Draft National Biosafety Framework for Albania

DECEMBER 2006

Abbreviations

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
EU	European Union
FAO	Food and Agriculture Organization
GMO	Genetically Modified Organisms
GEF	Global Environment Facility
HACCP	Hazard Analysis and Control at Critical Points
IFDC	International Fertilizer Development Center
MOA	Ministry of Agriculture (till September 2005)
MOACP	Ministry of Agriculture and Consumer Protection
MOE	Ministry of Environment (till September 2005)
MOEFWA	Ministry of Environment, Forests and Water Administration
MOH	Ministry of Health
NBC	National Biosafety Committee
NCC	National Coordinating Committee
NEA	National Executing Agency
NPC	National Project Coordinator
NEAP	National Environmental Action Plan
OECD	Organization for Economic Cooperation and Development
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

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PREAMBLE

Biotechnology has been practiced for ages, in the form of traditional agricultural, zootechnical food processing practices, or others, in order to achieve improved features of plants, animals, and food by-products, all of these with the aim to improve the living and well being.
During the latest decades, a new science called modern biotechnology, has undergone vigorous developments .

The concept of Modern biotechnology is officialy introduced in detail in the Cartagena Protocol on Biosafety.

According to this Protocol, by definition, 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;

Because modern biotechnology is still new, there is concern on how its products may impact on different aspects of life, such as health and biodiversity. At this point, the concept of biosafety is introduced, which, according to the Cartagena Protocol is referred to as *the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology*.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity originated during the second meeting of the Parties, held in November 1995. An Ad Hoc working group established for this purpose, focused specifically 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 . The Protocol was finalized and adopted in Montreal on 29 January 2000.

The Cartagena Protocol on Biosafety is ratified by Albania in May 2005.

The scientific revolution in the field of biotechnology culminated with products of modern biotechnology known as Genetically Modified Organisms or GMO's, (also known as Living Modified Organisms –LMO's - according to the Cartagena Protocol on Biosafety).
With the introduction of modern biotechnology,obtaining new heritable traits fast and precisely became a reality. New opportunities were open for fulfilling requirements in many fields, such as food, medicine, pharmaceuticals, etc.
On the other hand, this technology, being a powerful but , yet, newly created tool, may give rise to uncertainties and fears. Products of modern biotechnology might have an impact on biodiversity, thus raising environmental safety issues, but also they may impact human health. The scientific community and those who may benefit from products of biotechnology, such as farmers, industry, commercialists, must be sure that the public

takes an informed decision in regards to these products, before investing time, efforts and money.

The concept of Biosafety in Albania is still new. However, the awareness campaign conducted during the project “Development of a National Biosafety Framework for Albania”, in the form of workshops of wide participation, publications and media presentations, gave rise to active debates among parties of opposite beliefs with regards to introduction of GMO’s, debates which resolved into a positive attitute toward the project itself and future actions in regards to biosafety.

The draft law on Biosafety written during the project, was consulted by many stakeholder representatives and therefore the confidence was increased in the direction that Albania is really moving forward to having an appropriate system for handling GMO’s.

Chapter I

A biosafety policy

Summary

Albania does not have a clear Biosafety policy at present. Even existing policies in other areas largely ignore the issue of biosafety. Furthermore, there is a long list of strategies and policies incorporated in the National Strategy for Socio-Economic Development which Albania looks forward to draft and present in the near future, while it needs to prioritize so that the list does not remain a wish-list. One integrated part of this strategy is a Strategy for Agriculture and Food.

However, there is a general consensus for the need to draft a national strategy on biosafety. Nearly all experts agree on the emerging need for a stand-alone biosafety strategy, although this would require adaptation of existing strategies in related areas [1]

In addition, a national policy on biosafety is an important pillar sustaining the whole structure. National policies, strategies, and research agendas regarding biotechnology and biosafety, will provide the foundation for subsequent implementation of regulatory and other activities in the field of biosafety.

The Convention on Biological Diversity and the Cartagena Protocol on Biosafety

The Convention on Biological Diversity was opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993. Albania signed the convention in 1992 and became a party to this convention on 05 January 1994. Biosafety is one of the issues addressed by the Convention.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was finalized and adopted in Montreal on 29 January 2000 , entered into force on 11 September 2003, and is ratified by 134 countries up to July 2006[2]. The goal of the

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[1] Malltezi, J. 2005. Need for a biosafety policy. Report prepared for project "Development of a biosafety framework for Albania.

[2] Cartagena Protocol on Biosafety. http://www.biodiv.org/biosafety/. Site visited on September 2006.

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 (LMOs)”. The protocol creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

Albania has adhered the Cartagena Protocol of Biosafety with law Nr.9279, date 23.9.2004 “For accession of the Republic of Albania in the Cartagena Protocol on Biosafety of the Convention for Biological Diversity” and this Protocol has entered into force in May 2005.

National Policies and Relevance to Biosafety

Further below are explored some of the current policies in food safety, environment, biodiversity and sustainable development, and their relevance to biosafety.

As previously mentioned, a Strategy of Agriculture and Food was prepared and published in the frame of the National Strategy for Socio-Economic Development (NSSED), a result of a continous dialogue between the Government of Albania with the International Monetary Fund and the World Bank. This strategy is a relatively recent document ,published in year 2003.

A new Strategy on Environment is drafted through a project entitled “Environmental Legislation and Planning in Albania”, financed by the European Union.

In addition, but not less importantly, the European Ministry of Integration, through a Decision of the Council of Ministers, on May 2005, approved the National Plan for the Approximation of the Albanian Legislation to the European Union legislation. Short term (2005-2006), middle term (2007-2008) and long term (2009-2014) measures were represented in this document, in relation to each sector.

Food Safety

With regards to the Strategy of Agriculture and Food, one of the objectives of the agriculture and food sector, as mentioned in this document, is “Improvement of food safety and quality”. Actions in the direction of food safety and consumer protection are baesd on the Law Nr. 7941, “On food”, as well as several bylaws issued to make possible its implementation.

The existing law on food No.7941[3], approved by the Assembly on 31.05.1995 does not deal with food safety, although certain articles in the law (Articles 27 and 28) make a vague reference to control of food quality, while it is necessary to come up with new pieces of legislation for essential issues such as food safety.
According to the same document, the quality control of foodstuff is exercised on both domestic and imported products, as well as on food industry inputs. In this light, the main objective is to increase the efficiency of food stuff control and protect the producers. This intends to be achieved thorough completion of legislation, strengthening of institutions and laboratories in regards to phytosanitary, veterinary and food services.

According to the National Plan for Approximation of Legislation, a new law on Food, based on the EC General Food Law Regulation 178/2002, is being prepared by the Ministry of Agriculture and Food, which is still under drafting

Among long term priorities of National Plan for Approximation of Albanian Legislation to the European Union Legislation, actions to be taken in regards to use of Genetically Modified Organisms, are also included, specifically new regulations on GMO testing, tracing and labeling.

There have been several developments on the field of food safety, supported through foreign assistance and donors. The project on Food Control financed by the Italian Government (2003-5 - €2 m), supported the equipment of food control laboratories with laboratory machinery and training of laboratory staff on food control.

The project on food safety and control (CARDS MIP € 2 m), is proposed to be included in the CARDS programme for 2005-6 in order to address the gaps of the Albanian system on food standards, safety and hygiene. This project assists Albania on:

- Approximation of Albanian legislation of food safety with acquis communautaire,
- Setting up a National Authority on Food Safety
- Financial aid for strengthening of laboratories for food testing.

The Hazard Analysis and Control at Critical Points (HACCP) system is only recently being applied in a very small number of food enterprises in Albania. The Ministry of Health (MOH) and the Ministry of Agriculture (MOA) have jointly, and in cooperation with WHO, drafted a guide for HACCP system and its application. The guide is drafted based on Codex Alimentarius, Basic Principles of Hygiene, and the WHO/FAO instruments for training on HACCP, and serve as a tool assisting the MOH and MOA inspectors involved in food control[4].

[3] See annex 3: Relevant laws and regulations
[4] Ministry of Health, "Situation Analysis on Food and Feeding" Draft September 2005

There is a newly presented law in the Albanian legislation, namely law no. 9199 dated 26.02.2004 "On the production, processing, certification, and marketing of "Bio" products". However, this law, although mentions the Genetically Modified Organisms, does not focus much on them, as the object of the law – as can be noted from the title – is the "Bio" or organic products.

There are also a number of Orders issued by MOH, MOA, and other ministries addressed to the Customs Service at border crossing points. The orders refer to a better control of foods, including live animals, but these orders make no reference to GMOs.

Environment Protection and biological conservation

The draft strategy on Environment is completed by 2006, and is expected to be finalized and published by year 2007. This document so far does not foresee any evaluations, recommendations or actions in the field of biosafety. Although issues such as biodiversity protection and environmental impact assessment have been mentioned, biosafety is not tackled in any way. Since this document is still a draft, it would be a good opportunity to recommend that biosafety be included.

The Biodiversity Strategy and Action Plan[5] is approved in 1999. It is an ambitious and well elaborated document , covering most aspects of biodiversity protection and providing a holistic view of the overall situation. However, this document contains only one short paragraph on genetic diversity and doesn't tackle the issue of biosafety and GMO's.

Albania presented the revised National Environmental Action Plan (NEAP) in 2001.[6] The previous one dated back in 1993. Several policy papers have been produced since 1993, such as National Water Strategy, Biodiversity Strategy and Plan of Action, Energy Strategy, Strategy for Protection of Forests, National Plan for Health and Environment, etc., none of which relates to biosafety.

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5 MOEFWA, Strategjia e Biodiversitetit dhe Plani i Veprimit

6 MOEFWA, Plani Kombetar i Veprimit ne Mjedis, 2001

CHAPTER II
A regulatory regime for biosafety

Review and analysis of the current status of the regulatory and administrative instruments related to biosafety within the country

Relevant international obligations and instruments

The international treaties and agreements between the Republic of Albania and international organizations become a part of the Albanian legal system when certain procedures are pursued in accordance with the law no. 8371 dated July 9, 1998 "On recognition of the international treaties and agreements".

As a rule, the Council of Ministers approves in principle the international treaties and agreements which are signed in the name of the state and government. The international treaties and agreements may become a part of Albanian legal system and in force after their approval or ratification. Approval and ratification is completed with the approval of the law in the parliament.

Albania has signed and ratified a number of international environmental conventions *[7]. The international agreements are reflected in national legislation through the adoption of laws.

On 8 September 2000 Albania has been officially proclaimed a WTO Member by WTO bodies in Geneva. Albania has submitted to the WTO a list of concessions and commitments of market access on goods and list on specific commitments on services. Moreover, an agriculture schedule has been presented to the WTO.

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[7] *Convention "On Biological Diversity" opened to be signed in Rio De Janeiro on June 5, 1992. This Convention came into effect on December 29, 1993. Republic of Albania adhered on January 5, 1994*

September 2004 (when the law on accession of Albania to the Protocol of Biosafety was approved by parliament and became part of its legal system)

The Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, ratified by Albania on 26.10. 2000, law nr. 8672

International Plant Protection Convention Rome 1951, Ratified by the Republic of Albania on 10.05.1999. law nr. 8483.

World Trade Organisation, including (but not only) the main WTO Agreements likely to be of relevance to biosafety regulation:

- *The General Agreement on Tariffs and Trade (GATT)*
- *The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*
- *The Agreement on Technical Barriers to Trade (TBT Agreement).*

The different types of instruments at various levels of law making

Albania has a Civil law system. According to the Constitution approved by the law no. 8417 dated October 21, 1998 (hereinafter the "Constitution"), the Republic of Albania applies international law that is binding upon it. Therefore, the Albanian legislation presents a full spectrum of variety of rules and legal concepts driven from various traditions and legal systems as well as international law.

