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ÜNAL YILDIZ

ÖZGÜR TEMİZ

KAMİL HALİLOĞLU

NESRİN YILDIZ

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Legal regime of the application process for GMO products in Türkiye

Ünal YILDIZ[1,*], Özgür TEMİZ[1], Kamil HALİLOĞLU[2], Nesrin YILDIZ[3]
[1]Department of Public Law, Faculty of Law, Atatürk University, Turkiye,
[2]Department of Crop Field, Faculty of Agriculture, Atatürk University, Turkiye
[3]Department of Soil Science and Plant Nutrition, Faculty of Agriculture, Atatürk University, Turkiye

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Abstract: In Türkiye, in accordance with European Union harmonization laws, the Biosafety Act No. 5977 entered into force on September 18, 2010. The basic legislation regarding the application process is composed of the Biosafety Act, Regulations on Genetically Modified Organisms and Their Products, and Regulations on Working Procedures and Principles of Biosafety Board and Committees. Biosafety legislation foresees a special application procedure for genetically modified organism (GMO) food, food products, feed, and other products. The application regulated in the Biosafety Law is a special administrative procedure in nature. The primary objective of this study is to explain the legal regime of this application procedure. While explaining this issue, relevant limitations will be discussed in detail, and solutions will be presented for such limitations. This study was divided into two parts. The first part examines the basic concepts related to the application will be examined, including its scope and nature of the application, the prohibitions, and exceptions related to the application, the applicant, and the relevant authorities. The second part focuses on the application process, covering notifications to the applicant and reasons for rejection of the application, evaluation of the application, final decision stage, and simplified procedure.

Key words: GMO, Biosafety Board, administrative application procedure, risk assessment, TAGEM

1. Introduction

The establishment of biosafety legislation in Türkiye has spread over time. Between 1998 and 2009, biosafety legislation was partly governed by regulatory acts such as regulations and instructions (Soykan, 2007; Özcanalp, 2006; Oğuzlar, 2007; Güngör and Demiryürek, 2021; Haspolat, 2012). On October 26, 2009, the Ministry of Agriculture and Rural Affairs published the "Regulation on Import, Export, Control and Inspection of Genetically Modified Organisms and Products for Food and Feed Purposes" in the Official Gazette (Güngör and Demiryürek, 2021; Artemel, 2016). This regulation was enacted without a biosafety act and did not depend on such an act. Therefore, it has been criticized for being a transfer of legislative power by violating the provision in Article 124 of the Constitution stating that "*administrations can issue regulations to ensure the implementation of laws or regulations concerning their fields of duty*" (Güneş, 2008; Demir, 2011; Güleşçi, 2012; Kıvılcım, 2012). For this reason, the 10th Chamber of the Council of State suspended the execution of this regulation (Turkish Council of State, 2009a; Turkish Council of State, 2009b). In terms of scope and content, this regulation is quite similar to a biosafety act.

In Türkiye, the implementation of the Biosafety Act No. 5977, which aligns with European Union (EU) harmonization laws, commenced on September 18, 2010, following the country's acceptance of the Cartagena Protocol (Ateş, 2020a; Ateş, 2020b). Similarly, the Regulation on Genetically Modified Organisms and their Products, which is the implementation regulation of this Act, abolished the abovementioned Regulation and entered into force on September 26, 2010 (Artemel, 2016; Hayırlıdağ et al., 2015). This legislation, known as the Biosafety Act (BSA), was formulated by policymakers to address the risks associated with genetically modified products developed through advancements in technology and science by genetic engineers (Özdemir, 2017)[1]. Turkish biosafety legislation states that GMOs and their products

[1]Various criticisms have been brought against the law. The most significant is that the articles are not regulated in a fully understandable way. Additionally, it is stated that the articles lack clarity and detail, consisting of vague judgments that can be interpreted in different ways. Considering the importance of the law and its vulnerability to abuse, it is argued that its articles should be more detailed and contain more precise provisions. (Özcanalp, 2006; Güleşçi, 2012).

* Correspondence: unal.yildiz@atauni.edu.tr

largely comply with the provisions of the Biological Diversity Convention and the Cartagena Protocol (Çıvgın, 2016). The basic legislation regarding the implementation process consists of the Biosafety Act (BSA)[2], the Regulation on Genetically Modified Organisms and Their Products (GMO Regulation)[3], and the Regulation on Working Procedures and Principles of the Biosafety Board and Committees (BKKÇ Regulation)[4].

2. Basic concepts of application

2.1. Scope and nature of the application

According to paragraph 3 of article 1 of the BSA, veterinary medicinal products, human medicinal products, and cosmetic products licensed or authorized by the Ministry of Health are excluded from the scope of the Act. Applications cannot be made for these products within the scope of BSA, and they are subject to the provisions of their legislation. Since the law covers food, food products, feed, and other products, it has been criticized for being named the Act is the Biosafety Act because the concept of Biosafety is interpreted more broadly and includes laboratory safety and security, the Act does not address. In other countries, biosafety acts are often prepared jointly by the Ministry of Agriculture and Health and are very comprehensive. Therefore, it is argued that the Act should be named the "Act on Genetically Modified Organisms" (Demirkasımoğlu and İlhan, 2021).

The scope of the application consists of GMOs and products other than those specified in the article of the BSA. According to biosafety legislation, the primary focus of the application is on GMOs and products used as food and feed. In addition, the use and marketing of GMOs and their products are not limited to food and feed (Özdemir, 2017)[5]. GMOs and products used in different industrial sectors can also be included. The products used and produced within the scope of different industrial activities are subject to the provisions of biosafety legislation. For example, GMO soybean oil, which is the second main product obtained as a result of crushing imported soybean, was approved by the abolished Biosafety Board for use in the production of varnish, resin, plastic, soap, chemical, rubber, mineral oils, paper, and biodiesel for industrial purposes. Similarly, GMO soybean oil was approved by the board for use in the PVC industry. In addition, the Board requested that the oil obtained from processing GM soybeans, the import of which was approved by the board, be used as feed in the paint industry (Artemel, 2014).

