PROJECT OF IMPLEMENTATION OF
NATIONAL BIOSAFETY FRAMEWORK FOR TURKEY

GUIDELINES ON
CONTROL AND TRACEABILITY OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS

REPUBLIC OF TURKEY
MINISTRY OF FOOD AGRICULTURE
AND LIVESTOCK

TAGEM
R&D AND INNOVATION

GEF

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FOREWORD

In an effort to protect the environment and biodiversity against the potential risks of genetically modified organisms, the Cartagena Protocol on Biosafety -the first international document that is of a binding nature in this area- took effect around the world on 11 September 2003 and in Turkey on 24 January 2004. The protocol seeks to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also considering its risks to human health, and specifically focusing on transboundary movements.

The Biosafety Law, which was prepared by taking the Cartagena Protocol, the EU Acquis, the situation and needs of the country into consideration, was approved by the Turkish Grand National Assembly on 18 March 2010, published in the Official Gazette no. 27533 of 26 March 2010 and entered into force on 26 September 2010. The Biosafety Law aims 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 and 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.

Within the scope of the Biosafety Law the "Regulation on the Genetically Modified Organisms and Their Products" and the "Working Principles and Procedures of the Biosafety Board and Committees" were published on the Official Gazette No. 27671 of 13 August 2010.

In order to develop the capacity needed for ensuring biosafety within the scope of the national and international legislations, the project titled "Support for

the Implementation of the National Biosafety Framework of the Republic of Turkey" was prepared and accepted by the Global Environment Facility (GEF). The project was implemented between 2013 and 2017 under the coordination of the Directorate General of Agricultural Research and Polices (DGARP). Within the scope of the project, five guidelines were prepared by considering the works of national consultants and the contributions of the relevant partners obtained during the workshops, which were conducted at the preparation stages of some of the guidelines. The following guidelines have been developed: "Application Guideline", "Technical Guideline for the Risk Assessment of Genetically Engineering Crops and Derived Food And Feed", "Socio-economic Evaluation Criteria for the Decision-Making Process Regarding GMOs and Products", "Guidelines on Control and Traceability of Genetically Modified Organisms and Products" and "Legal Guideline".

Our General Directorate considers the works conducted for raising public awareness during the project, the documents prepared as outputs of the project and overall project experience significant gains. I hope that these guidelines, which were prepared within the scope of the project, will be useful. I also congratulate and thank everyone who contributed to the project, especially the UNEP-GEF Portfolio Manager (Biosafety) Alex Owusu-BINEY, Project Assistant Birgül GÜNER, Project team consisting of Hilal YÜCE ARSLAN, Ayfer ŞAHİN and Serdar AYDEMİR, national consultants Professor Emine OLHAN, Professor Mustafa Fadıl YILDIRIM, Associate Professor Remziye YILMAZ, Dr. Seval ÜNALAN and Fatih KAYA.

Dr. Yusuf ARSLAN
Project Coordinator

PRESENTATION

Our country has become a party to the Cartagena Biosafety Protocol, the first international document that has binding power in this regard, to ensure the protection of the environment and biodiversity against possible risks of genetically modified organisms.

The countries that are party to the Cartagena Biosafety Protocol must take legal, administrative and other measures that are necessary and appropriate to fulfill their obligations under the protocol.

Within this scope, Biosafety Law has been prepared and put into practice by taking into account the Cartagena Biosafety Protocol, the European Union acquis and the current situation and needs of our country.

According to the Biosafety Law and with a view to protecting human, animal and plant life and ensuring the protection and sustainable use of the environment and biological diversity; the import, export, 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.

In Article 7 titled "Procedures following the decision", the provisions of paragraph one "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" and the provisions of paragraph three "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" must be complied with.

In an effort to inform the actors dealing with GMOs and products thereof on the inspection and traceability of GMOs and products thereof in Turkey, this study was prepared under the coordination of the Directorate General of Agricultural Research and Policies, Department of Field Crops Research and within the scope of titled "Support for the Implementation of the National Biosafety Framework of the Republic of Turkey", which is supported by the United Nations Global Environment Facility Grant.

PROJECT OF IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORK FOR TURKEY

Operational starting date	:	30/09/2013
Official end	:	16/08/2017
Trust Fund	:	GEF
Period	:	GEF IV
Implementing Agency	:	UNEP
Project executing organization	:	Ministry of Food, Agriculture and Livestock (MFAL), General Directorate of Agricultural Research and Policies (GDAR)
Cost of Project	:	1.292.650$
Cost to the GEF Trust Fund	:	542.650 $
Co-financing	:	750.000 $
Project Coordinator	:	Dr. Yusuf ARSLAN
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CONTENTS

CHAPTER 1

INTRODUCTION AND GENERAL INFORMATION

With the development of modern biotechnology in the last 20 years, the primary production, i.e. farming, of Genetically Modified Organisms (GMOs) has grown exponentially within years, especially in the America Continent.

While 1.7 million hectares of land were planted in the world in 1996, this area has exceeded over 180 million hectares today. These large quantities of products from primary production are presented to the world market either directly or after being processed.

As of today, most of the soybean and corn trade in the world is made in the form of genetically modified (GM) soybean and GM maize. The most important use of GMOs and products thereof is the feed industry.

As Genetically Modified Organisms (GMOs) and the products produced therefrom are constantly increasing over the years, it is predicted that GMOs may have effects on human and animal health, environment and biodiversity.

Therefore, it has become an obligation to establish an administrative, legal and institutional structure, i.e. a biosafety system, and to operate it effectively, in order to ensure that the activities related to GMOs and products thereof are carried out safely and all the risks that may arise are prevented.

1. Legal and Organizational Structure;

1.1. Legal Structure:

In an effort to protect the environment and biodiversity against the potential risks of genetically modified organisms, the Cartagena Protocol on Biosafety -the first international document that is of a binding nature in this area- took effect around the world on 11 September 2003 and in Turkey on 24 January 2004.

