ISSUES OF BIOSAFETY AND AGRICULTURAL DIVERSITY IN GEORGIA - PRESENT SITUATION AND CHALLENGES FOR IMPROVEMENT

Workshop

Organized by the Biological Farming Association "Elkana"

June 8-9- 2006

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COURSE OF THE WORKSHOP

First day - June 8, 2006

Opening of the Workshop- Welcome Address

The workshop was opened by the director of "Elkana" Ms. Mariam Jorjadze. She thanked the workshop participants for coming and introduced foreign guests of the workshop - Mr. Rudolph Buntzel and Ms. Mariam Meyet. Mariam Jorjadze talked about the objective of the workshop and noted that the workshop aim was to sum up different opinions of the parties concerned (from both the governmental and non-governmental sectors) regarding ratification of the Cartagena Protocol on Biosafety by Georgian parliament and the draft Law on Genetically Modified Organisms; in addition, the workshop goal was to define the prospects of Georgia in terms of biosafety protection, which way to choose - that of regulations or restrictions. Mariam expressed hope for the possibility of bringing different positions into accord and of working out a common activity plan or strategy.

Introduction of participants/expectations

The participants introduced themselves (Annex 1) and briefly talked about their expectations from the workshop.

Following that, Mariam Jorjadze familiarized the participants with the working program of the workshop (Annex 2) and the work went on in accordance with the program.

Situation in Georgia in terms of biosafety

Mariam Jorjadze

Mariam Jorjadze talked about the situation in Georgia in terms of biosafety. In particular, she said: the Cartagena Protocol on Biosafety has not been signed by Georgia because Georgia failed to send its representative to Montreal when the Protocol was signed. At present, as one of the parties to the Convention on Biological Diversity, Georgia has committed itself to ratify the Cartagena Protocol, although, at this stage, the Parliament rejects the ratification. It should be mentioned that the lack of knowledge of biosafety issues is observable in both the Parliament and society. Frequently, mass media also tends to incorrectly interpret specific problems, contributing thus to the fears and panics. "Elkana" have been working on these problems since 1996 together with the Greens movement. We did much in the Parliament of the former convocation to clear up the issues. Currently, in the new Parliament, all has to be started anew. Although, our cooperation with the Biosafety Department of the Ministry of Environment and Natural Resources Protection has always been successful, be it earlier or now. This very Department has drafted the Law on Genetically Modified Organisms.
The draft Law on Genetically Modified Organisms was discussed by the acting head of the Biosafety Department Ms. Ana Rukhadze.

Ana Rukhadze

Ana Rukhadze discussed in detail the general provisions of the Cartagena Protocol on Biosafety (Annex 3) and the draft Law on Genetically Modified Organisms (Annex 4). Notable that Ms. Mariam Mayet made comments on the Draft Law (Annex 5).

The Cartagena Protocol on Biosafety was adopted in 2000 at an extraordinary meeting of Parties to the Convention on Biological Diversity, and it entered into force on 11 September 2003. In November 2000 the Global Environmental Fund (GEF) approved the global project of UNEP/GEF "Development of National Biosafety System", the main objective of which is to create the necessary bases in individual countries for acceding to the Biosafety Protocol and for actual implementing of its requirements. The project will also facilitate strengthening of regional and sub-regional cooperation in the field of biosafety. The UNEP/GEF global project "Biosafety National System Development" was initiated in June 2001 and is under process in over 100 countries of the world now.

The Ministry of Environment and Natural Resources of Georgia is responsible for implementation of the Biosafety National Development Project in Georgia.

In the event the Cartagena Protocol on Biosafety is ratified a set of laws has already been drafted to ensure implementation of its requirements encompassing a draft Law of Georgia on Genetically Modified Organisms and draft normative acts to be passed in association with it.

The draft law will place within the legal frameworks the use of genetically modified organisms and their products; ensure implementation of the obligations assumed under the Convention on Biological Diversity and other international agreements of Georgia as well as accessibility of information in the field of genetically modified organisms to society and its involvement in decision-making accordingly.

For the purpose of studying the attitude of population towards the genetically modified cultures and food products and determining the level of awareness around theses issues, an opinion survey was carried out. Surveyed were 1005 respondents, including 601 in rural areas and 404 in towns. The survey was conducted in Imereti, Guria, Kakheti, and Samtskhe-Javakheti regions.

In the course of the opinion survey, a subject of dispute was outlined, namely the spread of living modified organisms (LMOs) in the nature. In the draft Law this issue envisages compliance with a definite, complicated procedure, whereas the public opinion unambiguously asks for its banning.

A special workshop with the participation of foreign experts was designated to assessment of possible risks and management problems associated with the genetically modified organisms.

At the final stage of the project, after a group of law-makers had drafted a working option of the law, working meetings were held.

Discussion

The draft law provisions became the subject of a serious discussion. Especially strict position was fixed with regard to the introduction and spread in the nature of living modified organisms. The majority of the audence backed the banning of the entry of LMOs. Many arguments in favor of the banning were expressed; in partcular, it was said that the entry of LMOs into Georgia, even under lawful conditions, would not serve as a guarantee that they would not be spread in the nature uncontrollably and would not adversely affect the local biodiversity. An opinion was voiced that such products would, owing to their cheapness, prove to be even useful for the country's economy. This opinion was opposed by those stating that such little country as Georgia could not and should not consolidate it position on the world

market with cheap products. Georgia should be oriented at quality and unique nature of its biological diversity, and that the both factors might be endangered should the LMOs be introduced and spread on a large scale.

Ana Rukhadze commented on the issue and noted that the draft law was still at the Ministry and that it could be amended towards the unambiguous banning of the component (introduction of LMOs). At the same time, taking into consideration the European Community' regulations, the zones being free of such organisms (as background zones) could be established. Proceeding from this, Georgia could be declared as such a zone and fixed correspondingly in the law. As regards full banning, Ana Rukhadze noted that, according to an expert estimate, it would not be justified, for the announcement of a complete moratorium would endanger the production making use of the genetically modified raw material, components, etc. Many workshop participants refused to agree with such an argument. In their opinion, it would be better that a production making use of such raw material be closed. Discussion touched also on the products available on the market that contain genetically modified ingredients but lack the appropriate labeling, and the consumers are unaware of it. The draft law indicates the necessity of labeling, which will provide the consumer with the possibility of making a choice. However, the workshop participants also noted that, based on the situation existing in Georgia, the availability of the law in Georgia could not prevent falsification unless the law is really effective. The workshop participants touched on the risks of using the genetically modified products for food, especially in the baby food area. The employment of genetically modified components in the baby food products is prohibited in Europe. Big companies, when exporting their products to the countries like Georgia, frequently apply to double standards. Such was the situation in Russia where Nestle products (baby food) underwent examination. The examination revealed that they were genetically modified and that gave rise to a great scandal. Nestle imports baby foods in Georgia too, but our country lacks the sufficient capabilities to ensure their quality checking.

Quite contrary is the situation with respect to LMOs, which control, after their introduction into the nature, is practically impossible, especially in Georgia.

As regards ratification of the Biosafety Protocol, Ana Rukhadze noted that the ratification is one of the necessary preconditions for Georgia's receipt of financial assistance necessary for starting up an efficient system to control genetically modified organisms. The said assistance provides for further development of the legislative base, the equipment of laboratories, development of the research potential, and other activities.

Mariam Jorjadze briefly summed up the discussion results. She said: the Cartagena Protocol has not been ratified in Georgia; Georgia has a draft law concerning genetically modified organisms, with which most workshop participants are not satisfied. The relevant world experience could be shared and a moratorium on importation of genetically modified organisms in Georgia be announced, or Georgia be declared a zone free from such organisms. What arguments do we have in this direction? One of the serious arguments can be that Georgia, a country of rich biological diversity, is defined by Conservation International as one of 25 biological "hotspots" on earth. What capabilities does Georgia have to protect itself? What steps must be taken? What is the world experience in this direction? These questions will be discussed by a consultant from South Africa Ms. Mariam Meyet.

Training in biosafety legislation (Annex 6)

Mariam Meyet

Mariam Meyet talked about the Cartagena Protocol on Biosafety. She familiarized the participants with the background of creation and significance of this instrument. In particular, she mentioned that a dispute concerning the Cartagena Protocol took seven years - the largest producers of genetically modified organisms - the U.S.A., Canada and Argentine were seriously opposing the provisions contained in the Protocol and even managed to block many good ideas. What does the Cartagena Protocol represent? It is an international agreement on biosafety governing the transboundary relations associated with genetically modified organisms. The Protocol sets minimal requirements and standards without applying to local legislations - the signatory Party is authorized to work out own, stricter regulations.

Mariam Meyet familiarized the workshop participants with the South African experience. She noted that genetically modified crops are cultivated on pilot fields (0.5 million ha) in South Africa and that the local market is saturated with the genetically modified maize imported from Argentine. Mariam explained to the workshop participants how genetically modified organisms are registered and imported in the country. As a rule, the importing party presents information (file) about the imported products; however, frequently the importer itself decides what information should be accessible to the public. Thereafter, it is a standard practice that only 19 pages of a 200-paged document are provided to the public. Mariam Meyet mentioned that the non-governmental sector of the Republic of South Africa still manages to obtain full information and substantiation of import expediency of a specific LMO. On the website of the organization where Mariam works its is possible to see a list of up to 20 LMOs, the importation of which was blocked thanks to submission of a serious substantiation against such imports.

What position should Georgia choose in connection with the Cartagena Protocol and genetically modified organisms in general? Mariam Meyet noted that Georgia's major investments came from the World Bank and other American institutions, which fact should not be disregarded, for big countries (large manufacturers of LMOs) try to influence local legislations in this respect - as a rule, they undertake regulation of the biosafety issues as well.

What will happen if Georgian Parliament ratifies the Cartagena Protocol? In Mariam Meyet's opinion, this will enable Georgia to regulate trade relations with the U.S.A, Europe, and world trade organizations. If the Cartagena Protocol is ratified, the country will have the possibility to substantiate in each specific case, with due regard for risks, and reject the importation of LMOs. If the ratification fails to be carried out, the member country of the World Trade Organization will find it difficult to decline imports of soy, for example, from the U.S.A., without submission of scientifically reliable data, which possibly could be disregarded as well.

As regards a free zone, the issue, according to Mariam Meyet, is to be well thought out. No one can force a country to cultivate and release LMOs into the nature. However, serious arguments should be produced to justify the refusal to do so. In particular, the unique biodiversity of Georgia could be mentioned as one of the reasons to obstruct LMOs which, however, will require the availability of local research and scientifically based expert conclusions.

Discussion

The presentation by Mariam Meyet caused interest and questions on the part of the audience . To the question, whether the assumption of a free zone could be considered as tightening of the Cartagena Protocol requirement, Mariam Meyet answered positively noting, however, that the free zone assumption had to be consolidated with scientific considerations and substantiation. In Mariam's opinion,

Georgia has a chance to be recognized as a free zone, for it cannot be perceived by the world as a big market. To the question, what mechanism could be used to counteract the policy of large producers of LMOs, Mariam answered that such mechanisms are the will of the country's government, activity of the local NGOs and public. It is advisable that a council composed of NGOs be set up a decision-making and monitoring body in the field of biosafety. The biosafety issues in Georgia are raised on the intiative of the Ministry of Environmental Protection, which is correct. From this very standpoint Georgia should consider the issue. In South Africa, more emphasis is made on social aspects, in Europe - on health care, as for Georgia, it should prioritize the problems of environmantal and biodiversity protection.

Debates on LMOs in European Union - new aspects and issues (Annex 7)

Rudolf Buntzel

Rudolf Buntzel dealt with the European Union law on genetically modified organisms. He noted that the large producers of LMOs (U.S.A., Canada, Argentine) reveal concern for liberalizing the EU legislation, for they are well aware that such amendment of this law will lead to the softening of related laws in other countries. Rudolf Buntzel familiarized the workshop participants with the principles of the European law. He noted that the law is associated with the avoidance of risks, the so-called risk assessment principle. Even if the risk is not scientifically substantiated, the EU law considers that such risk really exists. Although, the World Trade Organization's attitude to the issue is ambiguous; for example, in 1986 a genetically modified hormone was produced, which is being used in cattle breeding to raise milk yield. The European Union rejected production of the hormone on the assumption that there was no milk deficit and that its overproduction would cause problems to farmers. The U.S.A. filed a protest against this position and won the process. The matter is that the WTO takes into account only of the health-related arguments. During the dispute, the EU gathered together well-known scientists who attempted to prove that the hormone adversely affected the animal health. Despite the above, the produced data was found to be insufficient and the EU lost the process. Notwithstanding it, the EU refused to accept the hormone and has to pay annually USD 300 million to the U.S.A. as a compensation for the damage (as assessed by the American side). In the end, no one can tout the application of LMOs and of its products on you; if you don't want them, you should either pay or use the right of choice (be it farmers, entrepreneurs or consumers) and don't buy. In such case, the genetically modified products should bear the necessary information and be appropriately labeled.

Labeling means that any genetically modified product has a label, which indicates that the product consists of genetically modified organisms or contains them. If the content of a genetically modified organism is less than 0.9%, it shall not be indicated on the label. This percentage has become a subject of a serious debate. A question was raised, where the percentage of a GMO should be determined, in the end product or in the raw material? If, for instance, it is determined in wheat, then after processing its content may increase and should be indicated so on the label.