In Türkiye, due to the absence of a comprehensive general administrative procedure act, specific administrative procedures are governed by various laws, such as the Access to Information Act or the Expropriation Act (Akyılmaz et al., 2023). Similarly, the application process outlined in the biosafety legislation is considered a specialized administrative procedure. Under the biosafety legislation, applicants are required to initiate this procedural process by applying to the relevant administrative authority and await its completion.

2.2. Prohibitions and exceptions in application

Prohibitions regarding the application are regulated in Article 5 of the BSA. Accordingly, it is prohibited to market GMOs and their products without approval, to use GMOs and their products or allow their use in violation of the Ministry's decisions, to produce genetically modified plants and animals, to use GMOs and their products for purposes other than those determined by the Ministry within the scope of marketing, and to use GMOs and their products in baby foods, infant formulas, follow-up foods, follow-on formulas, and supplementary foods for infants and toddlers[6]. Another prohibition has been added to these in subparagraph d of paragraph 1 of Article 6 of the GMO Regulation. According

[2]T.C. Cumhurbaşkanlığı Mevzuat Bilgi Sistemi (2010). Biyogüvenlik Kanunu, 5977 [online]. Website https://www.mevzuat.gov.tr/mevzuatmetin/1.5.5977.pdf [accessed 25 June 2023].

[3]T.C. Cumhurbaşkanlığı Mevzuat Bilgi Sistemi (2010). Genetik Yapisi Değiştirilmiş Organizmalar ve Ürünlerine dair Yönetmelik . [online]. Website https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=14203&MevzuatTur=7&MevzuatTertip=5 [accessed 25 June 2023].

[4]T.C. Cumhurbaşkanlığı Mevzuat Bilgi Sistemi (2010). Biyogüvenlik Kurulu ve Komitelerin Çalişma Usul ve Esaslarina dair Yönetmelik. [online]. Website https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=14202&MevzuatTur=7&MevzuatTertip=5 [accessed 25 June 2023].

[5]For the dissenting opinion that the application covers only food and feed related GMOs and products, see Özdemir (2017).

[6]The article states that the production of genetically modified animals is prohibited. However, it is a known fact that genetically modified mice are produced for use in experiments in the field of medicine. There is no prohibition on the importation of such animals in the article. It is argued that this is a contradiction. In addition, this ban is criticized because gene technology is highly advanced in the world and it can be used for the production of experimental animals. It is regulated in the article that the production of genetically modified plants is also prohibited, but there is no prohibition on importation. It is stated that genetically modified soybeans, corn, and tomatoes are the most commonly used products in the field of biotechnology. The question was asked whether they belonged to the category of genetically modified fruit or vegetable rather than to the category of genetically modified plants. While prohibiting the origin of the product, it is criticized that derivatives are allowed. On the other hand, it is stated that a genetically modified plant or fruit poses a higher risk compared to a product containing GMOs, which is considered less risky. Finally, the article regulates the prohibition of GMOs and products in baby foods, formulas, and supplementary foods for young children. While this ban protects infants and children against GMO products, it has been criticized for not protecting adults. Namely, adults who consume GMO foods will still be able to breastfeed their babies. Additionally, animals that are fed GMO feed can be consumed by everyone, including adults, children, and babies, after they are slaughtered. Similarly, soy lecithin, corn, and tomatoes, which can be genetically modified, may be found in foods such as chocolate and biscuits consumed by children (Gürpınar, 2014). Despite the ban on baby foods, GMOs were detected in baby foods sold on the market in 2014. This situation raised concerns and questions about the implementation of the Law (Durmaz Aksu, 2019).

to the relevant paragraph, if GMO products contain resistance genes to antibiotics used to treat humans and animals, the importation and marketing of these products are prohibited unless the Risk Assessment Committee report and the Ministry's decision determine that scientific research results on these resistance genes indicate they are not harmful to human, animal, and plant health, as well as to the environment and biological diversity.

There are a few exceptions in this regulation for the application of GMO products. The first of these is the research and development studies to be carried out in Türkiye in accordance with paragraph 1 of Article 7 of the GMO Regulation. It is not necessary to obtain permission from the Ministry for these, information on the subject of the activities to be carried out should be provided to the Ministry, and the Ministry must be informed about the results of the research within three months following the completion of the activities. The second of these is to obtain permission from the Ministry for GMOs and their products to be imported for research, development, and training purposes according to paragraph 11 of article 3 of the BSA and paragraph 2 of article 7 of the GMO Regulation[7]. The third of these is to obtain permission from the Ministry for each transit pass in the transit passage of GMOs and their products, according to paragraph 10 of article 3 of the BSA. The processes related to these exceptions are different from the application process, which is the subject of the study. These can be included in the concept of application in a broad sense, but they do not fall into the concept of application in the narrow sense that constitutes the subject of the study. As will be examined below, the concept of permission used here is different from the concept of positive decision (approval) (Aksu Kayacan, 2021).

2.3. Applicant

According to subparagraph f of paragraph 1 of Article 4 of the GMO Regulation, "*Applicant: refers to the gene owner or importer who applied before the first import*." It seems that the application covers only the importers. However, in paragraph 2 of Article 3 of the BSA, it is stated that "*for the first import of each GMO and its product, an application is made to the Ministry by the gene owner or the importer and for the GMO and its product developed domestically, the application is made by real or legal persons*". Therefore, there is no restriction for the application of GMOs and their products to be made only for import purposes. However, it is possible to deduce from this expression that real and legal people who can apply for GMOs and products developed domestically cannot be gene owners (Aksu Kayacan, 2021). On the other hand, according to paragraph 1 of Article 8 of the GMO Regulation, "*Before the first import of GMOs and products within the scope of this Regulation, the gene owner or importer for each GMO it contains and for GMO and products developed domestically, the developer or gene owner real and legal persons apply to TAGEM*". Accordingly, domestic real or legal persons can also be gene owners. Since the gene owner is an important concept, it was criticized that the definition is not regulated in biosafety legislation. The gene owner is defined in doctrine as "*the person holding the patent rights of the genetic material of the GMO and its products subject to the application*" (Artelemel, 2014). Finally, it is argued that the expression "real and legal persons" in the article should not be broadly interpreted to include any real or legal person not directly related to GMO products (Demir, 2011).

