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Report Highlights:

Turkey published its Biosafety Law and implementing regulations in 2010. This legislation has continued to disrupt trade and Turkey's domestic agriculture and food sectors. As of September 30, 2020, there are only 36 (10 soybean and 26 corn) events approved for feed use in Turkey. No events are approved for food use or cultivation. Turkey approved the production of three enzymes for industrial usage purposes by using Aspergillus oryzae improved by modern biotechnological methods in May 2020. Testing of imported products remains inconsistent and continues to be a considerable cost for importers. The Ministry of Agriculture and Forestry (MinAF) is the only authority for biotechnology approvals.

EXECUTIVE SUMMARY:

There are currently 36 approved genetically engineered (GE) soybean and corn traits allowed to be imported to Turkey for animal feed. The most recent new GE traits were approved in August 2017 and 13 applications are still pending approval. No GE traits have been approved for human food use, so any GE presence in food products is prohibited. For feed, any approved GE product that contains more than 0.9 percent GE must be labeled as GE. There is a zero tolerance for the detection of unapproved GE traits, and a 0.1 percent low-level presence (LLP) tolerance in feed for GE traits pending approval in the application process.

The Ministry of Agriculture and Forestry (MinAF) approved the production of three enzymes which are alpha-amylase (α -amylase), glucoamylase and hemicellulose, by using *Aspergillus oryzae* improved by modern biotechnological methods on May 6, 2020.

The Biosafety Board, which had been active since 2010, was abolished by Decree Law 703 on July 9, 2018. MinAF has been authorized to conduct the tasks and responsibilities of the abolished Biosafety Board as of August 1, 2018.

Many commodity trading partners in Turkey have encountered import problems due to Turkey's lags in approvals of GE traits compared to other importing and exporting countries (asynchronous approvals) for food and feed.

Turkey's very low threshold for pending and unapproved varieties and lack of approvals of many varieties, has caused uncertainty in the market and disrupted imports. Testing of imported products remains inconsistent and continues to be a considerable cost for importers. The unpredictable situation has increased corporate risk and costs, contributed to high food prices in Turkey, and led to increased public suspicion of GE products.

There is much misinformation in the Turkish media about GE products and their safety. This has resulted in a very skeptical public and widespread misunderstanding and fear about agricultural biotechnology.

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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 GEF: The Global Environment Facility 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 **UNEP: United Nations Environment Program** TAGEM: Agricultural Research and Policies General Directorate of Turkey

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. **PRODUCT DEVELOPMENT:**

There are no GE plants under development for commercial or research purposes in Turkey.

b. COMMERCIAL PRODUCTION:

Article 5(1) (c) of the Biosafety Law bans the production of GE animals and plants. Importation of GE seeds is also forbidden by the Law and by the seed circular, which is usually published every January by MinAF.

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 transshipments.

d. IMPORTS:

Due to insufficient domestic production and increasing demand, Turkey imports significant quantities of feed crops for its poultry, livestock, and aquaculture sectors. Previously, the United States was among the top suppliers to the Turkish market, but imports have been greatly affected by the limited number of GE events approved and testing measures taken by MinAF (see part B). Thus, in 2019 and 2020, imports from the U.S. have been reduced to almost zero.

Trade in food is also negatively affected by the impacts of the Biosafety Law, and some non-biotech products were rejected due to low-level presence of GE content, such as dust from GE corn or soy.

Some import violations of the Biosafety Law were prosecuted under the charge of "biological terror" and the accusation of causing harm to Turkey's agriculture, feed, and food sectors. With the intention of reducing the instances of prosecution for Low Level Presence (LLP) in imports, MinAF amended the implementing regulation of the Biosafety Law to define "contamination" in May 2014. According to some sources, this change appears to have had some impact in reducing overly harsh penalties, such as imprisonment. But 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, paragraph g).

