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Report Highlights:

There are no significant changes to the agricultural biotechnology situation in the Czech Republic in 2024. The country generally maintains a scientific approach towards biotechnology and became a vocal advocate for their adoption in the EU during its EU Council presidency. Czech farmers planted genetically engineered (GE) corn from 2005 to 2017. Cultivation ended as GE products became too difficult to market and sell on the European market. There are no cultivation bans on GE crops in the Czech Republic. Czech researchers continue small scale field trials. Some companies based in the Czech Republic use microbial biotechnologies in their production process.

EXECUTIVE SUMMARY

The Czech Republic is one of the few EU member states that allows commercial planting and field trials of GE crops. Planting began in 2005, peaked in 2008, but over time declined, and stopped in 2017. In 2023, field trials totaled an area of 0.405 HA including buffer zones, and 0.0687 HA excluding buffer zones. In 2024 the field trial area is estimated to remain at the same level. In the Czech Republic there are companies using microbial biotechnologies for pharmaceutical manufacturing and to produce food and feed additives.

Czech scientists and farm groups are vocal in their support for more crop biotechnology and frequently dispel myths spread by some non-governmental entities. Czech scientists and academia are regularly involved in international biotechnology-related events (conferences, workshops) and projects. They also advocate for regulatory changes at the national and European level to exclude modern genome editing techniques from the EU's more restrictive genetically modified organism ("GMO") regulatory framework.

Czech Ministries continue to vote in favor of new biotechnology events at the EU level, both for import and for cultivation. Czechs have also supported the option for other member states to impose biotech cultivation bans, citing a position of neutrality and mutual respect for member states' decisions regarding agricultural biotechnology.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) Research and product development

The Czech Republic is currently in a consortium with USDA's Agricultural Research Service and several EU member state research institutions (like the French INRA) that developed a bioengineered plum tree, called *HoneySweet*, that is resistant to the plum pox virus (Sharka). The consortium is seeking EU deregulation to allow for commercial release of the GE tree. While many field trials have been successfully completed, it is still expected to take several years before the product gains final approval.

b) Commercial production

The Czech Republic is one of a few EU member states that support a science-based approach towards biotechnology. Beginning in 2005, Czech farmers planted bioengineered Bt corn MON 810 and in 2010 they cultivated the newly approved bioengineered "Amflora" potato which produces a higher starch content sought for industrial application. Until the discontinuation of planting Bt corn, it was used in biogas production and in on-farm cattle feed, eliminating the need for commercial marketing of the product.

From a high of 5,090 HA in 2011, Czech farmers planted only 75 HA of Bt corn in 2016 (see *Table 1*). Over the years as major retail chains required farmers to certify that cattle were not fed any GM feed, marketing of GE corn became increasingly challenging. This resulted in Czech farmers discontinuing their planting of Bt corn in 2017. Cultivation of the GE potato Amflora lasted only one year after the developer BASF transferred its biotech operations to the United States due to the hostile political climate towards GE crops in Europe.

Table 1

Area (HA) of GE Crops in the Czech Republic													
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017 - 2024
Bt corn MON 810	250	1,290	5,000	8,380	6,480	4,678	5,090	3,050	2,560	1,754	997	75	0
Amflora Potato	0	0	0	0	0	147	0	0	0	0	0	0	0

The EU Directive (2015/412) allowed member states to "opt-out" of using GE seeds for cultivation without scientific justification. The Czech Republic did not opt-out. Nor does the country impose national or regional bans on the cultivation of GE crops.

c) Exports

The Czech Republic does not export GE products.

d) Imports

The Czech Republic has no ban on the import of GE crops, a main protein source for feed mixes. In the calendar year 2023, soybean meal imports totaled 361,726 metric tons (MT). Major suppliers are Brazil, Argentina, and United States. Most imports are trans-shipped through the main European ports in the Netherlands and Germany.

e) Food aid

The Czech Republic is not a food aid recipient and consequently faces no issues related to biotechnology that would impede the importation of food aid donations. Food aid to other countries is typically done through large international organizations by financial contributions. When provided, in-kind donations are typically non-GE as there is no GE crop production in the Czech Republic.

f) Trade barriers

There are no trade barriers that would be specific to the Czech Republic or emanating from its policy that would negatively affect U.S. exports.

