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Report Highlights:

There are no significant changes to the agricultural biotechnology situation in the Czech Republic in 2023. 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 bans on GE crops in the Czech Republic. 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, but over time declined, and stopped in 2017. In 2023, field trials are on an area of 0.47 HA, excluding buffer zones. In the Czech Republic there are companies using microbial biotechnologies for pharmaceutical manufacturing and for the production of food and feed additives.

Czech scientists and farm groups are vocal in their support for more crop biotechnology. With their rational and scientific approach to biotechnology, scientists and academia do not hesitate to publicly 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 are also advocates asking for regulatory changes at the national and European level to exclude modern genome editing techniques from the obsolete and 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, however, supported the option for other member states to impose biotech cultivation bans. They did so by citing the Czech position of strict neutrality on such scientific issues and to support other members' decisions, as they expect support for their own decisions to utilize the technology.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) Research and product development:

The Czech Republic is 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 with a rational and pragmatic 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. Over the years as major retail chains required farmers to certify that cattle were not fed any GM feed, marketing of the corn product became challenging. This resulted in Czech farmers discontinuing their planting of Bt corn in 2017. The cultivation of the GE potato Amflora lasted one year due to the hostile political climate towards GE crops in Europe and the developer, BASF, transferring its biotech operations to the United States.

Area (HA) of GE Crops in the Czech Republic													
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017 - 2023**
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 2022, soybean meal imports totaled 391,122 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. Over the last several years, imports of soybean meal from Austria have steadily increased. This reflects the growing demand for GE free animal feed.

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 contribution. When product is donated directly, there are no issues related to biotechnology, since currently there is no production of GE crops 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:

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 a 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 *Agricultural Biotechnology Annual European Union*, available at https://gain.fas.usda.gov/#/search.

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.

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 *(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 (*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 *(SCGMFF, website available only in*

Czech) was established in 2006 by the MoA to elaborate scientific opinions to 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 regulatory decisions are mostly tied to local political fights between parties forming the coalition. Also, new ministers tend to take a more neutral position. However, the *CzC GMO* keeps a stable, scientifically based position and rational approach.

Harmonized national legislation regulating this subject is 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 ("GM" crops). Detailed requirements stemming from the "Act on 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 in English at: https://www.mzp.cz/en/act_regulation_guideline.

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 *Agricultural Biotechnology Annual European Union* report available at: https://gain.fas.usda.gov/#/search. The European Commission lists its approved GE products on this website: https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en.

c) Stacked or pyramided event approvals/authorizations:

The Czech Republic implements EU legislation, for more information please see the *Agricultural Biotechnology Annual European Union* report available at: https://gain.fas.usda.gov/#/search.

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 an area of 4,700 square meters (m^2) (excluding buffer zones). They are done for research purposes and include:

- Plum trees with a modification conferring virus-resistance (resistance to plum pox), notified by the Crop Research Institute, Prague;
- Barley producing peptide LL-37 the cultivation is carried out and therefore notified by the company Usovsko; region Olomouc. These two field trials have continued for several years.

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 positive. Positions are based on scientific opinions. 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 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. 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 a legal status of the oligonucleotide directed mutagenesis (ODGM or ODM). According to *CzC GMO*, this technique results in a 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 typically asserts that the 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.

f) Coexistence:

The Czech Republic coexistence rules are defined by 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."

Legislation 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 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 a conventional corn and a Bt corn
- If a field is located near the Czech national border, the isolation distance for GE crop 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 *Agricultural Biotechnology Annual European Union* report available at: https://gain.fas.usda.gov/#/search.

On a national level, the Czech Republic, namely the Commodities and Feed Association, developed and introduced a new voluntary "GMO-free" (NON-"GMO") certification and labeling scheme in 2017. The Central Institute in Supervising and Testing (CISTA) 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, sub-paragraph d).

h) Monitoring and testing:

Foods and feeds are tested in the Czech Republic regularly for various contaminants and transgenic trait presence. Testing methodologies are required from the developers. When unapproved product (or product containing unapproved genetically engineered events) is 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).

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 in both areas: commercial and research. It cooperates with other governmental supervision bodies responsible for specific areas:

- Czech Agriculture and Food Inspection Authority (CAFIA) – food inspections and control. 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 also check for genetic modification in tomatoes, potatoes, and oilseeds.
- Central Institute for Supervising and Testing in Agriculture – seeds and feed 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.

- State Veterinary Administration – supervision of animal origin products.
- 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).

There are five authorized detection laboratories, including the National Reference Laboratory for GMO (NRL GMO), under the State Health Institute in Brno or the NRL GMO in the Crop Research Institute in Prague.

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) 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: https://www.mzp.cz/en/czech_biosafety_clearing_house.