Rudolf Buntzel mentioned that in terms of contamination, quite a different standard is being employed in biofarms. The contamination with GMO will lead to the loss of a status. If the contaminator proves that the contamination was unavoidable and was not preliminarily intended, it shall not be held liable. Rudolf Buntzel talked about a buffer zone and noted that there was not reliable information about how much one farm should be distanced from another. The European Commission is of the opinion that this is to be regulated by the countries in their legislation, yet it should not interfere with the free movement of products. In the case of contamination, the liability shall be imposed on the farmer who cultivates GMOs. The following procedure has been introduced: the GMO-cultivating farmer negotiates with his neighbor and agrees with him, although it is doubtful that such an agreement could be reached with everyone. Usually, there is a register indicating the GMO plots, but such register is not accessible to the farmers growing similar products. Although, problems still arise. For instance, a farmer has lost the sta-

tus as a result of contamination. He has several neighbors with GMO plots. Who is to be held liable? Where the contamination did come from? This issue should be also provided for in the local legislation. For instance, in such cases, the German legislation provides for joint liability.

Discussion

The presentation gave rise to many questions. The workshop participants wanted to know whether the European Union legislation allowed the sowing of LMOs. According to Rudolf, up to 32 genetically modified crops were allowed for cultivation; however, each country was authorized to tighten their legislation governing such issues. Some countries do follow this practice. Especially negative attitude to this is revealed by such countries as Germany, Austria, Luxemburg, Poland, and Greece. To the question, to what extent these countries manage to achieve their objective, Rudolf Buntzel answered that the countries challenge the European Union but lose the struggle. However, when the European Union sued the U.S.A, it itself used to resort to the arguments, which itself neglected in litigation with other countries. To the question concerning determination of the GMO content in a product, Rudolf answered that almost all European towns have such laboratories and that they are quite accessible. The problem consists in the fact that the importing party is to present methods of identification of a specific GMO. If the methods are incorrect or the party fails to produce them, identification of GMO will be complicated. In the end of the discussion, Rudolf Buntzel noted that pursuant to the law, if you were not sure of the specific product's safety, you might refuse to allow it into your country, but had to pay for it.

Teamwork - identification of major problems and principal strategies for future activities

Mariam Jorjadze presented an objective and format of the teamwork. She noted that based on the presentations and opinions voiced by the workshop participants, the following picture outlined: there is a draft law and if it is adopted by Parliament, what risks could be faced? What experience could be offered to the government to avoid these risks (threats)? There is an alternative - the announcement of a free zone, but it too has its strengths and weaknesses. How to act, what path to follow? Should the emphasis be made on the draft law (permits) or prohibitions (free zone)? Answers to these questions will enable us to work out future strategies.

Mariam proposed the workshop participants teamwork in the following format: the participants were divided into two teams and the team moderators were selected. Each team summed up and balanced opinions and presented its position at a joint session.

Presentation of teamwork results

Presentation of the Team 1's work
Team moderator - Mariam Jorjadze

The work performed by the Team 1 was presented by Marika Gelashvili. She spoke about the team's position and noted that in spite of serious risks, the team backed the adoption of the law, for this would make possible to introduce a definite control and enable the consumer to make a choice. Although, the team unanimously thinks that the law requires perfection; in particular, more clearly should be identified our negative attitude to the introduction into the environment of LMOs, the test conduct conditions should be elaborated and tightened, as well as the conditions of marking and labeling.

Presentation of the Team 2's work
Team moderator - Manana Gigauri

The work performed by the Team 2 was presented by Temur Gogoberidze. He noted that the team's position had definitely divided: majority (all less two members) is against regulation within the law framework; they think that Georgia should necessarily be announced a free zone. Although, the team is unanimous in assessing the risks related to the control mechanisms - in the both cases, the law adoption and/or the free zone announcement - the real activation of the control and monitoring system is necessary.

Consolidation of Group Works

After the presentations the group works were consolidated by the workshop participants (Annex 8).

Setting up of an action group

For the purpose of making legislative amendments to the draft Law on Genetically Modified Organisms and working out of a common working plan - strategy, the workshop participants decided to set up an action group. The action group was composed of the following members: Mariam Jorjadze (Elkana), Ana Rukhadze (Ministry of Environment and Natural Resources), Marika Gelashvili (Ministry of Agriculture), Manana Zhuruli (Georgian Ecological and Biological Monitoring Association), and Kukuri Dzeria (Institute of Viticulture, Viniculture and Winemaking)

End of first day of the Workshop

Mariam Jorjadze thanked the workshop participants for activity and constructive cooperation, provided information about the second-day activities of the Workshop, and thus the first day of the Workshop was ended.

Second day - June 9, 2006

Field visit to Samtskhe-Javakheti region

On the 2nd day of the Workshop the workshop participants went to visit Samtskhe-Javakheti region. The purpose of the visit was presentation of the work performed within the framework of Elkana's Agricultural Diversity Program.

The project's presentation was held in the Elkana's regional office in Akhaltsikhe. The head of the Agricultural Diversity Section Bidzina Peradze familiarized the participants with the Project "The Restoration, Conservation and Sustainable Use of Georgia' Agricultural Diversity". The report concerned the program priorities, the results achieved and future plans, which was followed by a discussion around the agrarian Diversity conservation issues.

The workshop participants examined the Tsnisi collection plots, following which the participants shared their impressions. Many interesting ideas and opinions were voiced, including about the Project sustainability.

The working part of the workshop being over, the participants made a sightseeing visit to the Sapara monastery and returned in Tbilisi in the evening.

Responses

- The newspaper "Akhali Versia" has published 2 articles "Food for Future Generation; Georgia - a Polygon of Genetically Modified Products"; and "Elkana Started to Cultivate Endangered Crops" (16/18 June 2006, No. 44/46);
- The newspaper "Sakartvelos Respublika" has published an article about the workshop
- An extensive topic was broadcast on the radio "Green Wave" on this July 4
- A press-release (Georgian/English versions) of the workshop distributed through Caucasian Environmental NGO Network (Annex 9).

First day - June 8, 2006

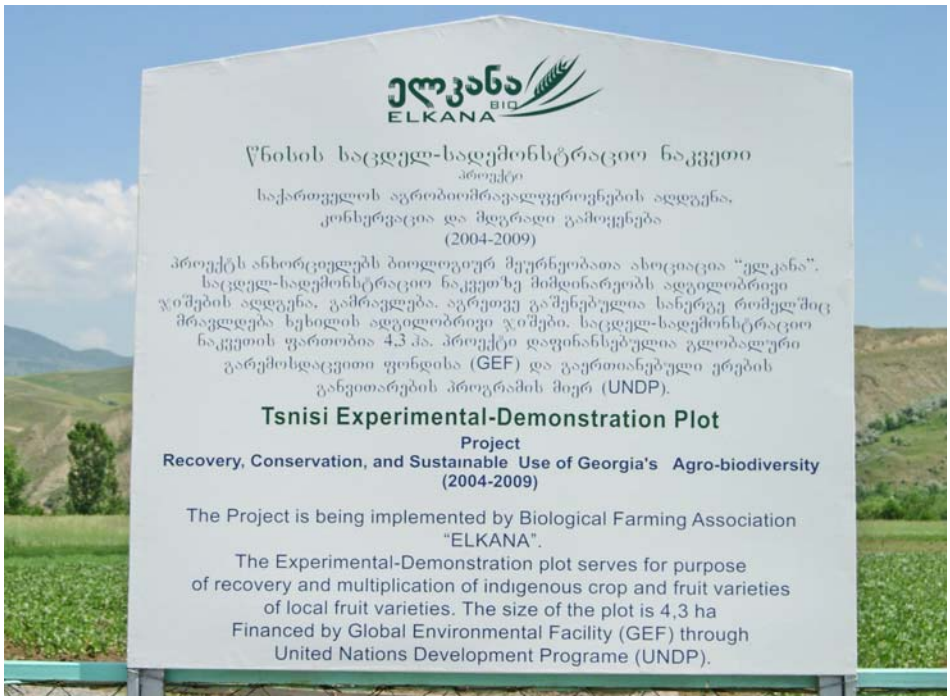
Opening of the Workshop

Mariam Meyet

Rudolf Buntzel

Presentation of teamwork results

Second day - June 9, 2006



Field Trip to Tsnisi Seed Multiplication Plot

Tsnisi Seed Multiplication Plot

The workshop participants on Tsnisi Seed Multiplication Plot

Agricultural Diversity Project presentation in the Elkana's regional office in Akhaltsikhe

ANNEXES

ANNEX 1

The participants List

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ANNEX 2

WORKSHOP PROGRAMME

8 JUNE, 2006
Venue: Elkana Office
#16 plot, 3rd Delisi str Tbilisi

09.30 - Registration of Participants
10.00 - Opening of the workshop, welcome speech and introduction to the workshop
10.15 - Goals and objectives of the workshop
10:30 - Introduction/expectations of participants
11.15 - Introduction to Biosafety situation in Georgia (Elkana, MoE)
11.45 - Questions, Discussions
12.00 - Coffee/Tea Break
12.20 - Inputs from foreign Experts (2)
13:30 - Questions Discussions
14.00 - Lunch Break
15.00 - Introduction to the Group work
15.20 - Group work to formulate main problems and major strategies for further action
16.40 - Coffee/Tea Break
17.00 - presentation of group work
17:30 - Discussion and formulation further plan of action
18.00 - Closure of the day

9 JUNE, 2006
Meeting Place for Departure:
Corner of Nutsubidze str. and 3rd Delisi str

08.00 - Start of the field trip to Samtskhe-Javakheti region
10.00 - Small snack on the way
11:30 - Visiting a seed multiplication plot and a fruit tree nursery in Tnisi
13.00 - Lunch in Akhaltsikhe
14.00 - Presentation of Elkana Agricultural Diversity Program
14.45 - Questions, discussion
15.30 - Summary of the workshop outcomes
16.00 - Coffee/Tea Break
16.30 - Excursion to the Sapara Monastry
18:30 - Dinner in Uraveli gorge
20:00 - Departure to Tbilisi
23:00 - Arrival in Tbilisi

ANNEX 3

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,
Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",
Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,
Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,
Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,
Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,
Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,
Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,
Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,
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,
Have agreed as follows:

Article 1
OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2
GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.
3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.
4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.
5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3
USE OF TERMS

For the purposes of this Protocol:
(a) "Conference of the Parties" means the Conference of the Parties to the Convention;
(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
(c) "Export" means intentional transboundary movement from one Party to another Party;
(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;
(e) "Import" means intentional transboundary movement into one Party from another Party;
(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a liv-

ing modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. 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 that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
2. The acknowledgement shall state:
(a) The date of receipt of the notification;
(b) Whether the notification, prima facie, contains the information referred to in Article 8;
(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.
3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.
4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10
DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.
2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:
(a) Only after the Party of import has given its written consent; or
(b) After no less than ninety days without a subsequent written consent.
3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:
(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;
(b) Prohibiting the import;
(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or
(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.
4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.
5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.
6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.
7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11
PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.
2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.
3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.
4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.
5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.
6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:
(a) A risk assessment undertaken in accordance with Annex III; and
(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.
7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.
9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12
REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.
2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:
(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
(b) Additional relevant scientific or technical information has become available.
3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.
4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13
SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:
(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and
(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.
Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.
2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14
BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.
2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.
3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.
4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15
RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.
3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16
RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mecha-

nisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
(d) Any methods and plans for emergency response.

Article 22
CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.
2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety
.

Article 23
PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:
(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24
NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.
2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25
ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.
3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26
SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27
LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process

with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.
3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.
4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.
5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.
6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.
3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.
4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:
(a) Make recommendations on any matters necessary for the implementation of this Protocol;
(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;
(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;
(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
(f) Exercise such other functions as may be required for the implementation of this Protocol.
5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.
8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5

above.

Article 30
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32
RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33
MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34
COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35
ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36
SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37
ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

ANNEX 4

Draft

GENETICALLY MODIFIED ORGANISMS ACT

Proposed Governmental Bill of Georgia on GMOs

Full title in direct translation : Draft Law of Georgia "On Genetically Modified Organisms"

Written and adopted in English by Malkhaz A.Dzneladze (M.Dz.)

FOR CONSULTATION AND OFFICIAL REVIEW

Note for citation and references:

Arrangement and hierarchy of sections, chapters etc.

Section / numbering order: I,II,III ... /

Chapter / numbering order: I,II,III ... /

Article / numbering order: 1,2,3 ... /

Paragraph / numbering order: 1,2,3... /

Subparagraph / numbering order: (a),(b),(c)... /

Section I
GENERAL PART

Chapter I
GENERAL PROVISIONS

ARTICLE 1. DEFINITIONS

1. The following provisions have effect for interpretation of this Act, except so far as the contrary intention appears:

(a) "organism" means any biological entity capable of replication or of transferring genetic material;

(b) "genetically modified organism" (hereinafter referred to as GMO[1]) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally and which possesses a novel combination of genetic material obtained through the use of modern biotechnology, that, in turn, means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family; these methods allow to overcome natural physiological reproductive or recombination barriers and, at the same time, they are not techniques used in traditional breeding and selection;

(c) "genetically modified product" means a preparation not capable of replication or of transferring genetic material and consisting of, processed GMO and/or containing any part/ingredient of processed GMO;

(d) "contained use" means any operation/manipulation (including development, handling, storing and disposal), undertaken for production[2], scientific, research, experimental or any other purposes, within a facility, installation or other physical structure, which involves GMOs, and that[3] are to be controlled by specific measures aimed at effective limitation of GMOs contact with, and their impact on, the human health and external environment;
(e) "deliberate release" means any intentional introduction into the environment of a GMO, for any other purpose than contained use and/or direct use as food and feed;

(f) "placing on the market" means making available to third parties GMOs or genetically modified products, whether in return for payment or free of charge. GMOs contained use, deliberate release and direct use as food and feed shall not be regarded as placing on the market;

(g) "transboundary movement" means movement (import, export, re-export and transit) of GMOs from a region under jurisdiction of one state to a region under jurisdiction of another state, or to a region which is out of any jurisdiction, given that the movement within this region concerns interests of at least two states;

(h) "biodiversity" means variability among wild fauna and flora, from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;

(i) "Biodiversity Convention" means Convention on Biological Diversity done at Rio de Janeiro on June 5, 1992; In respect to Georgia followed with ratification by the Parliament of Georgia on April 21, 1994;

(j) "Cartagena Protocol" means Cartagena Protocol on Biosafety to the Biodiversity Convention, done at Montreal on January 29, 2000;

(k) "Biosafety Clearing-House" means international mechanism established under the provisions of Biodiversity Convention and Cartagena Protocol in order to facilitate between states the exchange of scientific, technical, environmental and legal information on, and experience with, GMOs;

(l) "EU legislation" means regulations, decisions and directives, respectively of the European Commission, Council and the Parliament.