With the precautionary approach in the Cartegena Protocol on Biosafety and Principle 15 of Rio Declaration on Environment and Development, it is committed that an adequate level of protection shall be provided in the field of safe transport, treatment and use of live GMOs produced using modern biotechnology, which may have adverse effects on the conservation and sustainable use of biodiversity, in particular by considering risks to human health and cross-borders movements.

In order to fulfill the commitment made in the Cartagena Biosafety Protocol, by taking account of the situation and needs of our country and the European Union Acquis, the Biosafety Law No. 5977 was issued in the Official Gazette No. 27533 dated March 26, 2010.

A six-month transition period was envisaged to ensure that those engaged in GMOs and products thereof are able to comply with the law. Therefore, the Biosafety Law entered into force on September 26, 2010.

Biosafety Law aims 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 and it establishes a legal and administrative system.

Modern biotechnology applications operate in a wide range of fields such as crop production, food, animal husbandry, health, environment and industry.

However, the Biosafety Law excludes veterinary medicinal products, human and medicinal products licensed or permitted by the Ministry of Health, and cosmetic products.

Therefore, the Biosafety Law covers all other products and industries, except for the products that are specified to be out of scope, and it affects a wide area.

For the implementation of the Biosafety Law, two regulations were published in the Official Gazette dated 13 August 2010. These Regulations are;

- **"Regulation on the Working Principles and Procedures of the Biosafety Board and Committees"** which sets out the procedures and principles of the Biosafety Board, the list of experts and the formation, work and mandates and powers of the Committees,
- **"Regulation on the Genetically Modified Organisms and Their Products"** which sets out the procedures and principles related to research, development, processing, placing on the market, monitoring, utilization, import, export, transit, transportation, preservation, packaging, labeling and storage regarding the Genetically Modified Organisms.

1.2. Organizational Structure:

Within the scope of Article 9 of the Biosafety Law, a Biosafety Board is formed with the participation of representatives of relevant Ministries, universities and professional organizations, to carry out risk assessments of the applications regarding GMOs and products thereof.

The Biosafety Information Exchange Mechanism of Turkey (www.tbbdm.gov.tr) has been established in order to enable the public to easily access the information and decisions about biosafety and especially to make sure that the society becomes involved in the decision-making process.

The Biosafety Law vests the authority to conduct monitoring, inspection and control activities related to GMOs and products thereof to the Ministry of Food, Agriculture and Livestock.

The Ministry of Food, Agriculture and Livestock has been tasked with coordinating with other relevant Ministries the import of GMOs and products thereof which are stated to be used in industries other than seed, food or feed industry and controlled by other Ministries.

In addition, Article 8 of the Biosafety Law authorizes the Ministry of Food, Agriculture and Livestock to take urgent decisions and carry out all kinds of arrangements for the protection and sustainability of human, animal plant health, the environment and biological diversity in case that it is caused or predicted to be caused by GMOs and product thereof. This Article increases the efficiency of biosafety system in particular.

The Ministry of Food, Agriculture and Livestock has established an institutional structure together with the Ministry and local units in order to inspect and control plant health, animal health and food and feed safety within the scope of Law No. 5996 on Veterinary Services, Plant Health, Food and Feed.

Instead of establishing a separate institutional structure for the implementation of inspection and control activities related to GMOs, it has been decided to carry out the inspection and monitoring activities related to GMOs and products thereof through the institutional structure that carries out control and auditing activities related to plant health, animal health, food and feed safety in the current situation.

Inspection and monitoring activities related to GMOs and products thereof within the country are carried out by the Provincial Directorate of Food, Agriculture and Livestock.

However, the local organization of the Ministry to conduct the control at the entry into the country (import) stage depends on the source of the product (animal or vegetable) and the industry it will be put into use.

Generally speaking, GMO controls are also carried out by the Directorate of Agricultural Quarantine or the Directorate of Veterinary Border Control or the Provincial Directorate of Food, Agriculture and Livestock, which carries out checks on plant health or food or feed safety.

The Provincial Directorates, Directorates of Agricultural Quarantine and the Directorates of Veterinary Border Control, which are authorized for the control of plant health, animal health, food and feed safety, as well as the customs directorates to conduct the said controls were determined with “Communiqué

on Determination of Customs Administrations Authorized for the Entrance of the Specific Products which Are Subject to Inspection of the Ministry of Food, Agriculture and Livestock and Determination of Provincial Directorates of Food, Agriculture and Livestock Authorized to Handle Official Inspections" published in the Official Gazette dated 05 October 2013 and numbered 28786.

Since the provincial organization conduct the control changes depending on the source of the product (animal or vegetable) and the industry to be used, the Ministry of Economy publishes the " Communiqué on Import Inspection of Products Subject to Control by the Ministry of Food, Agriculture and Livestock" at the end of December each year in order to inform the and customs administrations.

In this Communique;

- List number ANNEX-1a/b covers products subject to Veterinary Control,
- List number ANNEX -2 covers Plant Food and Feed,
- List number ANNEX -3 and ANNEX-7 cover Products subject to Agricultural Quarantine Control.

The importer is required to apply to the competent provincial organization for the GMO controls, taking the abovementioned lists into consideration.

Table for Determining the Authorized Local Organization for GMO Controls at Import Stage				
Product	**List included**	**Purpose of Use**	**Ministry**	**Authorized General Directorate**	**Authorized Local Organization**
Plant or Plant Products	ANNEX-3 or ANNEX-7*	Seed or Production Material	Ministry of Food, Agriculture and Livestock (MoFAL)	Directorate General of Food and Control (DGFC) - Department of Border Inspection for Plant and Plant Products	Directorate of Agricultural Quarantine or Provincial Directorate of Food, Agriculture and Livestock
Plant or Plant Products	Annex-2	Food and Feed	MoFAL	DGFC - Department of Border Inspection for Plant and Plant Products	Provincial Directorate of Food, Agriculture and Livestock
Animal and Animal Products	Annex-1a/b	Food and Feed	MoFAL	DGFC - Department of Border Inspection for Animal and Animal Products	Directorate of Veterinary Border Control
Animal or Plant Products	Products which are included or not included in the lists but to be used in industries which are not in the control of the Ministry.	Purposes other than Food and Feed or Seed	Other Ministries under the coordination of MoFAL	DGFC and relevant General Directorates of other Ministries	Directorate of Agricultural Quarantine or Provincial Directorate of Food, Agriculture and Livestock And relvant units of other Ministries For example: 1-Controls on cotton to be used in textile industry shall be conducted by the Directorates of Agricultural Quarantine. 2- Controls on products to be used in bioetanole production shall be conducted by the Directorates of Agricultural Quarantine.

