measures for the protection of the population, animals and the environment from the impacts of dangerous biological factors and preventing of biological threats, the improvement of legislation in the field of regulation of access to genetic resources and information on nucleotide sequences, monitoring mechanisms and their use, as well as supervision and liability measures for a violation of sovereign rights of states over the benefits arising from their utilization [44].

In 2021, the concept of the draft Law "On Genetic Resources Management" was developed in accordance with the requirements of the Law "On Normative legal Acts" of the Republic of Belarus, which contains as follows:

1. Description of the subject matter of legal regulation and purposes for developing of the Law: the subject matter of legal regulation of the Law ― public relations on the use of genetic resources in scientific-research, production and other activities, as well as the benefits arising from their utilization; the purpose of developing of the Law is to establish legal, economic and organizational foundations for ensuring of access to genetic resources and the fair and equitable sharing of

benefits arising from their utilization, taking into account international commitments of the Republic of Belarus;

2. Analysis of legislative acts, international treaties and other international legal acts, legislative acts of foreign states related to the subject matter of the legal regulation of the Law, and their practical application: the Convention on Biological Diversity, the Nagoya Protocol, and the International Treaty on Plant Genetic Resources were analyzed; a review of options for entrenching the norms providing access to genetic resources in the legislation of foreign states (Norway, Sweden, Poland, Bulgaria, Australia, India, etc.) and interstate associations (the European Union, the African Union, the Eurasian Economic Union, and the Commonwealth of Independent States);

3. Analysis of legislation of the Republic of Belarus: the Constitution of the Republic of Belarus, the Laws of the Republic of Belarus "On Environmental Protection" of November 26, 1992 No. 1982-XII; "On the Animal Kingdom" of July 10, 2007 No. 257-3; "On the Plant Kingdom" of June 14, 2003, No. 205-3; "On Seed Production" of May 2, 2013 No. 20-3; "On Breeding and Seed Production of Agricultural Plants" of May 7, 2021 No. 102-3; "Forest Code of the Republic of Belarus" of December 24, 2015 etc.;

4. Evaluation of proposals of the state authorities concerned and other organizations for the need to change the legal regulation of public relations in the field of genetic resources management: the Ministry of Nature as the initiator of the Law development; the House of Representatives of the National Assembly of the Republic of Belarus; the Ministry of Foreign Affairs; the Ministry of Agriculture and Food; the Ministry of Forestry; the Ministry of Economy; the National Academy of Sciences of Belarus, etc.;

5. Review of the results of scientific research in the field of law and legal monitoring related to the subject matter of legal regulation of the Law; publications in the mass media, over the global computer network Internet, appeals from citizens and legal persons: the key directions of studies on access to genetic resources were formulated; the key studies of foreign scientists were analyzed (Canada, France, the UK, Australia, the USA, Spain, Denmark, Japan, Brazil, China, New Zealand, etc.);

6. Evaluation of possible amendments to legislative provisions and legal implications of such amendments: a conclusion was made that the adoption of the Law would not entail amendments to the conceptual provisions of legislation;

7. Conclusion on the need to prepare drafts of new regulatory legal acts, amendments, invalidation of regulatory legal acts in connection with the adoption of the Law: it will be required to adopt a number of Resolutions of the Council of Ministers of the Republic of Belarus; to introduce additions to some legislative acts regulating issues of the special use of flora and fauna objects involving the removal of wild plants (their parts) from their habitats, animals ― from their habitats, as well as the issues related to the implementation of administrative procedures in relation to citizens, legal persons and individual entrepreneurs;

8. Evaluation of the feasibility of the choice of the type of a normative legal act and the method of formalizing of the draft normative legal act in the form of a new normative legal act or a new version (wording) of a normative legal act:
Law is the normative legal act that consolidates the principles and norms of the legal regulation of the most important social relations;

9. Approximate structure and key provisions of the draft Law: an approximate structure of the draft Law is formulated, providing for a preamble and eight Chapters ("General Provisions", "State Administration and Regulation in the Field of Genetic Resources Management", "Access to Genetic Resources and their Use", "Rights and Responsibilities of the Subjects of Relations in the Field of Genetic Resources Management", "Procedure for Monitoring the Use of Genetic Resources. Checkpoints", "Sharing of Benefits Arising from the Utilization of Genetic Resources", "Control in the Field of Genetic Resources Management. Settlement of Disputes. Responsibility of the Subjects of Relations in the Field of Genetic Resources Management", and "Final Provisions") that include twenty nine Articles; in the course of the draft Law development, the structure formulated in the concept may undergo amendments;

10. Feasibility of financial and economic and other possible implications of the Law adoption: the adoption of the Law will allow establishing legal foundations for

ensuring of access to genetic resources and sharing of benefits arising from their utilization; the adoption of the Law will eliminate the gaps of the legal regulation of relations involving genetic resources management, consolidate and harmonize regulatory prescriptions providing for the comprehensive nature of legal regulation of a corresponding sphere of public relations; the draft Law shall not stipulate additional payments for the utilization of genetic resources; the adoption of the Law will establish financial and economic prerequisites for the development of innovation technologies, attracting investments to the economy of the country, ensuring the efficient use of genetic resources that are in the state ownership; it will facilitate the fuller realization of the rights of citizens to the enabling environment and general nature management, as well as the fulfillment of commitments under international treaties by the Republic of Belarus.

The development of the draft Law "On Genetic Resources Management" has been planned for 2023.

In this regard, it should be noted that during the development of regulatory frameworks for GEO handling as a genetic resource, the need will arise in respect to the specifics of the object to be taken into consideration. GEO handling shall be regulated by the Cartagena Protocol on Biosafety with the developed advance informed agreement procedure. In addition, the Biosafety Clearing-House is operational at the CPB that collects, *inter alia*, information on the inserted sequences of GEOs that determine a new valuable trait, including the data on the DNA identification of GEOs. Therefore, during the development of instruments for accessing of GEO as a genetic resource and obtaining of benefits from it, the strengthened synergy of two Protocols and facilitation of the development of a framework that includes the elements of the CPB mechanism may be required. Moreover, a number of deciphered nucleotide genome sequences and deciphered genes is increasing, which leads to the result where the inserted sequences of genes with a view of obtaining of GEO are often synthesized *de novo*. In this regard, such new term as "digital sequence information on genetic resources" (DSI) and DSI regulatory frameworks discussed and highlighted in section 3.2 should be taken into account.

1.4 National and Regional Technical Normative Legal Acts in the Field of Detection of Genetically Engineered Organisms

In the Republic of Belarus, the underlying normative legal act that establishes legal and institutional bases for ensuring of safety in genetic engineering activity is the Law "On Safety in Genetic Engineering Activity" of the Republic of Belarus of January 9, 2006 No. 96-3 with the scope aiming to protect human health and the environment, as well as facilitate the fulfillment by the Republic of Belarus of international commitments in the field of safety in genetic engineering activity [29].

National legislation stipulates control over management of genetically engineered organisms (GEOs) that are specified in technical normative legal acts regulating such sphere of detection as "genetically modified organisms" (GMOs). Moreover, control is stipulated over the content of genetically modified ingredients (GMI) obtained on their basis and included in food products, raw materials, feeds and food additives. Such regulation is important for fulfilling the requirements for products' labelling, and correspondingly, in the exercise of the right of citizens to obtain timely and accurate information on the products being realized [30; 42].

In the Republic of Belarus, in accordance with Article 5 of the Law "On the Protection of Consumer Rights" of the Republic of Belarus of January 9, 2002, the consumer right to obtain accurate information on food products, including the content of GMOs in them or their ingredients shall be exercised [30]. In this regard, the Resolution of the Council of Ministers of the Republic of Belarus "On some Issues Related to the Provision of Information to Consumers on Alimentary Raw Materials and Food Products" of April 28, 2005 No. 434 was adopted [43], regulating the presence of mandatory labelling on each item of consumer packaging in cases where alimentary raw materials or food products contain GMOs.

At the national level, technical normative legal acts that establish requirements for the content of GMO, GMI and genetically modified lines (GM lines) in food products, feeds and the agricultural raw material have been developed, integrated and are being used.

The Sanitary Norms and Rules "Requirements for Alimentary Raw Materials and Food Products" and the Hygiene Standard "Food Security and Food Safety Indicators of Alimentary Raw Materials and Food Products for Humans" shall establish sanitary and epidemiological requirements for alimentary raw materials and food products, their safety, handling and labelling [71].

In accordance with Paragraphs 102-104 of Chapter 4 "Labelling of Food Products" [71], the use of alimentary raw materials, containing GMOs, and/or ingredients obtained from GMOs shall not be allowed in the production of alimentary raw materials for pregnant and lactating women, and food products for baby food.

In part of labelling, the technical normative legal acts shall stipulate the following: for food products obtained using GMOs, including the products that do not contain deoxyribonucleic acid (DNA) and protein, the following information should be provided: "genetically modified products", or "the products obtained from genetically modified organisms" or "the products contains the ingredients of genetically modified organisms". "In the case, where the producer during the production of food products did not use genetically modified organisms, the content in food products of 0.9 % or less of GMOs is an accidental or technically irremovable impurity, and such food products shall not pertain to the food products containing GMOs. During their labelling, information on whether GMO is present or not shall not be provided" [45].

For food products obtained from genetically modified microorganisms (bacteria, yeast, and filamentous fungi the genetic material of which was changed using genetic engineering methods) (GMM) or using them, the following information shall be mandatory:

For those containing living GMM – "the product contains living genetically modified microorganisms";

For those containing non-viable GMM – "the product obtained using genetically modified microorganisms";

For those released from technological GMM or obtained using the ingredients released from GMM – "the product contains the ingredients obtained using genetically modified microorganisms". On the labelling of food products, information on the

presence of GMOs shall not be provided in relation to technological processing aids used, obtained from GMOs or using them.

The "Veterinary and Sanitary Rules for Ensuring the Veterinary and Sanitary Safety of Feeds and Feed Additives" establish that in feeds containing GM lines of soya and maize specified in Annex 2 to these Rules, the content of GM lines of more than 0.9% of each shall be allowed subject to the mandatory declaration of their presence in the Quality Certificate or the Quality and Safety Certificate by the producer [70].

In accordance with [70], grain feed and grain supplied for feed purposes may contain GMO lines only registered in accordance with the legislation of the State. In grain, containing GMOs, no more than 0.9% of non-registered GMO lines shall be allowed.

Technical Regulations of the Republic of Belarus "Feeds and Feed Additives. Safety" shall apply to feeds and feed additives released into circulation in the Republic of Belarus independently of the country of origin, apart from the feeds and feed additives conveyed in transit through the territory of the Republic of Belarus, and shall allow the use of feeds and feed additives that contain genetically modified objects of only authorized GM lines. At that, feeds, feed additives and forage mixtures of unauthorized lines of genetically modified objects shall not be allowed for use in circulation [72].

In the territory of the Republic of Belarus, as well as other member States of the Customs Union (the Russian Federation, the Republic of Kazakhstan, the Republic of Armenia, and the Kyrgyz Republic), in addition to national legislation and related normative legal acts in the field of GMO detection, Technical Regulations of the Customs Union (TR CU) shall apply that establish safety requirements for certain types of products, certification schemes and other conditions that confirm the conformity of goods or services. Technical Regulations of the Customs Union are on a par with the Technical Regulations of the National Standardization System. In connection with including the Customs Union in the Eurasian Economic Union as its integral part, the abbreviation of the new Technical Regulations has changed into TR EAEU. However, documentation with the previous abbreviation has not ceased to be in force and is binding.

Technical Regulations of the Standardization System of the Customs Union shall be valid in the territory of all its countries. This implies that producers, importers or their authorized persons must comply with the requirements established by this documentation in relation to their products. It follows from all the above that they shall apply in the cases as follows:

Distribution of products in the countries of the Union;

Import into and export of goods from the same countries.

Among all the Technical Regulations of the Customs Union related to food products, the main one is TR CU 021/2011 "On Food Safety". When applying this Technical Regulation, requirements of the Technical Regulations of the Customs Union that establish mandatory requirements for certain types of food products and related requirements for production (manufacturing), storage, transport (transportation), realization and recycling processes (hereinafter referred to as "the Technical Regulations of the Customs Union for Certain Types of Food Products"), supplementing and/or specifying the requirements of this Technical Regulation, should be taken into consideration. The Regulation TR CU 021/2011 establishes that in the production (manufacturing) of food products from alimentary raw materials obtained from the GMOs of plant, animal and microbial origin, the GMO lines that have passed state registration should be used, and in the case, where the producer did not use GMOs in food production, the content in food products of 0.9% or less of GMOs is an accidental or technically irremovable impurity, and such food products shall not pertain to the food products containing GMOs. TR CU 021/2011, as well as National Technical Normative Legal Acts in the field of food safety, shall prohibit the use of alimentary raw materials containing GMOs in the production (manufacturing) of food products for baby food, and food products for pregnant and lactating women. This requirement is also reflected in TR CU 027/2012 "On Safety of Certain Types of Specialized Food Products, Including Dietary Therapeutic and Dietary Preventive Nutrition", TR CU 023/2011 "Technical Regulations for Fruit and Vegetable Juice Products", TR CU 034/2013 "On Safety of Meat and Meat Products."

When evaluating (confirming) the conformity of food additives, flavors and technological processing aids, in addition information on the use of genetically modified organisms and ingredients derived from GMOs in the composition of food additives, flavors and technological aids shall be provided [68].

The norms included in the Technical Regulations of the Union "Food Products in Terms of their Labelling" shall allow customers to make a more informed and correct choice of food products [73]. The previous effective version of the Technical Regulations already obligated producers to inform customers about the use of GMO products in the production and the content of GMOs in them (over 0.9%) in the form of the wording as follows: "genetically modified product", "the product obtained from genetically modified organisms", "the product contains the ingredients of genetically modified organisms." However, the information could be provided in the small print and not in a strictly defined place, which did not always make it possible to notice it on the packaging. Now, the Technical Regulations indicate that the GMO label should correspond in its shape and size to the unified mark of product circulation in the market of the member States of the Eurasian Economic Union (EAEU); it should be applied in a way that it is easily readable and visible throughout the entire shelf life of food products.

With due regard to the above, it should be noted that in order to comply with safety requirements in the field of GMO detection for food products, feeds and agricultural raw materials, national and interstate standards for qualitative and quantitative GMO detection based on the nucleic acids' analysis are effective in the Republic of Belarus. GMO Detection Laboratories of the Republic of Belarus shall be guided by them (Table 2).

Thus, GOST ISO 21571-2018 establishes general requirements and specific techniques of the extraction, purification and qualitative evaluation of deoxyribonucleic acid. This standard should be used jointly with GOST ISO 21569-2009, GOST ISO 21570-2009 in part of analytical methods based on nucleic acids, including qualitative analytical methods established in GOST ISO 21569-2009 and quantitative in GOST ISO 21570-2009 correspondingly. The detection and identification of GM lines shall be carried out in accordance with GOST 34104-2017 [23–25; 67].

Table 2 – GMO Detection Laboratories accredited in line with the National Accreditation System

Organization	Address
National Coordination Biosafety Centre (Institute of Genetics and Cytology, NAS of Belarus)	27 Akademicheskaya St. 220072 Minsk Tel./Fax: +375 17 3781691 e-mail: ldgmo@igc.by
Republican Scientific and Practical Centre for Hygiene	8 Akademicheskaya St. 220012 Minsk Tel.:+375 17 3477370 Fax:+375 17 2723345 e-mail: rspch@rspch.by
Republican Centre for Hygiene, Epidemiology and Public Health	50 Kazintsa St. 220099 Minsk Tel.:+375 17 3987443 Fax:+375 17 3983226 e-mail: mail@rcheph.by
Minsk City Centre for Hygiene and Epidemiology	13 P.Brovky St. 220013 Minsk Tel.:+375 17 2020861 Fax:+375 17 3487890 e-mail: minskl@minsksanepid.by
Brest Regional Centre for Hygiene, Epidemiology and Public Health	11 Svobody Square, building "B" 224030 Brest Tel.:+375 162 536656/534139 Fax:+375 162 216769 e-mail: ocgie@brest.by
Gomel Regional Centre for Hygiene, Epidemiology and Public Health	49 Moiseenko St. 246001 Gomel Tel./Fax: +375 232 507465 e-mail: clerk@gmlocge.by
Grodno Regional Centre for Hygiene, Epidemiology and Public Health	58 Kosmonavtov Ave. 230003 Grodno Tel.: +375 0152 690565 Tel./Fax:+375 0152 755493 e-mail: csms@.csms.grodno.by
Mogilev Regional Centre for Hygiene, Epidemiology and Public Health	82 Grishina St. 212011 Mogilev Tel.:+375 222 740648 Fax: +375 222 740572 e-mail: oblmcge@tut.by
Belarusian State Institute of Metrology	93 Starovilenskiy Trakt 220053 Minsk Tel.:+375 17 3377799 Fax:+375 17 2449938 e-mail: info@belgim.by
Brest Centre for Standardization, Metrology and Certification	10/1 Kizhevatov St. 220041 Brest Tel.:+375 162 580870/537026/ 537212 Fax: +375 162 580871 e-mail: csm@brest.by
Vitebsk Centre for Standardization, Metrology and Certification	20 Bogdan Khmelnitskiy St. 210015 Vitebsk Tel.: +375 0212 480419/480408 Tel./Fax:+375 0212 426804 e-mail: info@vcsms.by
Grodno Centre for Standardization, Metrology and Certification	3 Obukhov St. 230003 Grodno Tel./Fax:+375 152 643136 e-mail: csms_grodno@tut.by

Continuation of Table 2

Gomel Centre for Standardization, Metrology and Certification	1 Lepeshinskiy St. 246003 Gomel Tel.: +375 232 263301 Fax:+375 232 263300 e-mail: mail@gomelcsms.by
Scientific and Practical Centre for Food, NAS of Belarus	29 Kozlova St. 220037 Minsk Tel.:+375 17 3950996/3752570 Fax:+375 17 3953971 e-mail: info@belproduct.com
Belarusian State Veterinary Centre	19a Krasnaya St. 220005 Minsk Tel.:+375 17 2904279/2847769 Fax:+375 17 2904275 e-mail: bgvcentr@gmail.com
Industry-specific Research Laboratory for DNA Technologies of Grodno State Agrarian University	10 Akademicheskaya St. 230023 Grodno Tel.: +375 29 2404721; +375 152 2684035 e-mail: labgen@mail.ru
Republican Unitary Enterprise “Central Research Laboratory”	222220 Oktyabrskiy Settlement Minsk Region Smolevichy District Tel.: +375 1776 56461 Fax: +375 1776 57073 e-mail: info.cnil@yandex.by

The national legislation of the Republic of Belarus establishes requirements for and methods of control over the quality and safety of food products, seeds, agricultural raw materials, feeds and feed additives in general, and in particular, products containing GMOs and/or obtained on their basis. GMO and GMI monitoring carried out by the Republican GMO Detection Laboratories accredited by the Belarusian State Accreditation Centre allows preventing that GM lines not declared in Quality Certificates and approved in this or that country, or unauthorized GM lines, which have not gone through the full cycle of a risk assessment, enter the country’s market in the batches of products destined for use by humans or as animal feeds and in the batches of seeds destined for large-scale growing in fields. Thus, monitoring allows ensuring the fulfillment of the commitments under the Cartagena Protocol on Biosafety.

CHAPTER 2
DETECTION AND IDENTIFICATION OF GEO AND KEY TERMS RELATED TO THIS AREA

2.1. Digital Sequence Information on Genetic Resources. Its Role in the Development of GEO and the Objects of Modern Biotechnology. Approaches to Address the Issue.

Over the past 20 years, the number of deciphered genomes has grown exponentially, leading to a significant increase both in the quality and quantity of publicly available genomic resources [18].

Most of them are publicly available in the GenBank Database and other key genomic data repositories. Despite the practical difficulties in deciphering of complex genomes and genomes with different levels of ploidy, technological advances, such as long-read sequencing and new digital tools, have made it possible to sequence and assemble almost any type of organism.

In early 2022, a new phase of the Earth BioGenome Project (EBP) was announced ─ a global attempt of genetic mapping of all plant, animal, fungi and other eukaryotic organism species [81].

The project functions as an International Network that brings together other networks and coordinates numerous group-level efforts at the regional and national levels, such as the California Conservation Genome Project (USA), the Darwin Tree of Life Project (the UK and Ireland), the Vertebrate Genome Project and a project on 10,000 bird genomes' sequencing (the Bird 10 000 Genomes Project, Denmark and China).

"The special feature on the EBP captures the essence and excitement of the largest-scale coordinated effort in the history of biology," said Harris Lewin, Chair of the EBP Working Group and Distinguished Professor of Evolution and Ecology at the University of California, Davis. "From fundamental science to breakthrough applications across a wide range of pressing global problems, such as preventing biodiversity loss and adapting food crops to climate change, the EBP's progress in sequencing eukaryotic life is humbling and inspiring. Achieving the ultimate goal of sequencing all eukaryotic life now seems within our reach."

The Earth is projected to lose from 30 to 50% of its biodiversity by the mid of this century, unless action is taken to curb climate change and protect the health of global ecosystems [83]. Development of a Digital DNA Sequences Library of all known eukaryotic organisms may help design effective tools enabling to prevent biodiversity loss and the spread of pathogens, monitor and protect ecosystems, improve ecosystem services.

Large-scale sequencing of genomes means that biological researchers from across the globe may now quickly and easily access genetic sequences through journal repositories, as well as private and public databases where deciphered information on genetic resources is stored. This means that in many cases it is no longer necessary to collect a physical sample and travel to different countries and regions where the biological resource originates in order to conduct research at the genetic level. Information stored in databases may be used for various purposes in biosciences, such as diagnosing of diseases and pests, adapting crops to climate change, controlling food quality or protecting endangered species, and, of course, developing of LMOs.

The target DNA sequence (or RNA for some organisms) is a key element both in the process of developing of LMOs and in elaborating of LMO detection methods. At that, information in databases on the sequences of inserted genes into LMOs is often limited to their general description, and exact data on the deciphered sequences of inserted genes into LMOs may not be available in them, especially for unauthorized LMOs. Also, inserted nucleotide sequences are patented, and patented sequences are usually poorly annotated, are accompanied by complex and numerous patent descriptions, and are difficult to link to a corresponding transgenic event.

Among country Parties to the Convention on Biological Diversity (CBD) and its Protocols, there are different views regarding the concept of Digital Sequence Information (DSI) on genetic resources and related terminology, the terms of access to DSI, the use of benefits arising from its commercial and non-commercial application and other DSI-related aspects.

Thus, the term “digital sequence information on genetic resources” is considered not final, but temporary prior to the adoption by the CBD Parties of the final term after agreeing on its scope. The DSI term was first considered at the Conference of the Parties to the CBD and the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol in 2016.

All Parties to the CBD recognize that the use of DSI significantly contributes to the achievement of the first two objectives of the CBD: the conservation of biological diversity and the sustainable use of its components, and that the DSI is important for research and development, especially in the areas such as food, agriculture and health care. However, there is a considerable debate about the implications of using DSI to achieve the third objective of the CBD and of the Nagoya Protocol, namely, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources [76].

Apart from the CBD and its Cartagena and Nagoya Protocols, topical discussions on DSI and related issues are held within the framework of other UN organs and organizations, international organizations and mechanisms, such as the Food and Agriculture Organization of the United Nations (FAO), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the Pandemic Influenza Preparedness (PIP) Framework, the process of the conservation and sustainable use of Marine Biodiversity of Areas Beyond National Jurisdiction (BBNJ), the World Health Organization, the World Intellectual Property Organization and the General Assembly of the United Nations. The issue related to the development of a uniform international instrument on DSI is rather difficult to solve, since it covers a wide variety of genetic resources, including such specific genetic resources as LMOs. With a view to addressing it, it is necessary to determine, first of all, the scope of information that covers the DSI term, while there is a different understanding of it at the level of the Parties to the CBD; in countries, the regulation of DSI appears to be at different levels ─ from already established various regulatory frameworks to their absence; there are developed regulatory frameworks or rules for resources that may fall under the DSI term, at the level of other

international organizations, patent legislation, open or closed databases in which the DSI is stored, etc.

At its 13th meeting, the Conference of the Parties to the CBD considered the issue of DSI and adopted Decision XIII/16 [20] in which it determined to consider at its 14th meeting any possible implications of using DSI for CBD objectives.

In this Decision, the Parties, other governments, indigenous peoples and local communities, as well as related organizations and stakeholders, were invited to voice views and corresponding information to the Executive Secretary on any of such potential implications. The Executive Secretary was requested to compile and summarize the views and information provided, as well as information from other sources, and to commission a fact-finding and scoping study on DSI to clarify terminology and concepts and to assess the extent and terms of DSI use in the context of the CBD and the Nagoya Protocol.

Pursuant to the Decision, an Ad Hoc Technical Expert Group (AHTEG) was established in order to:

(a) Consider the aforementioned compilation, synthesis and study to explore any potential implications of DSI use under the three objectives of the CBD and of the Nagoya Protocol and the ways of its accomplishment to achieve these objectives;

(b) Consider technical feasibility, as well as legal and scientific implications of existing DSI-related terminology;

(c) Identify different types of DSI related to the CBD and the Nagoya Protocol.

The AHTEG submitted its results to the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) for consideration. The SBSTTA reviewed the study results and made recommendations for identifying of potential implications of using DSI under the three objectives of the Convention at the 14th meeting of the CBD Conference. SBSTTA discussions demonstrated many divergent views, including debates on what the term DSI should include, as well as the use of databases, traceability, and benefit-sharing issues. At that, it was determined that the term DSI is not possibly most appropriate for different types of

information on genetic resources, and that it is used as a substitute until an alternative term has been agreed upon.

In 2018, the Conference of the Parties adopted Decision 14/20, which noted diverging views of the Parties on the issue of sharing of benefits arising from the application of DSI, and decided to initiate a science- and policy-based process stipulating the establishment of an Ad Hoc Technical Expert Group (AHTEG). In addition, the Parties also requested four expert studies with a view to their subsequent consideration by the AHTEG and other interested groups and the development of proposals and recommendations to assist the Parties in making a decision on DSI at the 15th meeting of the Conference of the Parties to the CBD.

In the first study requested by the Parties "Science-based and Peer-reviewed Fact-finding Study on the Concept and Scope of Digital Sequence Information on Genetic Resources and how Digital Sequence Information on Genetic Resources is Currently Used Based on the Existing Fact-finding and Scoping Study" [93], investigation of the DSI term was launched, as well as how access to, storage and management of DSI information, including through public and specialized databases, are implemented; how the process of new DSI generation based on the physical samples obtained from field and *ex-situ* collections takes place; mechanisms used to manage DSI accessed through databases or registries, including notifications of the terms of use, access and user agreements were considered, as well as DSI from the public domain. This review also looks at the ways in which DSI contributes to the conservation and sustainable use of biological diversity, including opportunities and challenges that arise.

As a follow-up to the first study and to assist countries in clarifying of DSI terminology and its concept, W. Houssen, R. Sara, and M. Jaspars carried out another study that further explored the possible scope of the DSI concept. As a result of the analysis performed, the authors formed four groups proposed to identify the DSI scope [90]. In this analytical study, the flow of information from the use of a genetic resource was considered, taking into account that at each stage the data/information obtained are gradually removed from the original genetic resource.

Proximity to the main genetic resource and additional information associated with each step of the study provides a logical basis for grouping the data that DSI covers.

• *Group 1* covers DNA and RNA. It has a narrow scope and proximity to a genetic resource and is limited by nucleotide sequence data associated with transcription.

• *Group 2* covers DNA, RNA and proteins. It has an intermediate scope and extends to protein sequences, thus including data and information related to transcription and translation. Two possible interpretations of the scope of this group are available: either the subject matter is strictly limited to nucleotide and protein sequence data, or it includes information related to transcription and translation in a broader sense, such as functional gene annotations, information on the expression of genes, epigenetic data, and protein molecular structures.

• *Group 3* covers DNA, RNA, proteins and metabolites. It has broader intermediate coverage and includes, in addition to the above information, metabolites and biochemical pathways, thus including information related to transcription, translation and biosynthesis.

• *Group 4* covers DNA, RNA, proteins, metabolites, as well as traditional knowledge, ecological interactions, etc. It has the widest scope and additionally includes information with the closest proximity to a primary genetic resource; it extends to behavioral data, covers information on ecological relationships and traditional knowledge, thus including the data related to transcription, translation and biosynthesis, and other supporting information.

The second peer-reviewed investigation considered current developments in the field of DSI traceability, including how DSI traceability is ensured in operational databases and how they can contribute to DSI-related discussions [77].

The third study aims to examine state and, where possible, private DSI databases, including the terms and conditions of granting or regulating of access, the scope of biological resources covered by the database and its size, the number of samples and their origin, guidelines, as well as DSI providers and users.

The fourth study focused on how national measures address the issue related to sharing of the benefits arising from the commercial and non-commercial use of DSI and address the issue of DSI use for research and development. The study took into consideration the materials submitted by the Parties, other governments, indigenous peoples and local communities, and related stakeholders, and organizations [82].

