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# GAIN Report

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## **Turkey**

### **Biotechnology - GE Plants and Animals**

#### **Turkey Biotechnology Report 2010**

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**Report Highlights:**

The regulations on agricultural biotechnology in Turkey have been changing frequently, often without notice, since October 29, 2009. As a result, there is a great deal of confusion about the regulations. A Biosafety Law will be implemented on September 26, 2010, however the final implementing regulations of the Law have not yet been published.

## **Section I. Executive Summary**

Turkey did not have any legislation regarding imports of agricultural biotechnology until October 26, 2009 when MARA published the “Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components” in the Official Gazette (No: 27388). The regulation banned the import of all transgenic crops and/or products containing transgenic ingredient and implemented a strict testing policy for products potentially containing biotech ingredients. The regulation was amended several times since then, often without notice. As a result, there is a great deal of confusion and uncertainty about biotech regulations in Turkey and trade in many products has been negatively impacted. In addition, the change in regulations led to a large amount of misinformation being spread and a general sense of public fear about the technology.

The Turkish Grand National Assembly approved a Biosafety Law (No: 5977) in March 2010, which will be implemented on September 26, 2010. The Law states that implementing regulations for the Law shall be published within three months.

In the interim until the Law is implemented in September, the amended October 26 Regulation remains in force. Under the current version of the regulation, last amended April 28, products can be imported if they contain events approved by the Scientific Committee. The Scientific Committee so far has approved all EU approved corn and soy events for feed except T-25 for corn, but has limitations on some of these events for use in food. The reasons behind the Committee’s decisions were not made public, and it is not certain what the status of the decisions will be under the new Biosafety Law.

Planting of biotech crops is banned in Turkey and labeling of products containing biotech ingredients is mandatory under both the current regulation and the Biosafety Law.

## **Section II. Plant Biotechnology Trade and Production**

### **Production**

Turkish Grand National Assembly adopted a Biosafety Law (No: 5977) on March 26, 2010. The law will be implemented six months from this date, on September 26.

According to Article-5 of the Law, the production of genetically modified plants and animals is banned. Despite pressure from various groups, officials have stated that the Ministry of Agriculture and Rural Affairs (MARA) has no intention to lift this restriction. The import of biotech seeds is also forbidden.

In 1998 MARA published a directive that allowed field trials. Between 1998 and 2004, there were field trials of corn, cotton and potatoes at public universities such as Ankara University, Ege University and Cukurova University. The trials were completed and the results were reported to MARA. No new crops have been introduced for experimental cultivation since then.

## Trade

Turkey is a major importer of bulk and semi- processed commodities and the United States is among the top suppliers to the Turkish market. The major imported commodities are cotton and soybeans. Turkey imports significant quantities of feed crops for its poultry and livestock sectors. In recent years, imports of DDGs and CGF have increased significantly. The Turkish feed sector depends heavily on imported raw materials due to insufficient domestic soybean production, and the relatively low cost and high quality DDGs are helping fill this demand.

Until the publication of a regulation on biotechnology in October 2009 Turkey did not have any legislation regulating the trade of transgenic crops. Immediately after the publication of the regulation, trade stopped. The regulation was subsequently amended several times and some trade resumed.

Cotton, soybeans, soybean meal, corn, and corn oil are among the top U.S. exports to Turkey.

Commodity	CY 2008		CY 2009	
	Quantity	Value	Quantity	Value
Cotton	347,000 MT	\$536 million	398,000 MT	\$487 million
Soybeans	497,000 MT	\$214 million	811,000 MT	\$341 million
Feed Ingredients	1,000,000 MT	\$238 million	677,000 MT	\$89 million
Corn	474,000 MT	\$73 million	314,000 MT	\$4 million
Corn Oil	68,000 MT	\$110 million	68,000 MT	\$52 million
Soybean Meal	142,000 MT	\$52 million	183,000 MT	\$79 million
<i>TOTAL*</i>	<i>2,528,000 MT</i>	<i>\$ 1,223 million</i>	<i>2,451,000 MT</i>	<i>\$ 1,052 million</i>

Source: USDA/ BICO trade data

\*For these commodities only

In CY 2008 the value of imported corn oil reached record levels. CY 2008 was also a very good year for DDGs and CGF imports (listed as feed ingredients in the table above).

## Section III. Plant Biotechnology Policy

Turkey did not have any legislation specifically covering agricultural biotechnology until October

26, 2009 when MARA published the “Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components” in the Official Gazette (No: 27388). The regulation banned the import of all transgenic crops and/or products containing transgenic ingredients and implemented a strict testing policy for products potentially containing biotech ingredients.

This instance led to sharp increases in the cost of feed ingredients as stocks vanished quickly, which negatively affected the Turkish feed, poultry and livestock sectors. These industries complained about the regulation to the government that the regulation was too strict and at the same time anti-biotech activists complained that the regulation was not strict enough, so that MARA was heavily criticized from both sides. In the end the Ministry had to amend the regulation three times in a six month period.

In the Turkish regulatory system, most trade related regulations are followed by internal directives which provide guidance on how to interpret the regulations, and are sent to port officials but not shared with the public. For the biotechnology regulation and subsequent amendments, these directives contained important information about how imported products should be handled. This lack of transparency led to a great deal of confusion among traders about what was required and this confusion was compounded by the frequency of amendments. Both of these factors led to significant losses for some importers and Turkish businesses, particularly those that had shipments arrive following sudden changes to import regulations.

Meanwhile, the Turkish Grand National Assembly passed the Biosafety Law on March 26, 2010 (No: 5977). The law states that it will be enforced 6 months after adoption, which means enforcement will begin on September 26, 2010. This law is a framework law and states that implementing regulations further determining the details of how the law is to be implemented shall be published by June 26 . Four separate draft implementing regulations were circulated for comment, however as of July 15, the final regulations have yet to be published.

Under the current regulation (based on an April amendment to the original October 26 Regulation) MARA established a Scientific Committee to assess genetic events approved in the EU. The Committee met twice in May 2010 and approved all soybean events and all but one EU approved corn events for feed use, and many of these for full or limited food use. The one EU approved event that was not approved by the Turkish Scientific Committee was T25 in corn. The full list of decisions by the Scientific Committee is given below. The names of the scientists on the committee were not release and neither were the reasons for any of its decisions.