2. In this Act, "environment", "natural and cultural environment" and "sustainable development" have the same meanings as in the Environmental Protection Act of 1996.

1 Abbreviation of "GMO" does not apply to Georgian-language original, because an abbreviation is not common practice in case of Georgian legal texts. (M.Dz.)
2 In this subparagraph, according to original text, definition of "production" is regarded also as "manufacturing" and "processing". (M.Dz.)
3 Operations/manipulations. (M.Dz.)

ARTICLE 2. SCOPE OF THE ACT

1. This Act lays down the legal requirements in the field of use of GMOs and genetically modified products (hereinafter referred to as "field of GMOs").

2. This Act shall not apply to drugs (pharmaceutical products) that consisting of, and/or containing of GMOs and genetically modified products, or parts/ingredients of GMOs and genetically modified products.

ARTICLE 3. GEORGIAN LEGISLATION IN THE FIELD OF GMOs

The Georgian legislation in the field of GMOs is based on the provisions of the Constitution of Georgia, international agreements and treaties of Georgia, this Act and other acts and statutory regulations.

ARTICLE 4. MAIN OBJECTIVES OF THE ACT

The main objectives of this Act are:

(a) to ensure achievement, protection and enhancement of, subject to safe for human health and environment, conditions;

(b) to promote implementation of the sustainable development principles, protection of biodiversity, human health and environment by the management of GMOs use;

(c) to define national policy in the field of GMOs;

(d) to resolve the global and regional issues in the field of GMOs under national scheme laws;

(e) to facilitate, in the field of GMOs, implementation of the principles for access to information and public participation in decision-making process;

(f) to ensure compliance with international obligations in the field of GMOs under Biodiversity Convention and other international agreements and treaties;

(g) to promote harmonization of the Georgian legislation with the European Union standards[4] in the field of GMOs.

ARTICLE 5. MAIN MANAGEMENT PRINCIPLES IN THE FIELD OF GMOs

1. The following main management principles shall be applied to the field of GMOs:

(a) "precautionary principle" - use of GMOs and genetically modified organisms shall only be permitted if, taking into account the state of science and technology, and the guarantee of safety measures in Georgia, no direct or indirect, immediate or delayed or long-term cumulative adverse effects on the environment, biodiversity and human health can be expected;

(b) "principle of integrity" - the state authorities, within the framework of their competencies, in particular by the adoption of statutory acts, financial policies, conditions and contents of public education and information provision, stimulating research and development works, as well as by providing other lawful measures, should ensure overall management of GMOs and genetically modified products;

c) "principle of subsidiary measures" - the state should guarantee measures for preventing or reducing the consequences of adverse effects created by use of GMOs and genetically modified products, if the natural or legal person is not identifiable or if the consequences cannot otherwise be prevented or reduced;

(d) "bioethical principle" - in decisions relating to the field of GMOs, it is necessary to take into account, in addition to human well-being, also considerations for safety of all other living organisms and life associations, biodiversity and the natural and cultural environment as a whole;

(e) "risk assessment principle" - use of GMOs on the territory of Georgia, where required under this Act, shall take place in such a way that a risk assessment is made in relation to possible adverse effects on the environment, biodiversity and human health;

4 According to the Partnership and Co-operation Agreement (PCA) between the EU and Georgia of April 22, 1996 (Article 57. Environment, Paragraph 3), cooperation in the field of environment, inter alia, shall take place particularly through the improvement of national laws of Georgia towards Community standards under EU legislation. (M.Dz.)

(f) "principle of liability" - any person guilty of an offence in the field of GMOs, shall be liable[5] in compliance with the law with regard to damages in the commission of the offence;

(g) "publicity and public participation principle" - general public has the right to be informed about GMOs and genetically modified products, and to be involved in the decision-making process in compliance with this Act.

2. In addition to the main management principles in the field of GMOs defined under paragraph 1 above, any natural or legal person, within a framework of planning and/or implementing of any action in the field of GMOs, shall be governed by the principles of environmental protection and human health protection policies, prescribed respectively under the Environmental Protection Act of 1996[6] and Health Protection Act of 1997.

Chapter II
RIGHTS AND OBLIGATIONS OF NATURAL AND LEGAL PERSONS IN THE FIELD OF GMOs

ARTICLE 6. RIGHTS OF NATURAL AND LEGAL PERSONS IN THE FIELD OF GMOs

1. Natural and legal persons have the right to:

(a) receive complete, objective and timely information in the field of GMOs in accordance with the rules established by the Georgian legislation;

(b) submit proposals to the relevant authorities and agencies on the improvement of GMOs management;

(c) facilitate implementation of state programs and policies in the field of GMOs;

(d) participate in decision making processes in the field of GMOs;

(e) be compensated for the damage caused to them as a result of contravention of this Act and GMO-related[7] legislation;

(f) appeal through the court a GMO-related decision that caused or is likely to cause significant harm to human health and environment.

2. Provisions of paragraph 1 above shall be applied to citizens of foreign countries and natural persons without citizenship, also to foreign legal persons that are operating within the territory of Georgia, except as otherwise provided by the Georgian legislation.

ARTICLE 7. OBLIGATIONS OF NATURAL AND LEGAL PERSONS IN THE FIELD OF GMOs

1. Every natural and legal person shall be obliged to:

(a) comply with the legal requirements under this Act and GMO-related legislation;

(b) notify relevant supervisory authority or announce publicly on circumstances, that they are aware of, concerning a risk raising from GMOs and\or genetically modified products.

2. Except as otherwise provided by the Georgian legislation, provisions of paragraph 1 above shall be applied to:

(a) citizens of foreign countries;

(b) natural persons without citizenship;

(c) foreign legal persons that are operating within the territory of Georgia;

(d) governmental agencies.

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5 According to Georgian law, definition of "liability" generally means disciplinary, or administrative, or civil, or criminal liability. (M.Dz.)
6 Environmental Protection Act of 1996 lays down general principles of environmental protection, e.g., polluter pays, public participation, waste minimization, compensation for environmental damage, precautionary etc principles. Health Protection Act of 1997 sets out principles for state policies in the field of public health protection. (M.Dz.)
7 In this article, according to the context of the original text, a reference to "GMO-related" includes also a reference to genetically modified products. (M.Dz.)

Chapter III
DIVISION OF RESPONSIBILITIES

ARTICLE 8. DIVISION OF RESPONSIBILITIES BETWEEN CENTRAL, REGIONAL AND LOCAL AUTHORITIES IN THE FIELD OF GMOs

1. Area of responsibilities of the central authorities[8] of the state in the field of GMOs shall be extended to:

(a) development of state policies and national strategy[9];

(b) establishment of national system for the management of GMOs and genetically modified products;

(c) execution of state supervision in law enforcement;

(d) implementation of international cooperation and appropriate measures to give effect to Georgia's obligations under an agreement with one or more other countries;

(e) other responsibilities prescribed under the Georgian legislation.
2. The Government of Georgia may designate, the whole territory of Georgia or part of it, as GMO free zone for the purposes prescribed under article 24.

3. Responsibilities of the regional authorities[10] and the local authorities[11] in the field of GMOs are defined under the Legislation of Georgia.

Section II
PRINCIPAL PART

Chapter IV
MANAGEMENT OF GMOs AND GENETICALLY MODIFIED PRODUCTS

ARTICLE 9. NATIONAL SYSTEM FOR THE MANAGEMENT OF GMOs AND GENETICALLY MODIFIED PRODUCTS

1. Regarding, and under the provisions of this Act and with a view to protecting human health, environment and biodiversity the national system for the management of GMOs and genetically modifies products shall be established.
2. The national system for the management of GMOs and genetically modifies products shall be designed using appropriate planning, monitoring, controlling, economic and legal instruments in the field of GMOs.

3. The national system for the management of GMOs and genetically modifies products shall include:

(a) management of the use of GMOs, where GMOs are used in the following ways:

- contained use;

8 In this article "central authorities" means any of the following: (a) Parliament of Georgia; (b) Government of Georgia; and (c) Governmental Executive Agencies (Ministries). (M.Dz.)

9 According to the Environmental Protection Act of 1996, GMO-related national strategy may become part of National Environmental Strategy and National Environmental Action Programme. (M.Dz.)

10 In this article "regional authorities" means any of the following: (a) Parliament, Government and Governmental Executive Agencies of the Abkhazian Autonomous Republic; and (b) Parliament, Government and Governmental Executive Agencies of the Adjarian Autonomous Republic. For a number of reasons responsibilities of the Abkhazian and Adjarian Autonomous Republics in a field of environmental protection are not fully and clearly defined yet by the Georgian legislation. With regard to environmental enforcement (e.g., control and supervision) matters this situation has been resulted in so called "two-fold jurisdiction", which in turn, is being dynamically changed. Because of this reason article 9 of the draft Act makes general reference to the legislation of Georgia in terms of potential GMO-related responsibilities of "regional authorities". (M.Dz.)

11 In this article "local authorities" means any of the following: (a) elected and executive bodies of the administrative districts and several cities which are not under jurisdiction of any district; and (b) elected bodies of the communities/municipalities. Responsibilities of the local authorities are currently under revision and most likely will be drastically changed in 2005. (M.Dz.)

- deliberate release into the environment; and

- direct use as food or feed;

- placing of GMOs on the market.

(b) management of placing on the market of genetically modified products.

4. For the purposes of this Act, transboundary movement of GMOs shall be a consistent part of a framework under the national system for the management of GMOs and genetically modifies products.

ARTICLE 10. COORDINATION AND INSTITUTIONAL ARRANGEMENTS

1. The Ministry of Environment Protection and Natural Resources (hereinafter referred to as MoEPNR) shall be responsible for overall coordination of the management of GMOs and genetically modifies products and relating arrangements.

2. Scientific Commission for GMOs (hereinafter referred to as Commission) and Intersectoral Advisory Council[12] (hereinafter referred to as Advisory Council) as non-administrative bodies shall be established with, and by the MoEPNR to ensure consultative and organizational arrangements under the provisions of this Act.

3. Decisions taken by the Council and Commission shall not be treated as administrative or obligatory for the MoEPNR and/or other entities and persons.

4. Statute, mandate and membership of the Advisory Council are determined under the Act "On the Government of Georgia" of 2004 and the Act "On Permits and Licenses" of 2002.

5. Regarding this Act, the Commission shall be established according to the requirements prescribed under this Act and paragraph 5, article 20 of the Act "On the Government of Georgia" of 2004.

6. The Commission shall consist of experts with relevant scientific background, who are appointed by the Minister of Environment Protection and Natural Resources (hereinafter referred to as Minister of EPNR). Members of the Commission shall not be governmental employees. The Minister of EPNR shall appoint only those experts, who, in prior of appointment, had been registered in the Database of GMO Experts. Regulations for the management of Database of GMO Experts and terms of references for the experts shall be laid down by the Minister of EPNR.

7. The Minister of EPNR shall lay down appropriate procedure for the Commission.

8. Expenses relating to work of the Commission shall be covered from the sums allocated for operation of the MoEPNR within the state budget.

Chapter V
MANAGEMENT OF THE USE OF GMOs
ARTICLE 11. USE OF GMOs

1. Authorization for the use of GMOs pursuant to this Act may arise through the consent (hereinafter referred to as "permit") for their use in the following cases:

(a) contained use of GMOs;

(b) deliberate release of GMOs into the environment;

(c) direct use of GMOs as food or feed.

2. In a case of placing on the market of GMOs, an user may commence activities without the permit.

12 Intersectoral Advisory Council is already established by the MoEPNR under the provisions of the Acts "On the Government of Georgia" of 2004 and "On Permits and Licenses" of 2002. This Council serves as non-administrative body to consult the MoEPNR on all-type of licenses and permits that are to be issued by the MoEPNR. The Council consists of representatives of the governmental agencies, individual experts and NGOs. Enactment of the GMO Act will require changes in the mandate of the Council in terms of indication of GMO-related matters - for this reason the GMO Act sets up subparagraph (d) under paragraph 1 of article 31, which stipulates need for amendment to the existing statute of the Council. See also paragraphs (3) and (4), article 10 of the GMO Act. (M.Dz.)

3. The MoEPNR, as national competent authority in the field of GMOs, shall be responsible for authorization of GMOs use by written permit.
4. To avoid doubt, nothing in this Act affects the operation of the Act "On Permits and Licenses" of 2002, any other powers or rights under the other acts, regulations or any other law in relation to a provision of this Act regarding a permit for the use of GMOs. Permit for the use of GMOs established under this Act, is not intended to exclude or limit and/or substitute any other permit, license or consent prescribed under any other law.

ARTICLE 12. PROCEDURE FOR AUTHORIZATION OF GMOs USE

1. Administrative procedure for authorization of use of GMOs shall be governed by the provisions of this Act, the Act "On Permits and Licenses" of 2002 and the Georgian legislation.