The above studies were reviewed at the AHTEG meeting on DSI [96]. The AHTEG mandate established by COP Decision 14/20 included:

to consider the compilation and synthesis of opinions and information, as well as the afore-mentioned peer-reviewed studies;

to develop options for operational terms and their definitions to provide conceptual clarity in relation to DSI, considering, in particular, a study on the conceptual clarity and scope of DSI and how DSI is currently used based on the existing fact-finding and review study;

to identify key capacity-building areas.

The AHTEG reviewed the technical and scientific scope of the terms associated with DSI and developed options for different scopes, terms and their definitions to ensure conceptual clarity. First, the experts considered options for clarifying the scope of DSI and terminology for various options. In clarifying the DSI scope, the AHTEG agreed that first three groups proposed in the study [90], may be considered as DSI, while corresponding information previously related to Group 4 in the study, including traditional knowledge associated with genetic resources, is not digital sequence, but associated information.

The experts also noted that it was important to achieve conceptual clarity on DSI in order to ensure legal clarity whatever the circumstances might be. Some experts noted that distinction among the groups may be more important for some benefit-sharing (e.g. bilateral) than other (e.g. multilateral) approaches. In addition, the importance and value of passport data for traceability (e.g. the country of origin where the biological sample was taken, sample coordinates, date the sample was obtained, its inventory number, a registrar or other unique identifiers), minimal information on the genome sequence specification (MIGS) of the

Genomics Standards Consortium. In reviewing the terminology, the experts discussed various terms appropriate for each of the groups and generalized the potential terminology [96].

The experts also considered potential implications resulting from the adoption by the Parties of one or another DSI coverage group with regard to traceability; use of information on DSI in research and innovative solutions in the field of life sciences; the International Nucleotide Sequence Database Collaboration (INSDC) as a resource for the open exchange and use of information on DSI. In addition, the potential implications of different groups or options for measures regulating access, benefit-sharing and compliance were considered.

In reviewing the study on domestic measures, the experts acknowledged that some countries currently regulate access to DSI, others may be waiting for an international consensus on this issue in accordance with the CBD and other multilateral environmental agreements, and still others stated that they do not intend to regulate access to DSI. The experts also noted that many different national ABS frameworks, dealing with DSI, produce problems for users, including those involved in basic non-commercial research and small and medium-sized enterprises.

It was noted that DSI may directly or indirectly result from the use of genetic resources. In this regard, the importance of a harmonized and cost-effective international approach to DSI was emphasized, and possible mechanisms for deriving of benefits arising from the use of DSI, including measures at the time of access (noting, for example, fixed fees for access or common approaches to licensing, database access agreements), open access with benefit-sharing driven by use or commercialization, and a feasible multistakeholder approach. The experts also noted that the discussion of potential implications for various groups of measures regulating access, benefit-sharing and compliance was of tentative nature and further discussions on this issue would be useful, and that the specified implications would depend on different approaches to benefit-sharing that might be adopted. It was noted, for example, that access measures would not be needed in the case of a limited transparency model and other multilateral approaches where use or commercialization entails benefit-sharing.

DSI-related issues and the outcomes of AHTEG activity on DSI were considered at the 24th meeting of SBSTTA (May 3-June 9, 2021 online and March 14-27, 2022 in person) and the 3rd meeting of the Subsidiary Body for Implementation (May 16-June 13, 2021 online and March 14-28, 2022 in person). The decisions are available at the links [97; 98].

The outcomes of the Ad Hoc Group, in accordance with Decision 14/20, were examined by the Intersessional Open-ended Working Group during the first and second parts of its 3rd meeting held online from August 23 to September 3, 2021 and in person on March 14-29, 2022 respectively [103] to support the preparation of the Post-2020 Global Biodiversity Framework (GBF). Following the first part of the 3rd meeting of the Working Group, a Contact Group on DSI was formed with the main objective of general support for intersessional work, including providing new views on how to address the DSI-related issue, in accordance with the CBD and the Nagoya Protocol, and based, *inter alia*, on information and elements contained in the first draft of GBF: CBD/WG2020/3/4 [84].

The need to update the synthesis of possible regulatory approaches, options or procedures and provide a basis for evaluating them against a set of existing criteria in order to identify the potential advantages and disadvantages of each was also emphasized.

With a view of providing support to this activity, Co-leads together with Co-chairs and the Bureau established an Informal Advisory Co-chairs Group on DSI. The group continued its activity until the 4th meeting of the Open-ended Working Group. At 3rd and 4th meetings of the Working Group, the results of the Informal Advisory Co-chairs Group on DSI were presented making it possible to develop at the 4th meeting of the Working Group draft recommendations for the fifteenth Conference of the Parties. It is important that this document contains proposals for the coverage and traceability of DSI, as well as a proposal for the establishment of a multilateral benefit-sharing mechanism for its use [64].

In addition, a consultant was hired prior to the next fifteenth Conference of the Parties to carry out further work on developing of coefficients to criteria in light of the

objectives a decision on DSI in GBF is striving to achieve. In parallel to these processes, an independent consultant was employed by the CBD Secretariat working on the review of the structure developed by the Informal Advisory Group and who is expected to provide proposals for possible changes to the GBF structure. The consultant will apply GBF to various regulatory options, requesting available data from countries, and will also make a number of recommendations for criteria in cases, where data are not available. It is expected that such an increased effort will encourage a decision on DSI to be made by the Conference of the Parties. Such a decision may have an impact on the regulation of LMOs as a valuable genetic resource, as well as sharing of benefits arising from its use.

Perhaps, a decision on DSI for LMOs will be one of the most challenging, since relations associated with LMOs are regulated by the CBD and the Cartagena and Nagoya Protocols. As already mentioned in Chapter 1.2, in the case of the development of mechanisms regulating LMOs as a genetic resource under the Nagoya Protocol, it is necessary not to complicate regulation and avoid duplication of efforts. It seems to us that in this context, while elaborating such a mechanism for LMOs, it would be advisable to assess the capabilities of the Biosafety Clearing-House (BCH), a long-standing mechanism under the Cartagena Protocol on Biosafety, which constitutes a global biosafety database with compiled information, including information on nucleotide sequences inserted into LMOs that define new valuable traits of an organism, information about the parent organism, the donor organism of a new valuable trait, as well as information in the field of detection and identification of LMOs. A detailed description of the BCH database and other databases on LMOs is provided in the next Chapter.

More detailed information on DSI debate processes within various CBD groups, decisions and documents, discussion results in the framework of the discussion forum with regard to criteria and proposed options of regulating of access to DSI and educational webinars, as well as information published in informational resources on DSI, is available at the link [21].

2.2. GEO Databases and GEO Detection Methods

For the convenience of storing and searching for information on genetically engineered organisms (GEOs, synonyms ─ living modified organisms (LMOs), genetically modified organisms (GMOs[2]), gene sequences, characteristics of such organisms, as well as on the fulfillment of commitments stipulated under international treaties and national legislation in relation to traceability, monitoring and control of GEO, such information is combined in various databases, among which the following may be distinguished:

- Biosafety Clearing-House (BCH) Database to the UN Convention on Biological Diversity;
- GMOMETHOD and GMO-Matrix of the Joint Research Centre of the European Commission;
- GM Approval Database – Database of the International Service for the Acquisition of Agri-biotech Applications (ISAAA);
- GM Crops Database "GenBit" LLC, the Russian Federation;
- CropLife International Database on the Commercial Status of Biotech Crop Seeds of CropLife International Member Companies (BIOTRADESTATUS);
- Unified Register of State Registration Certificates of the Eurasian Economic Commission;
- BioTrack, Database of the Organization for Economic Cooperation and Development;
- Data bank of the National Coordination Biosafety Centre of the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus.

2.2.1 Database of the Biosafety Clearing-House of the UN Convention on Biological Diversity (BCH)

The Biosafety Clearing-House (BCH) website provides a one-stop Platform for searching and sharing of information on living modified organisms (LMOs). It

[2] The Law No. 96-3 "On Safety in Genetic Engineering Activity" defines the term "genetically engineered organisms", and the Technical Normative Legal Acts of the Republic of Belarus in the field of detection and identification define the term "genetically modified organisms". In this regard, terminology may differ in certain sections of Chapter 2.

was established to assist in meeting of commitments under the Cartagena Protocol on Biosafety (Article 20). The website offers access to different scientific, technical, environmental, and legal information in six UN languages (Arabic, Chinese, English, Spanish, French, and Russian). All interested users may freely search and obtain information through the website. Registration is only required to provide information: after logging into the "Sign In" section, National Focal Points and National Authorized Users may provide national records, and Registered Users may provide reference records and manage them.

National records include national contacts such as National Focal Points, competent national authorities, national biosafety websites and databases; laws and regulatory frameworks: national laws, regulatory frameworks, guidelines, bilateral, regional and multilateral agreements; national reports; biosafety experts' roster; country decisions and other communications, including decisions on LMOs made in the framework of the advance informed agreement procedure; decisions on LMOs destined for use as food, feed or for processing that have been made in accordance with Article 11 of the Cartagena Protocol, risk assessment reports and other decisions and statements.

Reference records include records on LMOs, genetic elements and organisms, laboratories for LMO detection and identification, the BCH Virtual Library, a directory of international organizations involved in biosafety activities and on biosafety capacity-development, e.g. capacity-development projects, opportunities, needs and priorities in the area of capacity-development, as well as a catalogue of training courses etc.

Currently, the BCH Platform is undergoing significant changes: transition is being made to a new Platform providing a number of additional features to the website user. In order to facilitate transition to a new Platform, BCH users have been provided with access to training videos communicating information about the website operation and available at: https://bch3-vle.unep.org/.

The main page of the BCH website looks like this (Figure 5):

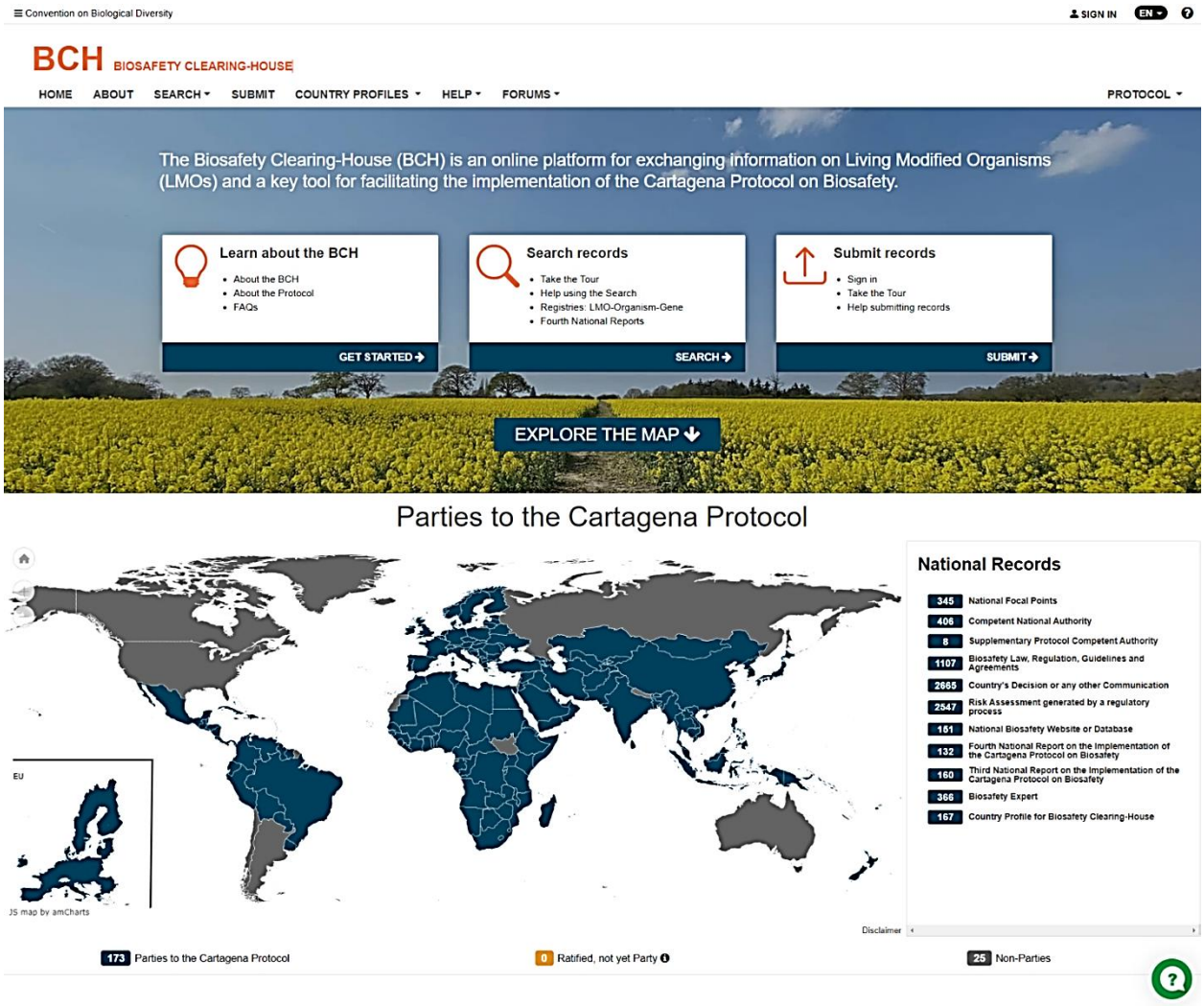


Figure 5 – Main page of the BCH website

The main menu of the Portal is located horizontally and includes seven sections listed in Figure 6:

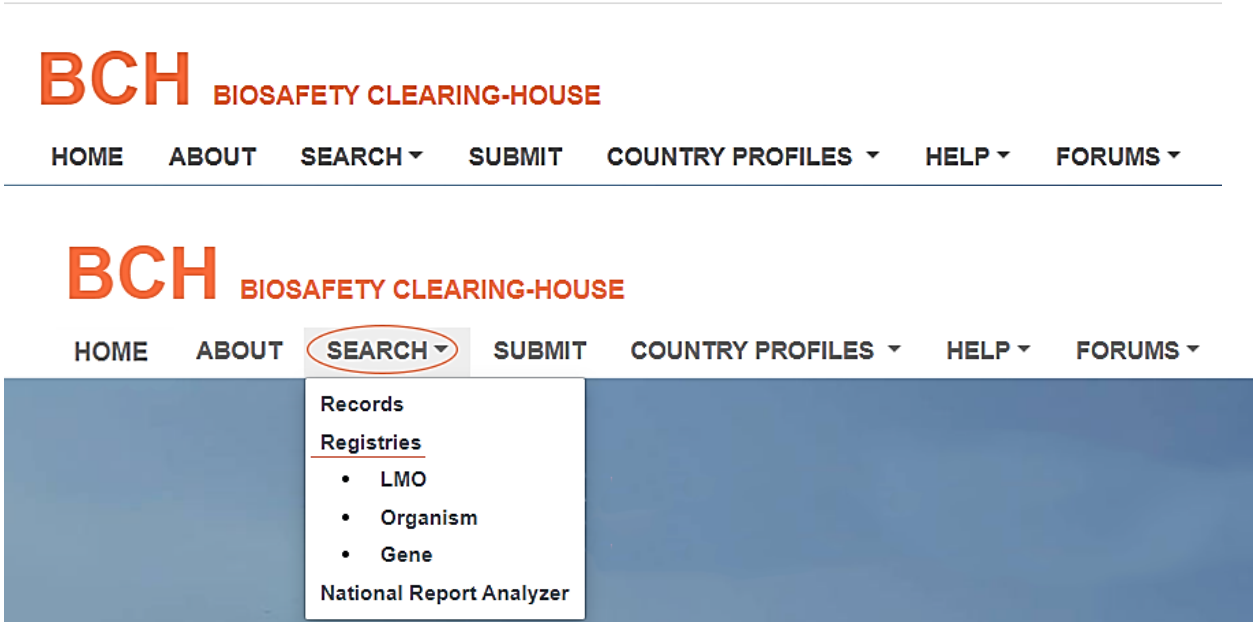


Figure 6 – Main menu sections of the BCH website

For a user seeking to obtain scientific, technical and legal information on LMO, the "Search" section (Figure 6) is of particular interest, which contains both LMO Registries on unmodified or parental organisms and a Registry of Genetic Elements, as well as an advanced search by records with filtering.

The "Records" tab allows searching through national and reference records. Information on LMOs, genetic elements and parental organisms can be found in the "Reference Records" section. "Living Modified Organisms" subsection contains information on all LMOs registered with the BCH, including transformation events, genetic modifications, and a unique identification code (if any) for each entry. All decisions and risk assessment reports relating to these organisms are available via links through associated records.

The LMO Registry provides a summary of all LMOs. This information is similar to the information available through the "Living Modified Organisms" subsection and is demonstrated in the form of a list of all registered LMOs. In the case, where it is necessary to conduct a search, this section contains a cross-reference to the "Search" section.

The Registry of Organisms includes summary information on donor organisms, recipient or parental organisms registered with the BCH Portal. The Registry includes links to the entries (records) on each individual organism, where additional information on corresponding biological characteristics can be found, including information on taxonomic classification, common name and origin, a center of origin and a center of genetic diversity. Links to records related to an organism are provided at the bottom of each individual record.

The Genetic Element Registry includes a summary of information on the genetic elements inserted into LMOs and registered with the BCH, including information on the donor organism, the novel characteristics of LMOs and biological functions. The Registry includes links to entries (records) on each genetic element, where more detailed information can be found. LMOs containing a particular genetic element are listed at the bottom of an individual record.

Search for required information about LMOs, organisms and genetic elements in the "Records" tab of the "Search" section (Figure 7).

Figure 7 – "Search" section structure of the BCH website

Figure 8 demonstrates the search engine design:

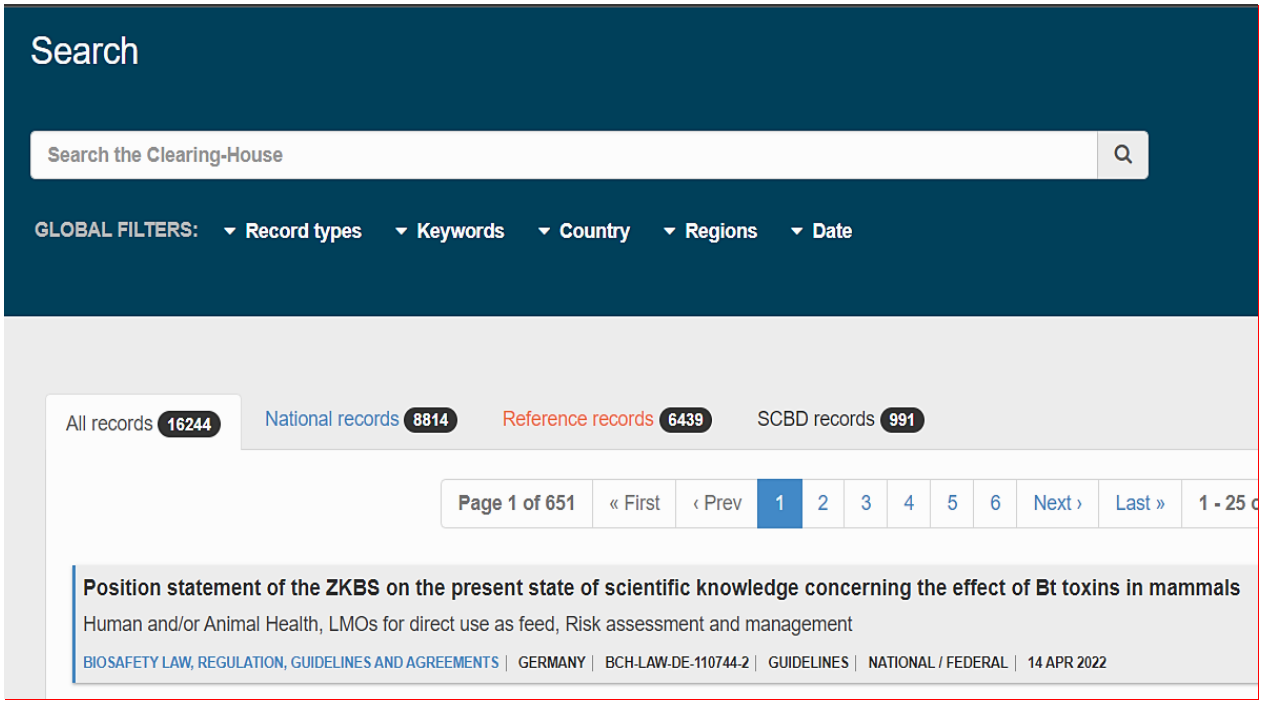


Figure 8 – Search engine design of the BCH website

This section provides an opportunity to use a free text search, filter results using global filters and sub-filters, display search results in a user-friendly way, share the results or download them as a spreadsheet.

The free text search window allows enquiring the entire database by entering a query at the user's choice. Such global filters as “Entry types”, “Keywords”, “Country”, “Regions”, and “Date” allow searching through the entire database by all entry categories.

When selecting the “Entry Types” filter, sub-filters appear on the left allowing you to sort your search results by selected entry types in such categories as “National Records”, “Reference Records”, and “Records Approved by the Secretariat of the Convention on Biological Diversity”.

The “Date” filter allows searching for posts published on a specific date or within a specific date range selected by the user.

A search by keywords, countries and regions allows sorting search results according to specified criteria.

Let’s consider a search algorithm using, as an example, the entry page requesting about GM corn resistant to the cotton bollworm and resistant to herbicides.

In order to find information of interest, you should enter a query in the search bar and press the “Enter” key or the button . At that, this query will be displayed in the form of a filter above the search bar, and the results that meet the query conditions will appear in the main area of the page. All results can be viewed as a single list or grouped into such categories as “National Records”, “Reference Records”, and “Secretariat Records”, indicating the number of records in each category (Figure 9).

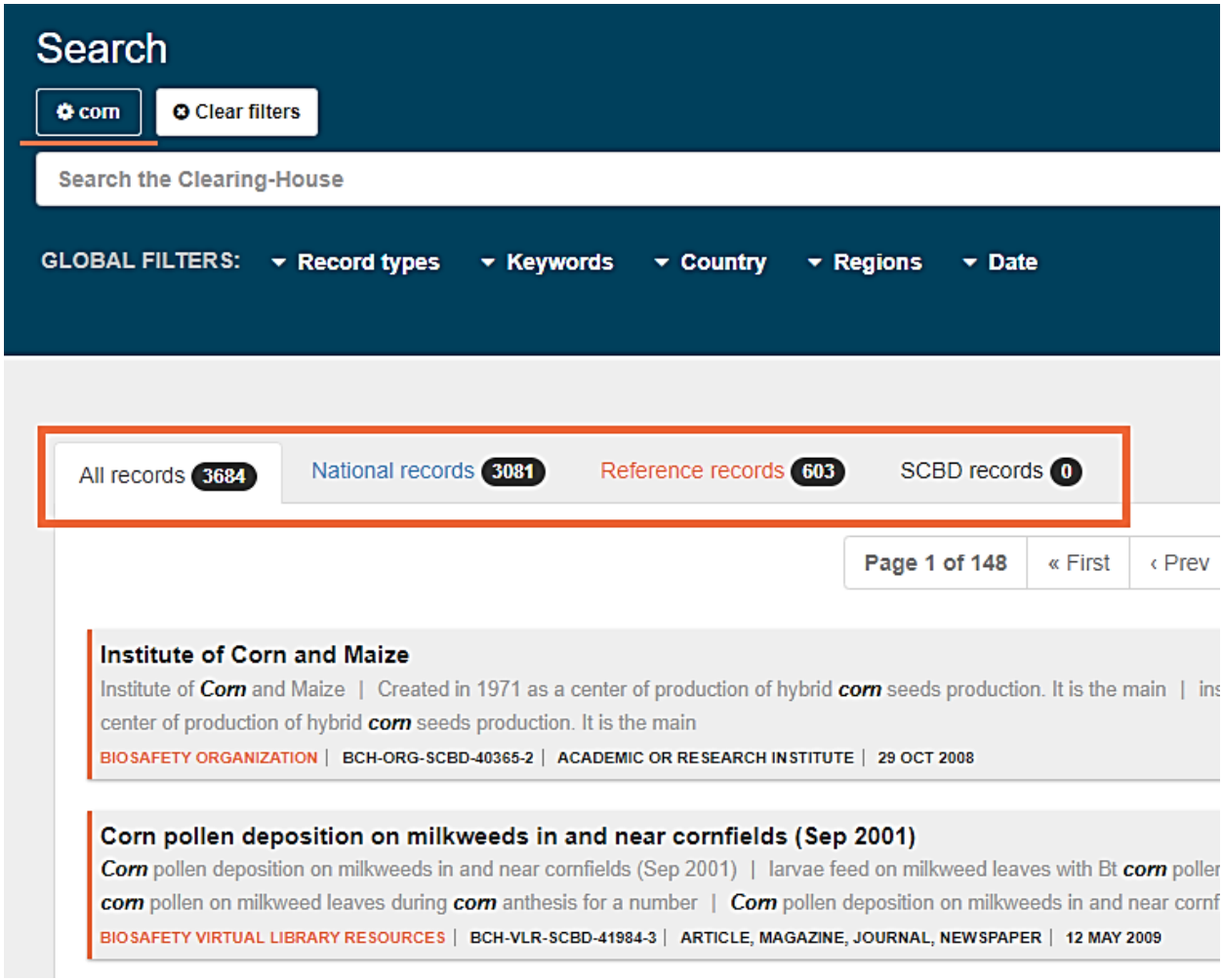


Figure 9 – Keyword search design on the BCH website

To narrow the search, let’s use a combination of global filters and sub-filters. To do this, in the global filter “Record types” in the category “Reference Records” add the sub-filter “Living Modified Organisms”, and in the filter “Keywords” — “Resistance to Diseases and Pests”. The global filters used are also displayed above the search bar. As additional filters are added, displayed results are updated.

The combination of filters and subfilters for this search is shown in Figure 10.

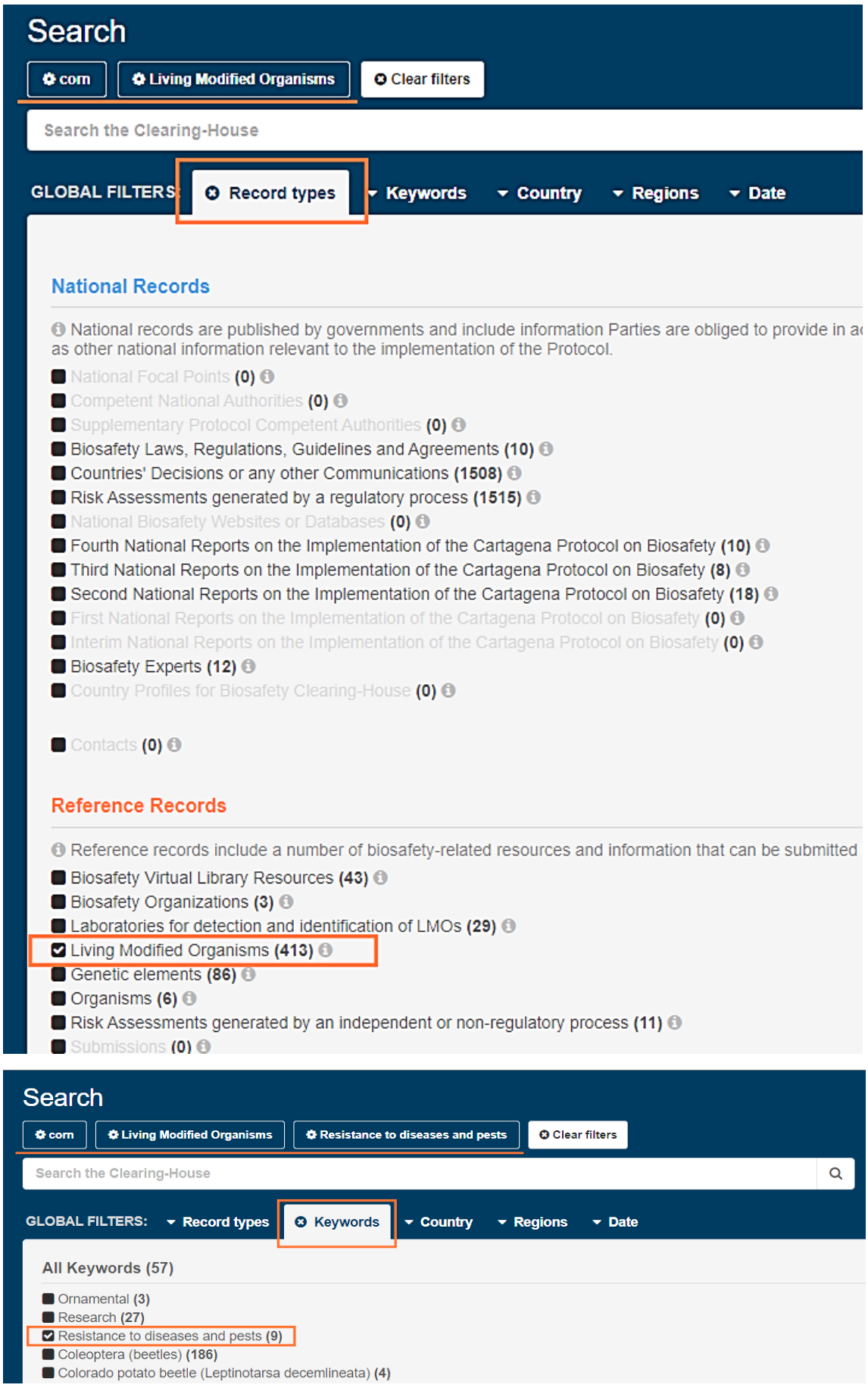


Figure 10 – Search filters and sub-filters on the BCH website

After filtering in such a way, the search result demonstrates nine matching records in the BCH Database. When choosing the sub-filter “Living Modified Organisms”, it becomes possible to additionally sort the results according to some criteria demonstrated in Figure 11. In the left menu, select the category “Modified Traits”, and the trait of interest in it.