Turkey has approved 26 corn and 10 soybean events for feed use, as of September 30, 2020. No GE traits have been approved for food use, so any GE presence found in food is illegal. Many commodity traders have encountered import problems due to Turkey's asynchronous approvals for food and feed.

Turkey's demand for protein for the feed sector is increasing the soybean requirement each year. 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. Although the prices for U.S. soy products are favorable, the concern of an LLP detection causes importers to avoid buying soybeans from the United States. This has essentially blocked imports of U.S. soybeans to Turkey in 2019 and 2020. Despite paying higher prices for feed materials, Turkish importers looked to other sources which had not yet commercialized newer biotech events, such as Brazil for soybeans, and Argentina for soybean meal. Testing of imported products remains inconsistent and continues to be a considerable cost for importers. The unpredictable situation has increased corporate risk and costs and contributed to increased public suspicion of GE products.

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:

- Although all GE events approved in Turkey have been approved in the European Union (EU), Turkey has approved fewer GE traits than the EU, causing trade disruptions (as producing countries begin commercializing varieties once they are approved in the EU and/or China).
- Turkey has zero tolerance for the detection of unapproved GE traits, except for a 0.1 percent tolerance in feed for GE traits pending approval in the application process.
- The frequency of taking samples and testing them depends on a declaration issued by the competent authority of the loading or origin country which states that the food/feed in question does or does not include GE. Turkey does not accept point of origin testing.
- The Biosafety Law contains severe liability, sanction, and penalty clauses that penalize noncompliance with large fines and five to twelve years in prison.
- Turkey approves traits separately for feed, food, and industrial products, which have led to instances of LLP and prosecution under the Biosafety Law's liability, sanction, and penalty provisions.

Currently there are 13 application pending assessment. No pending applications have been approved since August 2017 and no new applications have been made since 2018. Meanwhile, the lack of approvals exacerbates the asynchronous approvals issue causing problems for Turkish importers and the agriculture sector in Turkey.

PART B: POLICY

a. REGULATORY FRAMEWORK:

Turkey's regulation of agricultural biotechnology is governed by the Biosafety Law (Law No: 5977), implemented on September 26, 2010, and related implementing regulations. Imports of transgenic agricultural products are only allowed after approval of each event for each use; for example: food, feed, industrial (and products for specific industrial applications, such as: lubricant, ink, paint, and biofuel). There are two implementing regulations of the Biosafety Law published on August 13, 2010 by MinAF. These are "Regulation on Genetically Modified Organisms (GMO) and Products" and "Regulation on the Working Principles of the Biosafety Board and the Committees."

The law bans inclusion of GE ingredients in baby food and supplementary foods for young children, bans cultivation/production of GE plants and animals, and the planting of GE seeds.

Following the adoption of the Biosafety Law in 2010, MinAF established the Biosafety Board to review GE food and feed import applications and nominated the Agricultural Research and Policies General Directorate (TAGEM) of MinAF as the secretariat of the board. It had nine members who were high level bureaucrats from MinAF and other subject-related ministries. The board established two committees, Risk Assessment and Socio-Economic Assessment, which both needed to evaluate each application. Members of these committees were from the scientific community such as academia and public research institutes. All application dossiers were assessed by these two parallel committees and the Biosafety Board took the decisions for approval. The board acted independently in its decisions.

The Biosafety Board was abolished by the Decree Law No: 703 published in the Official Gazette on July 9, 2018. MinAF has been authorized to conduct the tasks and responsibilities of the abolished Biosafety Board via a Presidency Circular published in the Official Gazette on August 1, 2018. MinAF re-appointed TAGEM as the secretariat of the committees. 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 decision-making authority whether to approve the event in question, and that decision is published in the Official Gazette. Since the new system was implemented, MinAF has not approved any new events but did approve the production of three enzymes using *Aspergillus oryzae* improved by modern biotechnological methods in May 6, 2020. For more information about these enzymes, please see Chapter 3 of this report on Microbial Biotechnology.