2.4. Authorities in charge of application

The Biosafety Board in Türkiye was abolished with Article 206 of the Statutory Decree on Making Amendments to Certain Acts and Decrees to adapt to the Amendments Made in Constitution No. 703 and dated 2018[8]. On the other hand, the duties and powers of the Biosafety Board remained in the Act. With the Annex 1st article of this decree, it is regulated that the references made to the Biosafety Board shall be deemed to have been made to the board or authorities determined by the President. The Provisional Article of the Presidential Decree on the Presidential Organization dated 2018 and numbered 1, in summary, states that the duties and powers of the Biosafety Board will be transferred to the relevant authority with another Presidential Decree[9]. However, with the 2018-dated list (1) of Presidential Circular No. 3, the duties and powers of

[7]According to Article 7 of the GMO Regulation, an application is made to TAGEM for permission. TAGEM completes the permit procedures within 15 days and gives the permit to be submitted to the customs administration to complete the import procedures. Import transactions are carried out in accordance with the conditions specified in the permit obtained. The Ministry is informed of the result within three months following the completion of the research and development activities carried out in the country regarding the GMOs and their products that are allowed to be imported according to the article. The question of what will happen "if GMOs and their products to be imported for research and development purposes by TAGEM are not allowed" can be asked. TAGEM's decision not to grant permission is an administrative action. Therefore, an action for annulment can be filed for the annulment of this decision within 60 days from the notification of the decision to deny permission. In this case, the responsible and authorized court will be the Ankara administrative court.

[8]T.C. Cumhurbaşkanlığı Resmi Gazete (2018). Anayasada yapılan değişikliklere uyum sağlanması amacıyla bazı kanun ve kanun hükmünde kararnamelerde değişiklik yapılması hakkında kanun hükmünde kararname, No. 703. [online]. Website https://www.resmigazete.gov.tr/eskiler/2018/07/20180709M3-1.pdf [accessed 30 June 2023].

[9]T.C. Cumhurbaşkanlığı Mevzuat Bilgi Sistemi (2018). Cumhurbaşkanlığı kararnamesi, No. 1. [online]. Website https://www.mevzuat.gov.tr/mevzuatmetin/19.5.1.pdf [accessed 30 June 2023].

the Biosafety Board have been transferred to the Ministry of Agriculture and Forestry[10]. It should be noted that it is known that the duties and powers of administrations can be regulated by the Constitution, acts, or presidential decrees in accordance with Article 123 of the Constitution (Akyılmaz et al., 2023). The transfer of the duties and powers of the Biosafety Board to the Ministry through a circular, rather than an act or a presidential decree is open to discussion, since it contradicts the principle of legality of the administration.

On the website of the Turkish Biosafety Change Mechanism, it is stated that, with the Ministry's consent dated December 5, 2018 and numbered E. 3408293, the tasks of reviewing the applications made regarding GMOs and their products, as well as the secretariat services of the committees and other duties specified in the Biosafety Act and related regulations, were assigned to the General Directorate of Agricultural Research and Policies (TAGEM)[11]. The criticism above applies here as well. Duties and authorities in biosafety legislation should be regulated by acts or presidential decrees. This arrangement of duties and powers made with a single administrative act makes the administrative action illegal in terms of authority, form, and subject matter. Finally, it should be noted that since the references to the Biosafety Board in the present legislation remain as they are, their names are written according to the use of the duties and powers of the Board by the Ministry or TAGEM. Since the duties and authorities of the Ministry and TAGEM are regulated in presidential decrees and acts, criticisms on the grounds that necessary care is not taken in the creation of legislation are justified.

2.4.1. Ministry of Agriculture and Forestry

The Ministry of Agriculture and Forestry constitutes the highest administrative authority within the hierarchical institutional structure established within the scope of biosafety legislation. The Ministry is the first authority to address all applications regarding GMOs and their products. The ministry notifies the applicant about the application results, either positive or negative, or it is published in the official gazette. Communication with the applicant takes place through the ministry (Artemel, 2014). The name of the Ministry was previously the Ministry of Agriculture and Rural Affairs. Later, it became the Ministry of Food, Agriculture and Livestock. After the government system changed in 2018, the name of the Ministry was changed to the Ministry of Agriculture and Livestock (Aksu Kayacan, 2021). Although the current name of the Ministry is the Ministry of Agriculture and Forestry, the terms of the Ministry of Agriculture and Rural Affairs are still used in biosafety legislation. Since the references to the Ministry of Agriculture and Rural Affairs in the legislation actually refer to the Ministry of Agriculture and Forestry, such a case shows the delay in harmonization of the legislation. The duties and powers of the Ministry of Agriculture and Forestry are regulated in Article 8 of the BSA[12]. Among the duties and authorities of the Ministry, those related to the abolished Biosafety Board create a paradox since there is no longer a Board. The most important duty and competence of the Ministry regarding the application is to make a final positive or negative decision about the application, which belonged to the abolished Biosafety Board in the past.

It should be noted that the members of the abolished Biosafety Board were appointed by various ministries and undersecretaries[13]. The selection of the members of the

[10]T.C. Cumhurbaşkanlığı Mevzuat Bilgi Sistemi (2018). Cumhurbaşkanlığından genelge, No. 3 (2018). [online] Website https://www.mevzuat.gov.tr/MevzuatMetin/CumhurbaskanligiGenelgeleri/20180802-3.pdf [accessed 30 July 2023].

[11]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 20 June 2023].

[12]"b) *To obtain the information and documents requested by the Board and to report the results to the Board by conducting or commissioning the requested studies, trials, controls, and inspections.*

c) To implement the works and processes specified in this Law, to prevent, monitor, control, and inspect unwanted GMO contamination.

ç) To authorize real or legal persons to carry out studies on GMOs and their products, if deemed necessary, to supervise these authorized real or legal persons and to regulate the procedures and principles regarding them.

d) To develop, implement, or ensure the implementation of a strategy for the conservation and sustainable use of national biological diversity and genetic resources.

e) To take the necessary measures to inform the public about GMOs and their products and to ensure their participation into the decision-making process through the biosafety information exchange mechanism.

f) To determine the procedures and principles regarding the activities of the Board and scientific committees.

g) To cooperate with relevant institutions on border controls in order to prevent the circulation and use of GMOs and their products other than those regulated in this Law.

