

RESOLUTION

Round-table Meeting

on the International Technical Assistance Project of the Secretariat of the Convention on Biological Diversity “Capacity-building to Promote Integrated Implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the National Level”

Minsk, 25 May, 2016

INTRODUCTION

The project objective “Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity at the national level” is strengthening capacity of 10 countries that participate in the pilot project, including the Republic of Belarus to elaborate and test practical measures on the integrated implementation of the Cartagena Protocol on Biosafety (CPB) and the Convention on Biological Diversity (CBD). The project is carried out at the national level by the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus.

Each participating country of the pilot project is expected to integrate biosafety into National Biodiversity Strategies and Action Plans (NBSAPs), other institutional and Inter-institutional areas of activities, plans and programs, as well as strengthen National Inter-institutional Coordination Frameworks. In view of this, each pilot country should:

- analyze its existing national policies, strategies and activities relevant to biosafety;
- identify practical steps to be taken to integrate biosafety into NBSAPs and promote integrated implementation of the Cartagena Protocol and the Convention at the national level;
- generalize and document national experiences, good practices and lessons learned;
- organize cross-sectoral meetings, as well as awareness-raising activities for relevant policy makers, decision-makers and other key stakeholders.

The project objective is effectuated by preparation, peer review and discussion of the report based on desk study findings related to National policies, strategies and activities in the field of biosafety, development of recommendations for the integrated implementation at the national level of activities, directed at biosafety mainstreaming and conservation of biodiversity. The report and recommendations should be submitted to the CBD Secretariat.

With a view of the desk study analysis of the existing national policies, strategies and activities in the field of biosafety, on 25 May 2016 the Institute of Genetics and Cytology of the National Academy of Sciences of Belarus, vested with functions of the National Coordination Biosafety Center with support of the Secretariat of the Convention on Biological Diversity and the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus hosted a round-table meeting “Capacity-building to promote integrated implementation of the Cartagena Protocol on Biosafety and the

Convention on Biological Diversity at the national level”. 40 representatives of different institutional subordinations, the activity of which is related to biosafety issues in the Republic of Belarus took part in the round-table meeting. Members of the Expert Advisory Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus were among the participants of the meeting, as well as representatives of the involved ministries and other National government agencies that hold responsibility for the decision-making in regard to the release of GMOs into the environment, the GMO registration and their transportation (movement); representatives of the National Aarhus Center of the UN Convention to promote public participation in the discussion of environmental issues, including the biosafety ones and NGOs, engaged in environmental activities in the Republic of Belarus, representatives of Institutions, involved in genetic engineering activity and ensuring safety of genetic engineering activity in the self-contained systems.

Stages of Activity

1. Advance of a round-table meeting, the participants were provided with the desk study “Analysis of the implementation in the Republic of Belarus of the Cartagena Protocol on Biosafety and the Convention on Biological Diversity”.

2. In the course of the round-table session, the desk study results, including analysis of the National legislation of the Republic of Belarus in the field of safety in genetic engineering activity (GEA)*, the administrative and legal regulation of the activity, standards and methodology guidelines in the field of detection and identification of genetically engineered organisms, the analysis of practical activities and implementation of international projects at the national level that ensure the safety in genetic engineering activity, were heard.

3. The participants held a discussion of the desk study, including:

- coverage by the National legislation of biosafety areas within a framework of implementation of the Cartagena Protocol on Biosafety at the country level;
- other National, International, Multilateral (the Eurasian Economic Union, EAEU) Agreements (Treaties) that ensure safety in genetic engineering activity, including safety in use of genetically engineered organisms in economic activity: handling of food raw materials and food products, animal feeds, derived from GMOs or their components, medicinal products; mechanisms of the concerned public participation in decision-making in relation to GMOs;
- institutional and Inter-institutional mechanisms to control and coordinate safety in genetic engineering activity; means of building and strengthening of National Inter-institutional Coordination Mechanisms to provide a coordinated approach to implementation of Provisions of the Convention and the Protocol;

** Pursuant to the Law «On Safety in Genetic Engineering Activity», the genetic engineering activity is the activity, associated with the development of genetically engineered organisms, their release into the environment for testing, their use for commercial 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.*

- degree of involvement and integration of biosafety mechanisms into National Biodiversity Strategies and Action Plans (NBSAPs) and other relevant agency and Inter-agency plans, strategies and programs, national budgets, bilateral and multilateral cooperation programs (projects) at the national and international levels;
- mainstreaming biosafety issues among other projects / activities to obtain support from GEF funds, allocated for countries which are Parties to the Convention on Biological Diversity, with a view of biodiversity conservation.