NAME OF THE GENE	DECISION OF THE SCIENTIFIC COMMITTEE
1. Genetically modified corn variety with <b>Bt11</b> code	Committee has concluded that <b>Bt11</b> corn variety does not pose any risk if used as feed and food ( <u>except direct consumption such as fresh, canned, flour, semolina and products</u> )
2. Genetically modified corn variety with <b>DAS1507</b> code	Committee has concluded that <b>DAS1507</b> corn variety does not pose any risk if used as feed and food ( <u>except direct consumption such as fresh, canned, flour, semolina and products</u> )
3. Genetically modified corn variety with <b>GA21</b> code	Committee has concluded that <b>GA21</b> corn variety does not pose any risk if used as feed and food.
4. Genetically modified corn variety with <b>MON810</b> code	Committee has concluded that <b>MON810</b> corn variety does not pose any risk if used as feed and food ( <u>except direct consumption such as fresh, canned, flour, semolina and products</u> )
5. Genetically modified corn variety with <b>MON863</b> code	Committee has concluded that it is suitable that <b>MON863</b> corn variety is only used as feed.
6. Genetically modified corn variety with <b>MON863 x NK603</b> code	Committee has concluded that it is suitable that <b>MON863 x NK603</b> hybrid corn variety is <u>only used as feed.</u>
7. Genetically modified corn variety with <b>MON863 x MON810</b> code	Committee has concluded that it is suitable that <b>MON863 x MON810</b> hybrid corn variety is <u>only used as feed.</u>
8. Genetically modified corn variety with <b>NK603</b> code	Committee has concluded that <b>NK603</b> corn variety does not pose any risk if used as feed and food ( <u>except direct consumption such as fresh, canned, flour, semolina and products</u> )
9. Soybean(A2704-12)	Food and feed
10. Soybean(MON89788)	Food and feed
11. Soybean(MON40-3-2)	Food and feed

Currently import of soybean, DDGs, CGF and other products containing corn and soybeans are allowed if they do not contain T-25. In general, test results from an internationally accredited laboratory stating what is present are enough to allow products to enter, however exporters should talk to their importers about the details of what is required. There are many other requirements that must be followed, including labeling. The text of the current regulations is provided in Annex I of this report, however the internal directive, which gives detailed import requirements, is not a public document.

It is unclear what the status of the above approvals will be after the adoption of the Law.

## **Section IV. Animal Biotechnology**

There is no discussion about animal biotechnology in Turkey, however the Biosafety Law presumably covers this realm, as it states:

“The present Law governs all activities including but not limited to the research, development, processing, placing on the market, monitoring, utilization, importation, exportation, transit, transportation, preservation, packaging, labeling and storage regarding the Genetically Modified Organisms and products thereof. “

And

“Veterinary medical products and human medical products and cosmetics which acquired license or got approval from the Ministry of Health do not come under the scope of the present Law.”

## **Section V. Chronology of Events**

### **October 26, 2009**

MARA published “Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components” in the Official Gazette (No: 27388). Upon publication, the import of all transgenic crops and/ or products that contain transgenic ingredients was immediately banned.

### **October 30, 2009**

MARA published the 1<sup>st</sup> implementation directive of the Regulation. The directive required testing of 27 commodities during importation and banned import of any biotech products until the contained events are approved by the “Scientific Committee”.

### **December 3, 2009**

Consumers filed complaints about the regulation at the Council of State and won. The regulation was then suspended. Biotech imports were allowed to resume.

### **December 23, 2009**

MARA appealed to the Council of State and they agreed with MARA and allowed the regulation to be re-implemented. All biotech imports were again banned.

### **January 25, 2010**

MARA published a number of amendments and implementing directives for the Regulation between October 30, 2009 and January 25, 2010. All of the implementation directives were superseded by a new one on January 25, 2010. According to the directive; any GMO shipment, which had a *Control Certificate* (Import Permit) issued prior to January 20, 2010 and contained any GMO event approved in the EU (full list of 31 events were also included in the directive), was allowed to be imported to Turkey until March 1, 2010.

### **February 12, 2010**

The draft National Biosafety Law was reviewed at the Parliament's Agriculture Committee. The final draft was approved and sent to the General Assembly for final discussions, modifications and vote.

### **March 1, 2010**

Some articles of the January implementation directive related to the phase-in period expired. MARA did not extend the directive. This meant all biotech imports were again stopped.

### **March 18, 2010**

Parliament approved the Biosafety Law at the General Assembly.

### **March 26, 2010**

The Law was published in the Official Gazette (No: 27533) following approval by the President.

### **April 28, 2010**

The October 2009 Regulation was amended again. According to the amendment a Scientific Committee was given the authority to evaluate and make decisions on EU approved events.

### **May 7, 2010**

MARA internally published an implementation directive of the recent amendment, declaring the first approvals under the Scientific Committee, which were three soybean events: A2704-12, MON89788 and MON40-3-2. It also established a threshold of 0.9% for other EU approved events.

### **May 26, 2010**

The Scientific Committee published its second decision and approved all EU approved corn events except one (T25) for feed and/or food use.

# **Annex I - Unofficial Translation and Consolidated Version of October 26, 2010 Regulation and Subsequent Amendments, as of July 15, 2010**

*\*note: may change without notice \*\*some numbering and lettering of clauses may differ from Turkish version*

## **Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components**

### **SECTION-1**

#### **Objective, Scope, Legal Basis and Definitions**

##### **Objective**

**Article- 1** – (1) This directive determines the implementation of rules and principles of the decision making, processing, import, export, surveillance, registration, labeling, control and inspection services in regards to the food and feed that include the genetically modified organisms or include ingredient that contain a component of genetically modified organism or food and feed produced from genetically modified organisms in order to protect human life and health, animal health and welfare, consumer benefits and environment at the highest level.

##### **Scope**

**Article- 2** – (1) This directive;

- a) Comprises of the implementation of rules and principles of the decision making, processing, import, export, surveillance, registration, labeling, control and inspection services in regards to the food and feed containing genetically modified organisms& products and genetically modified organisms& products except seeds.
- b) Does not include products approved or licensed by the Ministry of Health.

##### **Legal Basis**

**Article- 3** – (1) This directive is based on the Article-10 of the Agriculture Law (Number 5488-Date: April 18, 2006), Decree Having the Force of Law on Establishment and Duties of the Ministry of Agriculture and Rural Affairs (Number 441-Date:August 7, 1991), Law on Adoption of the Amended Decree By-Law on the Production, Consumption and Inspection of Food (Number 5179-Date: May 27, 2004 ), Feed Law (Number 1734-Date: May 29, 1973) and Law on Preparation of Technical Regulations for Products (Number 4703-June 29, 2001).

##### **Definitions**

**Article- 4** – (1) The terms mentioned in this directive are:

- a. Unique Identifier: A numerical and alphanumerical encoding system allocating a code to each GMO which also includes the code of each transferred gene that it contains.
- b. Ministry: Ministry of Agriculture and Rural Affairs,
- c. GMO: Genetically Modified Organisms.
- d. Genetically Modified Organism: Organism, except human beings, whose genetic material is changed by utilization of modern biotechnology.
- e. GMO and Products: Genetically modified organisms and products that contain GMOs, are

- made from GMOs, contain GMOs but are not made only from GMOs and/ or partially made from GMOs.
- f. GMO Food: Food that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
  - g. GMO Product: Product that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
  - h. GMO Feed: Feed that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
  - i. Equivalent Product without GMOs: Equivalent food and feed that is produced without genetic modification technology,
  - j. Gene Owner: One that holds the patent rights for the gene or genes that is changed in the GMO and products.
  - k. Surveillance: Observation, analysis and control of GMO and products under a program in order to determine the effects on biodiversity, plant, animal and human health.
  - l. Traceability: Tracing, detecting and identifying GMO and products during all the stages of the production and distribution.
  - m. KKGGM: General Directorate of Protection and Control,
  - n. Committee: An independent, scientific and technical risk assessment committee that is anticipated to be established by this regulation.
  - o. Risk Assessment: The process of identification, determinations of attributes, identification of risk elements, and evaluation through scientific methods such as tests, analyses and trials of risks and risk sources that GMOs and products thereof may pose to animal, human and plant health, biological diversity and environment.
  - p. Risk Management:
  - q. TAGEM: General Directorate of Agricultural Research
  - r. TUBITAK: Scientific and Technological Research Council of Turkey.
  - s. TUGEM: General Directorate of Agricultural Production and Development
  - t. List of Experts: The list of experts that is prepared by the Ministry, who will direct the studies.