Following the presidential elections held on June 24, 2018, the Turkish Government itself has been reorganized by the Presidency Decree Law 1, published in the Official Gazette on July 10, 2018. Within the scope of this re-organization, Ministry of Food, Agriculture, and Livestock re-structured by merging with the Ministry of Forest and Water Affairs and became Ministry of Agriculture and Forestry (MinAF). The Decree Law 1 established nine Presidential Policy Councils. One of these councils is Council of Health and Food Policies, which has been given the tasks of developing policies, strategies,

and monitoring implementation in the area of biotechnology. The seven members of the Council were announced in the Official Gazette on October 10, 2018. Two are food/agriculture related members and the remainder are health/medical related, such as doctors, dentists, and dietitians. The role of the Council in the regulatory approval process is not clear. In April 2020, the President of Turkey announced that the food policies which are part of the current Council would be separated and a new Council of Food, Agriculture, Forestry and Livestock would be established to conduct tasks and responsibilities related to food policies. As of the date of this report, such a committee has not been established yet.

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. TAGEM decides whether or not the application is accepted and also the type of evaluation procedure (simplified or regular) which will be followed, within 90 days. Once decided, TAGEM informs the applicant about the status (whether the application is accepted or not) of the dossier within fifteen days. In order to apply under the simplified procedure, besides 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, and environmental health and biological diversity,
- Previous risk assessments that can be used regarding the relations of the GE 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,
- 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.

Unlike the regular procedure, decisions made using the simplified procedure are not published in the Biosafety Clearing House Mechanism of Turkey, which is the web platform for public opinion and information exchange, decreasing the time required for a decision. Once an application dossier is accepted and a review procedure is determined by TAGEM, in principle the regular procedure reviews are completed within 270 days. Note that this time is counted while the TAGEM Committees are conducting assessments. 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 assessments of Committees, 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.

In the past, MinAF had requested that international companies that have developed agricultural GE traits 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, these companies expressed concerns about the severe yet unclear liability provisions in the law, as well as the vagueness of the application procedures. 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. As a result, Turkish agriculture industry associations have submitted the dossiers instead and paid the application fees so they could import the feed needed for the sector.

Updates to Regulations

In May 2014, with the intention of reducing the instances of prosecution for LLP for imports, MinAF amended the implementing regulation of the Biosafety Law. It defined "contamination" in a product and established a 0.9 percent threshold, over which products are considered "contaminated." For example, GE feed can be used if the GE trait is under the 0.9 percent threshold and was approved for feed use.

However, the amendment does not clearly explain how "contamination" changes the ability to market products or commodities with unapproved GE traits. For detailed information, please see GAIN report "<u>Turkey Amends Biotechnology Regulation</u>" dated 5/29/2014.

Strategies and Programs on Biosafety

The High Planning Council (HPC) of Turkey adopted the "Biotechnology Strategy and Action Plan" in June 2015 to be implemented in the period of 2015-2018. The period of the Plan ended in July 2018. The Plan was the first adopted document which covered all aspects of biotechnology (agricultural, health, industrial) in one document and was created by high-level government authority. The HPC was chaired by the Prime Minister and the members consisted of Cabinet officials and other interested parties from related government agencies, the private sector, and academia. The Plan laid out a vision "to improve the level of technological information, increase the number of products with added value, and take place amongst the leading countries within the field of biotechnology."

General targets of the plan were:

- to regulate the legal and administrative structure
- to improve technical infrastructure
- to increase production capacity of products from GE components
- to improve agricultural, health, and industrial biotechnology sectors

Specific targets related to agricultural biotechnology were:

- to amend the Biosafety Law and other related legislation
- to determine the rules and principles of allocating "specifically controlled fields" to scientists for research and development and field trials

The abolished Biosafety Board was working on the issue of the allocation of "specifically controlled fields" to develop principles and rules for a system of controlled field trials for research and development activities. This was the only agricultural topic from the plan that was being actively worked. However, there is currently no publicly available information regarding the output of the board's work.