Summary

1. The meeting participants noted that legislative, administrative and legal systems of the Republic of Belarus, related to GMO safety, are very effective. The main law in this area of activities is the Law “On Safety in Genetic Engineering Activity” of 9 January 2006, №96 (hereinafter – the Law), elaborated on the basis of the Cartagena Protocol on Biosafety and aimed at the implementation of this international commitment. A number of by-laws to ensure safety in genetic engineering activity were elaborated in addition to this Law. At the same time, due to the increasing diversity of GMOs being developed by the global community and in the Republic of Belarus, it seems necessary to introduce changes and amendments in the Law “On Safety in Genetic Engineering Activity” and, where appropriate, in by-laws. The suggestions made are as follows:

1.1. In connection with the emergence of new methods in genetic engineering activity, to clarify the definition of the “genetically engineered organism” (GEO). The Law provides the following definition “a genetically engineered organism (genetically changed (modified, transgenic organism)) is a living organism containing a new combination of genetic material, produced by genetic engineering”. At the same time, new areas in genetic engineering activity, which do not imply the introduction of new genes into genome, are being developed. The genetic engineering event leads to a change in the combination of genetic material (e.g., gene knockout, protein engineering). The participants noted that it determines the need to clarify the definition.

1.2. The participants noted that Paragraph I of 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” determines that “Import into the Republic of Belarus and transit through its territory of genetically engineered organisms is allowed, provided that the exporter (the country, performing transit) is a Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted in Montreal 29 January 2000.” The Republic of Belarus is the EAEU member-state, but some Parties to this Treaty (e.g. the Russian Federation) are not Parties to the Cartagena Protocol that causes a legal problem in the implementation of Article 18 and the safe transboundary movement of GMOs. The participants were invited to approach the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus with a proposal to tackle the issue from the standpoint of eliminating contradictions in Article 18 of the Law with regard to the EAEU country membership and prepare a draft of respective alterations and/or additions to the Law and other normative legal acts.

1.3. Paragraph II of Article 15 of the Law “Safety Requirements for Release of Genetically Engineered Organisms into the Environment for Testing” defines that the “Release of non-pathogenic genetically engineered organisms into the environment for testing is carried out upon availability of a permit for release of non-pathogenic genetically

engineered organisms into the environment, issued by the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus”.

Paragraph II of Article 16 “Safety Requirements for Use of Genetically Engineered Organisms for Economic Purposes” defines that “Use for economic purposes of non-pathogenic genetically engineered organisms in the form of genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms is allowed upon the State Registration in the Ministry of Agriculture and Food of the Republic of Belarus. The State Registration is carried out upon a positive conclusion (positive findings) of the State Safety Expertise of genetically engineered organisms and positive test findings of genetically engineered organisms after their release into the environment by making entry with regard to registration-related genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms to the National Register of Genetically Engineered Varieties of Plants, Genetically Engineered Breeds of Animals and Strains of Non-Pathogenic Genetically Engineered Microorganisms. Availability of a State Registration Certificate confirms the fact of a State Registration of genetically engineered varieties of plants, genetically engineered breeds of animals and strains of non-pathogenic genetically engineered microorganisms.

The participants brought into focus that not all GMOs, intended for use in economic activity, are released into the environment. For example, non-pathogenic microorganisms, some transgenic animals – producers, contained and used in self-contained systems. Thus, it seems necessary to determine and make a distinction between State Registration procedures and risk assessment of GMOs, released and not released into the environment, determine testing procedures for the GMOs with no release into the environment, intended for use in economic activity. Remove from line 2 of Paragraph II, Article 16 the wording “on their release into the environment”.

1.4 It was noted that the Law does not sufficiently delineate and clearly determine the registration procedure for different varieties of GMOs (plants, animals, microorganisms; non-pathogenic, potentially pathogenic, pathogenic organisms). It deems it necessary to more clearly define in Articles 9,10, 11 Ministerial functions in relation to registration procedures for plants, animals, microorganisms, including potentially pathogenic and pathogenic ones.

1.5 In order to improve the State Expertise and for the purpose of further safe use of GMOs in economic activity, it is necessary to determine in the Law the importance of expert verification for the presence of new genetic material insertion during the State Safety Expertise. For example, make additions to Paragraph III of Article 20 “Objects of the State Safety Expertise of Genetically Engineered Organisms are as follows: new inserted sequences”.

1.6 Paragraph V of Article 3 of the Law “access to information in the field of safety in genetic engineering activity” shall be inserted the words “and public participation in decision-making”.

