NBSAP updating in the thematic field of

Biosafety

Situation Analysis

REC Caucasus

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Content

1. Policy and legal framework

1.1. National policy and legal framework

Biosafety issues are covered by only one strategic document at present in Georgia. Biodiversity strategy and Action Plan (NBSAP, adopted by decree of government No 25, 19.02.2005) defined following strategic goal: **To protect both the human population and biodiversity from potential threats from genetically modified organisms (biotechnology), through the strengthening the law and through increasing public involvement in decision making.** The following specific objectives are identified by NBSAP to achieve above mentioned goal:

- *To create a sufficiently enough legal basis to address biosafety issues in the country*
- *To develop effective official and public control mechanisms*
- *To ensure the transparency of any initiatives involving GM organisms or products*

The action plan 2005-2010 set up by NBSAP for Biosafety field is partially implemented. As already noted, no normative regulations have been adopted on biosafety. After 2005, certain progress was made on GMO detection and determination in regard with creation of scientific and technical capabilities. Biosafety issues are included in general and higher education programs. Public awareness raising activities have been partially implemented by NGO sector. The action plan introduced by NBSAP for biosafety and its implementation status is presented in the Appendix I.

In the National Environmental Action Program (NEAP 2011-2015) (adopted on 24 January 2012, the Order # 127 by the Government) describing the current situation of biodiversity, indicates that due to the absence of a biosafety system in Georgia the risks related to Living Modified Organisms (LMOs) are not regulated. It is also indicated that scale of risks from LMOs on bio and biodiversity is unknown, while it is important to develop sufficient risk management system. According to the program, appropriate action plan has not been developed.

Draft **"Strategy of development Georgian Agriculture for 2011-2021"** has been developed recently by the Ministry of Agriculture, which considers establishment of profitable, competitive and sustainable Agro-Food sector through enlargement of small and medium farms and formation of complete production chain. Document does not covered biosafety issues at all.

No relevant legislative and regulatory acts have been adopted in Georgia, which can determine LMO- related risk management procedures. Existing legislations and strategic documents for Environment and Agriculture are in indirect relation with biosafety issues.

Existing legislation and legislative initiatives are discussed below in three directions:

1. ***Biosafety*** – address the risks posed to the environment and human health when GMOs are released in to the environment either for research (e.g. small-scale or field-testing) or for commercial purposes. Biosafety instruments also address contained use of GMOs.

2. ***Food safety -*** address the risks posed to humans by genetically modified foods. General goal of these instruments is to minimize risks to humans presented by GMOs or their products used as foods themselves or as ingredients in food. Ideally the entire human food chain is examined, moving from the farm to the kitchen table. A related area is animal feed safety.
3. ***Consumer protection -*** primarily address the labeling of end products resulting from genetic engineering, such as food or animal feed. In general, these instruments are designed to: Protect the consumers' right to know and the right to make informed choices; and ensure fair trade practices.

Biosafety

In 2005 The Draft National Biosafety Framework for Georgia was elaborated under GEF/UNDP project on the development of national biosafety frameworks. The draft NBF for Georgia is represented as the complex comprising of a basic draft law on ``Genetically Modified Organisms`` and package of corresponding amendments to the existing national legislative acts. Due to existing necessity of creation of new approaches and regulatory mechanisms in the field of GMO, the following new norms were established by draft NBF:

- defines authorities and competence of Georgian Government in the filed of management and regulation of GMOs;
- states natural and legal persons' rights and obligations in the field of use of GMOs;
- Establishes an unified state/ national system for management and regulation of GMOs and Gimps. Also, this unified national system includes procedures for transboundary movement;
- provides that information in the field of GMOs is open and accessible for the general public. Also, it gives possibilities for public active participation and involvement in the early stages of decision-making process, monitoring and control;
- establishes and defines status and categories of GMOs free zones;
- determines responsible state authorities for control and supervision in the field of use of GMOs;

- states compensation for damage and liability for violations;

However, legislative and institutional amendments, implemented shortly after the development of the draft legislative package, conditioned the need for bringing administrative procedures, competences and other aspects, determined by the documents, in compliance with the new laws and regulations. For this purpose, the Ministry of Economic Development prepared Draft Government Resolution on Biodiversity Protection on the Territory of Georgia (2010). A working group was set up by order #587 of the Minister of Environment Protection and Natural Resources of Georgia of November 27, 2009 to develop regulations for GMO management. Under the order, the group was tasked with preparing Draft Law on Genetically Modified Organisms until May 1, 2010; however, work on the updated version of the draft law is yet in progress. It should be noted that at the initial stage it appears more advisable for the government to adopt a provisional regulatory act in the biosafety sphere that would imply more flexibility and opportunities for addressing the identified shortcomings. However, to achieve this, the government of Georgia needs to have corresponding commissions defined, or a corresponding legislative act or an executive order issued.

In 2010, the Ministry of Environmental protection prepared Draft of Environment Protection Code. Part 7, Chapter XXIII of the Draft Code regulates issues concerning genetic resources and biosafety: Availability of genetic resources; Biosafety; Consumer awareness about genetically modified products. However, this part of the Code's draft version still requires considerable improvement.

The Law of Georgia "On New Animal and Plant Species" (2010) that aims at regulating legal protection and use of new animal and plant species and concerns all new varieties and species of agricultural animals and plants, bans the application of genetic engineering methods to animal and plant genetic resources (Article 1). In compliance with the law, dissemination of seeds and seedlings is permitted only with quality and phytosanitary certificates (Article 46). Furthermore, additional requirements for dissemination of seeds and seedlings in Georgia were to be determined by a resolution of the Government of Georgia that is yet to be adopted.

At the same time, the current legislation fails to create any barriers for LMO import in Georgia. There are no restrictions in force concerning import and dissemination of new plant or animal species. Import of plant and animal materials is subject only to phytosanitary and veterinary control and requires only phytosanitary and veterinary permits and certificates (Law of Georgia **"On Licenses and Permits"**, 2005).

The legislation fails to reflect the legal requirements and commitments, envisaged by the Cartagena Protocol on Biosafety, concerning the Advance Informed Agreement Procedure (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). There are no appropriate regulations available for safe transportation, handling, use and introduction of LMOs.

The Law of Georgia **"On the System of Protected Areas"** (1996) sets indirect restrictions to LMO dissemination by banning introduction and dissemination of alien species in the protected areas (Article 20). The Law of Georgia **"On Wild Fauna"** (1996) prohibits introduction in nature of alien species and hybrid forms except for biological plant protection means (Articles 22 and 23).

Food Safety

From the standpoint of food safety, existing legislation and strategic documents don't deal with GMO, whether for human consumption or for fodder, nor with GMO based products.

