



Required Report: Required - Public Distribution

Date: November 20, 2023 **Report Number:** TU2023-0035

Report Name: Agricultural Biotechnology Annual

Country: Turkiye

Post: Ankara

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Nergiz Ozbag

Approved By: Michael Francom

Report Highlights:

Turkey's Biosafety Law, which went into effect in 2010, continues to threaten imports and imposes a heavy financial burden on the country's agri-food sector. As of September 2023, there were only 36 events (corn and soy) that were approved for feed purposes. There are no events approved for food use due to public concerns about the technology. The most recent approval occurred last December when the Ministry of Agriculture & Forestry (MinAF) reauthorized a stacked corn event (NK603 X MON 810) and cancelled the single MON 810 event. To date, eight enzymes produced from GE Aspergillus oryzae have also been approved for feed and industrial use. In addition, one microbial mass (strengthened and inactivated GE Aspergillus oryzae) for feed purposes has been approved.

EXECUTIVE SUMMARY:

The Ministry of Agriculture and Forestry (MinAF) is the competent authority under the Biosafety Law, which went into effect in 2010, for reviewing and authorizing new biotech events for plants, animals, and microorganisms. With the exception of enzymes derived from GE microorganisms, the commercial production of biotech plants and animals is prohibited. Approved GE crops, like soybeans, can only be imported and used for livestock feed. The production of food containing GE ingredients is not allowed.

MinAF has set a cap on the total number of approved plant events, including soybeans and corn, for feed at 36. Anytime a new event is added, another must be canceled to stay under this limit. There are nine pending plant events, some of which have been waiting for approval since 2015. The most recent approval was in December 2022 when the government reauthorized the GE stacked corn event (NK603 X MON 810) after MON 810 was canceled due to a domestic court decision. In addition to approved GE plant products for feed, MinAF has approved eight enzymes and one inactivated microbial mass made from GE *Aspergillus oryzae* for different industrial uses.

Imports of U.S. soybeans completely stopped in 2019-20 because new events that were being grown in the United States had not yet been approved in Turkey. However, after the approval of several pending events, imports resumed in 2021. Notwithstanding the resumption in trade, there are still concerns that imports of U.S. soybeans and other commodities could be interrupted if approvals are delayed.

Turkey's low level presence policy (LLP only applies to **feed** since no events have been approved for use in food. There is a zero tolerance for unapproved events in feed unless the event is pending MinAF approval, in which case the threshold is 0.1 percent. For approved events that aren't listed on the import documentation, the limit is 0.9 percent.

The stringent LLP policy, the arbitrary limit on approvals, inconsistent testing practices, along with the Biosafety Law's harsh penalties have created lasting uncertainty in the marketplace, disrupted imports, increased the cost of doing business, and contributed to higher agricultural prices in Turkey. According to one independent economic study, the cost burden of Turkey's "GMO regulations" on the country's agri-food sector was \$1.5-2.0 billion from 2009-2020.

There is periodic misinformation in the Turkish media about GE products and their safety. This has resulted in skeptical public opinion of biotechnology and widespread misunderstanding and fear about the technology.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY PART A: Production and Trade PART B: Policy PART C: Marketing

CHAPTER 2: ANIMAL BIOTECHNOLOGY PART D: Production and Trade PART E: Policy PART F: Marketing

CHAPTER 3: MICROBIAL BIOTECHNOLOGY PART G: Production and Trade PART H: Policy PART I: Marketing

ABBREVIATIONS:

Besd-Bir: Turkish Poultry Meat Procedures and Breeders Association CPB: Cartagena Protocol on Biosafety EU: European Union EPPO: European and Mediterranean Plant Protection Organization FAS: Foreign Agricultural Service of the United States Department of Agriculture FAO: Food and Agriculture Organization of the United Nations GE: Genetically Engineered HPC: High Planning Council **IPPC:** International Plant Protection Convention LLP: Low Level Presence MinAF: Ministry of Agriculture and Forestry of the Turkish Republic NGO: Non-governmental Organization OECD: Organization for Economic Co-operation and Development OIE: World Organization for Animal Health TAGEM: Agricultural Research and Policies General Directorate of Ministry of Agriculture and Forestry

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Article 5(1) (c) of the Biosafety Law bans the cultivation and production of GE plants and animals. This prohibition prevents the private and public sector from pursuing the commercial development of GE plant products. However, the law permits the regulated study and development of plant biotechnology for research purposes only. This research is very limited, according to academics, because of strict requirements and concerns over liability.

According to the Law and its implementing regulations, an application or permit is not required for agricultural biotechnology research, but the researcher must inform MinAF's Agricultural Research and Policies General Directorate (TAGEM) of the project within three months of its completion. Researchers must apply to TAGEM for a permit to import GE material and derived products for the purpose of research, development, and training or educational activities. TAGEM is required to make a decision to authorize the permit within 15-days.

Since MinAF has not yet established rules for conducting field trials, restrictions, research activities must remain in the laboratory stage. Despite these restrictions, in the last few years, Turkey's Scientific and Technological Research Council has increased the amount of grant money for biotech research projects. Universities are also teaching biotechnology courses and doing some limited research in this field.

