

GENETICALLY MODIFIED ORGANISM LEGISLATIVE CONTROL IN GEORGIA

Introduction

In June 2014 Georgia signed Association Agreement with the EU thus laying grounds for new cooperation legal framework. By signing the document Georgia has committed itself to carry out, within a specific timeframe, reforms in various areas. A range of issues has been identified in Nature protection, referring to habitat and species protection, wildlife and genetically modified organisms (GMO) trade, and fishery policy.

According to Article 55 of the Agreement “Georgia shall continue to gradually approximate its sanitary and phytosanitary, animal welfare and other legislative measures as laid down in Annex IV to this Agreement to that of the Union in accordance with the principles and procedure set out in Annex XI to this Agreement”. Annex IV provides that Georgia shall approximate its GMO legislation to that of the Union. It should be mentioned that the commitments for Nature protection, is underlines both in Environmental Protection part of the agreement, as well as within the DCFTA (Deep and Comprehensive Free Trade Agreement)¹. The one of such commitment was to introduce changes to GMO law and its full compliance with the EU directives.

In the present article we have tried to reflect the changes that have occurred in the GMO control field during the period of 2015-2016.

Baseline information

In 2008 Georgia joined the 29 January 2000 “Cartagena Protocol on Bio-safety” to the Montreal “Convention on Biological Diversity”² thus committing itself to develop appropriate legislative framework for GMO control. Six years after joining the Protocol, in 2014 Georgian Parliament adopted the law on “Living Genetically Modified Organisms”. Adoption of the law was very important given the fact that trade with genetically modified seeds and plants increases annually in the world, and they have already appeared in Georgian market.

The use of genetically modified organisms’ (hereinafter - GMO) has supporters and opponents; however, it has been proved that there is potential risk of adverse impact on human health, general environment and biodiversity. Hence, in order to ensure an appropriate security level when applying modern bio-technologies and using the organisms

¹ DCFTA - Deep and Comprehensive Free Trade Agreement.

² Georgian Parliament Resolution No.305-II of 26 September 2008.

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This policy brief is intended for public policy makers and practitioners; it will also be useful for those groups and individuals seeking to influence the policymaking processes.

This policy brief is also available in Georgian.

obtained thereafter, legal regulatory mechanisms were developed by many countries, and on an international level. In their turn, regulatory mechanisms were linked with Rio Convention "On Biological diversity" adopted at the United Nations Conference on Environment and Development in (Rio-de-Janeiro, 1992, which recognizes that living modified organism resulting from biotechnology may have adverse effect on the conservation and sustainable use of biological diversity, and that setting out an appropriate procedures are needed to minimize the risks related to their use.

Due to the lack of information, and comparatively short period of the wide use of GMOs, not allowing for study of their long-term adverse effect, the caution with which they are used is not surprising. This has been reflected in the EU countries' legislation, and in 11 March 2015 new regulation - Directive 2015/412/EU³ - of the European Parliament and of the Council, allowing the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

Regulatory Framework in Georgia

Law of Georgia on "Living genetically modified organisms" was basically developed on the basis of Directive 2001/18/EC⁴, as well as of the European Parliament and the EU Regulations 1829/2003/EC⁵ and 1830/2003/EC⁶ of 22 September 2003, and other legal acts. When adopting in 2014 the law consisted of three parts, 12 chapters and 34 articles. Currently, as a result of March 2016 amendment, two chapters and a number of articles have been removed from the law.

Main purpose of the law after the 3 March 2016 amendments is to declare Georgia a GMO free zone, that means the prohibition of introduction, placement on the market, import (except for the use in closed systems), and re-export of living genetically modified organisms⁷. The regulation extend on living genetically modified organisms, and does not include genetically modified products and pharmaceutical products, which may represent themselves or may contain genetically modified organisms, products or their ingredients.

The law intends to create the unified state system of bio-safety, that will represent the unity of accounting, planning, control, economic and legal mechanisms to govern the use of live GMO in a closed system and their introduction in the environment⁸.

Initially, the cornerstone of the law was the legal norm, which prohibited introduction of GMO into the environment on the territory of Georgia and only their use in a closed system was allowed, meaning "Any operation/manipulation at gene-modified organisms, or associated with gene-modified organisms (including their receipt, storage, and accommodation in the form of waste) within a facility, building or other physical structure, which requires compliance with specific conditions for the effective control of the contact with the surrounding environment and avoidance of the impact on the environment and

³ Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

⁴ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

⁵ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

⁶ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

⁷ Articles 1 "a" and 4.1 "g" of the "Law on Live genetically modified organisms".

