LAW OF GEORGIA  
ON LIVING GENETICALLY MODIFIED ORGANISMS  

Section I. General Part  

Chapter I - General Provisions  

Article 1 - Objectives of the Law  

a) In compliance with the international agreements operating in this area, to declare the territory of Georgia as an area free from living genetically modified organisms in order to protect people’s life and health as well as to preserve biodiversity and ensure its sustainable use;  
b) In accordance with the principles of environmental protection, to ensure the protection of people’s life and health, and the protection of animals, plants and the environment from the negative influences of living genetically modified organisms;  
c) In the area of the use of living genetically modified organisms, to ensure the performance of the duties determined by the Rio de Janeiro Convention on Biological Diversity of 5 June 1992, and the Cartagena Protocol on Biosafety to the Monreal Convention on Biological Diversity of 29 January 2000, as well as the performance of the duties determined by other international agreements of Georgia;  
d) To contribute to the availability of information in the area of the use of living genetically modified organisms, as well as to public involvement in the decision-making process;  
e) To create a legal basis for conducting scientific studies on living genetically modified organisms.  

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Article 2 - Scope of the Law  

1. This Law regulates legal relations in the field of the use of living genetically modified organisms (hereinafter – the field of genetically modified organisms).  
2. In the field of genetically modified organisms, this Law regulates:  
a) the use of living genetically modified organisms;  
b) their introduction into the environment;  
c) their placement on the market;  
d) their transportation and transboundary movement;  
3. The following issues do not fall within the scope of this Law:  
a) issues related to marketing genetically modified organisms;  
b) issues related to medicaments (pharmaceutical products) which can represent or can include living genetically modified organisms or their ingredients.  

Article 3 - Legislation of Georgia in the area of genetically modified organisms  

The legislation of Georgia in the area of genetically modified organisms includes the Constitution of Georgia, the international agreements and treaties of Georgia, this Law and other legislative and subordinate normative acts of Georgia.  

Article 4 - Definition of terms  

1. For the purposes of this Law, the terms used herein have the following meanings:  
a) living organism – any biological product with the ability to reproduce and/or transfer genetic materials, including sterile organisms, viruses and viroids;  
b) living genetically modified organism (hereinafter, genetically modified organism) – any organism, except for human, whose genetic material has been altered through unnatural methods, more specifically, through the use of modern biotechnological methods; this involves an alteration of an organism’s genetic material under artificial in-vitro conditions by using the method of a direct injection of nucleic acid into the organism’s cells or organelles or by
Article 5 - Basic principles of regulating the field of genetically modified organisms

1. The basic principles of regulating the field of genetically modified organisms are:

a) the harm prevention principle – the use of genetically modified organisms shall be permitted only if, taking into account the existing level of technological development and existing security measures in Georgia, they are not expected to make a direct or indirect, immediate or long-term influence on the environment, biodiversity and people’s health;

b) the principle of ensuring security by the state – through legal and regulatory control, finance policy, education, information provision, and other forms determined by the legislation of Georgia, within their competence, state agencies shall ensure control over genetically modified organisms;

c) the principle of bioethics – together with guaranteeing the well-being of people, a decision-making process in the area of genetically modified organisms shall involve consideration of the necessity of ensuring security for all other living organisms, the environment, and biodiversity, as well as the cultural environment;

d) (Deleted – 02.03.2016, №4799);

e) the precautionary principle – in the process of exercising state control in the area of genetically modified organisms, the absence of complete scientific research shall not result in omitting to take effective economic measures for the purposes of preventing the degradation of the environment;

f) the responsibility principle – violation of the requirements established in the area of genetically modified organisms by this Law and other legislative and subordinate normative acts shall result in the imposition of liability on the violator according to the severity of the violation;

g) publicity and public involvement principle – the public is entitled to receive full and objective information regarding genetically modified organisms, and, in compliance with established rules and procedures, to become involved in the decision-making process in the area of genetically modified organisms.
2. In the course of planning and executing activities in the area of genetically modified organisms, an operator shall be guided by the basic principles provided for by the Law of Georgia on Environmental Protection, as well as Food/Feed Safety, the Veterinary and Plant Protection Code, and the provisions on ensuring a safe environment for people's health determined by the Laws of Georgia on Health Care and Public Health.