* In case that the product to be imported is included in the lists of both Annex-2 and Annex-7, inspections related to GMO and products thereof are carried out by the provincial directorates of Food, Agriculture and Livestock.

CHAPTER 2

ISSUES TAKEN INTO ACCOUNT IN ESTABLISHING THE INSPECTION SYSTEM

The following considerations are taken into account in the inspections and controls to be carried out regarding biosafety.

1. Prohibitions:

According to the Biosafety Law, the following acts are prohibited and the inspection mechanism is shaped according to the prohibition clause.

a) Placing GMO and products thereof on the market without approval is prohibited.

In order for GMOs and products thereof to be placed on the market in our country at a certain price or free of charge, a positive decision as a result of the evaluations to be made by the Biosafety Board must enter into effect upon its publication in the Official Gazette.

Therefore, it is necessary to check whether a positive decision is made by the Biosafety Board related to the GMO determined in the inspections to be performed.

In addition, as it is understood from this article, entry of GMOs and products thereof into Turkey is not prohibited but its import and therefore its use is subjected to a predetermined approval procedure.

Genetically modified products approved by the Biosafety Board can be allowed to enter the country, and there is no problem in processing these products in line with their intended use and placing them on the market.

b) Using or letting others use the GMOs and products thereof in breach of Board decisions is prohibited.

In addition to the rules set out in the Laws and Regulations, new rules can be set by the positive decisions of the Biosafety Board on the conditions for duration of validity, procedures to be applied in import, purpose of use, data required for risk management and monitoring the market, monitoring conditions, documentation and labeling conditions, packaging, transportation, preservation and transportation rules, conditions for processing, waste and residual treatment and disposal, safety and emergency measures for the applications made by the importer or gene owner.

It must be controlled during the inspections whether the relevant parties comply with the rules set by the decisions of the Biosafety Board.

c) Producing genetically modified plants and animals is prohibited.

One of the purposes of the law is to ensure sustainability through the protection of the environment and biodiversity. To this end, the primary production of directly modified genetically engineered plants and genetically modified animals is prohibited.

Therefore, seeds/production materials and live animals that have been found to be the Genetically Modified Organism are strictly prohibited to enter the country except for agencies who are authorized to conduct research on them and those who receive R & D permission from the Ministry.

It is also necessary to control and monitor whether GM plants with germination ability permitted to enter the country for use in the feed industry are used as seeds and whether they are released freely into the environment.

In the Biosafety Law, there is no ban on the production of Genetically Modified Microorganisms (GMM). Therefore, if the Biosafety Board permits GMM, there is no problem in conducting controlled production in closed areas.

ç) Using GMOs and products thereof beyond the purpose and area indicated by the decision of the Board on the placing them on the market is prohibited.

Permission is given by the Biosafety Board in accordance with the intended use designated and requested by the applicant.

Therefore, the product allowed to enter the country should be used/handled and processed only in accordance with the intended use allowed in the Biosafety Board Decision.

In inspections to be carried out domestically, it is necessary to control whether the GMO and product thereof are used for the purpose and area determined by the Biosafety Board.

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 is prohibited.

Considering prudential principle and in accordance with this prohibition article for the protection of future generations, even if the Biosafety Board will take a positive decision for food use in the future, it is prohibited to use genetically modified organism and products thereof in baby food and baby formula, follow-on food and follow-on formula, baby and young children nutritional supplement.

2. Risky Product and Risky Country

In the "Regulation on Genetically Modified Organisms and Products Thereof" the definitions are as follows;

- Genetically Modified Organism (GMO): Any live organisms –except human beings– such as plant, animal or microorganism obtained through gene transfer by modern biotechnological methods.
- Genetically Modified Microorganism (GMM): Microorganisms whose genetic structure has been altered by way or processes other than natural recombinations,
- GMO and products thereof: Products partly or completely obtained from GMOs which contain or consist of GMOs.
- Products obtained from GMOs: Products partly or completely obtained from GMOs which do not contain GMOs themselves or do not consist of GMOs.

To ensure effective implementation of GMO inspections and controls and efficient use of public resources (time, personnel, laboratories), risk based (reduced or increased) inspection system is applied on the basis of risky products and risky countries.

2.1. Risky Product

Products that have been obtained by transferring genes using modern biotechnological methods and legally cultivated and traded in various countries, which were once subject to trade although their trade is not registered today and whose biotechnological researches have been completed in certain countries but have not yet been subject to registered trade are considered in the risky product category.

Within this scope, corn, soybean, rapeseed, cotton, papaya, potato, tobacco, sugar beet, rice, tomato, wheat, bean, eggplant, zucchini, sweet pepper, sugar cane, chicory, melon, plum clover, cottonwood poplar, petunia, carnation rose, turnip, grass, apple, shelled red lentils and flower pollen are considered in the risky product category.

This list is updated taking the developments in the world into consideration.

2.1.1. Products obtained from GMOs / Advanced Processed Products

Products such as sugar, sucrose, dextrin, invert sugar syrup, glucose syrup/powder, refined oils, maltodextrin, fermented organic acids and fermented drinks which are obtained from risky products but it is not possible to obtain enough DNA for GMO analysis as they are subjected to advanced processes such as high temperature, drying, distillation, chemical processes etc. or which do not contain DNA in their structure, are considered advanced processed products.