Research

Turkey's Biosafety Law permits the regulated study and development of plant biotechnology. However, the cumulative disincentives in the forms of official controls, approvals, liability, and prohibition on the cultivation of agricultural biotechnology have discouraged product development. According to the Law

and the implementing regulations, an application or permit is not required for agricultural biotech research. The researcher must inform MinAF's TAGEM about the research activity and its result(s).

Researchers must apply to TAGEM for permission to import GE material and derived products for the purpose of research, development, and training/educational activities. The amount of GE material and derived products to be imported is determined by TAGEM. The Law requires TAGEM to finalize the permit procedure within 15 days. Many academics agree that the procedures and requirements of the law discourage research. However, universities are still teaching biotechnology courses. The law's prohibition on cultivation and commercialization also discourages the private and public sector from pursuing the development of GE products.

b. APPROVALS:

Either the gene-owning technology companies or importers of GE crops may apply for approval of a GE trait in Turkey. Applicants are required to provide a dossier containing technical information and data on the trait to be approved and pay an application fee. The application fee is 25,000 Turkish Lira (TL) (\$3,278 where \$1 USD=7.6256 TL) per event in 2020. To date, none of the technology-owning companies have submitted an application to be reviewed by the Biosafety Board or MinAF. Instead, agriculture industry associations have made the applications.

Currently, there are 36 (10 soybean and 26 corn) events approved in Turkey for feed. Turkey approves stacked events as separate applications. 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)

Please see the current list of approved events and pending applications in the Annex

Timeline of Approvals:

In 2010, the Turkish Feedmillers' Association submitted applications for three EU-approved soybean events (feed use). The Biosafety Board decided to review the applications under the simplified procedure.

In January 2011, the Turkish Feedmillers' Association submitted applications for 22 EU-approved corn events to the Biosafety Board for feed use, and they were reviewed under the regular procedure. The Biosafety Board approved 16 corn events on December 24, 2011 and on April 21, 2012, rejected the other six corn events. The Biosafety Board has not published the reason for the rejections.

In January 2011, the Turkish Federation of Food and Beverage Associations submitted applications for all EU-approved soybean, corn, canola, and potato events for food use. However, because of intensive pressure from anti-biotech non-governmental organizations (NGOs) and the media, the Federation withdrew the applications for all events for food use. Therefore, currently, there are no approved events for food use in Turkey.

On April 25, 2013, the Board rejected 22 GE corn varieties to be used in the ethanol sector, three GE rapeseed varieties to be used in the feed sector, and one GE sugar beet variety to be used in the feed sector. There was no provided explanation for the rejections.

The Turkish Poultry Meat Producers and Breeders Association (Besd-Bir) submitted dossiers to the Biosafety Board for the approval of a total of 40 traits (10 soybean, 16 corn, four canola and 10 cotton) for feed use in between 2015 and 2018. The Biosafety Board accepted the applications for review under the simplified procedure. Five events (3 corn and 2 soybeans) were approved on July 16, 2015 for feed use. Eight events (6 corn and 2 soybean) were approved on November 5, 2015. Four events (3 soybeans and 1 corn) were approved on August 2, 2017. Besd-Bir withdrew 10 cotton applications in February 2018. As of September 30, 2020, the remaining 13 traits are still undergoing assessment. In the meantime, trade has been negatively affected due to unapproved events.