The only restriction is set for biological production. According to Governmental Standard 68:2007 on Main Requirements and Production Conditions of Biological Production of 2007, products produced through genetic engineering do not conform with biological production principles and should not be present in primary produce of crop production or animal husbandry for human consumption, neither in processed organic produce of crop production and animal husbandry. It should be noted that aforesaid standard has been elaborated based on *Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods* of the Codex Alimentarius Commission ((guidelines 32-1999, review 2001-1), European Regulation 2092/91 *On Organic Production of Agricultural Products and Indications referring thereto on Agricultural Products and Foodstuffs,* as well as on the basic standards of International Federation of Organic Agriculture Movements (IFOAM) on biological agricultural production and processing. It should be noted, that in EU Regulation EEC 834 has been published on June 28, 2007, also dealing with rules of organic agricultural production, introducing amendments to previously enacted legislation.

Law of Georgia on **Food Safety and Quality** (2005) regulates procedures of biological production certification and labeling (Article 12). By virtue of said article, certificate of biological produce is to be issued in case production process complies with the provisions of Georgian legislation and appropriate standards.

Law of Georgia on **Food Safety and Quality** (2005) defines legal framework for elaboration, implementation and coordination of state policy in the field of food safety. By virtue of the law, state policy in the field of the food safety is to be determined by the Ministry of Agriculture. The purpose of the law is to ensure protection of life, health and economic interests of the consumers of the

foodstuffs, taking into consideration efficient operation of the domestic market and its diversity. The law regulates general principles and requirements of the food and fodder safety, quality and labeling, obligations imposed on food/fodders producers and distributors, instruments of state control over food/fodders safety and quality, establishes competences of the state agency authorized to carry out control and supervision.

In 2010 **The Comprehensive Strategy and Legislative Approximation Program in Food Safety** was adopted by Government of Georgia (Decree #1756, 28.12.2010). The aim of the Government of Georgia as demonstrated in this Strategy and Legislative Approximation Program is to further develop legal and institutional framework in the food safety area and establish a solid food safety system in Georgia in line with the EU and international standards. The Strategy aims at: a) Analyzing the existing legislative and institutional framework and identifying possible shortcomings and needs. b) Describing the steps, Government of Georgia intends to take in order to introduce a solid food safety system in Georgia. c) Outlining principles and priorities by which the establishment of such a system should be guided. d) Identifying the needs, goals and challenges, associated with implementation of each component of the food safety system. e) Introducing timelines and stages in which the implementation should be ensured. For this purposes the Strategy is accompanied by the Legislative Approximation Program. The strategy is based on the 'from farm to fork' principle, which means that it will cover the whole chain from farm level to the final consumer. However GMO related risks management issues is not included in the Document. However, the risk control and management systems, mentioned in the document, can be applied to LMO's too.

Legislative Approximation Program for 2010-2014 was approved alongside with the Food Safety Strategy. The program does not mention the EU directives and regulations concerning biosafety and GMOs. Consequently, it does not envisage development of corresponding national legal documents.

The institutional framework of the food safety system in Georgia consists of a number of institutions. Efficient coordination of activities between the following institutions is essential for the establishment of a solid food safety system in Georgia and introduction of food safety official control:

- Ministry of Agriculture – responsible for policy-making in the field of food safety.
- Ministry of Labor, Health and Social Protection – responsible for participation in setting food safety parameters and norms and contribution to crisis management.
- The National Service of Food Safety, Veterinary and Plant Protection (hereafter NS) under the Ministry of Agriculture – responsible for food safety supervision, monitoring and control.

- Revenue Service under the Ministry of Finance (hereafter RS) – responsible for SPS border control. Officials performing SPS control at the border are hired by the Revenue Service. A special division for veterinary, sanitary and phyto-sanitary control was created within the Revenue Service in April 2007. This division is in charge of SPS control at the border and has authority to control and supervise daily work of phyto-sanitary and veterinary specialists of territorial units of the RS.

In case non-compliance is identified during the SPS control at the border, the RS makes decision on destruction or return of consignment and immediately notifies the NS via electronic means of communication.

Particular attention is paid to:

- Registration of food business operators and development of proper company databases.
- Introduction of official control mechanisms, most notably checks and inspections by the National Service for Food Safety, Veterinary and Plant Protection.
- Introduction of official control at the border, in particular by the Revenue Service.
- Ensuring efficient coordination between the National Service and the Revenue Service.
- Further develop the system of laboratories to facilitate introduction of official control system.

National Service for Food Safety has the responsibility for elaboration of risk assessment, and management and communication of risks. Hereby, elaboration of risk assessment methodology can be outsourced to the third party whereby introduction and implementation of risk assessment is under the responsibility of the NS. The third party may be a scientific or any other relevant institution, or qualified experts who provide necessary expertise and assistance for elaboration of risk assessment. In that case if such a decision is made in the future, the coordination of risk assessment activities should remain under the responsibility of the NS.

Strategy also outlines channels of cooperation between National Service and Legal Entity under Public Law - Revenue Service in conduction of border and quarantine control

Capacities of laboratory system are assessed. The State Unified Laboratory System is supervised by the Coordination Board, statute of which is adopted by the Government of Georgia (252 Decree of Government, November 15, 2007). It consists of high-ranking representatives of Georgian Government and chaired by the Minister of Labor, Health and Social Protection (159 Decree of Government, July 30, 2008). The State Unified Laboratory System consists of laboratories with different bio-safety levels. The Coordination Board of the State Unified Laboratory System facilitates coordination and cooperation between these laboratories.

The above-mentioned laboratories under the Ministry of Agriculture and NCDC under the Ministry of Labor, Health and Social Protection are dealing with Especially Dangerous Pathogens (EDPs) and function under the Biological Threat Reduction Program (BTRP). This program started in 2002 under the Department of Defense of the US, namely, Defense Threat Reduction Agency (DTRA). It should be mentioned that under the Biological Threat Reduction Program (BTRP), Central Reference Laboratory (CRL) has been established.

Strategy discusses possibility of establishment of independent inspecting agency with certain amount of authority. On later stages, Georgian government may elaborate legal framework providing for independent inspecting agencies within the state control system. If such legislation is indeed adopted, by all means it will comply with EU legislation, namely, complying with EC Regulation N882/2004. According to the latter, it is possible for the state controlling agency to delegate number of its functions to third independent party. As per international practice, third independent party may be represented by independent inspecting agency or private laboratory.

Consumers' Rights Protection

According to the Rules of Labeling provided under the law on Food Safety and Quality (Article 19), on December 11, 2009, Decree #2-231 of the Minister of Agriculture on **Adoption of Additional Requirements of the Food Labeling** has been enacted. Article 9 of the latter regulates GMO products labeling issues as follows:

1. Food produced by means of modern biological technologies containing more that 0, 9% of GMO components out of its total mass should bear appropriated indication on its label.

2. If the food product contains only one genetically modified ingredient, then indication of 'genetically modified organism' (GMO) should be placed near the brand name of the food product.

3. If the food product contains two or more ingredients, one of which is genetically modified, then GMO inscription should be placed in the list of ingredients alongside the ingredient which has been genetically modified.