Where advanced processed products are produced from GMO raw materials, these products are regarded as products derived from GMOs.

In order for products obtained from GMOs to be imported into the country, the relevant GMO must be approved by the Biosafety Board.

2.2. Risky Country

Countries that allow the primary production of GMOs, their use in the food and feed industries and trade and countries that allow GMOs use and trade even though they do not allow primary production are considered risky countries.

As a result of the reviews and evaluations made on international resources, countries such as North and South American countries, European Union countries, African countries, Egypt, Ukraine, Iraq, Russia, China, India and Iran have been identified as risky countries.

In case of risky products coming from risky origin, GMO controls are carried out within the framework of the analysis frequencies determined and constantly updated by the Ministry.

In imports of risky products not coming from risky countries, controls are made at reduced rates.

3. Biosafety Board Decisions

The following decisions were taken by the Biosafety Board as of the date this guideline was published:

- 7 Genetically Modified Soybean species were allowed to be used only as feed or feed raw materials in animal feed.
- 25 Genetically Modified Maize species were allowed to be used only as feed or feed raw materials in animal feed.

- Soybean oil obtained by processing of GM soybeans allowed entering the country are allowed to be used in paint industry, the alkyd resin industry and the metal industry as a mold release agent. However, such decision was not made for the oil obtained from GM maize.
- In import of such process agents as additive substance, enzyme etc. obtained from microorganisms, it has been decided that food and feed safety inspections should be carried out only under the Law No. 5996.
- **There is no Genetically Modified Organism approved for use in the food industry.**

Decisions taken by the Biosafety Board can be accessed via the website of Biosafety Information Exchange Mechanism of Turkey at www.tbbdm.gov.tr.

Import and production of foods which are declared to be used in the food industry or which are found to contain GMOs as a result of the controls shall not be allowed as there is no GMO approved by the Biosafety Board for food.

Entry into the country is allowed for feed that is found to contain less than 0,1% GMO that has been applied to the Biosafety Board but has not yet been approved or whose approval period has expired.

With respect to GMOs determined in the inspections carried out by the Ministry, it is taken into consideration whether the approval of the Biosafety Board is obtained and whether application for approval is made to the Biosafety Board related to the relevant GM variety.

CHAPTER 3

INSPECTION AND TRACEABILITY

1. Import Inspection;

1.1. Certificate of GMO or non-GMO

As required by clause a in paragraph 1 of Article 14 of the "Regulation on Genetically Modified Organisms and Products Thereof", a certificate issued by the competent authorities of the country of origin or country of loading or an analysis report from a laboratory of international accreditation is requested from the importing company at the stage of actual import and such certificate or report must show the amount of GMOs and products to be imported and the gene type they contain.

Documents prepared by the competent authorities of the country of origin or country of loading or, the documents of GMO analyses obtained from an internationally accredited laboratory which show that the product does not contain GMO are accepted by the Ministry as well.

If the above-mentioned documents are not submitted to the Ministry, GMO analysis is made within the scope of the analysis frequency determined, and in case of submission of these documents, **the GMO analysis is made at a reduced frequency.**

The documents mentioned above must be submitted to the Ministry during the actual import stage and attention must be paid to the following points in the document.

Document must;

1. a- Include the distinctive identification information and amount of the GMO in the product, or

   b- Include information that the product is not a GMO, does not contain GMOs, is not composed of GMOs, and is not derived from GMOs.

2- Include Product Name, quantity, identification information of the product (batch / serial number, transport vehicle or information to identify transport vehicle in bulk products).

3- Include information on at least the importer or exporter or manufacturer company.

4- The certificate must be issued by the competent authority or the internationally accredited laboratory on GMOs.

5- In case of submission of documents from internationally accredited laboratories on GMOs, the parameters analyzed ("including Promotor, Terminator such as GMO Screening Analysis p35S, tNOS, pFMV etc." and "GM types with/without Promotor / Terminator such as p35S, tNOS, pFMV etc.), if available, the types and quantities of GM detected and methods of analysis should be included.

6- The document described above is requested for import of microorganisms and products containing microorganisms and it is mandatory to provide this document.

7- For the import of advanced processed products, the certificate issued by the competent authority or the manufacturer's or importer's declaration that the product is not produced from a GMO raw material is sought. The documents to be issued by the manufacturer or importer must also contain product identification information as stated above.

1.2. The Stage of GMO Inspections

In the Regulation on Genetically Modified Organisms and Products Thereof, it is defined as follows: "Import: means taking of goods produced abroad in exchange at a certain price or free of charge and subjecting them to free circulation entry procedure".

Therefore, the inspections and controls to be carried out on the GMO and products thereof are required to be carried out at or before the stage of entry into free circulation and at the time and place requested by the importer company (on the ship or after being taken to the warehouse area).

However, the products to be taken to the customs area (warehousing) must be carried according to the rules on delivery and transportation determined in the Biosafety Board Decisions and must be stored according to the rules determined in the Regulation.

GMO controls must be made where the product comes to the customs and **where actual import controls are requested.**

1.3. Documents taken into account in GMO controls

The following documents to be presented by the importer to the Ministry shall be taken into account in GMO controls,

- Product component list
- Labeling information (original and/or in Turkish)
- Certificate,
- Invoice or shipping documents if available,
- Documents relating to GMO contents.

If the above-mentioned documents contain one or more of the products identified as risky for the GMO in the content of the product, GMO controls are carried out within the scope of the analysis frequency.

1.4. Conformity or non-Conformity for Import

1.4.1. Conformity for Import

As a result of document control or GMO analyses carried out during the import stage, Biosafety Board Decisions are taken into account in deciding whether product's entry into country is suitable or not.

If the same certificate content is to be discharged in more than one customs offices to be imported on the same ship and this situation is notified in advance to the provincial directorate, sampling is taken to represent the whole of the ship by the provincial directorate which performs the initial inspection and there is no GMO control again in other cases.