ğ) Emergency situations regarding the protection and sustainability of human, animal, and plant health, as well as the environmental and biological diversity. To prepare and implement emergency action plans that outline the methods to be applied in such cases.

h) To determine the threshold value according to the characteristics of GMOs and their products in line with the opinions of the Board.

i) To determine the procedures and principles regarding the labeling of products within the scope of this Law and products obtained from GMOs."

[13]According to the abolished Article 9 of the BSA, the Biosafety Board consisted of nine members. According to the article, four members of the Board were elected by the Ministry of Agriculture and Rural Affairs, two members by the Ministry of Environment and Forestry, a member by the Ministry of Health, a member by the Ministry of Industry and Trade and the last member by the Undersecretariat of Foreign Trade for three years. It has been criticized that the Board consists of members elected by bureaucrats. (Kıvılcım, 2012).

board by the ministries, whose purpose is to review the applications regarding GMOs and their products within the framework of scientific criteria, has been criticized because the parties of the board may be biased and misleading. In particular, the provision that the chairperson of the board be appointed by the Minister of Agriculture and Rural Affairs left the board in the shadow of political power and damaged the impartiality and credibility of the board. At this point, it was emphasized that the members of the board who should present scientific studies and opinions should be chosen not only from the government but also from scientists, environmental groups, and consumer organizations (Küçük, 2020). At this point, the abolition of the Board and the applications made by the Ministry of Agriculture and Forestry and TAGEM, which is affiliated with the Ministry, increased the debate on the impartiality and reliability of the activities on this issue. In this sense, an independent agency, which has a separate public legal entity and will be associated with the Ministry, should be established to scientifically review and decide on the applications made. It would be appropriate to select the members of this independent agency not only from the government wing but also from a wide range of individuals, groups, and organizations mentioned above.

2.4.2. General Directorate of Agricultural Research (TAGEM)

The General Directorate of Agricultural Research, which is a subunit of the Ministry, is not mentioned in the BSA. However, in the regulations of the BSA, direct references are made to TAGEM regarding the duties assigned to the Ministry. The duties that must be fulfilled by the administrative authorities within the scope of biosafety legislation are mainly carried out by TAGEM (Artemel, 2014). It should be noted that TAGEM is a directorate affiliated with the Ministry and does not have a separate public legal entity. According to paragraph 1 of Article 3 of the GMO Regulation, "TAGEM" stands for the General Directorate of Agricultural Research. However, the name of this Directorate has been changed to the General Directorate of Agricultural Research and Policies (Aksu Kayacan, 2021). Despite this change, the abbreviation TAGEM is still used. Including the new name of the Directorate in the Regulation will undoubtedly provide clarity on this issue.

The duties and powers of the TAGEM in biosafety legislation can be grouped under three headings: acting as an application authority, establishing a permitting authority, and carrying out the secretariat services of the Ministries and Committees (Artemel, 2014). The application and secretarial duties will be mentioned here. According to Article 8 of the GMO Regulation, applications regarding GMOs and their products are made to TAGEM. TAGEM evaluates the applications and decides whether to accept or reject them[14]. According to article 12 of the GMO Regulation, simplified transaction applications are also made to TAGEM. It is stated that the duties and authorities of the abolished Biosafety Board "*to form the selected scientific committees in the list of experts" and "to select the members of the committees from the list of experts for each application*" are also given to TAGEM. TAGEM thus forms a risk assessment and socioeconomic evaluation committee[15]. According to paragraph 4 of article 4 of the BKKÇ Regulation, TAGEM carries out the secretariat services of the scientific committees. According to paragraph 6 of article 4 of the regulation, the Biosafety Information Exchange Mechanism is determined by the TAGEM. The applications made to TAGEM in accordance with Article 8 of the GMO Regulation are announced to the public through the biosafety information exchange mechanism.

2.4.3. List of experts and committees

According to Article 3 of the BKKÇ Regulation, the list of experts refers to "*the list of people from whom the Committees will be elected and who have scientific competence related to the subjects within the scope of the Act*". The list of experts is not a body; it is a pool of experts. For each application related to GMO and its products, new committees are formed from different members selected from the list of experts. The committees consist of different people related to each application (Aksu Kayacan, 2021). Committee members are composed of experts selected from the list of experts (Artemel, 2014). According to Article 12 of the BSA, a list of experts is selected by the universities, The Scientific and Technological Research Council of Türkiye, and those working in the fields deemed necessary by TAGEM.

According to Article 2 of the BSA, the committee refers to "*committees formed by TAGEM to make scientific evaluations*". According to Article 12 of the BSA, the TAGEM establishes a risk assessment committee, socioeconomic evaluation committee for each application, and any other scientific committees as needed. According to the relevant article, the committees consist of eleven people. It is regulated in this article that the committees are independent while performing their duties and that no organ, authority, or person can give orders and instructions to the committees. The duties and powers of the committees are to determine the scientific adequacy of the information provided for risk assessment in applications made within the scope of the

[14]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 25 June 2023].

[15]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 26 June 2023].

BSA; to determine the test, experiment, trial, analysis, and other processes; to request additional information when necessary; to prepare risk assessment and socioeconomic evaluation reports; to evaluate all kinds of new data and information that emerged or obtained after the decision; to form a scientific opinion; to make scientific evaluations; and to inform the ministry and prepare a report. According to Article 8 of the BKKÇ Regulation, the decisions of the committees are not binding on the Ministry. The ministry retains the authority to make its final decision regardless of committee decisions. However, according to the same article, the Ministry makes its final decision by taking into account the evaluation reports of the committees, their decisions and the opinions of the public.

3. Application process

According to biosafety legislation, there are 4 types of applications are as follows: application for placing on the market, application for domestically developed GMOs and their products, application for release for experimental purposes, and application for indoor use of a GMO. The application for placing GMOs on the market is made before they are imported, and their products are imported for the first time. The application of domestically developed GMOs and products is to be made before they are put on the market (Güner and Yüce Arslan, 2017). According to the GMO Regulation, the information and documents requested vary based on the type of application.