Normative acts which are effective in the entire territory of the Republic of Albania are: (1) The constitution; (2) ratified international agreements; (3) the laws; and (4) normative acts of the Council of Ministers.

The Constitution is the highest and the fundamental law of the Republic of Albania. The provisions of the constitution are directly applicable, except when the Constitution provides otherwise.
Any ratified international agreement constitutes part of the internal legal system.

The laws and by-laws make up the Albanian legal system. The laws and by-laws acquire juridical force only after they are published in the Official Journal.

Overview of existing legislation with potential impact on GMO's

Despite the fact that there is not one single law in Albania dealing with GMO's, the survey on legal aspects of biosafety in Albania concluded with a list of laws related to biosafety and biotechnology, which can be used and adopted in the near future (please see (Annex 3)

More specifically, during the year 2002-2003 a full package of environmental laws were approved by the parliament, some of which might be closely linked with the biosafety legal framework as follows (Annex 3):

- The law "for environmental Protection"
- The law "for protected areas"
- The law "for environmental Impact assessment"

In addition, some efforts are invested in this issue by other organizations. For instance, the National Plan for the adaptation of the Albanian legislation to the European Union legislation , approved in May 2005 by the European Ministry of Integration, through a Decision of the Council of Ministers, represents the legislative and implementative measures to be taken short term (2005-2006), middle term (2007-2008) and long term (2009-2014) to each sector.

In short term, regarding the GMOs issue, the following measures are expected to be implemented: nomination of the GMO competent authority , development of risk assessment procedures, creation of a system to manage the data, etc. [8]

Food safety (including human health)

The normative act that partly guarantees food safety of products that may contain GMO's is law nr. 7941, dt. 31.05.1998, "On Food". In this law there is an article which foresees "the assessment of new products" . According to this article, "For assessment of new products, the sample and documentation must be submitted to the Ministry of Agriculture and Food, which , by cooperating with the Ministry of Health and Ministry of Environment, charge their institutions with assessment of these products".

Another legislative act is the Decision of Council of Ministers nr. 604, date 17.11.2000 "For labelling of food products". This decision does not oblige for declaring GMO content in food products.

Plant protection

In Albania, the protection of plant varieties is regulated by law nr. 8880, dt. 15.04.2002 "On the rights for plant breeding", prepared according to the Geneva Convention of International Union for Protection of new Plant Varieties (UPOV).

There are a number of other laws dealing with plant protection, cultivation, processing and marketing, which you may find reference for in Annex 3.

GMO legislation

During the project "Development of a National Biosafety Framework for Albania", a draft law on Genetically Modified Organisms has been prepared, which constitutes the first serious effort for a legislative instrument in the field of biosafety. This law is included as a separate annex to this document.

The new Draft law on Bosafety will regulate the safe transfer, handling and use of Genetically Modified Organisms, including those for contained use. The Law also covers the GMO's intended for import, export and transit.
All GMO users will be registered in a special registry, kept by the competent authority, which is the National Biosafety Committee (NBC). Also. Contained use of GMO's, according to this law, is allowed only in registered areas.

[8] . (paragraph 3.2.5.8 Genetically Modified Organisms, pages 706, 707).

How this law was concepted

Initially, three possible options were evaluated:

The first option is the current situation, which is specific laws that do not regulate GMO's and the ratified Cartagena Protocol, which is superior over the existing laws.

The second option is the possibility to amend the legislation through adaptation of existing laws which are not conform with the Cartagena Protocol on biosafety.

The third option is the preparation of a specific law on GMO's. This option was chosen for several reasons, among which are:

- The law posseses the status of *lex specialis* and as such, it is superior over the other more general laws;
- If a central monitoring institution will be created, it can only be created by law;
- Practices and experiences in other countries; etc.

Which countries have been taken as example?

Initially, two systems of OECD member countries were taken into consideration: the Czech Republic and the Slovak Republic. In addition, the Slovenian and Macedonian law were also reviewed.

Also, the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and the Cartagena Protocol on Biosafety were significantly considered.

In addition, a whole package of laws and decisions related to biotechnology and biosafety, attached as an annex to this document, provides the basis for further improvement of the legislative framework with respect to GMO's and much probably to the newly approved law on biosafety (Annex 1)

CHAPTER III
A system to handle notifications or requests for authorisations

Currently, there is no system to handle notifications or requests for authorizations on GMO's in Albania. However, the draft law on biosafety prepared in the frame of the project "Development of a National Biosafety Framework for Albania" covers in detail the system of authorizations. This draft law is constructed based on the principle of regulation of GMO and GMO products use, monitoring and controlling and also fulfilling the obligations that arise from international agreements.
The principle of regulation in this law implies that not every person shall handle GMO's and GMO products. *According to Article 4, the user (s) must be authorized prior to commence use of GMO and GMO products pursuant to this law* , therefore only those persons that are authorized conform the law and by-laws may use them. Moreover, only those GMOs and GMO products that are permitted by the respective authority maybe used by the authorized person (s).

The draft law prescribes thereof a full list of requirements for documentations concerning the requests for authorization *[article 6]*

The authorization may also be subject to revocation, as specified in Article 8.

A National Biosafety Committee is specified in this law and it is assumed to be the central authority for GMO and GMO products in the Republic of Albania. It will be a public entity and independent from any other authority but the Council of Ministers of the Republic of Albania. Its primary objective is to protect the health of human beings and animals, the environment and biological diversity from the negative effects of the introduction of GMO and GMO products (See articles 7 to 10).

The mandate of the National Biosafety Committee, as described in article 32 of the draft law, shall be:

- *α) to formulate, adopt and ensure the execution of the national biosafety policy of Albania, which shall be consistent with its objective;*
- *β) to authorize, suspend or revoke the authorization to use GMO and GMO products in the Republic of Albania;*
- *χ) to contribute to regulate and ensure the control on the GMOs and GMO products within the territory of the Republic of Albania;*
- *δ) to contribute to regulate and control the authorized persons within the territory of the Republic of Albania;*
- *ε) to hold and manage the GMO register.*

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The draft law also explicitely describes GMO's in (i) contained use, (ii) deliberate release and (iii) placing on the market.

Any use of GMOs shall be classified in one of the following four risk categories: negligible risk, low risk, moderate risk, or high risk.

The National Biosafety Committee shall define in regulations the criteria for classification into risk categories, and the criteria for defining the safety measures to be used, the risk management measures and the other conditions to be used for the specific risk category.

Applications for authorization to use GMO's and products thereof shall be submitted to the National Biosafety Committee (NBC). Any authorized user shall make a risk assessment prior to a GMO use.

The application for registration must contain additional information, such as data on the applicant, type of use of GMO and product, measures that will be taken to protect the health of human beings and animals, and biological diversity.

GMOs authorized for use under Low and Negligable Risk category may commence activity 30 days after issuance of the authorization by the NBC, while GMO's authorized for use under Moderate and High Risk may commence activity 90 days after such issuance.

The contained use from the authorized person shall only be undertaken in a containment area that complies with the requirements of article 3 on containment area, of article 6 on risk assessment and protective measures laid down in a regulation for each risk category by the National Biosafety Committee.

If the National Biosafety Committee, through its consultative body, the Biosafety Council, comprising of scientists from related institutions, obtains new information on an authorized GMO use under given conditions that might significantly impact the assessment of the risk on human and animal health, on the environment and on biological diversity, it shall, within 30 days of the date of obtaining such information, issue new conditions for the GMO use.

The National Biosafety Committee may also issue a decision to change the risk category for GMO and GMO product use.

The draft law covers in detail the import and export of genetically modified organisms, and also GMO's that are intended for transit. According to this law, only genetically modified organisms or products authorized by the relevant authority of the member state, for placing on the market, may be imported or exported.
More specifically, this law states that only persons authorized for contained use may be authorized for import and export exclusively intended for contained use. The same is

valid for persons intending to import or export GMO's for GMO release: those persons must be authorized exclusively for GMO release.
The law describes in detail the requirements regarding the information to be submitted and necessary documentation for import and export of GMO's.

Transit of genetically modified organisms or products containing GMO's through the territory of
the Republic of Albania from the place of entry to the place of exit may only take place in the transport means safeguarded against an undesirable leakage of genetically modified organisms or products containing GMO's into the environment, or against their loss or theft with regard to potential risk to human health and the environment.

The Biosafety Council, *[Chapter III of the draft law]* as the consultative structure to the NBC, will be an integral part of the NBC, which function shall be established in detail through regulations. The National Biosafety Committee shall make no decision on GMO use without prior consultation with this structure. Although the NBC , as according to the draft law, is only accountable to the Council of Ministers of the Republic of Albania, the opinion of the Biosafety Council shall be considered a mandatory part of the decision-making process .

CHAPTER IV
Systems for 'follow up' such as enforcement and monitoring for environmental effects

It is easily understandable from the draft law that the main authority responsible for enforcement and monitoring of environmental effects of GMOs and GMO products intended for contained use, release and placing on the market, is the National Biosafety Committee. However, mainly being the task of this Committee, enforcement and monitoring can be performed by any other body, either voluntarily or prescribed by regulations that will be designed following up this law.

It is a duty of this committee, specifically its inspectorates (article 40) (or any other body close to this committee, prescribed by potential future regulations) to assess the impact of GMO and GMO products on the environment and biological diversity; follow scientific and technical developments in the area of the use of GMO and GMO products; carry out inspections through its inspectorates, of the workplaces of users and sites of introduction into the environment in cooperation with administrative authorities; propose methods for testing of GMO and GMO products and propose equipment of workplaces for carrying out such tests, etc.

The draft law has foreseen a list of penalties as described in Article 46:
In case of violation of a provision of this Law or of any regulation or order of the National Biosafety Committee, the National Biosafety Committee may take the following actions or impose the following penalties:

a) Order the authorized person to submit to the National Biosafety Committee a satisfactory program of remedial action;
b) Order the authorized person to cease and desist from such infractions and undertakes remedial action;
c) Require that the authorized person cease some or all of its operations;

In making a decision on the penalty, the National Biosafety Committee shall take into consideration the seriousness of the infringement, the duration of the infraction and the detrimental consequences of the infraction that have occurred or if there is a hazard.

An emergency response plan is a mandatory requirement prior to issuing the authorization, in the case of use of GMO's and GMO products for contained use, deliberate release and placing on the market. *(*article 18)

Also according to the draft law, any authorized person must, no longer than 30 days after the expiry of the period for GMO release, or placing in the market, or within the period specified in the authorization, submit a Report to the National Biosafety Committee on the results of the GMO release, or placing on the market. (article 27). The responsible authority shall define in details the scope and content of the Report, through regulations.

CHAPTER V

Mechanisms for public awareness, education and participation.

Current situation of public participation mechanisms

In the Constitution of Albania , there are 2 crucial points about the right to information (Article 23). These are as follows:

- the right to information is guaranteed.
- everyone has the right, in compliance with the law, to get information about the activity of government authorities, as well as of persons who exercise governmental functions.

Albania signed the Aarhus Convention on 25.06.1998 and ratified it on 27.06.2001 .

The "Strategy and Action Plan for Implementation of the Aarhus Convention in Albania" is a document recently (May 2005) approved by the government. It represents a government policy based on encouraging the civil society, NGOs, business and individual organisations for a more active role in the field of environmental protection.

Two crucial issues were presented in this document: public awareness activities related to the Convention and adjustments in the new environmental legislation, in order to integrate the Convention requirements.

The second meeting of the Parties to the Aarhus Convention, which took place in Almaty, Kazakhstan, on 25-27 May 2005[9] , adopted an amendment to the Convention setting out more precise provisions on public participation in decision-making on deliberate release of genetically modified organisms. The amendment will enter into force once ratified by at least three-quarters of the Parties. So far, Albania has not yet taken any steps towards ratification of this amendment, but it is one of the short-term goals to be accomplished by the government and the NEA.