2. Any person must, before undertaking an action subject to permitting and aimed at use of a GMO or of a combination of GMOs, submit an application for the permit (hereinafter referred to as "application") to the MoEPNR. The application shall include information prescribed under article 13 of this Act, and shall be submitted to the MoEPNR in quadruplicate and simultaneously in electronic form. The application shall comply with general requirements for applications referred to in the General Administrative Code of 1999.

3. If the application is not complete, the MoEPNR shall, within 14 days of receiving the application, request in writing a complement thereof and shall suspend the administrative procedure for authorization. If the administrative procedure is suspended, the period for the issue of the permit shall not proceed.

4. If the application is complete, the MoEPNR shall, within 14 days of receiving the complete application, send the copies of application to:

(a) the Commission;

(b) Ministry of Agriculture (hereinafter referred to as MoA);

(c) Ministry of Labor, Health and Social Protection (hereinafter referred to as MoLHSP).

5. The Commission, the MoA and the MoLHSP, through the evaluation study on the potential risk to human health, environment and biodiversity, shall issue their conclusions on reasonability of permitting of GMOs use (hereinafter referred to as "standpoints") with a view to special requirements[13] for safe use of GMOs (contained use, deliberate release into the environment and direct use as food or feed). Special requirements for safe use of GMOs, as well as guidelines for conducting the evaluation study on potential risk to human health, environment and biodiversity and matters relating to outline (form) and content of the standpoints shall be jointly drafted by the MoEPNR, the MoLHSP and the MoA and submitted to the Government for further approval by the Decree. The Special requirements for safe use of GMOs shall cover, inter allia, matters related to classification with regard to contained use. Contained use should be classified into one of four classes, namely: class 1, if it is work in which the risk is negligible; class 2, if it is work in which there is low risk; class 3, if it is work in which the risk is moderate, or class 4, if it is work in which the risk is high. Classified contained use of GMO shall be treated in compliance with required containment and other safety measures and required provisions. The criteria to classify each contained use of GMO into a specific class, containment and other safety measures, rules of management and other conditions for individual class shall be specified by the Governmental Decree, mentioned in this paragraph.

6. If relevant scientific evidence and experience relating to potential risk and adverse effects of a GMO or combination of GMOs to human health, environment and biodiversity in terms of deliberate release and /or direct use as food or feed are not available with regard to Georgian conditions, evaluation procedure referred to in paragraph 5 above shall include field and/or laboratory testing. Moreover:

(a) GMOs field and laboratory testing shall not be subject to administrative authorization procedure for permitting;

(b) expenses related to GMOs field and laboratory testing shall be covered by an applicant;

(c) the MoLHSP and/or the MoA shall notify the MoEPNR on a scope and scale of, and expenses associated with, GMOs field and laboratory testing within 40 days of receiving the application from the MoEPNR. The MoEPNR informs the applicant on receiving of the notification from the MoLHSP and/or the MoA. The following prerequisites shall apply to implementation of the GMOs field and laboratory testing:

13 According to the context of the original Georgian language text of the Act - special requirements for safe use of GMOs will serve as criteria for assessement of the potential risk to human health, environment and biodiversity.

- implied financial warranty[14] of the applicant to cover cost of GMOs field and/or laboratory testing. The Ministry of Finances shall be responsible, in cooperation with the MoEPNR, for identification of legal and financial arrangements and conditions relating to implied financial warranty in each concrete case;

- presence of approved by the MoEPNR detailed plan (including time schedule, list of required equipment, monitoring programme, testing methods, emergency response plan and reporting scheme) for GMOs field and/or laboratory testing, elaborated either by the MoLHSP or by the MoA in cooperation with the applicant.

(d) GMOs field and/or laboratory testing is held by the MoLHSP or by the MoA through subordinate and/or independent entities specializing in the fields of environmental health[15], food quality control, seed control, phytosanitary, pest control, fertilizers, veterinary and biotechnology;

(e) guidelines[16] for GMOs field and laboratory testing as well as cost recovery tariffs[16] necessary for GMOs field and laboratory testing shall be laid down by the joint order of the MoLHSP and the MoA.
7. Within a framework under administrative procedure for authorization of GMOs use, the Commission, MoLHSP and the MoA, upon receiving the application from the MoEPNR, may require, through the MoEPNR, submission of additional information they consider relevant from the applicant. If the Commission, or the MoLHSP and/or the MoA requests new information it must simultaneously give its reasons for so doing.

8. The MoEPNR provides the Advisory Council with standpoints of the Commission, MoLHSP and the MoA referred to in paragraph 5 of this article. The Advisory Council shall make final recommendation to the MoEPNR in a form of a decision on GMOs use.

9. Recommendation of the Advisory Council, along with the standpoints of the Commission, MoLHSP and the MoA, shall be observed by the MoEPNR. The MoEPNR shall make administrative decision on granting of permit on GMOs use taking into account, inter alia, socio-economic considerations and circumstances.

10. The MoEPNR shall respond in writing to the applicant within 90 days of receipt of the application by either indicating that it is satisfied that the application is in compliance with this Act and that the administrative authorization procedure may proceed, or indicating that the application does not fulfill the conditions of this Act and that application is therefore rejected.

11. Permit for GMOs use shall be granted, or prohibition shall be issued in written within 270 days of receipt of the application. In case of GMOs laboratory testing this period may be extended up to 1 year, and in case of GMOs field testing up to the period of 3 years. A failure by the MoEPNR to issue its decision within the time scales set out in this paragraph shall not imply its permit to GMOs use. A permit granted out of the time scales set out in this paragraph shall not be legally valid. For the purpose to calculate the time scales referred to in this paragraph, no account shall be taken of any following periods of time:

(a) during which the MoEPNR is awaiting further information which it may have requested (as a result of demand from the side of the Commission, the MoLHSP or the MoA), from the applicant; or

(b) from a date when the MoEPNR informs the applicant on receiving of the notification from the MoLHSP and/or the MoA on a need of the GMOs field and/or laboratory testing up to actual date of starting of the GMOs field and/or laboratory testing.

12. A permit granted by the MoEPNR authorizes an applicant to use GMOs, in accordance with any limitations and conditions to which the GMOs use is subject, for one occasion[17], or permanently within a period of time and within the boundaries of predefined territory prescribed by the permit[18].

13. The MoEPNR within 10 days of taking administrative decision regarding to granting of permit (including modifications

14 Requirement for financial warranty is introduced to avoid situation of bona vacantia with regard to GMOs under field and/or laboratory testing. (M.Dz.)

15 Sanitary-higienic science and practice (including sanitary-higienic control). (M.Dz.)

16 Cost recovery tariffs are introduced to limit possibilities for arbitrary calculations from the side of the MoLHSP and/or the MoA. (M.Dz.)

17 Non-permanent occasion. (M.Dz.)

18 This paragraph 12 is inserted to justify legal meaning of a permit under this draft Act with legal meaning of a permit under the Act "On Permits and Licenses" of 2002, and also to highlight difference between a permit and a license in general. (M.Dz.)

of conditions to, suspension or termination of it[19]) shall make appropriate information publicly available through publication of it in the Official Gazette of Georgia[20] - namely, in its volume IV.

14. The Minister of EPNR shall lay down regulations relating to outline of permit.

15. Expenses related to authorization procedure for GMOs use shall be covered by an applicant. Cost recovery tariffs relating to authorization procedure for GMOs use, other than expenses related to GMOs field and laboratory testing, shall be laid down by the joint order of the Minister of EPNR, the Minister of LHSP and the Minister of Agriculture.

16. General conditions related to cases when permit shall not be granted are set out in the Act "On Permits and Licenses" of 2002.

17. A permit shall not be granted if scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of GMOs on the human health, environment and sustainable use of biological diversity in Georgia does not exist.

18. Any dispute as to a prohibition regarding to GMOs use may be subject to appealing against such a prohibition within the period of time prescribed by the administrative law[21] .

19. A permit is not transferable by a holder.

ARTICLE 13. SUPPLEMENTARY INFORMATION TO THE NOTIFICATION

1. The application referred to in paragraph 2 of article 12 shall include, but not limited to:

(a) a technical dossier on GMOs;

(b) risk assessment relating to potential adverse effects of GMOs to human health, environment and biodiversity;
(c) monitoring programme and methods of remediation and control;

(d) emergency response plan in the event of accident and/or unintended release into the environment;

(e) scheme for reporting to supervising authorities (manner and frequency of informing).

2. In a case of granting a permit, such a permit shall be supplemented with monitoring programme, methods of remediation and control, emergency response plan and reporting scheme in a finally approved by the MoEPNR form - as part of conditions to a permit.

3. The Minister of EPNR shall lay down the regulations relating to lists and further details of certain information contained in the application necessary for carrying out the evaluation study on GMOs potential risk to human health, environment and biodiversity - separately for contained use, deliberate release and use of GMOs as food or feed. Lists and details of certain information referred to in this article shall comply with requirements set out by the Cartagena Protocol and relevant EU standards.

ARTICLE 14. MANAGEMENT FOR PLACING ON THE MARKET OF GMOs

1. Management of placing on the market of GMOs shall be carried out through clear identification and labeling of GMOs and products containing, or consisting of GMOs (hereinafter referred to as identification and labeling of GMOs).

2. Identification and labeling of GMOs are subject to provisions under this Act and Consumer Rights Act of 1996.

19 Modifications of conditions to, suspension or termination of permits are regulated by the provisions of the Act "On Permits and Licenses" of 2002. According to the general requirements of that Act, modifications of conditions are subject to the same procedures as for initial conditions. As to suspension or termination - they are held in cases of violation of the conditions of a permit. (M.Dz.)

20 Official Gazette of Georgia consists of following 4 volumes (Volume I - Acts (Laws), Volume II - International Agreements and Treaties of Georgia, Volume III - Regulations, and Volume IV - Information). Volume IV contains different type of official data including information on administrative decisions taken by the governmental agencies etc. (M.Dz.)

21 General Administrative Code of 1999 and Administrative Procedural Code of 1999. (M.Dz.)

3. If labeling of GMOs is not possible due to an physical obstacle in terms of packaging circumstances or GMOs are not transferred to final consumer who will not use the product as part of any business operation or activity, GMOs shall be identified trough accompanied declaration which shall be transferred to, and held by a buyer or any other receiver at each stage of GMOs placing on the market.

4. The following information concerning labeling of GMOs shall be provided on a label or in accompanying declaration:

(a) the words "This product contains GMOs" whenever there is evidence of the presence of GMOs in the product;

(b) the words "This product may contain GMOs" where the presence of GMOs in a product cannot be excluded but there is no evidence of any presence of GMOs;

(c) the words "This product may cause ..... [specification of the particular reactions, allergies or other side-effects]" where it is known that a particular reaction, allergy or other side-effect may be caused by the product;

(d) where applicable, further or as a qualification to subparagraphs (1) and (2) above, the words "This product contains genetic material (nucleic acids) from GMOs" or "This product is based on raw materials from GMOs".

5. Placing on the market of GMO's is subject to all requirements laid down by the Georgian legislation in the field of protection of consumer rights.

6. Copy of accompanying declaration, mentioned in the paragraph 4 above, shall be sent to the MEPNR before placing on the market of GMO's.

Chapter VI
MANAGEMENT OF THE USE OF GENETICALLY MODIFIED PRODUCTS

ARTICLE 15. PLACING ON THE MARKET OF GENETICALLY MODIFIED PRODUCTS

1. Management of placing on the market of genetically modified products shall be carried out through clear identification and labeling of genetically modified products.

2. Placing on the market of genetically modified products does not require any permit and/or license.

3. Labeling of genetically modified products is subject to the requirements under the provisions set out in article 14 for labeling of GMOs.

Chapter VII
TRANSBOUNDARY MOVEMENT OF GMOs

ARTICLE 16. MANAGEMENT OF TRANSBOUNDARY MOVEMENT OF GMOs

1. Import of GMOs shall only be permitted if, prior to the import, a permit for GMOs use (for deliberate release, contained use and use as food or feed) has been issued in compliance with this Act.

2. Transboundary movement of GMOs is governed under the provisions of paragraph 1 above and advance informed agreement procedure prescribed by the Cartagena Protocol.

ARTICLE 17. INSTITUTIONAL ARRANGEMENTS FOR TRANSBOUNDARY MOVEMENT

1. The MoEPNR shall be designated as national focal point and competent national authority for the purpose of management of transboundary movement of GMOs under the requirements of the Cartagena Protocol.

2. Customs authorities shall be responsible for custom inspection and control over GMOs transboundary movement within the custom zone of Georgia.

Chapter VIII
TRANSPORTATION OF GMOs

ARTICLE 18. CONDITIONS OF SAFETY FOR GMOs TRANSPORTATION

1. GMOs shall be transported under conditions of safety (including safety requirements for packaging and handling), taking into consideration relevant international rules and standards. Special conditions of safety for GMOs transportation shall be laid down by the Minister of EPNR with due regard to the requirements prescribed in paragraphs 2, 3 and 4 bellow.
2. It shall be required that documentation accompanying GMOs that are intended for direct use as food or feed clearly identifies that:
(a) they "may contain" GMOs and are not intended for deliberate release into the environment;
(b) contact point for further information.
3. It shall be required that documentation accompanying GMOs that are destined for contained use clearly identifies:
(a) them as GMOs intended for contained use;
(b) contact point for further information, including the name and address of the individual and institution to which the GMOs are consigned.
4. It shall be required that documentation accompanying GMOs that are intended for deliberate release clearly identifies:
(a) them as GMOs for deliberate release;
(b) any requirements for the safe handling, storage, transport and use;
(c) contact point for further information and, in a case of trasboundary movement of GMOs, the name and address of importer and exporter and declaration that the movement is in conformity with the requirements of the Cartagena Protocol.

