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Report Highlights:

Hungary is one of the strongest opponents of transgenic engineering in the European Union. Maintaining the country's GE-free status is still a government priority. However, Hungary's scientific and agricultural organizations and breeding and research institutions are speaking out in support of non-transgenic genome editing. In the case of an enabling legislative environment in the EU, the country would be open to adopting innovative biotechnologies.

Executive Summary

Hungary does not produce genetically engineered (GE) crops, animals, or cloned livestock. The Government of Hungary (GOH) opposes the use of GE products in agriculture. Political parties in Hungary have historically held a firm anti-GE position.

Hungary's GE-free status is seen as a commercial and marketing advantage since EU member states are the primary destinations for Hungarian planting seed and grain exports. Still, the country has a structural shortage of animal protein feed and must import large quantities of soybean meal, of which about 90 percent is GE. Therefore, research programs and regional cooperation initiatives and agreements are targeted to increase domestic non-GE soy production and the use of alternative protein crops to reduce the country's dependence on protein feed imports.

This being said, financial, scientific, and agricultural organizations and plant breeding and research institutions are speaking out in support of precision breeding and the potential benefit of such technology for Hungary's agricultural economy. According to various factions, in line with studies on the EU status of new genomic techniques, the EU's directive on genetically modified organisms (GMOs) should be revised, potentially facilitating a path for the use of these new technologies. Both pro-biotech non-governmental organizations (NGOs) and anti-biotech conservationist groups have called for a new or amended/updated national act on biotechnology activities, including innovative biotechnologies.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY
PART A: PRODUCTION AND TRADE
a) RESEARCH AND PRODUCT DEVELOPMENT
b) COMMERCIAL PRODUCTION
c) EXPORTS
d) IMPORTS
e) FOOD AID
f) TRADE BARRIERS
PART B: POLICY
a) REGULATORY FRAMEWORK
b) APPROVALS / AUTHORIZATIONS
c) STACKED EVENT or PYRAMIDED EVENT APPROVALS / AUTHORIZATIONS
d) FIELD TESTING
e) INNOVATIVE BIOTECHNOLOGIES
f) COEXISTENCE
g) LABELING AND TRACEABILITY
h) MONITORING AND TESTING
i) LOW LEVEL PRESENCE (LLP) POLICY
k) INTELLECTUAL PROPERTY RIGHTS (IPR)
1) CARTAGENA PROTOCOL RATIFICATION
m) INTERNATIONAL TREATIES AND FORUMS
n) RELATED ISSUES
PART C: MARKETING
a) PUBLIC / PRIVATE OPINIONS

b) MARKET ACCEPTANCE / STUDIES	1
CHAPTER 2: ANIMAL BIOTECHNOLOGY	1
PART D: PRODUCTION AND TRADE	1
a) RESEARCH AND PRODUCT DEVELOPMENT	1
b) COMMERCIAL PRODUCTION	1
c) EXPORTS	
d) IMPORTS	
e) TRADE BARRIERS	
PART E: POLICY	
a) REGULATORY FRAMEWORK	
c) INNOVATIVE BIOTECHNOLOGIES	1
d) LABELING AND TRACEABILITY	
f) INTELLECTUAL PROPERTY RIGHTS	
g) INTERNATIONAL TREATIES AND FORUMS	
PART F: MARKETING	
a) PUBLIC / PRIVATE OPINIONS	1
b) MARKET ACCEPTANCE / STUDIES	
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	
PART G: PRODUCTION AND TRADE	1
a) COMMERCIAL PRODUCTION	
b) EXPORTS	
c) IMPORTS	
d) TRADE BARRIERS	
PART H: POLICY	
a) REGULATORY FRAMEWORK	1
b) APPROVALS / AUTHORIZATIONS	1
c) LABELING AND TRACEABILITY	1
d) MONITORING AND TESTING	
f) INTELLECTUAL PROPERTY RIGHTS	
g) RELATED ISSUES: none	
PART I: MARKETING	
a) PUBLIC / PRIVATE OPINIONS	1
b) MARKET ACCEPTANCE / STUDIES	1

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

In Hungary, there are no GE plants under development in agriculture or in the pharmaceutical industry, nor are there plans to commercialize such products in the near future. GOH maintains a ban on GE crop cultivation, specifically outlined in the Hungarian Constitution (called the Basic Law). As a result, institutes and universities conduct most of the agricultural biotechnology research in laboratory environments. In Hungary, approximately 100 facilities carry out closed-system gene technology activities, including, but not limited to, agricultural research.