GE plants are prohibited from being cultivated in Turkey and are, therefore, not used in producing antibiotics or pharmaceuticals for human or animal disease.

b) COMMERCIAL PRODUCTION

Article 5(1) (c) of the Biosafety Law bans the cultivation and production of GE plants and animals.

c) EXPORTS

There is no commercial production of GE crops in Turkey, and Turkey does not export GE crops to the United States or other countries, aside from grain transshipments.

d) IMPORTS

According to the Biosafety Law, Turkey has the authority to separately approve events for feed, food, and industrial products. As of September 2023, there were 21 corn and 15 soybean events approved for feed use. No GE events have been approved for food use, so any GE presence found in food is illegal.

Commodity traders have encountered import problems due to Turkey's asynchronous approvals for feed. Non-DNA-containing products derived from GE plant sources, like corn oil from GE corn, are subjected to the rules of Biosafety Law and are not allowed to be imported unless the event has first been approved for food use. Importation of GE seeds is also forbidden by the Law and by the seed circular.

The trade of non-biotech products, such as wheat and rice, have also been negatively affected by the impacts of the Biosafety Law. Shipments of these commodities have been rejected in the past because of

the Low-Level Presence (LLP) of GE content, such as dust from GE corn or soy. These rejections and changing market conditions have largely deterred U.S. companies from shipping these commodities to Turkey.

Some import violations of the Biosafety Law have been prosecuted under the charge of "biological terror" and the accusation of causing harm to Turkey's agricultural sector. With the intention of reducing the instances of prosecution for LLP in imports, MinAF amended the implementing regulation of the Biosafety Law to define the term "contamination" in the Regulation in May 2014. According to some sources, this change appears to have had some impact in reducing overly harsh penalties, such as imprisonment. Domestic poultry and livestock producers using imported feed products are still suffering from the financial burden of ongoing court cases and the GE traceability burden (see Part B, section (g)).

Testing of imported products remains inconsistent and continues to be a considerable cost for importers. The unpredictable situation has increased costs and contributed to increased public suspicion of GE products.

Due to insufficient domestic production and increasing demand, Turkey imports approximately half of its compound feed needs for its poultry, livestock, and aquaculture sectors. Previously, the United States was among the top suppliers of soybeans and distillers dried grains to the Turkish market, but imports have been greatly affected by the limited number of approved GE events and MinAF's testing measures (see Part B). Trade has been restricted out of concern that dust or minor LLP of GE traits in feed and food products would lead to the rejection of shipments.

The concern of LLP detection caused importers to avoid buying soybeans from the United States starting in 2018. By 2020, imports of U.S. soybeans were reduced to almost zero. Despite paying higher prices for feed materials, Turkish importers looked to other international sources for soybeans and derivative products. At the beginning of 2021, after MinAF approved six new GE soybean events, Turkish importers started buying U.S. soybeans again. From that time until June of this year, imports of U.S. soybeans have reached about 630,000 MT. However, imports of U.S. soybeans have slowed during the first half of 2023 because of competitive soybean imports from Black Sea suppliers. Notwithstanding the resumption in trade, there are still concerns that imports of U.S. soybeans and other commodities could be interrupted if approvals are delayed.

In January and April 2022, MinAF approved a total of three more soybean events which are commercialized in South America and not grown in the United States.

Please see Part B of this chapter for detailed information about the approvals.

e) FOOD AID

Turkey is not a food aid recipient country. As no GE products are approved for food use in Turkey, and Turkey is not a producer of GE products, food assistance products procured in Turkey would not be GE. Transit of GE products for food aid is allowed but must be permitted through MinAF which oversees document checks and monitoring.

f) TRADE BARRIERS

- Turkey has approved significantly fewer GE traits than the European Union. Currently, the government maintains an arbitrary cap on the total number of approved events at 36.
- Turkey's approval process is slower than approval systems in many countries.
- Turkey has a zero tolerance for the detection of unapproved GE traits, with the exception of a 0.1 percent tolerance in feed for GE traits that are pending approval.
- The frequency sampling and testing imported commodities depends on the foreign competent authority's declaration whether the cargo in question does or does not include GE. Countries that regulate and declare GE products are subject to stringent testing whereas countries that do not declare GE shipments are not subject to the same controls.
- The Biosafety Law contains liability, sanction, and penalty clauses that penalize noncompliance with large fines and five to twelve years in prison.

PART B: POLICY

a) REGULATORY FRAMEWORK

Turkey's regulation of agricultural biotechnology is governed by the <u>Biosafety Law</u> (Law No: 5977), implemented on September 26, 2010, and related implementing regulations. MinAF published two implementing regulations of the Biosafety Law published on August 13, 2010. These are "<u>Regulation on Genetically Modified Organisms (GMO) and Products</u>" and "<u>Regulation on the Working Principles of the Biosafety Board and the Committees</u>."

Following the adoption of the Biosafety Law in 2010, MinAF established a Biosafety Board to review GE food and feed import applications and nominated its Agricultural Research and Policies General Directorate (TAGEM) as the secretariat of the board. The board had nine members who were high level MinAF bureaucrats and other subject-related ministries. The board established two committees, the Scientific Risk Assessment Committee, and the Socio-Economic Assessment Committee to evaluate each application and make a recommendation for approval. These committees were made up of experts from the scientific community, such as academia and public research institutes. The independent Biosafety Board reviewed and, where appropriate, approved the committees' recommendations for final approval.