2. The participants particularly noted that on 10 October 2008 the Treaty on the Single Customs Territory and the Customs Union of the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation (the Eurasian Economic Community, EurAsEC) came into effect. Thus, following the entry into the Customs Union, EurAsEC member-states approved Technical Regulations of the Customs Union TR CU 021/2011 “On Safety of Food Products” and TR CU 022/2011 “Food Products in Terms of their Labeling”, as well as a set of standards and methodology guidelines in the field of GMO safety. Now

this Technical Regulation operates within a framework of Technical Regulations of the EAEU Customs Union. The experts, involved in the elaboration of the Technical Regulations and present at the round-table meeting, noted that this legislation is in line with European approaches in the field of GMO safety.

It was pointed out that the harmonization process of national legislations, standards and methodological approaches of EAEU countries continues. In particular, a threshold of 0% for labeling of products, raw materials used for their production and feeds, containing GMOs or their components has not been cancelled in the Republic of Belarus yet, while the Customs Union has established a threshold of 0,9% for the permitted GMOs. The meeting participants also note that the country has carried out work on the harmonization of normative legal acts and technical regulations: the by-law "Sanitary Norms and Regulations" came into effect, which establishes a threshold of 0,9% and a new version of the Law "On Quality and Food Safety" that previously established a non-threshold principle for food product labeling has been elaborated. A new version of the Law was brought in conformity with the TR CU and the EU legislation. The Law is at the initial stage of editing. The Republic of Belarus has also approved methodology guidelines "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms on Human Health. Instructions for use." Following the entry into the Customs Union, a list of standards that includes principles and methods of research (testing) and measurements for a GM-component in food products and food supplements, methodology guidelines "Food Products and Food Supplements. Biomedical Safety Assessment of Genetically Engineered Modified Organisms of Plant Origin. Methodical Guidelines" was determined.

With reference to the above, the meeting participants recommend to the designated authorities in the field of safety in genetic engineering activity:

2.1. Continue work on harmonization of the legislation of the EAEU member-states in terms of GMO labeling, GMO-containing products, derived from/or with use of GMOs, harmonization of interstate methodological approaches, standards and instructions with regard to the GMO detection and identification, risk assessment of GMOs and GMO-derived products.

2.2. Make additions to the Instruction "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms to Human Health" (Registration №076-0806) with clearly established standard procedures for toxicity and allergenicity assessment of GMOs with regard to their effects on human (and animal) health.

2.3. Put forward a proposal for elaboration of an interstate standard for the Customs Union member-states in accordance with the established in the Republic of Belarus Instruction "Procedures for Risk Assessment of Possible Harmful Effects of Genetically Engineered Organisms to Human Health", methodical guidelines (MU 2.3.2.2306-07.23.2.), introduced in the EAEU, as well operational guidelines of relevant international organizations (FAO). It is proposed to establish clear testing procedures and standards to risk assessment of GMOs for human health with a view of their use in the laboratories of accredited organizations that carry out testing. This work should be done at the interstate level of the Customs Union member-states.

2.4. There is a recommendation to the National Coordination Biosafety Center to initiate work on the joint meeting between the Expert Advisory Board on Safety of Genetically Engineered Organisms of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus and the Eurasian Economic Commission experts to determine standards and regulations for the Customs Union.

3. In the course of the project analysis carried out at the national level, it was established that biosafety issues had been included into priority directions of scientific research in the Republic of Belarus for 2011-2015. The projects were aimed at arranging safe test conditions for plant release into the environment, ecological and genetic monitoring, as well as scientific research in the biomedical assessment of the produced GMOs. At the same time, GMO biosafety issues were not included into the “Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity” for 2011-2020. In addition, the desk study shows that critical few of scientific researches were directed at the safety assessment of newly developed GMOs.

In this regard, it is recommended to:

3.1 Include biosafety issues of genetic engineering activity into the “National Strategy on Sustainable Social and Economic Development of the Republic of Belarus” and the “Strategy of the Republic of Belarus on the Conservation and Sustainable Use of Biodiversity” with a view of mainstreaming biosafety projects among the biodiversity ones.

3.2 Include biosafety issues of genetic engineering activity into priority directions of scientific research. Request the Ministries, involved in safety issues in the field of genetic engineering activity, to include scientific projects on human health risk assessment of GMOs being developed in the country and the projects aimed at the development of effective screening techniques and DNA-marking of GMOs, GMO-contained products, derived from/or with use of GMOs into the State Research Programs. Support of such projects is a prerequisite to subsequent safe release of GMOs into the environment, their use in economic activity and transboundary movement.