PART B: POLICY

a) Regulatory framework

Table 2

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismus	Organism	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	A biological entity, including a microbiological entity, capable of replication or of transferring heritable genetic material
Dědičný materiál	Heritable Genetic Material	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	Deoxyribonucleic or ribonucleic acid
Genetická Modifikace	Genetic Modification	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	The intentional alteration of the heritable genetic material of an organism involving the introduction of foreign heritable genetic material into the heritable genetic material of the organism or removal of part

			of the heritable genetic material from the organism in a way that cannot be achieved by natural recombination
Geneticky modifikovaný organismus (GMO)	Genetically Modified Organism (GMO)	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	An organism, with the exception of human beings, in which the genetic material has been altered by genetic modification through the use of some of the techniques listed in point 1, Annex 1 to this Act
Geneticky modifikovaný mikroorganismus	Genetically Modified Micro-organism	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	A microbiological entity, capable of replication or of transferring heritable genetic material, including viruses, viroids, animal and plant cells in a culture, whose heritable genetic material has been altered by a genetic modification
Genetický produkt	Genetic Product	Act No. 78/2004 Coll., on the use of genetically modified organisms and genetic products	Any preparation containing one or more genetically modified organisms that was produced or obtained in any other way, regardless the degree of its processing, and which is intended for placing on market
Uzavřený prostor	Contained Area	Act No. 17/1992 Coll., on the environment, as last amended	An area bounded by physical barriers, or by combination of physical barriers with chemical or biological barriers, which limit the contact of genetically modified organisms or genetic products with human beings, animals, and the environment

The Czech Republic is a member of the European Union and EU regulations apply. For more information on the EU regulatory framework relating to biotechnology, please refer to the *Biotechnology and Other New Production Technologies Annual*, prepared by our team in the U.S. Mission to the European Union in Brussels available at Search | Global Agricultural Information

Network (usda.gov).[1]

In the Czech Republic, the Ministry of Environment (MoE) is the competent authority handling the notification and regulation of agricultural biotechnology use in the Czech Republic. The MoE cooperates with the Ministry of Health (MoH) regarding potential risks to human health. The MoE also serves as a national focal point for the Cartagena Protocol on Biosafety as well as for the Biosafety Clearing-House.[2]

The Ministry of Agriculture (MoA) is responsible for animal health, crops, feeds, and agricultural risks associated with biotechnology. The MoE and MoA are advised by the Czech Commission for the use of Genetically Modified Organisms and Products[3] *(CzC GMO, website available only in the Czech language)*, an expert advisory body consisting of scientists, representatives from administrative authorities, and non-governmental organizations. The chair and the members of the Commission are nominated and designated by the MoE after consulting the MoH and MoA. The members are professionals from such organizations as the Academy of Sciences, universities, and research institutes. The activities of the *CzC GMO* cover the risk assessment of contained use, deliberate release into the environment and placing on the market of living modified organisms (LMOs), and products containing or consisting of GE traits, to include such traits in export and import. The MoA is the competent authority for food and feed enhanced through biotechnology and for rules for co-existence.

The Czech Environmental Inspectorate[4] (*website is now available in English, click on EN in the top right corner of the website*) is the Competent Authority with regards to governmental supervision of bioengineered events, cooperating with other governmental supervising bodies to complete this task.

The Scientific Committee on Genetically Modified Food and Feed[5] *(SCGMFF, website available only in Czech)* was established in 2006 by the MoA to provide scientific opinions on all the applications submitted for new GE food and feed in the EU and to review how the European Food Safety Authority (EFSA) deals with Member State comments to these applications. The *SCGMFF* is an independent body, whose members are Czech experts on risk assessment, especially from the human and animal health disciplines. The *SCGMFF* closely cooperates with the *CzC GMO*.

Political factors that may influence the country's position on biotech products are mostly tied to local political fights between parties seeking to join a governing coalition following elections. Also, new ministers tend to take a more neutral position. However, the *CzC GMO* is largely seen as keeping politics out of its procedures.