However, the Biosafety Board was abolished by the Decree Law No: 703 which was published in the Official Gazette on July 9, 2018. Shortly thereafter, MinAF was authorized to conduct the tasks and responsibilities of the abolished Biosafety Board via a Presidential Circular published in the Official Gazette on August 1, 2018. MinAF subsequently re-appointed TAGEM as the secretariat of the committees and TAGEM re-established the Scientific Risk Assessment and Socio-Economic Committees to review pending and any new application dossiers. After receiving both committees' evaluations, the Minister of MinAF has the exclusive decision-making authority to approve the event in question, and that decision is published in the Official Gazette.

Following the 2018 presidential elections, nine Presidential Policy Councils were established. One of these councils is entitled the "Council of Health and Food Policies," was assigned the tasks of developing policies, strategies, and monitoring the implementation of biotechnology. The Council has seven members, two of which are food or agriculture related members, and the remainder are health and medical professionals, such as doctors, dentists, and dietitians. The role of the Council in the regulatory approval process is unclear.

For more information about the approved events for feed, please see Part B, section (b) of this Chapter on Approvals and for information about the approved enzymes refer to Chapter 3 of this report on Microbial Biotechnology.

The Biosafety Law bans the planting of GE seeds, the cultivation of GE plants, and the production of GE animals. It also prohibits the inclusion of GE ingredients in baby food and supplementary foods for young children.

Legal Term (in	Legal Term (in	Laws and	Legal Definition
Turkish)	English)	Regulations where	(in English)
		term is used	
Modern	Modern	Biosafety Law	The application of
Biyoteknoloji	Biotechnology		in vitro nucleic acid
		Regulation on the	techniques enabling
		Working Principles	direct
		of the Biosafety	transfer of rDNA
		Board and the	and nucleic acid
		Committees	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.
		Diagofaty Law	
Constile Vanisi	Consticully	Diosalety Law	Any living
Degistirilmis	Modified Organism	Pagulation on the	Any inving
Organizma (CDO)	(CMO)	Working Principles	organisin -
Organiizina (ODO)		of the Biosofety	including plant
		of the biosalety	menualing plant,

Board and the Committees Regulation on	animal and microorganism – obtained through gene transfer by
Genetically Modified Organisms (GMO) and Products	modern biotechnological methods.

Application process and timeline

According to the Biosafety Law, either the gene-owning technology companies or importers of GE crops are allowed to submit applications for the approval of a GE event. Within 90 days, TAGEM decides whether or not the application is accepted and also the type of evaluation procedure, either simplified or regular. Once decided, TAGEM informs the applicant within fifteen days whether the application is accepted or not.

In order to apply under the simplified procedure, per the rules set by MinAF, the following conditions should be met:

- Taxonomy and biology of the gene source and the receptor live organism should be known.
- Sufficient information should be available regarding the possible effects on human, animal, environmental health, and biological diversity.
- Previous risk assessments that can be used regarding the relations of the GE event with other live organisms should not have indicated any negative effects.
- 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.
- The GE product should be approved in the country where it is developed or registered for release into the environment and placed on the market for consumption. (Article 3 (8) of Law)
- Authorization of GE product should not be expired in the country where it is developed.
- The results from the previous risk assessments as well as socioeconomic and ethical evaluations should be provided where available.

Once an application dossier is accepted and a review procedure is determined by TAGEM, in principle the regular procedure reviews are completed by the TAGEM Committees within 270 days. The 270-day clock stops when additional information or documents are requested from the applicant. In practice, the approval time for an application can take much longer than 270 days.

Based on the Committees' assessments, the Minister of MinAF decides whether or not to approve the event in question. Turkey requires an approval in the country of production before an application can be submitted in Turkey, which makes asynchronous approvals unavoidable.

Unlike the regular procedure, decisions made using the simplified procedure are not published in the <u>Biosafety Information Exchange Mechanism of Turkey</u>, the web platform in the Turkish language for public opinion and information exchange, decreasing the time required for a decision.

In the past, MinAF had requested that international companies that have developed agricultural GE events submit applications under the law as quickly as possible after the application has been approved in the country of origin in order to avoid trade problems. However, companies have expressed concerns about the vagueness of the application procedures, as well as the severe yet unclear liability provisions in the Biosafety Law. The liability provisions of the law include harsh penalties that may involve lengthy jail terms for unspecified "related parties." The law also lacks explicit guidance about what documents are required and how the applications will be evaluated. Furthermore, it contains onerous labeling and traceability requirements once the product arrives in Turkey.

Given the penalties and lack of clarity in the Biosafety Law, Turkish agriculture industry associations have instead submitted the dossiers and paid the application fees so they could import the feed needed for the sector. After a 10-year period of sector associations serving as applicants, a private feed company made an application for a GE soybean event in 2020 for the first time and received approval in 2021.

Updates to Regulations

The last noteworthy update to the Biosafety Law and its implementing regulations happened in May 2014. At that time, with the intention of reducing the instances of prosecution for LLP in imports, MinAF amended the implementing regulation of the Biosafety Law. The amendment defined the term "contamination" as used in the Biosafety Law and established a 0.9 percent threshold over which products are considered "contaminated." However, the amendment does not clearly explain how "contamination" changes the ability to market products or commodities with GE events that are unapproved in Turkey. For detailed information, please see GAIN report "Turkey Amends Biotechnology Regulation." Please also refer to Part B (i) regarding Turkey's LLP policy.