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Article 6 - Competence of Georgia's supreme state agencies and government agencies of Autonomous Republics of Abkhazia and Adjara in the area of genetically modified organisms

1. In the area of genetically modified organisms, the following activities fall within the competence of Georgia's Supreme state agencies:
   a) the formulation and implementation of a united state policy and strategy;
   b) the organisation of a united system for regulating genetically modified organisms;
   c) the imposition of state supervision over the fulfilment of the requirements of the legislation of Georgia;
   d) the fulfilment of obligations and the establishment of cooperation as determined by the international agreements and treaties of Georgia;
   e) the performance of other functions as determined by the legislation of Georgia.

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Section II - Main Part

Chapter II - Regulating the area of genetically modified organisms

Article 7 - Performance of activities in the area of genetically modified organisms

1. Genetically modified organisms shall not be introduced into the environment in the territory of Georgia. Violation of the above requirement shall incur criminal liability provided for by the legislation of Georgia.

2. Genetically modified organisms shall not be placed on the market in the territory of Georgia. Violation of the above requirement shall incur criminal liability provided for by the legislation of Georgia.

3. The use of genetically modified organisms in the closed system requires a relevant licence issued by the Ministry.

4. A licence for the use of living genetically modified organisms in a closed system shall be issued in compliance with General Administrative Code of Georgia, and in compliance with this Law, as well as with established rules under the Law of Georgia on Licences and Permits.

5. A licence for the use of living genetically modified organisms in a closed system does not cancel or change any other requirement or permission/licence to perform relevant activities in the territory of Georgia.

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Article 8 - Coordination of the regulation of the use of genetically modified organisms and provision of common organisational support

1. The coordination of the regulation of the use of genetically modified organisms shall be administered, and common organisational support throughout the territory of Georgia shall be provided, by the Ministry.

2. The Government of Georgia shall establish special requirements for treating genetically modified organisms in a closed system.

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Chapter III - Use of genetically modified organisms in a closed system

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Article 9 - Use of genetically modified organisms in a closed system

In a closed system, genetically modified organisms shall be used in compliance with the precautionary and harm prevention principles.

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Article 10 - Licence for the use of living genetically modified organisms in a closed system

1. The use of genetically modified organisms in a closed system requires a licence.

2. In order to obtain a licence provided for by this article, an application (hereinafter, application) shall be submitted to the Ministry in paper form and electronic form. The application shall meet the requirements established by the General Administrative Code and the Law of Georgia on Licences and Permits. An application shall be accompanied by:
   a) information on the location of the closed system;
   b) the identity document of the operator;
   c) identity documents of the project supervisor and a certificate of qualification;
   d) data on the person responsible for biological safety;
   e) the characterisation of the genetically modified organisms;
   f) an assessment of the potential threats (risks) that may be posed as a result of the administered activities;
   g) the monitoring programme and information on control methods;
   h) the emergency (response) scheme in order to avoid and neutralise negative influences on the environment and on people’s health;
   i) the scheme of submitting periodic accounts to the controlling bodies (hereinafter, accounts scheme).

3. A licence for the use of living genetically modified organisms in a closed system shall be issued if:
   a) the documents submitted by an applicant meet the conditions provided for by the legislation of Georgia;
   b) grounds for challenging the reliability of an operator and/or other person responsible for safety do not exist;
   c) the supervisor of the project and the person responsible for the biological safety are duly qualified to perform their duties;
   d) all security measures ensuring the avoidance and elimination of a threat have been taken;
   f) all legal norms ensuring the protection of security measures established by the Code of Labour of Georgia have been met.

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Article 11 - Administrative procedures

1. Administrative procedures for issuing a licence for the use of genetically modified organisms in a closed system shall be undertaken on the basis of the General Administrative Code of Georgia, this Law, as well as the Law of Georgia on Licences and Permits.