Unbiassed public information has been lacking until recently. Attached as an annex (Annex 2) is also a questionnaire developed by the project in regards to the "Impact of release of GMO's into the environment", which very well illustrates the lack of information or disinformation of public opinion. The media has been much influenced by one side or the other. There has been a lively debate on GMO's going on in Albania, concerning a wide range of issues such as release on the market, import and export. The opposite sides of the debate were some environmental NGO's against the government authorities.

[9] http://www.unece.org/env/pp/

Public awareness and participation has been increased during the timeframe of the Biosafety project, due to rather intensive activities. The Biosafety project with its workshops, seminars, leaflets, TV programmes, etc. , and organization of Coordination Committee meetings with participation of all stakeholders has contributed in this direction.

The draft law on biosafety contains provisions on the information recording, exchange and public awareness and participation in decision making process.

Specifically in regards to registration of GMO and GMO products users, it is required by this law that a GMO register shall be kept by the National Biosafety Committee and record for each authorized person various information. When an authorization has been granted, the National Biosafety Committee shall publish an announcement in the Official Gazette.

According to draft law, the National Biosafety Committee shall arrange for public consultation prior to making decision on the submitted request (Article 6, paragraph 8). According to this article, National Biosafety Committee shall arrange for public consultation at latest within 30 days of the expiration of the time-period for the opinion in writing pursuant to paragraph 7. The National Biosafety Committee shall make available to the public the information on public consultation including the place and date thereof , at least 5 days before the public consultation takes place.
The applicant for issuing authorization on GMO release or for placing on the market shall always take part in the public consultation. In the case of the applicant's absence, the National Biosafety Committee may suspend the public consultation. In such case the National Biosafety Committee shall lay down the place and date of a new public consultation at the expense of the applicant. New public consultation shall take place at least within 5 days of the date of suspension of the public consultation referred to in the second clause. The National Biosafety Committee shall inform the applicant on the place and date of the new public consultation.
The National Biosafety Committee shall draw up a record of the public consultation containing particularly the information on participation and conclusions of the consultation. The National Biosafety Committee shall be obliged to forward to the applicant the minutes of the public consultation within 5 working days of its termination and make it available to the public pursuant to Article 6, paragraph 9.

Being a party to the Cartagena Protocol on Biosafety, Albania is under the obligations to act in conformity with articles 20 and 23 in relation to information exchange and public participation and awareness.

A newly initiated project "Strengthening Capacity for Effective Participation in the Biosafety Clearing House" by the Albanian Government, is a significant step towards fulfillment of obligations rising from the accession to the CPB. Through this project, Albania is sharing relevant information in a Central Biosafety Clearing House Mechanism.

Workshops and conferences

Although it must be mentioned that a few activities aimed at raising public awareness on GMO's have previously taken place in Albania, workshops, conferences and other meetings organized in the frame of the biosafety project have gathered many stakeholders and enabled lively debates and exchange of information.

The first workshop during this project was "The National Meeting on Biosafety", organized in January 25, 2005 with the participation of approximately 200 stakeholders, representatives of all interested social groupings.

The workshop "Risk assessment and Management in the Framework of Biosafeety" (6-7 October 2005) was a good contribution to public awareness, but this workshop was aimed mainly at increasing knowledge of the scientific community which in the future would potentially deal with risk assessment and management of GMO's.

The symposium "Scientific, institutional and legal development for safe use of biotechnological products" (28 October 2005) organized by Institute of Biological Research in cooperation with the UNEP/GEF project "Development of a National Biosafety Framework for Albania" was a direct contribution to biosafety in Albania.

Several other workshops, meetings, public debates on television have been organized during this project.

Publications and media

There are already several publications related to GMO during 2003-2004. Most of them are published by NGOs. In general these publications represent transformation of scientific style and terminology into commonly understandable language. In these publications is expressed also the socio-economic and ethical dimension of introduction of GMOs in Albania. Due to rather strong reaction of environmentalists concerning hidden introduction of GMOs in the country through international aids, the GMO issue became a very preferred subject by media either written or electronic.

During the project "Development of a National Biosafety Framework for Albania", several leaflets, one brochure, and one debate on National Television, including an illustrative programme on GMO's, were organized.

Participation of Civil society representatives in GMO decision making

What is positive is that actually in the framework of Biosafety Protocol NGO's community is well presented in the Committee of UNEP/GEF project "Development of the National Biosafety Framework for Albania", which might lead to a broad consensus in the decision making process on GMOs not only in the frame of the project, but also in establishment rather fast of the intermediary appropriate decision of controlling the GMOs in Albania.

Recommendations

The Program of the new Government, where for the first time environmental objectives have a significant place and are clearly identified and spelled out, is already in place. The creation of the Ministry of the Environment, Forestry and Water Administration together with the four year objectives elaborated for the protection of the environment, compose the basis for further activities in the framework of public participation and information. This situation is an additional factor of hope for the public awareness and participation activities being better supported by the political and public administration bodies and having concrete results.

In order to improve the public knowledge, participation and awareness of activities involving GMO, the public authorities are encouraged to explore other mechanisms and measures. Such mechanisms and measures could include consensus conferences, round table discussions, stakeholders dialogues and citizens juries on issues relating to, for example the risk assessment and management of GMOs.

In addition, there is a number of scientific institutions eager to work with biosafety issues, such as the institutions depending on the Academy of Sciences, the Ministry of Education and Science, the Ministry of Agriculture, Food and Consumer Protection, etc., very well equipped with professional staff and experts, but which need equipment and capacity building specifically in relation to biosafety. These institutions could provide the basis for future implementation of the Biosafety Framework, and any strategies and programmes related to biosafety, in order to fulfill obligations arising from accession to the Cartagena Protocol on Biosafety.

Draft law on Biosafety

REPUBLIC OF ALBANIA
ASSEMBLY

LAW

No. […] dated […]

ON BIOSAFETY

According to Articles 59 para “d” section 1, 78, 81 section 1 and 83 section 1 of the Constitution of the Republic of Albania, on the proposal of the Council of Ministers,

CHAPTER I
GENERAL PROVISIONS

Article 1
Scope

1. This Law shall apply to all legally responsible persons using genetically modified organisms in the Republic of Albania.

2. This Law regulates management of genetically modified organisms and determines measures for preventing and reducing possible adverse environmental effects, especially in relation to preserving biological diversity, and on human and animal health, which could occur during contained use of GMOs, the deliberate release of GMOs into the environment or placing on the market GMOs or products containing GMOs or consisting of them or their combinations. This act also regulates the import and export of GMOs and products in the Republic of Albania.

Article 2
The scope of application of the law

1. The provisions of this Law shall not apply to the following methods of modifying the genetic material :

α) mutagenesis;
β) cell or protoplast fusion of cells of prokaryotic species that exchange genetic material by known physiological processes,
χ) cell or protoplast fusion of cells of eukaryotic species, including the production of hybridomas and plant cell fusion; and
δ) self-cloning consisting of the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting organism is unlikely to cause disease to humans, animals or plants.

If a genetically modified organism or product is a medicinal product or a product for protection of plants that is subject to registration pursuant to special legal regulations, then it shall not be subject to the provisions of this Act concerning the administrative procedure for the registration for placing on the market and on amendment thereof. The the authorization for placing on the market of such medicinal product or product for protection of plants according to the special legal regulation shall not be granted until the National Biosafety Committee issues an opinion containing a specific environmental risk assessment of the medicinal product or the product for protection of plants. The National Biosafety Committee shall be obliged to issue the opinion within 15 days after the receipt of a request from the relevant administrative body.

5. For the purposes of this Law the human organism shall not be considered as an organism or micro-organism or a genetically modified organism.

Article 3
Definitions

1. Wherever used in this Law, the following terms shall have the following meanings:

"Accident" shall be any event, in which a leak of GMO occurred and which presents a potential hazard to human beings and animals, the environment and biological diversity.

"Authorization" shall be an administrative act issued by the National Biosafety Committee granting the right and conditions to use GMO and GMO product and will be registered in the GMO Registry.

"Authorized person" shall be any person authorized by the National Biosafety Committee to use GMO and GMO product with or without conditions .

"Containment area" shall be a place bounded by physical barriers, or by a combination of physical barriers with chemical or biological barriers, which limit the contact of GMO and GMO product with human beings, animals and the environment.

"Contained use" shall be any activity in a contained area, in which organisms are genetically modified or by which genetically modified organisms are cultivated, stored, transferred, eradicated, disposed of or used in other manner.

"Emergency Response Plan" shall be a document containing the activities and measures carried out in the case of an accident, that lead to mitigation of the potential consequences thereof for the health of human beings and animals, for the environment and for biological diversity.

“Export” means intentional transboundary movement from one Party to another Party;

"Genetically modified organism" or "GMO" shall mean an organism and/or micro-organism, of which the genetic material has been altered through the use of modern biotechnology and has not occured naturally by the processes of mating and/or natural recombination;

"GMO product" shall be a preparation consisting of GMO, or a preparation containing a GMO or a combination of them, which is placed on the market.

"GMO release" shall be any introduction of GMO or combination of GMOs into the environment, for which no special containment measures are used to limit the contact of GMO with the environment and/or public and to ensure a high level of safety.

Deliberate release shall be any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms or its placing on the market, for which no containment measures have been used to limit their contact with the population and the environment with the aim to provide a high level of safety.

"GMO Registry" shall be a central register kept by the National Biosafety Committee that shall record the authorized persons, uses and authorizations for GMOS’s and GMO product including contained use, GMO release and placing on the market and import, export and transport in the territory of Republic of Albania. The registry is available for consultation by the public.

“Import” means intentional transboundary movement into one Party from another Party;

"Micro-organism" shall mean any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

"Organism" shall be any biological entity capable of replication or of transferring genetic material

"Person" shall be an individual, a physical person, or a legal entity or legal representative and any affiliate juridical persons;

"Placing on the market" shall be every requited or unrequited use of the GMO and GMO products by third persons on the market with the exception of use of the GMO for contained use or GMO release in compliance with this Law.

"Risk assessment" shall be an evaluation of possible harmful effects of GMO on human beings and animals, the environment and biological diversity.

"Risk" shall be any category of risk as listed in Article 12 which is expected from every use of GMO or GMO product, with direct or indirect immediate effects or delayed or cumulative long-term effects on the health of human beings and animals, the environment or biological diversity including *inter alia* the flora, fauna, soil fertility, disintegration of organic matters in the soil, food chain;

"Use of GMO and GMO product" shall mean any direct and intentional use of GMO or GMO products including contained use, GMO release and placing GMO on the market.

" User" shall mean any natural or legal person responsible for direct and intentional use of GMO and GMO products, including contained use, GMO release and placing of GMO on the market.

"Modern biotechnology" shall be the application of:

a. in-vitro techniques of nucleic acid, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid in an organel , or

b. Fusion of cells that do not belong to the same taxonomic family, beyond natural physiological and reproductive barriers, and not techniques applied in the traditional breeding and selection;

3. Words in the singular in this Law may be construed as plural and *vice versa* whenever the changes are necessary to effectuate the obvious intention of the provision in question.

Article 4
Authorization

1. Any user must be authorized prior to commence use of the GMO and GMO products in accordance with the provisions of this Law.

2. A person is duly authorized to use a GMO or GMO product when granted an authorization and is registered The authorization and registration are terminated by a revocation thereof, except when this Law provides otherwise.

3. The application for authorization and registration shall be submitted by any person intending to use GMO to the National Biosafety Committee. Any applicant shall use Albanian language in their documentation and correspondence in the Republic of Albania.

Article 5
Prohibitions

1. No person shall intentionally use GMO and GMO products in the Republic of Albania without an authorization issued by the National Biosafety Committee whether organized or not in the Republic of Albania.