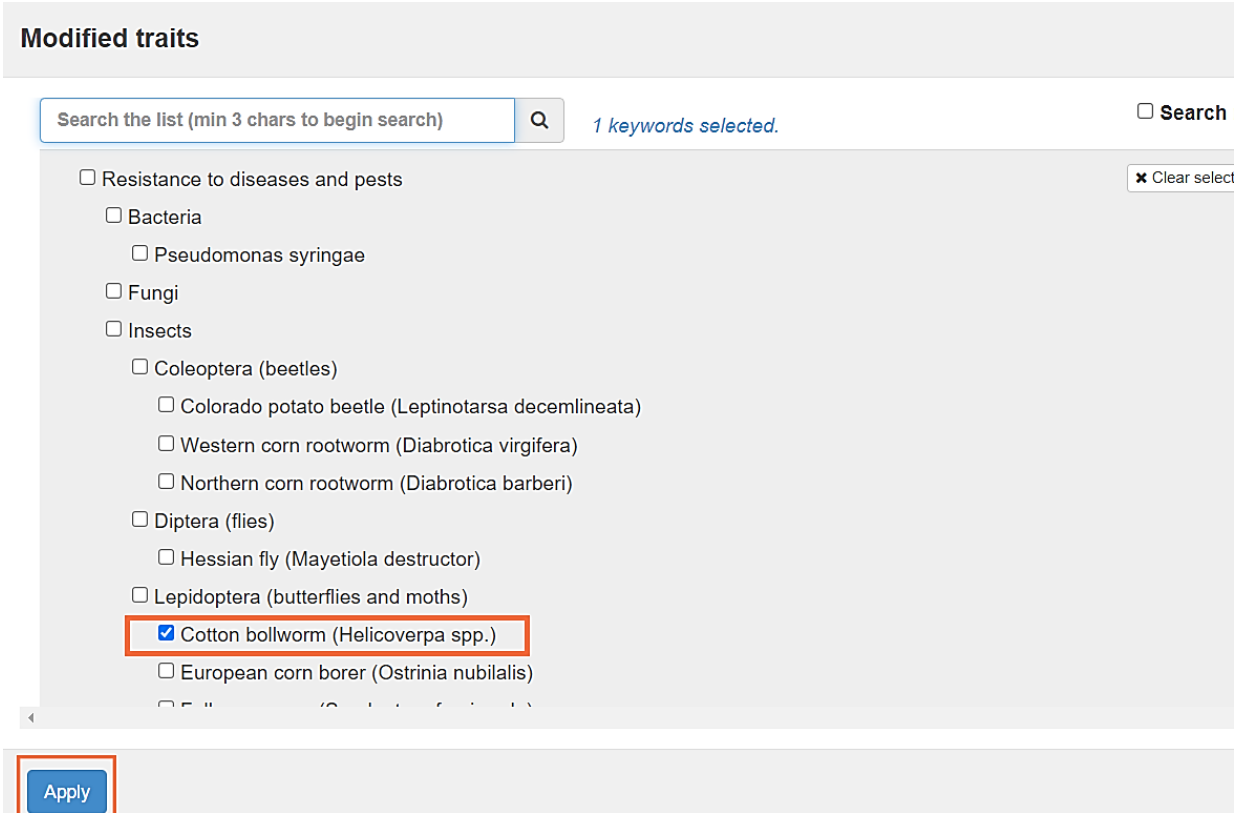


Figure 11 – Additional search criteria on the BCH website

The final search result looks like this (Figure 12):

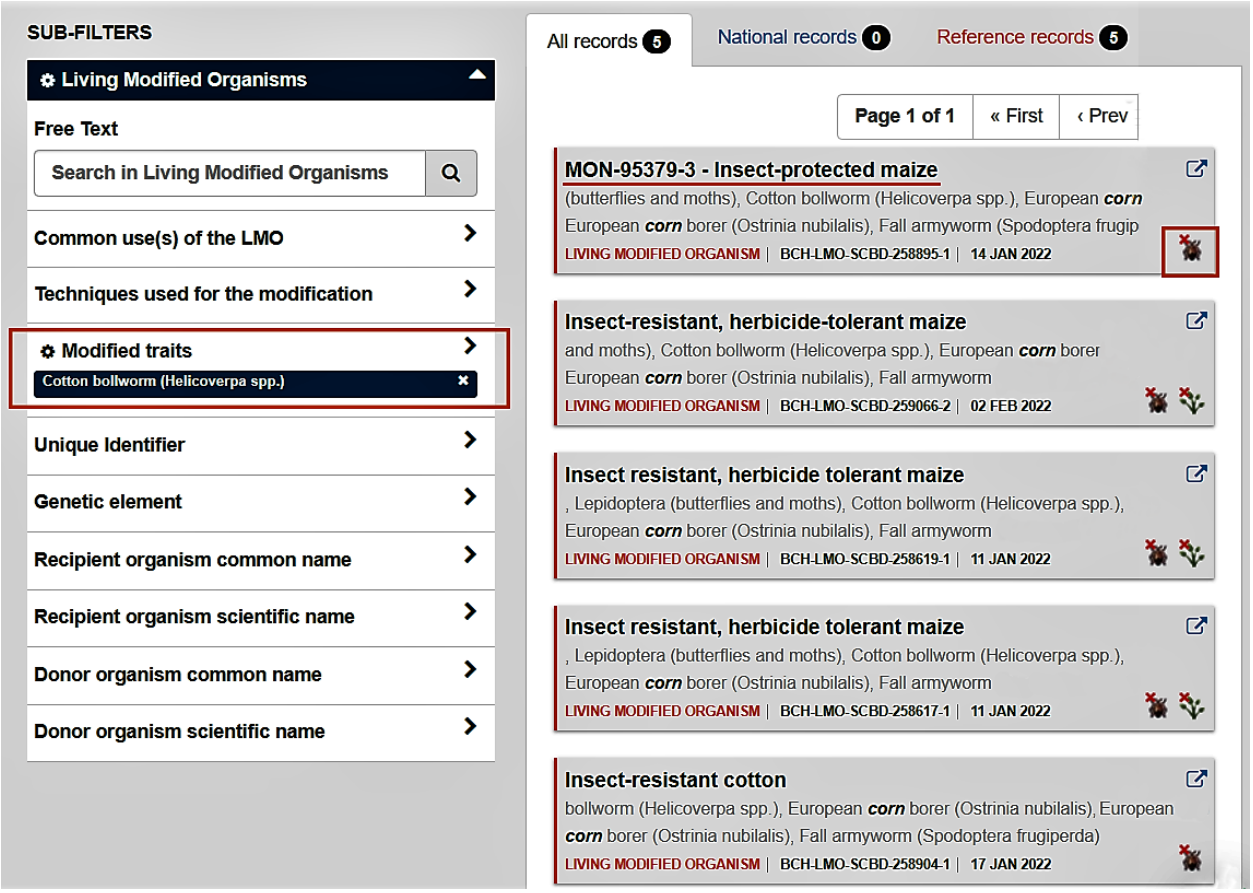


Figure 12 – The final search result on the BCH website

A click on an entry (record) that matches the search criteria allows opening the record page that contains detailed information about the item of interest (Figure 13).

Record pages of LMO Registry include the following sections: “Identification of the Living Modified Organism”, “Characteristics of the Modification Process”, “Characteristics of the LMO”, and “Additional Information”.

The section “Living Modified Organism Identity” contains the object’s name, a transformation event, a unique identifier, developers, and a brief description of object’s properties, a donor organism, and its collection or acquisition place.

The section “Characteristics of the Modification Process” indicates the vector used to transform an organism, a modification technique, a genetic construct itself shown graphically, inserted or modified genetic elements with cross-references to them according to record identifiers, as well as notes regarding the genetic elements present in the LMO.

The section “LMO Characteristics” provides insight into new acquired traits of the LMO compared to the parent organism.

In the section “Additional Information”, the user can find cross-references to other documents or databases that contain information about this LMO.

A

IVING MODIFIED ORGANISM (LMO) BCH-LMO-SCBD-258895-1 | PDF | PRINT

Decisions on the LMO Risk Assessments LAST UPDATED: 14 JAN 2022

Living Modified Organism identity

The image below identifies the LMO through its unique identifier, trade name and a link to this page of the BCH. Click on it to download a larger image on your computer. For help on how to use it go to the LMO quick-links page.

https://bch.cbd.int/database/record?documentID=258895

CBD

MON-95379-3
Insect-protected maize

Read barcode or type above URL into internet browser to access information on this LMO in the Biosafety Clearing-House © SCBD 2012

Name

Insect-protected maize EN

Transformation event

MON95379

Unique identifier

MON-95379-3

Developer(s)

- PERSON: BAYER CROPSCIENCE | BCH-CON-SCBD-111462-3

PERSON

Bayer CropScience
Bayer CropScience AG Alfred-Nobel-Str. 50 40789 Monheim am Rhein
Monheim am Rhein
40789, Germany
Phone: +49 21 73 - 38-0
Website: https://www.cropscience.bayer.com/en, https://www.cropscience.bayer.de/de-DE

RELATED ORGANIZATION

Bayer CropScience Deutschland GmbH
Private sector (business and industry)
Bayer CropScience AG Alfred-Nobel-Str. 50 40789 Monheim am Rhein
Monheim am Rhein
40789, Germany
Phone: +49 21 73 - 38-0
Website: https://www.cropscience.bayer.com/en, https://www.cropscience.bayer.de/de-DE

Description

The maize (*Zea mays*) was modified for resistance to Lepidoptera insects and to overcome Bt-resistance in insect pests. The maize expresses synthetic Cry1B.868 and Cry1Da_7 proteins (originally derived from *Bacillus thuringiensis*), which have a pore-forming mode of action that is independent of the receptors that other Bt toxins interact with. A selectable marker cassette (glyphosate tolerance) was removed using Cre-lox excision during the development of this line to result in a marker-free line. EN

Recipient Organism or Parental Organisms

The term "Recipient organism" refers to an organism (either already modified or non-modified) that was subjected to genetic modification, whereas "Parental organisms" refers to those that were involved in cross breeding or cell fusion.

BCH-ORGA-SCBD-246-6 ORGANISM | ZEA MAYS (MAIZE, CORN, MAIZE)
Crops

Characteristics of the modification process

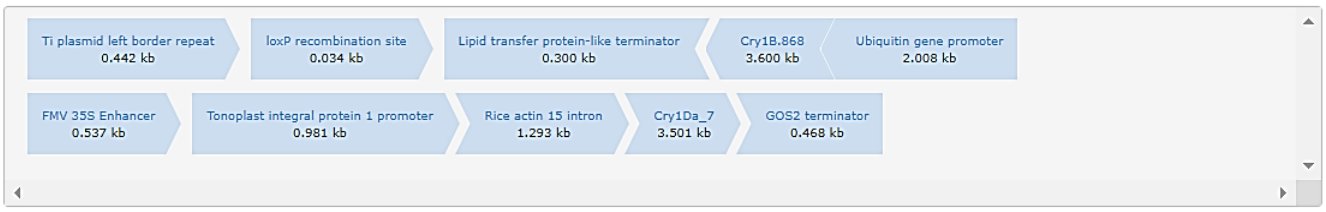
Vector

PV-ZMIR522223 EN

Techniques used for the modification

Agrobacterium-mediated DNA transfer

Genetic elements construct



B

Introduced or modified genetic element(s)

Some of these genetic elements may be present as fragments or truncated forms. Please see notes below, where applicable.

BCH-GENE-SCBD-103069-3 LOXP RECOMBINATION SITE
recombination site

BCH-GENE-SCBD-258891-1 LIPID TRANSFER PROTEIN-LIKE TERMINATOR | ORYZA SATIVA (RICE, ORYSA)
Terminator

BCH-GENE-SCBD-258889-1 CRY1B.868 | BACILLUS THURINGIENSIS (BT, BACILLUS, BACTU)
Protein coding sequence | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths), Fall armyworm (Spodoptera frugiperda))

BCH-GENE-SCBD-100362-7 UBIQUITIN GENE PROMOTER | (MAIZE, CORN)
Promoter

BCH-GENE-SCBD-105196-2 FMV 35S ENHANCER
Leader

BCH-GENE-SCBD-258892-1 TONOPLAST INTEGRAL PROTEIN 1 PROMOTER | SETARIA ITALICA - FOXTAIL MILLET, ITALIAN MILLET
Promoter

BCH-GENE-SCBD-258893-1 RICE ACTIN 15 INTRON | ORYZA SATIVA (RICE, ORYSA)
Intron

BCH-GENE-SCBD-258890-1 CRY1DA_7 | BACILLUS THURINGIENSIS (BT, BACILLUS, BACTU)
Protein coding sequence | Resistance to diseases and pests (Insects, Lepidoptera (butterflies and moths), Cotton bollworm (Helicoverpa spp.), European corn borer (Ostrinia nubilalis), Fall armyworm (Spodoptera frugiperda))

BCH-GENE-SCBD-258894-1 GOS2 TERMINATOR | ORYZA SATIVA (RICE, ORYSA)
Terminator

BCH-GENE-SCBD-101415-9 TI PLASMID LEFT BORDER REPEAT
Plasmid vector

Notes regarding the genetic elements present in this LMO

The modified maize contains two gene cassettes: synthetic *cry1B.868* and synthetic *cry1Da_7*.

The *cry1B.868* coding sequence is under control of a *Zea mays* ubiquitin promoter and an *Oryza sativa* lipid transfer-like protein terminator. The promoter contains the promoter, leader and intron sequences from the maize ubiquitin gene. High levels of transcription are expected in all tissues due to the constitutive nature of the promoter.

The *cry1Da_7* coding sequence is under control of a *Setaria italica* promoter and an *O. sativa gos2* terminator. The first intron of the rice actin 15 gene was also included and likely improves expression of the gene.

Note:

- Both *cry1B.868* and *cry1Da_7* sequences are derived from *Bacillus thuringiensis* sequences. Refer to the genetic element records for more information.
- During development of the modified maize, a *c4-epsps* cassette (rice tubulin A terminator; *cp4-epsps*; *Arabidopsis thaliana* chloroplast transit peptide 2; and rice tubulin A promoter) was removed using Cre-lox excision. The T-DNA right border was also truncated (lost) during transformation.
- Next-generation sequencing indicated that a single, intact copy of the the intended DNA insertion was present in the parental genome. No backbone or other unexpected sequences were detected.

EN

LMO characteristics

Modified traits

Resistance to diseases and pests
Insects
Lepidoptera (butterflies and moths)
Cotton bollworm (Helicoverpa spp.)
European corn borer (Ostrinia nubilalis)
Fall armyworm (Spodoptera frugiperda)

Common use(s) of the LMO

Feed
Food

Additional Information

Other relevant website addresses and/or attached documents

EUginius - MON95379 maize *(English)*
US11198887 - Corn transgenic event MON 95379 and methods for detection and uses thereof.pdf *(English)*
Application A1226 - Food derived from insect-protected corn line MON95379.pdf *(English)*
Pest Management Science - 2021 - Horikoshi - A new generation of Bt maize for control of fall armyworm Spodoptera.pdf *(English)*

A – sections “Living Modified Organism Identity”, “Characteristics of the Modification Process”; B – “LMO Characteristics”, “Additional Information”

Figure 13 – LMO record page on the BCH website

For most BCH records, the section “Detection Methods” (Figure 14) is also available. It contains links to cross-sources according to detection methods of a particular LMO line. Following the links, the user gets access to BCH-related resources — the sources of this information. Information on detection methods for the GM soybean line MON 89788-1 may be obtained, for example, from the GMOMETHOD Databases of the Joint Research Center of the European Commission and CropLife International; a link to it is provided in the sub-filter “Living Modified Organisms”.

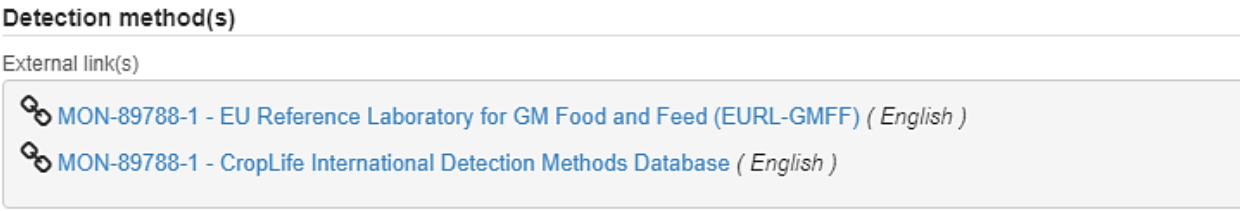


Figure 14 – Section “Detection Methods” on the BCH website

Decisions and risk assessments on LMOs are available at the top of the record page. When following these hyperlinks, the user gets to corresponding page tabs. The tab “Decisions on the LMO” (Figure 15) contains information about countries and the decisions they have made regarding a particular LMO.

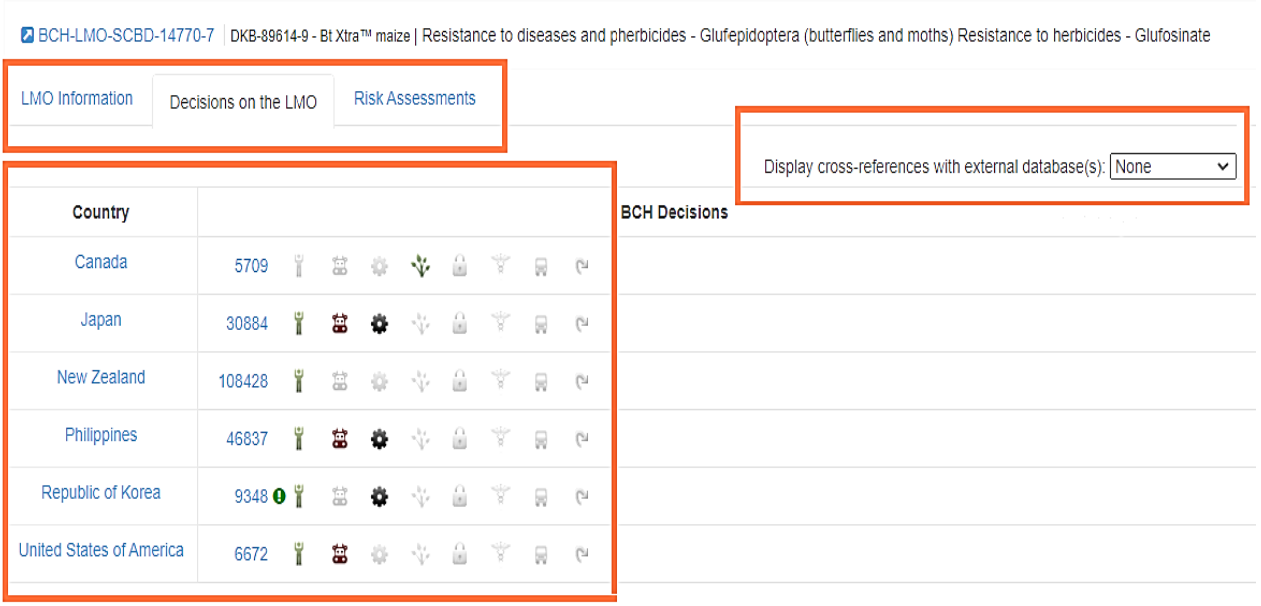
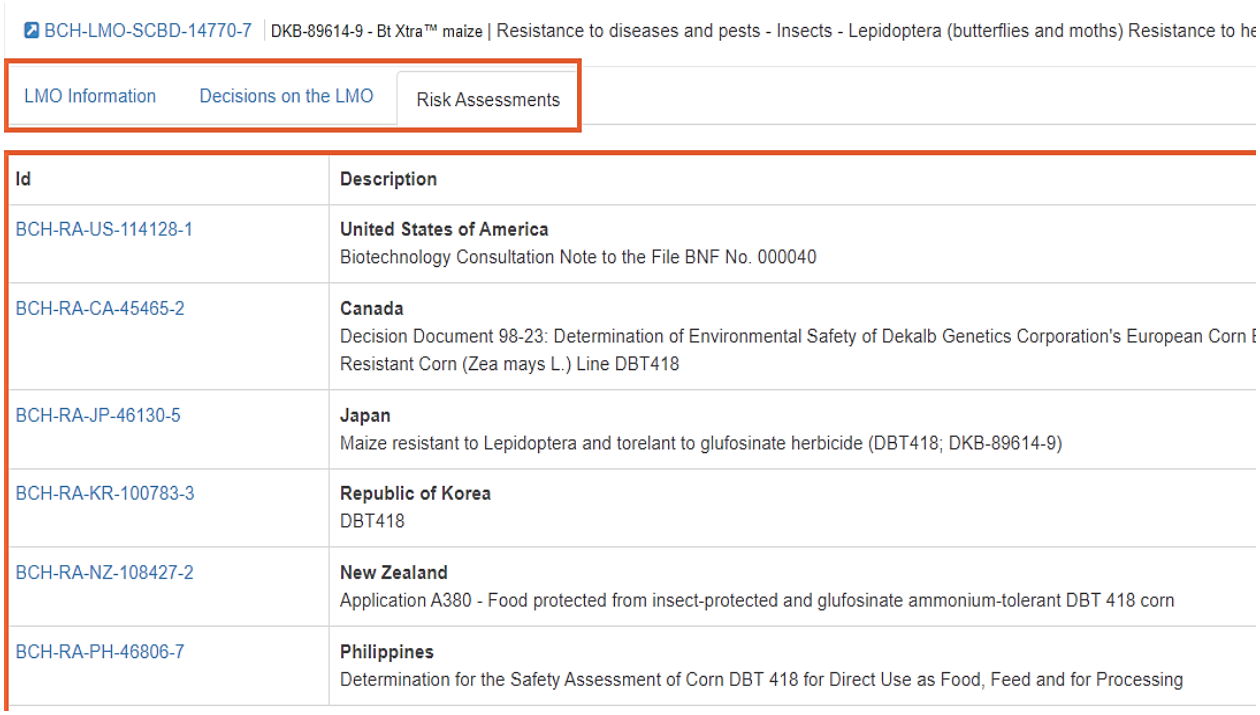


Figure 15 – Design of the “Decisions on the LMO” tab on the BCH website

In the right part of an active link, in the field “Display of Cross-references with External Databases”, the user may select other external databases and decisions on LMOs will be shown not only from the BCH, but also from selected databases.

The tab “Risk Assessment” (Figure 16) contains information on ongoing risk assessments of a given organism in various countries with cross-references to other corresponding decisions.

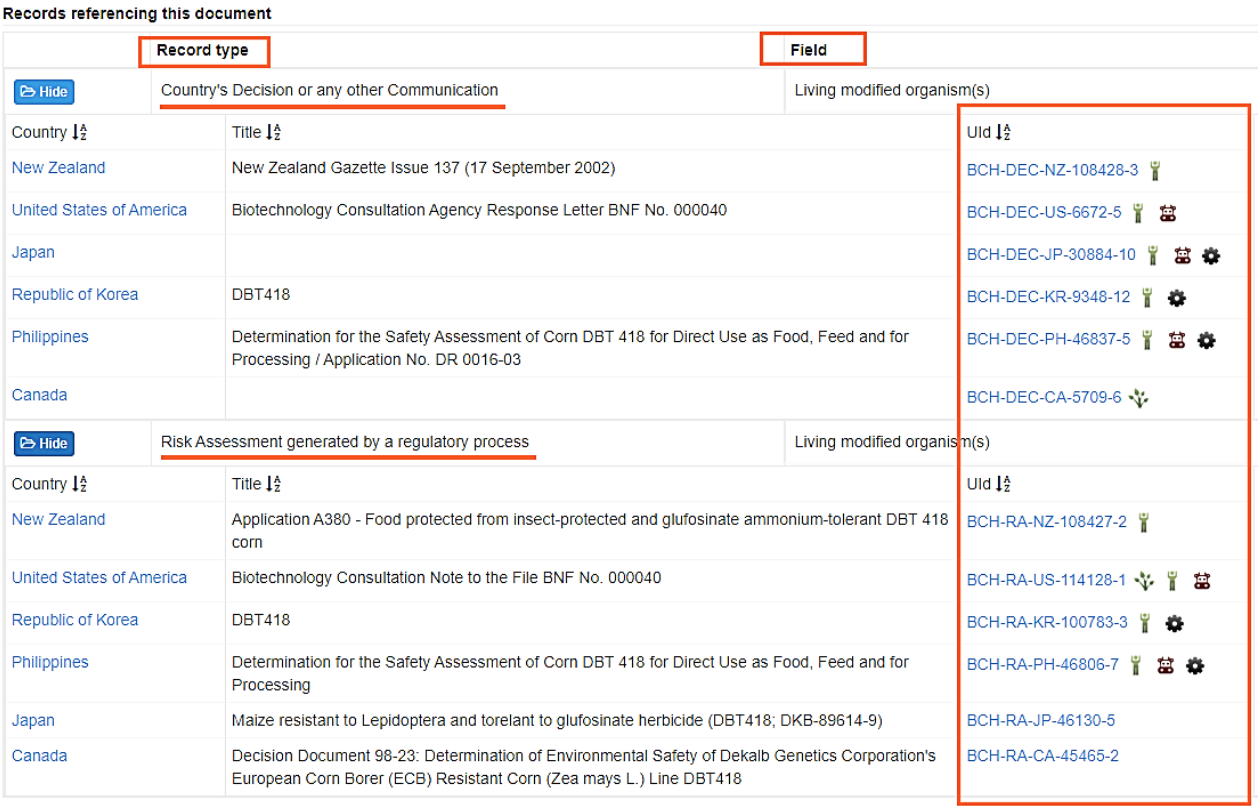


Id	Description
BCH-RA-US-114128-1	**United States of America** Biotechnology Consultation Note to the File BNF No. 000040
BCH-RA-CA-45465-2	**Canada** Decision Document 98-23: Determination of Environmental Safety of Dekalb Genetics Corporation's European Corn E Resistant Corn (Zea mays L.) Line DBT418
BCH-RA-JP-46130-5	**Japan** Maize resistant to Lepidoptera and torelant to glufosinate herbicide (DBT418; DKB-89614-9)
BCH-RA-KR-100783-3	**Republic of Korea** DBT418
BCH-RA-NZ-108427-2	**New Zealand** Application A380 - Food protected from insect-protected and glufosinate ammonium-tolerant DBT 418 corn
BCH-RA-PH-46806-7	**Philippines** Determination for the Safety Assessment of Corn DBT 418 for Direct Use as Food, Feed and for Processing

Figure 16 – “Risk Assessment” tab design on the BCH website

For some record pages, the section “Records Referencing this Document” is also available (Figure 17) and is presented as a structured list of BCH record types in which this page is mentioned.

Upon clicking the “Show” button, a list of BCH records appear sorted by the record type. An additional field is also used for sorting and allows grouping of records in a more structured way. For each record in the list, its unique identifier is available with a cross-reference to the record page, which makes it possible to quickly navigate through record pages in the database.



Records referencing this document

	Record type	Field	
Hide	Country's Decision or any other Communication	Living modified organism(s)	
Country	Title		Uid
New Zealand	New Zealand Gazette Issue 137 (17 September 2002)		BCH-DEC-NZ-108428-3
United States of America	Biotechnology Consultation Agency Response Letter BNF No. 000040		BCH-DEC-US-6672-5
Japan			BCH-DEC-JP-30884-10
Republic of Korea	DBT418		BCH-DEC-KR-9348-12
Philippines	Determination for the Safety Assessment of Corn DBT 418 for Direct Use as Food, Feed and for Processing / Application No. DR 0016-03		BCH-DEC-PH-46837-5
Canada			BCH-DEC-CA-5709-6
Hide	Risk Assessment generated by a regulatory process	Living modified organism(s)	
Country	Title		Uid
New Zealand	Application A380 - Food protected from insect-protected and glufosinate ammonium-tolerant DBT 418 corn		BCH-RA-NZ-108427-2
United States of America	Biotechnology Consultation Note to the File BNF No. 000040		BCH-RA-US-114128-1
Republic of Korea	DBT418		BCH-RA-KR-100783-3
Philippines	Determination for the Safety Assessment of Corn DBT 418 for Direct Use as Food, Feed and for Processing		BCH-RA-PH-46806-7
Japan	Maize resistant to Lepidoptera and torelant to glufosinate herbicide (DBT418; DKB-89614-9)		BCH-RA-JP-46130-5
Canada	Decision Document 98-23: Determination of Environmental Safety of Dekalb Genetics Corporation's European Corn Borer (ECB) Resistant Corn (Zea mays L.) Line DBT418		BCH-RA-CA-45465-2

Figure 17 – "Records Referencing this Document" tab design on the BCH website

For different organisms and record types, this Table may contain other grouping elements. Thus, for the hybrid of the living modified soybean line MON-87708-9 x MON-89788-1 (Figure 18), a more extended list of related record categories, including LMOs, LMO Detection and Identification Laboratories, risk assessments, and country decisions on LMOs is available.