Harmonized national legislation regulating this subject is found in Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products (Act on "GMOs"), as amended. "The Act on GMOs" covers contained use of "GMOs" (microorganisms, plants, and laboratory animals), deliberate release (field trials with "GM" plants and clinical trials with medicinal products containing "GM" microorganisms), trade, and placing on the market. Detailed requirements stemming from the "Act on

[1] https://gain.fas.usda.gov/#/search
[2] https://www.mzp.cz/en/czech_biosafety_clearing_house
[3] https://www.mzp.cz/cz/ceska_komise_pro_nakladani_gmo
[4] https://www.cizp.cz/en
[5] https://mze.gov.cz/public/portal/gmo

GMOs" (e.g., coexistence distances) are described in the implementation Decree 209/2004.

An amendment to Act 78/2004 Coll. was adopted in 2022. It incorporates into the Act relevant requirements of the Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain. The new requirements concern confidentiality of specific data in notification for deliberate release of "GMOs".

An English version of the Czech national regulatory framework related to biotechnology can be found on the Biosafety Clearing House website[6] in English.

b) Approvals/authorizations

Approvals for GE products used in food, feed, and cultivation are made at the EU level. More information about EU approvals can be found in the *Biotechnology and Other New Production Technologies Annual* report, prepared by our team in the U.S. Mission to the European Union in Brussels available at Search | Global Agricultural Information Network (usda.gov)[7]. The European Commission lists its approved GE products on this website.[8]

c) Stacked or pyramided event approvals/authorizations

The Czech Republic implements EU legislation, for more information please see our EU report Biotechnology and Other New Production Technologies Annual, available at Search | Global Agricultural Information Network (usda.gov).[9]

d) Field testing

Unlike most EU member states, the Czech Republic permits and is conducting field trials involving several different bioengineered events. In 2023, only two field trials were carried out on a total area of 4,050 square meters (m^2) (including buffer zones) and 687 m^2 (excluding buffer zones). These trials continue into 2024 and include:

- Plum trees with a modification conferring virus-resistance (resistance to plum pox), notified by the Crop Research Institute, Prague;
- Spring barley producing peptide LL-37, a research project of the Palacky University in Olomouc. The cultivation is carried out and therefore notified by the company Usovsko in Olomouc region.

e) Innovative biotechnologies

The Czech Republic's approach toward innovative biotechnologies (referred to as New Plant Breeding Techniques within the EU, and in other countries as genome editing) is generally positive and positions are based on scientific evidence. However, the Czech Republic follows the EU regulatory framework and on July 2018 the Court of Justice of the European Union (ECJ) ruled that such products are regulated under the "GMO" Directive.

The Czech Republic typically follows EFSA opinions. Regarding innovative biotechnologies, the *CzC GMO* agreed with the EFSA findings and commented on three techniques (cisgenesis, intragenesis, and

[6] https://www.mzp.cz/en/act_regulation_guideline
[7] https://gain.fas.usda.gov/#/search
[8] https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en
[9] https://gain.fas.usda.gov/#/search

zinc fingers). The finding stated that cisgenesis should not fall under the scope of the EU "GMO" Directive, as cisgenic and conventionally bred plants can exhibit similar genetic changes and hazards. The finding also ruled that intragenesis and zinc fingers result in a "GMO" and therefore do fall under the scope of the EU "GMO" legislation.

In response to an industry enquiry, the *CzC GMO* adopted a position on the legal status of the oligonucleotide directed mutagenesis (ODGM or ODM). According to *CzC GMO*, this technique results in genetic modification and the resulting organism falls under the scope of the EU biotech legislation.

To date, innovative biotechnologies have only been applied in contained spaces, for instance laboratories, greenhouses, breeding facilities or industrial premises. These applications were for research purposes. The ongoing projects use CRISPR/Cas9 or TALEN techniques. As per the ECJ ruling, these techniques are regulated per the EU "GMO" regulation.

To date, no project aimed at a deliberate release of a product originating from innovative biotechnologies ("NGTs") has been notified in the Czech Republic. Czech experts actively participated in the New Techniques Working Group at the EU level and in the discussions under the Cartagena Protocol on Biosafety.