2. No person organized outside the Republic of Albania shall be permitted to use GMO and GMO products, unless an authorization has been issued by the National Biosafety Committee.

4. No person shall intentionally make a misstatement of material facts or false representation or engage in any manipulative device or practice in relation to GMO and GMO products.

5. To the extent that the National Biosafety Committee believes that any person may be violating the provisions of this Article, it may conduct itself an investigation on such matter referred to it. If based on the results of such investigation that it may obtain, the National Biosafety Committee reasonably believes that a person is violating the provisions if this Article, it shall notify both the […].

CHAPTER II
AUTHORIZATION AND REGISTRATION

Article 6
Application

1. The application for registration and authorization shall be applied in writing to the National Biosafety Committee in such form as shall be prescribed by regulation.
The application for registration shall be accompanied by the following basic information:

a) personal and professional data in accordance with Law "On the Protection of Personal Data " No.8517, dated 22.07.1999 including qualification, and experience of the person applying for authorization to use GMO and GMO product;
b) type of use of the GMO or GMO product;
c) description of the use of the GMO or GMO product in accordance with the risk assessment, including measures for protecting of the health of human beings and animals,

2. The use of genetically modified organisms may proceed only based on authorisation pursuant to this Act.

3. Authorisation for the contained use shall arise from authorization for the contained use or a notification thereof. Detailed conditions for granting such authorisation are laid down in Article 15.

4. Authorisation for GMO release into the environment shall arise from authorization for the release into the environment. Detailed conditions for granting such authorisation are laid in article 19.

5. Authorisation for placing on the market shall arise from registration of the genetically modified organism or products thereof. Detailed conditions for granting of such authorisation are laid down in article 24.

6. The National Biosafety Committee may request an applicant for an authorization to submit further supporting information for its application if, in the opinion of the National Biosafety Committee, the basic information submitted is incomplete or insufficient, within 10 days from the date of receiving the application for authorization.

7. If the application for authorization does not contain all the requirements laid down pursuant to this Act, the National Biosafety Committee shall within this time-period invite the applicant to complement the application. The National Biosafety Committee in

the invitation shall state what was incomplete in the submitted application, and at the same time shall lay down the time-period for complementing thereof.
This time-period shall not be shorter than 30 days from the date of delivery of the invitation.
If the applicant fails to complement the request within the set time-period, the Ministry shall suspend the administrative procedure.

8. The National Biosafety Committee shall arrange for public consultation prior to making decision on the submitted request.

9. If in case of a request for issuing an authorization for GMO release or for placing on the market, the National Biosafety Committee receives negative opinion from its consultative structures, and/or from the public consultation session(s) , on introduction of the genetically modified organism or product thereof into the environment or on the placing thereof on the market, in which risk assessment results are doubted or an objection to insufficient protection of the health of human beings and animals, the environment and biological diversity is made, the National Biosafety Committee shall arrange for a second public consultation prior to making decision on the submitted request.

10. The National Biosafety Committee shall, pursuant to this Act, make the information available to the public
a) on the official board of the NBC,
b) through the Internet,
c) at least in one another appropriate manner in the municipality or region, on territory of which the immediate contained use or GMO release proceeds, or such handling with regard to all circumstances is expected

10. Additional information for the authorization shall be prescribed by regulation or guidance of the National Biosafety Committee.

CHAPTER III

NATIONAL BIOSAFETY COMMITTEE

1. The National Biosafety Committee shall be the competent authority for GMO and GMO products regulated by this law in the Republic of Albania and shall operate in accordance with the provisions of this law.

2. An indipendent consultative committee, the Biosafety Council, comprising of representatives from scientific institutions directly related to biosafety shall be established through regulation.

2. The National Biosafety Committee shall be a public legal entity.

Article 7

The National Biosafety Committee is accountable to the Council of Ministers of the Republic of Albania.
Notwithstanding the previous paragraph, and within the limits of its authority established by this Law, the National Biosafety Committee shall be independent from any other authority in the pursuit of its objective and the implementation of its mandate.

Article 8

1. The objective of the National Biosafety Committee is to protect the human and animal health, the environment and on biological diversity from potential risks arising from the introduction of GMO and GMO product

2. The mandate of the National Biosafety Committee shall be:

a) *to formulate, adopt and ensure the execution of the national biosafety policy of Albania, which shall be consistent with its objective;*
b) *to authorize, suspend or revoke the authorization to use GMO and GMO products in the Republic of Albania;*
c) *to contribute to regulate and ensure the control on the GMOs and GMO products within the territory of the Republic of Albania;*
d) *to contribute to regulate and control the authorized persons within the territory of the Republic of Albania;*
e) *to hold and manage the GMO register.*

Article 9

1. The National Biosafety Committee shall have the right to participate in, cooperate with, and to enter into agreements with international public agencies and with both public and private institutions abroad within its mandate.

2. The National Biosafety Committee shall cooperate with corresponding foreign authorities on a basis of reciprocity, with respect to the authorization and inspection of authorized GMO/GMO uses, including on authorized persons that operate directly in both of their respective jurisdictions.

3. The National Biosafety Committee may exchange with such foreign authorities information concerning any authorized person that operates in both of their respective jurisdictions, provided that such authorities undertake by a Memorandum of Understaning to respect the confidentiality of the information

Article 10

1. The National Biosafety Committee shall cooperate with the relevant bodies of the Republic of Albania in pursuing its objective, and shall, in accordance with this law, articles 8 and 9, and shall take the necessary actions to develop this cooperation as it deems necessary to ensure the fulfillment of its mandate.

2.The National Biosafety Committee shall deliver an opinion, prior to their approval by the People's Assembly and/or the Council of Ministers, on any normative act addressing matters outside of its mandate but which may impact directly or indirectly on the use of GMO and GMO products.

3. The National Biosafety Committee may submit, where appropriate, yearly analyses on GMO and GMO product, publish in the Official Gazette the analyses and submit proposals and measures to the Council of Ministers of the Republic of Albania.

4. The National Biosafety Committee shall provide biannual information as requested from relevant Ministries and other governmental entities as provided by regulation, with respect to the use of GMO and GMO products, and such entities shall provide information to the National Biosafety Committee from time to time , as set in regulation, as the National Biosafety Committee may process to request

Article 11

The further organization, management and implementation of the activity of the NBC shall be detailed in a regulation.

The National Biosafety Committee shall be organized and managed by the General Director.

Article 12
Approval or Refusal

1. Within 90 days from the date of its receipt of an application for an authorization and/or registration, the National Biosafety Committee shall grant authorization, with or without conditions , or deny the authorization and notify the applicant of its decision in writing. For the purposes of this paragraph, the date of receipt of an application for an authorization and/or registration is the date when the applicant meets all the criteria prescribed by this Law and by the regulation of the National Biosafety Committee.

2. The authorization shall be granted for a defined period of time [to be defined] and shall not be transferable.

3. In the authorization, the National Biosafety Committee shall lay down in writing, conditions, if any, for the use of GMO and GMO products. If any authorized user of that GMO as specified in the application, fails to comply within 30 days with the specified conditions of use or with any required condition of use and with any other condition specified in the authorization, the authorization shall become void. The National Biosafety Committee may extend the validity of the authorization, for a period not exceeding 90 days from the moment the definite period of time falls due.

4. The decision of the National Biosafety Committee refusing an authorization shall include the setting out of the reasons for which the authorization was refused.. The application may be denied when the information submitted pursuant to article 6 is insufficient for approval in the opinion of the National Biosafety Committee.

Article 13
Revocation

1. The authorization may be revoked before the end of its period of validity only by decision of the National Biosafety Committee (i) upon request of the authorized person; (ii) and upon one or more of the following ground

a) the authorization has been obtained on the basis of false information submitted by or concerning the applicant, including the qualifications or experience of any person assigned to transfer, handle or use, directly or indirectly, the GMO or other factual and/or information deceit that occurred in connection with the application;
b) use GMO or GMO products other than those prescribed in the authorization;
c) the authorization holder has not commenced use within 90 days from the issuance of the authorization or has ceased for more than 180 days to use GMO or GMO products;

d) the liquidation or bankruptcy of the authorized person or the authorized person has ceased to exist as an entity
e) the death of the authorized persons assigned to transfer, handle or use, directly or indirectly, the GMO;
f) another country that has already approved the use of a GMO or GMO product has had its authorization revoked;
g) in case of violation of a provision of this Law or of any regulation or order of the National Biosafety Committee, violation of any condition or restriction attached to an authorization, breach of any protective measure, or unsafe or unsound operation of any authorized person or assigned to transfer, handle or use, directly or indirectly, the GMO.

2. The National Biosafety Committee may revoke the authorization and remove from GMO registry the information on any authorized person if new scientific information that might change the conclusions of the risk assessment occur that consequently change the conditions under which the authorization was given and registered.

3. Any authorized person shall notify the National Biosafety Committee of any change in the information listed in the application pursuant to articles 6, 9, 15/16, 20/21,25/26 . The National Biosafety Committee within 90 days after the notification of the change shall decide whether it is necessary to submit a new application for authorization. A new application must be submitted by the authorized person within 30 days after this decision is notified to the authorized person .

Article 14
Registration

1. The GMO register shall be kept by the National Biosafety Committee and record for each authorized person the following information:

a) the identification of the applicant, and the names and addresses of any person assigned to transfer, handle or use, directly or indirectly, the GMO and GMO product for contained use or GMO release ;
b) the addresses of the workplace for contained usewhere the use of the GMO or GMO product will take place;
c) the description of the GMO or GMO product;
d) the type of use of the GMO or GMO product;
e) the period of validity of the decision on registration, and
f) copies of the documents submitted by the applicant, and conform article 44 on business secrecy.

2. The information concerning former authorized persons assigned to transfer, handle or use GMO's or GMO products, whose authorizations have been revoked or expired, shall be removed from the GMO register

3. When an authorization has been granted, the National Biosafety Committee shall publish an announcement in the Official Gazette

Article 15
Duties and undertakings

If the National Biosafety Committee obtains new information on possible hazards for the health of human beings and animals , eg in relation to herbicide use, plant health, the environment or biological diversity, resulting from the use of the GMO or GMO product, either during the period of assessing the application or after the authorization , it shall require the applicant or authorized person~~,~~ at the latest within 30 days of receiving the request, to

a) carry out a new risk assessment pursuant to article 11,
b) review the measures set forth in the current and previous applications pursuant to article 6, 13 and 16 and, if appropriate, change them so as to ensure protection of the health of human beings and animals, the environment and biological diversity.

Article 16
Risk Assessment

1. Any person intending to use GMO or GMO product shall be obliged to submit a risk assessment pursuant to article 6 to the National Biosafety Committee and classify the risk in accordance with this article.

a) as a part of the application for registration and/or authorization provided in article 6;
b) every year, regularly following the expiry of 1 year from the date of the last completed risk assessment;
c) within 30 days if required by the National Biosafety Committee according to this Law.
d) when new information that may change the risk assessment becomes available to the applicant/user

Additional circumstances where a risk assessment shall be submitted are prescribed by regulation of the National Biosafety Committee.

2. The risk assessment must contain an evaluation of potential direct and indirect adverse effects on human, animal and plant health, the environment and biological diversity, both immediate and delayed, in particular an evaluation of

a) the adverse impact on human beings,
b) the adverse impact on animal health
c) compromising the ability to treat a disease or to provide for effective prophylaxis resulting from resistance to antibiotics,
d) colonization and spreading of GMO in the environment,
e) the adverse effects of the natural transfer of inserted genetic material to other organisms

4. A separate risk assessment shall be carried out for each GMO and GMO product

Article 17
Risk Categories

1. Any use of GMO shall be classified in one of the following four risk categories: negligible risk, low risk, moderate risk, or high risk

2. The classification referred to in paragraph 1 of this Article shall take into account the containment and other safety measures specified by this Law.

