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Czech Republic

Agricultural Biotechnology Annual

Agricultural Biotechnology Annual 2016

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Report Highlights:

The Czech Republic maintains a scientific approach towards biotechnology. Bt corn (a genetically engineered [GE] product) is planted, but the area has significantly decreased in recent years due to difficulties marketing the corn commercially and using it as feed. Updated legislation eased the administrative process for contained use of genetic engineering in the 1st risk category and incorporated new European Union (EU) directive. Further slight legislative changes are foreseen in 2017, mainly in order to make the current legislation more comprehensive.

Section I. Executive Summary:

The Czech Republic has been one of the few EU member states allowing commercial planting and field trials of GE crops. In recent years, however, their area has been declining. In 2015 Czech farmers

planted only 997 hectares of Bt corn and in 2016 it dropped significantly to 75 hectares. Last time the area increased was in 2011, reaching 5,090 ha. Field trials in 2016 are conducted on an area slightly over 3 hectares, including buffer zones.

Czech scientists and farm groups are vocal in their support for more crop biotechnology. With its rational and scientific approach to biotechnology, scientists and academia do not hesitate to publicly dispel myths spread by some non-governmental entities.

Czech Ministries vote for new biotechnology events at the EU, both for import and for cultivation. Czechs however supported the option for other member states' to impose biotech cultivation bans. They did so 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 plant the technology.

Section II. Author Defined:

REPORT OUTLINE

CHAPTER 1: 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 new member state research institutions (like the French INRA) that has developed a bioengineered plum tree, called *HoneySweet* that is resistant to the plum pox virus. The consortium is now seeking EU deregulation to allow for commercial release of the GE tree. While many field trials have been successfully completed already, it is expected to take several years before the EU member states gain final approval.

b) Commercial Production

The Czech Republic is one of a few EU member states with a rational and pragmatic approach towards biotechnology. Since 2005 Czech farmers have been growing 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. Bt corn is used in biogas production and in on-farm cattle feed, eliminating the need for commercial marketing of the product. In 2016 Czech farmers planted only 75 hectares of Bt corn, which shows another significant year-on-year decline. The cultivation of the GE potato Amflora stopped after BASF transferred its operations to the United States due to the hostile political climate towards GE crops in Europe.

Area of GE Crops in the Czech Republic												
	2005	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
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
Amflora Potato	0	0	0	0	0	147	0	0	0	0	0	0

The Czech Republic did not opt-out from planting GE seeds under the new EU Directive (2015/412). Nor does it impose national or regional bans on growing of GE crops.

c) Exports

To avoid marketing issues, Czech farmers prefer to use the locally produced Bt corn. It is fed to animals or rather used as a feedstock for biogas stations.

d) Imports

The Czech Republic has no bans on importing of GE crops and imports bioengineered soybean meal, a main protein source for feed mixes. In 2015 the soybean meal imports totaled 407 thousand metric tons (MT). Major suppliers are Brazil, Malaysia and United States. Most of 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 contribution. When product is donated directly, there are no issues related to biotechnology, as vast majority of crops and products in the Czech Republic are from conventional production.

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

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. MoE cooperates with the Ministry of Health (MoH) regarding address of potential risks to human health. 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)*, 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 included such traits in export and import.

The Czech Environmental Inspectorate is the Competent Authority with regards to state supervision of bioengineered events, cooperating with other state supervising bodies to complete this task. The MoA is the Competent Authority in reference to food and feed enhanced through biotechnology and on rules for co-existence.

The *Scientific Committee on Genetically Modified Food and Feed (SCGMFF)* 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 States 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 point of view. 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 more neutral position. However, the *CzC GMO* keeps a stable, scientifically based position and rational approach.

National legislation regulating this subject is Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products (Act on GMOs), as amended by Act 345/2005 and Act 243/2016. The recent 2016 amendment eases administrative requirements for the 1st risk category: contained use of GE traits. It also incorporates EU Directive 2015/412 allowing national bans into national legislation.

Detailed requirements stemming from the "Act on GMOs" are described in the implementation Decree 209/2004.