⁸ before 2016 2 March amendments introduction of live GMO in trading networks was also governed by this law, which was prohibited under these amendments.

human health"⁹. The amendments introduced to the Law in 2016 exacerbated the requirements and virtually banned GMO import to the country.

Under the existing law Ministry of Environment and Natural Resources protection exercises coordination and general organizational support for GMO use on the territory of Georgia. The Ministry is also responsible for the relations with bio-safety intermediary mechanism¹⁰. Georgian government sets special requirements for GMO treatment within closed systems¹¹.

Part III of the Law governs the use of GMO in closed systems. In the initial version security levels for the use of GMO in closed systems were classified as follows: the first class security, when the use of GMO in a closed system does not pose a threat to human health and the environment, or is associated with a low risk; and second-class security, when the use of GMO in closed systems is associated with high risk for human health and the environment¹². After 2016 amendments to the law, this legal provision was removed from the law. Lawmakers justified the change so that all GMOs are equally dangerous and harmful. Currently use of GMO in a closed system is subject to the appropriate license¹³, issued by Ministry of Environment and Natural Resources Protection within 30 days after acceptance of the application¹⁴. The license applicant, alongside with all necessary information, shall provide to the Ministry: information about the person responsible for bio-safety, monitoring program and information about the methods of control, quick response plan in order to avoid and neutralize adverse effect on human health and the environment, and plan of submission of periodic reports to regulatory authorities¹⁵. The Ministry is obliged to publish the decision to grant a license for the use of GMOs in a closed system, to introduce changes therein, suspend it, renew or cancel¹⁶.

When using GMOs in a closed system, the person carrying out this activity is required to designate a responsible for bio-safety person and head of the project, who plans, runs and supervises the work. Their authorities shall be governed by internal regulations of the works¹⁷.

Since placement of a GMO on the market¹⁸ was prohibited under 2016 2 March amendments, part 4 of the law providing for legal framework of placing GMO on the market was removed. According to the provisions removed, if a live gene-modified organism belonged to the species allowed on the territory of Georgia under the ministerial order, its placement on the market did not need a special permit/license¹⁹.

Before the amendments Article 19 provided for the procedure of initial placement of non-registered live GMOs on the markets on the territory of Georgia: rules of making notification to the Ministry, deadline for the Ministry decision on the GMO import (from 90 days to 3 months), and liabilities of

⁹ Para 1 "d" of Article 4 of the Law on live Genetically modified organisms; Besides Para 2 of Article 6 provided for the right of Georgian government to fully or partially prohibit the use of GMO on the whole territory of Georgia or part of it.

¹⁰ Law "on Live genetically modified organisms" Article 24.

¹¹ Para 1 and 2 of Article 8 of the law on live genetically modified organisms; initially the law provided for the right of Ministry of Environment and Natural Resources Protection to keep a register of live GMO allowed for the import and marketing, or processing on the territory of Georgia, which was provided in the removed Para 3 and 4 of the same Article.

¹² Article 9 of the Law on Genetically modified organisms before introducing the amendment of 2 March 2016.

¹³ initially, the use of live genetically modified organisms in a closed system requires the operating license if it is classified as second-class security. The use of live genetically modified organisms in a closed system that has a first-class security does not require a license, and is performed in relevant administration on the basis of application.

¹⁴ Para 3 and 1 of Articles 7 and 12 of the Law on live genetically modified organisms".

¹⁵ Para 2 of Articles 10 of the Law on live genetically modified organisms".

¹⁶ Para 8 Articles 12 of the Law on live genetically modified organisms".

¹⁷ Articles 15, 16 and 17 of the Law on live genetically modified organisms".

¹⁸ Para 2 of Article 7 of the "Law on live Gene-modified organisms".

¹⁹ Article 18 of the "Law on live Gene-modified organisms".

scientific committee for live GMOs. Article 20 provided for security measures for the placement of live GMOs on the market. Hence, there were two procedures provided under the initial version of the Law for primary import of live GMO, emanating from the purpose of their use: “use in the closed system” and “placement on the market. These two procedures differed from each other by their complexity and duration. After the prohibition of the placement of GMO on the market, second procedure was canceled. Under Chapter 5 of current law import and re-export of live GMO in Georgia is prohibited (except when imported for the use in closed systems, as provided by this law). Besides, pursuant to Para 11 of Article 22 of the Law, only 5 kilograms of GMOs the same species for the use in one closed system are allowed for the import during one year²⁰.

Chapter 6 of the law sets out the need for compliance of transportation safety, packaging and identification conditions with the norms approved by Georgian Government.