According to the Biosafety Law, applicants must inform MinAF for requesting an extension of expiring events at least one year before the expiring date. Based on this requirement, the three soybean events (A2704-12, MON40-3-2 and MON89788) whose permits expire on 1/26/2021 will be banned for import to Turkey as of their expiration date since as of this report, no organization or company has made an application to MinAF for extension. Similarly, extension applications must be made for 13 corn events which were approved on 12/24/2011 (please see Table 1 in the Annex for the names of corn events) no later than 12/24/2020.

c. STACKED or PYRAMIDED EVENT APPROVALS:

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 on cultivation and commercialization discourages the private and public sector from pursuing the development of GE products. The Biosafety Board was working on the process for allocating "specifically controlled fields" to scientists for research and development field trials until it was abolished, but MinAF has not yet published any rule about this issue.

e. INNOVATIVE BIOTECHNOLOGIES:

In MinAF's scientific community and some academic platforms, gene editing has recently become a topic of discussion. 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: According to the Biosafety Law and regulations, any approved imported food or feed containing, consisting, or deriving from GE crops above the labeling threshold set by MinAF (in January 2011 this threshold was 0.9 percent via an internal Agriculture Ministerial Directive) must be labeled as a "GMO."

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.

Post's understanding of the testing process is that the quantitative PCR system is used in Turkey 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 samples is determined. This quantification step is carried out based on the number of copies to allow the simultaneous identification of GE events.

Designated local official laboratories conduct 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 (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.

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 has rolled out a new computer system for recordkeeping and tracking the movement of all GE products. 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 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."

i. LOW LEVEL PRESENCE (LLP) POLICY:

Turkey has a zero tolerance for unapproved LLP in 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 genes in their "intended use." This wording infers that feed is the "intended use" category, because so far only feed use is approved. Because genes are approved only for feed use, the threshold does not provide any utility to detections in food. In practice it seems the 0.9 percent "contamination" allowed refers to the limit allowed of an approved gene not listed on the import documentation as one of the GE genes in that shipment. MinAF has yet to clarify the implementation of the definition or threshold. MinAF intends for the definition and threshold to provide

some measure of security from prosecution as "contamination" is unintentional and beyond the control of the domestic party involved (importer, wholesaler, distributor, and retailer).

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 Biosafety Protocol on October 24, 2003 and entered it into force on January 24, 2004. MinAF is responsible for the implementation of the Cartagena Protocol on Biosafety (CPB).

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 is not actively participating in discussions related to GE plant or seed varieties with international organizations. MinAF only participates at the CPB meetings on an irregular basis regarding GE issues.

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). 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 and one-sided reporting in the media, to include popular health columnists, public and private opinion in Turkey are dominated by misinformation on possible hazards from the consumption of products derived from agricultural biotechnology. There is a widely believed 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.

Misleading health stories, such as claims that eating chicken fed from GE feed has negative health consequences, continued to show up in the media in 2019. However, it appears that consumption of those products has not been affected negatively due to these stories. To date, 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 "Economic impacts of the Biosafety Law and Implementing Regulations in Turkey on the Turkish importing and user sectors" in May 2012.

The study estimated the cost to the Turkish agricultural sector of Turkey's restrictive regulatory system for biotech and concluded "...the on-going annual cost can reasonably be expected to be between \$0.7 billion and \$1 billion and could be higher." According to industry, Turkey is currently losing an estimated \$1.2 billion a year in additional costs.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT: Article 5 of the Biosafety Law (Law No: 5977), adopted on March 26, 2010, 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 ban GE animal importation. If there were an application, the MinAF would have the authority to evaluate it though there has not been an application for the import of GE animals.

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), adopted on March 26, 2010, and related implementing regulations. Import of transgenic agricultural products (and this applies to GE animals) is only allowed after approval of each event for each use. For more information, please see Section II /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 (OIE), and 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 is skeptical of benefits from new agricultural technologies in general.

b. MARKET ACCEPTANCE/STUDIES:

This is currently not an issue in Turkey so there are no studies on consumer sentiment.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

On May 6, 2020, MinAF published Biosafety Decisions on the production of three enzymes which are alpha-amylase (α-amylase), glucoamylase and hemicellulase for industrial usage purposes by using *Aspergillus oryzae* improved by modern biotechnological methods. The developer is LIVZYM Biyoteknoloji Arastirma Gelistirme San. ve Tic. AS (LIVZYM AS) which is based in Istanbul, Turkey. LIVZYM AS just started the commercial production of these enzymes by using GE *Aspergillus oryzae*.

b) EXPORTS

MinAF approved GE A*spergillus oryzae* for the production of three enzymes (alpha-amylase (α -amylase), glucoamylase and hemicellulose) for industrial usage purposes. Since LIVZYM AS. has just started domestic production, there is no trade or export data available yet.

c) IMPORTS

Import of GE microorganism requires MinAF's approval based on a scientific risk assessment and socio-economic evaluation. There is no approved GE-microorganism for import purposes yet in Turkey. 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.