LLP is considered, globally, to be a compliance issue and not a food safety issue, and so defining LLP detections above 0.9 percent as a "contamination" is not in step with international standards like Codex Alimentarius.

b) APPROVALS/AUTHORIZATIONS

Either the gene-owning technology companies or importers of GE crops may apply for approval of a GE event in Turkey. Applicants are required to provide a dossier containing technical information and data on the event to be approved and pay an application fee. The current application fee is 81,000 Turkish Lira (TL) (\$2,977 where \$1 =27.203 TL) per event and the extension fee per previously approved event is 40,000 TL (\$ 1,470 where \$1=27.203 TL). To date, no technology-owning companies have submitted an application to be reviewed by the Biosafety Board or MinAF. Instead, Turkish agriculture industry associations and one private feed production company have made the applications. Under the Turkish Biosafety Law, approval for biotech events automatically expires after ten years and a new application must be made to renew the events.

Currently, there are 36 (15 soybean and 21 corn) events approved for feed. Among the approved events, there are several with approval dates from more than ten years ago. According to the implementing regulation, approvals of expiring events are automatically extended until MinAF renews the approval if

the applicant in question requests the renewal of the approval at least one year before it expires. In January 2021, the applicant filed to renew these events.

Please see the current list of approved events in below Table 1 and pending applications in Table 2. The approved events are also accessible through the **Turkish Biosafety Information Exchange Mechanism** at the link <u>http://www.tbbdm.gov.tr/OnayliGDO2.aspx</u> in the Turkish language. Approvals are officially announced by the Turkish Government in the Official Gazette at the link <u>https://www.resmigazete.gov.tr/</u> in the Turkish language.

Table 1: Approved Events for Feed

No	Product	Developer	Event	OECD Unique Identifier	Approval Date
1	Corn	Syngenta	Bt11	SYN-BTØ11-1	12/24/2011
2	Corn	DuPont Pioneer	DAS1507 (TC1507)	DAS- Ø15Ø7-1	12/24/2011
3	Corn	Dow AgroSciences LLC	DAS59122	DAS-59122-7	12/24/2011
4	Corn	Monsanto	NK603	MON-ØØ6Ø3-6	12/24/2011
5	Corn	Syngenta	GA21	MON-ØØØ21-9	12/24/2011
6	Corn	Monsanto	MON89034	MON-89Ø34-3	12/24/2011
7	Corn	Monsanto	MON88017	MON-88Ø17-3	4/21/2012
8	Corn	Syngenta	MIR604	SYN-IR6Ø4-5	7/16/2015
9	Corn	Monsanto	MON863	MON-ØØ863-5	7/16/2015
10	Corn	Bayer CropScience	T25	ACS-ZMØØ3-2	7/16/2015
11	Corn	Syngenta	Bt11xMIR604	SYN-BTØ11-1x SYN-IR6Ø4-5	11/5/2015

12	Corn	Syngenta	MIR162	SYN-IR162-4	11/5/2015
13	Corn	Syngenta	MIR604xGA21	SYN-IR6Ø4- 5xMON-ØØ21-9	11/5/2015
14	Corn	Monsanto	MON 87460	MON 8746Ø-4	8/2/2017
15	Corn	Monsanto	MON87427	MON-87427-7	1/23/2021
16	Corn	Dow AgroSciences LLC	DAS-40278-9	DAS-4Ø278-9	2/27/2021
17	Corn	DuPont (Pioneer Hi-Bred International Inc.)	4114	DP-ØØ4114-3	1/7/2022
18	Corn	Monsanto	MON87411	MON-87411-9	4/27/2022
19	Corn	Syngenta	MZIR098	SYN-ØØØ98-3	4/27/2022
	Corn			SYN-Ø53Ø7-1	10/13/2022
20	Com	Syngenta	5307		10/13/2022
20	Corn	Syngenta Monsanto	5307 NK603XMON810	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6	12/30/2022
20 21 22	Corn Soybean	Syngenta Monsanto Bayer CropScience	5307 NK603XMON810 FG 72	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6 MST-FGØ72-2	12/30/2022 1/23/2021
20 21 22 23	Corn Soybean Soybean	Syngenta Monsanto Bayer CropScience DuPont	5307 NK603XMON810 FG 72 DP305423	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6 MST-FGØ72-2 DP-3Ø5423-1	12/30/2022 1/23/2021 1/23/2021
20 21 22 23 24	Corn Soybean Soybean Soybean	Syngenta Monsanto Bayer CropScience DuPont Monsanto	5307 NK603XMON810 FG 72 DP305423 MON87701	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6 MST-FGØ72-2 DP-3Ø5423-1 MON-877Ø1-2	12/30/2022 1/23/2021 1/23/2021 7/16/2015
20 21 22 23 24 25	Corn Soybean Soybean Soybean Soybean	SyngentaMonsantoBayer CropScienceDuPontMonsantoDuPont (Pioneer Hi-Bred International Inc.)	5307 NK603XMON810 FG 72 DP305423 MON87701 DP356043	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6 MST-FGØ72-2 DP-3Ø5423-1 MON-877Ø1-2 DP-356Ø43-5	10/13/2022 12/30/2022 1/23/2021 1/23/2021 7/16/2015 11/5/2015
20 21 22 23 24 25 26	Corn Soybean Soybean Soybean Soybean Soybean	SyngentaMonsantoBayer CropScienceDuPontMonsantoDuPont (Pioneer Hi-Bred International Inc.)Bayer CropScience	5307 NK603XMON810 FG 72 DP305423 MON87701 DP356043 A5547-127	MON-ØØ6Ø3-6 x MON-ØØ81Ø- 6 MST-FGØ72-2 DP-3Ø5423-1 MON-877Ø1-2 DP-356Ø43-5 ACS-GMØØ6-4	10/13/2022 12/30/2022 1/23/2021 1/23/2021 7/16/2015 11/5/2015 11/5/2015