4. Food product not containing DNA and is produced on the basis of genetically modified organisms, is subject to mandatory labeling based on the declaration of the country of the origin of the raw product.

5. GMO containing unpacked food intended for retail trade should be enclosed with written informational notices-inserts and/or booklets, available for every consumer.

6. GMO containing food packed into small rations with surface less than 10 cm^2 should bear inscription of "genetically modified food product" or "containing GMO".

Based on the above rules, appropriate amendments have been made to the Code of Administrative Offenses of Georgia (Article 1543):
1. Breach of rules of labeling will be fined by 1,000 GEL
2. Repeated violation within one year of the previous offense will be fined by 5,000 GEL

When amendments to the legislation requiring GMO related labeling have been adopted, food control in the country was suspended, executive agencies not being authorized to carry out state control. Since January 3, 2011, the law has been fully enacted and inspections of food producers have begun, but as of today only few sampling on GMO detection has been collected. Main focus having been made on high risk producers, such as:
- products of animal origin
- infant food products
- conserved products with pH lower than 4,7
(high risk producers are defined by the law on Food Safety)

1.2. Georgia's International Obligations in Biosafety

Convention on Biodiversity (1992) and Cartagena Protocol on Biosafety (2003)

Convention on Biodiversity became the first multilateral agreement recognizing risks related to living modified organisms and defined countries' obligations with regards to management of said risks. Georgia joined Convention on Biodiversity in 1994. Several provisions of the Convention on Biodiversity directly deal with LMOs. For instance, according to Article 8 (g), parties are obliged to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms. It should be noted that based on Convention Resolution II/15 only those organisms are considered to be LMO that have new combination of genetic material produced by means of application of modern biological technologies. According to Clause 4, Article 19, countries - parties to the Convention should provide the countries LMO are to be introduced to with any available information about the use and safety regulations ... as well as any available information on the potential adverse impact of the specific organisms.

According to Clause 3, Article 19 of the Convention, parties have been provided with an opportunity of considering, within the framework of the Convention, the issue of preparing and

adopting a protocol, setting out appropriate procedures in relation to safe transfer, handling and use of LMOs. Accordingly, 2000 Conference of the Parties to Convention adopted Cartagena Protocol on Biosafety, enacted in 2003.

Georgia joined Cartagena Protocol on Biosafety on September 26, 2008, by virtue of Parliamentary decree. Protocol has been enacted in Georgia on February 2, 2009.

By virtue of the Protocol, unified system of standards and procedures is being established, providing for justified decision on introducing LMOs into each of the participating countries. As it has been noted above, Georgia haven't yet enacted legislative and administrative framework in order to fulfill obligations assumed under the Protocol

Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus Convention) (1998)

Aarhus Convention has been ratified by Georgia in 2000. Convention provides for mandatory and voluntary measures with regards to GMOs. Specifically, Article 4 of the Convention on Access to Environmental Information deals with information related to GMOs, and, by virtue of the same Article, public authorities are obliged to make such information available to the public without interest having to be stated and in the form requested and as soon as possible. As for public involvement into decision making on deliberate release of the GMOs into the environment, Aarhus Convention leaves it up to the parties to regulate in appropriate and feasible manner within the framework of national legislation (Article 6.11)

Amendments to the Convention adopted in Almay, Kazakhstan, on 2005 Second Meeting of the Parties to the Convention, dealing especially with the public participation in decision making on deliberate release of GMOs into environment and market networks. Said agreement haven't yet been enacted, as it hasn't been ratified by sufficient number of the Parties. Amendments to the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters have been translated into Georgian. No domestic procedures to ratify these amendments have as yet been initiated.

Purpose of adopting mentioned amendments was to define obligation of the Parties in a clearer way than it is set out by the current edition of the Convention; also, it was necessary to bring certain provisions into compliance with Cartagena Protocol, which, in its turn, defines obligations of the Parties with regards to informing the public and public participation in decision-making (Cartagena Protocol on Biosafety, Article 23). According to amendments to the Convention (and as opposed to provisions currently in force), the Parties will be obliged to incorporate provisions on informing the public and public participation in decision-making with regards to deliberate release

of GMOs into environment and their placement in the market network, specifically legally defining procedures, deadlines, type of information that can not be kept confidential, also obligation to inform the public about received notifications on deliberate release of GMOs into environment and provide information on risk assessment.

Georgian legislation doesn't reflect Aarhus Convention and Cartagena Protocol provisions on informing the public and public participation in decision-making with regards to GMOs. Current draft law *on Genetically Modified Organisms* provides for appropriate procedures, whilst governmental draft law *on Protection of Biodiversity in Georgia* provides only for information accessibility not defining any means to ensure public participation in decision-making.

International Plant Protection Convention (IPPC), 1951

Georgia is party of the IPPC from 2006. The Aim of the convention is to protect cultivated and wild plants by preventing the introduction and spread of pests. International Standard for Phytosanitary Measures #11 (ISPM No11) endorsed in April, on Pest Risk Analysis for quarantine pests including analysis of Environmental risks and living modified organisms, provides details for the conduct of pest risk analysis (PRA) to determine if pests are quarantine pests. It describes the integrated processes to be used for risk assessment as well as the selection of risk management options. It includes guidance on evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs). According to the standard plant pest risk from LMOs may be presented by:

- The organism(s) with the inserted gene(s) (i.e. the LMO)
- The combination of genetic material (e.g. gene from plant pests such as viruses) or
- The consequences of the genetic material moving to another organism.

Therefore, part of the supplementary text provides guidance on how to determine if an LMO is a potential pest.

World Organization for Animal Health

Since 1993 Georgia is a member of World Organization for Animal Health. Within the framework of said organization, International Office of Epizootics has elaborated guidelines on use of products derived through genetic engineering and biotechnologies in animal husbandry (2005)

Codex Alimentarius Commission

Since 1997 Georgia became member of Codex Alimentarius Commission and, accordingly, standards adopted within the framework of the Commission have been registered in the Georgian National Agency for Standards, Technical Regulations and Metrology (GEOSTM). Codex Alimentarius defines general principles and guidelines with regards to food safety and

harmlessness, including also the Code of Conduct with regards to release into environment of exotic biological objects (1996). The Code, having advisory capacity, doesn't have legal power. However, the Code plays important role with regards to genetically modified organisms, as within its framework number of standards have been adopted on safety of food produced by means of modern biotechnologies. For instance:

CAC/GL 44-2003 – Principles for the Risk Analysis of Food Derived from Modern Biotechnology provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.

CAC/GL 45-2003 – Guidelines for the conduct of Food Safety Assessment of Foods Derived from Recominant – DNA Plants, incorporating methodologies of foodstuff risk assessment comparing such food with 'doubles' derived by means of traditional technology, providing data and information identification to be used for such an assessment;

CAC/GL 46-2003 - Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms, incorporating methodologies of foodstuff risk assessment comparing such food with 'doubles' derived by means of traditional technology, providing data and information identification to be used for such an assessment.