According to paragraph 2 of Article 3 of the BSA and paragraph 2 of Article 8 of the GMO Regulation, a GMO and its products can be used for multiple purposes. Thus, an applicant may apply for a GMO product to be used and marketed both as food and as feed. However, according to the Act and the GMO Regulation, when an application is made for more than one use, a separate application is made for each purpose. The Ministry evaluates the applications made in this way as two separate applications for food use and feed purposes (Artemel, 2014). It is regulated that the result of an application made under paragraph 3 of Article 3 of the BSA will not set a precedent for other applications. TAGEM is the responsible and authorized administrative authority for the application.

3.1. Notification of the applicant and reasons for refusal of the application

According to biosafety legislation, the term "notification" is the notification refers to informing whether TAGEM has accepted the application. Paragraph 4 of Article 3 of the BSA stipulates that the Ministry will notify the application to the abolished Biosafety Board, which must send its acceptance and other evaluations to the Ministry within 90 days. The Ministry will then notify the applicant within 15 days (APPENDIX 1). However, it was stated on the website of the Biosafety Information Exchange Mechanism that TAGEM will decide whether the application made to TAGEM will be accepted within 90 days or whether it will be evaluated within the scope of the simplified procedure due to the abolition of the Biosafety Board. It is stated that the applicant will be notified of the evaluation results within 15 days following 90 days[16]. According to the relevant article of the Act, any time elapsed due to requests for additional information or documents will not be counted in the calculation of these periods.

The reasons for refusal of the application are described in paragraph 5 of Article 3 of the BSA and paragraph 5 of Article 8 of the GMO Regulation. Accordingly, applications are refused in cases where GMOs and their products poses a threat to human, animal, and plant health, as well as environmental and biological diversity; in cases where it is understood that the right of choice of the producer and consumer is eliminated; in cases where GMOs are perceived to deteriorate ecological balance and ecosystems; in cases where there is a risk of spreading GMOs and their products to the environment; in cases where GMOs jeopardize the continuity of biological diversity; and in cases where the applicant does not have sufficient technical equipment to implement the measures to ensure biosafety. If the application is rejected, an action for annulment can be filed against this decision, as it constitutes an administrative action. The Ankara Administrative Court is responsible and authorized to handle such cases. The period for filing a lawsuit is 60 days from the notification of the rejection decision to the appointment.

According to paragraph 4 of Article 3 of the BSA and paragraph 5 of Article 8 of the GMO Regulation, the "result" reached by the Ministry on whether the application will be accepted or not is reported to the applicant by the Ministry. The term "result" used here can cause ambiguity since this concept can be understood as a concept that expresses the final result of the application. However, the conclusion reached by the Ministry at this stage is related to the application made and not related to the GMO and its products, e.g., it is not about whether or not activities are approved, such as putting them on the market. The approval or negative decision to be made by the ministry constitutes the next step. The concept of a result refers to the decision to be made at the end of the process following TAGEM's notification to the applicant whether the application has been accepted by the TAGEM (Artemel, 2014).

3.2. Evaluation of the application

According to Article 4 of the GMO Regulation, evaluation is defined as "*just to be taken into consideration while reaching a decision for each application related to GMO, risk*

[16]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 02 July 2023].

assessment, and socioeconomic assessment to be made by the Committees on scientific principles, ethical assessment if needed and other assessments to be requested by the Ministry". According to article 3 of the BSA, the evaluation was made within 270 days. During this period, scientific committees are formed, they prepare scientific reports, the prepared reports are then presented to the public, and public opinions are evaluated by the committees[17]. The evaluation phase consists of risk assessment, socioeconomic assessment, and ethical assessment.

3.2.1. Risk assessment

According to item ü of paragraph 1 of Article 2 of the BSA and item h of paragraph 1 of article 4 of the GMO Regulation, risk assessment is defined as a "*four-stage process, which includes the identification of the risks and risk sources that may occur using scientific methods such as testing, analysis, trials; determination of their qualifications; evaluation; and determination of risk elements that GMOs and their products exert on human, animal, and plant health, biological diversity, and the environment*". According to paragraph 1 of Article 3 of the BSA, it is regulated that import, export, experimental release, and placing on the market of GMOs or their products, as well as the indoor use of genetically modified microorganisms, will be decided based on a risk assessment conducted according to scientific principles.

3.2.2. Socioeconomic assessment

According to subclause z of clause 1 of Article 22 of the BSA and subclause jj of clause 1 of article 4 of the GMO Regulation, socioeconomic assessment is defined as "*the evaluation conducted before making a decision on an application, encompassing all scientific assessments made to identify the socioeconomic costs that will arise from its effects of releasing GMOs and their products into environment and the utilization of GMOs on biological diversity, users, and farmers*".

3.2.3. Ethical assessment

According to subclause l of paragraph 1 of Article 4 of the GMO Regulation, ethical evaluation means "*the evaluation made to determine the possible effects and consequences of the release and use of GMOs and their products into the environment on the ethical values of consumers, users, and farmers*".

3.3. Final decision phase

According to item 2 of paragraph 1 of the BSA, the decision means "*the decision made by the Ministry according to the results of the risk assessment and socioeconomic assessment made based on scientific principles regarding an application made for GMOs or its products*". The decision constitutes the final decision to be made by the ministry regarding the application. The decision to be made can be positive or negative (Artemel, 2014). The time for the final decision starts after TAGEM notifies the applicant of the first evaluation result, and this period cannot exceed 270 days. During the 90-day application evaluation and 270-day final decision-making period, TAGEM and the committees may request additional information or documents, and the additional time required for these is not taken into account in the calculation of the period[18]. What will be included in the decision is regulated in Article 3 of the BSA[19].

3.3.1. Approval (positive decision)

The difference between permission and approval (positive decision) used in biosafety legislation needs to be explained. According to subparagraph u of paragraph 1 of Article 4 of the GMO Regulation, the permit refers to the "import permit granted by the Ministry for GMOs and their products to be imported for research and development purposes by institutions authorized to conduct research". According to clause gg of paragraph 1 of Article 4 of the GMO Regulation, approval means a "*positive decision made by the Board according to the results of the risk assessment and socioeconomic assessments made based on scientific principles and ethical assessment to be made when necessary regarding an application made for GMO or its products*". In short, approval is the positive decision of the Ministry based on an application made for GMO products; Permit, on the other hand, refers to the import permit to be obtained from the Ministry for GMOs to be imported for research and development studies (Artemel, 2014). According to the jurisprudence of the Council of State, for the Ministry to make a positive decision in the applications related to GMOs and products, scientific methods such as those regulated in paragraph 1 of Article 2 of the BSA should be used to demonstrate that it will not harm human, animal, or plant health, as well as the environment or biodiversity, and that it is safe (Turkish Council of State, 2019; Turkish Council of State, 2022; Turkish Council of State Administrative Appeals Assembly, 2017).