2. The Ministry shall examine the compliance of an application with the requirements stipulated under the law. In order to closely examine how carefully the requirements established by the law are met, the Ministry is authorised to require that the applicant submit additional information, if this is necessary to make a relevant decision.

3. (Deleted – 02.03.2016, №4799).

4. (Deleted – 02.03.2016, №4799).

5. (Deleted – 02.03.2016, №4799).

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Article 12 - Making decisions

1. A decision to grant or withhold a licence for the use of genetically modified organisms in a closed system shall be made by the Ministry within 30 days from receiving an application.
2. A licence for the use of living genetically modified organisms in a closed system entitles a person to the right to carry out activities determined by this Law in a certain area in compliance with the conditions provided for by this Law and the legislation of Georgia.

3. The decision on granting a licence for the use of living genetically modified organisms in a closed system, introducing changes to it, terminating, renewing or cancelling it shall be made by the Ministry in compliance with the procedures determined by the legislation of Georgia.

4. The form of a licence for the use of living genetically modified organisms in a closed system shall be determined by an order from the Minister.

5. For the purposes of using living genetically modified organisms in a closed system, an applicant shall pay a licence fee in compliance with the procedures determined by the legislation of Georgia.

6. In the event that a licence for the use of living genetically modified organisms in a closed system has been granted, the licence shall be accompanied by a monitoring programme, initially submitted by the applicant or amended by the issuer of the licence, as well as information regarding the control methods, the precautionary (response) plan and the accounts scheme.

7. Withholding a licence for the use of living genetically modified organisms in a closed system under the pretext of restricting the amount of issued licences is inadmissible, except for the cases provided for by the law.

8. Transferring a licence for the use of living genetically modified organisms in a closed system to another person is inadmissible.

9. Compliance with the licence conditions by the holder of a licence for the use of living genetically modified organisms in a closed system is controlled by the procedures determined by the legislation of Georgia.

Article 13 - (Deleted)

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Article 14 - Taking precautionary measures in the process of using genetically modified organisms in a closed system

1. Genetically modified organisms shall be used in a closed system on condition that the precautionary measures compatible with the existing level of scientific and technological development are taken.

2. Taking into account the existing level of technological and scientific development, the Government of Georgia shall set special requirements for treating genetically modified organisms. The relevant normative act shall define:

   a) organisational and technical measures which shall be taken in the process of using genetically modified organisms in a closed system;

   b) requirements which shall be met in the process of using genetically modified organisms in a closed system in order to avoid negative influences on the environment.

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Article 15 - Responsibilities of an operator

1. An operator is obliged to:

   a) determine security measures compatible with the existing level of scientific and technological development and try to implement them;

   b) gain information with regard to all kinds of security issues from a person accountable for biological safety and from the manager of a project, and where necessary, take consultations from the Ministry.

2. The appointment of a person responsible for biological safety and of a head of the project shall not release the operator from the responsibility to fulfil the obligations to provide security imposed on him/her under the legislation of Georgia.

Article 16 - Person responsible for biological safety

1. In the process of using genetically modified organisms in a closed system, an operator shall appoint a person with required knowledge and experience in a relevant field to be responsible for biological safety.

2. The person responsible for biological safety shall:

   a) provide supervision over the safe use of genetically modified organisms in a closed system and immediately inform the operator and the project manager regarding any fault detected in the course of activities;

   b) ensure the formulation of an emergency (response) scheme and the creation of its implementation tools.

3. The rights and duties of the person responsible for biological safety shall be determined by the by-laws of an enterprise, which are established by an operator.
Article 17 - Project manager

1. In the process of using genetically modified organisms in a closed system, an operator shall appoint a project manager with required knowledge and experience in a relevant field.

2. A project manager shall plan the course of activities, and manage and supervise them.
   
   He/she shall be responsible for:
   
   a) providing persons involved in the process of executing activities with information regarding security measures and risks as well as urgent actions to be taken in order to eliminate those risks;
   
   b) making efforts to implement safety measures.

