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Report Highlights:

Maintaining Hungary's GE-free status remains a government priority. Although the country's scientific and breeding institutions were supportive of genome editing, the EC's legislative proposal on NGTs was caught in a political crossfire in October 2023. Hungary's National Assembly launched a campaign against the EC's "stealth" legislation. The incumbent Hungarian EU Presidency is also trying to reopen discussions on NGTs and find a way out of the deadlock situation.

Executive Summary

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

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 a significant part is GE. Therefore, research programs and regional cooperation initiatives to increase domestic non-GE soybean production, and the use of alternative protein crops to reduce the country's dependence on protein feed imports are a high priority for the government.

Financial, scientific, and agricultural organizations and plant breeding and research institutions have spoken out in support of precision breeding and the potential benefit of such technology for Hungary's agricultural economy. However, maintaining the country's GE-free status has been among the government's highest priorities since 2004. Therefore, Hungary cited the Precautionary Principle and has not supported any initiative which would allow NGT products to be placed on the market without risk assessments. Additionally, the country advocates for a mandatory NGT labeling system to maintain freedom of choice for consumers and economic operators.

In October 2023, the EC's legislative proposal on NGTs was caught in a political crossfire. Hungary's National Assembly (86 percent of votes) launched a campaign against the draft legislation. Hungary raised concerns about the proposal and its perceived sovereignty violations and insisted on strong precautionary measures. Following up on this strong national (parliamentary) mandate, Hungary started its EU Presidency with a bold move in July 2024, trying to reopen EU discussions on NGTs issues. Hungary submitted a non-paper, which was sent to the participants of the EU's "Genetic Resources and Innovation in Agriculture" Working Group and raised fundamental questions again about the EC's draft legislation.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

In Hungary, there are no GE plants under development in the agriculture or in the pharmaceutical industries, nor are there plans to commercialize such products in the near future. The GOH maintains a ban on GE crop cultivation, as 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 in the <u>National Biodiversity Strategy for 2030</u>, 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>Institute of Genetics and Biotechnology</u> (IGB) of the <u>Hungarian University of Agriculture and Life Sciences</u> (MATE) focuses on the molecular and epigenetic analysis of phenotypic characteristics of crop plants, the clarification of protective mechanisms against abiotic and biotic stress effects, and the development of genome editing procedures.

The <u>Agricultural Research Institute</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 biotic and abiotic stress tolerance and adaptation, and quality in coarse grains. In addition to traditional introgression, molecular breeding methods (e.g. the CRISPR-Cas9 system) are used to produce plants of higher disease resistance and photosynthetic efficiency.

b) COMMERCIAL PRODUCTION

No GE crops or GE seeds on the market are produced in Hungary. In response to the amendment of Directive 2001/18/EC, 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 Act No. XXVII of 1998 on Gene Technology Activity (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 the 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 and many EU consumers have concerns regarding GE products.

d) IMPORTS

Hungary's biotech crop imports are controversial in terms of its asserted GE-free status. The country has a structural shortage of animal protein feed. The agricultural sector needs more than half a million MT of soybean meal and full-fat soybean meal annually, of which less than 20 percent is derived from domestic sources. The remaining demand (475,734 MT in MY2022/23) was satisfied mostly with

transshipped products from EU countries (typically from Slovenia and Germany) of which a significant part was GE. Ukraine has also become one of the main suppliers since 2023. This import dependence makes farmers and feed producers vulnerable to external market movements.

e) FOOD AID

Hungary is not a food aid recipient country. At the same time, the country maintains its role as a supplier to international food aid <u>programs</u>. Food aid consignments (e.g., processed and canned foods) are directly sent to war-torn and famine-affected regions. 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. The 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 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>, <u>and 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). Act No. <u>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 is a priority is 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.

Hungary's legislation on GE crops, animals, microbes and derived 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.