28	Soybean	BASF	CV127	BPS-CV127-9	8/2/2017
29	Soybean	Monsanto	MON87705	MON-877Ø5-6	8/2/2017
30	Soybean	Dow AgroSciences LLC	DAS-44406-6	DAS-444Ø6-6	2/27/2021
31	Soybean	Monsanto	MON89788	MON-89788-1	2/27/2021
32	Soybean	Monsanto	MON40-3-2	MON-Ø4Ø32-6	2/27/2021
33	Soybean	Bayer CropScience	A2704-12	ACS-GMØØ5-3	2/27/2021
34	Soybean	BASF	SYHT0H2	SYN-ØØØH2-5	1/7/2022
35	Soybean	Monsanto	MON87751	MON-87751-7	4/27/2022
36	Soybean	Dow AgroSciences LLC	DAS81419	DAS-81419-2	4/27/2022

Table 2: Pending Applications for Feed

No	Product	Developer	Event	OECD Unique Identifier	Application Date	Status
1	Soybean	Monsanto	MON 87769	MON-87769-7	4/30/2015	Pending
2	Canola	Monsanto	GT73 (RT73)	MON-ØØØ73-7	5/11/2015	Pending
3	Canola	Monsanto	MON88302	MON-883Ø2-9	5/11/2015	Pending

4	Canola	Bayer CropScience	MS8 RF3 MS8xRF3	ACS-BNØØ5-8, ACS-BNØØ3-6, ACS-BNØØ5-8 X ACS- BNØØ3-6	5/11/2015	Pending
5	Canola	Bayer CropScience	HCN28 (T45)	ACS-BNØØ8-2	5/11/2015	Pending
6	Soybean	Dow AgroSciences LLC	DAS-68416-4	DAS68416-4	7/13/2021	Pending
7	Corn	Monsanto	MON 87403	MON874Ø3-1	6/27/2022	Pending
8	Corn	Syngenta	MZHGOJG	SYN-ØØØJG-2	6/27/2022	Pending
9	Soybean	BASF	GMB151	BCS-GM151-6	6/27/2022	Pending

c) STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

Turkey treats stacked events as novel and processes their approval separately from the approval of each individual event in the stack. The Committees follow the same assessment procedures followed for individual events.

d) FIELD TESTING

Currently, Turkey does not have any field tests of products derived from agricultural biotechnology. The law's prohibition of cultivation and commercialization discourages the private and public sector from pursuing the development of GE products. TAGEM has been working on the process for allocating "specifically controlled fields" to scientists for research and development field trials but there is no publicly available information regarding this issue yet.

e) INNOVATIVE BIOTECHNOLOGIES

In MinAF's scientific community and some academic platforms, gene editing has been discussed for the last few years. However, Turkey has not determined a regulatory status of innovative biotechnologies in plants or plant products of said technologies.

f) COEXISTENCE

Since the Biosafety Law prohibits the cultivation of agricultural biotechnology, there is no coexistence policy in place in Turkey.

g) LABELING and TRACEABILITY

According to the Biosafety Law and implementing regulations, any approved imported food or feed containing, consisting of, or deriving from GE crops above the labeling threshold set by MinAF (established as 0.9 percent via an internal Agriculture Ministerial Directive in 2011) must be labeled as a "GMO" for consumers' right to know purpose. For the bulk products, "GMO" information must be

provided together with the products in question or must be visibly displayed immediately next to it for the final consumers. The conventional counterpart of any GE food or feed product may be labeled as "does not contain/consist of/derived from GMO" or "GMO Free."

Traceability clauses in the Biosafety Law and implementing regulations require that records be kept for a minimum of 20 years, detailing the unique identifier of the gene, quantity, supplier, and purpose of use, each time a product is processed or handled, from the time of import to the time of distribution to the market. The Turkish government rolled out a computer system for recordkeeping and tracking the movement of GE feed ingredients and products since 2017. The business operator (any person at each stage of business, such as importer, distributor, wholesaler, retailer etc.) must submit documents which contain information related to the GE feed ingredients and products via the computer system to MinAF and keep the records for 20 years.