Both, the "Act on GMOs" and its implementing Decree will be updated further, so that the text is more comprehensive. The coexistence distances might be slightly changed and important administrative forms required by the Ministries will be included in the new decree. The updated legislation should come into force in 2017.

b) Approvals

For information regarding bioengineered crops approved for cultivation, food or feed use, please refer to our Agricultural Biotechnology EU-28 Annual Report available at http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx .

c) Stacked or Pyramided Event Approvals

The Czech Republic implements EU legislation, for more information please see the EU-28 Biotechnology Annual Report.

d) Field-Testing

Czech Republic, unlike most EU member states, permits and is conducting field trials involving several different bioengineered events. In 2016 the area reached 3,156 square meters including buffer zones. Genetically engineered crops field test include:

- Flax with various modifications, notified by the Czech company Agritec (a small trial for research purposes);
- Plum trees with a modification conferring virus-resistance (resistance to plum pox), notified by the Crop Research Institute (a small trial for research purposes);
- Barley producing enzyme phytase, notified by the Institute of Experimental Botany, Czech Academy of Science (a small trial for research purposes).
- Barley producing additional cytokinin dehydrogenase in roots, notified by Palacky University (research project)

e) Innovative Biotechnologies

Czech Republic's approach toward innovative biotechnologies and what the EU is referring to as New Plant Breeding Techniques (NPBT) is rather positive; positions are based on scientific opinions.

The Czech Republic typically follows the EFSA opinions. In regards to NPBT, the *CzC GMO* commented on three: cisgenesis, intragenesis, and zinc fingers, and agrees with the EFSA findings. To date, no project aimed at a deliberate release of an NPBT product has been notified in the Czech Republic. Czech experts actively participated in the New Techniques Working Group at EU level and in the discussions under Cartagena Protocol on Biosafety.

In response to an industry enquiry, the 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 biotech legislation.
The *CzC GMO* has endorsed the applicability of the current risk assessment methodology in cases of

two NPBTs (cisgenesis/intragenesis and site-directed nucleases). Opinions on other NPBTs will follow.

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 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, more neighboring farmers now have to be informed prior to sowing. Farmers no longer need to mark the area of the biotech crop in the terrain.

The MoA complete guidance regarding cultivation of genetically engineered crops and their regulation is available in the document here.

Coexistence regulations require either:
1) A 70 meter buffer between fields with a conventional crop (i.e., corn) and a GE crop (i.e., Bt corn), or
2) A buffer zone of 25 rows of conventional crop around the GE crop field with a 20 meter buffer between the GE and conventional corn fields, or
3) An omission of the isolation buffer (distance between fields) if a 35 row buffer zone of conventional crop around the GE crop field.

For organic agriculture, a 200 meter isolation distance between the GE crop (i.e., Bt corn) and organic crop (i.e., corn) or a buffer zone of fifty rows of conventional crop (i.e., corn), plus a hundred meter isolation distance.

g) Labeling

Labeling is enforced by local authorities and follows EU labeling standards. 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 see the EU-28 Biotechnology Annual Report.

h) Monitoring and Testing

Foods and feeds are tested in the Czech regularly, for various contaminants, as well as transgenic trait presence.

The Czech Environmental Inspectorate is the Competent Authority for state supervision of the use of bioengineered events. It covers contained use as well as deliberate release into the environment in both areas: commercial and research.

It cooperates with other state supervision bodies responsible for specific areas:

- Czech Agriculture and Food Inspection Authority – food inspections and control. They test

every food product containing or produced from corn, soy, and rice for the presence of biotech material. The detection laboratories are able to check for genetic modification also in tomatoes, potatoes, oilseeds, and papaya.

- Central Institute for Supervising and Testing in Agriculture – seeds and feed supervision. They have 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 – are in charge of export and import.
- Regional Agricultural Agencies of the Ministry of Agriculture in charge of field control of cultivation (compliance with coexistence rules).

Six authorized detection laboratories are available for these authorities.

i) Low Level Presence (LLP) Policy

The Czech Republic does not have a policy on LLP. It does follow 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)

In this area, the Czech Republic adheres to EU legislation as well. The national regulation pertaining to 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, as well.

l) Cartagena Protocol Ratification

The Czech Republic has 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 Biosafety Clearing House website: http://www.mzp.cz/Biosafety/index.htm

m) International Treaties/Fora

The country has not been taking any significantly noteworthy positions within international fora. The international organizations Czech Republic has been a member of include the Plant Protection Convention (EPPO), 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 non-governmental organizations (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 GM 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. To the contrary, organizations like Greenpeace and some other green-oriented NGOs have published scandalous articles in order to threaten consumers. Czechs are known for being quite pragmatic, and when compared to other EU member states they appear as being rather liberal on this issue.