## **SECTION-2**

### **General Provisions and Conditions for Authorization**

#### **General Provisions**

**Article-5** (1) The import, marketing, registration and export of GMO food and GMO feed for consumption and processing purposes is banned if it is against the articles mentioned in this regulation. Ministry sets the methods and basis for the transit shipment of GMO food and GMO feed. Customs authorities shall not ask for additional documentation regarding GMOs for products covered by this Regulation.

(2) If the imported, produced or distributed GMO food or feed is detected to harm environment, human or animal health then the food or feed processor is obliged to take necessary precautions to protect the environment, inform the Ministry, consumers and other related authorities immediately and the processor is also obliged to recall the mentioned food or feed from the market.

(3) GMO products are banned in baby food, baby formula, continuation food and formula and in

food supplement for babies and young children.

(4) Ministry may make arrangements on the import and export ports for GMO food and feed.

(5) The Ministry has all the authority to regulate any matter and to take any precautions that are not mentioned under this directive.

### **Conditions for Authorization**

**Article-6** (1) The risk assessment is carried out by the scientific committees only once for each GMO and the assessment is based on the gene or genes that are modified with scientific methods.

(2) The decision document is prepared following each risk assessment showing that as a result of the research the GMO food or feed is not harmful to environment, human or animal health. The decision document must have at least below matters:

- a. The validity of the approval,
- b. Policies and procedures that needs to be applied for the import of GMO and products,
- c. The purpose of use and restrictions,
- d. Risk management, market inspection, and if needed production planning,
- e. Surveillance and traceability conditions,
- f. Documentation and labeling conditions,
- g. Packing, transportation, conservation and transfer conditions,
- h. Conditions for processing, waste and residual disposal,
- i. Security and emergency measures,
- j. Annual reporting conditions for the usage,
- k. Conditions regarding the transfer of ownership and/ or transfer of usage of the product,
- l. Usage and processing conditions depending on supply and purpose.

(3) Committee may make a decision on the commercialized genes, which have completed risk assessment and got approval for consumption by the EU. The list of genes that has been approved by the Committee is notified to the Ministry.

(4) Ministry may ask for public comments on the Committee's decision prior to approval.

(5) The decision of the Committee will be enforced after the approval of the Ministry.

(6) Ministry shall publish the information on approved GMOs and other information on GMOs on its website.

(7) In order to register approved GMOs and products and to allow traceability at every stage, the importers, processors and distributors of the GMO and products are obliged to make a declaration to the Ministry and transfer, transport and label the GMOs and products with appropriate documentation.

(8) The approval may be canceled by the Ministry if the conditions on the decision document is violated or new scientific research is done on the risks and harms of the product and some negative

outcomes are reached as a result of the usage of the product. The products are then re-called and disposed.

(9) The approval will be canceled if they don't follow the conditions on the decision document. The administrative enforcements are done depending on the reason of the cancellation.

(10) Products containing GMO cannot be used in any other way than the approved purpose.

(11) The owner of the gene is obliged to report to the Ministry and to take necessary precautions as soon as they find out about a new risk or suspicion about a risk.

(12) During the sale and distribution of GMOs and products, the owner of the gene is responsible for informing the buyers of the security rules and precautions about storage, processing and packaging of GMO and GMO products.

### **SECTION-3**

#### **Committee, Application and Working Groups**

##### **Committee**

**Article 7-** (1) A list of experts, who are responsible to search technical and scientific data, evaluate data and prepare reports about GMOs, will be prepared by the Ministry. The term of each specialist is two years. The experts' list will have experts or academicians from universities, The Scientific and Technical Research Council of Turkey (TUBITAK) and research institutes. A new committee of 11 members (selected from the experts' list) is established by the Ministry for each application.

(2) General Secretariat of the Committee is run by TAGEM. Committee shall meet by the request of TAGEM.

(3) Committee shall have meetings with the attendance of at least 9 members. Committee shall elect chairman for each application. The Committee shall take decisions with the absolute majority of those present. The justification of decision in favor and against the final decision shall be written and signed by the related members and sent to the Chairman as attachments to the decision.

(4) Committee shall make a decision about the application within 90 days after the first meeting. If the committee asks for additional documents and information, the 90 day period will be paused. The additional information and documents must be supplied within 30 days if committee asks for additional documents.

(5) If the committee disapproves an application, new application of the same product cannot be submitted at least one year following the disapproval date. The new application cannot be submitted without new scientific data.

(6) The announcement of the information to the public about application is subject to committee's approval upon the applicant's demand.

(7) The committee is responsible to Ministry for their activities.

### **Responsibilities and Duties of the Committee**

**Article 8-** (1) The responsibilities, duties and obligations of the committee are given below:

- a. Committee evaluates the application, prepare a report and present to the Ministry.
  - b. The committee is not allowed to give any information and document and is not allowed to make any statement about the application during the evaluation period without consent of the Ministry.
  - c. Depending on the need, the Committee may invite one or more experts from the “experts’ lists” to attend at the most two meetings and to provide advice only.
  - d) Committee is allowed to evaluate the commercialized genes approved by the EU for consumption and inform the Ministry of the results of the evaluation and notify Ministry on the approved genes.
- a. Committee determines the labeling conditions for GMO products.

### **Application**

**Article-9** (1) In order to have the first evaluation of the GMO product by the committee, the owner of the gene has to apply to the Ministry by providing the below documents and information:

- a. Information or documents that contain data about the gene or genes that change the structure of the GMO,
- b. All kinds of information and documents and supporting documents that pave the way for the method and reference material to detect the GMO,
- c. Information on the Unique Identifier,
- d. Information and scientific research results that are related to the GMO risk assessment application,
- e. Information on intended use and restrictions, and information and documents to support this part of the application,
- f. Information and documents that explain usage and production conditions
- g. Information and documents that show risk management, auto-control and production planning,
- h. Information and documents that explain monitoring and traceability,
- i. Information and documents that explain confiscation conditions, and treatment of wastes
- j. Safety, precautionary plan and practices and related information and documents
- k. Document showing the conditions if it is allowed to transfer the ownership of the GMO product, or the product can be used by somebody else, and if so, provide conditions for transfer and usage.
- l. Provide transportation, storage and transfer conditions of GMO food or feed materials that are applied for,
- m. Documents or certification approved by competent authority which proves that the gene or genes (which are applied for approval in Turkey) have been registered for and has been commercialized in the exporting country for at least 3 years prior to the application in Turkey.
- n. Documents approved by competent authority shows that registered variety is commercially

produced initially in the country where it is originally developed and other countries that have related legislations.