Chapter IX
ACCESS TO INFORMATION AND PUBLIC PARTICIPATION IN DECISION-MAKING

ARTICLE 19. ACCESS TO INFORMATION

1. Information in the field of GMOs shall be open and accessible for the general public.

2. Right to access information in the field of GMOs is guaranteed by the Georgian legislation and international obligations of Georgia[22] .

3. In addition to the provisions of this Act concerning the right of general public to access GMO related information, requirements of the General Administrative Code of 1999 shall be applied.

ARTICLE 20. CONFIDENTIAL INFORMATION

1. Application for the permit submitted in accordance with this Act may contain identification of information that is to be treated as confidential. Justification shall be given by an applicant in such cases upon request by the MoEPNR.
2. The MoEPNR shall consult the applicant if it decides that information identified by the applicant as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the applicant of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.
3. Each of the authority involved in administrative authorization procedure for GMOs use under this Act shall protect confidential information.
4. If an applicant withdraws or has withdrawn an application, the MoEPNR shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the MoEPNR and the applicant disagree as to its confidentiality.
5. The following information shall not be considered confidential:
(a) the name and address of the applicant;
(b) a general description of the GMO or GMOs;
(c) a summary of the risk assessment of the effects on the human health, environment and biodiversity;
(d) methods and plans for emergency response;
(e) any other information registered in the National Register of GMOs.

ARTICLE 21. NATIONAL REGISTER OF GMOs

1. For the purposes of this Act, the MoEPNR shall maintain the National Register of GMOs containing prescribed particulars of or relating to the management of GMOs and genetically modified organisms. Electronic version of the National Register of

22 E.g., Aarhus Convention. (M.Dz.)

GMOs shall be available through specially designated web-site.

2. The MoEPNR shall ensure that the following records are entered into the National Public Register of GMOs within the 2 day time period of receiving them:

(a) business names and registered offices or addresses of applicants for GMOs use (and any further information furnished in connection with them);

(b) dates and titles of granted permits (including general description of GMOs) and prohibition notices;

(c) contained use and its classification and addresses and properties of the premise;

(d) deliberate releases of GMOs into the environment, including an exact description of the location of release;

(e) characteristics of GMOs intended for direct use as food and feed;

(f) products and their placement on the market, including a description of the site in which the product is placed on the market;

(g) other records prescribed by the legislation.

3. The National Register of GMOs shall be kept by the MoEPNR as a public document. Anyone shall have the right to peruse the data from, and request and obtain an extract from the National Register of GMOs against payment of the costs, which may not exceed the material costs of communicating the data.

4. Data which in compliance with this Act are protected as confidential shall not be entered in the records referred to in the paragraph 2 of this Article.

5. Without any prejudice to the provisions under paragraph 2 above, detailed content, form and manner of keeping the National Register of GMOs shall be specified by the Minister of EPNR in the separate regulations.

ARTICLE 22. PUBLIC PARTICIPATION IN DECISION-MAKING

1. Under the procedure for issuing a permit for GMOs use referred to in this Act, the MoEPNR shall provide the general public with information on receiving of application within 5 days of receiving of application. This public announcement shall be made available through the specially designated web-site and publication in the Official Gazette of Georgia and at least in 2 nationwide newspapers.

2. Public announcement referred to in paragraph 1 above shall contain name and address of contact person of the MoEPNR who will be responsible for providing of required information to general public. Representatives of the public may provide the MoEPNR with their opinions, observations and standpoints within 90 days of the public announcement.

3. The MoEPNR shall ensure arrangement of consultations with public representatives within 45 days of the public announcement. Date and place of such consultations with public representatives shall be made available through the specially designated web-site and publication in the Official Gazette of Georgia and at least in 2 nationwide newspapers.

4. Opinions, observations and standpoints of the public representatives referred to in paragraph 2 above shall be taken into account during decision-making process concerning the GMOs use.

ARTICLE 23. INFORMATION SHARING WITH THE BIOSAFETY CLEARING-HOUSE

1. The MoEPNR shall be responsible body for relationships with biosafety clearing-house.

2. The MoEPNR shall ensure information exchange with biosafety clearing-house.

3. The MoEPNR shall make information and data received through biosafety clearing-house make publicly available.

Chapter X
FREE ZONES

ARTICLE 24. FREE ZONES

1. For the purposes of this Act, surface or aquatic territory of Georgia could be designated as a free zone from full or partial use of GMOs.
2. According to Article 8, decision on designation of a free zone is taken by the Government of Georgia - except the designation of free zones prescribed under the Article 25 of this Act.

ARTICLE 25. DESIGNATION OF FREE ZONES

1. For the purposes to protect environment and biodiversity and also for the purpose to promote sustainable development of the whole nation the following surface territories shall be designated (notwithstanding that the first sentence of paragraph 2, Article 24, generally applies in this case) as free of GMOs zones:
(a) protected areas;
(b) resort forests, green zone forests, soil, water and landscape protective forests and forests of special value within the boundaries of the State Forest Land Area.
2. Deliberate release into the environment of GMOs shall be strictly prohibited within the area of designated, pursuant to Paragraph 1 (Article 25), as free of GMOs zones.

Chapter XI
CONTROL AND SUPERVISION

ARTICLE 26. CONTROL AND SUPERVISION IN THE FIELD OF GMOs

1. The following authorities shall be responsible for carrying out control and supervision in the field of GMOs:

(a) The MoEPNR, which shall:

- be the central administrative authority in the field of GMOs use;

- execute supreme state supervision in the area of the GMOs use and genetically modified products from the point of view of protection of the human health, environment and biological diversity;

- maintains the National Register of GMOs;

- performs other duties and responsibilities according to the legislation of Georgia;

(b) The MoLHSP, which shall carry out state sanitary supervision and control regarding the GMOs and genetically modifies products;

(c) The MoA, which shall carry out state supervision and control regarding the GMOs and genetically modifies products within a scope of its competences[23];

(d) The Customs Authorities[24], which shall:

- take customs control over the consignments that are declared as GMOs and/or genetically modified products at border crossing points, to ensure that they are accompanied by the appropriate documents pursuant to this Act and the special legal requirements under the Cartagena Protocol;

- impound the goods, in case of discovery of any infringement against this Act or in case of suspicion thereof, inform the MoEPNR thereof and, in case of doubt, ask the MoEPNR for professional assistance;

- keep records of all consignments of GMOs and genetically modified products allowed to cross the border and enable the employees of the MoEPNR to pay particular attention to such records, copy information or make copies thereof, including providing this evidence in electronic form or by e-mail.

2. Control and supervision in the field of GMOs include:

(a) control how legal and natural persons comply with the provisions of the legal regulations laid down by the legislation of Georgia and international agreements and treaties of Georgia;

(b) control and supervision over sanitary, phytosanitary, pest control, veterinary, foodstuff quality and related legal provisions prescribed under this Act and legislation of Georgia;

(c) as result of inspection, imposment on legal and natural persons remedial measures and penalties for infringement against obligations pursuant to this Act;

(d) other measures prescribed by the legislation of Georgia.

3. Decisions relating to control and/or supervision in the field of GMOs may take place in accordance with established rules under the legislation of Georgia.

4. Any decision relating to control and/or supervision in the field of GMOs may become subject to appealing.

5. Without any prejudice to the provisions of this article and with due regard to Sanitary Code of 2003 and other relevant legislation, the MoLHSP shall perform supervision over the measures preventing adverse effects to human health from GMOs use and use of genetically modified products. Regulations for the above matter shall be laid down by the Minister of LHSP.

Chapter XII
COMPENSATION

ARTICLE 27. COMPENSATION FOR DAMAGE

1. If damage is caused to the natural environment and biodiversity as a result of insufficient care being exercised by the person using GMOs, compensation for the damage, inter alia, is payable to the state. Imposing of administrative or criminal liability shall not lead to exemption from responsibility to pay compensation for damage to the natural environment and biodiversity.

2. The amount of compensation for losses imposed on the natural environment and biodiversity shall be calculated through methodology and technique for evaluation of the compensations for damage, caused by the use of GMOs, to the natural environment and biodiversity. Regulations on the above methodology and technique shall be submitted by the Minister of EPNR to the Government of Georgia for further approval.

Chapter XIII
LIABILITY

ARTICLE 28. LIABILITY FOR VIOLATION OF THE GENETICALLY MODIFIED ORGANISMS ACT

Any person guilty of an offence for violation of this Act shall be liable according to disciplinary, administrative or criminal procedures under the legislation of Georgia.

Section III
TRANSITIONAL PART

Chapter XIV
SUPPLEMENTARY REGULATIONS TO BE APPROVED UPON ENACTMENT OF THE GENETICALLY MODIFIED ORGANISMS ACT

ARTICLE 29. SUPPLEMENTARY REGULATIONS

1. The following, supplementary to this Act, regulations shall be laid down in order to ensure proper implementation of the provisions of this Act:

(a) Decree of the Government "On Special Requirements for Safe Use of GMOs (Contained Use, Deliberate Release into the

23 These competences cover the following fields: food quality control, seed control, phytosanitary, pest control, and fertilizers, veterinary and to some extant biotechnology. (M.Dz.)

24 Currently under the management of the Ministry of Finances. (M.Dz.)

Environment and Direct Use as Food or Feed)"; and "On Guidelines for the Evaluation Study regarding the GMOs Potential Risk to Human Health, Environment and Biodiversity, conducted by the GMOs Scientific Commission, the MoLHSP and the MoA and Outline (Form) and Content of their Standpoints";

(b) Decree of the Government "On Regulations relating to the Methodology and Technique for Evaluation of the Compensations for Damage, caused by the Use of GMOs, to the Natural Environment and Biodiversity";

(c) Joint Order of the Minister of LHSP and the Minister of Agriculture "On guidelines for GMOs field and laboratory testing and cost recovery tariffs necessary for GMOs field and laboratory testing";

(d) Order of the Minister of EPNR "On the Regulations Relating to the Management of Database of GMO Experts and Terms of References for the Experts";

(e) Order of the Minister of EPNR "On Procedure for the GMOs Scientific Commission";

(f) Order of the Minister of EPNR "On Regulations relating to Outline of the Permit for GMOs Use";

(g) Joint Order of the Minister of EPNR, the Minister of LHSP and the Minister of Agriculture "On Cost Recovery Tariffs Relating to Authorization Procedure for GMOs Use";

(h) Order of the Minister of EPNR "On Regulations Relating to Lists and Details of Certain Information Contained in the Application for GMOs Contained Use, Deliberate Release and Use of GMOs as Food or Feed";

(i) Order of the Minister of EPNR "On Special conditions of safety for GMOs transportation";

(j) Order of the Minister of EPNR "On Regulations with respect to the Form and Manner of Keeping of the National Register of GMOs";

(k) Order of the Minister of LHSP "On Regulations concerning Supervision over Implementation of Preventing Measures against Adverse Effects caused by the GMOs Use and Genetically Modified Products to Human Health";

(l) Order of the Minister of EPNR "On Regulations Establishing Conditions for Registration and Further Management of the GMOs - Used Prior to the Date of the Enactment of Genetically Modified Organisms Act".

2. Regulations listed in subparagraphs (a), (b), (h), (i) and (j) of paragraph 1 above shall be subject to harmonization with the standards under the following EU legislation, where appropriate and where those standards are not in contradiction to the provisions of this Act:

(a) 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/EC (OJ L 106, 17.04.2001, p.1);

(b) Council Directive 90/219/EEC of 23 April, 1990 On the Contained Use of Genetically Modified Micro-organisms (OJ L 078, 26.03.1991, p.38);

(c) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September, 2003 On Genetically Modified Food and Feed (OJ L 268, 18.10.2003, p.1-23);

(d) 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 Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p.24-28).

ARTICLE 30. ENACTMENTS RELATING TO SUPPLEMENTARY REGULATIONS

Supplementary to this Act, regulations listed in Article 30 shall enter into force within 90 days upon enactment of this Act.

Chapter XV
PROVISIONS GOVERNING TRANSITIONAL MEASURES

ARTICLE 31. ADJUSTMENT OF EXISTING REGULATIONS TO THE PROVISIONS OF THE ACT

1. The Government of Georgia and the MoEPNR shall take measures necessary to comply with this Act in terms of promulgation of amendments to the following regulations:

(a) Decree of the Government of June 12, 2004 "On Statute of the Ministry of Environment Protection and Natural Resources" (Official Gazette of Georgia, Part III, 2004, #60, cl.526);

(b) Decree of the Government of May 21, 2004 "On Statute of the Ministry of Agriculture" (Official Gazette of Georgia, Part III, 2004, #54, cl.461);

(c) Decree of the Government of June 7, 2004 "On Statute of the Ministry of Labor, Health and Social Protection" (Official Gazette of Georgia, Part III, 2004, #58, cl.501);

(d) Order of the Minister of EPNR of November 2, 2004 "On Approval of the Statute of the Intersectoral Advisory Council with the Ministry of Environment Protection and Natural Resources" (Official Gazette of Georgia, Part III, 2004, #129, cl.1146);

2. Statutory acts listed in paragraph 1 of this article shall be amended within 30 days upon enactment of this Act.

ARTICLE 32. TRANSITIONAL PROVISIONS IN CONNECTION WITH THE REQUIREMENTS OF THE EU LEGISLATION CONCERNING THE GMOs

Repealings and substitutions with regard to the EU legislation listed in article 29 of this Act shall be applied, mutatis mutandis, to the provisions of the regulations listed in paragraph 1 of article 29 above.

ARTICLE 33. REGISTRATION OF GMOs USED PRIOR TO THE DATE OF ENACTMENT OF THE ACT

1. GMOs which were subject to deliberate release, or contained use and/or use as food and feed prior to the date when this Act comes into effect shall be registered in the National Register of GMOs at the latest within 1 year of the date when this Act comes into effect.
2. Minister of EPNR lays down by an order conditions of registration and further management of the GMOs used prior to the date of the enactment of this Act.