According to Article 11 of the GMO Regulation, the Ministry shall finalize its positive decision with its justifications, if any, the reasons for the dissenting vote and their signatures within 30 days at the latest from the date of the meeting. According to the article, the decisions of the Ministry enter into force upon their publication in

[17]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 05 July 2023].

[18]Türkiye Biyogüvenlik Bilgi Değişim Mekanizması (2018). [online]. Website http://www.tbbdm.gov.tr/ [accessed 30 June 2023].

[19]Accordingly, the decision includes validity period, procedures to be applied in import, purpose of use, data required for risk management and market control, monitoring conditions, documentation and labeling conditions; packaging, handling, preservation and transport rules; conditions for processing, waste and residue treatment and disposal; safety and emergency measures and how to make annual reports.

the official gazette. According to paragraph 1 of article 3 of the BSA, the validity period of the decision given for the applications that are determined not to pose a risk according to the risk assessment results is 10 years. In other words, if the final decision on the application is positive, the validity duration of this decision is 10 years. It is stated that the decision date should be taken as a basis for the applications that are determined not to pose a risk according to the risk assessment results regarding the 10-year period. In this case, the date of the decision made as a result of the risk assessment will be taken as the basis instead of the date of placing the GMO and its products on the market (Özen, 2015).

3.3.2. Negative decision

A negative decision by the Ministry about the application regarding GMOs means that the purpose of the use of GMOs and their products, which is the subject of the application, has not been approved. If the decision is negative, the decision is not published in the official gazette. The relevant person is notified. According to Article 11 of the GMO Regulation, if the Ministry's decision is negative, the applicant can apply to the Ministry within 60 days and request a review of this decision if he or she has new information that will cause the decision to change. According to this article, the Ministry reviews the decision within 60 days, taking into account the new information and notifying the applicant of the results (APPENDIX 2). The negative decision of the ministry is an administrative action. The administrative application regulated in this article is an optional administrative application due to the expression "may request" in the article. Therefore, the applicant may, if he wishes, first exhaust this discretionary remedy and, if the decision is still negative, file an action for annulment against the decision, or he can directly file an action for annulment by not resorting to the discretionary remedy at all. In this case, the responsible and authorized court will be the Ankara Administrative Court. The period for filing a lawsuit is 60 days from the notification of the refusal decision to the applicant or the notification of the refusal decision to the applicant in the optional application way. The approval process for GMOs and their products is slower in Türkiye than in EU countries (Celen, 2014; Brookes, 2012).

3.4. Immediate application procedure: a simplified process

According to Article 2 of the BSA, the simplified procedure refers to a "simplified decision-making process based on the available information and the previous risk assessments, ensuring that there is no harm to human, animal, or plant health, the environment or biological diversity, and there is no risk that may arise from GMOs and their products". Article 6 of the Act states that "For applications based on the information that there were not any risks that may arise from GMOs and their products and that there was no harm to human, animal, or plant health, the environment or biological diversity and on a previous risk assessment, by also taking the results of socioeconomic assessments, the simplified procedure" can be applied. According to the Act, there are various conditions for simplified transactions[20]. Since there is no 90+270-day application process in the simplified procedure, the simplified procedure can be qualified as an immediate application procedure.

According to paragraph 3 of Article 12 of the GMO Regulation, the simplified process is possible only for domestic applications for GMO or its products, which were previously released to the environment by another country or were allowed to be placed on the market for consumption. Therefore, to apply a simplified process for the first-time import, export, experimental release, placement on the market, or indoor use of genetically modified microorganisms, relevant GMOs or products must be the subject of biotechnological research (Demir, 2011). According to Article 12 of the GMO Regulation, in simplified procedure applications, the Ministry makes its decision in the first meeting after receiving the evaluation of the committees. If the decision is positive, it is published in the official gazette within 15 days from the date of the decision. If the decision is negative according to the regulation, an optional administrative application is made. Accordingly, in the case of an objection to a negative decision with new information and documents, the ministry discusses the objection at its first meeting. It determines the actions to be taken about the objection and the period during which the procedures will be completed and the ministry notifies the applicant of the result within 15 days at the latest. The article does not regulate the period in which an application can be made to the Ministry or the period within which the Ministry will decide on this issue. In terms of this application, which is a special administrative procedure, the deadline is not specified, and this is considered an important shortcoming. If the decision is negative, an action for annulment can be filed within 60 days, as this decision will be an administrative action. The responsible and authorized court will be the Ankara administrative court.

[20] According to paragraph 2 of Article 6 of the Law, these conditions are: knowing the taxonomy and biology of the living organism transferred with the gene source; having sufficient information about the effects of GMO on human, animal, environmental health, and biological diversity; availability of information regarding the absence of a negative effect obtained from previous risk assessments that can be used in relation to the relationship of GMO with other living organisms; availability of detailed methods and data for identification of the transferred genetic material and its determination in the living organism to which it was transferred.