World Trade Organization

Georgia became member of the World Trade Organization in 2000.

Before and after adoption of Cartagena Protocol intensive debates took and are still taking place around the issue of whether provisions of the Protocol comply with international order established within the framework of the World Trade Organization. According to Cartagena Protocol, parties to the Protocol are:

- 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.

Several provisions of Cartagena Protocol may be seen as restrictive on trade:

- importing country may prohibit introduction of LMOs to the country;

- importing country may impose market placement conditions (for instance, mandatory labeling) with regards to LMOs, which naturally will have an effect on competitiveness of the product on the market.

- oblige exporters to observe the whole range of obligations with regards to notification and identification, for instance, provide accompanying documentation stating the products in question contain LMOs.

- procrastinate risk assessment process during procedures of preliminary notification and preliminary permit on import.

Based on above said, in establishment of biosafety system and decision-making based on biosafety regime, rules and dispute resolution instruments provided for by World Trade Organization should be taken into consideration, including:

Agreement on the Application of Sanitary and Phitosanitary Measures (SPS): According to the article 2 of the agreement - Countries shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

Technical Barriers to Trade (TBT) This document has been enacted in 1995 and provides for elaboration of such regulations, standards, examinations and certification procedures that would not hinder international trade. This runs true also for biotechnologically derived imported or domestically produced food product packing and labeling.

EU Legislation

EU legislation on LMOs has been around sine 1990. It should be noted that EU ratified Cartagena Protocol on Biosafety. In order to ensure its implementation, in 2003 **Regulation 1946/2003 of the European Parliament and of the Council on Transboundary Movements of Genetically Modified Organisms** has been adopted.

-**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** defines procedure of issuing a permit on deliberate release into environment and market placement of LMOs. Term of validity of the permit is determined as being equal to 10 years. Also, by virtue of the Directive, LMO monitoring after its market placement becomes mandatory. Basic methodological principles of LMO related

risk assessment are also defined by the Directive. According to the Directive, public consultations and LMO labeling are mandatory. Before making a decision, European Commission is obliged to consult with appropriate scientific committee and Committee on Ethics. Under the directive, establishment of LMO register is required. Once every three years European Commission is obliged to publish a report concerning measures taken by member countries with regards to implementation of the Directive and experience gained through market placement of LMOs. The report incorporates social and economic analysis of benefits and losses with regards to individual LMOs.

Other directives and regulations related to the GMO are the following:

- Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

- Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (Text with EEA relevance)

- Council Directive 98/95/EC of 14 December 1998 amending, in respect of the consolidation of the internal market, genetically modified plant varieties and plant genetic resources, Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed potatoes, seed of oil and fiber plants and vegetable seed and on the common catalogue of varieties of agricultural plant species

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

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

- Commission Regulation (EC) No 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms

- Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

- Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms

It should be noted that European Commission already made several decisions on issuing permits for GMO market placing (including GM potatoes, carnation, rape and corn).

Apart from the above, by decrees of local governments, municipalities and individuals GMO free zones have been established across Europe (for instance, in Austria 14 lands have been declared GMO free zones, in Finland - 2 provinces, in France - 21 regions, in Norway - 1, in Poland - 16, in Spain - 4, in Sweden - 1 region and so forth, and Switzerland has declared moratorium on GMO cultivation till November, 2013. Source: http://www.gmo-free-regions.org/gmo-free-regions/list.html).

It would be feasible to carry out legal analysis in more detail to establish legal foundation of declaring a region as a GMO free zone, in order to have similar instruments established in Georgian legislation.

Revealed Problems and Recommendations

- As of today, despite its importance for conservation of local biodiversity and healthcare, biosafety is not considered to be one of the priorities of the national policy.

This may be caused by lack of basic information and appropriate research, providing decision-makers with appropriate basis for policy-making. For instance, there is no assessment of imports of GM seeding and planting stock and agricultural production required for agricultural development and food security; there is no assessment potential impact use of LMOs may have from environmental, social and economic standpoints.

- International instruments of biosafety are not yet fully applied. No notifications provided for under Cartagena Protocol for preliminarily justified consent procedure have as of yet been received by Georgia. Though Georgia does import agricultural products from the countries - parties to Cartagena Protocol and LMO producers. Though it is impossible to argue whether GM production have been imported from these countries or no, and if yes, why Cartagena Protocol procedures haven't been initiated.

- Georgia doesn't make use of the financial resources available within the framework of the Convention on Biodiversity for the purposes of establishing of biosafety system, creation of appropriate human resources and technical means and participation in biosafety mediatory instruments.

- Given the lack of appropriate legal requirements, LMOs imported into Georgia are not registered, no monitoring of release into environment or market placement is taking place. Law doesn't require declaration of GM seeding or planting stocks, their labeling, advance notification and consent on import. In the absence of labeling requirements, farmers do not know whether they are cultivating LMOs, consequently, it's impossible to establish changes in are under LMO crops which would have been a good indicator for assessment of impact on biodiversity.

As part of the national system of biodiversity monitoring currently being established, one of the selected indicators is change of total volume of imported GMO seeding stock. In order to uphold the indicator, it is necessary to define data collection and accounting measures.

- For lack of appropriate requirements, there is no LMO control of imported seeding and planting stock, as well as over food and fodder.

- System of LMO based food labeling is not in operation. Despite requirements set by the Decree of the Minister of Agriculture with regards to GMO labeling, also provisions of the law of Georgia on Food Safety and Quality requiring National Food Agency to carry out state control activities (the law has been fully enacted on January 3, 2001, and inspections of food producers have begun), as of today not a single sample has been taken for the purpose of GMO detection.

- Due to lack of appropriate accounting and monitoring system, there is no official data available on LMO spread and use. This informal data originates from various non-governmental organizations and press. This information is not being studied or checked by governmental agencies, so regions and channels of LMO spreading remain unknown.

- Because of high risk of genetic contamination of local varieties and their wild relatives, use of GM seeding and planting stock may impose serious threat on Georgia's agricultural and biological diversity. Consequently it is of high importance to ensure safe transboundary transportation and handling of LMOs in order to achieve appropriate level of protection for biodiversity conservation.

One of the solutions may be support for development of local seeding and planting stock production on the policy, human resources development and technology development levels.

- It would be feasible to start step-by-step adoption of appropriate amendments to primary and secondary legislation based on best international practices and taking into account already existing legislation on food safety, achieving by-and-by regulation of deliberate release and market

placement of LMOs, as well as safe transportation, transboundary relocation and use in closed systems. The effort may be put not into elaboration of new law on genetically modified organisms but rather with regards to integration of biosafety issues into legislation already regulating food safety field. For instance, obligation of the National Food Agency to carry out risk assessment, management and communication may be extended to include risk assessment methodology for living modified organisms in food or fodder to be directly consumed or processed.