3. The National Biosafety Committee shall define in regulations the criteria for classification referred to in paragraph 1 of this article , and the criteria for defining the safety measures to be used, the risk management measures and the other conditions to be used for the specific risk category.

Article 18
The Emergency Response Plan

1. The authorized person shall submit an Emergency Response Plan to the National Biosafety Committee
a) as a part of the application for registration and/or authorization provided in article 6;
b) every year, regularly following the expiry of 1 year from the date of the last submission of an Emergency Response Plan ,

2. Prior to the use of a GMO or GMO product and within 30 days of every subsequent submission pursuant to paragraph 1 letters b) and c) above , the authorized person shall provide the emergency response plan to the potentially affected municipalities accordingly to the place of use and, where appropriate, to persons that could be directly affected by any accident .

3. The emergency response plan must state the relevant information related to a potential hazard to the health of human beings and animals, to the environment and biological diversity as a consequence of an accident.

4. The National Biosafety Committee shall define in regulations the information that the Emergency Response Plan will contain.

CHAPTER IV
CONTAINED USE

Article 19
Containment Area

1. The contained use from the authorized person shall only be undertaken in a containment area that complies with the requirements of article 3 on containment area, of article 6 on risk assessment and protective measures laid down in a regulation for each risk category by the National Biosafety Committee.

2. In the case of any doubt on the class of risk, one risk category above shall be applied to the application, unless the reason for applying the lower risk category is justified.

Article 20
Authorization for Containment use

1. Any authorized person shall register the containment area for each contained use.

The information for the registration of the containment area shall be prescribed by regulation of the National Biosafety Committee.

Article 21
Risk assessment of the Containment use

1. The authorized person shall make and submit to the NBC a risk assessment prior to the contained use. The risk assessment for the contained use must contain the information set forth in article 11.

Additional information for the risk assessment for the contained use shall be prescribed by regulation of the National Biosafety Committee.

Article 22
Risk Categories of the contained use

2. A contained use with Negligible Risk category may commence 30 days after issuance of the authorization by the National Biosafety Committee pursuant to article 6.

3. Subject of issuance of the authorization by the National Biosafety Committee, the contained use of Low Risk category may commence within 30 days after the date of issuance of the authorization by the National Biosafety Committee pursuant to article 7. .

4. The contained use of Moderate and High Risk categories may commence within 90 days after (i) the date of authorization of use pursuant to article 7. For the authorization and registration pursuant to article 7, the application for authorization and registration must contain the information set forth in article 6 as well as the following information:

a) information on the function of the genetic modification,
b) a description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid permitting unambiguous identification of the GMO;

5. If the National Biosafety Committee obtains new information on an authorized contained use as it is effectively carried out or on intended changes in the contained use, that might significantly impact the classification in a given risk category of the contained use, it shall, within 30 days of the date of obtaining such information, issue new conditions for that contained use or conditions for suspension or termination of that contained use, including inactivation of the GMO.

6. The National Biosafety Committee may, on the basis of new or incorrect information ,take a decision to change the risk category for a contained use. In such a case, any authorized person shall be obliged, within 30 days, to ensure that the containment area used corresponds to the recommended risk category

7. If the authorized person obtains new information on an authorized contained use as it is effectively carried out or on intended changes in the contained use, that might significantly impact the classification in a given risk category of the contained use, it shall submit immediately the new information to the National Biosafety Committee and, depending on the decision of the National Biosafety Committee, apply for a new authorization for contained use of GMO under art 6.

8. Any authorized person shall regularly review the risk categories during the contained use.

9. During the contained use, any authorized person shall control the containment area and the protective measures regularly, as set by regulation, according to the code of practice.

CHAPTER V

GMO RELEASE

Article 23
GMO Release

1. Only an authorized person registered according to this Law may undertake a GMO release, as described in the registration.

2. Only GMO and GMO products that is authorized for GMO release may be released into the environment, under all the conditions set forth in the authorization.

Article 24
Application for GMO release

1. Any authorized person is registered into the GMO register for GMO release only if its application complies with the requirements for GMO release, risk assessment and protective measures laid down in accordance with article 12.3 for each risk category by the National Biosafety Committee.

2. An application for authorization of a GMO release must contain the information set forth in article 6.

Article 25
Risk assessment and registration of the GMO release

1. Any authorized user shall make a risk assessment prior to a GMO release. The risk assessment for the GMO release must contain the information set forth in article 11.

2. The GMO risk assessment for the GMO release must contain the information set forth in article 6 and 9 including also the information set forth by regulation of the National Biosafety Committee.

3. If the National Biosafety Committee obtains new information on an authorized GMO release under given conditions that might significantly impact the assessment of the risk on human and animal health, on the environment and on biological diversity, it shall, within 30 days of the date of obtaining such information, issue new conditions for the GMO release.

4. The National Biosafety Committee may, on the basis of new information, issue a decision to change the risk category for a GMO release. In such a case, the authorized person shall, without delay:

a) implement all the required measures for environment and human health protection,
b) inform the National Biosafety Committee on any expected or unexpected changes due to the new information, and
c) submit a new application.

5. If the authorized person obtains new information on an authorized GMO release or if during the activity of the GMO release unexpected changes occur, which might significantly impact the classification in a given risk category, the authorized person shall, without delay fulfill the requirements provided in the paragraph 4 of this article.

Article 26
Accidents

The authorized person shall take immediate actions in the case of an accident in accordance with the Emergency Responsive Plan, and immediately inform the National Biosafety Committee of:

a) the circumstances of the accident;
b) the type and quantities of GMO which have entered the environment from the containment area;
c) the measures required and undertaken;
d) any other information relevant for the assessment of the accident impact on the human and animal health, on the environment and on biological diversity,.

Article 27
Reporting

1. The authorized person, no longer than 30 days after the expiry of the period for GMO release, or within the period specified in the authorization, shall submit a Report to the National Biosafety Committee, on the results of the GMO release.

CHAPTER VI
PLACING ON THE MARKET

Article 28
Authorization for Placing on the Market

1. Only a person authorized according to this Law may place GMO and GMO product on the market, in accordance with the conditions of the authorization.

2. Only GMO and GMO product use that is authorized for placing on the market may be placed on the market under all the conditions set forth in the registration .

Article 29
Application for Placing on the Market

1. The authorized person is registered into the GMO register for placing on the market only if its application complies with the requirements for placing on the market, risk assessment and protective measures laid down in a regulation for each risk category by the National Biosafety Committee.

2. An application for authorization for placing on the market must contain the information set forth in article 6 .

Article 30
Risk assessment and registration of placing on the market

1. The authorized person, shall make a risk assessment prior to placing GMO and GMO product on the market. The risk assessment for placing on the market must contain the information set forth in article 11.

2. If the National Biosafety Committee obtains new information on the placing of a GMO and GMO product on the market under given conditions that might significantly impact the assessment of the risk on human and animal health, on the environment and on biological diversity , it shall, within 30 days of the date of obtaining such information, issue new conditions for the placing of the GMO and GMO product on the market.

3. The National Biosafety Committee may issue a decision to change the risk category for placing the GMO and GMO product on the market. In such a case, the authorized person shall, without delay:

a) implement all the required measures for environment and human health protection;
b) inform the National Biosafety Committee on any expected or unexpected changes due to the new information, and
c) submit a new application.

Article 31
Reporting

1. The authorized person, within the period specified in the authorization, shall submit a Report to the National Biosafety Committee, on the results of the placing on the market.

CHAPTER VII

Article 32
The authorization for Import, Export and Transit of GMO and GMO Products

Import and export of genetically modified organisms and genetic products
(1) Only genetically modified organisms or genetic products authorized for placing on the market may be imported or exported
(2) Only genetically modified organisms or genetic products authorized for placing on the market, or for which the authorization for placing on the market was granted by the relevant authority of a Member State, may be imported or exported.
(3) The person authorised for contained use shall be authorised to import or to export genetically modified organisms to which this authorisation applies, provided that they are exclusively intended for contained use.
(4) The person, who has been granted authorization for GMO release , shall be authorised to import or to export genetically modified organisms to which the authorization applies, provided that they are exclusively intended for GMO release.
(5) The person that intends to import or to export genetically modified organisms pursuant to paragraphs 3 or 4 of this article, shall, at the latest 5 days before effecting the import or export, be obliged to inform the National Biosafety Committee of the species and amount of genetically modified organisms that will be imported or exported, and of the supposed place of entry to or exit from the territory of the Republic of Albania.
(6) The importer or exporter of the genetically modified organism or product thereof, shall be obliged to immediately notify of the arrival of such goods at the place of entry to the relevant customs authority of the Republic of Albania.
(7) The importer or exporter of the genetically modified organism or product thereof, shall be obliged to submit to the customs authority the accompanying documents containing
a) specification of the genetically modified organism or genetic product,
b) information on the transported amount,
c) the name or names, surname, business name, place of business and tax identification number (if assigned) of the importer or exporter, if he is a physical person authorised to operate a business, or the name or business name and tax identification number (if assigned) of the importer or exporter, if such person is a juridicial person,
d) the name or names, surname, business name, place of business and tax identification number (if assigned) of the forwarder as well as of the person responsible for the shipment, if he is a physical person authorised to operate a business, or the name or business name and tax identification number (if assigned) of the forwarder as well as of the person responsible for the shipment, if such person is a juridicial person.
(8) In the case of the import or export of the genetically modified organism or product thereof, intended exclusively for contained use or introduction into the environment, the importer or exporter shall further be obliged to forward to the customs authority
a) the verified copy of the authorization for contained use or of the authorization for GMO release or the authorization for placing on the market
b) the copy of the emergency response plan.

(9) The persons that import, export or transit genetically modified organisms or genetic products shall be obliged to declare to the customs authorities in submitting the customs declaration the substantially information referred to in paragraphs 6 and 9.
(10) After carrying out the inspection, the customs authority
a) shall release the imported or exported genetically modified organism or genetic product into the proposed customs regime, provided that the conditions for release of goods laid down by this Act and special legal regulations are met, or
b) shall not release the imported or exported genetically modified organism or genetic product into the proposed customs regime, after prior informing the National Biosafety Committee and, where applicable, after prior consulting with it, if the conditions for release of the goods laid down by this Act and by special legal regulations are not met.
(11) The imported or exported genetically modified organism or product thereof may not be released into the proposed customs regime, if
b) the shipment containing the genetically modified organism or product thereof does not contain the accompanying documents pursuant to paragraphs 6 and 9,
c) the accompanying documentation pursuant to paragraphs 6 and 9 is incomplete, or
d) there are justified doubts about the origin or identity of the genetically modified organism or product thereof.

Transit of genetically modified organisms and products thereof

(1) Transit of genetically modified organisms or genetic products through the territory of the Republic of Albania from the place of entry to the place of exit may only take place in the transport means safeguarded against an undesirable leakage of genetically modified organisms or genetic products into the environment, or against their loss or theft with regard to potential risk to human health and the environment.
(2) The genetically modified organism or genetic product may not be released into the transit customs regime, if the requirement pursuant to paragraph 1 is not met.

Article 33
Business Secrecy

(1) The following persons shall be obliged to keep the secrecy about the facts, data and information, which are subject to the Law on Data Protection

1 a) inspectors if they have learnt of them while performing the inspection in facility,

2 b) employees of the NBC, if they have learnt them from the application or in proceedings according to this Act,

3 c) Any other person assigned by regulation

(2) The obligation of secrecy may be lifted by the authorized person and in case of data and information are needed for clarification and investigation of a criminal act

(3) The authorized person may mark the data or information made available during the performance of state inspection or set out in the authorization or in application for authorization as the subject to intellectual property or trade secret and require that they not be published. The content of the proposal shall be judged by the NBC, which shall inform the authorized person upon the result of the judging.