4. New breeding techniques (NBT) and their regulation in Europe and Türkiye

New breeding techniques (NBTs) are a set of innovative methods used in plant breeding to develop new crop varieties with desired traits. NBTs encompass a range of innovative genetic engineering methods that enable precise modification of an organism's genome. These techniques offer potential benefits for crop improvement, including increased yield, enhanced nutritional content, and greater resistance to pests and diseases. Unlike traditional breeding methods, NBTs allow for more precise and targeted modifications at the molecular level (Zimny et al. 2019) CRISPR/Cas9 system is one of the prominent and well known NBTs. CRISPR/Cas9 is a gene-editing tool that allows scientists to make precise changes to the DNA of an organism. It works by targeting specific sequences of DNA and cutting them, enabling the insertion, deletion, or modification of genes. CRISPR/Cas9 has revolutionized plant breeding by making it faster, more efficient, and more precise. Transcription activator-like effector nucleases (TALENs) are another gene-editing technology that works similarly to CRISPR/Cas9 but uses a different mechanism to target and edit specific genes. TALENs have been used in plant breeding to introduce specific genetic changes, such as enhancing disease resistance or improving nutritional content. Zinc finger nucleases (ZFNs) are engineered proteins that can be used to target and edit specific genes in a manner similar to CRISPR/Cas9 and TALENs. While not as widely used as CRISPR/Cas9, ZFNs have been employed in plant breeding to create novel traits in crops. Oligonucleotide-directed mutagenesis (ODM) is another technique that involves the use of short DNA fragments (oligonucleotides) to induce specific mutations in the genome of an organism. This method can be used to introduce precise changes in gene sequences to create desired traits. RNA interference (RNAi) is a mechanism that regulates the expression of genes by inhibiting the translation of mRNA molecules. In plant breeding, RNAi can be used to silence specific genes, leading to the suppression of undesirable traits or the enhancement of desirable ones. These NBTs offer several advantages over traditional breeding methods, including increased precision, speed, and efficiency in introducing desired traits into crops. They also allow breeders to bypass some of the limitations of conventional breeding, such as long breeding cycles and genetic linkage drag. However, like any biotechnological tool, NBTs also raise ethical, social, and regulatory considerations that need to be addressed to ensure their responsible use and acceptance by society (Lassoued et al. 2018).

As of today, the legal status of NBTs in Europe remains somewhat uncertain and subject to ongoing regulatory discussions and evaluations. The EU regulates GMOs through Directive 2001/18/EC and Regulation (EC) No 1829/2003. However, the application of these regulations to NBTs has been a matter of debate due to their precise nature and the ability to achieve genetic modifications without introducing foreign DNA into the organism (i.e., "genome editing"). Some argue that certain NBTs should not be classified as GMOs under existing EU regulations, while others maintain that they should be subject to the same regulatory framework as traditional GMOs.

In July 2018, the European Court of Justice (ECJ) issued a ruling stating that organisms obtained by mutagenesis, including certain NBTs, are subject to GMO regulations. This ruling clarified that organisms resulting from mutagenesis techniques, regardless of the method used, fall within the scope of GMO legislation. As a result, NBTs that involve the deliberate alteration of an organism's genetic material are subject to risk assessment, authorization procedures, and labeling requirements under EU GMO regulations. Following the ECJ ruling, discussions have continued within the EU regarding the appropriate regulatory approach to NBTs. The European Commission has launched initiatives to assess the regulatory framework for NBTs and explore potential updates or adaptations to existing regulations. In April 2018, the European Commission published a study on NBTs, which concluded that they have the potential to contribute to sustainable agriculture and innovation but also highlighted the need for clarity and consistency in their regulation.

In November 2021, the European Commission published a study on the application of NBTs in agriculture, food, and feed production. This study examined the state of the art, potential applications, and regulatory implications of NBTs, aiming to inform policy discussions and decision-making at the EU level (European Commission, 2021).

Overall, while the legal status of NBTs in Europe is currently governed by GMO regulations, ongoing discussions and evaluations may lead to potential updates or amendments to the regulatory framework in the future. It is essential to monitor developments in EU policy and legislation regarding NBTs to understand their evolving legal status and implications for agriculture, innovation, and food production.

As of the submission of this manuscript, Türkiye did not have specific regulations tailored to NBTs. Türkiye's approach to regulating GMOs, including those developed using NBTs, is guided by broader legislation related to biosafety and agriculture.

Türkiye has legislation governing the use of GMOs, primarily through the "Law on the Conservation of Biological Diversity and the Sustainable Use of Biological Diversity" (No. 5983), enacted in 2010. This law provides the legal framework for the regulation of GMOs, emphasizing risk assessment, monitoring, and public

consultation. Additionally, regulations may exist at the institutional level, with various ministries and agencies overseeing aspects related to GMOs and biosafety.

However, the specific legal status of NBTs within Türkiye's regulatory framework may not be explicitly defined. Given that NBTs represent a relatively new and rapidly evolving field of biotechnology, countries may still be developing or updating their regulatory approaches to address them.

It is essential that Turkish regulatory authorities define the legal status of NBTs in Türkiye. Additionally, ongoing developments in biotechnology regulation and policy may influence Türkiye's approach to NBTs in the future.

5. Similarities and dissimilarities between European and Turkish GMO regulations

GMO regulations in Europe and Türkiye exhibit both similarities and dissimilarities. In terms of similarities, both regions have established regulatory frameworks to govern the presence of GMOs in food and feed. Europe is known for having some of the strictest regulations globally regarding GMO thresholds and mandatory labeling, reflecting a cautious approach towards GMOs (Smith and Kong, 2021). Similarly, Türkiye has also implemented stringent regulations and penalties concerning GMOs and their products, indicating a shared concern for food safety and environmental impact (Bitir et al., 2020).

However, notable differences exist between Türkiye and Europe in GMO regulation. Europe, particularly the EU, has been characterized by a more skeptical and precautionary stance towards GMOs, leading to stringent regulations and a general aversion towards genetically modified food products (Madzak, 2021). In contrast, Türkiye's approach to GMO regulation may not be as stringent as that of Europe, potentially reflecting differing cultural perspectives and levels of public acceptance (Evrensel, 2013).

Moreover, the distinction between cisgenic and transgenic organisms within GMO regulation is a contentious issue in Europe, with current regulations not making a clear differentiation between the two approaches (Hove and Gillund, 2017). This lack of distinction poses challenges in applying existing GMO regulations to organisms that exhibit characteristics of both cisgenic and transgenic modifications (Hove and Gillund, 2017).

As a result, while both Europe and Türkiye have implemented GMO regulations to safeguard food safety and environmental concerns, differences in the stringency of regulations, public perception, and the treatment of different genetic modification techniques highlight the nuanced variations in GMO governance between the two regions.

6. Conclusion

Regarding the laboratory, production, import, and permit processes of GMO products, the scope of the legislation was not found to be sufficient in Türkiye. Although the name of the act suggests that it regulates all GMO-related products, it excludes human medicinal products and cosmetics. Therefore, separate legislation and specific procedures are needed for categories such as human medicinal products and cosmetics, which require distinct regulations. In this sense, due to the lack of legislative unity, the risk of uncontrolled inspection has arisen regarding products that could be classified both the food and medical product categories.