Along with the above, legislative amendments may be prepared from the standpoint of providing territorial restrictions on release of LMOs - for instance, imposing prohibition on cultivation of LMOs in all categories of protected territories (including protected landscapes and multiuse territories). It is also necessary to settle issues arising from coexistence of bio-farmers and those farmers who cultivate LMOs. Based on detailed legal analysis, local governance bodies and individual farmers should be entitled to declare territories LMO free zones. It is also necessary to examine possible restrictions on release into environment of those GMOs, whose wild relatives and local varieties are to be found in Georgia.

- Regulation means provided for under Cartagena Protocol should be reflected in National legislation in such a way as not to hinder observation of other international obligations of the country. Cartagena Protocol on Biosafety calls upon the parties to take into account global expert knowledge and competence in the fields of environment protection and human healthcare. This provision of the Protocol implies incorporation of the recommendations, standards and guidelines of Codex Alimentarius, FAO and WHO with regards to organisms derived through bio-technologies into national systems of biological safety.

- Appropriate assessments should be carried out in order to inform decision makers in order to shape out the national policy on biosafety.

- It would be advisable to incorporate into obligation of the National Food Safety, Veterinary and Plan Protection Service *to carry out risk assessment, management and communication* also LMOs in food and fodder to be directly consumed or processed, implementing appropriate methodology of risk assessment. Such a methodology may be based on Manual on Risk Assessment of Living Modified Organisms (UNEP/CBD/BS/COP-MOP/5/INF/22). It should also be noted that personnel of the mentioned Service is fully competent in traceability methodology for food and fodder. Establishment of such a system is required under EC directives 1829/2003 "On Genetically Modified Food and Feed" and 1830/2003 "concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms"

- Unified laboratory system and/or independent inspecting authorities appointing one/several labs, which, in case of need, would carry out GM examination and control of imported seeding plants and other LMOs, also food and fodder for direct consumption or for processing. It would be feasible for Coordinating Board in charge of the above said lab system would regularly plan inspections in order to prevent illegal movement of living modified organisms.

- It would be feasible, based on the requirements of the Cartagena Protocol, to establish competent agency on national level (or delegate rights and obligations to already existing agencies) that would be authorized to carry out state registration of transgenic food and raw materials, also reproductive materials according to identification data.

2. Programs and Projects in Biosafety

In 2002-2005 Georgia participated in UNEP/GEF supported global project - **National Biosafety Framework** development, pursuing the goal of establishing appropriate foundation for Cartagena Protocol ratification and observation of assumed obligations. The project has been conducted in 23 countries of the world.

In the course of the project documents have been elaborated to form a national biosafety framework, as well draft law on genetically modified organisms (see Chapter 11).

Project activities were carried out in pursuit of informing the public and raising public awareness. It should be noted that in 2004 in the course of the project public survey has been conducted in order to establish public attitude and level of awareness with regards to LMO cultures and foodstuffs, interviewing 1005 respondents throughout Georgia (Imereti, Guria, Kakheti, Samtskhe-Javakheti). Survey testified to negative and wary attitude of the population towards LMO products. 95% of the interviewed considered it mandatory to have LMO products labeled accordingly, whilst 90% would refuse to buy such products even if they were considerably cheaper. Survey also has shown low level of awareness among farmers with regards to positive and negative sides of using LMO cultures. Small portion of the interviewed farmers (16%) were sure it was necessary to import LMO seeding and planting stock, as well as fodder. 88% of the interviewed considered it government's duty to regulate LMO import and use.

In 2007-2011 Georgia, along with Armenia and Moldova, participated in **UN FAO regional project Capacity building in agricultural biotechnologies and biosafety for Armenia, Georgia and Republic of Moldova** (TCP/RER/3207 D)

In the course of the project, following trainings have been conducted:

1. Erevan, 2010 - LMO legislative regulation related issues, general provisions on risk assessment, basics of risk regulation, general principles and methodologies of assessment of genetically modified food products, methodology of describing genetic changes in donor and recipient organisms, methodology of assessment of potential toxicity and allergenicity of GM products, metabolic changes in GM food products, impact on different technological cycles of processing on GM raw materials and finished products, impact of GM seeding stock on biodiversity. 5 specialists from Georgia participated in this training.

2. Kishinev, 2011 - biotechnology teaching curricula and syllabi in higher education institutions, teaching, scientific and practical (legislative) aspects have been evaluated. (4 participants from

Georgia attended). The meeting decided to establish professional development teaching course on GMO detection and risk management. 4 specialists from Georgia participated in this training.

3. Tbilisi, 2011 - GMO risk communication. 5 specialists from Georgia attended. Topics discussed - public participation and awareness with regards to GMO.

In the course of the project level of development and needs of agricultural biotechnologies have been assessed. Working meetings with decision-makers, farmers' associations and business-operators have been conducted. Also, condition of Georgian laboratories has been assessed from the standpoint of finding means of further development of their capacity.

Public Campaigns

There is a strict position of the non-governmental sector with regards to necessity of the state regulation of LMO use (especially from the standpoint of release into environment) related risks.

The Greens Movement of Georgia regularly carries out public awareness campaigns with regards to LMO threats to environment and human health. These campaigns played significant role in making up public opinion.

Biological Farming Association Elkana supports development of organic agriculture in Georgia. Their main activity is consulting biological farms, extension of rural development services, increase of farmers' income, conservation of agricultural biodiversity. Association lobbies development of organic farming and, consequently, is negatively inclined towards liberation of LMOs.

3. Existing Scientific and Technical Capacities and Needs in GMO Biosafaty and Risk Management

Today no scientific research with regards to biotechnology, such as breeding of transgenic organisms and their study, is being carried out in Georgia due to scarcity or absence of scientific potential and technical equipment. The situation is worsened by high cost of research and reagents.

It should be noted that in general, Georgia has a long standing tradition of agricultural biotechnological research, especially in tea and wine production However there were not substantial biotechnology programs in Georgia when it was a republic of the Former Soviet Union. Currently, even those researches have dropped from their former scale Numbers of qualified scientists have emigrated, especially the younger ones. Equipment in the research centers has become obsolete and there are insufficient funds available for its replacement.

Ongoing projects include those devoted to research and production of a range of biologically active compounds for the agricultural, food/feed and pharmaceutical industries. Use is also being made of tissue culture techniques to produce virus-free planting material of potato and grapevine. A considerable amount of work has been done on biotechnology of microorganisms, geared towards production of useful metabolites. Most ongoing projects are funded nationally, but there are several international collaborative efforts.

In the field of biosafety proper in 2005-2012 four scientific projects have been implemented by Ivane Beritashvili Biomedicine Experimental Center, funded by National Scientific Fund. The goal of the research was testing, implementation and elaboration of GMO detection methodology. Detailed information on mentioned scientific projects can be found in Annex 2.