The implementing regulations also require that: "genetically modified organisms and products thereof are processed and stored in separate production lines. In the event that this is not possible, the production lines and storage facilities must be cleaned by the interested parties in a manner to prevent any contamination with genetically modified organisms and products thereof and the circumstance must be committed to records."

h) MONITORING and TESTING

The testing protocol of the government is not published. There is the potential for every shipment to be tested for GE content and unapproved GE traits. Designated local official laboratories conduct the import tests and the National Reference Laboratory in Ankara retests when results are contested. Products that receive a positive detection prior to customs clearance may be sent to another country or origin/exporting country or destroyed in the absence of first two choices (provided several conditions are met; please contact FAS/Ankara for more details as the conditions are fluid). The importer of a shipment found to contain an unapproved trait after clearing customs may be prosecuted for violating the Biosafety Law.

Post's understanding that Turkey uses the quantitative PCR system for detecting, identifying, and quantifying GE content. Three main steps are typically followed in routine product analysis with qPCR methods. First, the potential presence of any GE event is assessed by a screening approach targeting the most common transgenic elements found in GE events such as p35S (35S promoter from cauliflower mosaic virus) and tNOS (nopaline synthase terminator from *Agrobacterium tumefaciens*). According to the positive and negative signals observed for the screening markers tested, GE events potentially detected are identified in a second step using qPCR techniques. Finally, the amount of identified GE events present in the tested food/feed sample is determined. This quantification step is carried out based on the number of copies to allow the simultaneous identification of GE events.

i) LOW LEVEL PRESENCE (LLP) POLICY

Turkey has a zero tolerance for LLP of GE events not approved in Turkey for food, feed, and industrial products, subject to the liability provisions of the Biosafety Law. MinAF follows the approach of the Commission Regulation (EU) No: 619/2011 with legislation that allows trace amounts of unapproved biotech content in feed up to a "technical zero" level of 0.1 percent if the trace amount of GE content found is a trait currently being reviewed for approval.

On May 29, 2014, MinAF published a change to the regulation to define "contamination" and established a threshold of 0.9 percent for approved GE events in their "intended use." This wording implies that feed is the "intended use" category, because so far only events for feed use have been approved. Because GE events are approved only for feed use, the threshold does not provide any utility for detections in food. In practice it seems the 0.9 percent "contamination" refers to the allowed limit of an approved event not listed on the import documentation as one of the GE events in that shipment. MinAF has yet to clarify the implementation of the definition or threshold.

j) ADDITIONAL REGULATORY REQUIREMENTS

Article 5(1) (d) of the Biosafety Law prohibits the use of GE and products thereof in baby foods and infant formulas, follow-on formulas, and cereal-based supplementary foods for babies and young children.

Article 3(10) of the "Regulation on Genetically Modified Organisms and Products" thereof requires MinAF's permission for each transit passage of products containing GE content.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

The cultivation of GE crops is prohibited under the Biosafety Law, and so protection for patented seeds does not apply.

I) CARTAGENA PROTOCOL RATIFICATION

Turkey ratified the Cartagena Protocol on Biosafety (CPB) on October 24, 2003, and it entered into force on January 24, 2004. Turkey took CPB into consideration while preparing the Biosafety Law and its implementing regulations, but these legislations are not fully harmonized with CPB. Turkey sends a delegation to the CPB bi-annual Conference of the Parties serving as the Meeting of Parties on an irregular basis and does not actively participate in discussions. MinAF has recently nominated a representative for the CPB Ad-Hoc Technical Expert Group on risk assessment.

m) INTERNATIONAL TREATIES and FORUMS

Turkey is a member of several international organizations dealing with plant protection and plant health. These include the European and Mediterranean Plant Protection Organization (EPPO), the Organization for Economic Co-operation and Development (OECD), the Food and Agriculture Organization (FAO), International Plant Protection Convention (IPPC), and Codex. Turkey does not actively participate in discussions related to GE plant or seed varieties with international organizations. MinAF participates at some of their meetings on an irregular basis.

n) RELATED ISSUES

Turkey's Biosafety Law requires approval for use of products derived from agricultural biotechnology (excluding only pharmaceuticals and cosmetics, which are in the scope of the Ministry of Health). Food, feed, and other industrial uses of products derived from plant biotechnology require a separate application and approval.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Due to anti-GE campaigns, especially in the few years right after the Biosafety Law was published and reporting in the media (including popular health columnists and pop culture wellness experts), public

and private opinion in Turkey is dominated by misinformation on possible hazards from the consumption of products derived from agricultural biotechnology. There is a misperception that consuming GE products is linked to cancer. The Turkish government rarely refutes misinformation publicly, nor clarifies the science and safety behind the crops which are approved for use in Turkey or their approval process.

b) MARKET ACCEPTANCE/STUDIES

The fear of biotechnology by the Turkish public, producers, retailers, and consumers still continues. This is mainly due to anti-GE campaigns run by local and international anti-biotech NGOs such as the Chamber of Agricultural Engineers, Greenpeace, and the Friends of the Earth. Although public sentiment is resoundingly anti-GE, Turkey is import-dependent for plant-based protein for animal feed and some of these imported feed ingredients are GE.

Misleading health stories, such as claims that eating chicken fed with GE feed has negative health consequences, continue to show up in the media. Sales of animal products derived from animals fed with GE feed does not appear to be affected by such media misinformation. Post is unaware of any marketing studies that have evaluated Turkish consumer sentiment towards products derived from agricultural biotechnology.