Turkish legislation on GMO products revealed that different and overlapping regulatory sources have led to debates regarding the principle of legality. On the other hand, administrative decisions and measures and temporary solutions have been implemented to ensure the functionality of the regulations set by the Act and the Presidential Decree, without necessary updates or changes in the basic articles. This situation creates problems in terms of both administrative stability and predictability.

Since additional changes in application procedures and the decision processes regarding these application procedures have been made by the Presidential Decree and administrative decisions, insecurity is encountered in several aspects. The first of these is the weakening of the security of public officials in doing business based on the law. Second, the legal regime to which the GMO researcher, producer, and importer will be subject and the legislation to be applied to it becomes unclear. Finally, the fact that the liability mechanism is not clearly established in terms of the damage incurred by individuals or enterprises, which are the end consumers of GMO products, may cause unpredictable legal disputes.

Regulations must undergo a transparent administrative procedure within the scope of the Act to clearly define the responsibility, duties, and competence problems that arise in the application process. On the other hand, if all these processes are carried out by an independent agency in a way that will be least affected by the policy, problems of duty, competence, and responsibility will be eliminated. It is suggested that an independent agency, which is scientifically specialized in this subject and established by law, be established instead of having it be an issue that concerns the common jurisdiction of different ministries or administrative units. At the same time, the regulation and supervision of secondary legislation related to its field of expertise will increase the efficiency of the institution.

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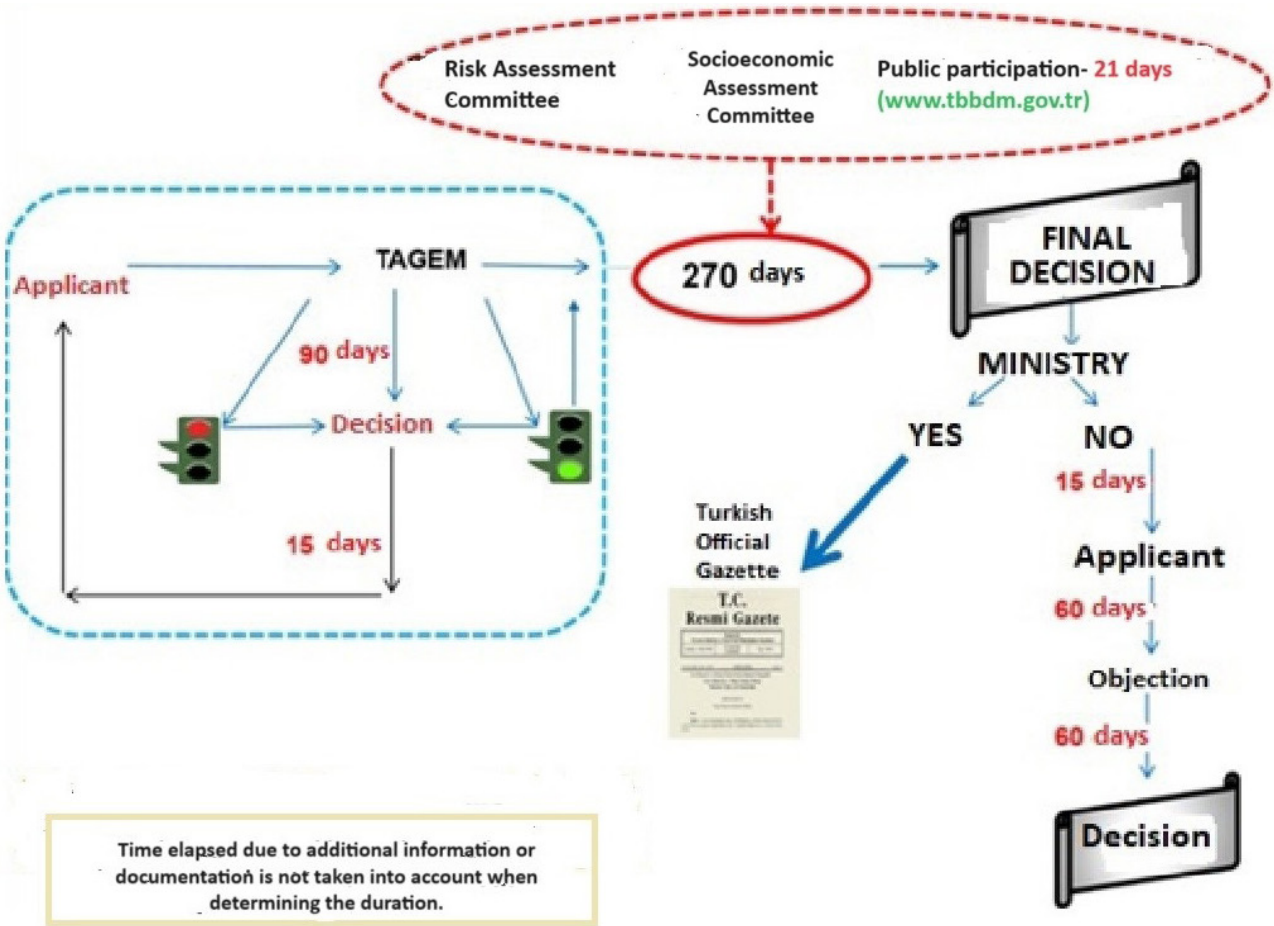
APPENDIX 1
Source: http://www.tbbdm.gov.tr/Surec2.aspx



APPENDIX 2
Evaluation timeline for TAGEM applications
1. Application review by TAGEM: 90 days
2. Notification to the applicant: 15 days
3. Ministry decisions (from notification to the applicant):
- Formation of the Scientific Committee
- Scientific report by the committee
- Presentation of the report to the public*: 270 days
- Evaluation of public opinion by the committee

4. Publication of a positive decision in the official gazette: 30 days
5. Objection period for negative decisions: 60 days
6. Evaluation of objection by the committee: 60 days
*Note: Public opinion is solicited if the application is evaluated as a new submission.
Source: http://www.tbbdm.gov.tr/Surec2.aspx