Based on the Ministry of Agriculture's estimate, more than 130 closed-system gene technology studies that apply new genomic techniques are conducted in the country. They are mostly conducted for the purpose of basic research. For example, research at the <u>Agricultural Biotechnology Institute</u> focuses on plants' defense mechanisms and host-pathogen interactions, plant development processes, and crop metabolomics. Optimizing the use of the CRISPR-Cas9 system - a genome editing technique - particularly for barley, wheat, and potatoes is among the Institute's objectives.

The <u>Center for Agricultural Research</u> is also active in plant science research. Its basic aim is to use local germplasm combined with the newest scientific and technical innovations to develop new generic plant genotypes, and to improve stress-adaption and quality in coarse grains. The Research Center also sees great potential in innovative biotechnologies and the applications of the CRISPR-Cas9 system. The Center has made many public comments in support of such innovations.

The European Court of Justice's (ECJ) decision put innovative biotechnologies under the EU's restrictive biotech legislation. However, government sources expressed support for non-transgenic genome editing in case of an enabling legislative environment in the EU, anticipating its positive impact on addressing future challenges of food security, agriculture, environmental, and climate protection. Hungarian plant breeding and scientific institutions have echoed this support over the past six years.

b) COMMERCIAL PRODUCTION

No GE crops or GE seeds on the market are produced in Hungary. In response to <u>Directive (EU)</u> 2015/412, which allows individual member states to ban GE cultivation, the Ministry of Agriculture expressed in 2015 that "it was an especially important strategic interest for Hungary, laid down in its Constitution, to ensure a GMO-free agriculture." Under this directive, Hungary demanded that all of its territory be shielded from pending applications to grow gene-altered crops in the bloc. Measures of the directive have been transposed into national law by the amendment of <u>Act No. XXVII of 1998 on Gene Technology Activity</u> (in Hungarian).

c) EXPORTS

There is no commercial production of GE crops in Hungary, and the country does not export GE products. For years, various factions (including GOH, as well as agricultural and business interests) saw the constitutional prohibition on genetic engineering in agriculture and the country's stated GE-free status as a marketing advantage since EU member states are the primary destinations for Hungarian exports.

d) IMPORTS

Hungary's imports of biotech crops are controversial in terms of its asserted GE-free status. The country has a structural shortage of animal protein feed. The agricultural sector needs around 550,000 MT of soybean meal and full-fat soybean meal annually, of which only 20 percent derives from domestic sources. The other 80 percent (464,000 Mt in 2021), of which about 90 percent is GE,

is imported as trans-shipped product from other EU countries, typically from Slovenia and Germany. This import dependence makes farmers and feed producers vulnerable to external market movements.

Considering the significant shortage of protein feed, the <u>National Agricultural Research and Innovation Center</u> (NARIC) and its <u>Research Institute of Agricultural Economics</u> are in strategic cooperation with the <u>Magyar Szója Nonprofit Kft</u> (the Hungarian Soy Non-profit Ltd; in Hungarian), and the <u>Hungarian Grain and Feed Association</u> (in Hungarian) to help in decreasing the sector's import dependence. The aim of these partnerships is to promote the cultivation of soybean and other protein crops within Hungary.

e) FOOD AID

Hungary is not a food aid recipient country. At the same time, its role as a supplier to international food aid programs is increasing. "The largest humanitarian operation in Hungary's history is going on to help war-torn Ukraine, and it will continue as long as it is needed," the Ministry of Foreign Affairs and Trade announced in June 2022.