Graham Brookes of PG Economics in Great Britain published the study "<u>Economic impacts of the</u> <u>Biosafety Law and Implementing Regulations in Turkey on the Turkish importing and user sectors</u>" in May 2012. The study estimated the cost to the Turkish agricultural sector of Turkey's restrictive regulatory system for biotech and concluded "...the ongoing annual cost can reasonably be expected to be between \$0.7 billion and \$1 billion and could be higher...". The study was updated by Graham Brookes of PG Economics in the fall of 2022 and concluded "...the cost burden incurred by the Turkish agri-food sector as a result of the "GMO" regulations comes to between \$1.53 billion and \$2 billion between October 2009-December 2020....". The study has been distributed to the related stakeholders in Turkey but has not yet been published online, as of October 2023.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT**

Article 5 of the Biosafety Law (Law No: 5977) bans the production of genetically engineered animals and plants.

b) COMMERCIAL PRODUCTION

GE animal production is banned.

c) EXPORTS

Not applicable.

d) IMPORTS

The Biosafety Law does not specific ban per se on imports of GE animals, but MinAF would first have to evaluate and approve an application for import. No application to import GE animals has been made.

e) TRADE BARRIERS

Not applicable.

PART E: POLICY

a) REGULATORY FRAMEWORK

Turkey's regulation of agricultural biotechnology is governed by the Biosafety Law (Law No: 5977), which was adopted on March 26, 2010, and related implementing regulations. Imports of GE agricultural products, which includes GE animals, is only allowed after approval of each event based on the intended use. For more information, please see Chapter I/ Part B (a).

b) APPROVALS

There are no approvals for GE animals.

c) INNOVATIVE BIOTECHNOLOGIES

There is no regulatory status of animals or animal products derived from innovative biotechnologies.

d) LABELING and TRACEBILITY

Products derived from approved GE animals would require a label indicating that it is or contains GE content.

e) INTELLECTUAL PROPERTY RIGHTS (IPR)

Not applicable.

f) INTERNATIONAL TREATIES and FORUMS

Turkey is a member of World Organization for Animal Health (WOAH) and the U.N. Food and Agriculture Organization (FAO), which deals with animal health. Turkey is not actively participating in discussions related to GE animals with international organizations.

g) RELATED ISSUES

Not applicable.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Turkish public opinion would likely be against animal biotechnology.

b) MARKET ACCEPTANCE/STUDIES

There are no studies on consumer sentiment related to market acceptance of animal biotechnology.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

In contrast to plant biotechnology, the production of microbial biotechnology products is allowed. In May 2020, MinAF issued its first approvals for three industrial enzymes made from the GE-improved *Aspergillus oryzae* fungus. Since that time, the Ministry has approved five other enzymes made from the same GE fungus for feed and industrial usage purposes. Please see the approved and pending enzymes in Tables 3 and 4 in Part H(b) of this Chapter.

b) EXPORTS

The Turkish government does not keep trade statistics for enzymes derived from GE microorganisms or non-GE microorganisms.

c) IMPORTS

Import of GE microorganisms requires MinAF's approval based on a scientific risk assessment and socio-economic evaluation. At this time, there are no approved GE microorganisms for import purposes.

MinAF requires a non-GE attestation provided by the competent authority of origin or exporting country or an analysis report provided by an internationally-recognized accredited laboratory for the microorganism to be imported. If this attestation is not provided, the product is not allowed to be imported. If a product arrives at Turkish customs without an attestation, the product might be directed to another country or sent back to the origin country on the decision of the importer and exporter.

Based on the decision taken by the now-abolished Biosafety Board in 2015, a non-GE attestation is not required for the import of food ingredients such as enzymes, food additives, food processing aids, etc. derived from GE microorganisms. These ingredients are not controlled at import to verify whether it is derived from GE microorganism or non-GE microorganism. For this reason, there is no import data available for food ingredients derived from GE microorganisms.

D) TRADE BARRIERS

Post is unaware of any trade barriers for food ingredients such as enzymes, food additives, food processing aids, etc., derived from GE microorganisms.

PART H: POLICY

c) REGULATORY FRAMEWORK

MinAF is the regulatory authority for agricultural biotechnology. Production or import of GE microorganisms and products derived from GE microorganisms are only allowed after the approval of each microorganism and/or ingredient for each use. Please see detailed information on regulatory framework, which is also valid for microbial biotechnology, in Chapter 1, Part B, section (a) of this report.

Legal term (in official language)	Legal term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Genetik yapısı değiştirilmiş mikroorganizma (GDM)	"Genetically Modified Microorganism (GMM)"	Biosafety Law " <u>Regulation on</u> <u>Genetically Modified</u> <u>Organisms (GMO)</u> <u>and Products</u> " Regulation on the Working Principles of the Biosafety Board and the Committees	A micro-organism which the genetic material has been altered in a way other than natural recombination.

b) APPROVALS/AUTHORIZATIONS

Production or import of GE microorganisms and products derived from GE microorganisms are only allowed after the approval of each microorganism and each ingredient for each use.

Article 3(1) of the Biosafety Law states that the contained use of GE microorganisms is only approved based on a scientific risk assessment. In 2018, following the private sector's applications to approve three different enzymes derived from GE *Aspergillus oryzae*, MinAF established a new Scientific Risk Assessment Committee specifically for reviewing the applications. Applications were also reviewed by the Socio-Economic Committee. To date, eight enzymes produced by GE *Aspergillus oryzae* have been approved. In addition, one microbial mass (strengthened and inactivated GE *Aspergillus oryzae*) for feed purposes has been approved.