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), International Union for the Protection of New Varieties of Plants (UPOV), Organization for Economic Co-operation and Development (OECD), UN Food and Agriculture Organization (FAO), and World Trade Organization (WTO).

n) Related issues: N/A

PART C: MARKETING

a) Public/private opinions:

Several NGOs are active in the country, both for and against biotechnologies. The focus is mainly on the production and use of GE crops. The scientific community has been quite proactive and vocal, emphasizing a rational approach and the benefits of the 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 green-oriented NGOs have published scandalous articles to scare consumers. Czechs are known for being quite pragmatic, and when compared to other EU member states they appear to be rather liberal on this issue.

In 2021, The Public Opinion Research Centre in cooperation with the Czech Academy of Sciences conducted a special survey called Food 2021. The summary of the report is accessible in English here: https://cvvm.soc.cas.cz/media/com_form2content/documents/c6/a5453/f77/OR211025_ENG.pdf. The survey shows among other things that even though Czech consumers say they are familiar with the term "genetically modified crops," they have very little interest in this subject. More than three-quarters of the Czech public think that food labels should include information about whether a food item or its ingredients have been genetically modified. Nearly half of respondents said they would be willing to take medicines that contain genetically modified organisms.

b) Market acceptance/studies:

Farmers face difficulties marketing Bt corn. As a result, when cultivated they primarily used their GE crops on-farm as a livestock feed or for biogas production. However, retail buyers of meat and milk products are now requiring that farmers guarantee that their livestock are not fed with bioengineered feed. As a reaction to this requirement, the area of Bt corn planted decreased to zero hectares of Bt corn being planted as of 2017. Another reason for the decline in Bt corn acreage is that the country'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.

Czech consumers in general do not have a problem buying food products containing bioengineered traits. They are more concerned about other issues, such as 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 in the Proceedings of the National Academy of Sciences of the United States: https://www.pnas.org/content/117/4/2108.

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 has 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

d) Imports:

The Czech Republic imports genetics from other countries and some of these genetics most likely originate from clones.

e) Trade barriers:

The main trade barrier remains EU policies (see Policy section below).

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 (EC) 258/97 on Animal Cloning and Novel Foods.

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."

The 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). Authorization process: The entity that intends to use GE animals notifies 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. GE animals include fruit fly *(Drosophila)*, nematode (*Caenorhabditis*), hen/chicken, moth (*Bombyx*), laboratory mouse, laboratory rat, rabbit, pig, tropical frog *Xenopus Laevis*, and the tropical fish *Danio rerio* and *Orizyas latipes*.

For information regarding genetically engineered animal approvals at the EU level, please refer to the *Agricultural Biotechnology Annual European Union* report available at: https://gain.fas.usda.gov/#/search, or directly to European Commission website: https://ec.europa.eu/food/plants/genetically-modified-organisms_en.

c) Innovative biotechnologies:

The ECJ ruling stated 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 market.

d) Labeling and traceability:

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

In September 2017, the Czech Association for Commodities and Feed (SPKK) 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 the 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 the mutual recognition of their "Ohne Gentechnik" standards. For more background please refer to the VLOG statement available at: https://www.ohnegentechnik.org/en/news/article/czech-and-german-ohne-gentechnik-standards-mutually-recognized.

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 https://www.bezgmo.cz/index.php/en/. They are very similar to the German scheme. There are two types of labels used, one is solely for food, the other one for non-food products (i.e., feed):

e) Additional regulatory requirements: 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), Codex Alimentarius Commission (CAC), Organization for Economic Co-operation and Development (OECD), UN Food and Agriculture Organization (FAO), and World Trade Organization (WTO). The country has not taken any significantly noteworthy positions within international fora.

h) Related issues:
None

PART F: MARKETING

a) Public/private opinions:
To date there have not been significant discussions on the topic of animal biotech or cloning that would divide the general public into distinctive opinion groups. The scientific community has been supportive, sometimes publishing popular 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 D: PRODUCTION AND TRADE

a) Commercial production:
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 a clinical trial. You can find more information at the Czech Republic's Biosafety Clearing House website: https://www.mzp.cz/en/decisions.

In the Institute of Chemical Process Fundamentals of the Czech Academy of Sciences, there is a Research Group of Algal and Microbial Biotechnology. Their research focuses on the use of microorganisms in environmental and food technologies. For more details about the research group and their projects, please see their website at: Research Group of Algal and Microbial Biotechnology | Departments | Institute of Chemical Process Fundamentals (cas.cz).

There are a limited number of 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 "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.

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:

https://webgate.ec.europa.eu/fip/GMO_Registers/ and https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-register_en. 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 at https://www.upv.cz/en.html 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, and FAS post is not aware of any market acceptance studies.

Attachments:

No Attachments