Food aid consignments (e.g., processed and canned foods) are directly sent to the war zone and to the ethnic Hungarian populations of Ukraine in the Sub-Carpathian region, as well as to Transylvania in Romania. Those consignments do not involve any kind of GE food products.

f) TRADE BARRIERS

One of the most sensitive issues in Hungarian agriculture is the maintenance of the country's GE-free status. GOH opposes the use of GE products in agriculture. In this respect, all parties in Hungary hold a strong anti-GE position. Nevertheless, there is no legal or de facto ban on the trade of GE products except for the domestic marketing and use of GE seeds and propagating materials. Cultivation of plants with GE traits are strictly prohibited in the territory of Hungary.

PART B: POLICY

a) REGULATORY FRAMEWORK

In Hungary, the Ministry of Agriculture takes the lead on regulating GE crop cultivation, trade, and processing. The <u>National Food Chain Safety Office</u> (NFCSO) (in Hungarian) is the top government organization handling the technical aspects of GE products such as inspection, testing, and registering plant varieties.

Although the Ministry of Agriculture formally makes approvals, the <u>Gene Technology Advisory Committee</u> (in Hungarian) evaluates biotech activities and products in Hungary. It provides professional opinions on applications submitted to gene technology authorities and makes recommendations on their acceptance or refusal. The Ministry of Agriculture, the Ministry of Interior, the <u>Hungarian Academy of Sciences</u> (HAS), the <u>National Research</u>, <u>Development</u>, and <u>Innovation Office</u>, and non-governmental organizations (NGOs) nominate the members of the Advisory Committee. Ministries typically nominate scientists or experts from think tanks.

Since 2006, Hungary has been following its GE-free strategy (<u>Parliamentary Resolution No. 53/2006</u> – in Hungarian). <u>Act No. LIII of 1996 on nature conservation</u> was the country's first law to include

provisions on GE organisms. Today, the main piece of biotech-related legislation is <u>Act No. XXVII of 1998 on Gene Technology Activity</u>. Based on this act, it has priority to prevent Hungary's domestic production from unregulated entry of GE plant varieties and to give expanded powers to environmental, agricultural, and industrial biotechnology authorities. For direct consumption of imported food and feed containing GE materials, the act orders the use of legal and administrative procedures corresponding to the EU.

Hungary's legislation on GE crops, animals, and microbes as well as on their products is fully harmonized with the EU, transposing directives into national law. EU regulations pertaining to GE products are directly applied.

Below is an abbreviated list of those rules and regulations regarding biotechnology.

- Decree No. 82/2003. (VII. 16.) (in Hungarian) on rules of registration and reporting of gene technology activity, and on the documentation that must be enclosed in the notification (application for authorization) of such activity.
- Joint Decree No. 111/2003. (XI. 5.) (in Hungarian) on procedures that must be considered as gene technology activities as well as on authorities that are entitled to control them.
- <u>Decree No. 128/2003. (XII. 19.)</u> (in Hungarian) on the organization and the activity of the Gene Technology Advisory Committee.
- <u>Decree No. 48/2004. (IV. 21.)</u> (in Hungarian) on production and marketing of arable seeds.
- Government Decree No. 132/2004. (IV. 29.) (in Hungarian) on the authorization procedure of gene technology activity as well as on liaising with the European Commission in the course of that.
- Decree No. 142/2004. (IX. 30.) (in Hungarian) on certain rules of gene technology activity in the field of agriculture and industry.
- Joint Decree No. 31 of 2006 (IV. 29.) (in Hungarian) on imports and distribution of genetically modified feedstuffs.
- Decree No. 86/2006. (XII. 23.) (in Hungarian) on coexistence measures on the cultivation of genetically modified, conventional, and organic plants.
- Decree 53/2013. (VI. 17.) (in Hungarian) on safeguard clause procedure on seeds of inbred lines and hybrids of MON 810 corn.

As there are no uniform rules and regulations on labeling of GE-free food and feed within the EU, Hungary developed its own system. <u>Decree No. 61/2016</u> (IX. 15) (in Hungarian) on labeling GE-free products entered into force on September 20, 2016.