- o. Documents and information showing that the GMO does not have a close relative variety or wild species in Turkey in order to protect Turkey's flora and fauna,

(2) Committee may ask for additional documentation if necessary.

(3) Committee shall deny the application when necessary documents and information is not supplied within the given time.

(4) The result of an application does not constitute to be exemplary for another application. The approval is valid for the importation for the specific shipment and the follow up shipments of the same product. However, other requirements for importation should also been met.

### **Working Groups**

**Article- 10** (1) TAGEM may establish working groups. TAGEM is responsible to decide on the number of the members and the duration of the meetings. The working groups, chosen from the experts' list may be formed to work on below issues:

- a. To provide advice on strategies and policies that Turkey should adopt by following the international developments,
- b. To make assessments on GMOs and GMO products for the sensitive consumer groups and to advice on the products,
- c. To advice the Ministry on internationally consumed GMOs and products,
- d. To inform necessary government bodies on risky products that are approved for production,
- e. To prepare biosafety risk scenarios for the immediate term, short-term and long-term and to provide suggestions for solutions.
- f. To provide advice on precautions for emergency situations depending on Turkey's needs.

## **SECTION-4**

### **Import, Processing, Export, Storage, Export, Labeling, Monitoring, Surveillance, Inspection and Control of GMO Products**

#### **Import**

**Article-11** (1) Below issues are considered for the import of GMOs and products that have been assessed by the Committee and their import has been approved in the decision document:

- a) A document noting the GMO event and its amount, which is issued by the official authorities of the exporting or shipping country, is required from the importer or an analysis report is requested from an internationally accredited laboratory.
- b) The Ministry has the authority to analyze the shipments for control and inspection.
- c) The frequency of the analyses is based on the risk and is determined by the Ministry.

(2) The following principles are applied to the imports that are declared to be GMO free but have a risk of containing GMOs:

- a) The products that have the potential to have GMOs are determined by the Ministry. The frequency of the analysis of these products is determined by the approval of the Ministry. This is updated by the Ministry, if needed.
- b) The products are analyzed based on the determined frequency. If the analysis results are

appropriate, the product is allowed to be imported.

c) If the product is confirmed to contain GMOs as a result of the analysis, then the product is not allowed to be imported. The importer, exporter and the exporting country of these products are added to the risk list.

(3) The importer is obliged to supply all kinds of information, documents, products and materials including analysis methods and special materials that might be needed, which are required for the evaluation and control processes.

### **Processing and Storage of GMO products**

**Article-12** (1) In order to use imported GMO and products in food or feed materials' production, food or feed processor, in the application for permission and registration must meet the criteria below, in addition to the criteria mentioned under food and feed legislation:

a) The following documents and information about the raw materials that are GMO or products must be submitted to the Ministry within one month:

1) Information about from whom and how much (material) is obtained,

2) In which way these products will be used.

3) Label and/ or transcript of the required documents that must accompany GMO and products.

b) GMO food or feed must be processed in a line and stored in a place that is different from non-GMO food or feed line and storage area. If the same production line is used, it must be cleaned accordingly.

c) If there are perceived risks after the production, necessary precaution plans, and other extra precautions concerning transport and storage must be declared to the Ministry.

d) The requirements for safe disposal and destruction of waste and residues must be determined and declared to the Ministry.

### **Export of GMO Products**

**Article- 13** (1) In exports the request of the buyer country is noted and processes are carried out accordingly. If the importing country does not have any requests regarding the GMO's, then general export legislation is used.

### **Labeling of Food**

**Article- 14** (1) "According to the provisions of this regulation, if a GMO food is approved then the following criteria must be used in labeling in addition to the requirements mentioned under Turkish Food Codex Legislation (published on the Official Gazette No:23172 on 11/16/1997). "

a) If the GMO is composed of one component the labeling should contain "genetically modified" or the product name of the raw material name should contain "produced from genetically modified...".

b) If the GMO is composed of multiple components in addition to "genetically modified..." or "produced from genetically modified..." statements, the component list must have the above statements in parenthesis. Font size should be the same.

c) Bulk products must contain documents with labeling information.

d) In addition to the above mentioned labeling requirements, if the GMO food differs from the non-GMO food in regards to composition, nutritional effects, and nutritional values; the label must note these. It is required to have nutritional labeling for GMO foods with nutritional composition

differences.

e) If the GMO food differs from the non-GMO food, the label should contain health warnings about health risks that might arise from the use of these products.

### **Labeling of Feed**

**Article-15** (1) According to the provisions of this regulation, if a GMO feed or raw material of feed is approved then in addition to the feed labeling regulations, the following criteria must be used in labeling.

a) GMO feed must have the statement “genetically modified...” next to its name. This statement could also be added as a foot note under the components. In this case, the font size should not be smaller than the font size of components.

b) Feed made from GMO product must have the statements “produced from genetically modified...” next to its name. This statement could be added as a foot note under the components. In this case the size of font characters should not be smaller than the font size components.

c) Bulk feed must have documents with the labeling information.

d) If the GMO feed differs from the non-GMO feed, the label must make note of composition, nutritional effects, purpose of usage, and health declaration for specific animal kinds or categories.

e) If there are no non-GMO equivalents for the feed that is produced by GMO’s, the nature and the characteristics of the feed must be listed on the label.

### **Surveillance and Traceability**

**Article-16** – (1) Importers or exporters, processors, storing facilities, distributors and retailers of GMO and products must keep records, ensure traceability, and keep unique identifier numbers and all necessary documents with the product, during/until the end of the process where the consumer obtains the products.

(2) Importers or exporters, processors, storing facilities, distributors and retailers of GMO and products must store necessary documents and information for 20 years and must have a record/archive system for these documents.

(3) Whether the conditions in the GMO and products decision document is followed, is inspected by officers assigned by the Ministry. If there are complaints, agencies assigned by the Ministry processes these in accordance with the articles of this regulation and related legislations.

### **Inspection and control**

**Article-17** – (1) Inspection and control of GMO and products is carried out according to the articles of this regulation and related legislations.

## **SECTION-5 Others and Final Provisions**

### **Sampling and analysis**

**Article-18** (1) Procedures about sampling and laboratory analysis of GMO food and feed shall be determined by the Ministry.

### **Punitive Articles**

**Article- 19** – (1) Action is taken against those who act against the articles of this regulation in accordance with the legislations listed below:

- a. Law number 4703, articles 11 and 12,
- b. Law number 5179, article 29,
- c. Law number 1734, articles 12, 13, and 14,

### **Implementation**

**Article-20** – (1) This legislation goes into effect immediately upon the date of publication.

### **Execution**

**Article-21** - (1) The provisions of this Regulation are executed by the Minister of Agriculture and Rural Affairs.

## **Annex II. Unofficial Translation of Turkish National Biosafety Law**

Official Gazette No: 27533

Law Number: 5977

Publication Date: March 26, 2010

# **LAW ON BIOSAFETY**

## **SECTION ONE**

### **Objective, Scope and Definitions**

#### **Objective and Scope**

**ARTICLE 1** – (1) The objective of the present Law is to establish and implement a biosafety system in order to prevent the potential risks of the genetically modified organisms and products thereof obtained through modern biotechnological means within the context of scientific and technological advancements; protect human, animal and plant health; safeguard and ensure the sustainable use of the environment and biological diversity and to determine the procedures and principles governing the control, regulation and monitoring of these activities.