3. The rights and duties of the project manager shall be determined by the by-laws of the enterprise established by the operator.

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Chapter IV - (Deleted).

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Article 18 - (Deleted)

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Article 19 - (Deleted)

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Article 20 - (Deleted)

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Chapter V - Regulating transboundary movements of genetically modified organisms

Article 21 - Tools for regulating transboundary movements of genetically modified organisms

Transboundary movements permitted by this Law are regulated by the procedures of predetermined validity determined by the Cartagena Protocol on Biosafety in compliance with the requirements determined by this Law.

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Article 22 - Regulating transboundary movements of genetically modified organisms

1. The importation of genetically modified organisms in order to introduce them into the territory of Georgia is inadmissible.

2. An operator or an importer may not import more than 5 kilograms of genetically modified organisms of the same kind for the purposes of using them in a closed system.

3. In the case of importation of genetically modified organisms for the purposes of using them in a closed system, the importer shall obtain a licence for the use of living genetically modified organisms in a closed system before carrying out the first intended transboundary movement of these organisms.

4. Before carrying out the first intended transboundary movement of genetically modified organisms for the purposes of using them in a closed system, the importer shall inform the Ministry in written form regarding his/her intention.

5. Within 30 days of receiving the notice mentioned in paragraph 3 of this article, the Ministry shall examine the compliance of this notice with the requirements provided for by paragraph 2 of this article, and shall inform the submitter of the notice regarding the procedures which are determined by the legislation of Georgia and the fulfilment of which are mandatory in order to obtain initial approval and subsequently to import the genetically modified organisms into the country.

6. The Ministry issues approval for transboundary movements of genetically modified organisms, which entitles the importer to the right to import genetically modified organisms for the purposes provided for by the licence.
3. The Ministry shall systematize and make information from mediation mechanisms of biodiversity available to the public.

   g) information regarding reconsidering a decision in compliance with Article 12 of the Cartagena Protocol on Biodiversity.

8. State control and supervision of compliance with the requirements of importing/re-exporting genetically modified organisms determined by this law is provided by the legal entity under public law called the Revenue Service of the Ministry of Finance of Georgia (the Revenue service). The Revenue Service shall immediately inform law-enforcement agencies about the importation of genetically modified organisms (except for instances, provided for by this law, where such organisms are imported for the purposes of being used in a closed system) or their re-exportation, while in case of the importation of genetically modified organisms in a closed system, the Revenue Service shall inform the Ministry regarding the quantity of the imported genetically modified organisms, as well as their manufacturers.

9. Transboundary movements for the purposes of transporting genetically modified organisms do not require a licence and are carried out on the basis of a preliminary notification filed with the Ministry.

10. A preliminary notification shall be filed with the Ministry by a person carrying out a transit operation. This notification shall include information proving that the genetically modified organisms are being exported in compliance with the legislation of a state to which these organisms are being exported and the requirements by the Cartagena Protocol on Biosafety have been observed.

11. The Ministry shall examine whether the requirements for transportation of genetically modified organisms determined by this Law have been observed and, within 30 days of receiving a request, the Ministry shall either approve the request or reject it.

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Article 23 - (Deleted)

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Article 24 - State agency responsible for handling mediation mechanisms of biodiversity

1. The state agency responsible for handling mechanisms of biodiversity envisaged in the Cartagena Protocol on Biosafety is the Ministry.

2. The Ministry shall provide a mediation mechanism of biodiversity with the following information determined by the Cartagena Protocol on Biosafety:

   a) according to Article 11 (5) and Article 20 (1) (a) of the Protocol, information regarding the legislation of Georgia, which handles the issues related to the use of the Cartagena Protocol on Biosafety;

   b) contact details of the body responsible for receiving information regarding the unplanned transboundary movements envisaged in Article 17 of the Cartagena Protocol on Biosafety;

   c) information regarding bilateral, regional and multilateral agreements and treaties envisaged in Article 20(3)(b) of the Cartagena Protocol on Biosafety;