(4) The data and information, which has been recognised by the NBC as the subject to intellectual property or trade secret shall not be published, nor supplied to other persons and foreign state authorities even in case the authorized person has drawn back the application for issuing of the authorization.

(5) The subject to intellectual property or trade secret shall not be the following data and information:

1 a) general characteristics (description) of a genetically modified organism,
2 b) commercial name and address of the authorized person,
3 c) commercial name of user and in case of import, commercial name of foreign producer and importer,
4 d) assignment to the risk class of the contained use and its respective level of containment,
5 e) result of the risk assessment and its review,
6 f) evaluation of foreseeable effects, in particular harmful effects on humans or environment.

Article 34
Conflicts of interests

Any member of the Biosafety Council or the scientific committee, including any other persons authorized to examine GMO and GMO product, the General Director and employees of the National Biosafety Committee, shall leave any meeting and/or procedure where an issue raising the conflict of interest is discussed, and shall refrain from voting and/or reporting on any matter related thereto.

Article 35
Labelling

(1) The person that places on the market the genetically modified organism or product thereof, and the person that provides the genetically modified organism exclusively for the purpose of contained use or release into the environment, shall ensure that the packaging of the genetically modified organism or genetic product has a visible label clearly stating “genetically modified organism” or “this product contains a genetically modified organism”or “this product contains genetically modified organisms”;
this text shall appear also in the accompanying documents and in all stages of the product processing.
The National Biosafety Committee in its decision on granting the permission may also lay down further requirements for the labelling.

(2) The person that places on the market the genetically modified organism or product thereof, within his or her business activity, shall ensure that the packaging or if it is not possible the accompanying document, also contains the following information
a) the commercial name of the product,
b) the name of genetically modified organism,
c) the name or names, surname, business name, place of business and tax identification number (if assigned) of the person authorized for this genetically modified organism or product thereof, if he or she is a physical person authorised to operate a business; or the name or business name, place of business and tax identification number (if assigned), if such person is a legal person,
d) the conditions and purpose of the use of the genetically modified organism or product thereof, authorized for placing on the market,
e) guidance on the manner of obtaining further information that are contained in the authorization for placing on the market, pursuant to this Act,
f) information on occupational safety and personal protective equipment in such cases when the use of genetically modified organisms or product thereof, requires the equipment or measures beyond scope of those commonly used.
The National Biosafety Committee, in the authorization for placing on the market may also lay down additional requirements on the labelling.
(3) For products where adventitious and technically unavoidable traces of genetically modified organisms authorized for placing on the market can not be excluded, the National Biosafety Committee, after discussing with the responsible authorities concerned, shall establish by regulation the threshold minimum of such traces; if the values of the traces in the product are below the threshold minimum, this product shall not have to be labelled according to paragraphs 1 and 2.
(4) the conditions for placing on the market and requirements on packaging and labelling of the products that are laid down by the special legal regulations, shall be in no way prejudiced by this provision.

Article 36

Public consultation

(1) In cases pursuant to Article 6, paragraph 8, the National Biosafety Committee shall arrange for public consultation at latest within 30 days of the expiration of the time-period for the opinion in writing pursuant to paragraph 7. The National Biosafety Committee shall make available to the public the information on public consultation including the place and date thereof in the manner pursuant to Article 6, paragraph 9 at least 5 days before the public consultation takes place.
(2) The applicant for issuing authorization on GMO release or for placing on the market shall always take part in the public consultation. In the case of the applicant's absence, the National Biosafety Committee may suspend the public consultation. In such case the National Biosafety Committee shall lay down the place and date of a new public consultation at the expense of the applicant. New public consultation shall take place at least within 5 days of the date of suspension of the public consultation referred to in the second clause. The National Biosafety Committee shall inform the applicant on the place and date of the new public consultation.
(3) The National Biosafety Committee shall draw up a record of the public consultation containing particularly the information on participation and conclusions of the consultation. The National Biosafety Committee shall be obliged to forward to the applicant the minutes of the public consultation within 5 working days of its termination and make it available to the public pursuant to Article 6, paragraph 9.
(4) The right to information pursuant to special legal regulations shall not be prejudiced by this Act.

CHAPTER VIII
GENERAL ADMINISTRATIVE PROCEDURES

Article 37
General principle

Unless otherwise provided in this Law, the National Biosafety Committee applies the Code of Administrative Procedures in carrying out its duties.

Article 38
Obligation to inform

1. The authorized person is obliged to provide any information within the scope of this Law, upon a request of the National Biosafety Committee and at any time during the authorization period.

2. Where an authorized person does not supply the information requested within the period set in the request of the National Biosafety Committee ,or supplies incomplete information, the National Biosafety Committee may demand the information concerned by reasoned decision.

3. The National Biosafety Committee reasoned decision referred in paragraph 2 of this article shall set the legal basis, the purpose and the time limit within which such information must be provided, as well as the stipulated sanctions in this Law in case of incompliance with the request or decision.

4. The authorized persons shall not refuse giving to the National Biosafety Committee any information requested pursuant to paragraph 3 of this article, even if it has commercial secrets

Article 39
Duties of public administration

Central and local administration structures as well as other public institutions are obliged to co-operate with the National Biosafety Committee to ensure the collection of necessary information and evidences as decided by the National Biosafety Committee.

Article 40
Investigation Control

1. The National Biosafety Committee shall be responsible for requesting and coordinating the investigation and inspection of all authorized uses of GMO and GMO products, as well as the authorization of all persons using GMOs in the Republic of Albania. To that end, the National Biosafety Committee may request the control of any office and

document in relation with the authorized uses of GMO and GMO product, including the authorized person.

2. The inspection and investigation on behalf of National Biosafety Committee shall be carried out, jointly or separately, by:

a) State Environmental Inspectorate
b) State Sanitary Inspectorate

3. The designated Inspectorate or National Biosafety Committee conduct together all the necessary inspections and investigations pursuant to the provisions of this Law according to the procedures stipulated by the Biosafety Council and relevant Inspectorates.

Article 41
Inspections

The inspectorate and/or other authorized persons designated by the National Biosafety Committee to inspect may carry out searches by:

a) entering at any time into the premises, the means of transport, and on the land of authorized persons;
b) examining the books and other records, irrespective of the medium on which they are stored, such as in a written or electronic form.
c) taking or providing copies, of or extracts from the books or records;
d) sealing any premises or books or records during the inspection, for not more than 72 hours, if this is necessary for the investigation;

Article
Seizure 42

1. If it is necessary for the inspection, the inspectors of the Inspectorate and/or other authorized persons designated by the National Biosafety Committee may seize objects which may be of importance as evidence in the inspections. The person affected by the seizure shall be informed thereof without undue delay.

2. The investigators must take minutes, a copy of which shall be presented to the person affected by the seizure. The person affected shall be informed of the right to request judicial review of the seizure.

Article 43
Hearings of the parties

Before the National Biosafety Committee takes a final decision on the inspection, the authorized person has the right of being heard on the subject of the proceedings of the inspection. The National Biosafety Committee shall base its decisions on the inspection, only on the basis of arguments on which parties concerned have been able to comment.

Article 44
Complaining against decisions on the inspection

A complaint can be made against the National Biosafety Committee decisions on the inspection, at the Tirana Court of Appeal, within 30 days from the notification on the decision of the inspection.

The complaint does not suspend the decision on the inspection. The Tirana Court of Appeal may decide for a suspension, entirely or partly of this decision.

Article 45
Custom Administration

The customs authorities shall

a) control consignments that are declared as import and export of GMO or GMO products at border crossing points, to ensure that they are accompanied by the appropriate documents pursuant to article 29 of this Law and to the special regulations for transit, export and import,
b) confiscate the goods, in case of discovery of any infringement against this Law , inform the National Biosafety Committee thereof and, in case of doubt, ask the National Biosafety Committee for professional assistance,
c) keep records of all consignments of GMO and GMO products allowed for import and export and enable the employees of the National Biosafety Committee to access such records, make excerpts therefrom, copy information or make copies thereof.

CHAPTER IX
INFRACTIONS AND ADMINISTRATIVE PENALTIES

Article 46

1. The measures and penalties provided for infractions described in this article shall be determined in particular cases by the National Biosafety Committee

2. In case of violation of a provision of this Law or of any regulation or order of the National Biosafety Committee, violation of any condition or restriction attached to an authorization issued to an authorized person by the National Biosafety Committee or unsafe or unsound operation of the authorized person, the National Biosafety Committee may take the following actions or impose the following penalties:

a) Order the authorized person to submit to the National Biosafety Committee a satisfactory program of remedial action;
b) Order the authorized person to cease and desist from such infractions and undertakes remedial action;
c) Require that the authorized person cease some or all of its operations;
d) Imposes fines not to exceed […] million leks;
e) Suspend the authorization for a period not to exceed 12 months;
f) Take over the use of GMO and GMO product of the authorized person for a period not to exceed 12 months or
g) Revoke the authorization of the authorized person.

In making a decision on the penalty, the National Biosafety Committee shall particularly take into consideration the seriousness of the infringement, the duration of the infraction and the detrimental consequences of the infraction that have occurred or if there is a hazard.

Article 47

The violation of the provisions of article 5 and the other obligations in this Law on the part of any other persons besides the authorized person shall constitute a criminal offense. Penalties in accordance to article 57 shall be imposed to such persons or they shall be sentenced up to 3 year's imprisonment as described in article 5.

Article 48

The measures and penalties provided in article 57 shall not preclude application of other civil penalties or criminal penalties as provided in other legislation in force.

Article 49

Any fines imposed in accordance with article 57 shall be cashed for the account of the State Budget.

Annex 2

Report on the Questionnaire on GMO's

On results of the questionnaire of consumed foods by the citizens interview, on the framework of the project *"Development of the National Biosafety Framework for Albania"* funded by the Ministry of Environment of Albania and UNEP / GEF.

Professions of the interview people.

In the framework of this project we interviewed more than 718 persons but only these people filled our questionnaires and give us the answers of our questions. We tried to select the equal number between the males and females, representative of all ages of our population, and representatives of all the educated levels also. It is important to mention here that the consumers with high level of education and cultured gave to us a better answer. In some of the cases the interviewed even the questioners were anonymous were afraid to give to right answers.

We used our personal contacts and emails and phones. After we worked through the results we compile the follow tables and graphs:

Table 1, represents the professions of the interviewed people. In this table is presented the division according the levels of education also.