Samples are taken from only one batch of products of the same component, but of more than one batch coming in the same shipment. If the result of the analysis is positive, all batches of products are allowed to enter the country.

Besides, except for the control of GMOs, plant health, food or feed safety controls are made and the products which are legally approved are allowed to enter the country, and a declaration of conformity is sent to the customs office indicating that the entry of the products into the country is appropriate or this situation is reported via the Single Window System.

a- Products to be use in Feed Industry

As a result of document control or GMO analyses carried out during the import phase, the Biosafety Board makes the necessary evaluations and permits the entry into the country of the feeds identified as containing GMOs and/or products thereof approved for placing on the market as feed after the labeling rules are fulfilled.

In addition, feeds that are not identified with GMO as a result of the official controls are allowed to enter into the country.

According to Article 14 of the Law, the records of the products allowed by the Ministry to be imported as containing GMOs are kept on the basis of the company and GMO.

b- Products to be use in Food Industry

As a result of document control or GMO analyses carried out during the import phase, food not identified with GMO are allowed to enter the country.

c- Seed and Production Materials

As a result of document control or GMO analyses carried out during the import phase, seed and production materials not identified with GMO are allowed to enter the country.

d- Products to be used in Other Industries

As a result of document control or GMO analyses carried out during the import phase, products to be use in other industries (cotton to be used in textile industry or maize to be used in bioetanole production) not identified with GMO are allowed to enter the country.

1.4.2. Non-Conformity for Import

The feeds identified with the GMOs and products thereof which are not approved by the Biosafety Board are not allowed to enter the country.

As there is no type of GM approved by the Biosafety Council for food, foods identified with GMOs are not allowed to enter the country.

Besides, entry into the country is not allowed for feed that is found to contain more than 0,1% GMO that has been applied to the Biosafety Board but has not yet been approved or whose approval period has expired.

Non-conformity is addressed to the customs authorities with regards to products for which entry into the country is found to be unsuitable, or non-conformity is reported via the Single Window System.

1.5. GMO Products not allowed to be Imported to Country

The following provisions apply to GMOs and products that are not allowed to enter the country.

A- Rejected.
   1. Returned to the country of origin or dispatch
   2. Sent to a country other than the country of origin of dispatch (a 3rd country)

B- Allowed to be subjected to Special Processing

C- Allowed to be used for other purposes

D- Disposed of.

A- GMO and Rejection of Products:

Products identified as non-conforming to the Biosafety Regulation through import controls can be returned to the country of origin at the request of importer.

However, upon requests for shipment to a third country, relevant authority of the destination country should notify the Ministry about approval of products.

B- Special Processing:

In case a unifactorial product (paddy, shelled red lentils etc.) is determined as containing any GMO contaminant of another product type within the official controls of import process, the importer may request application of any physical special processing methods such as peeling and washing to ensure decontamination.

The Regulation on the Genetically Modified Organisms and Their Products identifies GMO contaminant as: “GMO contamination refers to GMOs that contaminate a

product, which either has been subject to gene modification technology or not, during production, manufacturing, handling, preparing, processing, packaging, transport or storage including the primary production stage, or GMOs that cannot be technically avoided, prevented or that has adventitiously contaminated the product due to environmental factors" and according to this definition, the **threshold of %0.9 or below is used for contamination level** (Low Level Presence)."

The decision regarding the request of special processing is taken after the first examination. Therefore, together with a written objection to results of the first examination, the importer should submit an application for special processing to the local organization responsible for the control process.

Products identified with GMO contamination may be permitted for application of special processing methods such as shelling, washing, peeling etc.

After special processing, new samples are taken from the products and following steps are determined in line with the results of a second examination.

Within this scope, entry of products identified as containing one or more genes approved by the Biosafety Board into the country is permitted for the purpose of placing them on the market as feed.

However, the Biosafety Board forbids any use of GMO and products thereof in foods. The foods identified as contaminated with GMO are not allowed to be placed on the market.

C- Use for other purposes:

Where products are determined to be non-conforming for the entry in terms of intended purpose of use stated in official documents through official controls within the import process, the importer may request a change in the purpose of use.

The importer should submit the request for a change in the purpose of use after the first examination.

Entry of products into country is permitted when the GMOs determined through the GMO Scanning analyses are approved by the Biosafety Board and the importer declares that the product will be used in accordance with the permitted purpose of use.

For instance; where a product identified as containing a type of GM maize is approved for the purpose of using in food industry, but after the controls the Biosafety Board allows its use only in feed industry, upon request of the importer, entry of the product may only be permitted to be used in feed industry.

D- Disposal:

Although the national regulations do not permit entry of GMO and products thereof into the country, products identified as containing GMO have a commercial value in global markets.

In this regard, it is requested from the importer to send relevant product to the country of origin or a third country. According to the provisions stated by the Biosafety Board, a decision for the disposal of the product is taken against the product in case it cannot be shipped to the country of origin or a third country or cannot be used for any other purpose.

2. Labeling

During the import process and upon arrival to the country of destination, products are controlled in terms of labeling in an effort to avoid any misunderstanding in public opinion, ensure public awareness and prevent unfair competition among companies.

2.1. Labeling as GMO

In line with the decision of the Biosafety Board and only for approved types of genes, the sublimit for GMO labeling (labeling threshold) was determined as 0.9% and entered into force.

According to the Labeling Provisions of the Regulation on the Genetically Modified Organisms and Their Products and the Biosafety Board Decisions, in case of "being obtained from GMO or containing any component obtained from approved GMO or containing GMO or being made of GMO" with the rates over the labeling threshold determined by the Ministry (0.9%), the feed product should be appropriately labeled before being placed on the market or the relevant information should be written in sales sheets.

It is not mandatory to label the feed products identified with GMO levels under the threshold limit (0.9%) within document controls or analyses as GMO. However, these products cannot be labeled as non-GMO, either.