   d) information regarding unplanned and illegal transboundary movements carried out on the territory of Georgia provided for by Articles 17 and 25 of the Cartagena Protocol on Biosafety;

   e) in accordance with Article 15 and Article 20 (3) (c) of the Cartagena Protocol on Biosafety, information regarding an authorised administrative body which issues a licence on the use of living genetically modified organisms in the closed system within 15 days after making a decision in compliance with Article 11 and Article 20 (3) (d) of the Cartagena Protocol on Biosafety;

   f) risk assessments and the brief on the results of ecological surveys made by the Ministry;

   g) information regarding reconsidering a decision in compliance with Article 12 of the Cartagena Protocol on Biosafety.

3. The Ministry shall systematize and make information from mediation mechanisms of biodiversity available to the public.

Chapter VI - Transportation of Genetically Modified Organisms

Article 25 - Safety measures in the process of transportation of genetically modified organisms

1. In the process of the transportation of genetically modified organisms in Georgia, the requirements on “the conditions of safety, labelling, packaging and identification in the process of transportation of genetically modified organisms in Georgia” laid down by ordinance of the Government of Georgia shall be observed.

2. (Deleted – 02.03.2016, N4799).

3. In the process of the transportation of genetically modified organisms in Georgia, the accompanying documents shall include the following
a) that the product represents a genetically modified organism, and is being transported in Georgia for the purposes of using it in a closed system;

b) the name, address and other data of the contact person in order to obtain additional information regarding the goods, as well as the name and address of the person to whom the goods are being sent.

4. d) (Deleted – 02.03.2016, N=4799).

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### Chapter VII - Availability of Information in the Field of Genetically Modified Organisms and Public Involvement in Decision-making Process

#### Article 26 - Availability of information in the field of genetically modified organisms

1. Information in the field of genetically modified organisms shall be transparent and available to the public.

2. The availability of information in the field of genetically modified organisms shall be ensured by the legislation of Georgia as well as by international treaties.

3. With regard to the availability of information provided for this article, the requirements envisaged in Article 3 of the General Administrative Code of Georgia, as well as the provisions of this article, shall be used.

#### Article 27 - Unified registry of living genetically modified organisms

1. The Ministry shall establish the unified registry of living genetically modified organisms, which keeps information regarding genetically modified organisms used in a closed system. Together with a paper-based version of the registry, its electronic version, which will be placed on a special webpage, shall also be established.

2. Within two days after receiving any kind of information in the field of genetically modified organisms, the following information shall be included in the unified registry of living genetically modified organisms:

   a) the names and addresses of the people (in the case of a legal person, the legal name of the business and the legal form of ownership), who have filed an application to the Ministry;

   b) information regarding each particular instance of issuing a licence for the use of living genetically modified organisms in a closed system, which shall include a description of the general characteristics of the relevant genetically modified organism, as well as the name of the recipient of the licence;

   c) information regarding the place where the genetically modified organism was manufactured, as well as the persons involved in the manufacturing process, the description of the organism and its general characteristics;

   d) data regarding the characteristics of the relevant genetically modified organism, its location and the person carrying out operations in the closed system;

   e) other data determined by the legislation of Georgia.

3. The unified registry of living genetically modified organisms is a public document. Any person is entitled to inspect the registry in the shortest period of time and, for payment of a charge determined by the legislation of Georgia, receive a copy of the entire registry or of a particular section of the registry.

4. Information deemed to be confidential under the legislation of Georgia shall not be included in the registry.

5. Procedures for introducing a form of the unified national registry for living genetically modified organisms and the manner of keeping the registry are determined by order of the Ministry.

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### Chapter VIII – State Control and Supervision in the Field of Living Genetically Modified Organisms and Liability for Violation

#### Article 28 - State control and supervision in the area of living genetically modified organisms

1. The state agencies authorised to perform state control and supervision activities in the area of genetically modified organisms are as follows:

   a) the Ministry, which:

      a.a) in compliance with the Cartagena Protocol on Biosafety, fulfils the functions of a state coordinating centre and a competent state agency;
Article 29 - Liability for violating this Law

Liability for violating this law is determined by the legislation of Georgia.