The Czech Republic asserts that EU legislation on "new genomic techniques" is based on legislation from 20 years ago. It believes this legislation should be adapted to technical and scientific progress as soon as possible. The Czech Republic plays an active role in EU negotiations as well as in drafting the Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their products and amending Regulation (EU) 2017/625 proposal.

f) Coexistence

The Czech Republic coexistence rules are defined by the Act on Agriculture no. 252/1997 last amended by Act no. 382/2022, and Decree no. 89/2006, amended by Decree no. 58/2010, and Decree no. 392/2016 "On Conditions Pertaining to the Growing of Genetically Modified Crops."

Legislative amendments were designed to remove administrative duplicities and to add guidance accommodating future situations (e.g., growing of biotech soybeans). The primary changes included: (1) Farmers are no longer required to notify MoA in writing prior to sowing. (2) Neighboring farmers must be informed prior to sowing. (3) Farmers no longer need to mark the area of the biotech crop in the terrain.

The updated coexistence regulation lists requirements for three different crops – potatoes, corn, and soybeans, to cover possible future scenarios. It introduced a new isolation distance for the planting of GE crops near the national border, which is 400 meters. In reality, it would be 450 meters, as the land register adds a 50 m tolerance for technical purposes, i.e., national border adjustments. Isolation distances for growing Bt corn do not change significantly:

- A minimum buffer of 70 meters distance between fields with conventional corn and Bt corn
- If a field is located near the Czech national border, the isolation distance for GE crops is 400 m
- A minimum buffer of 200 meters distance between fields with organic corn and Bt corn
- One row of conventional corn with a minimum width of 70 cm around Bt corn can make up for 2 meters of a minimum isolation distance.

g) Labeling and traceability

Labeling and traceability are enforced by local authorities and follow EU labeling standards and traceability regulations. Packaged foods and feeds derived and/or containing biotechnology enhanced ingredients must be labeled. "Contains GMOs" is a typical example of a product label statement found on the Czech market. For more information on EU biotechnology labeling requirements and traceability rules see the *Biotechnology and Other New Production Technologies Annual*, prepared by our team in the U.S. Mission to the European Union in Brussels, available at Search | Global Agricultural Information Network (usda.gov).[10]

On a national level, the Czech Republic, namely the Commodities and Feed Association[11] *(website available in Czech language only)*, developed and introduced a new voluntary "GMO-free" (NON-"GMO") certification and labeling scheme in 2017. The Central Institute in Supervising and Testing (CISTA[12]) conducts the oversight. Producers, traders, and transportation companies can use the certification, which was created to be compatible with German and other EU "GMO-free" standards, and to help Czech producers market their products on the EU common market. More details and the label pictures can be found in the Labeling chapter of this report's Animal Biotechnology section below (Chapter 2, Part E, paragraph d).

h) Monitoring and testing

Foods and feeds are tested in the Czech Republic regularly for various contaminants and transgenic trait presences. Testing methodologies are required from the developers. When unapproved products (or products containing unapproved genetically engineered events) are found on the market, it must be withdrawn from the market, destroyed, and reported to the EU Rapid Alert System for Food and Feed (RASFF).[13]

The Czech Environmental Inspectorate is the Competent Authority for government supervision of the use of bioengineered events. It covers contained use and deliberate release into the environment for both commercial use and research. It cooperates with other governmental supervision bodies responsible for specific areas:

- The Czech Agriculture and Food Inspection Authority[14] *(CAFIA website, English version)* – conducts food inspections. CAFIA conducts testing based on their Annual Control Plan. Products that are listed in the Plan are typically those that often appear in the RASFF. In 2019 CAFIA tested 69 samples of food products containing or produced from corn, soy, flax seed, papaya, and rice for the presence of biotech material. The detection laboratories[15] *(the linked PDF document prepared by the MoE is in English)* also check for genetic modification in tomatoes, potatoes, and oilseeds. There are five authorized detection laboratories, including the National Reference Laboratory (NRL).
- The Central Institute for Supervising and Testing in Agriculture – covers seeds and feed