2.2. Labeling as non-GMO

According to the Regulation on the Genetically Modified Organisms and Their Products, labels of equivalent non-GMO food/feed products may contain any information indicating that the products do not contain any GMO, are not composed of GMO or made of GMO.

The Regulation describes equivalent non-GMO products as "any product of food or feed which has not been processed with genetic modification technology and does not contain any kind of GMO".

a- Labeling as non-GMO for Feed :

As the Biosafety Board permits the use of GM Maize and GM Soybean in feeds, labels of feed products with equivalent "soybean and soybean products" or "maize and maze products" that do not contain GMO in compounds may include any information indicating that the products "do not contain GMO or are not composed or made of GMO".

Labeling feed products as non-GMO is non-obligatory and based on voluntariness. Furthermore, in an effort to avoid any public misunderstanding that import of other kinds of feed products with GMO compounds is permitted by the authorities, it is not allowed to label feed products containing equivalent non-GMO types of products unapproved by the Biosafety Board, other than maize and soybean, (such as canola and cotton) as non-GMO, even though they are often merchandised all over the world.

b- Labeling as non-GMO for food:

As the Biosafety Board forbids any use of GMO and products thereof in food products, entry of GMO and products thereof into the country for the purpose of use in food industry is not allowed.

In an effort to avoid any public misunderstanding that import of GMO and products thereof is allowed by the authorities, it is forbidden to label food products containing equivalent non-GMO types of products as non-GMO.

In this regard, it is not allowed to place any statement, figure or logo on labels of food products indicating that the product does not contain any GMO, is not composed and made of GMO.

Such information on labels is also forbidden in any languages other than Turkish.

3. Sampling, Analysis and Assessment

3.1. Sampling:

Samples should be taken in accordance with the sampling methods determined by the Ministry and in consideration of the intended use of the products.

GMO samples from the feed products should be taken in accordance with the provisions of "the Regulation on Sampling for Official Control of Feed and Methods of Analysis" which was published on the Official Gazette No. 29955 of 21 January 2017 pursuant to EU legislation.

Sampling methods for food are also set forth in "the Sampling Method for GMO Control in Food" in reference to aforementioned provisions.

Sampling process of the products intended for use in seeding is implemented in accordance with "the Regulation on Sampling for GMO Analysis of Seed".

Points to take into account during the sampling process;

1. Competent authorities should take all relevant measures to avoid any possible contamination.
2. Sampling devices and methods, workbenches and sample containers to be used during the process should be clean and dry. The controllers should keep records of all conditions related to cleanliness.
3. Samples to be taken for GMO Control should be in quantities determined by sampling methods.
4. Samples taken for GMO analysis should not be disrupted and used for any other kind of analyses. Likewise, samples for other analyses should not be disrupted and used for GMO analysis.
5. The competent officials should submit objections (if any) before the "Sampling" report is signed. Objections regarding the sampling process shall not be accepted after this phase.
6. In domestic controls, samples should be taken from the raw materials rather than processed products. Samples should be taken from processed products only if the former is not applicable.

3.2. Analysis and Assessment:

1. Samples taken for GMO Control should be conveyed to competent laboratories accredited by the Ministry for the use of GMO analyses. List of laboratories authorized by the Ministry is accessible in www.tarim.gov.tr.
2. Analyses are conducted in accordance with "the Instructions on the Implementation of GMO Analysis Strategy".

a- For food, analyses are conducted within the scope of GMO Scanning Applications.

b- For feed, analyses are conducted within the scope of GMO Scanning Applications and quantitative analyses are applied for the determined GM types.

c- For seeding and propagating products, analyses are conducted within the scope of GMO Scanning Applications.

3. Objections to results of the first analysis on the GMO sample should be submitted within 7 working days after the notification. Requests for special processing or change in intended purpose of use should also be submitted within this period. In case of any objection to results of the first analysis, the replicate sample is sent to a reference laboratory and used as a basis for further solutions.

4. Results of the analysis are assessed in accordance with the Biosafety Regulation and product's intended purpose of use. Entry of products not approved by the Biosafety Board into the country is not permitted.
   Entry of foods, seeding products and propagating materials identified as containing GMO into the country is not allowed.

5. GMO and products thereof approved by the Biosafety Board are assessed in consideration of the labeling threshold value.

6. Where relevant application is submitted to the Biosafety Board but not yet approved by the Board or the period given for approval expires, feeds identified as containing a type of GM at the threshold of 0.1% or below are considered as conforming for entry to the country.

4. Export Control of GMO and Products Thereof:

Export of GMO and products thereof and feeds obtained by processing these products is permitted when they are approved for entry into the country for the purpose of use in feed industry after the controls within import process.

Products not approved by the Biosafety Board cannot be imported for the purpose of export. Therefore, relevant GMO controls are applied to raw materials and products pursuant to the Domestic Processing Regime.

Products containing GMO are stated in the "Health Certificate" or "List of Appendices annexed with the Certificate" or "Certificate of Analysis annexed to the Certificate" issued within the export process.

All other relevant controls are applied in case that the purchasing (destination) country requests any other process in addition to the provisions mentioned above.

5. Transit Pass Controls of GMO and Products Thereof

Transit pass of all GMO and products thereof approved or not approved by the Biosafety Board (with or without application for approval) through the country is permitted.

Only document controls and identification controls are implemented during transit passes and the competent authorities to permit transit pass of products are determined as Provincial Directorates/ Directorates of Agricultural Quarantine /Directorates of Veterinary Border Controls.

Whether all necessary safety measures to prevent contamination of GMO and products thereof are taken by the competent operator and the documents of transportation are under seal are critical matters of transit pass processes.

Within this regard, the competent operators should apply to the relevant Directorate (Provincial Directorates/ Directorates of Agricultural Quarantine / Directorates of Veterinary Border Controls) by submitting all required documents containing information about the quantity of products, country of origin, type of GMO contained (and the certificate of analysis showing distinctive identities), means of conveyance, exit custom details and measures to be taken until arrival to exit customs.