Chapter IX - Indemnification of Damage

Article 30 - Legal procedures for regulating indemnification of damage

1. In the area of genetically modified organisms, damage sustained as a result of the activities envisaged in this Law shall be indemnified in compliance with the procedures on environmental protection provided for by the legislation of Georgia.

2. In the course of activities envisaged in this Law, in case of an encroachment upon a person's right to life or the infliction of harm on a person's health or the environment, liabilities to indemnify damage shall be imposed on the operator. He/she shall be held liable to indemnify the damage which has been sustained by the hazardous features of genetically modified organisms.

3. The imposition of liability does not result in the offender's exemption from the obligation to indemnify the damage caused as a result of violating this Law, in compliance with the established procedures.

4. Procedures for calculating environmental damage caused by the harmful effects of genetically modified organisms are determined by an ordinance of the Government of Georgia.

5. In order to guarantee the proper performance of their duties to a third person, an operator shall obtain insurance for their business activities in a private insurance company, in compliance with the legislation of Georgia.

6. An operator shall be released from the liability to indemnify the damage if this damage is a direct consequence of civil disorders, wars, natural disasters or other unavoidable circumstances.

Article 31 - The Principle of subsidiarity

The state shall ensure the reduction and/or elimination of the negative effects of the use of genetically modified organisms, if a person responsible cannot be identified or the elimination and/or reduction of negative consequences is otherwise impossible.
Chapter X - Transitional Provisions

Article 32 - Normative acts to be adopted in relation to the entry into force of the Law
1. The Government of Georgia shall, not later than 1 August 2015, adopt ordinances on:
   a) the Criteria for Defining the Class of Safety for the Use of Living Genetically Modified Organisms;
   b) the Conditions of Safety, Labelling, Packaging and Identification in the Process of Transporting Genetically Modified Organisms to Georgia;
   c) Border Controls upon the Movements of Genetically Modified Organisms Crossing the Border of Georgia;
   d) Special Requirements for Treating Living Genetically Modified Organisms;
   e) the Procedures for Calculating Environmental Damage from Harmful Effects of Living Genetically Modified Organisms;
   f) Expert Methodology, the Form and Principles for Drawing up Expert Conclusions on Potential Negative Effects of Living Genetically Modified Organisms on the Environment, Biodiversity and People's Health;
   g) Special procedures for Registering Living Genetically Modified Organisms Marketed and Used in Closed Systems in the Territory of Georgia;
2. Before 1 January 2015, the Ministry shall formulate and approve:
   a) procedures for managing databases of experts in living genetically modified organisms and minimum qualification requirements for such experts;
   b) the regulation and constitution of the scientific commission of living genetically modified organisms;
   c) a form of licence for the use of living genetically modified organisms in a closed system;
   d) the ordinance on the unified registry of living genetically modified organisms;
   e) a form of request on registering living genetically modified organisms;
   f) procedures for referring living genetically modified organisms used in a closed system in Georgia and placed on the market before 1 January 2015, to the unified register of living genetically modified organisms, as well as the conditions for regulating them.

Article 33 - Transitional provisions with regard to genetically modified organisms used in the territory of Georgia before 1 January 2015
1. Within a year from 1 January 2015, genetically modified organisms used in closed systems and marketed in the territory of Georgia before January 1, 2015, shall be included in the unified register of living genetically modified organisms.
2. The inclusion of genetically modified organisms provided for by paragraph 1 of this article in the unified register of living genetically modified organisms may not be considered as the issuance of a licence on the use of genetically modified organisms, as determined by this Law, in a closed system.

Chapter XI - Final Provisions

Article 34 - Entry into force
1. This Law, except for Articles 1-31 and 33, shall enter into force upon its promulgation.
2. Articles 1-31 and 33 of this Law shall enter into force on 1 October 2015.

President of Georgia
Giorgi Margvelashvili
Kutaisi
18 September 2014
No 2656-Ib