[10] https://gain.fas.usda.gov/#/search
[11] https://spkk.cz/
[12] https://mze.gov.cz/public/portal/en/ukzuz/portal
[13] https://food.ec.europa.eu/food-safety/rasff_en
[14] https://www.szpi.gov.cz/en/default.aspx
[15] https://www.mzp.cz/C125750E003B698B/en/current_information/$FILE/OERES-List_of_GMO_laboratories-20191127.pdf

supervision. The Institute has been testing both domestically produced and imported seeds since 2006, namely corn, soy, and rapeseed for the adventitious presence of bioengineered events.
- The State Veterinary Administration – supervises animal origin products.
- The State Institute for Drug Control – covers medicinal products.
- Custom Authorities – oversee exports and imports. Testing of imports is quite rare, as there are almost no direct imports to the Czech Republic. Commodities, feeds, and foods are typically transshipped through other EU countries, where testing and monitoring is conducted at the ports of entry.
- Regional Agricultural Agencies of the Ministry of Agriculture – oversee field control of cultivation (compliance with coexistence rules).

i) Low level presence (LLP) policy

The Czech Republic does not have a policy on LLP but follows the "technical solution" guidance of an allowance of 0.1 percent outlined in EU Regulation 619/2011. This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of genetically modified organisms for which an authorization procedure is pending or the authorization of which has expired. The Czech Republic has been open to imports with LLP of bioengineered events and at the time of the EU debate, unequivocally supported a resolution of the issue so that imports could be resumed.

j) Additional regulatory requirements

N/A

k) Intellectual property rights (IPR)

The Czech Republic adheres to EU legislation. The national regulation pertaining to the protection of new plant varieties is Act 408/2000, which incorporates the principles of the International Union for the Protection of new Varieties of Plants (UPOV[16]) system. The Central Institute in Supervising and Testing (CISTA) is the responsible body for this area. Czech agricultural associations and non-governmental organizations (NGOs) support the UPOV plant certificate system rather than the patent system.

l) Cartagena protocol ratification

The Czech Republic ratified the Cartagena Protocol on September 11, 2003. All regulations of the Cartagena Protocol on Biosafety are in place. The MoE is the Competent Authority relating to the Cartagena Protocol on Biosafety. More details can be found at the Czech Republic's Biosafety Clearing House website[17] *(in English).*

m) International treaties/forums

The country has not taken any significant or noteworthy positions within international fora. The Czech Republic is a member of the European and Mediterranean Plant Protection Organization (EPPO) under the International Plant Protection Convention (IPPC), the Codex Alimentarius Commission (CAC), the International Union for the Protection of New Varieties of Plants (UPOV), the Organization for Economic Co-operation and Development (OECD), the UN Food and Agriculture Organization (FAO), and the World Trade Organization (WTO).

[16] https://www.upov.int/portal/index.html.en
[17] https://www.mzp.cz/en/czech_biosafety_clearing_house

n) Related issues

None.

PART C: MARKETING

a) Public/private opinions

Several NGOs are active in the country, both for and against biotechnologies. Debate is focused mainly on the production and use of GE crops. The scientific community has been quite proactive and vocal, emphasizing a science-based approach and the benefits of technology by disseminating accurate information on the topic. In 2010 Czech scientists published the "White Book on Genetically Modified Crops," with the goal in their own words to, "shorten the period of false apprehension of genetically modified crops in Europe." The book calls for science-based, rather than politically influenced decision-making process regarding genetically engineered crops.

Pro-biotech NGOs in the country include the Czech Biotechnology Society and Biotrin. On the other side of the debate, organizations like Greenpeace and some other anti-GE NGOs have published scandalous articles to scare consumers. Compared to other EU member states the Czech public appears to be more in favor of GE liberalization.

In 2024, The Public Opinion Research Centre[18], which is a research department of the Institute of Sociology of the Academy of Sciences of the Czech Republic, published two surveys: "Czech Public Opinion on the Issue of GM Crops – Food 2024"[19] and "Czech Public Opinion on CRISPR/Cas9 Technology – Food 2024."[20] *(The links provide English summaries, the full text is available in Czech language only.)*

The first survey indicates that Czech public interest in genetically modified crops is relatively low. According to the survey, a quarter of respondents (25 percent) expressed interest, however, most replied that they are not interested in this issue (75 percent).