Table 1. Legal terms applied in Hungary's legislation on biotechnology

Legal term (in	Legal Term	Laws and	Legal Definition
Hungarian)		Regulations where	
		term is used	

Természetes szervezet	Natural organism	Act No. XXVII of 1998 on Gene Technology Activity	Any biological entity, with the exception of human beings, capable of reproducing and transferring its genetic material.
Géntechnológiával módosított szervezet	Genetically modified organism (GMO)	Act No. XXVII of 1998 on Gene Technology Activity	Any natural organism in which the genetic material has been altered by genetic modification, including the progeny of such organisms carrying the properties appearing as a result of these modifications.
Géntechnológiai módosítás	Genetic modification	Act No. XXVII of 1998 on Gene Technology Activity	Any method which extracts a gene or any part thereof from the cells and transplants it into another cell or introduces synthetic genes or gene fragments into a natural organism to alter the genetic material of the recipient.
Géntechnológiával módosított termék	Genetically modified product	Act No. XXVII of 1998 on Gene Technology Activity	Any preparation consisting of or containing a genetically modified organism or a combination of genetically modified organisms which is placed on the market.
Zárt rendszerű felhasználás	Contained use	Act No. XXVII of 1998 on Gene Technology Activity	Any activity in which microorganisms are genetically modified or in which such genetically modified microorganisms are cultured, stored, transported, destroyed, disposed of, or used in any other way and for which specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

b) APPROVALS / AUTHORIZATIONS

In Hungary, the cultivation of GE crops is constitutionally prohibited. There are no GE plants approved for production. Data on experimental releases authorized decades ago can be found on the <u>Hungarian Biosafety Website</u>.

Regarding the import of food and feed with GE content, Hungary applies EU-harmonized legislation. Approval of GE products at EU levels falls under Regulation (EC) No 1829/2003. The EU legislation gives responsibility for scientific risk assessments to the European Food Safety Authority (EFSA) in cooperation with the Member States'(MS) scientific bodies. After EFSA has reviewed the application to assess food safety and provided a scientific opinion, the European Commission and the Member States review and vote upon the application for market approval. A full list of approved GE products as well as products for which an authorization procedure is pending is available at: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm

c) STACKED EVENT or PYRAMIDED EVENT APPROVALS / AUTHORIZATIONS

Hungary follows EFSA's guidelines for stacked events. At the EU level, stacked events are subject the provisions of EU Regulation No. 503/2013, Annex II.

d) FIELD TESTING

Field tests for GE crops have not been approved in Hungary since 2012, according to the <u>Hungarian Biosafety Homepage</u>. Previous tests were conducted for scientific purposes only in corn, tobacco, potato, sugar beet, wheat, and barley. None of these crops were ever commercialized.

e) INNOVATIVE BIOTECHNOLOGIES

Since 2004, Hungary has been one of the strongest opponents of transgenic engineering in the EU. However, Hungary's Ministry of Agriculture, financial, scientific, and agricultural organizations and plant breeding and research institutions have spoken in support of precision breeding.

It was an important milestone that the Hungarian Academy of Sciences published a <u>report</u> (in Hungarian) in 2017, concluding that genome-edited products should not be considered "GMOs" as defined – and prohibited – by the Hungarian Constitution. The Hungarian Academy of Sciences also stated that Hungary would stand to benefit from innovative biotechnologies as they become more widely used.

In 2018, Hungary's Agriculture Minister also outlined his opinion in support of genome editing, arguing that precision breeding without the introduction of foreign DNA must be supported and cannot be regarded as genetic modification. In line with his opinion, the Ministry of Agriculture and GOH's ally organizations such as the National Chamber of Agriculture became more open to dialogues on agricultural innovation even in terms of non-transgenic technologies.

After the decision from ECJ, which included products from innovative biotechnologies under the EU's "GMO" legislation, the National Chamber of Agriculture and the Association of Hungarian Farmer Cooperatives and Societies issued a press release, including the following statement: "It is necessary to carry out the needed scientific research on and risk assessments of genome editing to eliminate any possible adverse effects on human health and the environment. With delays or neglect of these methods, we run the risk of isolating European and domestic agriculture from the benefits of innovative developments, as opposed to the rest of the world. In parallel, there is also a risk of losing research capacities that would allow us to join agricultural developments after the risk assessment of these technologies."