Based on the decision taken by 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 not aware of any known trade barriers for food ingredients such as enzymes, food additives, food processing aids etc. due to being derived GE microorganisms.

PART H: POLICY

a) **REGULATORY FRAMEWORK**

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

b) APPROVALS

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 Biosafety Law states that contained use of GE microorganism is only approved based on a scientific risk assessment. After LIVYZM AS made an application for the approval of GE-*Aspergillus oryzae* for the production of alpha-amylase (α -amylase), glucoamylase and hemicellulose for industrial usage purposes, MinAF established the Scientific Risk Assessment Committee for the scientific risk assessment and Socio-economic Committee for the socio-economic evaluation. After the assessments of these two committees, MinAF approved the GE-*Aspergillus oryzae* for the production of three enzymes for industrial usage and published the approval decisions on the Official Gazette on May 6, 2020. The timeframe took approximately two years from the application stage to the announcement of the decisions in the Official Gazette.

The validity of these approvals is ten years. The following Unique Identity Codes (UIC) are given for GE-*Aspergillus oryzae*;

- UIC of Aspergillus oryzae for Alpha-amylase (α-amylase) production is LIVZ-101;
- UIC of Aspergillus oryzae for Glucoamylase production is LIVZ-102;
- UIC of Aspergillus oryzae for Hemicellulase production is LIVZ-103

Official controls of these enzymes are subject to the rules of Law no. 5996 on Veterinary Services, Phytosanitary, Food, and Feed, which is enforced by MinAF. LIVZYM AS. has just started commercial enzyme production by using LIVZ-101, LIVZ-102 and LIVZ-103.

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 microorganisms do not require GE labelling nor tracing due to being GE-microorganism derived. These ingredients are labelled according to the Law no 5996 on Veterinary Services, Phytosanitary, Food, and Feed enforced by MinAF to ensure food and feed safety and inform consumers about ingredients of foods.

d) MONITORING AND TESTING

For a GE-microorganism to be imported into Turkey, approval must be given by MinAF. Currently there is no GE-microorganism approved for import purpose. For the microorganism itself or products containing the microorganism, the exporter must provide a non-GE microorganism attestation issued by a competent authority of origin or exporting country or analysis report provided by an accredited laboratory which is internationally recognized. 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 send back to the origin country with the decision of importer and exporter.

For products containing GE-microorganism derived ingredients such as enzymes, food additives, food processing aids, etc. there is no testing requirement for the evidence of genetic engineering in imports and exports. 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 ("Law") 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. The Law 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. The Law 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 is no protected or registered product produced and marketed via microbial biotechnology in Turkey yet.

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 researchers who have been conducting research outside of Turkey to reverse brain-drain and support and accelerate the research and development activities in many areas, including the industrial usage of biotechnology. Within this scope, the Turkish government 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 http://gain.fas.usda.gov/ or visit our website: <u>http://www.fas.usda.gov/</u>.