Records referencing this document

	Record type	Field
Show	Laboratory for detection and identification of LMOs	LMO(s) detectable by the laboratory
Show	Risk Assessment generated by a regulatory process	Living modified organism(s)
Show	Country's Decision or any other Communication	Living modified organism(s)
Show	Living Modified Organism	Recipient Organism" or "Parental Organisms
Show	Living Modified Organism	Related LMO(s)

Figure 18 – "Records Referencing this Document" tab design for the soybean line MON-87708-9 x MON-89788-1 on the BCH website

By opening the section “Laboratories for Detection and Identification of LMOs”, the user has a chance not only to look through a list of laboratories able to detect a specific GM organism, but also by clicking on the laboratory record identifier, to get more detailed information about it both on the BCH and related websites (Figure19).

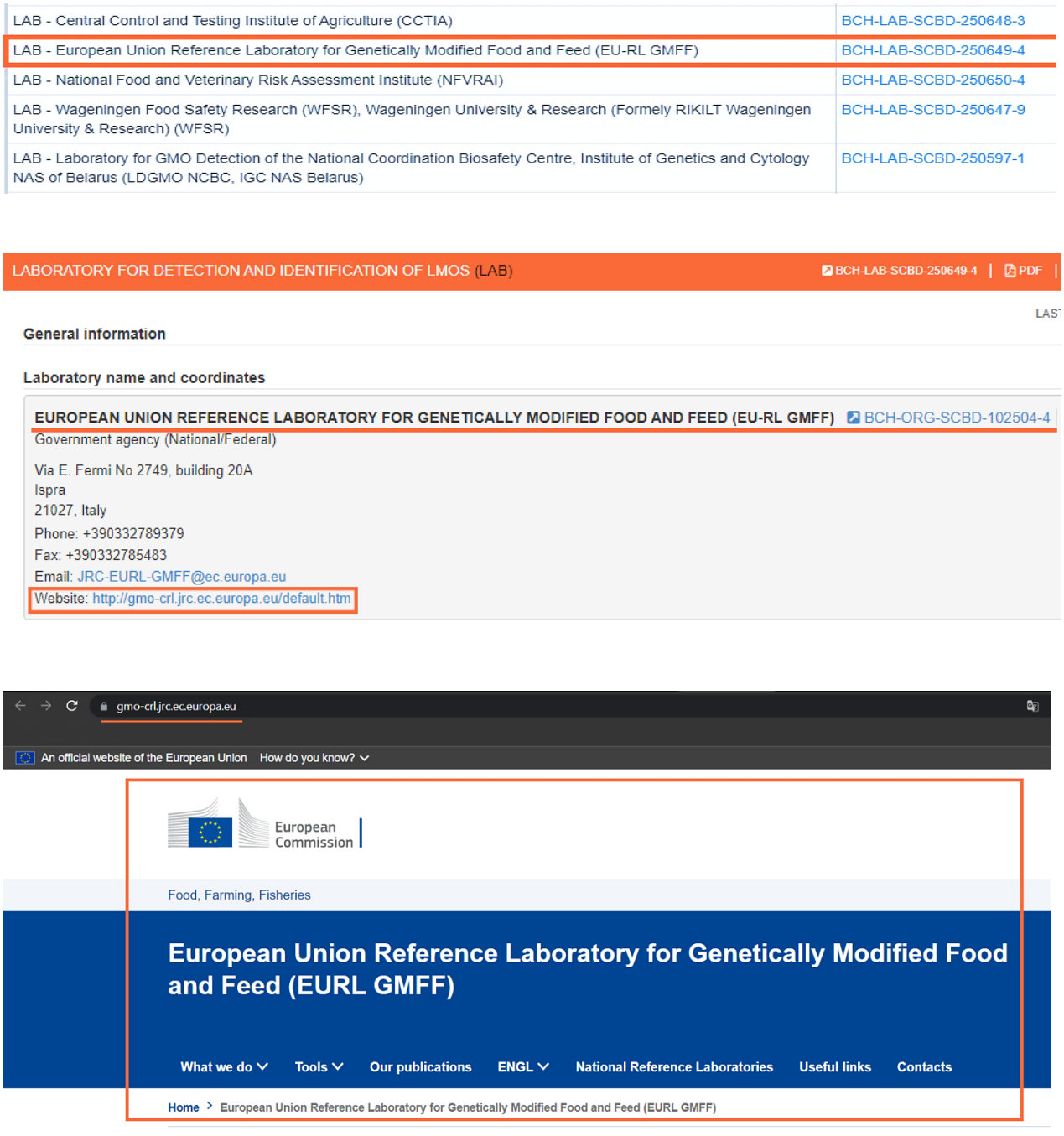


Figure 19 – Example of navigation through the section “Laboratories for Detection and Identification of LMOs” on the BCH website

Thus, when choosing a Platform to search for information on LMOs, the Biosafety Clearing-House Database is one of most preferable, as it contains not only a complete set of links to information provided by the Governments of the Parties in accordance with the Cartagena Protocol and exhaustive information on LMOs, but also links to external databases.

2.2.2 GMOMETHOD and GMO-Matrix of the Joint Research Centre of the European Commission

The European Union Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) performs the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU marketing authorization procedure. It also assists European Union National Reference Laboratories in controlling of GMOs in EU Member States. The Laboratory was organized by the Joint Research Centre of the European Commission and is in constant liaison with the European Network of GMO Laboratories. The website of this Centre includes two instrumental tools: GMOMETHOD and GMO-Matrix.

GMOMETHOD provides information on EU reference methods for GMO analysis.

The tool assists control laboratories in selecting appropriate methods for GMO screening and the identification of GM lines; it provides underlying data on the experimental Protocol and information about the effectiveness of this or that method, design validation, plasmid standards, reference materials, and links to published articles or verification reports.

The tests performed by both the core European Union Reference Laboratory and European Union National Reference Laboratories represent DNA-based detection methods approved in accordance with the principles and requirements of international standards and may, therefore, guarantee consistent and reproducible test results. The data presented in the GMOMETHOD section were obtained from peer-reviewed journals and are published after passing a full cycle of validation, or

the final reports of collaborative studies in the framework of the European Network of GMO Laboratories.

This site allows selecting methods for the qualitative or quantitative analysis of GMO or GM lines, and then after choosing a method, you need to select a target specific for the detection of GMO or a specific GM line: an event, a construct, or a specific element. It is also possible to choose a method that is specific for the identification of a required taxon, either a species-specific method validated directly for a taxon, or combined for the simultaneous detection of GMOs (Figure 20). Identification of species-specific DNA characteristic for a certain type of organism is required for the subsequent quantitative determination of GMOs or an individual GM line in a sample. Then, after selecting the desired method and specificity type, a window appears with the method identifier (ID) and the title (Figure 21). After selecting the desired method, all required information will be listed: polymerase chain reaction (PCR) methodology, nucleotide sequences of primers and probes, dyes used in particular PCR, and nucleotide sequences obtained during PCR.

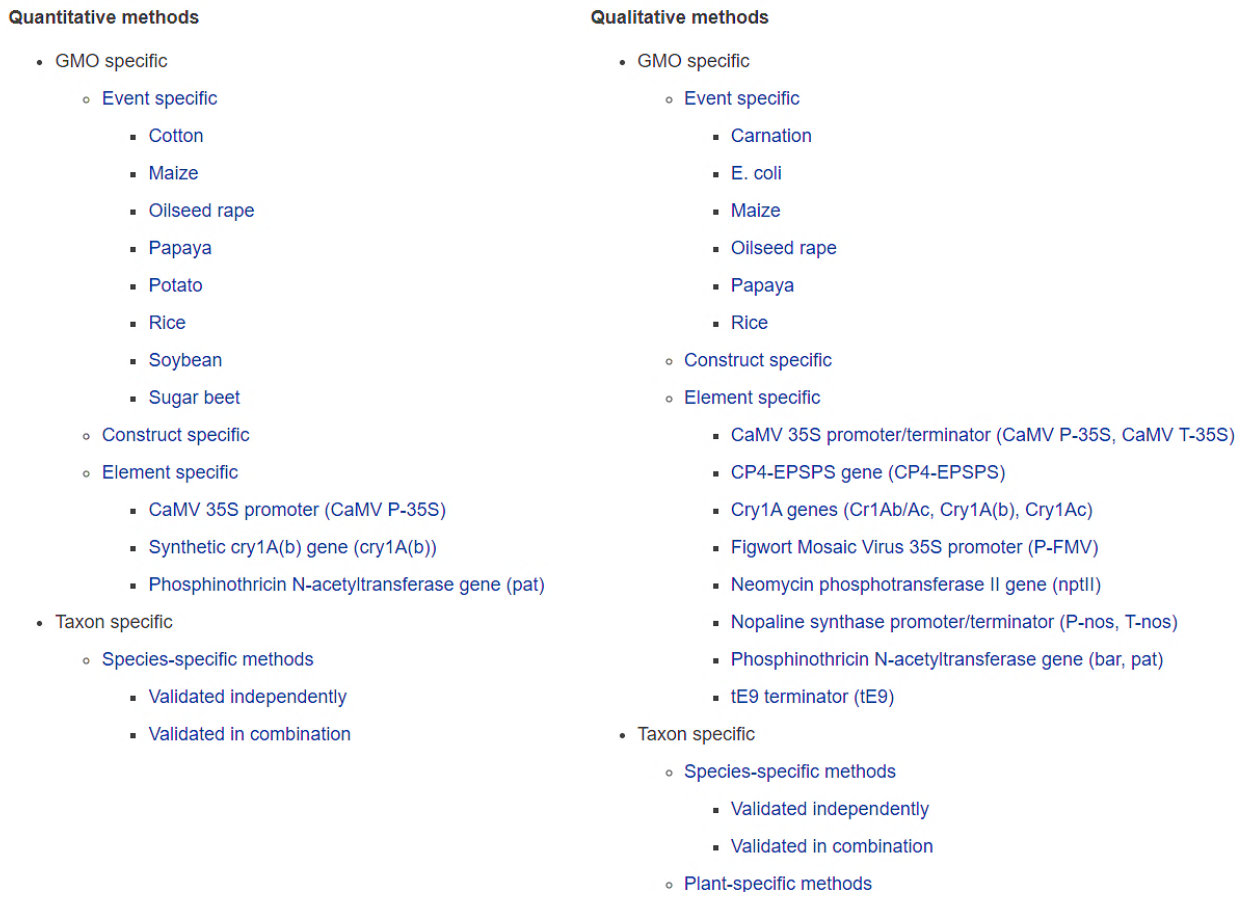


Figure 20 – Choosing a method in the GMOMETHOD tool

Results for query [id:QT-TAX*]		
Nr	ID	Title
1	QT-TAX-GH-019	Quantitative PCR method for detection of cotton alcohol dehydrogenase C gene
2	QT-TAX-ZM-011	Quantitative PCR method for detection of maize alcohol dehydrogenase 1
3	QT-TAX-BN-001	Quantitative PCR method for detection of oilseed rape acyl-ACP thioesterase gene (Jacchia et al., 2014)
4	QT-TAX-GM-003	Quantitative PCR method for detection of soybean lectin gene
5	QT-TAX-ZM-002	Quantitative PCR method for detection of maize high-mobility-group gene
6	QT-TAX-ZM-006	Quantitative PCR method for detection of maize starch synthase IIb gene
7	QT-TAX-BN-003	Quantitative PCR method for detection of oilseed rape cruciferin A gene (Jacchia et al., 2019)
8	QT-TAX-GM-009	Quantitative PCR method for detection of soybean lectin gene (Mazzara et al., 2007).
9	QT-TAX-GH-020	Quantitative PCR method for detection of cotton alcohol dehydrogenase C gene
10	QT-TAX-BN-002	Quantitative PCR method for detection of oilseed rape cruciferin storage protein (Savini et al., 2013).
11	QT-TAX-GM-002	Quantitative PCR method for detection of soybean lectin gene
12	QT-TAX-GH-018	Quantitative PCR method for detection of cotton alcohol dehydrogenase C gene (Mazzara et al., 2007).
13	QT-TAX-GH-015	Quantitative PCR method for detection of cotton fiber-specific acyl carrier protein gene
14	QT-TAX-ZM-001	Quantitative PCR method for detection of maize alcoholdeydrogenase 1 gene
15	QT-TAX-ST-010	Quantitative PCR method for detection of potato UDP-glucose pyrophosphorylase gene (Savini et al., 2006).

Figure 21– Method identifiers (ID) and their titles in the GMOMETHOD tool

The section “GMO Matrix” compiles PCR predictions *in silico* for the GMO detection. This tool assists control laboratories in developing of screening strategies and interpreting of results. Computer modeling is performed using primer and probe sequences from the GMOMETHODS database and GMO sequences from the Internal Database. The latter includes nucleotide sequences provided by applicants for GMO authorization or retrieved independently from nucleotide/patent databases in the public domain.

The GMO-Matrix interface is quite simple and straightforward. Screening in the section “Select GMO(s)” may be carried out both by a taxon (a certain plant species) and an individual GMO. The section “Selected Method(s)” allows choosing a method that is event-specific, construct-specific, or element-specific. For example, the section “Select GMO(s)” allows choosing a specific plant species, and the section “Selected Method(s)” allows choosing a specific GM screening element (individual GM promoters, terminators, or target genes).

Standard testing of samples for the presence of GM lines includes 2 stages:

– Large-scale screening by known promoters, terminators and individual target genes, which allows assuming that specific GM lines are present in the sample;

– Identification of GM lines.

The GMO-Matrix programme may be used both at the stage of prediction of screening elements to be detected in samples (preliminary prediction of all types of specific elements that will allow the detection of GMOs at the planning phase of an experiment), as well as for predicting the presence of specific GM lines after large-scale screening and the experimental detection of individual screening elements. The example below shows a prognosis for the detection of genetically modified maize in the case of experimental detection of the following screening elements: the P-35s promoter and the T-nos terminator (Figure 22).

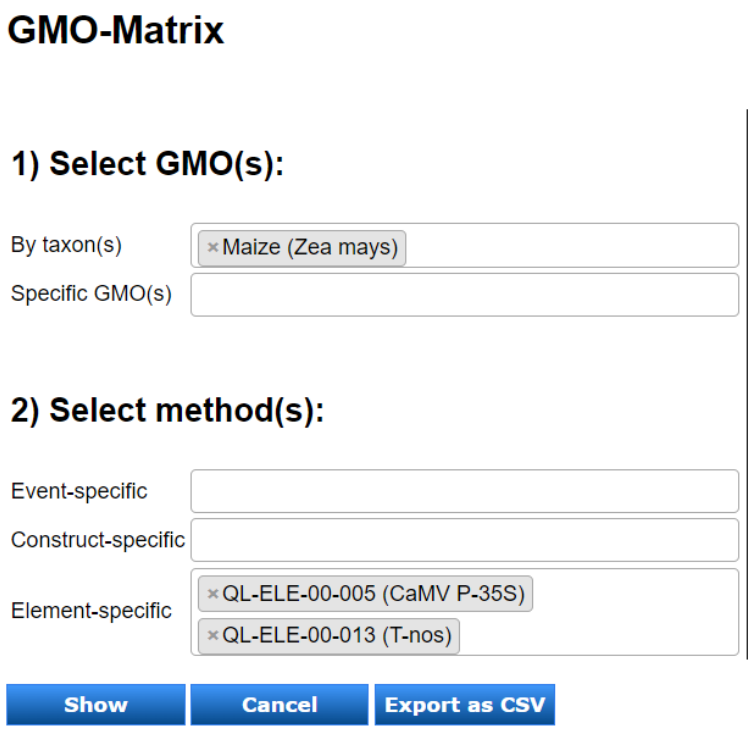


Figure 22– Selection of the analyzed taxon and elements to be used for the prediction of the presence of GMO or individual GM lines in the sample

Prediction results (Figure 23) will be demonstrated in the form of a Table that lists GM maize lines vertically, and horizontally, the elements (the CaMV P-35S promoter and the T-nos terminator) by which annealing of primers is predicted for the identification of individual GM maize lines, where 0 – the amplification of elements is not predicted; 1 – the amplification is predicted, but low specificity of primer annealing is assumed; and 2 – the amplification is predicted.

	QL-ELE-00-005 (CaMV P-35S)	QL-ELE-00-013 (T-nos)
1507 Maize (DAS-01507-1)	2	0
3272 Maize (SYN-E3272-5)	0	2
59122 Maize (DAS-59122-7)	2	0
Bt176 Maize (SYN-EV176-9)	2	0
LY038 Maize (REN-00038-3)	0	0
MIR604 Maize (SYN-IR604-5)	0	2
MON 810 Maize (MON-00810-6)	2	0
MON 863 Maize (MON-00863-5)	1	2
MON 88017 Maize (MON-88017-3)	2	2
NK603 Maize (MON-00603-6)	2	2
T25 Maize (ACS-ZM003-2)	2	0

Figure 23 – Prediction results on the GM maize line identification in GMO-Matrix

When a particular GM line is selected in the GMO-Matrix Database, the transition occurs to the BCH Database, where all known information on this GM line is stored.

2.2.3 GM Approval Database of the International Service for the Acquisition of Agri-biotech Applications (ISAAA)

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) is a non-profit international organization that shares advances in modern biotechnologies with key stakeholders through exchanging of knowledge and supporting of capacity-building initiatives and partnerships.

The ISAAA website provides access to the Database of authorized GMOs (GM Approval Database) that have been approved for commercialization/field-planting, as well as for imports as food and feed. Information records are generated from public documents on country decisions in English, based on the information posted on the BCH website and other databases, and peer-reviewed scientific articles. The Database may be accessed from the tab “GM Approval Database” from the drop-down menu in the top right corner of the website.

The main menu of the database is located horizontally and represented by the following sections (Figure 24):

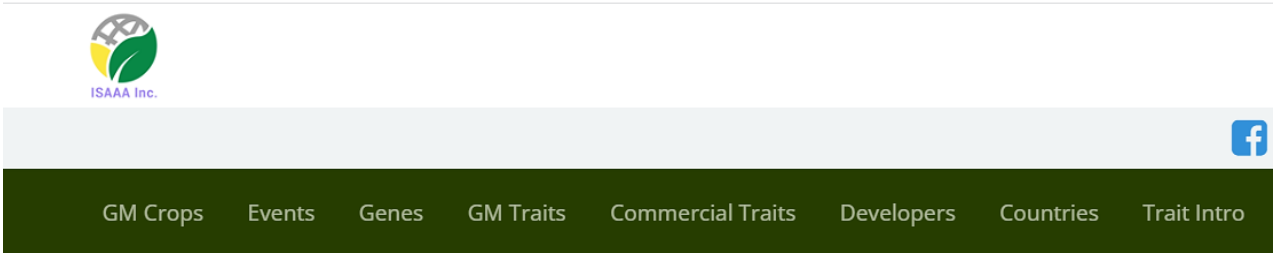


Figure 24 – The main menu of the GM Approval Database

The search engine is located directly on the main page of the Database. The user has a chance to search for information of interest using the following filters: GM crop name, commercial trait, GMO developer, country of origin, GM crop type of approval (as food or feed, or for cultivation). The search engine design is demonstrated by Figure 25:

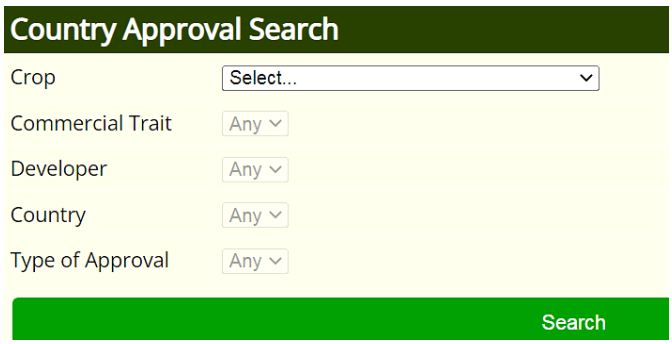


Figure 25 – Search engine design of the GM Approval Database

A report on the results of Database search queries is shown in the form of Tables with the main characteristics of GM crops. It should be noted that the ISAAA Database is linked to other information sources (the BCH Database, the European Register of Authorized GMOs etc.) via hyperlinks in the section “Documents and Links” (Figure 26).

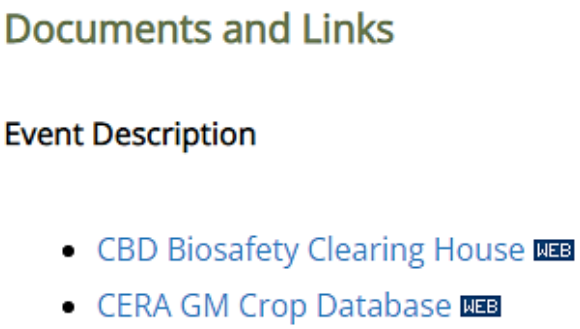


Figure 26 – Design of the section “Documents and Links” of the GM Approval Database

An example of the system response based on the results of the search for the Bt11 GM line of maize (X4334CBR, X4734CBR) is demonstrated by Figure 27:

A

Event Name: Bt11 (X4334CBR, X4734CBR)

Event Code : SYN-BTØ11-1
Trade Name: Agrisure™ CB/LL

Crop: *Zea mays L.* - Maize, Corn

Developer: Syngenta

Method of Trait Introduction: Microparticle bombardment of plant cells or tissue

GM Traits: Glufosinate herbicide tolerance , Lepidopteran insect resistance

Commercial Trait: (Stacked) Herbicide Tolerance + Insect Resistance

Basic Genetic Modification

Gene Introduced	Gene Source	Product	Function
pat	*Streptomyces viridochromogenes*	phosphinothricin N-acetyltransferase (PAT) enzyme	eliminates herbicidal activity of glufosinate (phosphinothricin) herbicides by acetylation
cry1Ab	*Bacillus thuringiensis* subsp. kurstaki	Cry1Ab delta-endotoxin	confers resistance to lepidopteran insects by selectively damaging their midgut lining

B

Regulatory Approvals: Country, Year and Type of Approval

Country	Food direct use or processing	Feed direct use or processing	Cultivation domestic or non-domestic use
Argentina	2001	2001	2001
Australia	2001		
Brazil	2008	2008	2008
Canada	1996	1996	1996
China	2002 *	2002 *	
Colombia	2009	2008	2008 *
European Union	1998 *	1998 *	
Indonesia	2011		
Japan	2001	2003	2007
Malaysia	2012	2012	
Mexico	2007		
New Zealand	2001		
Nigeria	2019 *	2019 *	
Paraguay	2012	2012	2012
Philippines	2003 *	2003 *	2010 *
Russia	2008 *	2006 *	
Singapore	2017		
South Africa	2002	2002	2003
South Korea	2003	2006	
Switzerland	2003 *	2003 *	
Taiwan	2004		
Thailand	2013		
Turkey		2011	
United States	1996	1996	1996
Uruguay	2004 *	2004	2004 *
Vietnam	2014	2014	

* point mouse arrow over year for notes

Last updated: June 1, 2022

Documents and Links

Event Description

- CBD Biosafety Clearing House WEB
- CERA GM Crop Database WEB

C

Regulatory and Biosafety Information

- Agri-Food and Veterinary Authority of Singapore PDF
- Biosafety Scanner WEB
- Brazil - Conselho de Informacoes sobre Biotecnologia (CIB) WEB
- Brazil CTNBio WEB
- Canadian Food Inspection Agency WEB
- CBD Biosafety Clearing House WEB
- DA - BPI Approval Registry 2014 PDF
- European Commission WEB
- European Food Safety Authority PDF
- Food Standards Australia New Zealand PDF
- Japan Biosafety Clearing House PDF
- Malaysia Biosafety Clearing House PDF
- National Biosafety Management Agency Decision-Nigeria PDF
- Philippines - Department of Agriculture PDF
- US Department of Agriculture - APHIS PDF
- US Environmental Protection Agency PDF
- US Food and Drug Administration WEB
- USDA-FAS GAIN Report - China 2018 PDF

Detection Methods

- EU Reference Laboratory for GM Food and Feed WEB
- EU Reference Laboratory for GM Food and Feed WEB
- EU Reference Laboratory for GM Food and Feed PDF
- GMO Detection Method Database WEB

Figure 27 – A, B, C: Search results for the GM maize line Bt11 (X4334CBR, X4734CBR) in the GM Approval Database

2.2.4 GenBit Database

GenBit is a GM Crops Database (including the genetic elements of constructs) registered across the globe. The Database was developed by "GenBit" LLC (the Russian Federation) and includes information on the registration of genetically modified plants in the Russian Federation and the European Union (lines in the process of being canceled for marketing authorization are not included).

Lines (transformation events) with the same set of inserted genetic elements are combined into one entry. The GenBit Database search is demonstrated in the form of a Table that includes a GM plant species, a genetic event, a sense gene, a promoter, a terminator, markers, and comments. Comments have the following designations and interpretations: **HT** - herbicide tolerance; **IR** - insect resistance; **IY** - increased yield; **MS** - male sterility; **MUT** - obtained via mutagenesis (when own natural mutant gene of the species/genus is inserted and employs regulatory sequences of the host organism); **PQ** - altered product quality; **PR** - pathogens/disease resistance; **VR** - virus resistance; **RF** - restored fertility; **ST** - abiotic stress tolerance; **STBS** - stacked event obtained with traditional breeding and selection; **RUS** - approved in the Russian Federation (not for growing); **EU** - authorised in the European Union; **n/a** - information not available (Figure 28).

Показывать по 10 записей Поиск: рис

Культура	Линия / событие	Смысловой ген	Промотор	Терминатор	Маркер	Примечания
Рис	CL121, CL141, CFX51	als				MUT, HT / BASF
Рис	Huahui No. 1	cry1Ab/Ac	pActin1	tNOS	hph	IR / Huazhong Agricultural University
Рис	IMINTA-1, IMINTA-4	als				MUT, HT / BASF
Рис	IR-00GR2E-5	crt1, psy1	pUbiZM1, pGluA2	tNOS	pmi	PQ / International Рис Research Institute
Рис	LLRICE06, LLRICE62	bar	p35S	t35S		HT, RUS (LLRICE62) / Aventis
Рис	LLRICE601	bar	p35S	tNOS		HT / Aventis
Рис	PWC16	als				MUT, HT / BASF

Figure 28 – GenBit Database: search line and search data view

The GenBit Database makes it possible to establish the presence of main screening elements (promoters and terminators) for a particular GM line, as well as target genes that allow the identification of this line.

GenBit, along with the Database of the European Union Reference Laboratory for Genetically Modified Food and Feed, is sufficiently informative for the development of both experimental screening strategies for GM lines and their identification. GenBit has links to key International GMO Detection Databases and the Databases of Reference GMO Detection Laboratories, including GMO detection methods.

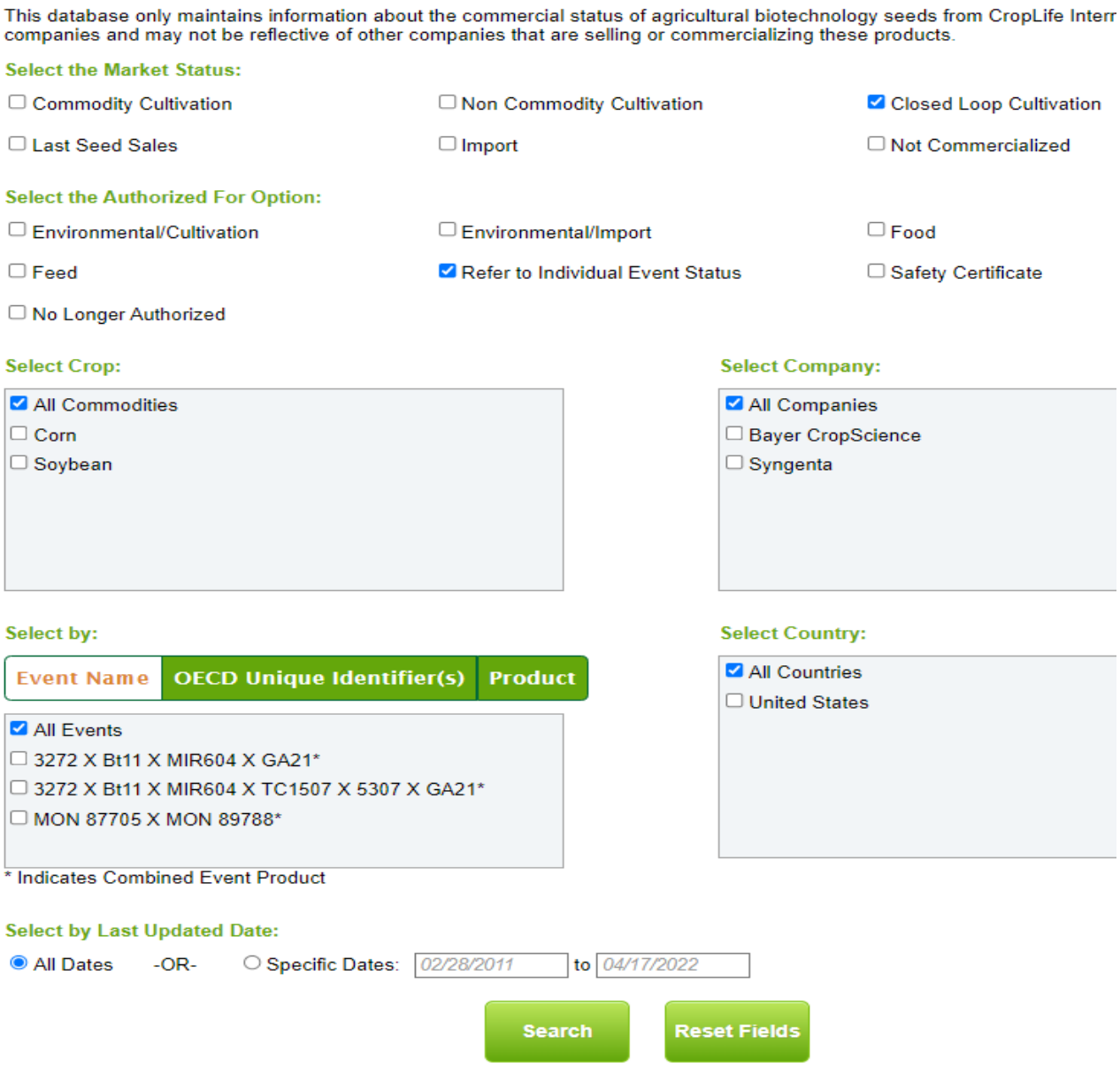
2.2.5 CropLife International Database on the Commercial Status of Biotech Crop Seeds of CropLife International Member Companies (BIOTRADESTATUS)

The BIOTRADESTATUS website was developed to collect information on the commercial status of seeds for agricultural biotechnologies. Information about own products in the Database is published by CropLife International member companies — BASF Plant Science LP; Bayer; Dow AgroSciences LLC; Monsanto Company; Pioneer, a DuPont business; and Syngenta Seeds, Inc. At that, all Database information must be independently verified by appropriate government agencies.