In a June 2016 survey conducted by The Public Opinion Research Centre, included were 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 comparison of the results with a research done by the Pew Research Centre in the United States.

The survey revealed that most of the Czechs are simply not interested in the topic of GE foods (78 percent). More than half of consumers (55 percent) never check food labels for such information, one quarter of them (26 percent) check only seldom, 12 percent of consumers check for such info often, and only three percent check all the time.

Czechs consider consuming GE foods less safe, when compared to the U.S. consumers. One quarter of Czech consumers (26 percent) evaluates consumption of GE foods as dangerous. On the other hand, 21 percent perceives it as problem-free. Information that the food is GE would influence purchasing decision in one quarter of consumers (26 percent). Out of these, eight percent would definitely not buy such food; one quarter would rather take the food out of their shopping cart. More than one in five (22 percent) consumers out of this group would hesitate whether to buy the food or not. When asked about availability of information on the topic, 70 percent of respondents stated that there is definitely (34 percent), or rather lack of (36 percent) information on the topic. Only three percent think that there is definitely enough information on the topic available.

b) Market Acceptance/Studies
Farmers are facing difficulties to market Bt corn, therefore they primarily use that crop on-farm as a

livestock feed or for biogas production. However, retail buyers of meat and mainly milk products are now requiring farmers' guarantee that their livestock are not fed with bioengineered events. The acreage of Bt corn planted has decreased in reaction over
the last few years. Another reason for the decline in Bt corn acreage is that the country's major export markets for agrarian products are neighboring biotech-free EU states, such as Austria and Germany.

Czech consumers in general do not have a problem buying food products containing bioengineered events. 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
In the Czech Republic there are no genetically engineered animals or cloning under commercial development.

Animals used for research purposes notified and authorized for contained used are: fruit fly *(Drosophila)*, nematode (*Caenorhabditis*), hen, moth (*Bombyx*), laboratory mouse, laboratory rat, rabbit, pig, tropical frog *Xenopus Laevis*, tropical fish *Danio rerio* and *Orizyas latipes*.

The Czech Republic does not have a specific system in place that would monitor imported genetics of clones. The EU blanket ban on cloning of farm animals is not seen as appropriate, 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 GE animals for food or feed use, and no notification of the use of GE animals for food use or other agricultural use has been filed with the EU.

Likewise, there are no commercial applications of animal cloning.

c) Exports
N/A

d) Imports
Country imports genetics from other countries and some of them also originate from clones.

e) Trade Barriers
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, and 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 in the same way as any other GE organisms 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. 346/2005 Coll ., 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 MoH and covers the area of "novel foods."

The projects using GE animals that have been authorized in the Czech Republic so far fall under the scope of contained use. The 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 risk assessment, a description of proposed containment measures and handling of the GE products including their transport, storage, and disposal of waste.

b) Innovative Biotechnologies

Several years ago, the Czech Authorities assessed a notification of a research project using DNA vaccines for treatment of animals. As the research was in an initial phase, it was decided to take precautions by considering the treated animals to be GMOs.

c) Labeling and Traceability

The Czech Republic has been following the EU regulations in this area. There is, one exception: animal product labels cannot have a "GMO-free" statement on them. As there are no GE animals available for consumption on the European market, it would be considered as misleading of a consumer. The label can however include a longer statement explaining that the product comes from an animal that was fed (or not) GE feed. This is related to the recent situation when retails chains were requiring a certification that milk and meat they buy from their suppliers comes from animals that were not fed GE feed.

d) Intellectual Property Rights (IPR)

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

e) International Treaties/Fora

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 been taking any significantly noteworthy positions within international fora.

f) Related Issues

n/a

Part F: MARKETING

a) Public/Private Opinions

So far there have not been significant discussions on the topic of animal biotech or cloning that would divide the general public into distinctive opinion groups. Scientific community has been supportive, sometimes publishing in popular-science based articles introducing and explaining basic facts on animal biotechnology.

b) Market Acceptance, Market Studies

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