Annex

| 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 | DuPont Pioneer | DAS1507xNK603 (TC1507 X NK603) | DAS-Ø15Ø7- 1xMON- ØØ6Ø3-6 | 12/24/2011 |
| 5 | Corn | Monsanto | NK603 | MON-ØØ6Ø3-6 | 12/24/2011 |
| 6 | Corn | Monsanto | NK603 x MON810 | MON-ØØ6Ø3- 6xMON- ØØ81Ø-6 | 12/24/2011 |
| 7 | Corn | Syngenta | GA21 | MON-ØØØ21-9 | 12/24/2011 |
| 8 | Corn | Monsanto | MON89034 | MON-89Ø34-3 | 12/24/2011 |
| 9 | Corn | Monsanto | MON89034xNK603 | MON-89Ø34- 3xMON-ØØ6Ø3-6 | 12/24/2011 |
| 10 | Corn | Syngenta | Bt11xGA21 | SYN-BTØ11- 1xMON-ØØØ21-9 | 12/24/2011 |
| 11 | Corn | Pioneer | 59122x1507xNK603 | DAS-59122-7xDAS- Ø15Ø7xMON- ØØ6Ø3-6 | 12/24/2011 |
| 12 | Corn | Dow AgroSciences LLC | DAS1507x59122 (TC1507 X DAS-59122- 7) | DAS-Ø15Ø7-1xDAS- 59122-7 | 12/24/2011 |
| 13 | Corn | Monsanto | MON88017XMON810 | MON-88Ø17-3 x MON-ØØ81Ø-6 | 12/24/2011 |
| 14 | Corn | Monsanto | MON88017 | MON-88Ø17-3 | 4/21/2012 |
| 15 | Corn | Monsanto | MON810 | MON- ØØ81Ø-6 | 4/21/2012 |
| 16 | Corn | Dow AgroSciences LLC | 59122xNK603 | DAS-59122-7xMON- ØØ6Ø3-6 | 4/21/2012 |
| 17 | Corn | Syngenta | MIR604 | SYN-IR6Ø4-5 | 7/16/2015 |
| 18 | Corn | Monsanto | MON863 | MON-ØØ863-5 | 7/16/2015 |
| 19 | Corn | Bayer CropScience | T25 | ACS-ZMØØ3-2 | 7/16/2015 |
| 20 | Corn | Syngenta | Bt11xMIR604 | SYN-BTØ11-1x SYN-IR6Ø4-5 | 11/5/2015 |
| 21 | Corn | Syngenta | MIR162 | SYN-IR162-4 | 11/5/2015 |

Table 1: Approved Events (For Feed)

| 22 | Corn | Syngenta | MIR604xGA21 | SYN-IR6Ø4- 5xMON-ØØØ21-9 | 11/5/2015 |
|----|---------|--|-------------------|-----------------------------|-----------|
| 23 | Corn | Monsanto | MON863xMON810 | MON-ØØ863- 5xMON-ØØ81Ø-6 | 11/5/2015 |
| 24 | Corn | Monsanto | MON863xNK603 | MON-ØØ863- 5xMON-ØØ6Ø3-6 | 11/5/2015 |
| 25 | Corn | Monsanto | MON89034xMON88017 | MON-89Ø34-3x MON-88Ø17-3 | 11/5/2015 |
| 26 | Corn | Monsanto | MON 87460 | MON 8746Ø-4 | 8/2/2017 |
| 27 | Soybean | Bayer CropScience | A2704-12 | ACS-GMØØ5-3 | 1/26/2011 |
| 28 | Soybean | Monsanto | MON40-3-2 | MON-Ø4Ø32-6 | 1/26/2011 |
| 29 | Soybean | Monsanto | MON89788 | MON-89788-1 | 1/26/2011 |
| 30 | Soybean | Monsanto | MON87701 | MON-877Ø1-2 | 7/16/2015 |
| 31 | Soybean | Monsanto | MON87701xMON89788 | MON-877Ø1- 2xMON-89788-1 | 7/16/2015 |
| 32 | Soybean | DuPont (Pioneer Hi- Bred International Inc.) | DP356043 | DP-356Ø43-5 | 11/5/2015 |
| 33 | Soybean | Bayer CropScience | A5547-127 | ACS-GMØØ6-4 | 11/5/2015 |
| 34 | Soybean | Monsanto | MON 87708 | MON-877Ø8-9 | 8/2/2017 |
| 35 | Soybean | BASF | CV127 | BPS-CV127-9 | 8/2/2017 |
| 36 | Soybean | Monsanto | MON87705 | MON-877Ø5-6 | 8/2/2017 |