BIOTRADESTATUS includes regulatory information on GM seeds, including products that may contain combined events and their placement at the market.

The Database makes it possible to sort records by the directions of approvals for use in economic activity, intended use of a product, an organism, a development company, a country, a line name, or the unique identifier of the Organization for Economic Cooperation and Development. The user may also select a timeline for the last record update. Search engine and search result layouts are demonstrated on the following page (Figure 29).

Links to the Platform data are published by key GM Organisms Databases, and the BIOTRADESTATUS Database also provides links to third-party websites.



UNITED STATES

Company	Product	Event	OECD	Crop	Market Status	Authorized For	Updated
Bayer CropScience	Vistive Gold	MON 87705 X MON 89788	MON-877Ø5-6 X MON-89788-1	Soybean	Closed Loop Cultivation	Refer to Individual Event Status	08/07/2019
Syngenta	Agrisure Duracadeade 5122E	3272 X Bt11 X MIR604 X TC1507 X 5307 X GA21	SYN-E3272-5 X SYN-BTØ11-1 X SYN-IR6Ø4-5 X DAS-Ø15Ø7-1 X SYN-Ø53Ø7-1 X MON-ØØØ21-9	Corn	Closed Loop Cultivation	Refer to Individual Event Status	05/08/2020
Syngenta	Enogen/Agrisure re 3000GT	3272 X Bt11 X MIR604 X GA21	SYN-E3272-5 X SYN-BTØ11-1 X SYN-IR6Ø4-5 X MON-ØØØ21-9	Corn	Closed Loop Cultivation	Refer to Individual Event Status	05/08/2020

Figure 29 – Search engine and search result layouts in the CropLife International Database

2.2.6 Databank of the National Coordination Biosafety Centre of the Institute of Genetics and Cytology, NAS of Belarus

Article 22 of the Law [29] stipulates that within the framework of information support in the field of safety in genetic engineering activity (GEA) the National Coordination Biosafety Centre of the Institute of Genetics and Cytology, NAS of Belarus (NCBC), shall collect, analyze and systematize information, and form a Databank on GEOs. To do this, within five days from the date of issuance of a permit for the release of non-pathogenic GEOs into the environment for testing (the Ministry of Natural Resources), a State Registration Certificate for GE plant varieties, GE animal breeds and strains of non-pathogenic GE microorganisms (the Ministry of Agriculture and Food), a conclusion (an authorization document) for import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory of potentially pathogenic and pathogenic GEOs (the Ministry of Health), and the State Customs Committee of the Republic of Belarus, within five days after the cargo with GEO has crossed the Customs Border with the Eurasian Economic Union in the Republic of Belarus, shall submit corresponding documentation to the NCBC. The Resolution of the Council of Ministers of the Republic of Belarus of June 12, 2019 No. 382 [61] determines that an authorized organization for carrying out of a GEO risk assessment shall be obliged to submit, within five days from the date of conclusion of a contract with an applicant, materials to the NCBC. In addition, the Resolution [49] determines that the main assignments of the National Coordination Biosafety Centre shall be as follows: collection, analysis and systematization of information on the legislation of the Republic of Belarus and scientific research on biosafety issues, a risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment, testing of genetically engineered objects, 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, as well as information on biosafety issues from international information systems and information networks, in accordance with the legislation of the Republic of Belarus, international treaties of the Republic of Belarus; providing of

information on biosafety issues to legal entities and individuals. Thus, the NCBC may request corresponding information.

In accordance with the Resolution [50], the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus", which performs the functions of the National Coordination Biosafety Centre, is the owner and operator of the Databank and shall provide legal entities and individuals with full, timely and accurate information in the field of safety in genetic engineering activity from the Databank by posting it on the website www.biosafety.by (Figure 30) over the global computer network Internet and/or in hard copy.

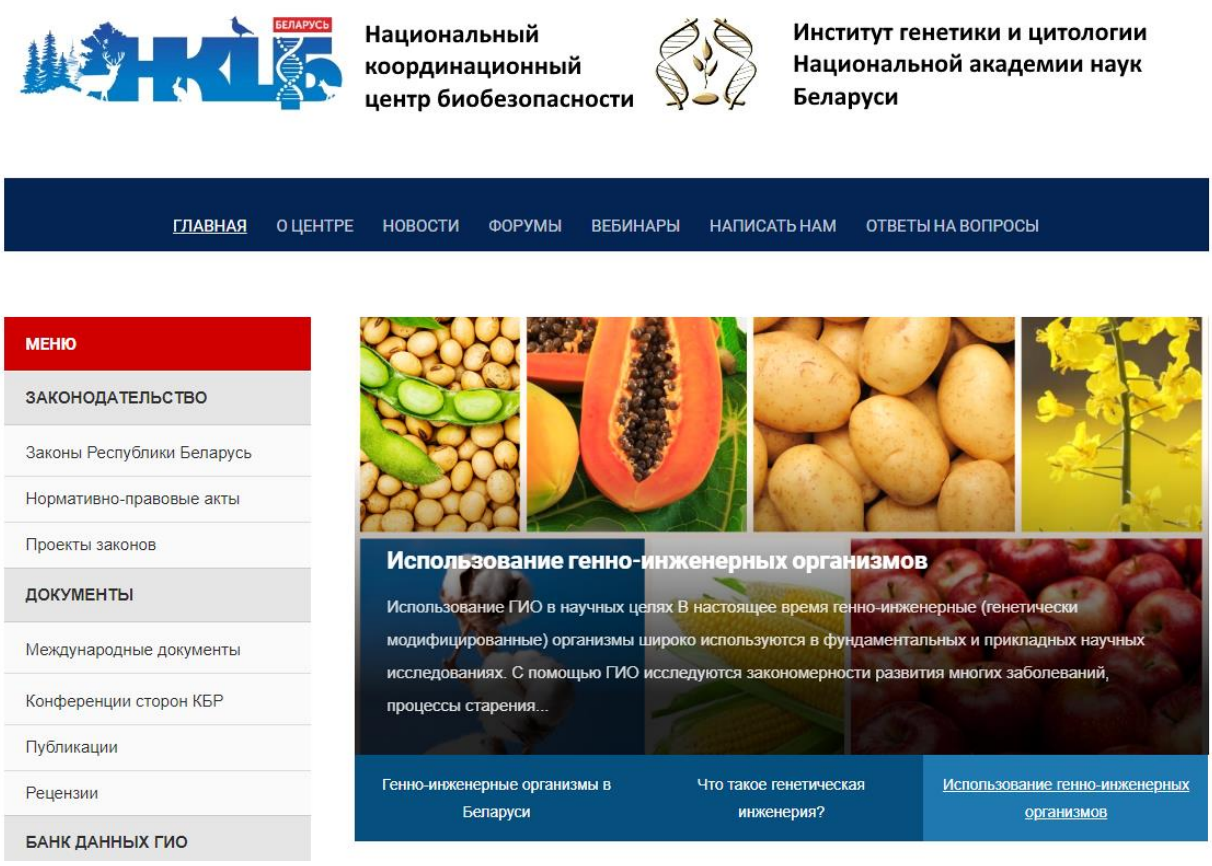


Figure 30 – The main website page of the National Coordination Biosafety Centre

All aforementioned information shall be placed with the NCBC Databank registered in the Register of Information Resources of the Republic of Belarus (Registration Certificate of May 16, 2019 No. 13419184013). In accordance with legislation in the field of safety in genetic engineering activity, the information shall

also be posted in full, except for confidential, by the NCBC on the national website biosafety.by registered in the Register of Information Resources of the Republic of Belarus (Registration Certificate of May 4, 2019 No. 1341918198).

The Databank includes the following sections:

Use of GEOs. The section provides up-to-date information on the use of GEOs in scientific research, for medical purposes, agriculture, top countries in GEO crops, genetically engineered animals and other areas of use.

GEOs in Belarus. This section provides information on the use of GEOs in the economic activity in Belarus, the release of GEOs into the environment for testing, the study of GEOs in self-contained systems, and information on organizations involved in such activity and the GEOs they are developing is provided.

Genetic engineered ingredients in food and feed. The section provides a review of the legislation of the Republic of Belarus in the field of labelling of GE products, GM lines of soybeans and maize authorized for use in the feeds in the Republic of Belarus, a list of food raw materials and food products subject to monitoring for the presence of GEOs in Belarus, analytical materials on the GMO detection prepared by the NCBC, a list of accredited Laboratories for GMO Detection for food raw materials and food products in Belarus, a GMO detection manual; a Register of Genetically Modified Organisms, genes and DNA sequences is provided in the form of cross-references to the BCH and GenBit Databases.

GMO detection. The section includes information in the field of accredited NCBC activity, including all information on testing of food, feed and raw material for food production for the presence of genetically modified ingredients (GMI) by year.

Public discussions. The section contains information on the risk assessment of possible adverse effects of GEOs for discussion by all stakeholders within the framework of the regulation procedure [61].

Risk assessments. The section contains full information on all GEOs directed for undergoing of a risk assessment of possible adverse effects of genetically engineered organisms on human health and the environment in accordance with [29; 61], including information on a risk assessment of possible adverse effects of

genetically engineered organisms, conclusions of the state expert examination on safety of genetically engineered organisms, minutes of the meeting of an Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus, minutes of public discussions, State Registration Certificates for new strains of GE microorganisms, GE animal breeds and GE plant varieties, as well as information on the personal composition of an Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus.

Experimental fields for testing of non-pathogenic genetically engineered organisms during their first release into the environment. The section contains full and reliable information about the experimental fields that meet biosafety requirements, where GEOs are tested in Belarus, including their passports and addresses.

In addition to the GEO Databank, the following sections are posted on the NCBC website updated with new information:

Legislation:

- Laws of the Republic of Belarus;
- Normative legal acts;
- Draft Laws.

Documents:

- International documents;
- Conference of the Parties to the CBD;
- Publications;
- Reviews.

The BCH website includes sections “Conferences” and “Projects”, which contain up-to-date information on national, regional and international conferences held by the NCBC and implemented International Scientific and Technical Assistance projects with all presentations and training materials. A “Webinar” section with information and training materials is provided, including about the

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” held for the employees of GMO Detection Laboratories and the employees of the customs authorities of the Republic of Belarus.

Links to the Biosafety Clearing-House to the CPB, the profile of Belarus on the BCH website and the LMO BCH shareable database, training materials of the UN Environment Program developed in the course of the BCH III project, links to the ABS NCC website, websites of the main bodies of the State administration in the area safety in genetic engineering activity of the Republic of Belarus and international organizations. The main page constantly updates news in the field of safety in genetic engineering activity, including new guidelines developed in the field of GEO detection and identification, risk assessment, and CBD Technical Series are published (Figure 31).

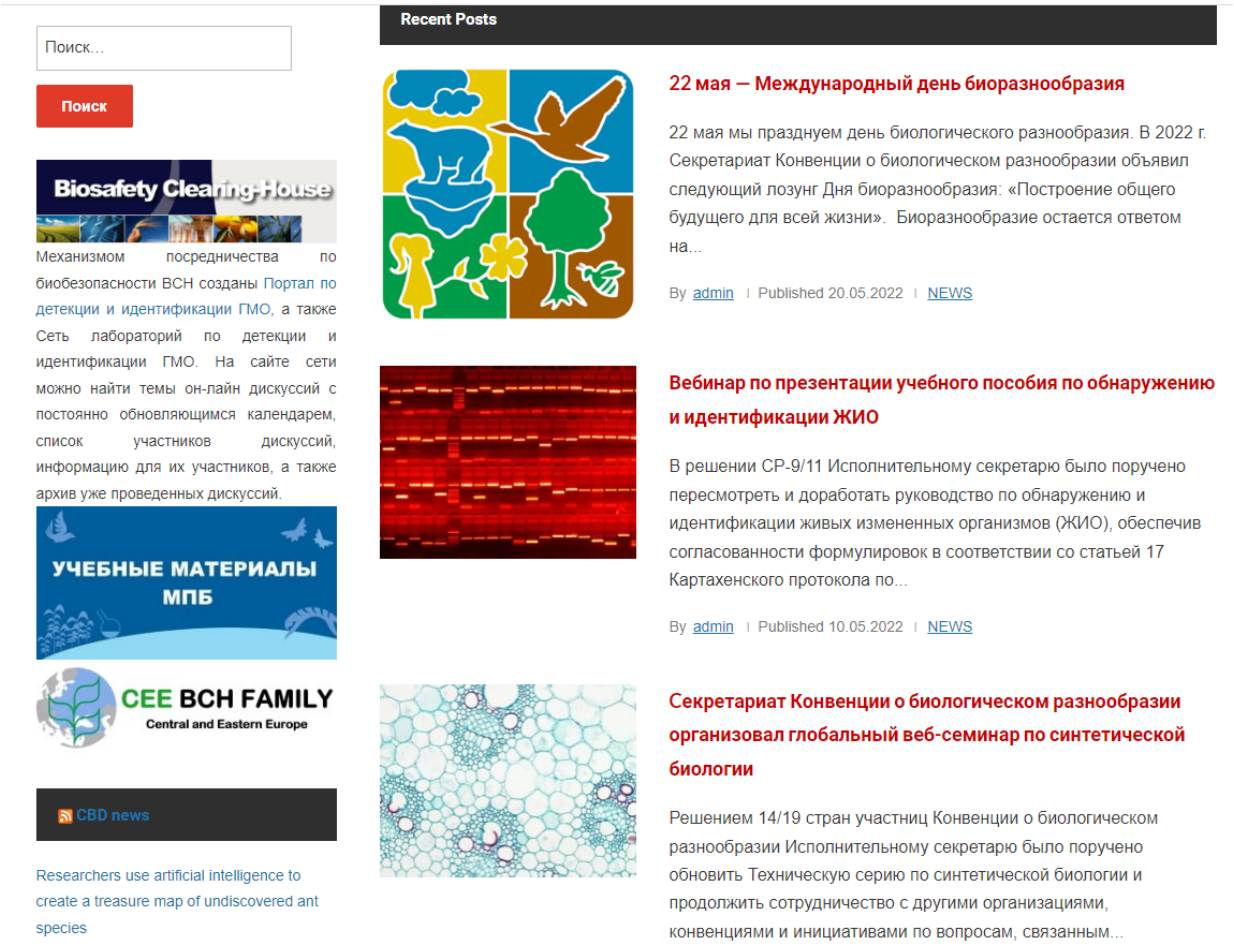


Figure 31 – News updates on the website of the National Coordination Biosafety Centre

Summing up, it is worth noting that despite a variety of Platforms that provide scientific, technical and legal information on GM organisms, they all work in synergy, supplementing information on GMOs, which undoubtedly enables users to get the most complete picture of the matter of interest for them. The information on databases presented in this book is not exhaustive, however, we have tried to present databases that provide comprehensive information about developed GMOs that are at different stages of commercialization and/or release into the environment, about nucleotide sequences inserted into the parent organism for the purpose of obtaining of GMOs, developed and validated methods for the detection and identification of GMOs. Such information may be of great use for GMO Detection Laboratories in developing of strategies for testing the diversity of GM lines.

2.3. GMO Detection and Identification Methods

All detection and identification methods of the GMOs of plant origin are divided into three groups:

– chemical;

– immunological;

– PCR method.

Chemical methods are aimed at determining of compounds that can be synthesized in cells in response to the insertion of foreign genes: novel mRNA, novel protein, enzymes, oligosaccharides, high molecular fatty acids, vitamins, hormones, etc. If the chemical composition of a food product changes as a result of genetic modification, chemistry methods may be used for its identification ─ chromatography, spectrophotometry, spectrofluorimetry etc. that identify a specific change in the chemical composition of a product. Thus, genetically modified soybean lines G94-1, G94-19, and G168 have a modified fatty acid composition, a comparative analysis of which showed an increased content of oleic acid in genetically modified soybean (83.8%) compared with its traditional analogue (23.1%). The use of gas chromatography in this case makes it possible to detect the

genetic modification of soya even in such products that do not contain DNA and proteins, e.g. refined soybean oil [38].

Immunoenzyme (immunological) analysis are based on the use of specific antibodies to bind a modified protein and their subsequent quantification. They are the simplest in terms of performance, of a relatively low cost, and allow identifying a specific protein that carries a novel trait. Currently, test systems that may be used to quantify a modified protein in products, such as soy protein isolates and concentrates and soy flour, have been developed. One of the types of an enzyme immunoassay, an ELISA test, involves the detection of specific proteins expressed in transgenic plants. A commercial ELISA test example is demonstrated by Figure 32.

Figure 32 – Reagents kit for the GMI detection using the immunoenzyme method [85]

One of the limitations of this method is its low efficiency in evaluating of products that have undergone any kind of technological treatment (high temperature, acidic medium, and enzymatic treatment) that causes almost complete denaturation of DNA molecules. It is also necessary to take into account the fact that in many cases the level of protein expression in different parts of plants is different, and often in organs used for food the expression level can be very low (below 0.06%), which complicates an enzyme immunoassay. When examining, for example, sausage and confectionery products, baby food, nutrient and dietary food and supplements, an enzyme immunoassay is not appropriate.

In order to detect GMOs in the grain flow, enzyme immunoassay techniques with express kits are used [14]. The advantages of this technique are that it may be used for the qualitative analysis for the presence/absence of one or many modified proteins with the minimal provision of laboratory equipment directly at the production facility.

For the quantitative evaluation of the presence of a GM protein, an enzyme-linked immunosorbent assay (ELISA) is used. ELISA is based on a specific antigen-antibody reaction. Previously, the minimum amount of a GM protein had to reach at least 1% to obtain a sufficient signal for detection [1]. Currently, there are already test strips for determining the content of GMOs with an accuracy of 0.1%. An example of a commercial GMO test strip is demonstrated by Figure 33 [16].

Figure 33 – Test strips for determining of GMO content in the raw material [75]

The Polymerase Chain Reaction (PCR) method. The PCR method lies in the detection of a foreign insertion/recombinant DNA. It has several modifications and is currently most wide-spread, since it aims to directly detect a foreign insertion in modified genome sequence. However, in this case, DNA is difficult to detect in products processed at high temperatures or in the conditions of aggressive chemical compounds, but a list of products limiting the potential of this method is not that high: protein hydrolysates, modified starches, sugar, ethyl alcohol, and refined oils. Reference Laboratories recognized across the globe, including the Joint Research

Center of the European Commission, have declared this method as a standard one. The detection of GMOs using PCR is performed in such countries as Germany, Italy, Spain, Ireland, Portugal, Slovenia, Switzerland, Norway, Austria, Belgium, Canada, Denmark, Finland, Japan, South Korea, Sweden, Great Britain, the Russian Federation, the Republic of Belarus and many other countries.

A real-time polymerase chain reaction (RT-PCR) continues to lead the way in the detection of GMOs. RT-PCR has been used to detect gene modifications in both raw materials and processed products, but in addition to it, such GMO detection methods as microarrays, PCR with subsequent detection by capillary gel electrophoresis (CGE), loop-mediated isothermal amplification, digital PCR and next generation sequencing are being developed [10; 16].

Despite the fact that real-time PCR is the most effective method for the detection of GMOs and the qualitative and quantitative determination of GM lines, in order to simultaneously determine a number of targets in one tube and reduce the cost of an assay, a qualitative PCR method with the primers labeled with fluorescent dyes is used with the subsequent determination of built-in nucleotide sequences using capillary gel electrophoresis (CGE). The simplicity and accuracy of this method was demonstrated for the simultaneous detection of 9 targets at once in one test tube: GM maize varieties T25, GA21, TC1507, MON863, MON810, and NK603; genetic constructs BT176 and BT11, and the maize housekeeping gene hmga [2]. Figure 34 shows the scheme for detecting of GMOs using CGE.

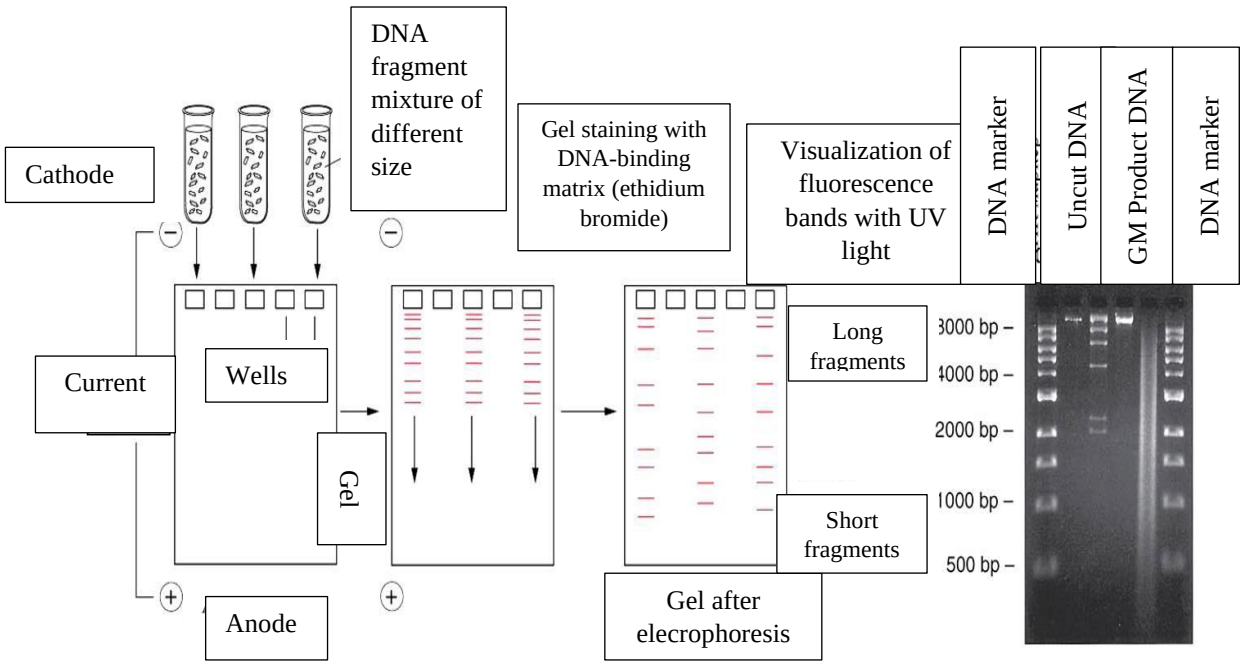


Figure 34 – GMO detection scheme using CGE [32]

The limit of detection for CGE was up to 0.1% for each GM line. To date, various primers for multiplex PCR have been developed for detecting of three or more varieties of GM cotton, soya, and maize [3; 4; 9]. However, the aforementioned method has a number of drawbacks, since it requires painstaking efforts during the development of primers and optimization of assay conditions. Its implementation also requires specialized devices, which may not always be available to the laboratory. Since this technique is not usually used for the quantification of transgenic events, there is a need for its authentication and validation [10; 11].

Microarray technology (microarrays, DNA arrays) — technology for the high-throughput detection of GMOs. When using a microarray, a large number of genetic elements are detected in parallel in complex DNA samples in one assay. Diminutiveness, high sensitivity and performance are the main advantages of this technology [12]. Figure 35 shows a photo illustration of microarray technology. The key idea is that many specially designed probes to GMO and probes that duplicate a DNA sequence in the sample are placed on a solid surface in small areas in the form of dots in rows intersecting at a right angle. DNA isolated from a sample is subjected

to hybridization with an array of probes, and then it is labeled with fluorescent dyes. During the hybridization stage, the labeled DNA segment remains bound to probes based on the principle of complementarity. The longer the length of complementary DNA sequences, the stronger bond will be. After hybridization, the sequences that did not bind to probes are removed, and then the fluorescence intensity of each point of the surface is measured with immobilized DNA probe complexes [14].

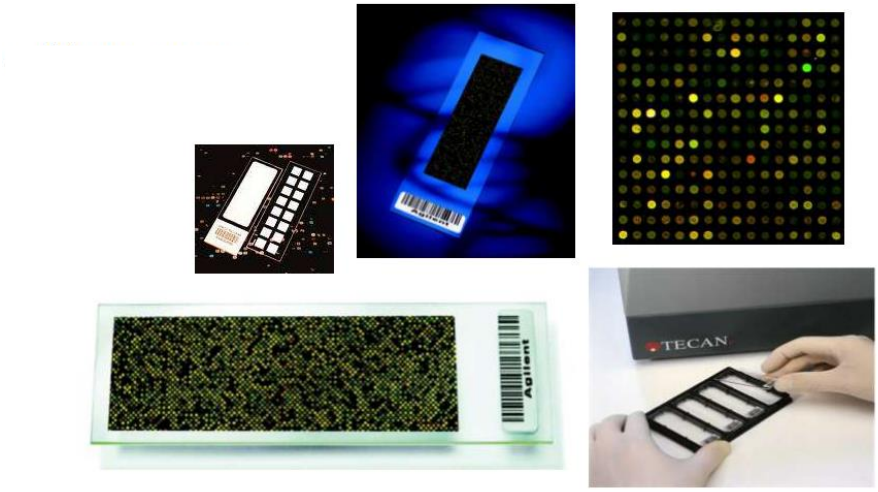


Figure 35 – Microarray technology [62]

Loop-mediated isothermal amplification (LAMP) is a relatively new technology that has been recently applied to detect the transfer of foreign genes [5; 6]. LAMP stipulates the use of four different primers that identify at least six different segments of desired DNA. The reaction is initiated by one of primer pairs having both the same and opposite sequences of the target DNA region. The reaction takes place at a constant temperature of 60-65℃, and then another pair of primers is involved in the loop formation. The isothermal amplification product is identified by the “ladder” pattern of DNA distribution after agarose gel electrophoresis. LAMP is a relatively simple and efficient PCR variant that does not require expensive equipment. A water bath with a heating block is sufficient to run a reaction, but this method also has its limitations. One of them is associated with the difficulty of selecting primers associated with the need to combine their specificity to the selected gene region and the low probability of dimer formation among them. The other one is the difficulty associated with deciphering of assay results with a small amount of a product. Thirdly, there is a high risk of

contamination and, and in addition, there are huge difficulties in the development of multiplex PCR using the loop-mediated isothermal amplification technology.

Droplet Digital PCR (ddPCR) is a technique enabling to overcome the problems associated with performing quantitative PCR, especially, the presence of PCR inhibitors or a small number of copies of transgenic DNA. It is one of the most reliable methods currently in use for the quantitative evaluation of GMOs, especially for the identification of unauthorized GM lines the content of which in food and feed is normally extremely low. When conducting digital PCR, a probe is placed in a large number of isolated microwell reactors. At that, a composition of the PCR mixture for the reaction is the same as for quantitative PCR (binding buffer, polymerase, primers, fluorescent probes or a dye). After thermal cycling of the entire set of microwells-reactors, the fluorescent signal is detected using a special spectrophotometer (reader). The GMO detection scheme using ddPCR is shown in Figure 36. Despite the advantages of ddPCR in comparison with RT-PCR, this method is more laborious and cost-intensive for routine laboratory analysis where urgent analysis is required and cannot wait to fill all the holes of the plate for PCR.