A significant majority of respondents (82 percent) have encountered the term "genetically modified crops", of which a tenth (10 percent) know with certainty what this term refers to, less than half (48 percent) approximately know what this term means, and the remaining less than a quarter (24 percent) have already encountered this term, but do not know what it refers to. When compared to previous surveys this result indicates a slight increase in general knowledge regarding biotechnology.

More than a fifth (21 percent) of Czech citizens consider genetic modification of crops to be morally unacceptable, more than two fifths (41 percent) think the opposite, and more than a quarter (28 percent) remain on the border between agreement and disagreement.

According to the second survey, the vast majority (85 percent) of the Czech public has never heard of

[18] https://cvvm.soc.cas.cz/en/

[19] https://cvvm.soc.cas.cz/en/press-releases/other/other/5873-czech-public-opinion-on-the-issue-of-gm-crops---potraviny-food-2024

[20] https://cvvm.soc.cas.cz/en/press-releases/other/other/5875-czech-public-opinion-on-crispr-cas9-technology---potraviny-food-2024

the CRISPR/Cas9 method. Almost three-quarters (74 percent) of the Czech public support using CRISPR/Cas9 for therapeutic purposes. However, 77 percent oppose its use to enhance athletic performance. Around 81 percent are willing to undergo genetic modification to save their own life or their child's life, with similar support (79 percent) for eliminating severe health problems.

b) Market acceptance/studies

Farmers face difficulties marketing Bt corn. As a result, when farmers still cultivated Bt corn they primarily used it on-farm as livestock feed or for biogas production. However, retail buyers of meat and milk products frequently require that farmers guarantee that their livestock are not fed with bioengineered feed. As a result, Bt corn cultivation ended in 2017. Bt corn also fell out of production as the Czech Republic's major export markets for agrarian products are neighboring EU countries, such as Slovakia, Austria, and Germany, which are trying to limit their use of GE feeds.

According to local sources, Czech consumers in general do not have a problem buying food products containing bioengineered traits. They are more concerned about other issues, such as the price and origin of the product.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Cloning is an animal biotechnology that developers frequently utilize in conjunction with other animal biotechnologies such as genetic engineering and is therefore included in this report.

PART D: PRODUCTION AND TRADE

a) Research and product development

In 2020, a team of Czech scientists from the Institute of Molecular Genetics of the Czech Academy of Sciences and the Biopharm Company announced that they had developed a chicken resistant to avian leukosis virus, through precise CRISPR/Cas9 editing of the NHE1 gene. For detailed information please refer to an article[21] in the Proceedings of the National Academy of Sciences of the United States.

The Czech Republic does not have a specific system in place to monitor imported genetics of cloned animals or the offspring of cloned animals. The EU ban on the cloning of farm animals is not seen as appropriate by the Czech agricultural sector, as it may prevent farmers from preserving some valuable genetic material.

b) Commercial production

In the Czech Republic there are no commercial applications approved for the use of GE animals as food or feed, nor have there been applications at the EU level of the use of GE animals for food use or other agricultural use. Likewise, there are no commercial applications for animal cloning.

c) Exports

N/A

[21] https://www.pnas.org/doi/10.1073/pnas.1913827117

d) Imports

The Czech Republic imports livestock genetics (i.e. bovine semen) from other countries and some of these genetics most likely originate from clones.

e) Trade barriers

The Czech Republic follows EU policies which create trade barriers for animal biotechnology (see Policy section below, in Chapter 2, Part E, paragraph a).

PART E: POLICY

a) Regulatory framework

The Czech Republic does not have a specific national legislation on cloning in place. It implements the EU legislation. Cloning is regulated on the EU level by Regulation (EU) 2015/2283[22] on Animal Cloning and Novel Foods.

For the table of legal terms please see *Table 2* and Chapter 1, Part B, paragraph a of this report and the EU Biotechnology and Other New Production Technologies Annual report, prepared by our team in the U.S. Mission to the European Union in Brussels available at Search | Global Agricultural Information Network (usda.gov)[23]

Genetically engineered animals are regulated the same as any other GE organism in the Czech Republic. The basic national legal instrument is Act no. 78/2004 Coll., the "Act on GMOs," as later amended, with the implementation of Decree No. 209/2004. The competent authority handling the notifications and regulation on the use of GE traits/products in the Czech Republic is the MoE. The responsibility for the regulation of food originating from GE animals comes from the MoH and the MoA covers the area of "novel foods."