The owner or carriers should take all necessary measures during loading and discharging processes in order to prevent contamination. For this purpose, products should be packaged by special materials resistant to tearing and fracture, vehicles to transport bulk products should be stretched with tarp to prevent contamination to the environment or the products should be carried with hardtop vehicles or containers.

The relevant Directorate permits transit pass of GMO and products thereof only after it is ensured that all necessary measures are already taken. Exit of these products approved for entry into the country should be confirmed by the relevant exit customs.

6. Domestic GMO Controls for products to be used in Food Industry

As a resulf of the controls within the import process, entry of GMO and products thereof to be used in food industry into the country is not allowed.

Further controls are implemented to ensure that products entered into the country in purpose of use in feed industry are not used in food industry.

Where products are identified to be processed and placed on the market as food in violation of the Biosafety Law, responsible operator shall be turned to prosecution and placement of the products on market is prohibited.

7. Domestic Control and Traceability of GMO and Products Thereof to be used in Feed Industry

7.1. Domestic Control

Following the document controls or GMO analyses within the import process; entry of feeds assessed and determined as containing GMO and products thereof but approved by the Biosafety Board for placement on the market for the purpose of use in feed industry is only permitted if all labeling rules are met. All permitted products are monitored and checked to ensure conformity with the labeling and traceability rules.

According to the Biosafety Law, the Regulation on the Genetically Modified Organisms and Their Products and the Biosafety Board Decisions, GMO and products thereof on free movement inside the country should be monitored and all necessary traceability measures should be taken by the competent authorities.

Importers, processors and sellers of GMO feeds have certain responsibilities as referred to in Article 7 of the Biosafety Law and all competent operators should act in accordance with the requests of the Ministry regarding control and monitoring processes.

According to the paragraph (2) in Article 17 of the Regulation on the Genetically Modified Organisms, to follow up the distribution and selling process of the processed product, processor of feed products should keep all records about origins and quantities of purchased products, documents regarding the purpose of use, relevant forms prepared for purchased, processed and exchanged products and submit these documents to the Ministry when necessary.

The Ministry monitors all relevant processes to check compliance with provision of the Biosafety Board, regarding GMO and products thereof. In order to ensure traceability, necessary records should be kept during the import and free movement of GMO and products thereof and the Ministry should be notified about all processes. Labels of products should comply with the regulations as well.

All consignment invoices or delivery notes issued and used by the operators during processes of import, processing, storage, placement on the market should contain relevant information about the GMO and their products together with GMO types and quantities. Moreover, all competent bodies are severally responsible for ensuring monitoring and traceability pursuant to the Regulation. The relevant operators are held responsible in case of any failure in ensuring traceability.

According to the clause E of the Biodiversity Board Decisions titled as "Monitoring Conditions", the competent authorities should be notified about all information related to the imported maize and soybean products to be used in feed industry, including places of storage, quantity of stored and transported products, means of conveyance and delivery address, processing plants and quantity of products to be processed, market distribution, outlets in provinces and districts, types and quantity of packages, transportation and conservation measures and monitoring data. In this regard, all competent operators should act in accordance with the Traceability provisions as referred to in Article 21 of the Regulation on Genetically Modified Organisms and Their Products and prepare semiannual monitoring reports to be submitted to the Biosafety Board.

Soybean oil products obtained from domestically processed GM soybean is allowed to be used in paint and alkyd resin industries and as mold release agent in metal industry, but not in feed. However, oil products obtained from GM maize can only be used in feed industry as the decision does not apply to this product type.

For each purchased, processed, exchanged products and batches, the operators should fill in the "Entry Form for GMO and Their Products" and keep this form for a period of twenty (20) years to be submitted in controls of the Ministry.

ANNEX-4

ENTRY FORM FOR GMO AND THEIR PRODUCTS/PRODUCTS OBTAINED FROM GMO	
Data of the Purchased Product	
Vendor	
Invoice date and number	
Quantity (kg/ton/l/unit)	
Distinctive Identification No. of the GMO Type	
GMO Decision Number	
Batch/Serial Number *	
Vehicle registration plate(s) **	
Data of the Processed Product (If any)	
Name of the product	
Quantity (kg/ton/l/unit)	
Batch/Serial Number *	
Data of the Sold Product	
Purchaser	
Invoice date and number	
Quantity (kg/ton/l/unit)	
Distinctive Identification No. of the GMO Type	
Batch/Serial Number *	
Vehicle registration plate(s) **	

* Not applicable to bulk products.

** Given in enclosed if required.

Company Executive / Owner

Name, Signature, Stamp

Furthermore, all competent operators, particularly the importer company, who place GMO and products thereof on market and/or process, distribute and commercialize these products should inform each other about possible damages and the liabilities in case of damages. In this regard, the entry form given above should be kept up to the process where the product reaches the end consumer.

Transportation of GMO and products thereof should be carried out in accordance with the Biosafety Board Decisions. For this purpose, products should be packaged by special materials resistant to tearing and fracture, vehicles to transport bulk products should be stretched with tarp to prevent contamination of products to the environment or the products should be carried with hardtop vehicles or containers.

7.2. Traceability

Provincial Directorates are authorized to ensure traceability for GMO and products thereof and to take all necessary measures within this scope. This authority entails relevant Directorates to keep all traceability records and perform all necessary controls regarding the GMO and products thereof permitted to be used as feedstuff, throughout the processes of entry, movement, processing and storage. Details about distribution of GMO feed products in our country is summarized in the chart given below.