The approval timeframe is approximately one and half years from the application stage to the announcement of the decisions in the Official Gazette. Approvals are valid for 10 years.

These approvals are accessible through the Turkish Biosafety Information Exchange Mechanism at the link <u>http://www.tbbdm.gov.tr/OnayliGDO2.aspx</u> in the Turkish language and through the Official Gazette at the link: <u>https://www.resmigazete.gov.tr/in Turkish language</u>. Please see approved and pending products from GE *Aspergillus oryzae* in Tables 3 and 4.

No	Microorganism	Developer	Unique Identifier Code	Product	Approval Date
1	Aspergillus oryzae	LIVZYM AS	LIVZ-101	Enzyme – Alpha-amylase (α-amylase)	5/6/2020
2	Aspergillus oryzae	LIVZYM AS	LIVZ-102	Enzyme – Glucoamylase	5/6/2020
3	Aspergillus oryzae	LIVZYM AS	LIVZ- 103	Enzyme – Hemicellulase	5/6/2020
4	Aspergillus oryzae	LIVZYM AS	LIVZ-105	Enzyme Protease/Mucorpepsin EC 3.4.23.23	1/7/2022
5	Aspergillus oryzae	LIVZYM AS	LIVZ-104	Enzyme – Phytase	4/27/2022
6	Aspergillus oryzae	LIVZYM AS	LIVZ-106	Enzyme – Lipase/Triacylglycerol Lipase (EC 3.1.1.3)	10/13/2022
7	Aspergillus oryzae	LIVZYM AS	LIVZ-107	Enzyme – Glucose Oxidase (EC 1.1.3.4)	10/13/2022
8	Aspergillus oryzae	LIVYZM AS	LIV-108	Mixture of Endo-1,4-beta- glucanase (E.C.3.2.1.4) and Endo-1,4-beta- xylanase (EC 3.2.1.8)	10/13/2022
9	Aspergillus oryzae	BIOWASTE AS	BT-101	Inactivated microbial biomass	10/13/2022

 Table 3-Approved products from approved GE-Aspergillus oryzae

No	Microorganism	Developer	Product (Enzyme)	Application Date	Status
1	Aspergillus oryzae	LIVZYM AS	Phospholipase A1(EC3.11.32)	12/2/2022	Pending
2	Aspergillus oryzae	LIVZYM AS	Microbial Collagenase (EC 3.4.24.3)	12/2/2022	Pending
3	Aspergillus oryzae	LIVZYM AS	Protease/Thermo mycolin (EC 3.4.21.65)	12/2/2023	Pending
4	Aspergillus oryzae	LIVZYM AS	Chymosin (EC 3.4.23.4)	5/5/2023	Pending
5	Aspergillus oryzae	LIVZYM AS	Asparaginase (EC 3.5.1.1)	5/5/2023	Pending

 Table 4-Pending products from pending GE-Aspergillus oryzae

c) LABELING and TRACEABILITY

Based on the decision of the abolished Biosafety Board, ingredients such as enzymes, food additives, and food processing aids that are derived from GE microorganisms do not require GE labelling nor tracing. These ingredients are labelled according to Law No. 5996 on Veterinary Services, Phytosanitary, Food, and Feed that is enforced by MinAF to ensure food and feed safety and inform consumers about ingredients of foods.

D) MONITORING and TESTING

There is no testing requirement for evidence of GE for imported or exported products containing GE microorganism-derived ingredients such as enzymes, food additives, food processing aids, etc. These products are not monitored in the aspect of being derived from GE microorganisms.

e) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

The Law on Industrial Property No.6769 (link in Turkish) was adopted on December 22nd, 2016, by the Turkish Parliament and entered into force by its publication in the Official Gazette No. 29944 dated January 10th, 2017. Law No. 6769 is an enforceable piece of legislation regulating trademarks, patents, designs, utility models, geographical indications, and traditional product names in line with EU standards and Turkey's local requirements. Law No. 6769 encompasses applications, registrations and post-registration processes regarding trademarks, geographical signs, design, patent, utility model and traditional product names and legal and criminal sanctions concerning the violation of these rights. There are no protected or registered microbial biotechnology agricultural products.

g) RELATED ISSUES

Not applicable

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Misinformation on possible hazards from the consumption of products derived from agricultural biotechnology has continued to be disseminated by anti-GE campaigns and non-science-based reporting in the media. However, the Turkish government has issued a general invitation to Turkish researchers who have been conducting research outside the country to return to Turkey, and support and accelerate the research and development activities in many areas, including the industrial usage of biotechnology. The Turkish government has supported the production of enzymes derived from GE microorganisms for industrial usage purposes based on the idea that the enzymes themselves are not GE since they do not have DNA. There is no negative public or private opinion on the production of enzymes by modern biotechnology.

b) MARKET ACCEPTANCE/STUDIES

There are no market acceptance studies or research on microbial biotechnology in Turkey.

Further Information: For the most up-to-date reports on Turkey's agriculture situation and policies, use the search function at <u>https://gain.fas.usda.gov/#/</u> or visit our website: <u>https://www.fas.usda.gov/</u>.

Attachments:

No Attachments