Comments made by the Minister of Agriculture seemed to echo this belief. According to Minister

István Nagy, although Hungary must accept the ECJ's judgement, the "GMO" legislation should be revised. Still, the official position from GOH on genome editing is not yet publicly available.

Since 2018, the Ministry of Agriculture has been in listening mode, unlike professional organizations and research institutions. The latter ones highlighted widely shared concerns about the ECJ's ruling, which equates products developed using targeted forms of mutagenesis with genetically modified organisms. Joining EU-wide initiatives, they called on the European Parliament and the European Commission to rethink the EU's stance on genome editing of crop plants to enable Europe to compete in sustainable food production and keep up with the speeding pace of innovation in agriculture. These institutions wanted to reverse the ECJ's ruling on innovative biotechnologies. Hungary's Biological Research Center highlighted the need for new EU legislation to enable farmers to use new technologies and to produce higher yields while decreasing the use of chemicals and water.

f) COEXISTENCE

The Government approved its Coexistence Regulation in November 2006 (see the "Biotech update 2006"; report <u>HU6015</u>) by the amendment of <u>Act No. XXVII of 1998 on Gene Technology Activity</u> (Chapter III). This act, as well as <u>Decree No. 82/2003</u> (in Hungarian) and <u>Decree No. 86/2006</u> (in Hungarian) outline the rules for coexistence of organic, conventional, and GE crops. These rules determine all the conditions that are designed to prevent the uncontrolled spread of GE crops and their mixing with non-GE products, and to include buffer distances, cleaning of machinery, and separate storage.

g) LABELING AND TRACEABILITY

Hungary follows the EU's labeling standards. If GE content is above 0.9 percent per ingredient, it must be indicated on the item's label. Meat and other animal products derived from animals fed on GE feed do not require a distinctive label.

Since there are no uniform rules and regulations on labeling of GE-free food and feed in the EU, Hungary developed its own labeling system (for the specific legislation, see Chapter 1, Part B, subparagraph a). This legislation provides special labeling of GE-free food, feed, and processed products as well as labeling of GE-free honey, meat, fish, eggs, and milk from livestock fed on certified GE-free feed. The application of the "GMO-free" labeling is voluntary.

For a product to be labeled "GMO-free," it must not contain any GE organisms or derive from livestock fed on GE material. Labeling claims must be verified by the producers. Producers and traders of food labeled as being GE-free are obliged to ensure the traceability of the products including raw materials. According to the national law, food products of plant origin can still be labeled as "GMO-free" in case of minute GE content (i.e., traces of GE material up to 0.1 percent) if the content is adventitious or technically unavoidable. However, animal feed can be used in GE-free meat, fish, milk, and egg production if it is not required to be labeled due to its GE ingredient content under Regulation (EC) No. 1829/2003. This means that the permitted GE content in "GMO-free" feed is 0.9 percent.

The "GMO-free" label cannot give the impression to customers that the product has special sensory and nutritional features, and its effect on environment and health is better than similar products. In addition, products that have no licensed GE version on the market cannot be labeled as "GMO-free."



Certifying mark for labeled products derived from GE-free production

h) MONITORING AND TESTING

Hungary is a major seed exporter, and the genetic purity of seeds is highly important to producers. Plant propagation materials (including seeds) go through sampling and laboratory analysis for the presence of GE traits. Official controls apply to Hungarian crops and seeds from other EU member states and non-EU countries. Under the rules, third country seed imports are subject to mandated testing for GE presence, paid for by importers or distributors. Imported seeds from EU member states must be accompanied by a negative GE test from an EU accredited laboratory. Farmers can only use seeds that have been certified as GE-free.

Corn, rapeseed, soybean, rice, flaxseed, potato, pepper, sweet potato, tomato, wheat, and avocado products were the targets of GE testing efforts over the past years. However, petunia and dianthus plants were also tested for GE traits.

i) LOW LEVEL PRESENCE (LLP) POLICY

Hungary applies a zero-tolerance policy for LLP of GE products in feed, following the measures of Commission Regulation (EU) No. 619/2011. It lays down the methods of sampling and analysis for the official control of feed as regards presence of GE materials. The EU defined "zero" with a "technical solution" level of 0.1 percent.

j) ADDITIONAL REGULATORY REQUIREMENTS: none

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

In Hungary, there is no specialized intellectual property rights legislation for GE products. Genetically engineered crops cannot be planted commercially. In general terms, the country is against patents on genetic materials. Application for national plant variety protection can be filed with the Hungarian Intellectual Property Office, while the application for EU plant variety protection can be submitted directly to the Community Plant Variety Office.