- <u>Decree No. 82/2003. (VII. 16.)</u> (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.
- <u>Decree No. 111/2003. (XI. 5.)</u> (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.
- 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.
- Decree No. 48/2004. (IV. 21.) (in Hungarian) on production and marketing of arable crop seeds.
- <u>Decree No. 142/2004. (IX. 30.)</u> (in Hungarian) on certain rules of gene technology activity in the field of agriculture and industry.
- <u>Decree No. 31 of 2006 (IV. 29.)</u> (in Hungarian) on imports and distribution of genetically modified feedstuffs.
- <u>Decree No. 86/2006. (XII. 23.)</u> (in Hungarian) on coexistence measures on the cultivation of genetically modified, conventional, and organic plants.
- <u>Decree 53/2013. (VI. 17.)</u> (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 (IX. 15)</u> (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 Hungarian)	Legal Term	Laws and Regulations where term is used	Legal Definition
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 the EU level 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 EC 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/dyna2/gm-register/.

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 <u>EU Regulation No. 503/2013</u>, 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 financial, scientific, and agricultural organizations and plant breeding and research institutions have spoken in support of non-transgenic precision breeding.

In 2017, the Hungarian Academy of Sciences published a <u>report</u> (in Hungarian) 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.

After the decision from the European Court of Justice in 2018, 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."

Regarding the highlighted need for proper health and environmental risk assessments, Hungary's position on NGTs calls for labeling and traceability guarantees. As the EC presented its <u>proposal for a new regulation on plants produced by certain NGTs</u> on July 5, 2023, Hungary made it clear, that the country's GE-free agricultural production is anchored in its constitution. Since the EC's proposal

would not allow the Member States to decide for themselves whether or not to grow plants produced with NGTs on their territories, Hungary contested the proposal and cited the precautionary principle to prohibit any initiative to allow NGT products on the market without "appropriate risk assessments."

Governmental press releases stated that the Ministry's priority was to strengthen and maintain food and feed security and to protect the interests of traditional farmers, especially organic farmers. "For this reason, the regulation must include guarantees that ensure proper labeling and traceability of NGT products and allow their exclusion from organic farming. Only by maintaining mandatory labeling can consumer choice be guaranteed."

On October 9, 2023, the Hungarian Parliament's Committee on European Affairs examined the EC's regulatory proposal on NGTs, and scrutinized its compliance with the <u>principle of subsidiarity</u> laid down in the Treaty on European Union. Under this principle, decision should be made at the lowest possible level. The Committee concluded that the draft regulation violated the principle of subsidiarity as it did not take regional and national specificities into account. Additionally, the proposal contained no provision to maintain the member states' sovereignty, which would give them the right to decide whether they want to cultivate gene-altered crops on their territory or not. The Committee believes that all the EU Member States should maintain the power granted by the <u>amendment of Directive</u> 2001/18/EC in 2015 regarding the cultivation of GMOs for all categories of NGTs."

On October 9, 2023, the Parliament's Legislative Committee also discussed and adopted the report of the European Affairs Committee.

The comprehensive parliamentary debate over the report was held on October 10, 2023, with the participation of all political parties, as a part of the agenda of the National Assembly's fall session. The Parliament issued a resolution (No. 21/2023) on October 25, 2023, on the adoption of the European Affairs Committee's report. Accordingly, the Hungarian Parliament found (by 171 votes in favor, 12 against, and one abstention) that the EC's draft regulation violates the principle of subsidiarity and called on the President of the National Assembly (the Speaker of the House) to forward the European Affairs Committee's reasoned opinion to the presidents of the European Parliament, the European Council, and the European Commission.

On April 24, 2024, in its final plenary session, the EU Parliament endorsed the EU Commission's proposal to widely deregulate NGTs, but EU governments failed to agree on gene-editing rules on June 27, 2024. The Commission's proposal on NGTs was withdrawn from the agenda after it emerged in preliminary talks that there was insufficient support to reach a qualified majority. Despite this setback, Hungary submitted a non-paper right after the start of its EU Presidency (July 1, 2024), trying to reopen discussions on unsolved NGT issues, including those that already had a qualified majority. Germany and neighboring countries, such as Austria, Croatia, Romania, and Slovakia welcomed the discussion paper, but those member states which supported the EC's regulatory proposal showed less interest in the initiative. At the same time, in its role as EU President, Hungary claims that it wants to find a way out of the deadlock situation.

f) COEXISTENCE

The Government approved its Coexistence Regulation in November 2006 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) outlines 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 "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 their 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, commodities that have no licensed GE alternative 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, wheat, rapeseed, soybean, rice, potato, flaxseed, pepper, sweet potato, tomato, avocado, petunia, and dianthus were the targets of GE testing efforts over the past years.