GMO Laboratory

Currently GMO study and analysis is of crucial importance in Georgia because of the following reasons: to assess seed and food quality and safety, to meet consumer demand, to protect local biodiversity, to implement legislation according to international obligations especially after ratification of Cartagena Protocol. The implementation of GMO legislation requires reinforcement of suitable scientific basis for monitoring of GMOs.

At the stage there is only one officially accredited laboratory in the field of GMO detection – at **Institute for Horticulture, Viticulture and Wine making,** which has been certified by Legal Entity under Public Law - *The Unified National Body of Accreditation - Accreditation Center.* Mentioned laboratory being annually inspected and is being re-certified every three years. From the standpoint of study of genetically modified organisms and products the lab is equipped with all

necessary apparatus and reagent, including so called *Real-Time PCR,* capable of both quantitative and qualitative analysis of GMOs, though the laboratory hasn't been ordered to carry out quantitative analysis yet. The laboratory mainly carries out qualitative analysis of GMOs. Also, orders are mainly for export goods, such as alcohol-free beverages, bay leaf, tea and so on. One qualitative testing costs 200 GEL. From the standpoint of methodology, detection exercised through identification of 35S promoter, the one being used for marking majority of genetically modified organisms (but not for all). Up to day, the laboratory hasn't got reaction positive on GMO content.

Ivane Beritashvili Biomedicine Experimental Center, laboratory of the genome structure and function. In 2004 GMO study was started at the biotechnology group of the Institute of Molecular Biology and Biological Physics (Tbilisi, Georgia). Since 1st of March, 2008 the Laboratory for GMO analysis was established on the basis of this group. This was the first laboratory engaged with GMO analysis in Caucasus region (Georgia, Armenia and Azerbaijan). At present GMO group belongs to the laboratory of the genome structure and function of the Ivane Beritashvili Biomedicine Experimental Center. The members of the Laboratory are highly qualified experts of molecular biology, biotechnology and biochemistry. Several members of this group have worked in the advanced research centers in Europe and USA including European GMO accredited lab. GMO laboratory collaborates with the Institute of Chemical Biology of Ilia State University (Tbilisi, Georgia). The students of the University are participating in the research projects. It should be noted that the head of the laboratory has been trained in biosafety and GMO detection.

The laboratory is equipped with some necessary equipment and devices for molecular biology and biotechnological research in order to perform DNA-based qualitative detection and analysis for GMOs, such as: thermal cycler for PCR, apparatus for agarose gel electrophoresis, transilluminator, microcentrifuges, thermostats, etc. They don't have quantitative analysis equipment (Real-Time PGR).

Laboratory at Faculty of Exact and Natural Sciences of Javakhishvili State University is equipped with some necessary devices to perform DNA-based qualitative detection and analysis for GMOs through PCR method,

Within the framework of TEMPUS project further capacity building for laboratories is planned. Mentioned laboratory has been selected in the course of the FAO project for regional training in GMO detection, to be conducted in the first half of the current year. For the purposes of the training, the laboratory will be provided with all appropriate reagents and other materials under FAO project.

As for other laboratories, **Central Reference Laboratory,** operating within the framework of Cooperative Threat Reduction program (CTRO, has been build by means of biological threat

reduction program of the US Government (BTRP) funding and has been fully equipped with modern equipment. **Legal Entity under Public Law - Levan Samkharauli National Forensics Bureau Biological Laboratory,** also appropriately equipped.

Identified Problems and recommendations

Existing scientific potential required for risk assessment and management is very scarce. Almost none of the universities or research centers under them are purposefully studying GMO related risks and risk assessment and management issues.

The number of scientists trained in biosafety is very small, experience being especially scarce from the standpoint of risk assessment, management and appropriate mitigating measures.

Nowadays, there is only one laboratory accredited for GMO detection which, naturally, once national legislation on biosafety is adopted, won't be able to cope with demand, be it from private sector or from those governmental agencies whose authority it will be to carry out biosafety control and monitoring.

Of course, potential of other laboratories are to be taken into account too, though their profile is different, being more focused on education, scientific research, medical and other purposes.

Another problem is imposed by limited nature of GMO identification methodology practiced in accredited laboratory. As it has been mentioned above, nowadays identification is carried only via 35S promoter. If genetically modified organism has been derived through some other promoter, existing methodology would be useless for its detection. Another problem is imposed by high cost of the analysis.

Establishment of appropriate scientific potential should be supported, expert registration and creation of the database of the experts with specialized experience in the field of biosafety risk assessment and management would be desirable.

4. Educational Programs in Biosafety

General Education

According to National Curriculum, adopted under Decree #36/N of the Minister of Education and Science of Georgia on March 11, 2011 that will remain in force till 2016, modern biotechnology and genetic engineering has been included into the biology curriculum of the intermediary level (10th to 12th grades). According to the Biology Standard, upon completion of the biology curriculum, the student should be able to demonstrate appropriate knowledge and be able to discuss positive and negative sides of genetic engineering. Curriculum includes: general description of genetic engineering methods (*plasmids, restrictase, vectors),* biotechnologies related to genetic engineering, genetically modified organisms and biological safety.

In accordance with National Curriculum, aforesaid subjects have been included into biology textbooks. For instance, N.Zaalishvili and N.Iosebashvili Biology Textbook, 10th Grade, contains quite appropriately measured and sufficiently sophisticated material for the students of the target age group on basic principles of genetic engineering and biosafety, also examples modern genetic technologies' application.

Higher Education

Bachelor's level curricula incorporate modern biotechnologies and biosafety in various disciplines, included molecular biology, genetics, biotechnology and others.

In several higher education institutions in Georgia there are bachelor, master and PhD level programs in molecular biology and biotechnologies that incorporate GMO detection and biosafety issues.

The new bachelor program in Applied Biosciences and Biotechnology has been developed within the framework of an EC Tempus funded project: 'Developing new applied biosciences and biotechnology curricula' at the Faculty of Exact and Natural Sciences of **Javakhishvili State University.** The bachelor program has been launched form 2009-2010 academic years. The project is being implemented by an international consortium that along with Iv.Javakhishvili Tbilisi State University (grant coordinator) includes three leading European universities – the University of the West of England, UK (grant holder), Dublin Institute of Technology, Ireland, University of Alicante, Spain, Paulo & Beatriz – Consultores Associados, Portugal and Aristotle University of Thessaloniki, Greece.

Bachelor level curriculum includes the following sub-curricula: Healthcare Biotechnology, Food Biotechnology and Agricultural Biotechnology. Practical training in GMO detection is provided for in

the course of the bachelor level curriculum. Bachelor level students are also offered an opportunity to undergo industrial professional practice in biotechnological centers, providing them with the chance to get first-hand experience of biological technology.

It should be noted that university entrants' interest towards the subject in increasing (in 2009-2019 and 2010-2012 school years the program has been selected by 25 and 22 students, in 2011-2012 - by 48.