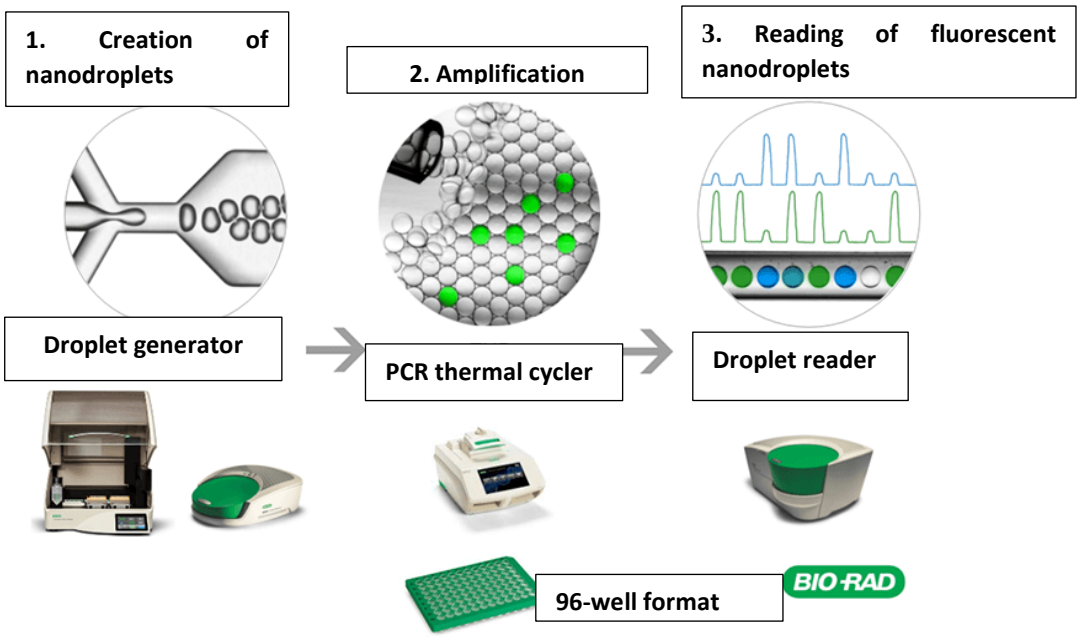


Figure 36 – GMO detection scheme using ddPCR [65]

The methods used for the detection and identification of GMOs obtained using well-known modern biotechnologies, e.g. agrobacterial or bioballistic transformation, were described above. At that, the development of new GMO generations, which differ from previous generations obtained by "traditional" methods of genetic engineering [96], has been growing exponentially in recent years. These methods include CRISPR/Cas9, CRISPR/Cas3 and other CRISPR/Cas modifications [78] that are beginning to be actively used in plant breeding. At the same time, difficulties arise with regard to the control of such organisms, since it is currently possible to determine that this is a novel organism obtained using modern biotechnology only if a DNA sequence or a gene not originally present in this plant is inserted. GMO testing is mainly based on the detection of recombinant DNA inserted during transformation, which makes it possible to distinguish GMO from traditional breeding varieties [86; 91]. In the case, where several nucleotides are removed or added, it is hardly possible to prove that this is not a process of traditional breeding or mutagenesis. For the same reason, difficulties arise with regard to the identification of such organisms using conventional detection methods.

For the detection of GMOs obtained using CRISPR/Cas technology, several other alternative multiplexing strategies have been considered, such as a combination of PCR and capillary gel electrophoresis, a combination of PCR and microarrays, Luminex technology (biotinylated targets amplified using single or multiple PCR assays and analyzed using flow cytometry) [11]. In order to increase the specificity of real-time PCR when detecting single nucleotide polymorphisms, it is proposed to use an adapted version of real-time PCR, e.g. with the use of blocked nucleic acids (LNA), or to conduct RNase H-dependent real-time PCR [79]. Some other modifications of real-time PCR have been developed and are commercially available. An example is KASP, where KASP primers (usually three) are specifically designed to target a single nucleotide polymorphism (SNP) of interest, an insertion or a deletion of short sequences in the genome (InDel) [8; 17].

Next generation sequencing (NGS) is one of the most recent state-of-the-art methods being developed for the identification of GMO. This technology allows for

parallel mass decoding of a DNA region sequence [13]. NGS is an effective tool for detecting of transgenic organisms in the absence of any information about foreign genes in GMO [14], for identifying of a gene insertion region, DNA regions adjacent to the gene, as well as the number of copies of an inserted gene [10]. There are two main types of NGS: single-region sequencing and whole-genome sequencing [13]. Upon availability of information on the insertion region of a foreign gene, sequencing of a separate region may be carried out that considerably saves time and an assay cost per sample. But there are cases, where the region of a gene insertion is not known, and it is necessary to determine a foreign DNA sequence at an unknown location in the genome. In this case, a DNA library is formed containing information about an inserted gene. Using bioinformatics methods, it is possible to compare the obtained data with the information from databases about the genome of an investigated species and known gene modifications [7]. The information obtained allows the development of new primers for the amplification of a gene from an unknown insertion region. Disadvantages of this technology lie in its high cost and the need for highly qualified specialists and equipment for data manipulation and their analysis. However, despite methodological difficulties, a number of authors suggest that in the near future this technology will become an accurate tool enabling a search for new GMO [10].

Approaches to the Detection and Identification of Authorized and Unauthorized GMOs

Routine screening for the detection of GMOs includes the following steps:

- sample preparation;
- DNA extraction;
- qualitative analysis of screening sequences (identification of authorized and unauthorized lines as appropriate);
- quantitative analysis and calculation of uncertainties in measurements.

When conducting research using real-time PCR, it is necessary, with a view of preventing contamination, to divide working areas territorially in such a way that

a laboratory process would be one-directional coinciding the principle “Point of no Return” [66]:

- premises for the acceptance and registration of a sample;
- premises for the sample preparation;
- premises for DNA extraction;
- premises for the preparation of a reaction mixture and DNA amplification.

At all stages, PCR analysis must be performed in premises equipped with bactericidal irradiators, using appropriate specialized equipment and by qualified personnel.

Preparation of samples for research shall be carried out in compliance with GOST ISO 21571-2018, instructions for the use of reagents for the DNA purification of commercial test systems. Also, a process of preparing of samples for GMO detection research is described in detail in the training manual on the detection and identification of living modified organisms developed by the Secretariat of the Convention on Biological Diversity in cooperation with the Network of Laboratories for the Detection and Identification of LMOs [101].

The main principle involves the isolation/extraction of DNA present in the sample matrix and then simultaneous or subsequent purification of DNA from PCR inhibitors. The most common method for extracting of DNA from a wide variety of matrices is phenol-chloroform. This method includes a lysis step (thermal lysis in the presence of sodium dodecyl sulfate (SDS) and highly concentrated ethylenediaminetetraacetic acid (EDTA)) and subsequent removal of contaminants (e.g. lipophilic molecules, polysaccharides and proteins) and nucleases from the aqueous phase containing DNA, using phenol and chloroform. Final ethanol precipitation concentrates DNA and removes salts and residual chloroform [25].

Taking into account aggressive and dangerous properties of phenol, it is advisable to use, as an alternative, the method of DNA extraction from food products, feed, and the agricultural raw material based on DNA binding to silicate sorbents in the presence of chaotropic salts and the subsequent elution of DNA in a

low-salt buffer. In order to improve the lysis of samples, they should be treated with a lysing solution containing proteinase K [34].

An approximate set of commercial reagents for DNA extraction is demonstrated in Table 3.

Table 3 – Complement of reagents for DNA isolation

Composition	**Complement**
DNA sorbent	1 test tube – 1,5 ± 0,05 ml
Lysing solution	1 test tube – 0,6 ± 0,05 ml
Sorbent solution	1 flacon – 35 ± 1 ml
Cleansing solution	1 flacon – 50 ± 1 ml
Eluting solution	1 flacon – 4 ± 0,1 ml

Using this commercial test system as an example, let's consider DNA extraction in more detail:

– Add 400 µl of a sorbing solution and 12 µl of a lysing solution to each tube. Add an exogenous internal control sample (ICT) in a volume of no more than 10 µl;

– Add 100 µl of sample to each tube with sorbing and lysing solutions. Add 100 µl of an elution solution to a tube marked with NEC (negative extraction control); in a PEC tube (positive extraction control) – 100 µl of a positive control sample (PCS);

– Mix samples using Vortex for 1 min and place in a thermostat preheated to 65°C for 1 hour. Depending on the specifics of a sample, it is allowed to change the time interval of incubation from 1 min to 3 hours;

– If a sample is turbid or precipitation is formed, it is necessary to centrifuge samples at 10 000 rpm for 5 minutes. Transfer the resulting supernatant into a new tube of 1.5 or 2 ml;

– Resuspend the DNA sorbent, intensively mixing on the Vortex. Add 30 µl of the resuspended DNA sorbent to each tube with a separate tip, and then close the

caps tightly. The samples must be periodically (2 times) mixed on the Vortex for 2 minutes;

– Precipitate the DNA sorbent at 10 000 rpm for 30 sec. Remove the supernatant. Add 300 µl of a cleansing solution to each sample and mix thoroughly on the Vortex;

– Precipitate the DNA sorbent at 10 000 rpm for 30 sec. Remove the supernatant. Add 500 µl of a cleansing solution to each sample and mix thoroughly on the Vortex;

– Precipitate the DNA sorbent at 10 000 rpm for 30 sec. Remove the supernatant. Add 500 µl of a cleansing solution to each sample and mix thoroughly on the Vortex;

– Precipitate the DNA sorbent at 10 000 rpm for 1 min. Remove the supernatant. Place test tubes with the sorbent with open caps in the thermostat at 65°C for 5 min to dry the DNA sorbent;

– Add 50 µl of an elution solution to each sample, mix on the Vortex and incubate at a temperature of 65 °C for 5 min;

– Precipitate the DNA sorbent at 10 000 rpm for 1 min. A supernatant contains the purified DNA ready for PCR. For long-term storage of samples, it is recommended to transfer the supernatant to new tubes. It is allowed to store the obtained DNA sample at a temperature not exceeding 4°C for twenty-four hours, at a temperature not exceeding minus 16°C within a period of three months; at a temperature not exceeding minus 68°C within a period of one year.

With the DNA samples obtained at the extraction stage, an amplification reaction of a DNA region is carried out using primers specific to this region and the Taq polymerase enzyme. The PCR method is based on the ability of DNA polymerases to carry out the targeted synthesis of a complementary DNA strand using an existing single-stranded DNA matrix, ramping a small oligonucleotide primer complementary to the region of this matrix up to several thousand or even tens of thousands of chains. By raising the temperature, the reaction can be stopped with the subsequent denaturation the DNA obtained. If there is an excess of a primer

in the reaction mixture, then by significantly lowering the temperature so that the primer could again bind to the same complementary DNA region, and by adding a new portion of an enzyme, it is possible to set the temperature required for the polymerization reaction again, and thus running the reaction once again, to increase the amount of the previously obtained product. Multiple (cyclic) repetition of this procedure makes it possible to accumulate a significant number of copies of the DNA region starting with the given primer. At that, if a thermostable DNA polymerase is used, then the DNA "copying" reaction may be run without adding a fresh portion of the enzyme after each cycle.

Each PCR cycle includes the following stages:

- DNA denaturation;
- annealing of primers;
- elongation of the DNA chain.

The first stage includes the denaturation of DNA present in the sample. To do this, the reaction mixture, including a DNA matrix with a DNA region to be amplified, is heated up to 92-96 ºC, as a result of which double-stranded DNA molecules unwind with the formation of two single-stranded molecules.

At the second stage, the primers are annealed (attached) to the target DNA with the formation of short double-stranded DNA regions required to initiate DNA synthesis.

At the third stage, DNA polymerase binds to the formed "primer-matrix" complexes, and the elongation of a DNA chain occurs: simultaneous copying of DNA from two primers complementary to DNA regions on opposite chains and located in such a way that DNA polymerization from one primer leads to the DNA chain synthesis, which at a certain distance contains a DNA region complementary to another primer. DNA chains synthesized during the first cycle of PCR serve as matrices for the second cycle of amplification. In subsequent amplification cycles, amplicons serve as a matrix for the synthesis of more and more new chains.

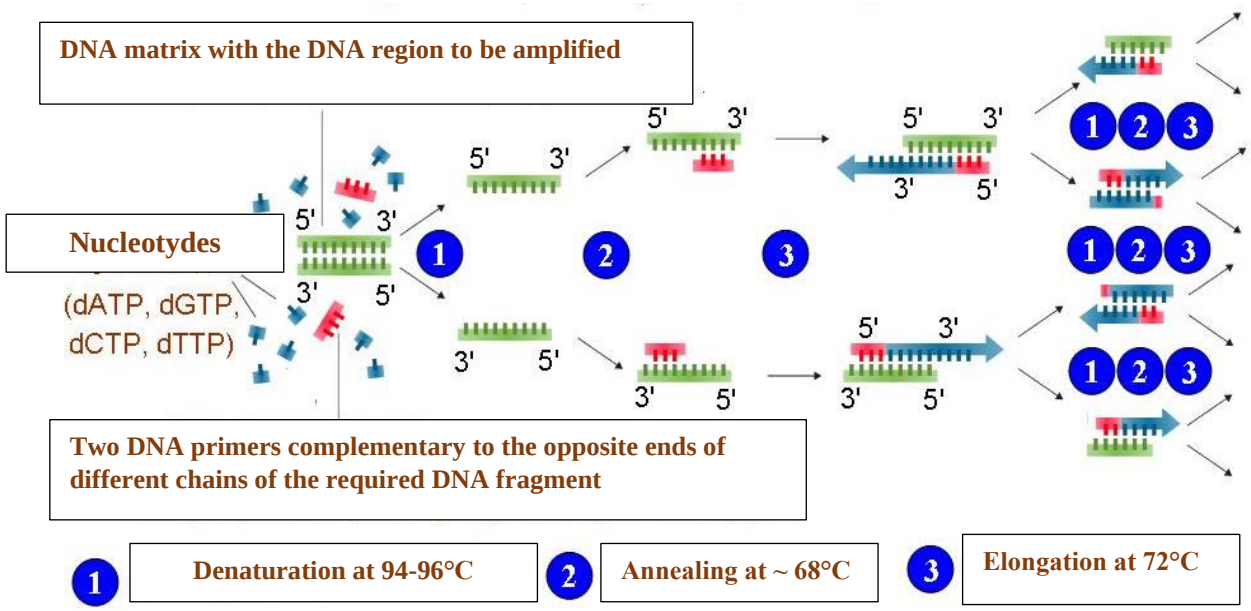


Figure 37 – PCR process scheme [69]

To date, there are several main methods for detecting of PCR results:

Electrophoretic:

– in agarose gel;

– in polyacrylamide gel;

Fluorescent hybridization:

– registration of product after the completion of the amplification reaction;

– detection of reaction product after the amplification reaction is over "Endpoint Analysis";

- real-time product detection.

An electrophoretic detection method is based on the separation of DNA molecules by size. In this case, visualization of results is carried out in the agarose or polyacrylamide gel plate adding a special DNA dye, e.g. ethidium bromide. When pouring using combs, wells are formed in the gel into which amplification products are added. The gel plate is placed in a horizontal gel electrophoresis apparatus and a constant voltage source is connected. Negatively charged DNA starts moving in the gel from a negatively charged cathode to a positive anode. At that, shorter DNA molecules move faster than long ones. Then, the gel is placed on a transilluminator

filter, where the UV energy absorbed by the DNA is transferred to the dye causing it to fluoresce.

The most common and practical method of fluorescence-hybridization detection is real-time product registration. This type of detection is based on the use of intercalating dyes (EtBr, SYBR Green I, SYBR Gold, LCGreen, SYTO 9, and Eva Green) or fluorophores as part of oligonucleotide hybridization probes that have the ability to glow as a result of the absorption of light energy and the analysis of results during amplification. Compared with the electrophoretic method, real-time detection of analysis results minimizes the risk of contamination with PCR products and thus reduces the number of false positive results.

An approach to detecting and identifying of authorized and unauthorized GEO is quite laborious and includes screening of main GM sequences, which makes it possible to demonstrate that a given product contains GM components, as well as specify which GM lines it may contain. Depending on the components that make up the test sample, a list of screening sequences may differ. During the planning phase of an analysis, a researcher should predict all possible specific genetic elements to identify GMO and suggest the presence of specific GM lines after detecting of individual screening sequences in the analyzed sample. For this purpose, you can use special databases (e.g. GMO-Matrix) demonstrated in Section 2.2.

At present, the main genomic sequences by which screening is performed are CaMV 35S, FMV 35S, and SsuAra promoters, NOS and E9 terminators, as well as pat, bar, and cp4EPSPS nucleotide sequences. By the detection of 35S, FMV, and NOS screening sequences, it is possible to identify all permitted maize lines in the Republic of Belarus [70], since each of them contains one or more screening sequences (CaMV 35S, FMV 35S, and NOS).

As an example, let's have a closer look at the screening scheme for a multicomponent soya-based sample. Using software, e.g. GMO-Matrix, to predict annealing of screening elements with the possible subsequent identification of soybean lines, it is necessary to search by a taxon, selecting the common name “Soybean (*Glycine max*)”.

As a result of such a search, it is possible to find out the probability of annealing followed by the determination of GM soya lines the presence of which is expected in the soybean sample, using the following screening elements: CAMV P-35S, CP4-EPSPS, P-FMV, P-NOS, T-NOS, T35SpCAMBIA, pat, bar, cry1Ab/Ac, nptII, and tE9. From the entire spectrum of screening elements presented in the database, a combination of sequences of two promoters CAMV P-35S, P-FMV, and one terminator T-NOS and the sequence of the sense gene Cry1Ab/Ac will allow identifying seven out of nine GM soybean lines authorized for use at present time in the Republic of Belarus [70]. The presence of the GM soybean line MON87701, containing only the SsuAra promoter, may be identified in the test sample using reagents for the detection of the SsuAra promoter, the E9 terminator, and the cry1Ac sense gene, or using a specific commercial kit for this line. At the same time, the soybean line BPS-CV127-9 may only be identified using a specific commercial kit for this line. Since the GMO-Matrix program cannot predict the hybrid MON87701 x MON89788 allowed in the Republic of Belarus, a conclusion about the presence of this hybrid in the sample should be made after experimental verification of the presence of individual lines MON87701 and MON89788.

The screening scheme (Figure 38) based on the detection of CaMV 35S, FMV 35S, and SsuAra promoters, and NOS and E9 terminators, the nucleotide sequences of the gene npt II, pat, bar, and cp4epsps for soybean describes the GMO detection procedure step by step.

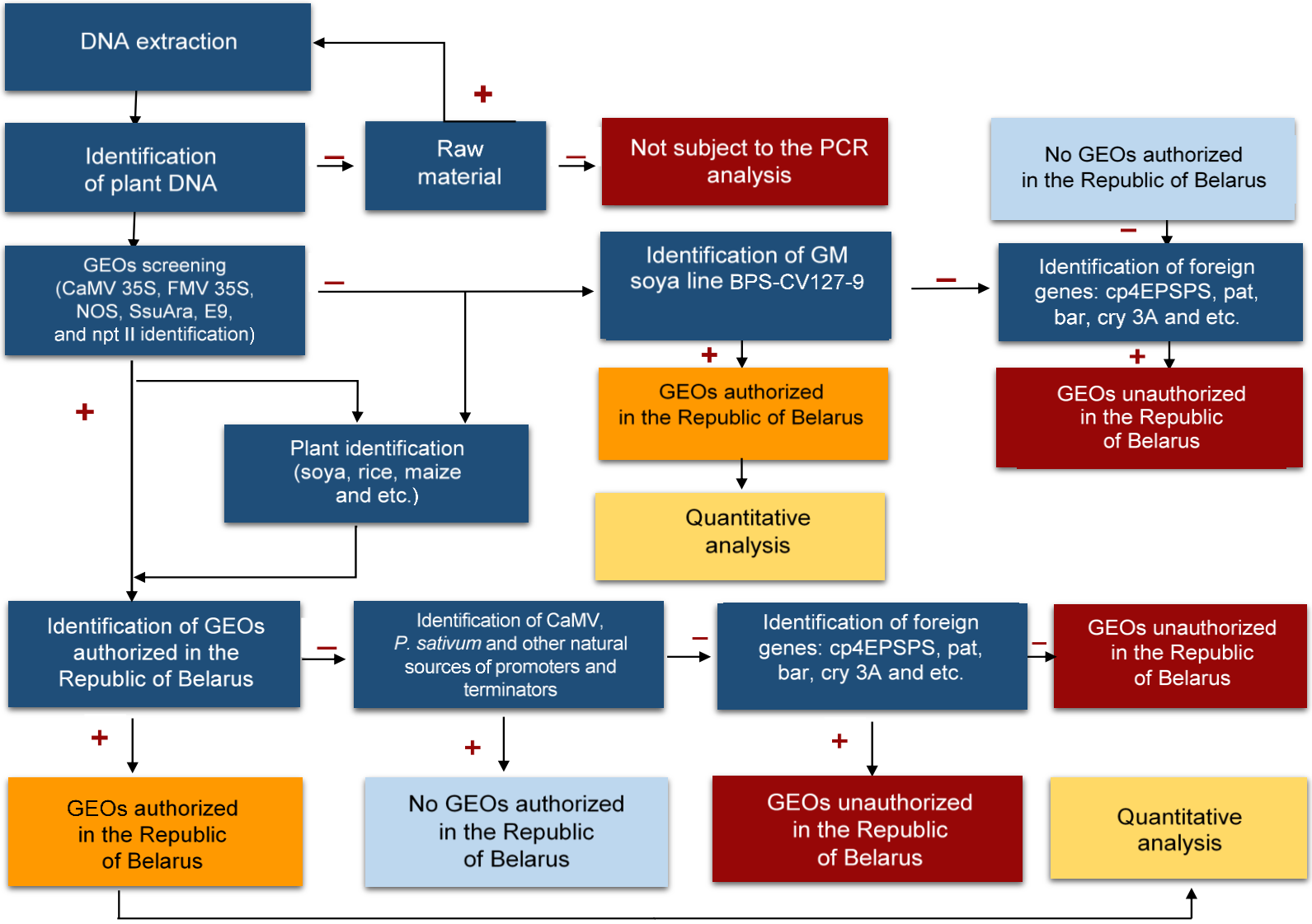


Figure 38 – Screening scheme [40]

With a view of searching for information about genetically modified lines authorized in the Republic of Belarus and EAEU, specialized search websites may be used:

– GM plant lines that have passed a risk assessment and authorized in the EAEU territory are provided in the Unified Register of State Registration (uniform form of the Customs Union) at the link as follows: https://portal.eaeunion.org/sites/odata/_layouts/15/Portal.EEC.Registry.Ui/DirectoryForm.aspx?ViewId=1631d8b8-efd5-4a46-80d9-e252e7986bb&ListId=0e3ead06-5475-466a-a340-6f69c01b5687&ItemId=231#;

– Register of State GML Registration Certificates (a single form of the Customs Union, part of the Russian Federation) of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing is available at the link as follows: http://fp.crc.ru/evrazes/?type=max;

– A list of GML authorized for circulation in the Republic of Belarus can be found at the NCBC website at: http://www.biosafety.by/wp-content/uploads/2019/01/razreshennye_linii.pdf;

– A list of GML authorized in the Russian Federation and the European Union can be found at the GenBit website https://www.genbitgroup.com/ru/gmo/gmodatabase/ using RUS or EU keywords for a search;

– A search for GML authorized in other non-EEU countries may be carried out using the Databases of the Biosafety Clearing-House to the Cartagena Protocol on Biosafety at the link https://bch.cbd.int/en/, the OECD "BioTrack Product Database" at https://biotrackproductdatabase.oecd.org or the Database on Authorized GM Events of the International Service for the Acquisition of Agri-biotech Applications at http://www.isaaa.org/gmapprovaldatabase.

CaMV 35S promoters (from cauliflower mosaic virus) and/or FMV 35S (from figwort mosaic virus) are contained in 76% of all GM plants registered across the globe and the NOS terminator (from the bacterium *Agrobacterium tumefaciens*) is present in 66 % correspondingly. However, now other regulatory sequences are more frequently used during the development of novel GMO lines. Therefore, the

detection of main regulatory sequences (CaMV 35S, FMV 35S, and NOS) during the screening of GMOs may not be sufficient to identify all authorized and unauthorized GM lines. Lines that have not passed the state risk assessment procedure in this or that country shall be recognized as unauthorized.

Information on the specific elements and sense genes that constitute the composition of unauthorized GM soybean lines allowing effective screening for their detection is demonstrated in Table 4.

Table 4 – A list of GM soybean lines unauthorized in the territory of the Republic of Belarus

GM line	**Sense gene**	**Promoter**	**Terminator**
DAS-81419-2	Cry1Ac, cry1F, pat	AtUbi10, CsVMV	t-ORF-23, t-ORF-1
DAS-68416-4	aad-12	AtUbi10, CsVMV	t-ORF-23, t-ORF-1
GU262	pat	p35S	t35S
GU 94-1	gm-fad2-1	p35S, p-7S	tNOS, t-phas
GU-94-19	gm-fad2-1	p35S, p-7S	tNOS, t-phas
G 168	gm-fad2-1,	SAMS, KTi3	t-gm, t-KTi3
DP-305423	gm-hra		
DP-356043	gat, gm-hra	SAMS, SCP1	t-Pinil, t-gm
MON87769	Pj.D6D, Nc.Fad3	p-75	tE9, ttml3
MON 87705	cpt4epsps, fad2, fatb	p-7S, FMV, p-TSF1	tE9
MON 87708	dmo	p-PC1SV	tE9
MON 87751	cry1A.105, cry2Ab2	pActin2, pSsuAra	t-MT, t-Pt1
MON 87712	CS-BOX32-ARATH, cpt4epsps	FMV, p-e35S, p-TFS1	tE6, tE9
W62	bar	p35S	Tnos, T-Ssu
W98	bar	p35S	Tnos, T-Ssu
IND410 (Verdeca HB4)	CS-HD4, bar	p-HD4, p35S	tNOS

During the period of data submission to the NCBC by Republican Accredited Test Laboratories in the field of GMO detection (1998-2021), MON 87705 and MON 87708 were identified from all of the aforementioned unauthorized GM lines.

At that, in 2021, in accordance with the Directive of the Department of Veterinary and of Food Supervision of the Ministry of Agriculture and Food of the Republic of Belarus of October 29, 2021 No. 06-11/3368, GM soybean lines MON87708 and DAS 44406 were included in the list of lines authorized in the Republic of Belarus.

In the case, where it is impossible to detect unauthorized GM lines according to the screening scheme, they should be identified only using a specific commercial kit for this line.

For the types of GMO other than soybean and maize, the presence of screening sequences should be verified using the aforementioned databases, which also helps pre-determine the presence of authorized and unauthorized GML.

With a view of quantification of GMOs, and GM lines in particular, in food products, feed, and the agricultural raw material, the use of quantitative real-time PCR is required.

Let’s consider a procedure for the quantification of GMOs using one of the commercial test systems as an example. The analysis includes the steps as follows:

– DNA extraction (in the case of no preliminary screening; if screening was carried out, then the resulting material of extracted DNA may be used);

– Preparation of the PCR mixture;

– Analysis and interpretation of the results obtained.

Let’s consider an example, where the total reaction volume is 25 µl, the DNA sample volume is 5 µl.

To prepare the PCR mixture, unfreeze all reagents (if necessary), mix and discharge drops using short-term centrifugation.

In addition to test samples (N), each amplification setting should include three control assays: a negative extraction control (NEC) – 1 tube, a negative PCR control (K-) – 1 tube, and a positive PCR control (K+) – 1 tube.

To prepare the Master Mix in a 1.5 ml test tube:

$V = 12,5 \cdot (N + 7,5)$ µl of the PCR reagent + $7,5 \cdot (N+7,5)$ µl of primers,

where N – the number of test samples without control reactions.

Mix the resulting mixture by turning the tube five times, precipitate by short-term centrifugation and add 20 µl to the microtubes in which amplification will take place. Using a tip with a filter, add 5 µl of DNA of the studied samples to the prepared tubes.

In order to quantify, for example, the content of the 35S promoter or identify a specific GM line, standards, corresponding to the purpose of the study, are used in the concentration range of 40 – 400 000 copies. 5 µl of the corresponding standard and 20 µl of the premix are added to individual strips that do not contain the sample under study.

The next step is to set up control amplification reactions:

– negative extraction control (NEC) – add 5 µl of NEC + 20 µl of premix to the tube;

– negative control (K-) – add 5 µl of NEC + 20 µl of premix to the tube;

– positive control (K+) – add 5 µl of PEC + 20 µl of premix to the tube.

Place the tubes prepared for PCR into the amplification block. Program the device, according to the manufacturer's instructions, and perform real-time PCR.

Amplification parameters for the C1000 Touch Thermal Cycler CFX 96 Real-Time PCR are demonstrated in Table 5.

Analyze measurement results using the thermal cycler software. The research result is calibration curves and the calculated number of copies of lectin and the GM soybean line in the sample using the introduced values of standards.

Calculation of the GM soybean line percentage is performed according to the formula:

$$X = \frac{Q_{GM}}{Q_L} \cdot 100\ \%,$$

where X – the GM soybean line percentage, %;

Q_{GM} – the number of GM soybean line copies, copies/µl;

Q_L – the number of lectin copies, copies/µl.

Table 5 – Amplification parameters [35]

Step	Temperature, °C	Time, c	Number of cycles
Initial denaturation	95	120	1
Denaturation	95	10	10
Annealing/Elongation	63	30	
Denaturation	95	10	30
Annealing/Elongation/Detection by FAM/Green, HEX/Yellow, Rox/Orange, Cy5/Red channels	63	30	

Also, to automate calculations and their interpretation, the template (if any) of a commercial test system may be used.