(2) The present Law governs all activities including but not limited to the research, development, processing, placing on the market, monitoring, utilization, importation, exportation, transit, transportation, preservation, packaging, labeling and storage regarding the Genetically Modified Organisms and products thereof.

(3) Veterinary medical products and human medical products and cosmetics which acquired license or got approval from the Ministry of Health do not come under the scope of the present Law.

#### **Definitions**

**ARTICLE 2 – (1)** The definitions of the terms used in the present Law are as follows:

- a) **Unique identification:** A numerical and alphanumerical encoding system allocating a code to each GMO which also includes the code of each transferred gene that it contains.
- b) **Minister:** Minister of Agriculture and Rural Affairs.
- c) **Ministry:** Ministry of Agriculture and Rural Affairs.
- ç) **Simplified procedure:** Abridged decision making procedure based on the available information and previous risk assessment indicating that there is no risk that may arise from a GMO or product thereof and that it does not harm human, animal and plant health, the environment and the biological diversity.
- d) **Biosafety:** Safe conduct of activities regarding GMOs and products thereof in a manner to protect human, animal, plant health, the environment and biological diversity.
- e) **Biosafety information exchange mechanism:** Information exchange system to be established to facilitate the exchange of scientific, technical and practical information and documents to inform public and participation to decision making process on GMOs and products thereof at national and international level.
- f) **Biosafety system:** The whole of the administrative, legal and institutional structure ensuring biosafety and all activities carried out to this effect.
- g) **Biodiversity:** Differences within and between species, including also ecosystems.
- ğ) **Contaminants:** Materials, Those are not added deliberately to food and feed but present in the food due to the contamination including during primary stage of production, processing, preparations, treatments, wrapping, packaging, transportation, or storage or environmental contamination except foreign substance like animal feather or parts of bug.
- h) **Living organism:** Biological entities including microorganisms, sterile organisms, virus, virion and viroids of which genetic material can be reproduced or transferred.
- ı) **Experimental release into the environment:** Execution of experimental activities on a GMO in a restricted area and under controlled conditions, in a manner to prevent its contact with the external environment.
- i) **Genetically Modified Organism (GMO):** Any live being –except human beings– obtained through gene transfer by modern biotechnological methods.
- j) **Products obtained from GMOs:** Products partly or completely obtained from GMOs which do not contain GMOs themselves or does not consist of GMOs.
- k) **GMO and products thereof:** Products partly or completely obtained from GMOs which contain or consist of GMOs.
- l) **Interested party:** Those who are engaged in activities including but not limited to the research, development, processing, placing on the market, monitoring, utilization, importation, exportation, transit, transportation, preservation, packaging, labeling and storage regarding the Genetically Modified Organisms.
- m) **Process:** Any process that is done so that GMO and products thereof can be used as food, feed or other purposes and significantly changes the initial condition of the product.

**n) Monitoring:** All sorts of observation, control, inspection and monitoring works carried out in all stages of processing and distribution chain of a GMO or product thereof placed on the market, after determining that it does not pose any risk and that it does not harm human, animal and plant health, the environment and the biological diversity.

**o) Contained use:** Any operation involving GMOs, undertaken within a controlled facility or laboratory having in place biological, chemical and physical measures that totally prevent their potential negative effects on human, animal and plant health, the environment and the biological diversity.

**Ö) Decision:** Decision adopted by the Biosafety Board regarding an application submitted for a GMO or product thereof, following scientific risk assessments and socio-economic evaluations.

**p) Committee:** Committees formed by the Board to carry out the scientific assessments.

**r) Board:** The Biosafety Board

**s) Modern biotechnology:** The application of in vitro nucleic acid techniques enabling direct transfer of recombinant deoxyribonucleic acid (rDNA) and nucleic acid into cells or organelles, or fusion of cells between different species and classes outside the taxonomic family, that overcome natural physiological reproductive barriers beyond the techniques of conventional breeding and selection.

**ş) Handling:** Any activity related to GMOs including but not limited to packaging, labeling, transfer, transportation and storage taking into consideration the measures to be taken to ensure the protection of human, animal, plant health, environment and biological diversity.

**t) Placing on the market:** Placing on the market of all products coming under the present Law against payment or free of charge.

**u) Protocol:** The Cartagena Biosafety Protocol to the UN Convention on Biological Diversity approved for ratification under the Law #4898 dated 17/06/2003 and ratified by the decision of the Council of Ministers #2003/ 5937 dated 17/07/2003.

**ü) Risk assessment:** The four stage process of identification, determinations of attributes, identification of risk elements, and evaluation through scientific methods such as tests, analyses and trials of risks and risk sources that GMOs and products thereof may pose to animal, human and plant health, biological diversity and environment.

**v) Risk communication:** The interactive exchange of information and opinions throughout the risk analysis process in regards to the hazards and risks, risk-related factors and risk perceptions among risk assessors, risk managers, and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;

**y) Risk management:** The process of assessing, choosing and implementing suitable alternative prevention and control options in consultation with interested parties, considering risk assessment and other legal factors to ensure that the GMOs and products thereof are used and handled in accordance with the purposes and rules established on the basis of risk assessment results.

**z) Socio economic evaluation:** Evaluation and studies (evaluated before the

decision made on the application) that are based on science to find out the effects and socio economic cost that are related to the environmental release of GMO and products thereof to biodiversity, to the user and to the farmer.

## **SECTION TWO Fundamental Principles**

### **Application, Evaluation & Decisions**

**ARTICLE 3 –** (1) With a view to protecting human, animal and plant life and ensuring the protection and sustainable use of the environment and biological diversity; the importation, exportation, experimental release into the environment, placing on the market of GMOs and products thereof and contained use of genetically modified microorganisms are permitted in accordance with the results of scientific risk assessments. Decisions issued for applications determined as not posing risk are valid for ten years.

(2) For the first importation of each GMO or product thereof applications are submitted to the Ministry by the importer or the proprietor of the gene, or in the case of locally developed GMOs by a private or corporate person. It is compulsory to indicate in the application the purpose of use of the GMO or product thereof and information about the content of application. Applications may be submitted for more than one purpose of use, in which case each purpose will be treated as a separate application.

(3) The outcome of a certain application does not set precedence for another one.

(4) Received applications are conveyed to the Board by the Ministry. The Board notifies the Ministry within ninety days whether the application is accepted or not, as well as its other observations. The Ministry informs the applicant to this effect within fifteen days. Time elapsed for the presentation of additional information and documentation does not count towards this period.

(5) Application for the approval of GMO and products thereof will be rejected under the following conditions:

a) It threatens human, animal and plant health, the environment and biological diversity.

b) It undermines the freedom of choice of the producers and consumers

c) It disrupts the ecological equilibrium of the environment and of the ecosystem.