Hungary is an active participant of negotiations under the <u>International Union for the Protection of New Varieties of Plants</u> and the International Convention for the Protection of New Varieties of Plants.

1) CARTAGENA PROTOCOL RATIFICATION

The Hungarian Parliament ratified the Cartagena Protocol on January 13, 2004. Government Decree

No. 226/2008 (IX.11) (in Hungarian) laid down the rules for implementation. The publication of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was adopted by Act No. CLXXI of 2013 (in Hungarian).

With respect to the Convention on Biological Diversity (see <u>the sixth national report</u>), Hungary created a <u>National Strategy for the Conservation of Biodiversity</u> (NSCB) for the period of 2015-2020. Following its objectives, the elaboration of a new strategy for 2021-2030 has already started, and the <u>draft of the new NSCB</u> (in Hungarian) is available for public consultation.

The new draft NSCB suggests actions to eliminate the potentially harmful effects of modern biotechnology on biodiversity, for example:

- "Maintaining Hungary's GE-free status by a complete ban on the cultivation of GE crops.
- Increased monitoring of seeds, feed, and food to filter out items contaminated with GE traits.
- Supporting research activities and providing resources for the development of detection methods for new genomic techniques and for the environmental effects of their resultant organisms."

m) INTERNATIONAL TREATIES AND FORUMS

Hungary is an active member of different intergovernmental and standard setting international organizations (e.g., Organization for Economic Co-operation and Development; World Trade Organization; Codex Alimentarius; Food and Agriculture Organization of the United Nations - International Plant Protection Convention; etc.). Despite the relatively small market size of the country, Hungary can leverage its regional influence as a member of these organizations, especially through the EU representation and regional alliances such as the Visegrád Group (V4).

n) RELATED ISSUES

Since Hungary is only 20-25 percent self-sufficient in soybean meal, the membership and participation of Hungarian soybean grower and processing companies, nonprofit organizations, and research institutes in the <u>Donau Soja (Danube Soy) Organization</u> stimulate the region's non-GE soybean production and aim to reduce the country's large-scale dependence on imports.

According to the Eastern and Central European Member States that participate in the Donau Soja Organization, developing and increasing the EU's plant protein production could be a way of effectively addressing food security, environmental issues, and climate challenges that European agriculture is facing. In this regard, Hungary raised its voice at the <u>Agriculture and Fisheries Council</u> meetings in favor of the EU's GE-free production. "GMO-free crops that meet European standards could contribute to environmental and climate goals," Hungary's Minister of Agriculture, István Nagy outlined at the Council's meeting in 2020. As a reappointed minister in 2022, he confirmed that position at his hearing in front of the Sustainable Committee of the National Assembly. The Minister stated that he would continue to use all means necessary to maintain the country's GE-free status.

PART C: MARKETING

a) PUBLIC / PRIVATE OPINIONS

Hungarian consumers' careful attitude to GE products has been under pressure from anti-technology campaigns for years. The press often publishes negative opinions about GE ingredients in food and feed. At the same time, consumers' choices and attitudes are mostly influenced by price sensitivity, the availability of substitute goods, and – to a lesser extent – by their awareness of new technologies and products.

b) MARKET ACCEPTANCE / STUDIES

While several surveys point to the increasing health awareness of domestic buyers, other studies have shown that price continues to be the most decisive criteria for consumers in Hungary. In this regard, it is worth noting that the replacement of GE soybean meal in animal feed rations with conventional products would result in higher food prices if there were real or available protein feed alternatives in the needed amount. Currently, high inflation, soaring energy, feed and food prices, and the challenges that the livestock sector is facing are acting against the replacement of cheaper GE meals. Note: Food prices in Hungary rose by an annual 35.2 percent in September 2022 as the price of bread jumped 76.2 percent and dairy products cost 66.3 percent more than a year ago.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

