**Information on Legislation of Georgia in**

**the area of genetically modified organisms**

The Law of Georgia on “Living Genetically Modified Organisms” regulates legal relations in the field of the use of living genetically modified organisms (hereinafter – the field of genetically modified organisms)

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 of Environmental Protection and Agriculture (hereinafter the Ministry).

One of the objectives of the law is to declare Georgia a free zone, that implies to ban the introduction of genetically modified organisms into the environment, their placement on the market, as well as their re-exportation and import, except where they are imported to be used in a closed system. Accordingly, the introduction of genetically modified organisms into the environment, the placement on the market, import, re-export is prohibited on the territory of Georgia.

According to the Law, use genetically modified organisms is allowed in a closed system, which requires a license issued by the Ministry. Genetically modified organisms in transit are allowed as well.

Use of genetically modified organisms in a closed system: any operation/manipulation for scientific-research or experimental purposes, within an installation, building or other physical structure, held on or related to genetically modified organisms, including receiving, storing and placing them as food waste, and which requires the maintenance of special conditions in order to effectively restrict the release of genetically modified organisms into the environment, and avoid its effect on the environment and people's health.

Introduction into the environment – the release of genetically modified organisms into the environment.

Placement on the market – any activity making genetically modified organisms available to a third person (including ultimate customers) in return for definite payments or free of charge, except where genetically modified organisms are intended to be used in a closed system;

Transboundary movement – export, import, transit or re-export or any movement of genetically modified organisms from a region under the jurisdiction of a definite state into a region under the jurisdiction of another state or through such region, or the movement of genetically modified organisms in a region or through a region which is not under the jurisdiction of any state, on the condition that this type of movement falls within the authority of at least two states;

**Use of genetically modified organisms in a closed system**

The use of genetically modified organisms in a closed system requires a license. According to the law, in order to obtain a license 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 licenses 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 characterization 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 program and information on control methods;

h) the emergency (response) scheme in order to avoid and neutralize negative influences on the environment and on people's health;

i) the scheme of submitting periodic accounts to the controlling bodies (hereinafter, accounts scheme).

Transfer to another person of the license for use of living genetically modified organisms in a closed system is prohibited. The license for the use of living GMO 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.

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 authorized to require that the applicant submits additional information, if this is necessary to make a relevant decision.

A decision to grant or withhold a license for the use of genetically modified organisms in a closed system shall be made by the Ministry within 30 days from receiving an application.

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

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

Transferring a license for the use of living genetically modified organisms in a closed system to another person is inadmissible. The operator of the activity is obliged to:

ა) Organizational 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.

The developer is required for each genetically modified organism in a closed system using biological safety designate a responsible person who has the relevant knowledge and practical experience in the relevant field.

A person responsible for biological safety is obliged to:

1. Carry out supervision over the safe use of genetically modified organisms in a closed system and immediately inform the operator and the project

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

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 operator.

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

**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.

It is prohibited for an operator or an importer to import more than 5 kilograms of genetically modified organisms of the same kind per year for the purposes of using them in a closed system

In the case of import of genetically modified organisms for the purposes of using them in a closed system, the importer is obliged to obtain a license for the use of living genetically modified organisms in a closed system before carrying out the first intended transboundary movement of these organisms.

Before carrying out the first intended transboundary movement of genetically modified organisms for the purposes of using them in a closed system, the importer is obliged to inform the Ministry in written form regarding their intention.

Within 30 days from receiving the notice, the Ministry shall examine the compliance of this notice with the requirements and shall inform the submitter of the notice regarding the procedures which are determined by the legislation of Georgia and are mandatory in order to obtain initial approval for future imports of genetically modified organisms into the country.

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.

An approval for transboundary movements of genetically modified organisms shall be issued within a month after submitting a written request, except for instances when approval is issued for the purposes of issuing a relevant license on the basis of the applicant's requirement.

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 using 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.

 **Transboundary movement of genetically
modified organisms for the purpose of transit**

Transboundary movement for transit of genetically modified organisms does not require a license and is carried out on the basis of prior notification to the Ministry.

A preliminary notification must be sent to 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 the country to which these organisms are being exported and the requirements by the Cartagena Protocol on Biosafety have been considered.

The Ministry examines whether the requirements for the transportation of genetically modified organism are preserved and within 30 days after the submission of the relevant application makes a decision on refusal or satisfying the application.

**Transportation of Genetically Modified Organisms**

Safety, labeling, packing and identification of the genetically modified organisation must be protected on the territory of Georgia. The enclosed documentation should indicate that the product represents a genetically modified organism; as well as the name, address and other information of the contact person.

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

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.

 **State Control and Supervision in the Field of**

 **Living Genetically Modified Organisms**

The Ministry, within its competency, carries out state supervision and control in the area of genetically modified organisms; The Ministry of Finance of Georgia carries out customs control on genetically modified organisms of the transboundary movement and performs other functions under the legislation of Georgia.