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Report Highlights:

There are no significant changes to the agricultural biotechnology situation in the Czech Republic in 2021. The country generally maintains a scientific approach towards biotechnology. Czech farmers planted genetically engineered (GE) corn starting in 2005. However, that ended in 2017. This change in planting practices is a result of producers deciding that this product is too difficult to market and sell in the European market. The Czech Republic has not imposed any bans on GE crops. There are companies that use microbial biotechnologies in their production.

EXECUTIVE SUMMARY

The Czech Republic is one of the few EU member states that allows commercial planting and field trials of GE crops. In recent years, however, this planting area declined. In 2015, Czech farmers planted only 997 hectares (HA) of Bt corn, in 2016 it dropped significantly to 75 HA, and 2017 was the first year in more than a decade, that no Bt corn was planted. In 2021, field trials are on an area of 0.07 HA, excluding buffer zones. In the Czech Republic there are companies using microbial biotechnologies for pharmaceutical manufacturing and for 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, in order to exclude the 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) 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 - 2021**
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

2020, soybean meal imports totaled 350,626 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:

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) 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.

The last amendment of the Decree was published in July 2021 and will enter into force as of February 1, 2022. The amendment implements changes that are related to the digitalization of procedures of Czech public authorities. Recent updates incorporated into the national legislation EU Directive 2018/350 and EU Regulation (EU) 2019/1381.

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/Biosafety/acts_regulations_guidelines.html.

b) Approvals:

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 at this website: https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en.

c) Stacked or pyramided event approvals:

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 2019, the field trials involved three GE crops on an area of 0.1 HA. In 2020, only two field trials were carried out on an area of 860 square meters (m^2) (3,050 m^2 including 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 (research project of the Palacky University in Olomouc), the cultivation is carried out and therefore notified by the company Usovsko; region Olomouc. These two field trials continued in 2021 on a similar area of 660 m^2, (3,099 m^2 including buffer zones).

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 rather positive; positions are based on scientific opinions. However, the Czech Republic follows the EU regulatory framework and, the July 2018 Court of Justice of the European Union (ECJ) ruled that such products are regulated under the "GMO" Directive.

The Czech Republic typically follows the 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.

Innovative biotechnologies have so far been applied in contained use only, mostly for basic research. The ongoing projects use the techniques CRISPR/Cas9 or TALEN. 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 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.

f) Coexistence:

The Czech Republic coexistence rules are defined by Act on Agriculture no. 252/1997 amended by Act no. 441/2005 and 291/2009, 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: Farmers are no longer required to notify MoA in writing prior to sowing. However, neighboring farmers must be informed prior to sowing. 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, in order to cover possible future situations. It introduces new isolation distance for 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 (UKZUZ) 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.

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 Identification and DNA Fingerprinting, the Crop Research Institute, Prague available for these authorities.

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 (UKZUZ) 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 in September 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: http://www.mzp.cz/Biosafety/index.htm.

m) International treaties/forums:

The country has not taken any significant or noteworthy positions within international fora. The Czech Republic has been 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 have been 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 rational approach and 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 in order 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.

The latest survey of public opinion was done in 2019 and follows up on a survey, conducted by The Public Opinion Research Centre in June 2016 that included a series of questions connected to GE food. The aim of the survey was to find out whether the respondents were interested in the issue and how familiar they were with it. Subsequently, they were asked how often they monitored GE food or product ingredients data found on product labels. The last part of the survey was a set of statements regarding the safety of eating GE food, scientific knowledge of their impact on human health, and their purchasing decisions on GE food. The report also offered a comparison of the results with research done by the Pew Research Centre in the United States. The same survey was repeated in June 2017 and June 2019.

The survey results have not changed dramatically over the years. The 2016 survey revealed, and the 2019 survey further confirmed, that most Czechs are simply not interested in the topic of GE foods (78 percent in 2016, 81 percent in 2019). More than half of consumers never check food labels for such information, approximately one quarter of them check only seldomly, 10 (2016) and 15 (2019) percent of consumers check for such information often, and only four percent check all the time. In 2017, as well as in 2019, more Czechs considered consuming GE foods less safe when compared to the U.S. consumers. In 2019, one quarter of Czech consumers (25 percent) evaluated consumption of GE foods as dangerous. On the other hand, 22 percent perceives this consumption as problem-free. Information that the food is GE would influence the purchasing decision in 22 percent of consumers. Out of these, eight percent would definitely not buy such food.

When asked about availability of information on the topic in 2016, 70 percent of respondents stated that there is definitely (34 percent) or somewhat (36 percent) lack of information on the topic. Only three percent thought that there was definitely enough information on the topic available. In 2019 only three percent of consumers thought there was definitely enough information available. A positive development is that out of the 70 percent of respondents, who did not think there was enough information available, now 26 percent think that there is definitely a lack of information and 44 percent of consumers stated that there is somewhat of a lack of information on the genetically modified foodstuffs available.

b) Market acceptance/studies:

Farmers face difficulties to market Bt corn. As a result, in the past, 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 has decreased over the last few years resulting in 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 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 are therefore included in this report.

PART D: PRODUCTION AND TRADE

a) Product development:

Last year 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 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 amended by the Act no. 371/2016, 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 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:

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: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm or https://ec.europa.eu/food/plants/genetically-modified-organisms_en.

c) Innovative biotechnologies:

The ECJ case ruling stated that "organisms" of innovative biotechnologies (genome editing, New Breeding Techniques) are considered GE (see Part B, paragraph e above). The Czech Republic hasn't 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. Recently, 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 new 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 (UKZUZ) 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. This year, 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 new Czech voluntary standard was, according to information provided by the SPKK, approved by the EU. Detailed description and requirements are available in Czech at the SPKK website (*in Czech*). 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 has been 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/Biosafety/decisiones.html.

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 an exception of some pharmaceuticals and vaccines.

b) Approvals:

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 website. The list of GE products for which an authorization procedure is pending is also available on EFSA's website https://www.efsa.europa.eu/en/topics/topic/gmo under Status Tracker link in point 10. 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, and 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:

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