ç) If there is a risk of GMO propagating itself or its characteristics in the environment.

d) It endangers the sustainability of biological diversity

e) If applicant does not have sufficient technical capacity to implement the measures to ensure biosafety.

(6) The decision time line starts upon the Ministry's notification to the applicant of the decision mentioned in the preceding Paragraph 4, and cannot exceed 270 days. Time

elapsed for the presentation of additional information and documentation does not count towards this period.

(7) The applicant presents a letter of request stating those items of information to be kept confidential. Before deciding to fully or partially honor such request, the Ministry interactively exchange information and opinions with applicants on the demand of confidentiality request. Following this process Ministry takes the necessary measures and informs the applicant. Name and address of the applicant or importer, purpose of use of the GMO or product thereof, their characteristics, unique identification data, common and scientific names, donor organism of the transferred gene, country of origin of the receptor and donor organisms, general description of the transfer method, all emergency procedures and plans and summary of the risk assessment cannot be considered as confidential.

(8) Applications must include the requested document showing that the GMO or product thereof is approved in the country where it is developed or registered for release into the environment, placing on the market for consumption and that such approval is currently valid, the production and consumption is continuing and it has been on the market for a certain length of time as indicated by the Ministry.

(9) Importation applications for the purpose of experimental release into the environment or placing on the market are submitted separately to the Ministry prior to importation or, if developed locally prior to placing on the market.

(10) It is compulsory to obtain a permit from the Ministry for each transit passage of GMOs and products thereof. Transit passages are performed in compliance with the conditions stated in the written permit of the Ministry and with the provisions of the Customs Law #4458 dated 27/10/1999.

(11) Permission is obtained from the Ministry for GMOs or products thereof to be imported for the purpose of scientific research by institutions authorized to carry out such research. Importation is performed in compliance with the conditions stated in the written permit. For the contained use for experimental purposes of GMOs and products thereof and genetically modified microorganisms, those who are carrying out these works must meet the contained use standards and conditions, and measures to be applied in case accidental release into the environment must be in place. It is obligatory to keep the Ministry informed of the experimental works and their results.

(12) Scientific risk assessment and socio-economic evaluation reports regarding applications for GMOs or products thereof are announced to the public by the Board through the biosafety information exchange mechanism for public consultation. The Board has to complete its final evaluation report, considering also the opinions presented during the public consultation, and must present its favorable decision to the Ministry within thirty days at the latest from the date of meeting, together with all signatures and motives of eventual contrary votes. Decisions of the Board enter into force after promulgation in the Official Gazette.

(13) In the event that the application is refused, the applicant is notified in writing by the Ministry. Should there be new information that may warrant a change of decision the applicant may request the Ministry to review the decision. In this case the Board reviews the decision considering the presented new information within 60 days and informs the Ministry of the result for conveyance to the applicant. The final decision is announced to the public.

(14) When board did not take committees decision into consideration, board should need to announce the justification.

(15) The decision includes the following points:

- a) Validity period.
- b) Importation formalities.
- c) Purpose of use.
- ç) Necessary data for risk management and market supervision
- d) Monitoring conditions.
- e) Documentation and labeling conditions.
- f) Packaging, haulage, storage and transportation rules.
- g) Processing and waste and residue treatment/disposal conditions.
- ğ) Safety measures and emergency procedures.
- h) Method of annual reporting.

(16) The applicant may apply to the Ministry at least one year before the expiration date for the extension of the validity period. This request is evaluated by the Board and its result is notified to the Ministry for conveyance to the applicant. If the result of application for extension can not be completed in a year then the validity of the past approval will automatically be extended until the new decision is announced.

(17) The procedures and principles regarding the implementation of the present Article are established by a regulation.

#### **Risk Assessment, Socio-Economic Evaluation and Risk Management**

**ARTICLE 4 – (1)** Each GMO or product thereof for which an application is submitted under the present Law, is separately subjected to a risk assessment and socio-economic evaluation based on scientific principles. In the event that the submitted information is not deemed sufficient, renewed experiments, tests, analyses and research works may be requested from the applicant. Expenses related to the risk assessment and socio-economic evaluations are covered by the applicant.

(2) Risk assessment is made separately for each application. In the course of the risk assessment field trials including laboratory, greenhouse and field tests; nutrient analyses, toxicity and allergy and other eventual tests that are deemed necessary must be submitted by the applicant.

(3) For consideration in the decision process, a socio-economic evaluation is

carried out in order to ascertain the effects of the GMOs on the protection and sustainability of biological diversity and on consumers and users.

(4) Risk management principles are determined for the GMOs and products thereof for which an application is submitted, on the basis of the results of risk assessment and socio-economic evaluation. A detailed risk management plan is prepared. Preparation and implementation of this plan is the responsibility of the applicant.

(5) The procedures and principles regarding the implementation of the present Article are established by a regulation.

### **Prohibitions**

**ARTICLE 5 –** (1) Following acts regarding GMOs and products thereof are prohibited:

- a) Putting GMO and products thereof to the market without approval
- b) Using or letting others use the GMOs and products thereof in breach of Board decisions.
- c) Producing genetically modified plants and animals.
- ç) Using GMOs and products thereof beyond the purpose and area indicated by the Board in the placing on the market decision.
- d) Using GMOs and products thereof in baby food and baby formula, follow-on food and follow-on formula, baby and young children nutritional supplement.

### **Simplified Procedure**

**ARTICLE 6 –** (1) Applications based on the available information and previous risk assessment indicating that there is no risk that may arise from a GMO or product thereof and that it does not harm human, animal and plant health, the environment and the biological diversity can be subjected to a simplified procedure, considering also the results of the socio-economic evaluation.

(2) In order to apply under the simplified procedure, besides the rules to be set forth by the Ministry the following conditions should be met:

- a) Taxonomy and biology of the gene source and the receptor live organism should be known.
- b) Sufficient information should be available regarding the possible effects on the human, animal and environmental health and biological diversity.
- c) Previous risk assessments that can be used regarding the relations of the GMO with other live organisms should not have indicated any negative effects.
- ç) Detailed methods and data should be available to enable the definition of the transferred genetic material and its identification within the live organism where it is transferred.

(3) The procedures and principles regarding the implementation of the present Article are established by a regulation.

### **Procedures following the decision**

**ARTICLE 7 –** (1) Following the placing on the market of the GMOs and products thereof,

the Ministry controls and supervises whether the conditions stated in the decision are observed or not, and if there are any unexpected effects on human, animal, plant health, the environment and biological diversity. The analyses to be carried out for this purpose are performed by the laboratories designated by the Ministry. The importer is obliged to fulfill the requests related to the control and supervision procedures.

(2) Decisions may be revoked by the Board, in the event of a breach of the conditions stated therein or emergence of new scientific information about any risks related to the GMO or product thereof. Upon revocation of the decision the GMO or product thereof in question is recalled from the market. Those which are found to have negative effects on human, animal, plant health, environmental or biological diversity are destroyed at once, whilst the property of those which are not found to have negative effects are transferred to the public. The expenses pertaining to the measures to be taken by the Ministry pursuant to the present Paragraph and other expenditures are collected from the interested parties, taking into consideration the tort and responsibility.