Projects using GE animals that have been authorized in the Czech Republic to date fall under the scope of contained use. Authorized GE animals are classified as risk category 1 or 2 (minimal risk). In order to obtain authorization, the entity that intends to use GE animals must notify the MoE. The notification must include a risk assessment, a description of the proposed containment measures, and a description of the proposed handling of the GE products, which must include the transport, storage, and disposal of waste.

b) Approvals/authorizations

Cloned or GE or animals are approved for research purposes only. Approved research GE animals have included fruit flies *(Drosophila)*, nematodes (*Caenorhabditis*), hens/chickens, moths (*Bombyx*), laboratory mice, laboratory rats, rabbits, pigs, tropical frogs (*Xenopus Laevis)*, and the tropical fish (*Danio rerio* and *Orizyas latipes)*.

No GM animals, or food or feed from GM animals, have been authorized for placement on the market in the EU, nor have any applications been made by industry for approval.

[22] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02015R2283-20210327&from=EN
[23] https://gain.fas.usda.gov/#/search

c) Innovative biotechnologies

In 2018, the ECJ ruled that "organisms" of innovative biotechnologies (genome editing, New Breeding Techniques) are considered GE (see Part B, paragraph e above). The Czech Republic has not issued its own specific guidelines for these animals, and none of these animals are on the EU market.

d) Labeling and traceability

The Czech Republic follows EU regulations in this area. Major retail chains have required a certification that the milk and meat they buy from their suppliers do not come from animals fed with GE products. They are requiring this in order to label the product as "GMO-free," which has resulted in a voluntary certification scheme.

In September 2017, the Czech Association for Commodities and Feed[24] (SPKK *website in Czech language only*) with the support of the Ministry of Agriculture introduced a "NON GMO" standard that allows labeling of animal origin products as "GMO-free" and sets conditions and requirements. Not only producers, but also traders and transportation companies can use this voluntary certification scheme and labeling. The Central Institute in Supervising and Testing (CISTA) conducts oversight. The "NON GMO" standard is compatible with similar schemes in other EU states. It was intended to help those farmers, who trade with neighboring states, primarily Germany. In 2021, the Czech Association for Commodities and Feed and the German Association for Food without Genetic Engineering (VLOG) have reached an agreement on mutual recognition of their "NON GMO" and "Ohne Gentechnik" standards. For more background please refer to the statement[25] available at VLOG website (*in English).*

This Czech voluntary standard was, according to information provided by the SPKK, approved by the EU. Detailed description and requirements are available in English at a dedicated website.[26] They are very similar to the German scheme. There are two types of labels used, one is solely for food *Image 1*, the other one for non-food products (i.e., feed, see **Error! Reference source not found.**):

Image 1

Image 2

e) Additional regulatory requirements:

[24] https://spkk.cz/
[25] https://www.ohnegentechnik.org/en/news/article/czech-and-german-ohne-gentechnik-standards-mutually-recognized
[26] https://www.bezgmo.cz/index.php/en/

N/A

f) Intellectual property rights (IPR)

Czech authorities are currently not considering preparing legislation to specifically address intellectual property rights for animal biotechnologies on a national level.

g) International treaties/forums

The Czech Republic is a member of international organizations including the World Organization for Animal Health (OIE), the Codex Alimentarius Commission (CAC), the Organization for Economic Co-operation and Development (OECD), the UN Food and Agriculture Organization (FAO), and the World Trade Organization (WTO). The country has not taken any significantly noteworthy positions within international fora regarding animal biotechnology.

h) Related issues

None.