Ivane Javakhishvili Tbilisi State University also runs TEMPUS supported Master's level program - Applied Bioscience, launched in January 2010. Duration of the project is 3 years and it is being carried out by international consortium. In the course of the project, 5 leading universities of Georgia and Armenia are to establish new Master's program in applied biological sciences. The program pursues the goal of preparing the students not only for prospective careers in science, but also for their employment in different biology-related industries, research institutes or other organizations. New Master's program in applied biological sciences provides for several main areas, including - food biotechnologies, agricultural biotechnologies, healthcare biotechnologies and environmental biotechnologies.

Master's degree program contains *Genetically Modified Organisms and Environmental Safety* module. For 2011-2012 school years 5 students have been enlisted for the program. It should be noted that this is a joint program with Agricultural University of Georgia (sub-program - Agricultural Biotechnology), and Akaki Tsereteli University (sub-programs: Healthcare Biotechnology, Food Biotechnology and Environment Protection Biotechnology).

All sub-programs of Applied Bioscience and Biotechnologies will be served by university laboratory fully equipped with modern scientific research equipment. This laboratory will be used for teaching of modern methods of molecular biology and biotechnologies, students will be mastering biochemical, molecular-genetic, sytodiagnosis, histiodiagnosis, microbiological, physiological, immunological and other diagnostic technologies; will master polymerase chain reaction (PCR) method, will learn how to derive and use human, animal and plant cell tissue cultures for *in vitro* experiments, methods of identifying and finding genetically modified products.

Teaching of modern biotechnologies of different complexity is also going on in **Ilia State University**, incorporating *Molecular Biotechnology and Biochemistry* PhD program. Goal the program pursues is to study by means of molecular biology and modern biotechnology methods genetically modified plant organisms (GMO) and food products derived from them; study of fundamental problems of biochemistry; research topics being: traceability of genetically modified organisms in food; development of new methods and nano-biotechnologies of genetically modified organisms detection; study of cell regulation principles; separation of biologically active substances and study of their effects in normal physiological conditions and in pathological

conditions. Right now, in the faculty of Master's and PhD programs doctorate thesis is being worked on under the title of *Impact of Food Processing on Genetically Modified Organisms Detection.*

In biophysics, laboratory practice is being conducted for the benefit of the students of Master's degree program in Ivane Beritashvili Experimental Biomedicine Center, enabling them to master GMO detection methodology.

Identified Problems and recommendations

Regardless of Bachelor, Master and PhD level programs, teaching of modern biotechnologies in Georgia is lagging behind modern level of development of this science. High education programs don't offer enough knowledge from his standpoint of GMO related risk assessment and management. Teaching laboratories aren't adequately equipped. There is a need for professional development of scientific personnel.

Strengthening of existing Bachelor, Master and PhD level programs from the standpoint of GMO related risk assessment and management should be supported. Creating links with leading universities in order for training and professional development of personnel is recommended.

5. Extension

Unfortunately, there is no extension system operating in Georgia at the state level by now. Ministry of Agriculture of Georgia has developed the strategy of agriculture development that covers and considers implementation of extension system at the state level in Georgia. Next step would be development of the according action plan to meet the results set by the mentioned strategy. It should be mentioned that several NGOs acting in Georgia are providing extension services to beneficiaries on their own (Elkana, Mercy corps, CARE).

Additionally, it should be mentioned that the level of knowledge and awareness regarding international standards and regulations generally is relatively low. According to the survey conducted by International Financial Corporation (IFC) only 1/5-th of the firms have a basic or detailed knowledge of international food-safety standards (EU food safety and quality regulations, Codex Alimentarius, HACCP, Global GAP, ISO22000:2005, ISO9001:2008, GMP and GHP).

Identified Problems and Recommendations

Level of farmer awareness with regards to advantages and drawbacks of GMO production and related risks is low. There are no specific educational modules for farmers. In absence of GMO seeding and planting stock labeling requirement, farmers do not know whether they are using such stock. Though importers of seeding and planting stock state that they do not import GMO derived stock as local farmers would refuse to buy it.

It would be feasible, whilst establishing extension system in accordance with agriculture development strategy, to incorporate modules on farmer awareness raising and education on GMO related risks, as well as GMO safe handling, storage and transportation issues.

Annex 1.

NBSAP of Georgia, Action Plan for 2005-2010: Biotechnology and Biosafety, Status of Implementation

	Activity	Indicator	Status of implementation
1	Prepare for ratification of the Biosafety protocol	Biosafety protocol ratified	**Completed** Georgia joined Cartagena Biosafety Protocol on September 26, 2008, by virtue of the Parliamentary Decree.
2	Prepare a draft law on biosafety and organize public hearings on this	Law on biosafety adopted	**Not completed** In 2005 draft law **On Genetically Modified Organisms** has been prepared. Consultations have been conducted with international experts and local non-governmental organizations who supplied remarks and recommendations. Though, because of basic legislative and institutional changes that occurred shortly after elaboration of the draft law, certain regulations, procedures and competences of the draft law became incompliant with the legislation in force. In 2008 Ministry of Economic Development prepared draft Decree **on Protection of Biodiversity in Georgia,** establishing permit and license issuing procedures in accordance with legislation in force. In November 2009, by decree of the Minister of Environment Protection and Natural Resources working group has been established to pursue *preparation o legislative framework related to genetically modified organisms* (Decree of the Minister of Environment Protection and Natural Resources #i-587, 27/11/2009). By conditions of the decree, the working group should have elaborated draft law *on Genetically Modified Organisms* by May 1, 2010, though work on updated drat law hasn't yet been completed.
3	Develop biosafety control mechanisms and designate or set up a responsible agency	Transparent control mechanisms in place; Agency responsible for controlling all risks	**Not completed**

		associated with import, use and release of GM organisms designated or established	
4	Strengthen the national capacity for enforcing biosafety	At least one laboratory capable of detecting content of GM organisms in raw materials as well as in products in existence	**Partially completed** Following laboratories have appropriate GMO detection equipment: 1. Certification Body of the Institute for Horticulture, Viticulture and Wine Making - Testing Laboratory - laboratory being accredited with Legal Entity under Public Law - *The Unified National Body of Accreditation - Accreditation Center* to carry out GMO analysis 2. Ivane Beritashvili Experimental Biomedicine Center Genome Structure and Function Laboratory 3. Ivan Javakhishvili Tbilisi State University Exact and Natural Sciences Faculty Biology Department Laboratory However above mentioned laboratories are not full equipped for quantity and quality detection of GMOs.
5	Prepare education programs and organize workshops for different target groups	At least 2 workshops held annually	**Partially completed,** mainly through effort of non-governmental organizations.
6	Organize regular TV and radio programs and press conferences on biosafety	At least 3 TV and 4 radio programs produced and 2 press conferences held annually	**Partially completed**
7	Integrate biosafety principles into general education programs	A supplementary textbook of biosafety produced which is officially approved by the Ministry of Education and is	**Partially completed** According to National Curriculum, approved of by the Minister of Education and Science Decree #36/B of March 11, 2011, to remain in force till 2016, subjects of modern biotechnology and genetic engineering have been introduced into biology curriculum for intermediary level (10th to 12th grades).