(3) In order to ensure traceability, it is compulsory to submit declarations to the Ministry, keep the necessary records, make available a copy of the decision and to comply with the labeling rules during the entry into and circulation within the country of GMOs and products thereof. Each GMO and product thereof is assigned a unique identifier and registered. Documents related to registered GMO and products thereof should be kept for 20 years.

(4) Any product containing a higher level of GMOs or products thereof than the thresholds established by the Ministry must be clearly labeled as containing GMO.

(5) The interested parties are obliged to notify the Ministry at once and take the necessary measures should a new risk or risk suspicion regarding the GMOs or products thereof come to their knowledge.

(6) When placing a GMO or product thereof on the market, the interested parties are obliged to inform the clients of the safety rules and measures indicated in the decision regarding the handling, processing, storage, transportation and other operations.

(7) The procedures and principles regarding the implementation of the present Article are established by a regulation.

### **SECTION THREE**

#### **Duties & Authorities of the Ministry; Board & Committees**

##### **Duties & Authorities of the Ministry**

**ARTICLE 8-** (1) Duties and authorities vested with the Ministry are as follows:

- a) To provide convenient working conditions to the Board and to perform the secretarial functions of the Board.
- b) To obtain the information and documents and to perform or get performed and

report the results of the research, trial, control and inspections requested by the Board.

c) To ensure the implementation, prevention of unintended GMO contamination, monitoring, control and inspection of the procedures and formalities set forth in the present Law.

ç) If so deemed necessary, to empower real or corporate persons to carry out works on GMOs and products thereof, to supervise such empowered persons and to establish the relevant procedures.

d) To develop, implement or have implemented strategies for protecting and exploiting national biodiversity and genetic resources.

e) To take the necessary measures to ensure the information and participation in the decision process of the general public, through the biosafety information exchange mechanism.

f) To establish the procedures and principles pertaining to the activities of the Board and scientific committees.

g) To cooperate with relevant institutions regarding border checks to prevent the movement and use of GMOs and products thereof other than those governed by the present Law.

ğ) To prepare and implement emergency action plans and determine methods against unforeseeable circumstances related to the protection and sustainability of human, animal plant health, the environment and biological diversity.

h) To establish threshold values for GMOs and products thereof in accordance with their characteristics by taking Board's decision into consideration.

ı) To establish the procedures and principles pertaining to the labeling of products coming under the present Law and products obtained from GMOs.

(2) Under necessary conditions the Ministry shall cooperate with related stakeholders, institutions and Ministries on the implementation of this law.

(3) Ministry is responsible to prepare and implement emergency action plan in order to prevent possible damage to environment, biological diversity, agricultural production, human health related to GMO and products thereof in case of an accident that may occur during the processes of those products.

(4) With a view to protecting human, animal plant health, the environment and biological diversity the Ministry is authorized adopt precautionary measures and all sorts of dispositions regarding the products coming under the present Law such as total or partial recall, expropriation, returning the product to its origin, temporary suspension of the activities, disposal of the product, prohibition of supply to the market, trade and processing.

### **Biosafety Board**

**ARTICLE 9-** (1) Biosafety Board is formed to evaluate the applications regarding GMOs and products thereof, and to carry out the other duties indicated in the present Article.

(2) The Board consists of a total of nine members: four designated by the Ministry of Agriculture and Rural Affairs, two by the Ministry of Environment and Forestry, one from

the Ministry of Health, one from the Ministry of Industry and Trade, and one from the Undersecretariat of Foreign Trade. At least one of the two members, who are selected by the Ministry, should be selected from among the representatives of universities and one should be selected from among the professional organizations. The President of the Board is designated by the Minister. The President of the Board designates a member to deputize him in his absence.

(3) President and members of the Board cannot be appointed for more than two terms.

(4) Appointments to the vacated membership positions, including the presidency, are made within one month at the latest by the respective ministers.

(5) Members of the Board must have at least a graduate degree and the qualifications stated in the Civil Servants Law #657 dated 14/07/1965, Art. 48, Paragraph A, Sub-Paragraphs 1, 4, 5, 6 and 7. The members of the Board must have a minimum of five years experience in areas that come under the present Law.

(6) President and the members of the Board may not be discharged before the end of their term in office. However, the terms of office of the President and the members of the board are terminated by Minister should it become evident that they cannot perform their duties due to severe illness or disablement, loss of the necessary conditions of eligibility or in the event that they act in contravention to the present Law.

(7) The President and members of the Board, their spouses as well as consanguineous and affinal relatives up to and including second degree cannot engage in any commercial activity or own capital market instruments related to activities or sectors on which the Board may issue decisions. The offices of those who contravene the dispositions of the present Sub-Paragraph are terminated at once by the Minister.

(8) The President and members of the Board cannot take up employment in the private establishments engaged in activities or acting in the sectors regulated under the present Law, for three years following termination of their offices.

(9) The members of the Board are entitled to a daily attendance fee for each meeting they attend, for a maximum of twelve meeting days per year, in an amount to be calculated by multiplying 5000 by civil servant wage coefficient. In cases where the payment of a *per diem* is due, the highest Civil Servant *per diem* is paid pursuant to Per Diem Law #6245 dated 10/02/1954.

### **Working Principles of the Biosafety Board**

**ARTICLE 10-** (1) The Board is independent in the performance of its duties. No organ, office, body or person can issue orders or instructions to the Board.

(2) The Board convenes upon the invitation of the President with a determined agenda. The agenda of each meeting is prepared and notified to the members at least

one week prior to the meeting by the President of the Board. The meetings are not considered adjourned until all items of the agenda are deliberated upon.

(3) The quorum for a valid meeting is seven members and the decisions are adopted by at least a majority vote of five. The decisions are committed to the minutes of the meeting and signed.

(4) Members who fail to attend a total of three meetings in the course of one calendar year without a valid excuse are considered as resigned from membership and this circumstance is annotated through a decision of the Board. Those members who fail to sign the Board decisions in due time although they were present in the meeting and did not cast a vote of objection, or those who fail submit in writing the grounds of their vote of objection are warned in writing. In the event that this circumstance is repeated thrice in one calendar year, the member is considered as resigned. Such circumstances must be annotated and decided upon in the third meeting that the member failed to attend, and notified to the Ministry.

(5) The members of the Board cannot participate in debates and cast votes in issues related to their spouses, adopted children as well as consanguineous and affinal relatives up to and including second degree.

#### **Duties and authorities of the Biosafety Board**

**ARTICLE 11 – (1)** Duties and authorities of the Board are as follows:

- a) Forming the list of specialists.
- b) Forming the scientific committees whose members are selected from the list of specialists
- c) Selecting the members of the scientific committees from the list of specialists for each application.
- ç) Forming the Board decisions by taking into consideration of risk assessment and socio-economic evaluation reports.
- d) Taking into consideration the monitoring reports, submitting decisions to the Ministry regarding sanctions such as partial or complete revocation of the decision, prohibition and recall.
- e) Forming the ethics committee

#### **Formation, Duties & Authorities of the Scientific Committees**

**ARTICLE 12 – (1)** For each application the Board constitutes a risk assessment committee, a socio-economic evaluation committee and if need be, other scientific committees. These committees consist of eleven members.