PART F: MARKETING

a) Public/private opinions

To date there have not been significant discussions on the topic of animal biotechnology or cloning that would divide the general public into distinctive opinion groups. The scientific community has been supportive, sometimes publishing science-based articles introducing and explaining basic facts on animal biotechnology to the general public.

b) Market acceptance/studies

FAS Prague is not aware of any market studies related to animal biotechnology and genetically engineered animals.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) Commercial production

The Czech Republic uses genetically engineered organisms (viruses, bacteria, parasites) for medical research. The goal of such projects is to develop/define prophylactic and therapeutic approaches, and to conduct clinical trials. According to an official report provided by the MoE, "the number of clinical trials of medicinal products containing GM cells or viruses (adeno-associated virus or human cells genetically modified by means of retroviral or lentiviral vectors, e.g. CAR-T) increased significantly. In 2023, the Ministry of the Environment issued ten consents for deliberate release of GMO or a combination of GMOs for the purpose of clinical trials. Of these, six new clinical trials were approved, and four previously approved clinical trials were extended to new clinical sites. In 2024, two new projects were approved and the other two are expected to be submitted to MoE for authorization soon. Most of these activities were carried out under the contained use regime of EU Directive 2009/41/EC on the contained use of genetically modified micro-organisms. The number of premises notified for the contained use of GMOs has increased slightly since 2022, with more than 130 research institutes,

universities and companies now using GMOs. Only three laboratories are now classified in BSL 3 (as of September 24, 2024), the others are classified as BSL 1 or 2. Another application for authorization to use GMOs in BSL 3 is in the pipeline."

There are a few commercial companies (FAS post is aware of two larger companies, multi-nationally/foreign owned) that produce ingredients derived from microbial biotechnology in the Czech Republic. The ingredients are intended for pharmaceuticals, specialized food supplements for human and animal nutrition, and for products improving food quality.

b) Exports

There are no official statistics or estimates on exports of agricultural and food industry microbial biotechnology products. The microbial biotech-derived food ingredients exported by the Czech Republic are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. The Czech Republic exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

c) Imports

There are no official statistics or estimates on imports of agricultural and food industry microbial biotechnology products. The microbial biotech-derived food ingredients imported by the Czech Republic are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. The Czech Republic imports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

d) Trade barriers

There are no trade barriers that would be specific to the Czech Republic or emanating from its policy that would negatively impact U.S. exports.

PART H: POLICY

a) Regulatory framework

The Czech Republic does not have a specific national legislation on microbial biotechnology in place and implements the EU legislation. In cases where GE microbes are used during the production, the Czech "Act on GMOs" and the other local biotech legislation apply. These legislations assert that resulting products cannot contain foreign DNA, with the exception of some pharmaceuticals and vaccines.

For more information consult the EU Biotechnology and Other New Production Technologies Annual report, prepared by our team in the U.S. Mission to the European Union in Brussels available at **Error! Hyperlink reference not valid.**[27]

b) Approvals/authorizations

There are no GE microorganisms approved for introduction to the market, except for some pharmaceuticals – vaccines and gene therapy. The full list of approved GE products, as well as products for which an authorization procedure is pending, is available on the European Commission's websites:

[27] https://gain.fas.usda.gov/#/search

The GMO Register[28] and the Information on notifications submitted under Directive 2001/18/EC[29]. Products of microbial technology, predominantly food ingredients, are not differentiated from their conventionally produced counterparts in the previously mentioned Union lists above.

c) Labeling and traceability

EU legislation applies. There is no specific national policy on microbial biotechnology.

d) Monitoring and testing

Imports of products, such as food supplements or ingredients which can be expected to be produced using GE microorganisms, are tested for presence of foreign DNA.

e) Additional regulatory requirements

There are no additional biotechnology-related regulatory requirements that would negatively impact U.S. exports of microbial biotech-derived food ingredients.

f) Intellectual property rights (IPR)

The Czech Republic adheres to EU legislation. The relevant institution in the Czech Republic is the Industrial Property Office. The English version of the website is accessible here[30] and it contains, among other useful information, an overview of the current national legislation.

g) Related issues

None

PART I: MARKETING

a) Public/private opinions

While microbial biotechnology medical research and production is generally well received, microbial biotechnology in food production is less known and typically not discussed.

b) Market acceptance/studies

The general public has limited awareness of microbial biotechnology in food production. For public opinions related to the CRISPR/Cas9 method please refer to a survey described at the Chapter 1, Part C, paragraph b of this report.

[28] https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-register_en
[29] https://webgate.ec.europa.eu/fip/GMO_Registers/
[30] https://upv.gov.cz/en#

Attachments:

No Attachments