Table 2: Pending Applications (For Feed)

| No | Product | Developer | Event | OECD Unique Identifier | Status |
|----|---------|----------------------|---------------------|---|---------|
| 1 | Soybean | Monsanto | MON 87769 | MON- 87769-7 | Pending |
| 2 | Soybean | DuPont | DP305423 | DP- 3Ø5423-1 | Pending |
| 3 | Soybean | Bayer CropScience | FG 72 | MST- FGØ72-2 | Pending |
| 4 | Corn | Monsanto | MON863xMON810xNK603 | MON- ØØ863-5 X MON- ØØ81Ø-6 X MON- ØØ6Ø3-6 | Pending |
| 5 | Corn | Syngenta | Bt11xMIR604xGA21 | SYN- BTØ11-1 X SYN- | Pending |

| | | | | IDCOA 5 | [] | |
|----|------------------------|-------------|----------------------------------|---------|----------|--|
| | | | | IR6Ø4-5 | | |
| | | | | X MON- | | |
| | | | | ØØØ21-9 | | |
| | Corn | | | MON- | | |
| | | Monsanto | | 89Ø34-3 | | |
| | | | | X DAS- | | |
| 6 | | | MON89034x1507xMON88017x5912 2 | Ø15Ø7 X | Pending | |
| 0 | | | | MON- | I chang | |
| | | | | 88Ø17-3 | | |
| | | | | X DAS- | | |
| | | | | 59122-7 | | |
| 7 | Com | Managata | MON97407 | MON- | | |
| 7 | Corn | Monsanto | MON87427 | 87427-7 | Pending | |
| | | | | MON- | | |
| | | | | 89Ø34-3 | Pending | |
| 0 | ~ | | | X DAS- | | |
| 8 | Corn | Monsanto | MON89034x1507xNK603 | Ø15Ø7-1 | | |
| | | | | X MON- | | |
| | | | | ØØ6Ø3-6 | | |
| | | Dow | | | | |
| 9 | Corn | AgroScience | DAS-40278-9 | DAS- | Pending | |
| | | s LLC | | 4Ø278-9 | 0 | |
| 10 | a 1 | | GT73 (RT73) | MON- | D l' | |
| 10 | Canola | Monsanto | | ØØØ73-7 | Pending | |
| | | | | ACS- | | |
| | | | | BNØØ5- | | |
| | | | | 8, | | |
| | | | | ACS- | | |
| | | Bayer | MS8 | BNØØ3- | | |
| 11 | Canola CronScience KF3 | | б, | Pending | | |
| | | | ACS- | | | |
| | | | BNØØ5-8 | | | |
| | | | | X ACS- | | |
| | | | | BNØØ3-6 | | |
| | | Dovon | | ACS- | <u> </u> | |
| 12 | Canola | Bayer | T45 | BNØØ8-2 | Pending | |
| | | CropScience | | MON- | | |
| 13 | Canola | Monsanto | MON 88302 | | Pending | |
| | | | | 883Ø2-9 | | |

| No | Microorganism | Developer | Unique Identifier Code | Product (Enzyme) | Approval Date |
|----|--------------------|-----------|------------------------------|------------------------------|---------------|
| 1 | Aspergillus oryzae | LIVZYM AS | LIVZ-101 | Alpha-amylase (α-amylase) | 5/6/2020 |
| 2 | Aspergillus oryzae | LIVZYM AS | LIVZ-102 | Glucoamylase | 5/6/2020 |
| 3 | Aspergillus oryzae | LIVZYM AS | LIVZ-103 | Hemicellulase | 5/6/2020 |

Table 3: Approved enzymes from GE-Aspergillus oryzae

Attachments:

No Attachments