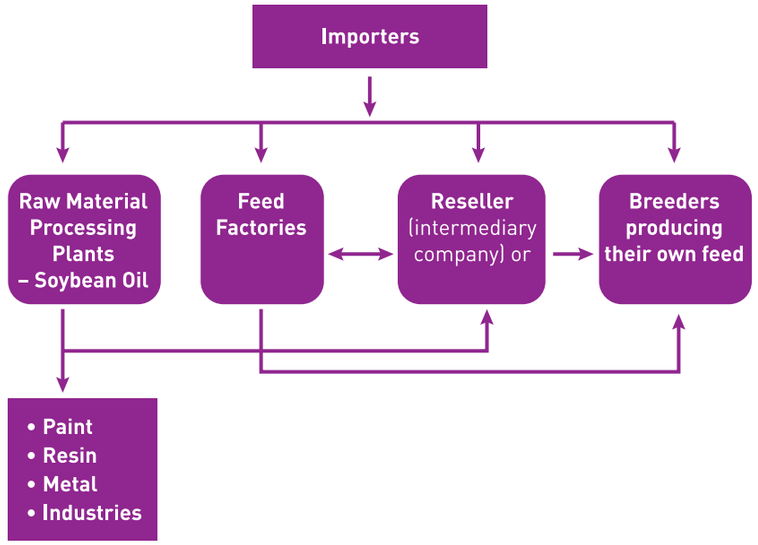

Figure 1 | GMO Feed distribution chart

According to the Biosafety Law, cultivation of GMO products is forbidden in our country. Soybean and maize products that are permitted to be used in feed industry are obtained through import from other countries. GMO maize, soybean and products thereof may be commercialized within the country after the necessary controls are applied within the import process. Importer companies sell these products to feed factories, resellers or dealers, breeders who produce their own feed and raw material processing plants. Other intermediary companies are allowed to purchase and sell these products as well. All these companies keep traceability reports about processes of entry, movement, processing and storage of GMO products and inform relevant Directorate of Provincial Food Agriculture and Livestock on a monthly basis. Provincial Directorates prepares semiannual traceability reports and send them to the Directorate General of Food and Control. Accuracy of these reports and information is checked by the Official Controllers during regular visits to companies.

Semiannual traceability tables prepared by the Provincial Directorates of the Directorate General of Food and Control (DGFC) are analyzed and used in final GMO Monitoring Reports. GMO Monitoring Reports are conveyed to the Biosafety Board Secretariat before being submitted to the Board. A chart regarding the monitoring notification process is given in Figure 2.

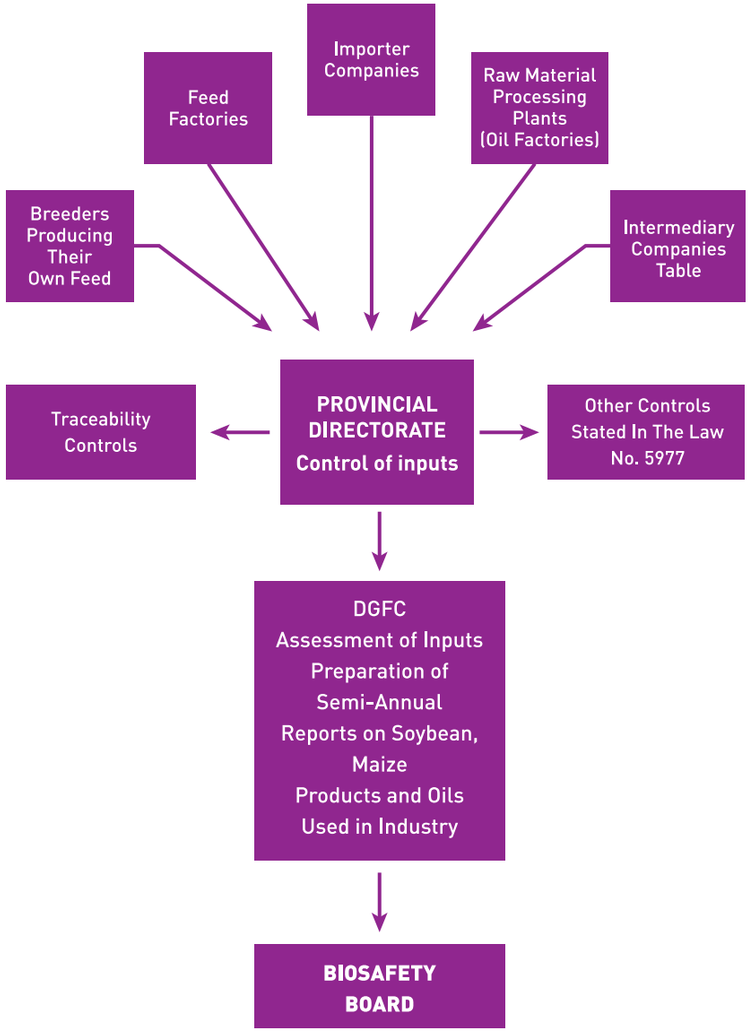

Figure 2 | Monitoring Notification Chart

Points to take into account during traceability control;

- All consignment invoices or delivery notes issued and used by the competent operators during processes of import, processing, storing, placing on the market should be checked in order to ensure existence of relevant information about GMO and their products, including GMO types and quantities of products.
- Companies/entities are controlled to ensure **"Entry Form for GMO and Their Products/Products Obtained from GMO"** given in Annex-4 of the Regulation on Genetically Modified Organisms **is regularly filled out.**
- All the data stated in **"Entry Form for GMO and Their Products/Products Obtained from GMO"** are compared with invoices or dispatch notes in terms of conformity.
- Quantities and vendors given in traceability records submitted to Provincial Directorates are checked in terms of conformity.
- Labels or invoices/dispatch notes of commercialized products are controlled in terms of conformity with the GMO Regulation.
- Sales declared by the vendor are controlled in terms of accuracy by occasional visits to purchasers.
- In case of any violation against GMO traceability and labeling provisions, legal action is taken according to the Biosafety Law No. 5977.

PROJECT OF IMPLEMENTATION OF
NATIONAL BIOSAFETY FRAMEWORK
FOR TURKEY

GUIDELINES ON
CONTROL AND TRACEABILITY OF
GENETICALLY MODIFIED
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