Chapter 7 of the Law provides for the need for access to information on GMO. The same chapter sets out the rules of keeping register. The register shall be kept by Ministry of Environment and Natural Resources Protection and be accessible to the public.

Chapter 8 of the Law lists governmental agencies authorized for the state control and oversight in GMO sector, and their competences.

Chapter 9 covers legal regulation of compensation for damage. Pursuant to Para 2 of Article 30 responsible for the damage caused by GMOs rests with the executor of activities. It should be mentioned that one of important innovations of the Law is the establishment of “the vicarious liability of the State”. According to this principle the State assumes responsibility for the eradication/reduction of negative consequences of the use of GMOs if the person causing the damage cannot be identified, or if it is impossible to reduce or avoid negative impact in the given situation.

The table below illustrates how basic issues regulated under the law changed after the March 2016 amendments:

Comparison table

Legal norms	Initial law (as of September 2014)	The Law as of July 2016
Purpose of the Law	General purpose: protection of the environment and human health, lay the foundations for GMOs scientific research, public access to information etc.	to ensure that Georgia is declared a zone free from GMOs

²⁰ it is not clear what "5 kilo of GMO" means, if it is planned to use gene-modified tree, bush, seaweed or, even, the microorganisms.

The incidence of the law	All live gene-modified organisms except human beings. With the exception of medicines and gene-modified product.	Unchanged
term definition		The term of declaring the free zone has been introduced
GMO regulation principles	Risk assessment principle, on the basis of which GMOs were classified (first-class and second-class security levels) and keeping the register of GMOs allowed for import, placement on the market and/or processing.	Cancelled
GMO-related activities	It was allowed to use GMOs in closed systems and place on the market. Introduction of GMOs into the environment was prohibited.	Placement on the market was banned
License to operate	The use of live genetically modified organisms of first-class security in a closed system did not require a license, just a notification to the Ministry. Activities with second-class security GMOs were subject to licensing	Use of GMO in a closed system requires licensing.
Licensing authority	Ministry of Environment and Natural Resourced protection	Ministry of Environment and Natural Resourced protection
Licensing procedures	A key link in the issuance of the license was GMOs scientific committee, whose conclusion on the use of GMOs was decisive and ultimate	The procedure is simplified and the requirements for legal framework of creating scientific committee, and its tasks and responsibilities were cancelled.
Placement of GMO on the market	GMOs allowed on the territory of Georgia (enlisted in the register-registered) could be placed on the market (without licensing). The list of allowed GMOs would be approved by Minister of Environment and Natural Resources Protection	Placement of GMOs on the market was banned

GMO trans-boundary shipment	Basically in accordance with the procedure established by the Cartagena Protocol	GMO import was restricted and allowed only for the use in closed systems. At the same time not more than 5 kilo GMO could be imported during 1 year for the use in one closed system.
GMO import general rules	GMO may be imported under the consent of Ministry of Environment and Natural Resources Protection through the established procedure	Unchanged
Import of GMO for the use in a closed system	In order to obtain the consent of the Ministry, an importer for this purpose shall have received the license on the use of GMOs in closed systems prior to the first trans-boundary shipment	Unchanged, because GMOs may be imported to the territory of Georgia only for this purpose
GMO re-export and transit	Does not require a license and can be executed on the basis of pre-notification of the Ministry	Re-export has been banned; the same norm is in force for transit
Keeping a common register of GMOs	The register shall be kept with Ministry of Environment and Natural Resources Protection. The register maintained records on the use of GMO, and information on GMO species allowed for placement on the market in Georgia.	The norm was changed and only the information about GMOs used in closed systems are maintained in the register.

Conclusion

The Law of Georgia “On Live Gene-modified Organisms” basically complies with European parliament and the Council directives, and other European countries’ legislations, especially its initial version, where the need for risks assessment and its importance are stressed. Procedures for licensing GMO-related activities (including the establishment of scientific commit scientific committee for live genetically modified organisms), their registrations and keeping the register also comply with EU requirements. The amendments introduced tightened the requirements of the law.

At first sight Georgia seems more protected against the spread the GMO. However, given the capacity of state structures it is hard to believe that the country is fully protected. One cannot exclude possible accidents during the transportation of GMOs from neighboring countries where the control is equally

weak; besides the may be imported illegally, or natural transfer of GMO genetic material in the event of the existence of GMO crops in border regions etc. Without relevant knowledge and experience it will be difficult to control the spread of GMOs and to protect Georgia's biodiversity against possible GMO-caused adverse effect.



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