Table 1. The professions of the interviewed people according education

Professions of the interviewed people according education	over 17 years	13-17 years	9 - 12 years	under 8 years	Total
agronomist	1	5	1	0	7
albanolog	1	0	0	0	1
animator	0	1	0	0	1
cashier	0	1	1	0	2
teacher	5	48	1	0	54
barmen	0	1	1	0	2
barber	0	0	1	0	1
biologist	11	4	0	0	15
private business	0	0	2	0	2
bodyguard	0	0	1	0	1

dentist	2	0	0	0	2
designer	0	1	0	0	1
educator	0	2	7	0	9
economist	4	14	1	0	19
electrician	0	0	3	0	3
pharmaceutical	1	0	0	0	1
farmer	0	0	1	8	9
supplier	0	0	2	0	2
football player	0	0	1	0	1
journalist	3	1	0	0	4
hunter	0	0	1	0	1
geographer	0	1	0	0	1
geologist	0	0	2	0	2
graphs	0	1	0	0	1
cook	0	0	5	1	6
hydraulic	0	1	0	0	1
nurse	0	1	0	0	1
computer manager	0	2	0	0	2
engineer	4	17	0	0	21
IT	1	1	0	0	2
ex- military	1	0	0	0	1
lawyer	3	2	0	0	5
waiter	0	3	4	0	7
researcher	2	1	0	0	3
expert	0	1	0	0	1
chemist	1	0	0	0	1
consultant	1	0	0	0	1
countable	0	1	0	0	1
training coordinator	0	1	0	0	1
ironworks	0	0	2	1	3
laboratory manager	0	1	1	0	2
accounting	0	0	1	0	1
carpenter	0	0	3	0	3
mechanical	0	1	4	0	5
manager	2	3	1	0	6
miner	0	0	0	1	1
doctor	6	0	0	0	6
(TVSH) assembler	0	0	1	0	1
bricklayer	0	0	5	2	7
musicologist / violinist / choreograph	0	3	0	0	3
cook assistant	0	1	0	0	1
employee	2	3	1	0	6
pupil	0	0	28	1	29
military police	0	3	0	0	3
no answer	0	8	27	3	38
hairdresser	0	0	4	1	5
cleaner	0	0	2	0	2
pedagogue	2	1	0	0	3
retired	0	2	5	9	16
translator	0	1	0	0	1

fishermen	0	0	4	0	4
pilot	0	1	0	0	1
Prof. of Pedagogy Sciences	1	0	0	0	1
worker	0	0	4	7	11
sociologist	0	2	0	0	2
sewing	0	0	7	4	11
sanitary	0	1	0	0	1
secretary	0	2	0	0	2
sales	0	3	74	4	81
driver	0	1	11	0	12
domestic	0	0	2	6	8
environmental specialist	2	0	1	0	3
fish specialist	0	2	0	0	2
postgraduate student	2	0	0	0	2
student	0	201	0	0	201
unemployed	0	0	7	2	9
technician	0	1	0	0	1
tractors worker	0	0	1	0	1
trader	0	2	13	0	15
military	0	1	1	0	2
veterinary	0	2	0	0	2
zoo technical	0	1	1	0	2
	58	358	246	50	712
without showing the education					6
Total					**718**

Table 2 gives the places were the interviews took place and the groups of the persons interviewed in these places. The idea was to interview not only the institutions and the organizations but also the consumers and the sales in different markets directly.

The interviewer selected except the capital Tirana two other cities Korça and Shkodra as two bigger cities with traditions in Albania, two transboundary cities. It was selected also the Polytechnic University of Tirana, not casually the students of the first level of this university because they are selected from all the counties of Albania. In this way we could select the opinions and preferences of all representatives of different cities in Albania and also the knowledge's and preferences of the new generation for the issues treated in the questionnaire.

Table 2. The places where the questioner took place

The places	**The groups of the interview people**	
Biological Institute of Tirana	biologist	
Science Academy of Tirana	sciences researcher	
Regional Environmental Center - Email list	email list-member	different institutions
UNDP office - Tirana -		

email communication				
Personal list of emails	intellectuals			
Polytechnic University of Tirana	pedagogues	students	employees of the administration	
Other Institutions and NGOs - Shkodra	intellectuals	NGOs representatives		
Environmental NGOs - IV National Assembly	NGOs representatives	intellectuals invited		
Market Place "Avni Rustemi" - Tirana	sales	buyers	passengers	
Market Place near Medresea - Tirana	sales	buyers	passengers	
Shops in the "Siri Kodra" street - Tirana	sales	buyers	passengers	
Shops in the Barrikada street, Durres street - Tirana	sales	buyers	passengers	
Shops at the railway station - Tirana	sales	buyers	passengers	
Shalom Restaurant - Tirana	clients	kitchen staff		
Juvenilja Restaurant- Tirana	clients			
"Korca" Restaurant - Korca	clients	kitchen staff	passengers	
Children gardens private "Eden" – Tirana	educators	kitchen staff	parents of the children	
Food market - Korca	sales	buyers	supplier	trader
Vegetables and Fruits Market - Korca	sales	buyers	supplier	trader
Restaurant - Korca	kitchen staff	clients		
Vegetables and Fruits Market - Bilishti	sales	buyers		
Children's Garden - Bilishti	educators	parents of the children		
"Fuat Babani" Middle School - Bilishti	teachers	pupils		
Bars and restaurants along the Tirana – Korca national road:				
Librazhd	kitchen staff	clients	passengers of the busses and vans	
Perrenjas	kitchen staff	clients	passengers of the busses and vans	
Pogradec	kitchen staff	clients	passengers of the busses and vans	

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The following two graphs present the content of the interviewed groups of people according to the level of education and the fact if they visited other countries except Albania or no. This fact it was though as important by the interviewer. The reason was to collect the opinions and comments of the individuals than can compare our products with other products traded in the other countries, with GMOs or not. It was worth the selection of the Korça and Shkodra counties because as these cities are in the borders of Albania

south and north respectively, the farmers and the citizens had the possibility to visit the neighbor's countries.

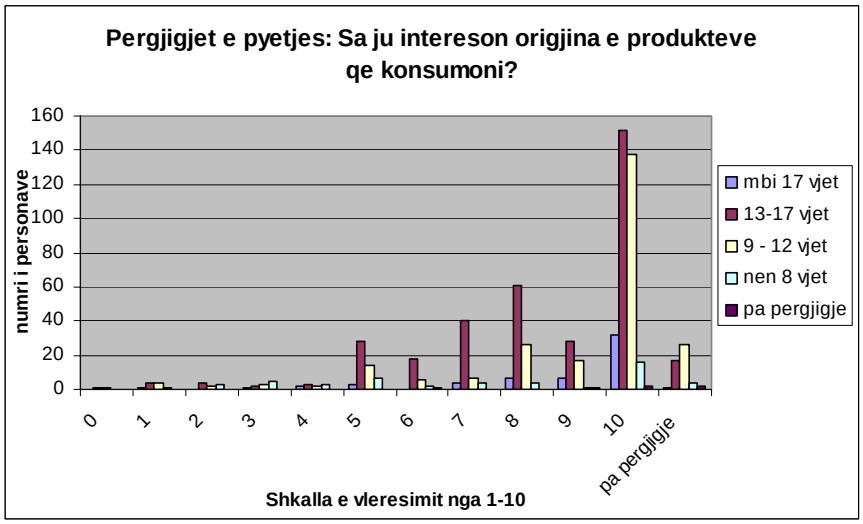
Below there are presented the results of the questionnaire according the questions:

1. Which is your priority when you select the food product during the purchase (*or the sale*): **the price** or **the quality**?

As we can see, the consumers added as the answer also the option "quality and price" in order to reflect their concentration in the questionnaire.

2. Please can you show how important is the origin of the products that you buy (*or sale*) for you as consumer (*or trader*) using the scale from 1 to 10 [1 minimum, 10 maximum]:

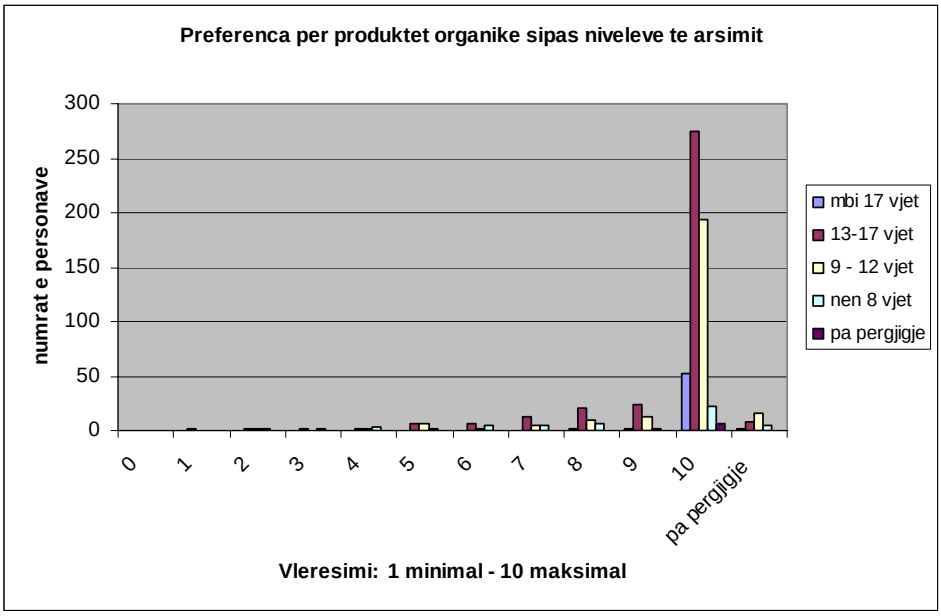
The answer of this question according to the education level is presented with the graph below:



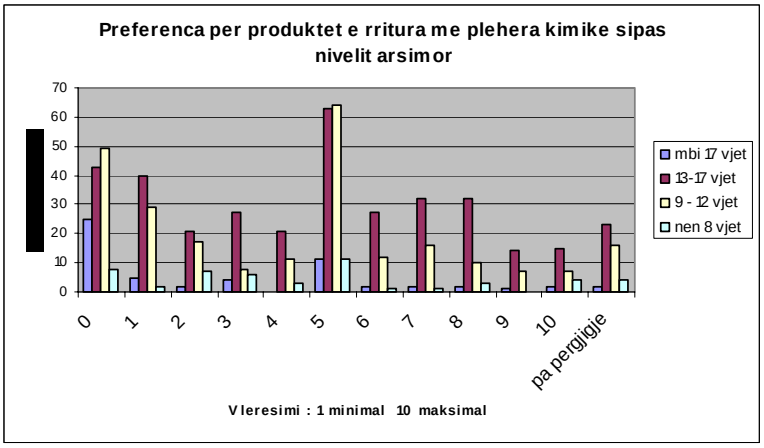
In this question also we collect answers from the interviewed people starting with the scale from zero and there were also some of them that gave no answer.

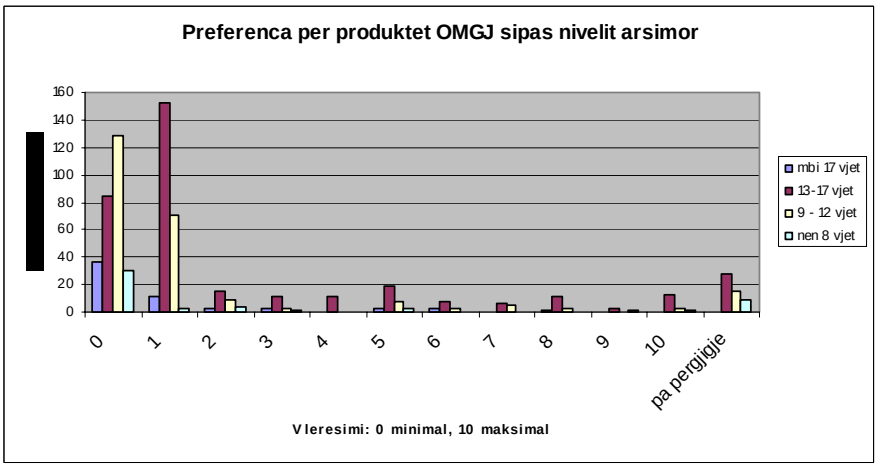
3. Please, list below, using the scale from 1 to10 [1 minimum, 10 maximum], your preferences for purchase (or sale) for each of the food products presented here:
organic product [natural], _____
products growth using the chemical fertilizer _____
genetically modified products, [GMO] _____

Below we present the answers according to the level of education also.