In accordance with GOST ISO/IEC 17025-2019 “General Requirements for the Competence of Testing and Calibration Laboratories”, each accredited Testing Laboratory must have and apply procedures for evaluating of measurement uncertainties. In order to assess the accuracy of the results obtained, the measurement uncertainty is used [31]. Uncertainty Estimation Techniques — a document containing a mathematical analysis of measurement accuracy.

Uncertainty of measurement results on the quantitative content of GM soybean lines by real-time PCR in food products, feed and the agricultural raw material shall be calculated in compliance with STB ISO 5725 requirements [74].

When evaluating the accuracy of quantitative methods used for determining the GMO content, measurement uncertainty is more often estimated using an empirical approach.

The term “accuracy” includes a combination of a random error (precision) and a total systematic error (correctness) (Figure 39).

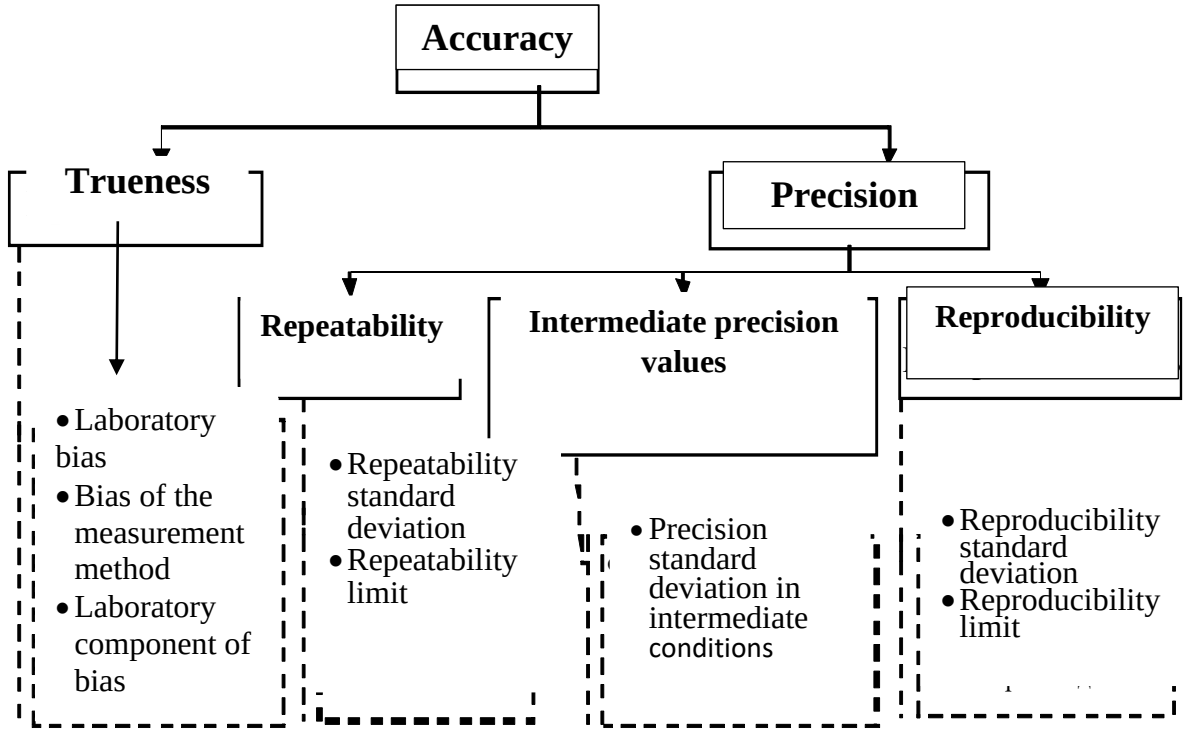


Figure 39 – Accuracy (correctness and precision) of test results [31]

In order to assess intermediate precision (within-laboratory reproducibility), it is necessary that:

– the samples under study contained different concentration levels of GM soybean lines;

– the samples should be analyzed twice and independently of each other in two parallels (different operators, different equipment, and different time intervals).

Correctness may be assessed by calculating the laboratory bias – the difference between the mathematical expectation of the measurement results obtained in a particular laboratory and the accepted reference value.

To calculate measurement uncertainty, a researcher needs to:

– get the measurement result;

– assess accuracy indicators;

– calculate the standard uncertainty;

– calculate the expanded uncertainty;

– generate the total measurement result.

The process of uncertainty calculation is also discussed in more detail in the Guidance Document on Measurement Uncertainty for GMO Testing Laboratories of the European Commission of the Joint Research Center of the Institute for Reference Materials and Measurements [92].

ANNEX A

Key Terms and their Definitions

"Biological diversity" (CBD term) means the variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"Biological resources" (CBD term) includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Biotechnology" (CBD term) means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Genetic material" (CBD term) means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" (CBD term) means genetic material of actual or potential value.

"Genetically engineered organism" (genetically changed (modified, transgenic) organism) (the term used in the Law "On Safety in Genetic Engineering Activity" of the Republic of Belarus of January 9, 2006 No. 96-3 (hereinafter referred to as "the Law") means a living organism containing a new combination of genetic material obtained using genetic engineering.

"Genetic engineering" (the term used in the Law) means technology for obtaining of new combinations of genetic material by means of extracellular manipulations with nucleic acid molecules and transfer of designed gene constructs into a living organism as a result of which their incorporation into and activity in this organism and its progeny are achieved.

"Genetic engineering activity" (the term used in the Law) means the activity associated with the development of genetically engineered organisms, carrying out of operations with genetically engineered organisms in self-contained systems, their

release into the environment for testing, use for economic purposes, import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms, their storage and deactivation;

"Genotype" (the term used in the Law) means an aggregate of all inheritable characters of an organism information on which is encoded in genes.

"Living modified organisms" (CPB term) means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

"Living organism" (CPB term) means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

"Living organism" (the term used in the Law) means any biological system capable of transferring or replicating (reproducing) genetic material, including sterile organisms, viruses and viroids;

"Synthetic biology" (Secretariat of the Convention on Biological Diversity, 2015) means a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems [99].

"Modern biotechnology" (CPB) means the application of:

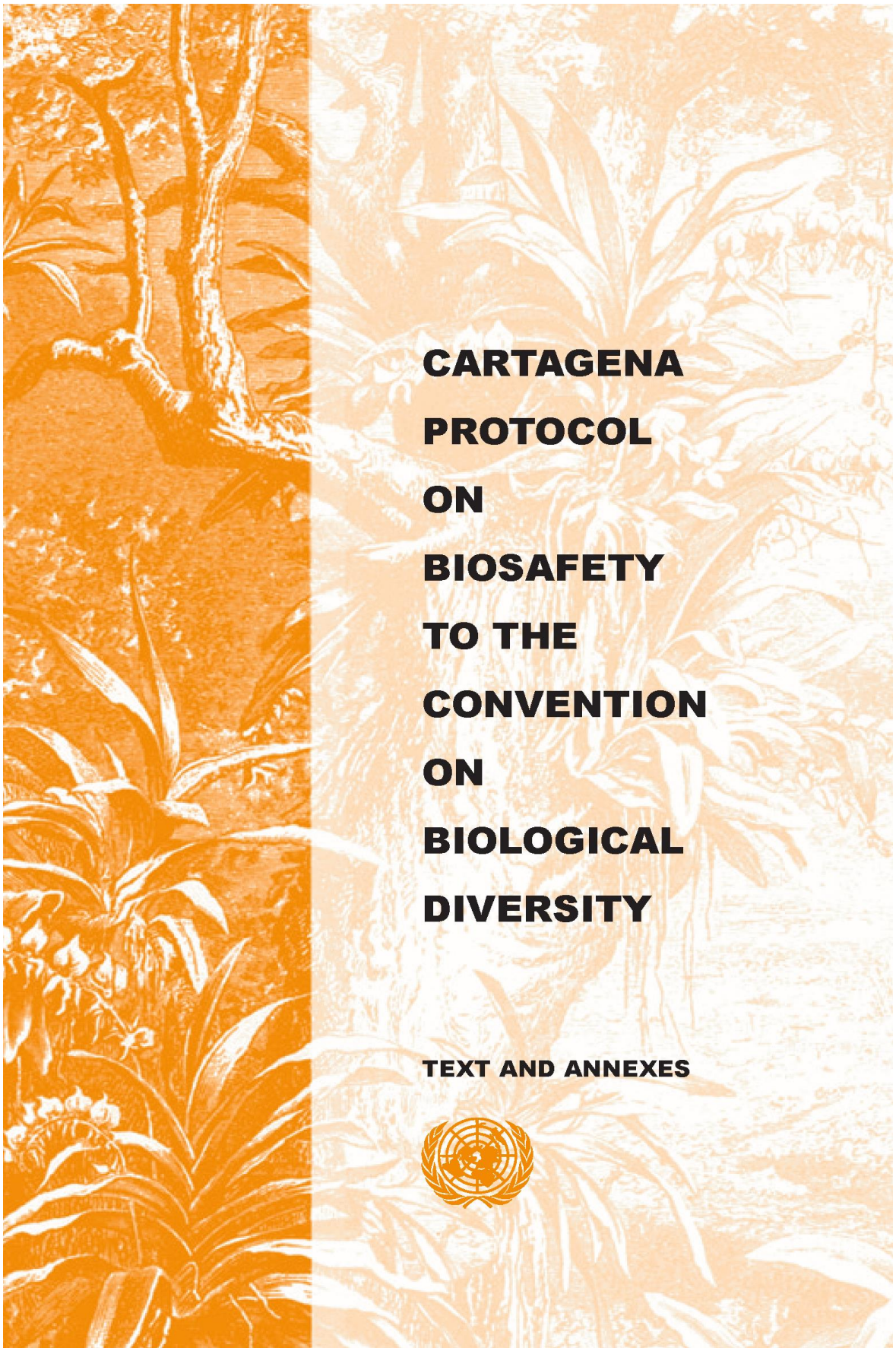
a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

"Country providing genetic resources" (CBD) means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

ANNEX B

Cartagena Protocol on Biosafety to the Convention on Biological Diversity



CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEXES

Montreal, 2000

Montreal, 2000

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Introduction

The Convention on Biological Diversity was finalized in Nairobi in May 1992 and opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5 June 1992. It entered into force on 29 December 1993. Today, the Convention is the main international instrument for addressing biodiversity issues. It provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources.

Biosafety is one of the issues addressed by the Convention. This concept refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care. The Convention clearly recognizes these twin aspects of modern biotechnology. On the one hand, it provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity (for example, in Article 16, paragragh 1, and Article 19, paragraphs 1 and 2). On the other hand, Articles 8(g) and 19, paragraph 3, seek to ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health. Article 8(g) deals with measures that Parties should take at national level, while Article 19, paragraph 3, sets the stage for the development of an international legally binding instrument to address the issue of biosafety.

At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. After several years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalized and adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties.

The conclusion of the Biosafety Protocol has been hailed as a significant step forward in that it provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article
1
OBJECTIVE

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.

Article
2
GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article
3
USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article

4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article

5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article

6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article
7
APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article
8
NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article
9
ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article
10
DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article

11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article
12
REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article
13
SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article
14
BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article
15
RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article
16
RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article

17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article
18
HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; 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 living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, 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.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article
19
COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article
20
INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21
CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article

22
CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities

and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article
23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article
24
NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article
25
ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article
26
SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article
27
LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article
28
FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article
29
CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article
31
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article
32
RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article
33
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article
34
COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article
35
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article
36
SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article
37
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits

its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article
38
RESERVATIONS

No reservations may be made to this Protocol.

Article
39
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article
40
AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Living modified organism.* Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

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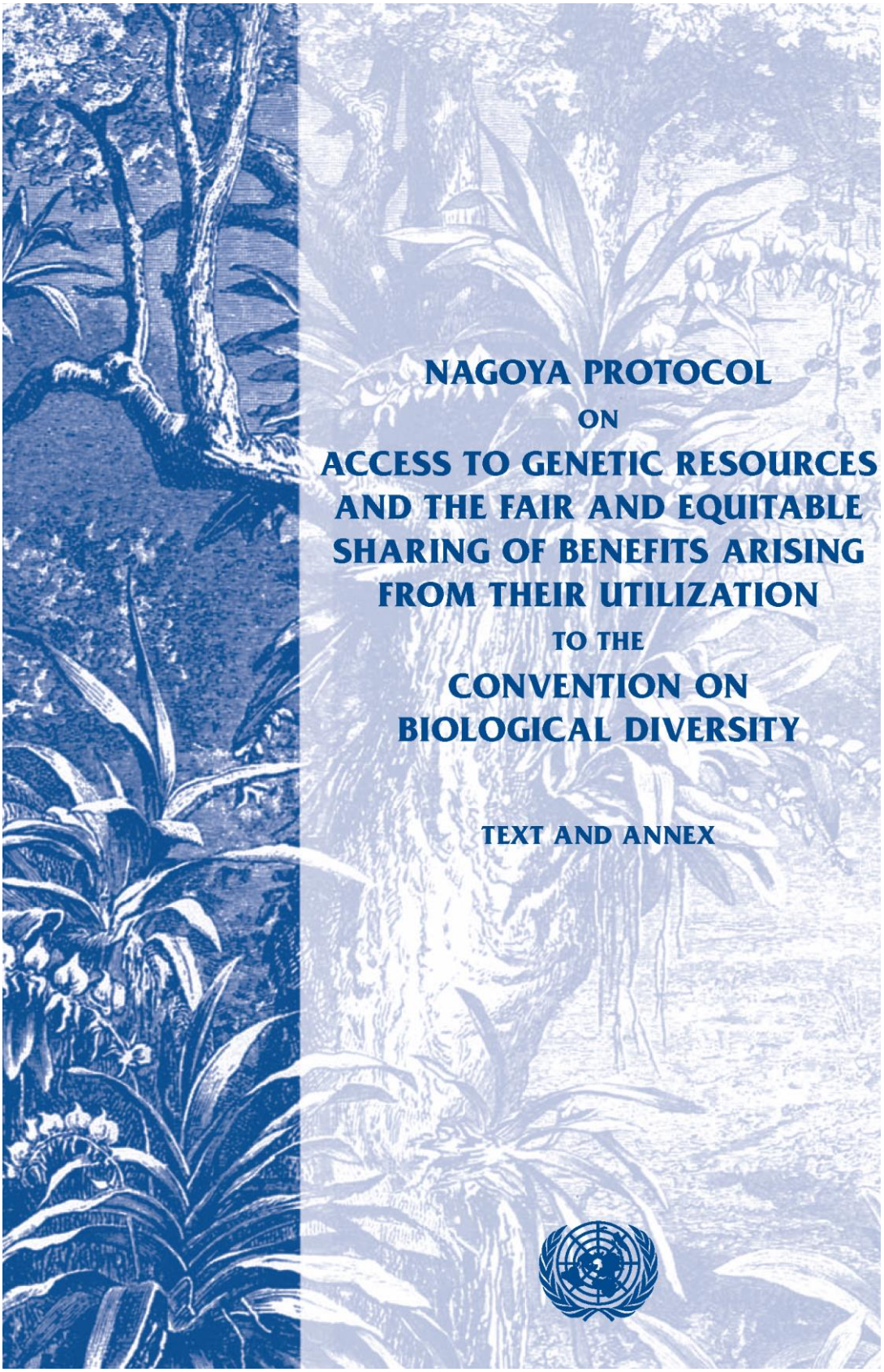
ANNEX C

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity



NAGOYA PROTOCOL

ON

ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION

TO THE

CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEX

SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY
MONTREAL

Convention on Biological Diversity
United Nations

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For further information please contact the Secretariat of the Convention on Biological Diversity

Introduction

The Convention on Biological Diversity was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio "Earth Summit") and entered into force on 29 December 1993. The Convention is the only international instrument comprehensively addressing biological diversity. The Convention's three objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

To further advance the implementation of the third objective, the World Summit on Sustainable Development (Johannesburg, September 2002) called for the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The Convention's Conference of the Parties responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives.

After six years of negotiation, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted at the tenth meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan.

The Protocol significantly advances the Convention's third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to genetic resources will contribute to ensuring the sharing of benefits when genetic resources leave a Party providing genetic resources. In addition, the Protocol's provisions on access to traditional knowledge held by indigenous and local communities when it is associated with genetic resources will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being.

NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

Article

1

OBJECTIVE

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article

2

USE OF TERMS

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Convention" means the Convention on Biological Diversity;

(c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) "Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article
3
SCOPE

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article
4
RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article
5
FAIR AND EQUITABLE BENEFIT-SHARING

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article
6
ACCESS TO GENETIC RESOURCES

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to

genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Article 7
ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article
8
SPECIAL CONSIDERATIONS

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article
9
CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Article
10
GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article
11
TRANSBOUNDARY COOPERATION

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article
12
TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article
13
NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall

forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Article
14
THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharing;

(b) Information on the national focal point and competent national authority or authorities; and

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article
15
COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
16
COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING FOR TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
17
MONITORING THE UTILIZATION OF GENETIC RESOURCES

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

(i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

(ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;

(iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required

by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

(a) Issuing authority;

(b) Date of issuance;

(c) The provider;

(d) Unique identifier of the certificate;

(e) The person or entity to whom prior informed consent was granted;

(f) Subject-matter or genetic resources covered by the certificate;

(g) Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

Article 18
COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article
19
MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article
20
CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article
21
AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 22 CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia,* the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

Article
23
TECHNOLOGY TRANSFER, COLLABORATION AND COOPERATION

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article
24
NON-PARTIES

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Article
25
FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties

with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 26
CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat

of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 27
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article 28
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article
29
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

Article
30
PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

Article
31
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

Article
32
SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

Article
33
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article
34
RESERVATIONS

No reservations may be made to this Protocol.

Article
35
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article

36

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

(c) Participation in product development;

(d) Collaboration, cooperation and contribution in education and training;

(e) Admittance to *ex situ* facilities of genetic resources and to databases;

(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;

(g) Strengthening capacities for technology transfer;

(h) Institutional capacity-building;

(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;

(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;

(l) Contributions to the local economy;

(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;

(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(o) Food and livelihood security benefits;

(p) Social recognition;

(q) Joint ownership of relevant intellectual property rights.

ANNEX D

The Law of the Republic of Belarus "On Safety in Genetic Engineering Activity" of January 9, 2006 No. 96-3

**Non-binding translation*

Registered in the National Register of Legal Acts
of the Republic of Belarus of January 17, 2006 No. 2/1193

LAW OF THE REPUBLIC OF BELARUS
of January 9, 2006 No. 96-3

ON SAFETY IN GENETIC ENGINEERING ACTIVITY

Adopted by the House of Representatives on December 8, 2005
Approved by the Council of the Republic on December 21, 2005

(as worded in the Law of the Republic of Belarus of December 24, 2007 No. 299-3; of November 10, 2008 No. 444-3; of July 2, 2009 No. 31-3; of January 4, 2010 No. 109-3; of January 4, 2014 No. 130-3; of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-3)

This Law establishes legal and institutional frameworks for ensuring safety in genetic engineering activity and aims to protect human health and the environment and implement the international commitments of the Republic of Belarus in the field of safety in genetic engineering activity.

CHAPTER 1
GENERAL PROVISIONS

Article 1. General Terms and their Definitions

The following general terms and their definitions shall be used for the purposes of this Law:

"Safety in genetic engineering activity" means the state of protectability achieved by implementing measures aimed at the prevention or reduction of possible adverse effects of genetically engineered organisms on human health and the environment to the safe level in carrying out of genetic engineering activity;

"Release of genetically engineered organisms into the environment for testing" means introduction of genetically engineered organisms into the environment;

"Genetic engineering" means technology for obtaining of new combinations of genetic material by means of extracellular manipulations with nucleic acid molecules and transfer of designed gene constructs into a living organism as a result of which their incorporation into and activity in this organism and its progeny are achieved;

"Genetic engineering activity" means the activity associated with the development of genetically engineered organisms, carrying out of operations with genetically engineered organisms in self-contained systems, their release into the environment for testing, use for economic purposes, import into the Republic of Belarus, export from the Republic of Belarus and transit through its territory of genetically engineered organisms, their storage and deactivation;

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Genetically engineered organism" (genetically changed (modified, transgenic) organism) means a living organism containing a new combination of genetic material obtained using genetic engineering;

"Genotype" means an aggregate of all inheritable characters of an organism information on which is encoded in genes;

"State legal entities" means legal entities (unitary enterprises, institutions, and state associations) whose property is state-owned and owned by them on the basis of the right of economic management or operative administration;
(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Living organism" means any biological system capable of transferring or replicating (reproducing) genetic material, including sterile organisms, viruses and viroids;

"Conclusion (an authorization document) on 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" means a document confirming the right for import into the Republic of Belarus, export from the Republic of Belarus, and transit through its territory of a certain genotype of potentially pathogenic and pathogenic genetically engineered organisms and of non-recurring nature;
(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Self-contained system" means a system, where operations with genetically engineered organisms are undertaken, equipped with special facilities and devices that eliminate contact of genetically engineered organisms with the environment and impact on it;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Use of genetically engineered organisms for economic purposes" means breeding and/or rearing/cultivation of genetically engineered animals, genetically engineered plant varieties, and strains of non-pathogenic genetically engineered microorganisms for the production of agricultural and microbiology products;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

"Non-pathogenic genetically engineered organisms" means genetically engineered organisms incapable of causing human diseases;

"Deactivation of genetically engineered organisms" means activities aimed at the isolation of genetically engineered organisms, as well as their destruction, including by burning in specialized facilities, to prevent harmful effects of genetically engineered organisms on human health and the environment;
(the Paragraph introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Pathogenic genetically engineered organisms" means genetically engineered organisms capable of causing human diseases;

"Permit for release of non-pathogenic genetically engineered organisms into the environment for testing" means a document issued by the specially authorized Republican Body

of the State Administration in the field of safety in genetic engineering activity to legal entities and/or individual entrepreneurs, confirming a right to the release of non-pathogenic genetically engineered organisms of a certain genotype into the environment for testing;

"Risk of possible harmful effects of genetically engineered organisms on human health and the environment" means a combination of the likelihood of adverse effects of genetically engineered organisms on human health and the environment and the magnitude of the consequences of such effects, leading to an emerging threat to human health and the environment;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

"Potentially pathogenic genetically engineered organisms" means genetically engineered organisms, which may cause human diseases under certain conditions;

"Strains of non-pathogenic genetically engineered microorganisms" means hereditarily supported homogeneous cultures of bacteria, viruses, and fungi containing a new combination of genetic material obtained using genetic engineering, incapable of causing human diseases.

The terms "pathogenic biological agents" and "potentially pathogenic microorganisms" used in this Law shall be applied in the meanings defined by Article 1 of the Law "On the Sanitary and Epidemiological Well-being of a Population" of the Republic of Belarus of January 7, 2012 No. 340-З.
(Part II of Article 1 introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-З; as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Article 1-1. Legal Regulation of Relations in the Field of Safety in Genetic Engineering Activity
(introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Relations in the field of safety in genetic engineering activity shall be regulated by this Law and other legislative acts in the field of safety in genetic engineering activity, international treaties of the Republic of Belarus and international legal acts that constitute the Law of the Eurasian Economic Union.

If an international treaty of the Republic of Belarus establishes other rules than those of this Law, then the rules of an international treaty shall apply.

Article 2. Scope of the Present Law
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

The present Law shall regulate relations in the field of safety in genetic engineering activity.

This Law shall not apply to relations associated with the application of genetic engineering to a human being, his/her organs and tissues, handling of pharmaceutical preparations, food raw materials and food products, and animal feeds derived from genetically engineered organisms or their components.

In carrying out of operations with potentially pathogenic microorganisms and pathogenic biological agents that are genetically engineered organisms, the requirements of the legislation in the field of sanitary and epidemiological welfare of population shall apply, taking into account the specifics established by legislation in the field of safety in genetic engineering activity.

With regard to relations arising in connection with import into the Republic of Belarus, export from the Republic of Belarus, transit through its territory and use of genetically engineered organisms that are subject to export control, this Law shall apply in part not regulated by legislation in the field of export control.

Article 3. Basic Principles to Ensure Safety in Genetic Engineering Activity

Basic principles to ensure safety in genetic engineering activity shall be as follows:

Taking of precautionary measures in carrying out of genetic engineering activity;

Scientifically substantiated, integrated and individual approaches to risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-3);

Access to information on safety in genetic engineering activity.

Article 4. Objects and Subjects of Relations in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Objects of relations in the field of safety in genetic engineering activity shall be genetically engineered organisms and rights to carry out genetic engineering activity.

Subjects of relations in the field of safety in genetic engineering activity are as follows:

State bodies that exercise state administration and control/supervision in the field of safety in genetic engineering activity, as well as the Expert Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection (hereinafter referred to as "the Expert Board");
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Legal entities and individual entrepreneurs involved in genetic engineering activity;

Organizations authorized to carry out risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment (unless otherwise provided, hereinafter referred to as "authorized organizations").

Article 5. Measures to Ensure Safety in Genetic Engineering Activity

Safety in genetic engineering activity shall be ensured by:

Adoption (issuance) of normative legal acts, approval and enforcement of technical normative legal acts in the field of safety in genetic engineering activity and their implementation;

Issuance of conclusions (authorization documents) on import, export or transit of potentially pathogenic and pathogenic genetically engineered organisms and permits for release of non-

pathogenic genetically engineered organisms into the environment for testing by specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З);

Carrying out of State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Keeping record of genetically engineered organisms in accordance with legislation;

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З);

Planning and fulfilling of activities to ensure safety in genetic engineering activity;

Carrying out of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Performing of control/supervision over safety in genetic engineering activity;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Establishing responsibility for a violation of requirements for legislation on safety in genetic engineering activity;

Implementing other measures for safety in genetic engineering activity in accordance with legislation.

CHAPTER 2
STATE ADMINISTRATION IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITY

Article 6. State Administration in the Field of Safety in Genetic Engineering Activity

The State Administration in the field of safety in genetic engineering activity shall be exercised by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus and specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity.

Specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity shall be the Ministry of Natural Resources and Environmental Protection, the Ministry of Health, and the Ministry of Agriculture and Food.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Article 7. Powers of the President of the Republic of Belarus in the Field of Safety in Genetic Engineering Activity

The President of the Republic of Belarus shall determine the state policy and execute other forms of state regulation in the field of safety in genetic engineering activity in accordance with the Constitution of the Republic of Belarus, this Law and other legislative acts.

Article 8. Powers of the Council of Ministers of the Republic of Belarus in the Field of Safety in Genetic Engineering Activity

The Council of Ministers of the Republic of Belarus shall:

Adopt normative legal acts in the field of safety in genetic engineering activity;

Establish a procedure and terms of issuance of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing;
(as worded in the Law of the Republic of Belarus of November 10, 2008 No. 444-З)

Establish a procedure for issuance of conclusions (authorization documents) on 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;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Paragraphs 5-7 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З;

Establish a list of organizations authorized to carry out risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, as well as a procedure for carrying it out;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Establish a procedure for the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

The Paragraph excluded. – The Law of the Republic of Belarus of January 4, 2014 No. 130-З;

Establish a procedure and terms of providing information from the databank on genetically engineered organisms;

Exercise other powers in the field of safety in genetic engineering activity in accordance with the Constitution of the Republic of Belarus, Acts of the President of the Republic of Belarus, this Law and other laws.
(as worded in the Law of the Republic of Belarus of November 10, 2008 No. 444-З; of December 18, 2018 No. 154-З; of January 4, 2022 No. 145-З)

Article 9. Powers of the Ministry of Natural Resources and Environmental Protection in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

The Ministry of Natural Resources and Environmental Protection within the scope of its competence shall:
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Issue permits for release of non-pathogenic genetically engineered organisms into the environment for testing;

Establish safety requirements for self-contained systems to perform operations of Risk Level I in genetic engineering activity;

Establish in coordination with the National Academy of Sciences of Belarus safety requirements for experimental fields and other objects destined for testing of non-pathogenic genetically engineered organisms upon their first release into the environment;

Establish in coordination with the National Academy of Sciences of Belarus a procedure for testing of non-pathogenic genetically engineered organisms upon their release into the environment;

Establish a procedure for deactivating of non-pathogenic genetically engineered organisms;

Establish a procedure for notifying the Ministry of Natural Resources and Environmental Protection by the owner of non-pathogenic genetically engineered organisms or the person, realizing their import into the Republic of Belarus, 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 their release into the environment for testing;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Establish a procedure for keeping record by legal entities and individual entrepreneurs of non-pathogenic genetically engineered organisms developed by them and exported from the Republic of Belarus;

Exercise control over compliance with requirements for legislation on environmental protection in the areas of conservation, protection, reproduction and use of wild plants and animals listed in the Red Book of the Republic of Belarus, tree and shrub vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not the objects of hunting and fishing; protection and use of waters; waste management in carrying out of genetic engineering activity;

Deliver/direct a proposal for the suspension of/ban on the activities of legal entities and/or individual entrepreneurs until the elimination of infringements serving as a basis for the delivery/direction of such a proposal in case of detected legislative violations that pose a threat to the environment;

Raise grievances with legal entities and/or individual entrepreneurs that have caused harm to the environment and make court claims to indemnify for the harm caused to the environment;

Apply to court with a statement on the suspension of activities of legal entities and/or individual entrepreneurs in case of detection of legislative violations that pose a threat to the environment in the case, where they make a decision that the suspension of activities is inexpedient;

Exercise other powers in accordance with this Law, other acts of legislation in the field of safety in genetic engineering activity and other legislative acts.