(2) The list of specialists is compiled from among members of universities or the Scientific & Technological Research Council of Turkey as well as those who are working in areas deemed necessary by the Board.

(3) Duties and authorities of the committees are as follows:

- a) To determine the scientific sufficiency of the information provided for risk

assessment regarding the applications filed under the present Law.

b) To determine the required tests, experiments, trials, analyses and other actions and to request additional information if need be.

c) To prepare risk assessment and socio-economic evaluation reports.

ç) To form a scientific opinion, evaluating all sorts of new data and information that emerge or is obtained after the decisions are taken.

d) To make scientific assessments, to inform the Board and to prepare reports.

(4) Scientific evaluation reports prepared by the committees are considered as restricted documents and cannot be presented to any real or corporate person, institution or establishment apart from the Board. Except for unlawful acts, committee members cannot be held responsible for the scientific evaluation reports that they prepare.

(5) The committees are independent in the performance of their duties. No organ, office, body or person can issue orders or instructions to the committees.

(6) The members of the committees are entitled to a daily attendance fee for each meeting they attend, for a maximum of twelve meeting days per year, in an amount to be calculated by multiplying 5000 by civil servant wage coefficient for those who are not holding a public office and 3000 for those who are simultaneously holding a public office. In cases where the payment of a *per diem* is due, the highest Civil Servant *per diem* is paid pursuant to Per Diem Law #6245.

(7) Members who fail without a valid excuse, to attend two meetings on the same application despite invitation, are considered resigned and replaced by a new member appointed by the Board.

### **Obligations**

**ARTICLE 13** – (1) The personnel of the Ministry and the members of the Board and committees cannot divulge the confidential information, documents and trade secrets that they obtain in the course of their duties to anyone but the offices entitled to this effect by the law, and they cannot use them for their own benefit or for that of third parties.

## **SECTION FOUR**

### **Civil Responsibility, Administrative Sanctions & Penal Clauses**

#### **Basic Principles of Responsibility**

**ARTICLE 14** – (1) Those who perform activities related to GMOs or products thereof are responsible of the damages on the protection and sustainability of human, animal, plant health, the environment and biological diversity even if they have duly obtained permits under the present Law. This responsibility is also valid even if no damage results from a GMO or product thereof, understood to be not complying with the conditions stated in the application and in the decision.

(2) Those who exercise activities of contained use, placing on the market for food, feed, processing or consumption purposes, importation and transit passage of GMOs and

products thereof without obtaining a permit and those who release into the environment and produce GMOs are responsible of all sorts of damages resulting from said activities.

(3) In order to attribute an inflicted damage to GMOs, the damage must originate from the new characteristics of the organisms, their reproduction or modification or the transfer of the organism's modified material to other organisms. In the determination of responsibility arising from the damage, if the damage in question is originating from the genetic modification in agricultural, forestry, food and feed products is taken into consideration.

(4) Those who cause or aggravate damages due to handling the GMO's placed on the market for any purpose whatsoever in a manner contrary to the conditions of the decision or otherwise, and those who commercially produce, process, distribute or market the same are severally responsible of these damages.

(5) Those who place on the market, commercially process, distribute or market the GMOs and products thereof are obliged to inform one another about the possible damages and responsibility arising there from.

(6) Those who handle GMOs are obliged to cover the expenses of the measures required to be taken according to the results of the risk assessment in order to prevent or alleviate any eventual damage to the environment. Those who are responsible of damages are also obliged to cover the expenses of restoring the damaged or destroyed elements of the environment to their original forms or replacing them with identical elements of the same value.

(7) The right to claim compensation for the damages inflicted by GMOs and GMO products continues for two years after the suffering party realizes the emergence of the damage and the identity of the responsible; and in any case for twenty years after the occurrence of the event that caused the damage.

(8) The aforementioned responsibility dispositions do not apply in case it is determined that the damage is caused by natural disasters such as flood, hail, landslide, earthquake or gross negligence of those who suffered the damage or of third parties.

#### **Administrative sanctions and penalties**

**ARTICLE 15 –** (1) Those who import, produce and release genetically modified plants or animals into the environment, contrary to the rule of this law are punished with prison terms of five to twelve years and with judicial fines lower than 10,000 days.

(2) Those who import or process the GMOs or GMOs and products thereof under the provisions of this law, use, put on to the market, sell, and hand over for the purposes in areas other than the ones indicated on the import permit or buy for trading purposes, accept, transport or hold by knowing this attributes of products are punished with prison terms of four to nine years and with judicial fines of lower than 7000 days.

(3) Those who import or process the products obtained from GMOs under the provisions of this law, use, put on to the market, sell, and hand over for the purposes in areas other than the ones indicated on the import permit or buy for trading purposes, accept, transport or hold by knowing this attributes of products are punished with prison terms of three to seven years and with judicial fines of lower than 5000 days.

(4) Those who get permission under the rule of this law by submitting false information in the applications are punished with prison terms of one to three years provided that there is no other crime committed which requires more penalty. Obtaining a decision on the basis of false information for importation, processing, usage, putting to the market, sales, hand over, accepting, transporting or holding of GMO, GMO and products thereof and products obtained from GMOs under this unlawfully obtained decision is punished in accordance with the above mentioned penalties.

(5) In the event that the acts defined in the present Article are committed within the activities of a corporate body and benefit of corporate body, the corporate body in question is sanctioned with an administrative fine of 100,000 to 200,000 Turkish Liras according to the severity of the act. Besides security sanctions that are specific to the corporate body should also be taken.

(6) Applicants who fail to fulfill their obligations under Article 7 of the present Law are sanctioned with an administrative fine of 10,000 Turkish Liras to 30,000 Turkish Liras for each failure provided that their actions are not subject of any other abuse.

(7) Those who exercise contained use of GMOs and products thereof contrary to the rule of this law are sanctioned with an administrative fine of 10,000 Turkish Liras provided that their actions are not subject to any other abuse.

(8) Those who contravene the dispositions of Sub-Paragraph (8) of Article 9 are punished pursuant to Article 4 of the Law on Working Restrictions of Former Public Office Holders #2531 dated 02/10/1981.

(9) Court is responsible to determine the administrative sanctions under sub-paragraph 5 and public prosecutor is responsible to determine the administrative sanctions under sub- paragraphs 6 and 7 of the present Law. Administrative fine charged according to the Law is paid within one month after its notification.

## **SECTION FIVE**

### **Regulations & Final Dispositions**

#### **Regulations**

**ARTICLE 16** - (1) The regulations related to the implementation of this Law shall be published by the Ministry within three months at the latest from the date of the publication of the Law.

#### **Effectiveness**

**ARTICLE 17** - (1) The present law enters into vigor six months after the date of its publication.

**Execution**

**ARTICLE 18** - (1) The provisions of the present law are executed by the Council of Ministers.