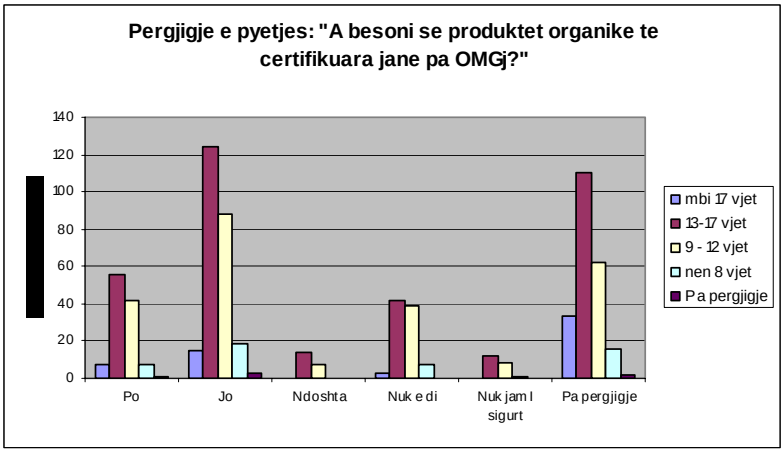
It is obvious that 77% of the interviewed persons give the maximum evaluation the organic products [natural].





4. Do you think that the certified organic products are not GMO?

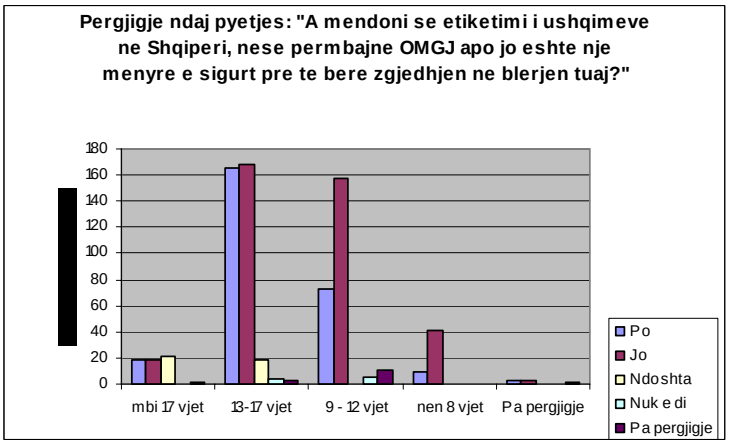
Below we present the answers according to the level of education also.



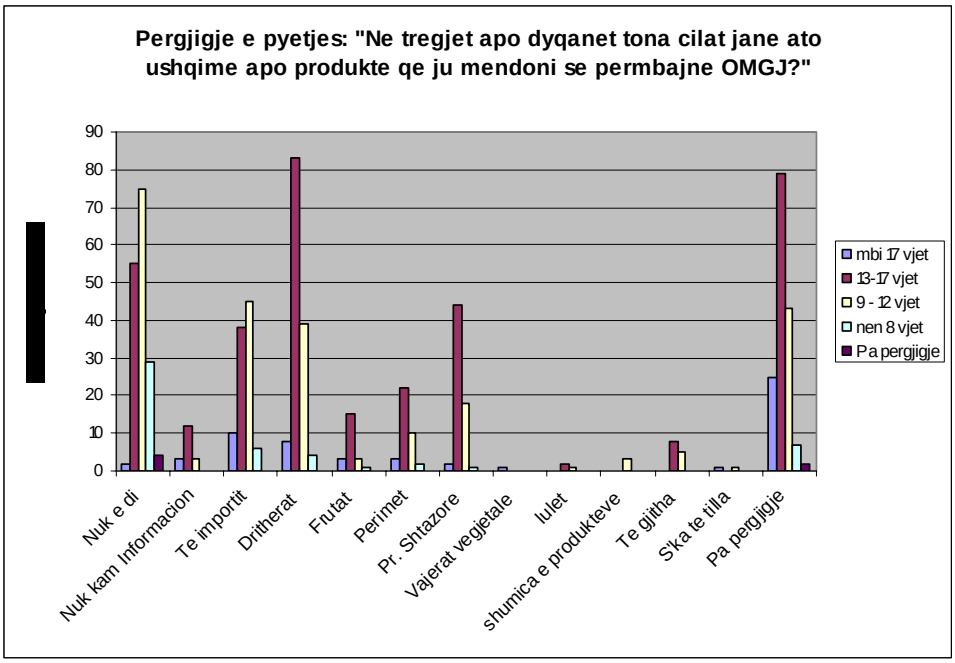
5. Do you think that the labeling of the food products in Albania (with or without GMOs) it is a safe manner for you to select them during the purchase (or the sale)?

Yes _____ No_____

Below we present the answers of this question according to the level of education also.



6. Which kind of food products or agricultural products do you think that can contain GMOs in our markets or shops?



The following table, Table 3, gives to us a detailed list of all kind of the products mention by the interviewed even we used the three groups of products mention above to build the graphs.

Table3. Sorts of the food products mention by the interviewed persons.

Sorts of the food with GMOs mention by the interviewed persons			
over 17 years	**13-17 years**	**9-12 years**	**under 8 years**
bread	bananas	bean pod	tomatoes
tomatoes	cookies	bananas	fruits

cereals
decorative flowers
meat
corn
apples
rise
peaches
chicken
peppers
corn and soy varieties by import

peas
watermelon
bread
blackberries
chocolates
tomatoes
cereals
barley
deserts

kidney beans
fish filet
fruits
quince
livestock feed with GMOs
gyros of soufflés

wheat
date
carrots
cucumbers
kiwi
flowers
mayonnaise
macaroni
flour
meat
meat
apple
nectarines
rise
potatoes
chips
eggplant
vegetables
soft drinks
melon
peach
orange
ham
chicken
milk
grape
watermelon
pomegranate
soy
peppers
spinach
conserved food
package food

dairy
tea with granules
pear
dairy product
cheese
tomatoes
cereals
kidney beans
fruits

butter
cottage cheese
wheat
garlic

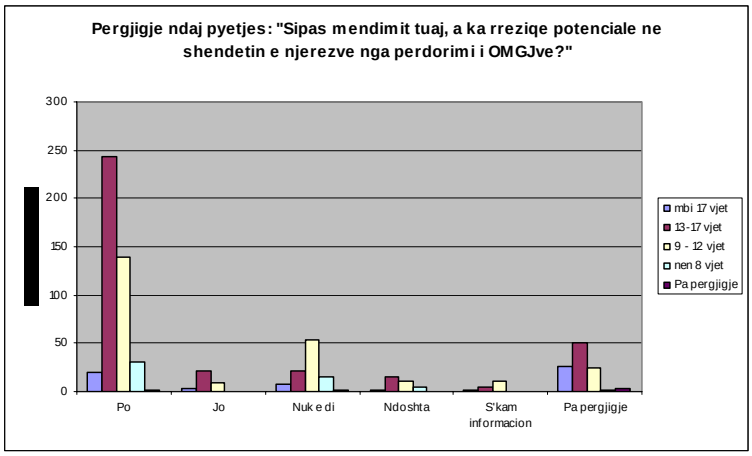
carrots
cucumber
concentrate for livestock
yogurt
cabbage
flowers
flour
meat
conserved meat
corn
apples
nectarines
rise
potatoes
eggplant
imported vegetables
fish
meat products
chicken
onion
milk
grape
salami
watermelon
soy
peppers
cucumber
wines
eggs
vegetables

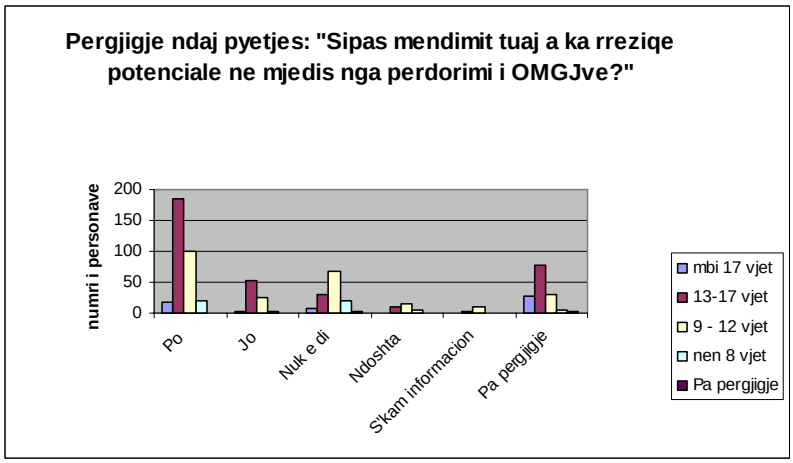
wheat
corn
meat
potatoes
vegetables
fish
drinks
chickens

kids food
oil
eggs
Ice cream and imported cookies

7. Is there any potential risk from the use of the GMOs according to your opinion? Yours comments about this subject are very important. Please write them down as the following:
in human health _____
in environment _____
in economy _____

The followings graphs present the answers of these three questions in total and specific for each of the group of the interviewed persons according to their level of education.




Pergjigje ndaj pyetjes: "Sipas mendimit tuaj a ka rreziqe potenciale ne mjedis nga perdorimi i OMGJve?"
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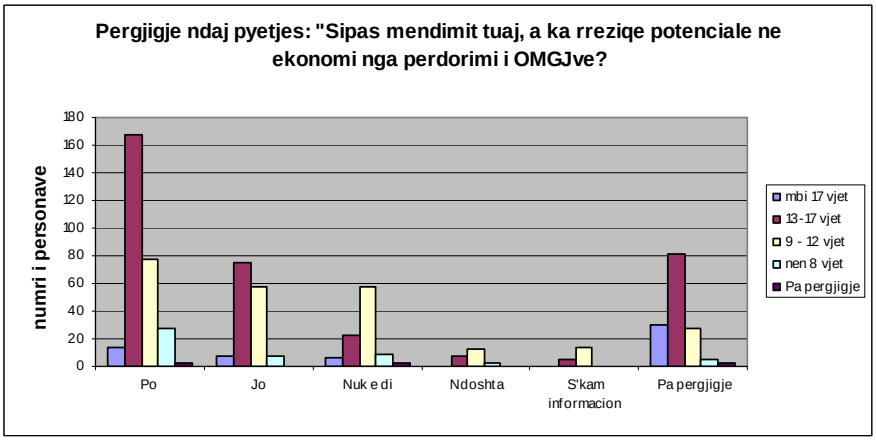
Pergjigje ndaj pyetjes: "Sipas mendimit tuaj, a ka rreziqe potenciale ne ekonomi nga perdorimi i OMGJve?
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Annex 3

Main laws related to biosafety

Law Nr.8880, date 15.4.2002 "for the rights of plant selectioners"
Objective: Protection of the rights of persons who select, discover and develop new plant varieties.

Law Nr. 7941, date 31.5.1995 "On food"
Objective: This law defines the conditions for producing, processing, conserving, distributing, controlling and trading of food products for people, in order to protect the health and interest of consumers.

Law Nr. 8934, date 5. 9.2002 "for Protection of the Environment"
Objective: This law regulates the relationships between humans and the environment, protects environment components and processes, ensures materials for sustainable development, through fulfilling the necessary framework for implementing the constitutional request for an ecologically clean environment.

Law Nr. 9199, date 26.2.2004 "For Production, Processing, Certification and Marketing of BIO products"
Objective:
a) Stimulating local organic production
b) Creation of the necessary legislative framework
c) Definition of conditions for production, processing, transport, certification and control of agricultural and food products, with plant and animal origin, which are produced, processed and/or imported and marketed as Bio.

Law Nr. 8990, date 23.1.2003 "for Environmental Impact Assessment"
Objective:

a) The general, integrated and timely assessment of environmetal impacts, of projects or activities that need to be implemented, by preventing and mitigating the negative impacts on the environment.

b) An open and unbiassed process of evaluation, through participation of central and local authorities, public, NGO's, proposers and physical and juridicial persons, specialized in this area.

Law Nr. 8906, date 6.6.2002 "for Protected Areas"

Objective: The object of this law is the proclamation, protection, administration, management and sustainable use of protected areas and their natural and biological resources ; facilitation of conditions for development of environmental tourism ; information and education of public and direct and indirect economical gains, from the local populations, the private and public sector.