Article 10. Powers of the Ministry of Health in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

The Ministry of Health within the scope of its competence shall:
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Establish safety requirements for self-contained systems in performing of operations of Risk Levels II, III, and IV in genetic engineering activity;

Issue conclusions (authorization documents) for 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;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З);

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Establish safety requirements for the transport of potentially pathogenic and pathogenic genetically engineered organisms;

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З

The Paragraph excluded. – The Law of the Republic of Belarus of January 4, 2010 No. 109-З

Establish a procedure for keeping record by state legal entities of potentially pathogenic and pathogenic genetically engineered organisms developed by them, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З);

Keep record of potentially pathogenic and pathogenic genetically engineered organisms developed in the Republic of Belarus, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory;

Organize supervision over compliance with legislative requirements for the sanitary and epidemiological welfare of a population in carrying out of genetic engineering activity;
(as worded in the Law of the Republic of Belarus of January 4, 2014 No. 130-З)

Exercise other powers in accordance with this Law, other acts of legislation in the field of safety in genetic engineering activity and other legislative acts.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З);

Article 11. Powers of the Ministry of Agriculture and Food in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

The Ministry of Agriculture and Food within the scope of its competence shall:
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Adopt/issue normative legal acts and approve, enforce technical normative legal acts in the field of safety in genetic engineering activity;

Exercise, in accordance with the procedure established by the Council of Ministers of the Republic of Belarus, State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms and issue their State Registration Certificate;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Organize supervision over compliance with legislative requirements in the field of pedigree work, veterinary medicine, seed production, quarantine and protection of agricultural plants in carrying out of genetic engineering activity;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Exercise other powers in accordance with legislative acts in the field of safety in genetic engineering activity and other acts of legislation.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

CHAPTER 3
OBLIGATIONS OF PERSONS CARRYING OUT OF GENETIC ENGINEERING ACTIVITY. SAFETY REQUIREMENTS FOR CARRYING OUT OF GENETIC ENGINEERING ACTIVITY

Article 12. Obligations of Persons Carrying out of Genetic Engineering Activity

Legal entities and individual entrepreneurs carrying out of genetic engineering activity shall:

Observe safety requirements for genetic engineering activity established by normative legal acts, including technical normative legal acts mandatory for compliance;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No.154-З)

Plan and implement measures for ensuring safety in genetic engineering activity carried out by them;

Have a permit for release of non-pathogenic genetically engineered organisms into the environment for testing in cases, where they are tested in the environment;

Use for economic purposes only genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms that have their State Registration Certificate or its copy;
(as worded in the Law of the Republic of Belarus December 18, 2018 No. 154-З; of January 4, 2022 No. 145-З)

Ensure separate containment of genetically engineered organisms during their transport and storage;

Provide for carrying out of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment and during the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms materials, containing complete and reliable information about genetically engineered organisms, as well as measures for preventing of possible harmful effects of genetically engineered organisms on human health and the environment;
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З; of January 4, 2022 No. 145-З)

The Paragraph excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З);

Organize and exercise production control in the field of safety in genetic engineering activity;

Fulfill requirements/directions of authorized state bodies and their officials exercising control/supervision in the field of safety in genetic engineering activity to remedy established violations of legislation on safety in genetic engineering activity;
(as worded in the Law of the Republic of Belarus of January 4, 2014 No. 130-З; of December 18, 2018 No. 154-З)

Perform other obligations in accordance with this Law and other acts of legislation in the field of safety in genetic engineering activity.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Part II of Article 12 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З.

Article 13. Risk Levels of Genetic Engineering Activity

When carrying out operations with genetically engineered organisms the following Risk Levels of genetic engineering activity shall be established:
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Risk Level I – operations with non-pathogenic genetically engineered organisms;

Risk Level II – operations with potentially pathogenic genetically engineered organisms;

Risk Level III – operations with pathogenic genetically engineered organisms capable of causing dangerous infectious diseases and spreading of infection and for which effective prevention and treatment measures are known;

Risk Level IV – operations with pathogenic genetically engineered organisms, which are

pathogens of particularly dangerous infectious diseases demonstrating the ability to spread quickly, and for which effective prevention and treatment measures are not known.

Individual entrepreneurs shall have the right to carry out genetic engineering activity of Risk Level I only.

The genetic engineering activity of Risk Levels II, III and IV shall be carried out solely by state legal entities.

Article 14. Safety Requirements for Genetic Engineering Activity in the Self-Contained System

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

When carrying out of operations of Risk Level I of genetic engineering activity in the self-contained system, safety requirements for self-contained systems established by the Ministry of Natural Resources and Environmental Protection must be observed.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

When carrying out operations of Risk Levels II, III and IV of genetic engineering activity in the self-contained system, safety requirements for self-contained systems established by the Ministry of Health must be observed.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 15. Safety Requirements upon Release of Genetically Engineered Organisms into the Environment for Testing

Release of potentially pathogenic and pathogenic genetically engineered organisms into the environment for testing shall not be allowed.

Release of non-pathogenic genetically engineered organisms into the environment for testing shall be carried out, provided there is a permit for release of non-pathogenic genetically engineered organisms into the environment issued by the Ministry of Natural Resources and Environmental Protection. A permit shall be issued, taking into account recommendations of the Expert Board for admissibility of release of non-pathogenic genetically engineered organisms into the environment. A permit obtained upon first release of non-pathogenic genetically engineered organisms shall be valid upon subsequent release of genetically engineered organisms of a certain genotype into the environment.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-4; of January 4, 2022 No. 145-3)

Testing of non-pathogenic genetically engineered organisms upon their first release into the environment must be carried out in experimental fields and other facilities specially equipped to prevent possible harmful effects of these organisms on the environment and that comply with safety requirements established by the Ministry of Natural Resources and Environmental Protection subject to agreement with the National Academy of Sciences of Belarus.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 16. Safety Requirements for the Use of Genetically Engineered Organisms for Economic Purposes
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Use of potentially pathogenic and pathogenic genetically engineered organisms for economic purposes shall not be allowed.

Use for economic purposes of non-pathogenic genetically engineered organisms in the form of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms shall be allowed upon their State Registration with the Ministry of Agriculture and Food.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Realization of genetically engineered organisms to legal entities and individual entrepreneurs for subsequent use for economic purposes shall be carried out with the delivery of a copy of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms to them.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 16-1. State Registration of Genetically Engineered Animals, Genetically Engineered Plant Varieties and Strains of Non-pathogenic Genetically Engineered Microorganisms
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)
(introduced by the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms destined for release into the environment shall be carried out taking into account of recommendations of the Expert Board for admissibility of use of non-pathogenic genetically engineered organisms for economic purposes after testing conducted in line with safety requirements stipulated by Article 15 of this Law by entering information related to the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

State Registration of strains of non-pathogenic genetically engineered microorganisms not destined for release into the environment shall be carried out taking into account recommendations of the Expert Board for admissibility of use of non-pathogenic genetically engineered organisms for economic purposes by entering information related to the State Registration of strains of non-pathogenic genetically engineered organisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms shall be confirmed by their State Registration Certificate.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Article 17. Safety Requirements during the Transportation of Genetically Engineered Organisms

Means of transport used for the transportation of non-pathogenic genetically engineered organisms must be equipped with devices that exclude the possibility of unauthorized release of genetically engineered organisms into the environment.

Transportation of potentially pathogenic and pathogenic genetically engineered organisms must be carried out in accordance with legislation in the field of transport of hazardous cargo and safety requirements during the transportation of these organisms established by the Ministry of Health.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3; of January 4, 2022 No. 145-З)

Article 18. Safety Requirements for Import into the Republic of Belarus, Export from the Republic of Belarus and Transit through its Territory of Genetically Engineered Organisms
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-3)

Import into the Republic of Belarus and transit through its territory of genetically engineered organisms shall be allowed, provided that the exporting country (the country exercising transit) is a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity adopted in Montreal on 29 January 2000.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Import into the Republic of Belarus of non-pathogenic genetically engineered organisms shall be allowed for:

Scientific research without release of non-pathogenic genetically engineered organisms into the environment for testing upon notification of the Ministry of Natural Resources and Environmental Protection by the owner of non-pathogenic genetically engineered organisms or the person realizing their import into the Republic of Belarus, in accordance with the procedure established by this Ministry;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Testing with release of non-pathogenic genetically engineered organisms into the environment after obtaining a permit for release of non-pathogenic genetically engineered organisms into the environment the issuance of which is stipulated by Part 2 of Article 15 of this Law.

Use for economic purposes, provided that there is information related to the State Registration of genetically engineered organisms in the State Register of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms in line with Article 16-1 of this Law.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

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 by the owner of non-pathogenic genetically engineered organisms or the person realizing their transit through the territory of the Republic of Belarus, in accordance with the procedure established by this Ministry.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The export of non-pathogenic genetically engineered organisms shall be allowed upon notification of the specially authorized body (organization) of the destination country and obtaining of consent to import.

The import into the Republic of Belarus of potentially pathogenic and pathogenic genetically engineered organisms shall be exercised for scientific purposes only.

A right to 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 possessed by state legal entities only.

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 availability of a conclusion (an authorization document) on import into the Republic of Belarus, export form the Republic of Belarus and transit through its territory of potentially pathogenic and pathogenic genetically engineered organisms issued by the Ministry of Health, in accordance with international legal acts constituting the Law of the Eurasian Economic Union and a procedure established by the Council of Ministers of the Republic of Belarus.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The rules stipulated by Parts 5-7 of this Article shall apply to potentially pathogenic and pathogenic genetically engineered organisms in line with the list determined by the international legal act constituting the Law of the Eurasian Economic Union.

In case of import into the Republic of Belarus and transit through its territory of genetically engineered organisms in breach of the requirements of this Article, these genetically engineered organisms shall be subject to immediate removal from the Republic of Belarus by the owner of genetically engineered organisms or the person who has realized their import into the Republic of Belarus.

Article 19. Safety Requirements for Deactivation of Genetically Engineered Organisms
(as worded in the Law of the Republic of Belarus of December 18, 2018 No.154-3)

Genetically engineered organisms classified in accordance with legislation as waste shall be subject to deactivation, including the remains of non-pathogenic genetically engineered plants, animals and microorganisms upon completion of testing in experimental fields and in self-contained systems, including genetically engineered organisms:

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

Used for economic purposes by legal entities and individual entrepreneurs without the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms or its copy.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Deactivation of non-pathogenic genetically engineered organisms, including those classified in accordance with legislation as waste, shall be carried out in accordance with the procedure

established by the Ministry of Natural Resources and Environmental Protection.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Deactivation of potentially pathogenic and pathogenic genetically engineered organisms, including those classified in accordance with legislation as waste, shall be carried out in accordance with the procedure established by the Ministry of Health.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

CHAPTER 4
RISK ASSESSMENT OF POSSIBLE HARMFUL EFFECTS OF GENETICALLY ENGINEERED ORGANISMS ON HUMAN HEALTH AND THE ENVIRONMENT

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Article 20. Risk Assessment of Possible Adverse Effects of Genetically Engineered Organisms on Human Health and the Environment

Risk assessment of possible adverse effects on human health and the environment shall be carried out to establish admissibility of their release into the environment for testing or use for economic purposes based on the identification of genetically engineered organisms and the study of materials containing information on genetically engineered organisms, as well as measures to prevent possible harmful effects of genetically engineered organisms on human health and the environment.

Non-pathogenic genetically engineered organisms upon their first release into the environment for testing and during the State Registration of genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered organisms destined for use for economic purposes shall be subject to risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Objects of risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be as follows:

Samples of genetically engineered organisms;

Materials containing information on genetically engineered organisms, as well as measures for preventing of possible harmful effects of genetically engineered organisms on human health and the environment.

21. Carrying out of Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health and the Environment. Expert Board

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be regulated by this Law and carried out in accordance with a procedure established by the Council of Ministers of the Republic of Belarus.

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be carried out on the basis of a request of a legal entity or an individual entrepreneur, its initiators (hereinafter “a person concerned”) to one of authorized

organizations.

Risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment shall be carried out at the expense of a person concerned in accordance with the civil law contract concluded between a person concerned and an authorized organization.

A person concerned may not act in the capacity of an authorized organization.

An authorized organization shall, within five days from the date of the conclusion of a contract on risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, submit materials containing information on a genetically engineered organism, as well as measures for preventing of possible harmful effects of a genetically engineered organism on human health and the environment, to the State Scientific Institution "Institute of Genetics and Cytology of the National Academy of Sciences of Belarus" fulfilling the functions of the National Coordination Biosafety Centre (hereinafter referred to as "the National Coordination Biosafety Centre") for the publication of the specified information on its official website over the global computer network Internet to discuss with legal persons and individuals.

Legal persons and individuals may, within 60 (sixty) days from the publication date of the specified information on the official website of the National Coordination Biosafety Centre over the global computer network Internet, familiarize themselves with it and direct their comments and proposals to the National Coordination Biosafety Centre, which shall consolidate the received comments and proposals and within 10 days direct them to the Ministry of Natural Resources and Environmental Protection for consideration at the Expert Board's Meeting upon adopting recommendations on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

Based on risk assessment of possible harmful effects of genetically engineered organisms on human health and the environment, an authorized organization shall prepare a Protocol containing conclusions on admissibility/inadmissibility of release of genetically engineered organisms into the environment for testing or use for economic purposes issued to a person concerned. The specified Protocol shall not be limited in time.

A protocol on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes, as well as comments and proposals received by the National Coordination Biosafety Centre from legal persons and individuals shall be considered at the Expert Board's Meeting. Recommendations accepted based on the conclusions of the Expert Board's Meeting on admissibility (inadmissibility) of release of genetically engineered organisms into the environment for testing or use for economic purposes shall be taken into account in making of a decision: by the Ministry of Natural Resources and Environmental Protection — on the issuance (non-issuance) of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing; by the Ministry of Agriculture and Food — on the issuance (non-issuance) of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-3)

The Expert Board is a collegial consultative body and shall be formed from a number of officials of specially authorized Republican Bodies of the State Administration in the field of safety

in genetic engineering activity, scientists and other specialists. A provision on the Expert Board and its members shall be approved by the Ministry of Natural Resources and Environmental Protection.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

CHAPTER 5
INFORMATION AND RECORD KEEPING IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITY

(as worded in the Law of the Republic of Belarus of July 2, 2009 No. 31-З)

Article 22. Informational Support in the Field of Safety in Genetic Engineering Activity

(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

The following shall be implemented within the framework of informational support in the field of safety in genetic engineering activity:

Collection, analysis and systematization of information on safety in genetic engineering activity;

Formation of the Databank on genetically engineered organisms;

Furnishing of information on safety in genetic engineering activity to legal entities and individual entrepreneurs;

Information exchange with Coordination Biosafety Centres of other states and international organizations.

In order to form a Databank on genetically engineered organisms and achieve other objectives specified in Part 1 of this Article, specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity shall submit related information to the National Coordination Biosafety Centre within five days from/after:

Issuance of a permit for release of non-pathogenic genetically engineered organisms into the environment for testing;

Issuance of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms;
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Issuance of a conclusion (an authorization document) for 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;

Receiving of notification of 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 release into the environment for testing.

The State Customs Committee of the Republic of Belarus shall, within five days after the cargo with genetically engineered organisms has crossed the Customs Border of the Eurasian Economic Union in the Republic of Belarus, submit related information to the National Coordination Biosafety Centre.

(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Information shall be submitted to the National Coordination Biosafety Centre according to forms established by State Bodies specified in this Article subject to coordination with the National Academy of Sciences of Belarus.

A right to obtain full, timely and accurate information in the field of safety in genetic engineering activity contained in the Databank on genetically engineered organisms shall be guaranteed to legal entities and individuals.

A procedure and terms of information delivery to legal entities and individual entrepreneurs from the Databank on genetically engineered organisms shall be established by the Council of Ministers of the Republic of Belarus.

Article 23. Excluded
(Article 23 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Article 24. Requirements for Information on Safety of Genetically Engineered Organisms during their Transportation and Storage
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Information on safety of genetically engineered organisms during their transportation must be shown on packaging (container, another object destined for containing (keeping) of genetically engineered organisms) and include:

Name of a genetically engineered organism;

Number and issuance date of the State Registration Certificate for genetically engineered animals, genetically engineered plant varieties and strains of non-pathogenic genetically engineered microorganisms (for genetically engineered organisms destined for use for economic purposes);
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Data on transportation, storage, application and deactivation methods for genetically engineered organisms;

Name and location of a legal entity or a surname, a proper name, a patronymic (if any) and a place of residence/stay of an individual entrepreneur forwarding genetically engineered organisms;

Name and location of a legal entity or a surname, a proper name, a patronymic (if any) and a place of residence/stay of an individual entrepreneur genetically engineered organisms are forwarded to;

Transportation of genetically engineered organisms shall be carried out upon availability of accompanying documentation stipulated by legislation in the field of cargo transport and international legal acts constituting the Law of the Eurasian Economic Union.

Information on safety of genetically engineered organisms during their storage must be shown on packaging (container, another object destined for containing (keeping) of genetically engineered organisms) and include data specified in Paragraphs 2-4 of Part 1 of this Article.

Article 25. Record of Genetically Engineered Organisms Developed, Imported into the Republic of Belarus, Exported from the Republic of Belarus and Conveyed in Transit through its Territory
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Legal entities and individual entrepreneurs exercising genetic engineering activity shall keep records of non-pathogenic genetically engineered organisms developed by them and exported from the Republic of Belarus in accordance with the procedure established by the Ministry of Natural Resources and Environmental Protection.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

State legal entities shall keep record of potentially pathogenic and pathogenic genetically engineered organisms developed by them, imported into the Republic of Belarus, exported from the Republic of Belarus and conveyed in transit through its territory, in accordance with the procedure established by the Ministry of Health, as well as submit to the Ministry of Health data on such genetically engineered organisms, in accordance with the procedure established by this Ministry.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

CHAPTER 6
CONTROL (SUPERVISION) IN THE FIELD OF SAFETY IN GENETIC ENGINEERING ACTIVITY
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Article 26. Control (Supervision) in the field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Control over compliance with the requirements of legislation on environmental protection during the exercise of genetic engineering activity shall be part of control in the areas of conservation, protection, reproduction and use of wild plants and animals included in the Red Book of the Republic of Belarus, tree and shrub vegetation and other wild plants within the boundaries of inhabited localities, as well as wild animals that are not objects of hunting and fishing; conservation and use of waters; waste management and shall be exercised by the Ministry of Natural Resources and Environmental Protection, its territorial bodies determined by the Council of Ministers of the Republic of Belarus.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Supervision over compliance with requirements for legislation in the field of sanitary and epidemiological welfare of a population in carrying out of genetic engineering activity shall be part of the state sanitary supervision over compliance, subject to checks, with legislation in the field of sanitary and epidemiological welfare of a population and shall be exercised by authorities and institutions that carry out the state sanitary supervision determined by the Council of Ministers of the Republic of Belarus.

Supervision over compliance with legislative requirements in the field of pedigree work, veterinary medicine, seed production, quarantine and protection of agricultural plants in carrying out of genetic engineering activity shall be part of state supervision over pedigree work, supervision in the field of veterinary medicine, seed production, quarantine and protection of agricultural plants and shall be exercised by the Ministry of Agriculture and Food, the Veterinary and Food Supervision Department of the Ministry of Agriculture and Food, state organizations reporting to the Ministry of Agriculture and Food determined by the Council of Ministers of the Republic of

Belarus.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

Control/supervision in the field of safety in genetic engineering activity shall be exercised in accordance with the procedure established by legislation on control/supervision activity and other acts of legislation.

Article 27. Production Control in the Field of Safety in Genetic Engineering Activity
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)
(as worded in the Law of the Republic of Belarus of January 4, 2014 No.130-З)

Part 1 of Article 27 excluded. – The Law of the Republic of Belarus of December 18, 2018 No. 154-З.

Legal entities and individual entrepreneurs carrying out genetic engineering activity shall organize and exercise production control in accordance with the procedure established by them in order to check compliance with requirements for safety in genetic engineering activity established by normative legal acts, including technical normative legal acts mandatory for compliance.
(as worded in the Law of the Republic of Belarus of December 18, 2018 No. 154-З)

Production control over safety in genetic engineering activity shall be exercised at own cost and expense and from other sources of funding in accordance with local acts developed and approved by a legal entity or an individual entrepreneur, in accordance with the procedure established by specially authorized Republican Bodies of the State Administration in the field of safety in genetic engineering activity.
(as worded in the Law of the Republic of Belarus of January 4, 2022 No. 145-З)

CHAPTER 7
FINAL PROVISIONS

Article 28. Bringing this Law into Effect

The present Law shall enter into effect in six months after its official promulgation, except for this Article and Article 29, which shall become effective from the official promulgation date of this Law.

Article 29. Bringing of Legislative Acts of the Republic of Belarus into Line with this Law

The Council of Ministers of the Republic of Belarus within six months from the date of the official promulgation of this Law shall:

Prepare and introduce, in accordance with the procedure established by the House of Representatives of the National Assembly of the Republic of Belarus, proposals for bringing of legislative acts in line with the present Law;

Bring Decisions of the Government of the Republic of Belarus in line with this Law;

Ensure that Republican Bodies of the State Administration reporting to the Council of Ministers of the Republic of Belarus bring their normative legal acts in line with this Law;

Ensure the adoption of normative legal acts required for the implementation of the present Law;

Adopt other measures required for the implementation of the present Law.

President of the Republic of Belarus A. Lukashenko

ANNEX E

Decision Adopted by the Conference of the Parties to the Convention on Biological Diversity

14/20 Digital Sequence Information on Genetic Resources

UNEP

CBD

Convention on Biological Diversity

Distr.
GENERAL

CBD/COP/DEC/14/20
30 November 2018

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Fourteenth meeting
Sharm El-Sheikh, Egypt, 17-29 November 2018
Agenda item 18

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

14/20. Digital sequence information on genetic resources

The Conference of the Parties,

Mindful of the three objectives of the Convention,

Recalling Articles 12, 15, 16, 17 and 18 of the Convention,

Mindful of the increasing generation and use of digital sequence information on genetic resources, its publication in both public and private databases and advances in data analytics,

Noting that the term "digital sequence information" may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed,

Recognizing the importance of new technologies for the current and future utilization of genetic resources, and noting that the media in which information is stored and shared is continuously evolving,

Considering that the post-2020 global biodiversity framework will provide guidance on the long-term strategic directions to the 2050 Vision for Biodiversity,

Noting the relevant discussions on digital sequence information on genetic resources and related issues in other United Nations bodies and instruments, such as the Food and Agriculture Organization of the United Nations, the International Treaty on Plant Genetic Resources for Food and Agriculture, the World Health Organization, the World Intellectual Property Organization and the United Nations General Assembly,

1. *Recognizes* the importance of digital sequence information on genetic resources for the three objectives of the Convention which are mutually supportive, although further work is needed to provide conceptual clarity on digital sequence information on genetic resources;

2. *Recognizes* that access to and use of digital sequence information on genetic resources contributes to scientific research as well as to other non-commercial and commercial activities in areas such as biological diversity, food security and human, animal and plant health;

3. *Recognizes* also that further capacity to access, use, generate and analyse digital sequence information on genetic resources is needed in many countries, and *encourages* Parties, other Governments and relevant organizations to support capacity-building and technology transfer, as appropriate, to assist in the access, use, generation and analysis of digital sequence information on genetic resources for the conservation and sustainable use of biodiversity and benefit-sharing;

4. *Notes* that the generation of digital sequence information on genetic resources in most cases requires access to a genetic resource, although in some cases linking the digital sequence information to the genetic resource from which it was generated may be difficult;

5. *Also notes* that some Parties have adopted domestic measures that regulate the access to and use of digital sequence information on genetic resources as part of their access and benefit-sharing frameworks;

6. *Further notes* that, as there is a divergence of views among Parties regarding benefit-sharing from the use of digital sequence information on genetic resources, Parties commit to working towards resolving this divergence through the process established in the present decision, with the aim of strengthening the fulfilment of the third objective of the Convention and Article 15, paragraph 7, without prejudice to the circumstances to which this article applies;

7. *Notes* that, when genetic resources are accessed for their utilization, mutually agreed terms can cover benefits arising from the commercial and/or non-commercial use of digital sequence information on these genetic resources, in accordance with applicable domestic measures;

8. *Decides* to establish a science- and policy-based process on digital sequence information on genetic resources as set out in paragraphs 9 to 12 below;

9. *Invites* Parties, other Governments, indigenous peoples and local communities, relevant stakeholders and organizations to submit their views and information:

(a) To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources;

(b) On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources;

10. *Invites* Parties, other Governments and indigenous peoples and local communities to submit information on their capacity-building needs regarding the access, use, generation and analysis of digital sequence information on genetic resources, in particular for the three objectives of the Convention;

11. *Decides* to establish an extended Ad Hoc Technical Expert Group, [1] including the participation of indigenous peoples and local communities, and *requests* the Executive Secretary, subject to the availability of resources:

(a) To compile and synthesize the views and information submitted pursuant to paragraphs 9 and 10 above;

(b) To commission a science-based peer-reviewed fact-finding study on the concept and scope of digital sequence information on genetic resources and how digital sequence information on genetic resources is currently used building on the existing fact-finding and scoping study;[2]

(c) To commission a peer-reviewed study on ongoing developments in the field of traceability of digital information, including how traceability is addressed by databases, and how these could inform discussions on digital sequence information on genetic resources;

(d) To commission a peer reviewed study on public and, to the extent possible, private databases of digital sequence information on genetic resources, including the terms and conditions on which access is granted or controlled, the biological scope and the size of the databases, numbers of accessions and their origin, governing policies, and the providers and users of the digital sequence information on genetic resources and encourages the owners of private databases to provide the necessary information;

(e) To commission a peer-reviewed study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources and

[1] The Ad Hoc Technical Expert Group will be convened in accordance with the modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice, except that there will be five experts nominated by each of the five regions.

[2] Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol (CBD/DSI/AHTEG/2018/1/3).

address the use of digital sequence information on genetic resources for research and development, taking into account the submissions provided in paragraph 9;

(f) To convene a meeting of the extended Ad Hoc Technical Expert Group to:

(i) Consider the compilation and synthesis of views and information and the peer-reviewed studies referred to above;

(ii) Develop options for operational terms and their implications to provide conceptual clarity on digital sequence information on genetic resources, considering in particular the study referred to in paragraph 11(b) above;

(iii) Identify key areas for capacity-building;

(iv) Submit its outcomes for consideration by a meeting of the open-ended working group established under decision 14/34 to be held prior to the fifteenth meeting of the Conference of the Parties;

12. *Requests* the open-ended working group established under decision 14/34[3] to consider the outcomes of the extended Ad Hoc Technical Expert Group and to make recommendations to the Conference of the Parties at its fifteenth meeting on how to address digital sequence information on genetic resources in the context of the post-2020 global biodiversity framework;

13. *Requests* the Executive Secretary to cooperate with other intergovernmental organizations to inform them of the process defined above and to take into account the work, approaches and outcomes that these organizations generate in the area in question.

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[3] Decision on the preparation of the post-2020 global biodiversity framework (item 17).

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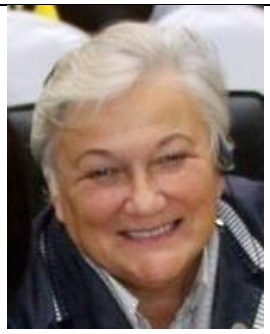	**Elena MAKEYEVA** PhD in Biology, Associate Professor Head of the National Coordination Centre on Access to Genetic Resources and Benefit-sharing Institute of Genetics and Cytology of the National Academy of Sciences of Belarus National Focal Point for the Nagoya Protocol in Belarus
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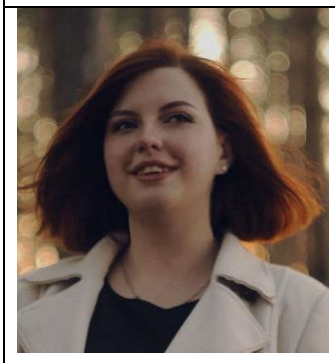
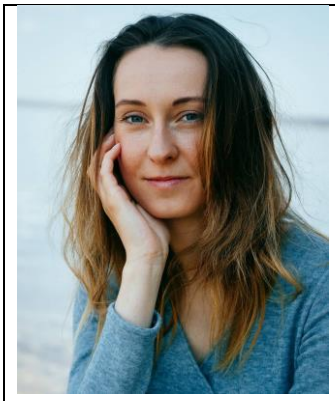
	**Viktoriya ASTAPCHYK** Junior Research Scientist National Coordination Biosafety Centre Institute of Genetics and Cytology of the National Academy of Sciences of Belarus

	**Nadezeya DROBAT** **Research Scientist** National Coordination Biosafety Centre Institute of Genetics and Cytology of the National Academy of Sciences of Belarus
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