3. For the purposes of this Act, registration of GMOs, pursuant to paragraph 1 above, shall be legally equalized to the permit for the use of GMOs under the provisions of this Act.

Section IV
FINAL PART

Chapter XVI
FINAL PROVISIONS

ARTICLE 34. ENACTMENT

This Act shall come into effect on December 31, 2005.

President of Georgia - /Signature/

Done at City of Tbilisi, this ....th day of ….. 2005.

ANNEX 5

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COMMENTS ON PROPOSED BILL OF GEORGIA ON GMOS

By Mariam Mayet
African Centre for Biosafety
May 2006

The African Centre for Biosafety (ACB), in friendship, submits these comments on the Proposed Bill of Georgia on GMOs, (full title Draft Law of Georgia: On Genetically Modified Organisms).

DETAILED COMMENTS

Article 1: Definitions

(c) "genetically modified product" it may be appropriate to add the following words at the end of the clause " whether or not transgenic material is detectable";

(d) "contained use" the words "limitations of GMOs contact with" should be changed to "prevent contact of GMOs with" in order for the definition to be more scientifically accurate;

(f) "placing on the market" this definition needs more attention, particularly since it is an activity for which no permit is required. What needs to be made clear is that the placing of the market of GMOs or products of a GMOs relate only to those GMOs that have already previously been authorised for food, feed and processing;

Article 2: Scope of the Act

GM Pharmaceuticals

Whilst it is not known whether GM pharmaceuticals are regulated by other legislation in Georgia, we would like to point out the following in relation to GM pharmaceuticals:

There is a great deal of confusion about how exactly, pharmaceuticals for humans that are GMOs, are dealt with by the Biosafety Protocol. Clearly, GM pharmaceuticals that do not fall within the definition of "living modified organism" of the Biosafety Protocol is excluded from the scope of the Protocol. However, the Biosafety Protocol does not exclude GMOs that are pharmaceuticals for humans, from the scope of the Protocol. The Protocol merely excludes the Advanced Informed Agreement (AIA) procedure and Article 12 dealing with review of decisions from applying to those genetically modified pharmaceuticals for humans that are addressed by relevant international agreements and organizations, such as the World Health Organisation (WHO). Furthermore, it is unclear to what extent such relevant agreements and organizations need to 'address' GMOs that are pharmaceuticals in order for the AIA and Article 12 of the Protocol not to apply to such GMOs. The view has been expressed that information available so far shows that no pharmaceutical for humans are covered by any other agreement or organization in their condition as a GMO and are therefore covered by the Protocol.

In any event, genetically modified plants and animals used to produce pharmaceuticals are not exempt from the provisions of the AIA procedure of the Protocol. According to the rules of the WHO and its member states, it is highly unlikely that the actual genetically modified plant or animal will ever receive approval as a pharmaceutical as such. More so as further processing

to achieve a standardized, reliable pharmaceutical will in any event be necessary. Furthermore, the exemption of the Protocol does not apply to genetically modified pharmaceuticals that are not dealt with by relevant international agreements or organizations nor where such agreements or organizations do not directly address the environmental and biodiversity impacts of a GMO. The exemption will also not apply to genetically modified pharmaceuticals that are intended for veterinary purposes. Additionally, an importing Party has the sovereign right to require a risk assessment prior to the import of any GMO for any use.

In the light of the above, the current exclusions as articulated in Article 2(2) of the Georgian Bill should be carefully considered, in the light of the following:

" the likelihood of Georgia's ratification of the Biosafety Protocol;
" that the Protocol applies to pharmaceuticals for humans that are GMOs; and
" legislative vacuum that may occur if GM pharmaceuticals and pharmaceuticals that are GMOs, are excluded from the scope of the Protocol.

ARTICLE 4: OBJECTIVES OF THE ACT

What appears to be missing is a clear commitment to avoid the risks posed by GMOs. In "management of GMOs" in (b) is worrying because this already assumes that the risks are acceptable and that they can be managed. In (f), it may be appropriate to make some reference here to the Biosafety Protocol, as the only international environmental agreement that regulates GMOs. In regard to (g) harmonisation with the EU standards, the implication may be, that GMOs approved in terms of the EU standards may be pushed through the Georgian legislative framework later on.

ARTICLE 5: PRINCIPLES

We point out that in (f) the "principle of liability" needs to be more carefully considered. Liability for damages suffered or caused by GMOs, or activities relating to GMOs, is not linked to criminal offences arising from non-compliance with the law. Damage can also arise from an activity that is "legal." Indeed, the tension that needs to be resolved legally speaking, is the implementation of the precautionary principle on the one hand, and activities that cause damage but which has been permitted in terms of GMO/biosafety laws.

ARTICLE 6: RIGHTS OF NATURAL AND LEGAL PERSONS

Our general comments are that the following rights must be clearly spelt out:

(a) the rights of the public to information. In this regard, it is important that clear criteria be developed to distinguish between confidential business information and all other information that falls within the public domain. It is not sufficient to leave this open, and say that it will be resolved in accordance with existing legislation, as specific provisions are required to deal with GMOs. Access to information by the public to industry risk assessment and data is one of the most important contentious areas concerning biosafety regulation. This issue is also discussed further in these comments;
(b) Scope of engagement by the public. It is not appropriate for legislation to determine the scope of the engagement by the public by limiting this to "proposals …on the improvement of GMO management" in (b) because this presupposes that the public will be in favour of GMO authorisations and will be concerned about the management of risks.
(c) It is not appropriate for legislation to ask that the public facilitate the implementation of state programs and policies in (c)-but instead, the public has the right to interrogate the appropriateness of policies and its implementation;
(d) With regard to (d), care should be taken to ensure that participation in the decision-making does not include the applicant and other members of the public that have an interest in the application;
(e) In relation to (e), we reiterate that liability for damage and compensation for such damage is not linked necessarily to contravention of legislation, as already discussed above; and
(f) The right of appeal in (f) should also be available for possible socio-economic harm.

ARTICLE 7: OBLIGATIONS OF NATURAL AND LEGAL PERSONS

In related to Article 7(1)(b), it is suggested that more attention be given to the obligations that rest on the person who obtains the permit in the first place, concerning not only risks but new or pertinent scientific information concerning the particular GMO in question or parts of its genetic construct. This type of clause must be linked with provisions that create a corresponding duty on the part of the regulators to re-consider a decision where approval in respect of a particular GMO has been granted. Furthermore, it is important to create a mechanism for the public to initiate a process to review approvals in the light of new scientific information on potential adverse effects. We strongly recommend that a mechanism be created which the public can trigger, in order to bring new scientific information to the attention of regulators. We believe this to be a fundamental right to administrative justice, taking into account the evolving nature of the scientific information regarding GMOs. We also point out that the Biosafety Protocol deals specifically with Review of Decisions.

ARTICLE 9: NATIONAL SYSTEM FOR MANAGEMENT OF GMOS

We do not know what the word in the Georgian language is for "management" but certainly, in the context of English biosafe-

ty parlance, the term "management" connotes management of risks in the context of approvals.

ARTICLE 11: MANAGEMENT OF USE OF GMOS

We note that the scope of GMOs to be regulated pertains to those GMOs for which permits will be required. These include, GMOs for contained use, deliberate release and for import for direct use as food, feed and processing. Does this mean that the import of GMOs for non-food, non-feed uses will not be regulated under this legislation and therefore fall between the cracks? What about field trials? Arguably, they could fall under the definition of "deliberate release" but we are really not sure because of the exemptions created by Article 12(6)(a), discussed below.

In regard to Article 11(3), it is important to also create corresponding rights to refuse permit authorisations, and to make it clear that the right to grant any authorisation is subject to the objectives, principles and provisions of the Act.

ARTICLE 12: PROCEDURE FOR AUTHORISATION OF GMOS USE

1. In relation to Article 12(5), we highlight here, the first sentence, which appears to presuppose that a permit will be issued and that risk management measures will be set out for the "safe use" of GMOs, by the taking of "special measures." While it is welcome that decision-making is structured in a way that ensures a form of participatory democracy, the fact remains that the work of the MoA and MoLHSP and MeEPNR is structured towards providing opinions on the "safe use of GMOs" and thus, presupposing that the GMO in question can be safely used.
2. Whilst it is important to confer powers to grant permits, it is equally important to confer powers to refuse permits based on a risk assessment, environmental assessment and socio economic assessment. It is also equally important to confer clear powers to ban GMOs or the use of GMOs for a particular purpose, as well as the use of certain types of dangerous technologies or outdated technologies, for instance like the use of antibiotic resistant gene markers, which have been banned in the European Union, Norway etc, as well as risky constructs such as the cauliflower mosaic viral promoter.
3. The term "guidelines for conducting the evaluation study on potential risk…" is extremely important but is something that must in any event take place, as a condition precedent, before any activity in relation to any GMO is permitted in Georgia, whether such activity relates to environmental releases or to imports of GMOs as food, feed, processing. The role of technical experts involved in GMO regulation is an extremely important one and care should be taken to ensure that sufficient powers are given to it, to develop comprehensive Risk Assessment 'toolkits' as being currently been done in South Africa belatedly, after more than a decade of environmental releases and imports. Such a toolkit should serve as the most important decision-making tool and basis for environmental releases, for ecological risk assessment for pre-environmental; criteria also for post release monitoring as well as methodologies and criteria for a full environmental impact assessment; criteria for food safety evaluation and socio-economic considerations. Already, the Georgian GMO Bill contemplates standards for contained use which is welcome and these should be developed as soon as possible, based on international best practice, taking into account the risks posed by GMOs to the environment, if there should be any likelihood of escape from contained conditions. Here we must stress that field trials are not experiments that fall within the scientific definition of contained use. Either a GMO is subject to laboratory testing, or it is a release.
4. Article 12(6) is extremely worrying because the operation of the precautionary principle (as set out in the first part) should not be linked with the permitting of field trials because this defeats the purpose of taking precautionary action. Further laboratory work is the correct option and where this option will not provide the information required to make a biosafety decision, then the application should be refused. We are extremely concerned about the provisions of Article 12(6)(a) in so far as it relates to field trials. Field trials must come under extremely close regulatory scrutiny. How else will the authorities in Georgia exercise regulatory control over field trials? Does this mean Georgia will become an experimental laboratory for GMOs? We are unclear what the intention is behind this provision.
5. What is also extremely worrying is that the risk management plan for field trials is to be compiled and agreed upon, by government agencies, in co-operation with the Applicant. This appears to defeat the purpose in a way, for biosafety regulation, which is supposed to be: the regulation of an industry, its technology and its products.
6. We point out that insofar as field trials are concerned, special tools must be developed that address the following environmental risks:

- Detrimental effects on non-target organisms
- Gene flow to wild relatives or non-transgenic varieties;
- Development of weediness
- Development of resistance or tolerance
- Production of novel toxins
- Recombination of bacteria or viruses to produce new pathogens
- Impacts of changes in agricultural management practices on biodiversity
- Loss of crop genetic diversity
- Cumulative, synergistic, compound and scaling effects
- Unanticipated consequences

In this regard, we note the provisions of Article 12(6(e) and reiterate that until these guidelines have been drafted, no field trials should be permitted.

7. We welcome the reference to the mandatory taking into account of socio-economic considerations in Article 12(9) and look forward to seeing some criteria being developed for these considerations.
8. We welcome the provision in Article 12(10) that the MoEPNR is entitled to reject an application. Our concern though persists that the right to reject an application must also exist in relation to any activity concerning a GMO, including the right by the DoH to reject an application concerning a GMO on human health considerations. This must be made more explicit in the legislation and this must be linked to the operation of the precautionary principle.
9. Care should be taken to not grant field trial permits for such extended periods of time as 3 years, as contemplated in Article 12(11). This is not appropriate in a biosafety law. In South Africa for instance, field trial permits are granted only for one growing season at a time. Thereafter, the results are evaluated and then a decision is made whether or not to proceed with further field trials. During the field trial, periodic inspections should also be conducted by government agencies to ensure compliance with biosafety measures and these reports must form an integral component of decision-making for further field trials.
10. We are not sure why appeal provisions are provided in sub-para 18, in respect only of prohibitions and why corresponding rights are not also created for the public to appeal against approvals? This is an extremely important point.

ARTICLE 13: NOTIFICATION

We are unable to comment meaningfully on the provisions of this Article until we have had sight of the actual requirements regarding risk assessment that the applicant is required to comply with. Suffice to say at this juncture that the provisions of the Biosafety Protocol are minimum international standards and much room exists for improvement. Nevertheless, we make the following contributions:

1. Many of the risk assessment data that served as a basis for decision-making in the US and elsewhere is old and dated and cannot and should not serve as a basis for Georgia to simply leap into field trials without applications for field trials and all deliberate releases for that matter, being subject to rigorous regulatory scrutiny;
2. The information requested of an applicant needs to take into account the following:

- Transgenic (or genetically modified) crops are associated with potentially significant environmental risks;
- At present our knowledge and understanding of the ecological impacts of transgenic crops is inadequate.
- It is widely acknowledged that more, scientifically rigorous ecological research on the environmental risks of trans genics is critical.
- There is an imbalance in the speed at which the technology has been adopted versus the rate at which research is being commissioned to investigate environmental risk.

According to the position of the Ecological Society of America ((Snow et al. Genetically engineered organisms and the environment: current status and recommendations. Ecol. Appl. 15, 377-404, 2005)
oSome GMO's could play a positive role
oGMO's could have negative effects under certain circumstances
oGMO's that present novel traits will need special scrutiny
oMore extensive studies of benefits and risks are needed
oRelease should be prevented if scientific knowledge about possible risks is clearly inadequate
oPost-release monitoring will be needed in some cases to identify, manage and mitigate risk
oScience-based regulation should incorporate a cautious approach, recognizing the context-dependence of risks
oEcologists, agricultural scientists and molecular biologists need wider collaboration and broader training

We therefore reiterate that comprehensive tools for the assessment of GMOs prior to their release into the environment must be developed.