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. <u>Government Decree No. 226/2008 (IX.11)</u> (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 <u>Act No. CLXXI of 2013</u> (in Hungarian).

With respect to the Convention on Biological Diversity (see <u>the sixth national report</u>), Hungary's new <u>National Biodiversity Strategy for 2030</u> (NBS) was approved and issued on August 8, 2023.

NBS suggests actions to "keep the GMO-free status of agriculture" with the help of:

- A "total prohibition on the cultivation of genetically modified crops"
- "Increased monitoring of seeds, feed, and food products to detect GMO contaminated lots"
- "Immediate and safe destruction of contaminated lots and any sprouted crops."

NBS aims at "minimizing environmental risks from non-agricultural use of GMOs" by:

- "Strengthening risk assessment of gene technology activities"
- "Monitoring of relevant waste management rules and other precautionary approaches for contained uses of GMOs"
- "Inspecting at least 30 percent of authorized gene technology activities annually"
- "Detecting, withdrawing, and destroying GMOs illegally released on the market."

NBS also pays attention to "improving knowledge of detection methods and environmental impacts on organisms obtained by new genomic techniques in order to ensure proper monitoring and prevent adverse impacts on biodiversity."

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 country's relatively small market size, Hungary can leverage its regional influence as a member of these organizations, especially through EU representation and regional alliances such as the <u>Visegrád Group</u> (V4).

n) RELATED ISSUES

Since Hungary is about 20 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.

During bilateral meetings with USDA representatives over the past years, Hungary's Minister of Agriculture, István Nagy stressed that Hungary's goal was to strike a balance between the aspects of competitiveness and climate protection. He confirmed that climate goals could only be achieved through innovation. His opinion was echoed at an informal meeting of EU agriculture ministers and officials in Budapest (Hungary) on September 10, 2024. Hungary emphasized that its EU presidency would hold "intense discussions" to reach conclusions on the post-2027 farm budget. The Hungarian minister also added that EU ministers wanted to create a balance between the requirements that farmers need to meet and their competitiveness. "We also agree that we must keep up the contribution of agriculture to the green transition and we need to make farmers interested in it through incentives," he said.

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 total replacement of GE soybean meal in animal feed rations with conventional products would result in higher prices if there were available protein feed alternatives in the needed amount.

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. At the same time, research is conducted to create translational animal models of human disorders and for biotechnology purposes as well, applying state of the art genome editing techniques and genomic approaches.

The <u>Institute of Genetics and Biotechnology</u> of <u>MATE</u> is the most active agricultural research facility in animal biotechnology. Its precision breeding and model animal genetics research groups aim to create GE model animals (mouse, rabbit) and to provide a technological basis for precision developments. In addition to the CRISPR-Cas9 system, they are using transposon-based transgenesis and traditional gene delivery methods as well. While the development of genetic, genomic and biotechnology approaches directly support agricultural objectives, these groups also represent a special segment of research providing high-value animal models for non-food purposes. For example, recent projects involve rabbit models of heart and cardiovascular diseases and a mouse model of autism.

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 is <u>the Gene Technology Advisory Committee</u> (in Hungarian), which receives and evaluates GE applications for biotechnology experiments.

Hungary has no country-level legislation related to the commercial use and trade of clones, their offspring, or products derived from these animals. The 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 <u>Hungarian Intellectual Property Office</u>.

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 biotech-derived 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.

<u>Regulation (EC) No 1331/2008</u>, which establishes a common authorization procedure for food additives, food enzymes, and food flavorings, and <u>Regulation (EU) 2015/2283</u> on novel foods, are both excluded from the EU's GE food and feed regulation (<u>Regulation /EC/ No 1829/2003</u>). 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 Technologies Annual</u>.

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 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 tend to be skeptical regarding its necessity. By contrast, research institutes have raised their voice in favor of genome editing in microbial biotechnology.

b) MARKET ACCEPTANCE / STUDIES Most products produced from microbial biotech-derived fo

Most products 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