		included in the list of compulsory textbooks	There are in several higher education institutions of Georgia Bachelor, Master and PhD level programs on molecular biology and biotechnologies, incorporating GMO detection and biosafety issues.
8	Produce publications on biosafety in the Georgian language	At least 3 publications produced during 5 year period	**Partially completed**
9	Develop effective mechanisms for information exchange within the country and internationally	Easily accessible information network established; Web page prepared and placed on internet	**Not completed**
10	Set up a public biosafety monitoring system	A work plan for biosafety monitoring and relevant indicators prepared by the end of 2004; At least 2 public institutions working on biosafety issues.	**Partially completed** Since 2002 Greens movement of Georgia carries out surveys among food producers and importers in order to find out attitude of different companies towards use of genetically modified ingredients and inform the public upon the findings. Apart from that, the movement, with support of its foreign partners follows developments abroad and spreads information about any hazards through Georgian press. One of the indicators selected within the national system of biomonitoring under construction now, is changes in total amount of imported GMO seeding stock. It is necessary to define measure required to start collecting and processing data.

Annex 2. Scientific projects related to GMO detection

1	Implementation of DNA technologies for food analysis in Georgia	Institute of Molecular Biology and Biological Physics	2005-2006	Georgia's State scientific program	Qualitative detection DNA technology has been implemented in Georgia. Stages of DNA analysis procedure have been optimized: DNA extraction, DNA quality check through gel-electrophoresis and spectrophotometer, DNA analysis by means of polymerase chain reaction.
2	Study of food DNA amplifiability for detection of genetically modified organisms	Institute of Molecular Biology and Biological Physics	2008-2009	GNSF/ST 07/8-273 / 69200 GEL	Impact of plant variety, food matrix, DNA extraction methodology, amplicon and DNA modification on the DNA amplifiability and detection of genetically modified organisms in food products. Internationally approved methods of genetically modified food screening have been established in Georgia.
3	Tracing of genetically modified organisms in processed food	Ivane Beritashvili Biomedicine Experimental Center, laboratory of the genome structure and function (Co-participant Ilia State University)	2010- 2012	#GRANT/ST 09_262_8-150 / 150 000 GEL	Multiplex PGR methods of simultaneous genetically modified organisms (GMO) detection in conservative sections in food for fast and efficient GMO screening. Impact of thermal processing of food on GMO detection has been studied. It is expected to establish impact of various parameters of thermal, chemical and mechanical processing on GMO detection in processed food.
4	Development of the multiplex nanobiotechnology for control of the genetically modified organisms STCU/GNSF# 5054	Ivane Beritashvili Biomedicine Experimental Center, laboratory of the genome structure and function	10.2010 – 09.2012	Ukraine Science and Technology Center/ Shota Rustaveli National Scientific Fund STCU/GNSF# 5054 / 34480 USD	Method of simultaneous detection of genetically modified organisms (GMO) in soy, corn and wheat, PGR method of conservative sectors simultaneous identification for GMO screening It is expected to have new precise, cheap and fast nano-biotechnology methodology, such as DNA micro-area processing, developed, optimized and harmonized internationally for simultaneous detection of soy, corn, wheat and potato and screening of genetically modified organisms

Annex 3. List of organizations consulted in the process of assessment

1. Ministry of Environment Protection (Service of Biodiversity Protection, Department of Environmental Policy and International Relations, Agency of Protected Areas);
2. Ministry of Agriculture (Rural Development Department, National Food Agency);
3. Ministry of Finance Revenue Service Economic Border Guard Service
4. Economic Analysis and Policy Department of the Ministry of Economic Development of Georgia;
5. State Regulation Agency for Medical Activities;
6. Ivane Javakhishvili Tbilisi State University, Faculty of Exact and Natural Sciences, Biology Department;
7. Ilia State University, Ivane Beritashvili Experimental Biomedicine Center, Genome Structure and Function Laboratory.
8. Georgian Agricultural University.
9. Biological Farming Association Elkana
10. Agrokartu Ltd
11. „Garemo da analitika“ Ltd
12. Biotechnology Center for Agriculture.
13. Institute for Horticulture, Viticulture and Wine Making, GMO accredited Laboratory.

Annex 4. Refernces and related web-sites

1. Georgian National Program of Environment Protection Activities (2011-2015);
2. Strategy of Agricultural Development of Georgia (working draft, February 2012)
3. National Biosafety System, Georgia , Draft, developed by GEF/UNDP project, 2005
4. Draft law of Georgia on Genetically Modified Organisms, 2005.
5. Draft Government Resolution on Biodiversity Protection on the Territory of Georgia (2010).
6. Order #587 of the Minister of Environment Protection and Natural Resources of Georgia of November 27.
7. Georgian Code of Environment Protection, working draft
8. Law of Georgia on New Species of Animals and Plants, 2010
9. Law of Georgia on Licensees and Permits, 2005
10. Law of Georgia on System of Protected Territories, 1996
11. Law of Georgia on Wild Fauna, 1996
12. Law of Georgia on Food Safety and Quality, 2005
13. National Strategy for Food Safety and Legal Approximation Program of Georgia 2010
14. Ministry of Agriculture of Georgia Decree #2-231, on Approval of Additional Requirements on Food Labeling, 2009.
15. Convention on Biodiversity
16. Cartagena Biosafety Protocol
17. Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention
18. International Plant Protection Convention (IPPC).
19. ISPM No11, Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms
20. Applications of Genetic Engineering for Livestock and Biotechnology Products, Worlds Organization for Animal Health
21. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, CAC/GL 44-2003, Codex Alimentarius
22. Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, CAC/GL 45-2003, Codex Alimentarius
23. Guideline for the Conduct of Food Safety Assessmnet of Foods Produced Using Recombinant-DNA Microorganisms CAC/GL 46-2003, Codex Alimentarius
24. Agreement on the Application of Sanitary and Phitosanitary Measures, WTO
25. Agreement on Technical Barriers to Trade, WTO
26. Third National Report on Implementation of Aarhus Convention, 2010;
27. Review of Current Situation with Genetically Modified Organisms in Georgia, Greens Movement of Georgia/Friends of the Earth - Georgia, 2008.

28. National Agro food Chain Needs Assessment Report, FAO, 2011
29. National Curriculum, 2011-2016.
30. National Report on the State of the Environment (2007-2009), Ministry of Environment Protection, 2012
31. Code of Administrative Violations.
32. UNECE, Environmental Performance Reviews, Georgia, Second Review, 2010
33. Assessment report of the priority components of the biodiversity of Georgia, GEF/UNDP,
34. National Report on the State of the Environment (2007-2009), Ministry of Environment Protection, 2012

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http://www.unece.org/env/pp/welcome.html

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