With regard to food safety issues, we point out that due regard must be given to critical biosafety concerns, such as allergenicity. In this regard, we refer the to our work on assessing Syngenta's application for a food safety clearance for its GM maize event 604 Mir at www.bioasfetyafrica.net

ARTICLE 14: MANAGEMENT FOR PLACING ON THE MARKET

1.In relation to Article 14 (4)(a) and (b), we point out that labelling should not be linked to whether transgenic material is detectable or not. Either a product has or has not been derived from a GMO. Where Georgian law requires proper traceability, labelling of products will be a relatively simple feat to accomplish. Furthermore, we point out that consumers need to be given accurate information so they can chose to avoid GM products. For instance, soya oil that is derived from GM soya will in terms of Article 14(4)(b) escape the "contain GMOs" requirement where the transgenic DNA is not longer detectable. Furthermore, this type of artificial distinction will create a loophole, because some testing methods favour more accurate labelling, whereas others may give many false negatives.

ARTICLE 16: TRANSBOUNDARY MOVEMENT OF GMOs

We point out explicit reference should be made to GMOs imported for the purpose of field trials. This will also give a clear signal that the Georgian legislation adopts a step-wise approach to GMO regulation.

ARTICLE 18: CONDITIONS OF SAFETY FOR GMOS

We believe that the provisions of Article 18 should be substantially amended to come in line with the outcome of the recent third Meeting of the Conference of the Parties (COP MOP) held in Curitiba, Brazil 2006.

ARTICLE 20: CONFIDENTIAL INFORMATION

Care must be taken to distinguish between "confidential information" and "confidential business information" (CBI). Only genuine confidential business and industrial trade interests need to be protected as this can be objectively determined. However, "confidential information" to be determined by the applicant is extremely subjective and can result in arbitrary with-holding of information form the public, which cannot be the intention of the legislation, taking into account the provisions of Article 19, dealing with access to information.

We welcome the provisions of Article 20(2) and recommend that in addition to this provision and the provisions on Article 20(5), a set of criteria be developed for the determination of CBI and non- CBI. For instance, even though a summary of the risk assessment is guaranteed to be made available to the public, the applicant will still be entitled to persuade the regulators that some parts should be excluded vital non- CBI biosafety information.

ARTICLE 21: NATIONAL REGISTER FOR GMOS
We believe that information as to the facilities where GMO activities under contained use, is being conducted should be record-ed in the national registers and these should be periodically updated.

In addition, the trial sites of field trials must be placed in the public domain.

Where GMOs are imported as food, feed and processing, the countries of origin of the GMOs and the quantities must be recorded and made available for public scrutiny, as well as full details of the international grain traders responsible for the ship-ping. This requirement is very important, in the light of the resolution of Article 18(2)(a) of the Biosafety Protocol dealing with identification of bulk GMO shipments.

ARTICLE 23: INFORMATION SHARING WITH THE BSC

In regard to information sharing with the Biosafety Clearing House, regard should be had to Article 20(3)(a) of the Biosafety Protocol, which refers to information required by Parties for the Advanced Informed Agreement procedure, some of which is expressly required to be submitted to the BCH, which includes:

- Notification of intended export from the Party of export or the exporter;
- Information required under Annex I of the Protocol;
- Acknowledgement of the notification of intended export from the Party of import;
- Decision by the Party of import on whether to approve, prohibit or restrict the import and any relevant reasons for that decision;
- Where relevant, information on the domestic regulatory framework governing the import of GMOs from the Party of import;
- Additional information from the Party of export;
- Information on risk assessment;
- Information on review of decision;
- Information on simplified procedures.

In addition, Parties are also required to submit to the BCH:

- Decisions by a Party regarding transit of specific GMOs through its territory;
- Written notices of decisions approving, prohibiting or restricting the first intentional transboundary movement of GMOs for intentional introduction into the environment;
- Final decisions regarding the domestic use of GMOS to be traded for direct use for food, feed and processing;
- Notice of reviews of decisions regarding intentional transboundary movement;
- Notice of simplified procedures regarding intentional transboundary movement and GMOs exempt from the AIA procedure;
- Notice of bilateral, regional and multinational agreements and arrangements with other Parties regarding intention al transboundary movements of GMOs;
- Notice of unintentional transboundary movement of GMOs;
- Points of contact for notification of unintentional transboundary movement;
- Information on illegal transboundary movements.

Since Georgia has already embraced several provisions of the Biosafety Protocol, it will be wise to also consider implement-ing the provisions of Article 20 of the Biosafety Protocol.

We also point out that linked to information sharing, access to information and transparency, is the information that needs to be exchanged in the event of an accident or an unintentional transboundary movement.

In the event of an unintentional transboundary movement occurring, Article 17(1) of the Biosafety Protocol requires Parties to send the notification to:

- Any affected or potentially affected States;
- The Biosafety Clearing-House; and
- Where appropriate, relevant international organisations.

The drafters should ensure that they give full effect to the provisions of the Biosafety Protocol and not provide for half-measures. The relevant international organisations are not identified in the Biosafety Protocol but depending on the circumstances of the release may include organisations with appropriate expertise.

Additionally, Article 17(3) requires that the notification contain specific information, such as:

(a) available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO;
(b) information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party;
(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, as well as available information about possible risk management measures;
(d) Any other relevant information; and
(e) A point of contact for further information.

ARTICLES 24 AND 25: GM FREE ZONES

Whilst the provisions dealing with GM free zones are very welcome, the issue of whether or not "deliberate release" is also meant to cover field trials, should be clarified. Certainly, GM free zones should exclude specifically, all activities related to GMOs.

ARTICLE 27: COMPENSATION

In regard to Article 27(1), why is compensation for damage to the natural environment and biodiversity payable to the state only? Why is liability linked to the exercise of reasonable/sufficient care and not based on strict liability? In other words, in order for compensation to be payable, the state would have to show that the person using the GMO did not exercise sufficient care. Why is the user of the GMO only responsible and not the applicant or permit holder, which will also include the biotechnology company?

What about socio-economic harm? What about damage to human health? Animal health? These are not addressed.

ARTICLE 28: LIABILITY

It must be noted that civil liability for damage caused to human and animal health, socio-economic harm, damage to the environment and biodiversity may arise irrespective of compliance with the legislation. These are separate issues, requiring special treatment, in accordance with the discourse currently taking place internationally on this subject, in terms of Article 27 of the Biosafety Protocol.

ANNEX 6

Training In Biosafety Legislation
By Mariam Mayet
African Centre for Biosafety
www.biosafetyafrica.net

OVERVIEW OF TRAINING

- NTRODUCTION TO BIOSAFETY LAWS
- OVERVIEW OF BIOSAFETY PROTOCOL
- OVERVIEW OF TYPICAL BIOSAFETY REGULATION BASED ON EXPERIENCE
- KEY ISSUES FOR GEORIGA

BIOSAFETY LAWS = BIOSAFETY?

BIOSAFETY LAWS: DIFFERENT PARADIGMS

Permitting system based on step by step, case-by-case assessment, evaluation, and decision-making

HEAVILY INFLUENCED BY INTERNATIONAL DISCOURSE
In other words, a Risk Management approach-accept and management risks

Precautionary Principle, uncertainty of science
Biosafety system =Biosafety First
Bans and restrictions
GM Free Zones
Testing
Mandatory Labelling
Liability and Redress

BIOSAFETY PROTOCOL KEY FEATURES

Emphasis on transboundary movements and not comprehensive
Substantial Equivalence
Precautionary Principle
Different GMOs
Minimum standards-lowest common denominator for biosafety
International Obligations: Key Question, if Georgia were to ratify?

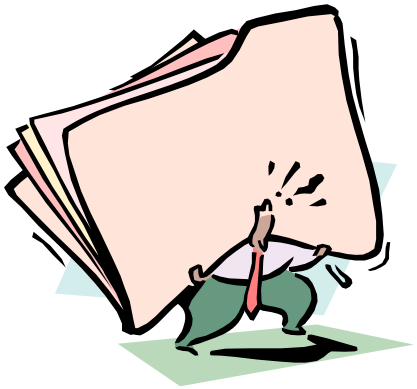
KEY INSTITUTIONS INVOLVED

Executive Council=interdeparmental bodies
(Competent Authority)
Advisory Committee
=scientific body
Biosafety Focal Points
Inspectorate
Others

UNDERSTANDING TERMINOLOGY USED FOR PERMITTING

Prior Informed Consent
Notification
Risk Assessment
Risk Evaluation
Risk Management
Confidential Information or CBI
Biosafety Clearing House

BEHIND CLOSE DOORS?



Applicant furnishes information-RA (™)
Distribution amongst institutions
Risk Evaluation (key person usually)
Recommendations, and meetings
Public Participation?
Access to Information, CBI
Decision, permit granted with/without conditions

KEY ISSUES FOR GEORGIA

Implications of Ratification of Biosafety Protocol
Geopolitical issues, and harmonisation of EU legislation
GM Free Zones
Biosafety Law (Key Issues: GM pharmaceuticals, Liability and redress; field trials)

ANNEX 7

The GMO Debate in the EU –New Aspects and Issues

Presenation to the Workshop on Biosafety by ELKANA, Tbilisi
June 8-10th, 2006
By Rudolf Buntzel
Church Development Service, Berlin/Germany

Main GM-Legislation in the EU

Directive on the Deliberate Release of GMOs into Environment2001/18/EC (needs to be adopted by national legislation of member states) (field trials and commercialisation)
Novel Food and Feed Regulation 1829/2003/EC (the market of GM produced and contained food/feed)
Tracibility and Labelling Regulation 1830/2003
Directive 90/219/EC on Contained Use of GMMs
Regulation on Transboundary Movements of GMOs (EC/1946/2003)
Principles for the Implementation of Environmental Impact Assessment
Mandatory Requirements for the Post-Market Monitoring
Missing: - EU-Rules for Coexisting
- Seed-Regulation (maximum thresholds for seed purity)
- Rules for Recall

.Main Feature of EU GM-Regulation

GM is a risk technology
The precautionary principle does not allow any risk
„other legitime factors" taken into account
There is freedom of choice for farmers and consumers (labelling)
authorisation on a case-by-case safety assessment
No assumption of „substantial equivalence"
The applicant must prove the safety; governmental peer review
Transparency by a public register

Authorisation Process

A company files an application for commericalisation (called „notification") to a national authority.
Authorisation is granted on the basis of an evaluation of potential risks.
National authority makes „assessment report" and submits it to other member states.
Other members may make observations to the competent national authority.
Once authorised in one EU-country, it will be allowed to move throughout the EU.
Placing it on the market in conformity with the conditions set out.
EU-Commission decides independently, based on EFSAŕs opinion.
If EU-Council fails to reach a qualified majority, decision goes back to the EU-Commission.
Authorisation has maximum duration of 10 years; may be renewed, if certain conditions are met (like results of post-market monitoring).

Public Involvement in Approval Process

The notification is made public by internet (http://gmoinfo.jrc.it).
Also public is the Assessment report of the national authority and opinion of EFSA (http://efsa.eu.int)
Public has possibility to provide comments on notification and assessment report.

Tracebility

Objectives: To facilitate control (in case of withdrawal) and to verify labelling claims
All operators in the markting chain have to identify their suppliers and the buyers.
The kept records need to be held for five years.
Need to make info available to public authority on demand.
For products „containing GMOs": operators need to transmit info with product, including unique identifier.

Labelling

Equal treatment for food, feed and goods for processing; for pre-packed and loose products.
Labelling also, if no tansgenic DNR is detectable („consisting out of an GMO" or „containing a GMO")
No labelling and tracebility requirements for traces below a limit of 0.9 %
- in the end product
- if unavoidable and unintentionally (adventitious)

No labelling for animal products

For non-authorised but assessed GMOs: threshold of 0.5 %

EU-Coexistence Guidelines
EU Guidelines for best practices to ensure co-existance of GM-crops with GM-free agriculture
Based on experiences from segregation practices in certified seed production
Have to be translated into national regulations.
Need to be crop-specific, according to probability of admixture of varierties
The national rules may not represent a potential barrier to free circulation of authorised crops.
Some members states rules have been refused by EU.
The base is to stay within the limit of the labelling requirement (0.9 %)

National Coexistence Regulation
Responsibility rests with the farmers, who grow GM-crops
Advice: come to an agreement among neigbors
Introduction of a national register about the location of GM fields, with varying degree of details.
Most rules: the GM farmer has to inform the non GM-neighbors about their intention to grow GM-crops
No consensus about the necessary distances between GM-fields and non-GM fields of same variety; no scientific advice.
No practical experiences yet in EU about the efficiency and feasibility of different segregation distances.

Liability Regulation by § 36a in German Law
Farmers, who grow GM crops, are liable to all impairment
In case of an „substantial impairment“: only economical; need of proof of damage.
Ease of proof, who did the damage; in case it is not unequivocal: joint liability
The liability is independent of compliance to „good agricultural practice“

Where does government come in in matters of liability?
Demand by pro-GM circles: state liability fond
Best way to promote innovative technology
Reasoning: because of governments authorisation and testing of risk.
A common fond by all (or some) stakeholders for regulation of all damage, where no unequivocal polluter can be found and all farmers have complied to the „good practices“.