In Hungary, there is no commercial use of GE animals and clones for agriculture. Biotechnology for genetic improvement is mainly related to livestock breeding. The <u>Agricultural Biotechnology</u> <u>Institute</u> of NARIC is the most active agricultural research facility in animal biotechnology. NARIC focuses on exploring the genetics of bovine diseases and works on the adaptation and development of genome editing tools for precision breeding. They are also involved in the functional characterization of pluripotent stem cells and working on models for biotechnology applications.

b) COMMERCIAL PRODUCTION

Hungary does not produce any livestock clones, offspring of clones, GE animals, or products derived from animal biotechnologies in agriculture. There is no information available on the production of GE animals for biomedical or experimental purposes.

c) EXPORTS

Hungary does not export GE animals, livestock clones, or products from these animals including genetics.

d) IMPORTS

There are no imports of GE animals. Although no legislation regulates the import of semen or embryos from clones, livestock clones or genetics from these animals are unlikely to be imported into Hungary. The increasingly better and improved traits and top-quality genetics from new sires available on the market make it unnecessary.

e) TRADE BARRIERS

See Chapter 1, Part A, subparagraph f).

PART E: POLICY

a) REGULATORY FRAMEWORK

Genetic engineering, including animal biotechnology, is regulated by <u>Act No. XXVII of 1998 on Gene Technology Activity</u>. The Ministry of Agriculture takes the lead and makes decisions regulating biotech issues. NFCSO is the top government organization that handles technical aspects such as inspection and testing. The administrative body, that receives and evaluates GE applications for biotechnology experiments, is the Gene Technology Advisory Committee (in Hungarian).

Hungary has no country-level legislation related to the commercial use and trade of clones, their offspring, or products derived from these animals. GOH supports the EU's efforts to create common EU legislation and institutions governing animal cloning. At the same time, Hungary is still a vocal opponent of GE animal products.

For more information, see Chapter 1, Part B, subparagraph a), and consult the <u>EU27 Biotechnology</u> and Other New Production Technologies Annual.

b) APPROVALS / AUTHORIZATIONS

In Hungary, there are no GE animals approved or registered for use.

c) INNOVATIVE BIOTECHNOLOGIES

In Hungary, breeding and scientific institutions see the necessity and the potential of innovative biotechnologies. For more information, see Chapter 1, Part B, subparagraph e).

d) LABELING AND TRACEABILITY

Hungary does not produce or trade in any livestock clones, GE animals, and their offspring or products. Although GE laboratory animals are used in biomedical and animal biotechnology experiments, they are not released. Therefore, there is no policy for labeling and traceability related to livestock clones and GE animals.

e) ADDITIONAL REGULATORY REQUIREMENTS: none

f) INTELLECTUAL PROPERTY RIGHTS

There is no specialized intellectual property rights legislation for animal GE products. Applications for animal patents can be filed with the Hungarian Intellectual Property Office.

g) INTERNATIONAL TREATIES AND FORUMS

Hungary actively participates in the work of several multilateral and intergovernmental organizations such as the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, and Codex Alimentarius related to animal health and food safety issues. In general terms, the country is against GE animals, but there is no specified position on animal biotechnologies.

h) RELATED ISSUES: none

PART F: MARKETING

a) PUBLIC / PRIVATE OPINIONS

The Hungarian public is quite critical of products coming from advanced production technologies. Animal cloning and food products made from cloned animals trigger concerns. Hungarian consumers are skeptical of the necessity and usefulness of food made from cloned or GE animals. At the same time, public opinion is quite positive about animal biotechnology used for medical purposes.

b) MARKET ACCEPTANCE / STUDIES

Public views on animal products connected with cloning and genetic engineering are expected to be similar to those held for GE crops. These products are likely to be rejected by most of the food retail chains in Hungary.