What could be the damage?
Genetic adulteration by a transgenic event through pollen flow, seed comingling or inadvertent transfer.
Loosing bio-certification
Loosing organic contract premium or other GM-free premium
Costs of recall of adulterated products
Change of environmental or ecological balance
Loss of purity of farmersr seed
environmental damage is excluded by EU Environmental Liability Directive (like atomic power)

Threshold for Seed Purity
The threshold for unintentional presence of GMO in seed should be much lower than in FFP.
No agreement about this threshold in EU.
Many want it at the level of technical detectability.
Commission finds 0.5 % acceptable.
It should be crop specific

Balance between the EU-Commission and the Member States
Permanent conflict between GM-friendly position of EU Commission and GM-sceptical Member States (Germany, Greece, Austria, Hungaria, Lux)
Members succeded in more stringent legislation (like more tight and clear precautionary principle, regards to indirect and long-term impact, biological diversity of non-agricultural ecosystems, safeguard for members)
In return: EU-Commission has authority to adopt GMOs in case of no qualified majority, if EFSA gives clearance.

Tension between EU-Commission and Member States
Safeguard Clause: if a Member State has justifiable reasons that authorised GMO constitutes a risk, it may restrict or prohib-it sale.
Invoked in 10 cases (France, Germany, Lux, UK, Hungary, Greece, Austria).
EFSA decided: no new evidence; overturned bans
Member States refused to withdraw bans on other legal grounds.
Refering to Bt 176, MON 810, Ms1xRf1, Topas 19/2
Conflicts unresolved; Commission strengthened by WTO verdict.

Applications under Regulation (EC) 1829/2003 on Genetically Modified Food and Feed [GM Food Feed applications] Last

updated: 12 Mai 2006

Since 18 April 2004, Genetically Modified Food and Feed applications are regulated in the European Community under Regulation (EC) 1829/2003 It provides for a single Community procedure for the authorisation. The European Food Safety Authority (EFSA) is responsible for the scientific assessment of genetically modified food and feed. 32 applications are on the list, involving the crops maize (24), rice, sugr beet, cotton, potato, soybea, oilseed rape
http://efsa.europa.eu//science/gmo/gm_ff_applications/catindex_de.html

Commercialised GM-Crops in the EU

Only two varieties are commerically used so far: GM-maize Bt 176 and MON 810
58.000 ha GM-maize in Spain
In all other EU-countries only a few hundert ha for field trials.

Authorised products, entered in the Community Register of GM Food and Feed

Newly authorised: Bt 11 (syng.), NK 603 (Mon), Mon 863, GA 21 (Mon), DAS 1507 (Pioneer) (all maize)
So far authorised: 26 varieties (13 maize, 5 cotton, 6 rape seed, 1 soya, 2 others)

- of which 12 are for feed use
- 10 for release; others for market FFP.

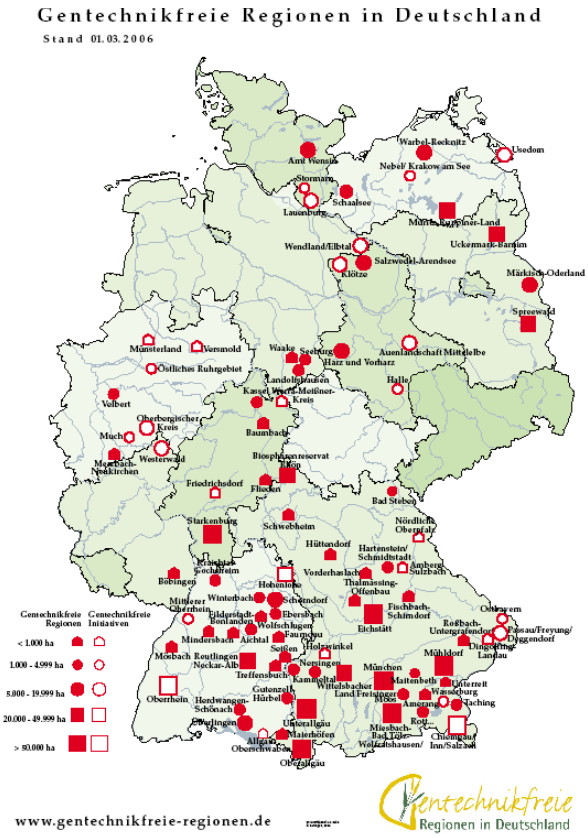
. Companies notified so far: Plant Gentic Systems, Monsanto, Bayer Crop Science, Pioneer, Syngenta, Novo Nordisk, Ajinomoto

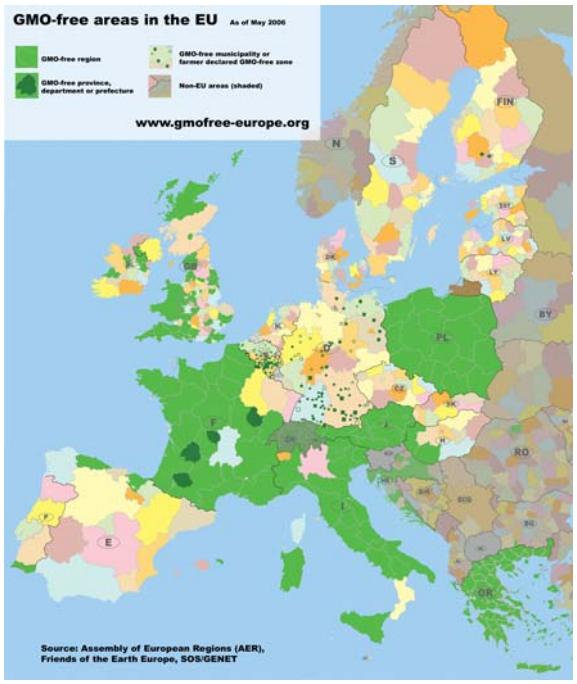
Why the genetic free zones?

Legal base: Art. 26a of EU Release Guidelines state that Member States may protect different forms of agriculture.
If there is no other appropriate way to garantee purity of seed, it may declare the region GM-free.
But the region must be limited as much as possible.
A reason must be given for each crop and kind of produce seperately.

More stringent Assessment in EU

Strong criticism on EFSA by Member States; frustration, because in all 10 cases of authorisation, the EU Commission was not supported by qualified majority.





April 2006: EFSA challenged in EU-Council by Commissionrs Submission: EFSA should:

- more focus on long-term risks
- more emphaisis on impact on biodiversity
- EU Commission will not automatically follow advice of EFSA
- if there is new evidence, the EU Commission might withdraw its authorisation
- more close cooperations between EFSA and authorities of Member States
- announced that these are only first steps for more stringent authorisation procedures

. In return, the EU-Commission expects that resiliance of 5 Member States will vanish.
Decision will be taken on this June 26/27, 2006, by EU-Council.

EU admits GM food uncertainty

The EU Commission pushed through authorisation and forces Member States to lift bans, despite admission in WTO Panel that there were „large areas of uncertainty"
In support of its stance, the Commissio told WTO: „it is apparent from the scientific advice that there is no unique, absolute, scientific cut off threshold available to decide whether GM product is safe or not".
Giving evidence behind closed doors:

- new and complex risks are emerging,
- health risks canot be excluded,
- vary according to regions,
- cinsideerable reservatiions about risk assessment by own EFSA
- biotec companies provide poor quality applications.

ANNEX 8

Consolidation of Group Works

FREE ZONE ANNOUNCEMENT

Risks (-)

- How perfect the mechanism of control will be;
- Control exercise-related problems;
- Free zone announcement will not ensure banning imports and control of GMOs;
- Free zone will not prevent transfer of genes and their impact on the environment;
- Illegal imports of GMOs;
- Proceeding from experience available in the country, exercise of strict control over GMOs and imports thereof will be impractical;

- Positive aspects (cheap products, economic effect) that can be related to imports of the specific product/technology will be excluded;
- Reduction of a range of products;
- Future prospects will weaken economically;

- The whole world should be announced a free zone to prevents all risks;
- I back complete banning of GMOs;
- I see nothing positive;

- Problems with the EU, WTO, large producers and exporters of GMOs;
- Opposition with the WTO and possible sanctions;
- Penal sanctions from the WTO; possible complication in relations with the U.S.A.; non-compliance with the EU legislation;
- Unsuccessful litigation in the International Court of Law, penalties for exporting GMOs;
- Problems with the WTO;
- Economic conditions of the country will not cope with WTO penalties.

Opportunities (+)

- Organic agriculture and biodiversity are the attractive aspects conducive to the country's economic development;
- Transformation of Georgia into a country producing Organic Products;

- Minimizing risks to human health;
- Guaranteed preservation of environmental balance, animal health and biodiversity;
- Exclusion of risks and probability of endangering human health and biodiversity through cultivation and consumption of healthy food products;

- Positive in relation with a free zone will remain only its declaration;

- It will help protect the country and its population from GMOs;
- Preservation of the unique biodiversity of Georgia;
- It's nice to live in a zone where biodiversity is not threatened by GMOs;
- Non-degeneration of local varieties;
- Preservation of biodiversity;
- Less threatened local biodiversity even under conditions of illegal imports of GMOs;

- Free zone will reduce to a certain extent introduction and propagation of GMOs.

EXISTING DRAFT LAW

Risks (--)

- Risks associated with field tests, generally due to difficulties of buffer zones creation in Georgia;

- Problems of control over release of GMOs in the environment;
- Full control is not be possible even if the Law is adopted
- Law will not prevent the spread of GMOs;
- I am not sure that the Law will enter into force; the enforcement mechanism is not identified;
- Is there a system of control in Georgia?
- Danger of improper control over GMOs and of the resultant releases in the country;

- Draft Law will complicate identification/labeling of processed products containing GMOs in the country;

- Threatened local biodiversity;
- Contamination of endemic varieties;
- Putting of the Law in force will threaten Georgian, indigenous gene-plasm and lead to the contamination of the ancient and rich gene pool of Georgia;

- The passing of the Law as it is presented now is not reasonable for another 5 years;
- As long as I remember, all governments used to violate existing laws - the presents authorities are no exception;

- The Law will, possibly, fail to govern the risk-prone issues;
- Adoption of the Law might be complicated, simply because it will require a respective amendment of many other laws;

- Adoption of the Law in itself will lead to the growing of risk factors in relation to human health;
- It might cause increase of tumor diseases;

- Introduction and release of GM seed material;
- Adoption of the Law will contribute to imports of GMOs for research purposes or in other lawful forms;

- The Law should be considered by the entire community, with the participation of all concerned parties.

Opportunities (+)

- I am against this Law;
- The Law has no positive aspects;
- At the present stage of Georgian agricultural development, I see no positive aspects in the Law adoption;
- Adoption of the Law is associated with a risk that Georgian products would lose their unique properties; based on this and also other considerations, introduction of GMOs should be banned;
- To my mind, better to announce Georgia a zone free from GMOs;

- Non-adoption of the Law will increase danger of unauthorized imports of GMOs and their release in the country;
- Given the WTO membership and the international position of Georgia, the adoption of a maximally strict law might prove to be the only solution;
- At least we shall have a definite mechanism against the WTO;

- Labeling of products containing GMOs will give the population an opportunity to make a choice;

- Less problems with the U.S.A. and Canada in trade relations;

- GMOs are inevitable, and it is good that the Law will initiate care over biodiversity;
- A system of control over GMOs has been established which, based on the appropriate conclusions, might prove to be really useful for biosafety.

ANNEX 8

PRESS-RELEASE

Workshop - Issues of Biosafety and Agricultural Diversity in Georgia - present Situation and Challenges for Improvement

On June 8-9, 2006 the Biological Farming Association "Elkana" conducted workshop "Issues of Biosafety and Agricultural Diversity in Georgia - Present Situation and Future Perspectives".

The first day of the workshop held in Elkana office was financed by EED, Germany, in the frame of "Joint Advocacy Project"; the second day dedicated to the field session was supported through GEF/UNDP financed project "Recovery, Conservation and Sustainable Use of Georgia's Agricultural Diversity".

The workshop was attended by the representatives of the Ministry of Environment and Natural Resources, the Ministry of Agriculture, Research Institutions, Farmers Organisations, NGOs, Foreign experts and Media.

The objective of the workshop was to share international experience on biosafety and to consent the positions of participants on regulation issues of GMOs and genetically modified products.

The Ministry of Environment and Natural Resources of Georgia through the financial support of GEF/UNEP has developed a draft Law on GMOs, which lays down the legal requirements in the field of trans-boundary movements and use of GMOs and genetically modified products. On the workshop the officer in charge of Head of Biodiversity Department of the Ministry of Environment and Natural Resources Ms Ana Rukhadze made overview of the draft law. The workshop participants got acquainted with Mariam Mayet's /African Centre of Biosafety, South Africa/ comments on the draft law and, also, with her presentation on different paradigms of bisafety laws; Mr. Rudolf Buntzel /EED, Germany/ made presentation on GMO Debates in EU.

The workshop participants stressed that the absence of the biosafety regulatory system in Georgia poses a big threat of:

- Illegal import and cultivation of transgenic crops (danger to local agricultural diversity and coun try's organic farming perspectives);
- Uncontrolled imports of genetically modified food products (problem of labelling and control);
- Experimental testing on GMOs, which are restricted or prohibited by law in other states, through financial support of foreign companies

The workshop has revealed that there is sharply negative attitude, fear and precaution towards use of GMOs and genetically modified products; also, discussions were held on control mechanism - regulation versus total ban.

It was decided to create an initiative group to develop joint strategy and plan of action to ensure the appropriate amendments in the draft law.

The field session on June 9 was conducted in Elkana office in Akhaltsikhe. The workshop participants got acquainted with the achievements of the project "Recovery, Conservation and Sustainable Use of

Georgia's Agricultural Diversity" and, also, visited seed multiplication plot in Tsnisi.

The workshop report is under preparation. Georgian and English versions of the report in PDF format will be available on Elkana web page: www.elkana.org.ge by August 15, 2006.

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The information about the workshop (press release) is distributed through participating organization information sources, mass media and information networks.