Although several biotechnology companies, university knowledge centers, and bio-incubators deal with research on animal biotechnology in Hungary, market surveys on the sale and use of GE animals and clones are not available. Biotech companies could gain ground mainly on the market of veterinary molecular diagnostics and marker-assisted selection.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Hungary's food and grain processing industry uses recombinant microorganisms and their enzymes for ethanol, isosugar, cheese, and lactose-free production as well as for starch processing.

There is a wide assortment of recombinant microbes applied in the food industry, especially in the dairy business including mesophilic, thermophilic, and acid-producing cultures, probiotics, molds, and yeasts: Aspergillus niger var. awamori, Bifidobacterium infantis, Bifidobacterium breve, Bifidobacterium longum, Brevibacterium linens, Corynebacterium flavescens, Escherichia coli K12, Débaryomyces hansenii, Geotrichum candidum, Kluyveromyces marxianus, Kluyveromyces lactis, Lactobacillus brevis, Lactobacillus casei, Lactobacillus delbrueckii, Lactobacillus helveticus, Lactobacillus plantarum, Lactobacillus rhamnosus, Lactococcus lactis, Lactococcus paracasei, Leuconostoc mesenteroides, Saccharomyces cerevisiae, Staphylococcus carnosus, Staphylococcus xylosus, Streptococcus salivarius, Streptococcus thermophiles, Tricoderma reesei, etc. There is no information available about techniques used to alter these microbes.

b) EXPORTS

Although there is no information available about the trade of GE microbes, Hungary exports alcoholic beverages, dairy, and other processed products which may contain microbial biotechderived food ingredients.

c) IMPORTS

Hungary imports recombinant microbes and microbial biotech-derived food ingredients, such as chymozin, lactase, and riboflavin. Trade data is not available.

Likewise, imported alcoholic beverages, dairy, and processed food products may contain biotechderived food components.

d) TRADE BARRIERS

See Chapter 1, Part A, subparagraph f).

PART H: POLICY

a) REGULATORY FRAMEWORK

Hungary's legislation on GE microbes is fully harmonized with the EU, transposing directives into national law. EU regulations pertaining to GE products are directly applied.

Regulation (EC) No 1331/2008, which establishes a common authorization procedure for food additives, food enzymes, and food flavorings, and Regulation (EU) 2015/2283 on novel foods, are both excluded from the EU's GE food and feed regulation (Regulation /EC/ No 1829/2003). Thus, approved food enzymes and novel food produced with GE microorganisms are not considered GE products.

For more information, please consult the <u>EU27 Biotechnology and Other New Production</u> Technologies Annual.

b) APPROVALS / AUTHORIZATIONS

For approvals and the authorization of GE microorganisms and their products intended for food, Hungary applies EU-harmonized legislation, which is based on the EFSA's risk assessment.

Independently of whether food additives, enzymes, and flavorings are products of GE origin or not, the list of authorized substances can be found in the Annex of <u>Commission Regulation (EU) No 1130/2011</u>.

c) LABELING AND TRACEABILITY

Food ingredients produced with GE microbes do not require labeling as GE products. Still, food substances derived from or produced from GE microorganisms, containing detectable genetic material, must be labeled as GE materials (for more information, please see Chapter 1, Part B, subparagraph g).

d) MONITORING AND TESTING

The NFCSO's annual monitoring activity to identify the presence of ingredients derived from GE organisms does not test for microbial GE content in food products.

e) ADDITIONAL REGULATORY REQUIREMENTS: none

f) INTELLECTUAL PROPERTY RIGHTS

There is no specialized intellectual property rights legislation for microbial GE products. Applications for patents can be filed with the <u>Hungarian Intellectual Property Office</u>.

g) RELATED ISSUES: none

PART I: MARKETING

a) PUBLIC / PRIVATE OPINIONS

Although the public is quite critical of new biotech achievements in the food industry, public awareness on microbial biotechnology is very low. Consumers' approach is skeptical regarding its necessity. By contrast, research institutes have also raised their voice in favor of genome editing in microbial biotechnology.

b) MARKET ACCEPTANCE / STUDIES

Most produced from microbial biotech-derived food ingredients no longer contain any evidence of genetic engineering. Therefore, microbial biotechnology and its public acceptance are not a focus of discussion and market studies.

Attachments:

No Attachments