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Report Highlights:

Poland opposes the use of genetic engineering in agriculture. Although the current regulatory framework technically allows genetically engineered (GE) seeds to enter commerce, the law stipulates they cannot be planted. While Poland's 2006 Feed Act includes provisions banning livestock feed containing GE ingredients, they have never been enforced and have been postponed several times. In December 2022 the Government of Poland (GOP) issued another two-year postponement of the provisions which ban GE feed ingredients, including U.S. soybean meal, until January 1, 2025. The Polish meat industry is putting pressure on the government to extend suspension of the import ban even longer.

EXECUTIVE SUMMARY

Poland is one of the European Union's (EU) major agricultural producers. According to the EU's Principle of Primacy, EU regulations supersede national laws, within the rules established by the Treaty of Poland's accession to the Common Market. While most Polish scientists and some commercial farmers support advanced agricultural technologies, agricultural biotechnology remains a contentious and politicized issue in Poland. According to public opinion research, 70 percent of Poles oppose agricultural biotechnology. Studies indicate that general awareness about biotechnology among Polish society remains limited. Environmental organizations and consumer groups regularly protest its use in agriculture.

On January 28, 2013, following the adoption of the 2012 Seed Act, Poland issued two regulations officially banning the cultivation of 235 GE maize varieties, including MON 810 and the Amflora potato. Although the current regulatory framework technically allows GE seeds to enter commerce, GE seeds cannot be legally planted or used for cultivation.

Poland's 2006 Feed Act (OJ 2006 No. 144, item.1045) includes provisions which prohibit the processing, marketing, and use of GE feed and/or derived ingredients (mostly imported soybean meal) to poultry or other livestock. On November 4, 2016, the Polish Parliament voted in favor of the Act, but due to significant pressure from local poultry and livestock producers Parliament has postponed the livestock feed ban several times. Most recently, the GOP postponed enforcing the biotech feed ingredient ban until January 1, 2025. The Polish meat industry is currently putting pressure on the government to suspend the import ban and prolong this suspension for an additional four years.

Currently, the issue of GE animal production is not part of Poland's political or civil discourse. While some animal biotech research is conducted, these animals cannot be produced commercially.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

There are no commercial GE crops produced in Poland. Several institutions conduct basic research under confined conditions, including plant breeding (occasionally with foreign companies or research institutions) and environmental impact studies of GE plants.

b) COMMERCIAL PRODUCTION

On January 28, 2013, Poland banned GE cultivation through an amendment to the 2006 Seed Act. This amendment prohibited 235 maize varieties, including MON 810 and the Amflora potato (a product with an expired approval), from cultivation. Although GE seeds are still technically allowed to enter legal commerce, they cannot be legally planted or used in any practical way. In 2015, Poland declared that it would "opt out" of GE cultivation under EU Directive 2015/412, which allowed Member States to restrict or prohibit GE cultivation within their sovereign territory without scientific justification.

c) EXPORTS

Not applicable.

d) IMPORTS

Poland imports significant quantities of biotech-derived feed ingredients from South America and the United States despite provisions of the 2006 Feed Act that ban biotech livestock feed. In practice, the GOP has never enforced the Act's provisions banning GE feed ingredients. In addition, the ban has been postponed several times since 2006, including most recently until January 1, 2025. The Polish meat industry is currently putting pressure on the government to suspend the import ban and prolong this suspension for an additional four years. Poland is the EU's largest poultry producer and imported soybean meal provides Polish poultry and other livestock producers with an efficient, low-cost, and nutritious plant protein. Poland currently imports upwards of 2.5 million metric tons (MMT) of GE soybean meal from Argentina, Brazil, and the United States.

e) FOOD AID

Poland is not a food aid recipient or commodity donor. Poland is traditionally a cash donor.

f) TRADE BARRIERS

Poland imposes all EU-legislated trade barriers on imported biotech products. If the 2006 Feed Act ban on feed ingredients derived from biotech crops enters into force on January 1, 2025, it would present a significant trade barrier to U.S. soybean meal exports to Poland.

PART B: POLICY

a) REGULATORY FRAMEWORK

EU regulations on biotech products apply to Poland, and the Polish Law follows the EU definition of "genetically modified organisms (GMO)" (see current EU Agricultural Biotechnology Annual Report, which can be found at the <u>FAS GAIN Report Database</u>).

i. Table of terms

Legal Term (in	Legal Term	Laws where term is	Legal Definition (in
Polish)	(in English)	used	English)
Organizm	Genetically Modified	Law on	GMO is understood as
genetycznie	Organism (GMO)	Microorganisms and	a non-human
zmodyfikowany		Genetically Modified	organism in which the
(GMO)		Organisms (Law on	genetic material
		"GMOs"),	has been altered in a
		consolidated version,	way that does not
		Journal of Laws. 2022	occur naturally by
		item 546	crossbreeding or
			natural
			recombination, using
			techniques:
			(a) nucleic acid
			recombination
			involving the
			formation of new
			combinations of
			genetic material
			by incorporating
			nucleic acid molecules
			obtained by any
			means outside the
			organism into a virus,
			bacterial plasmid or
			vector, and their
			transfer to a recipient
			in which they do not
			occur naturally,
			but in which they are
			capable of continuous
			replication,
			(b) direct
			incorporation of
			hereditary material
			prepared outside the
			organism, including

	microinjection,
	macroinjection
	or microencapsulation,
	(c) cell fusion,
	including protoplast
	fusion, or
	hybridization
	techniques that result
	in the fusion of two or
	more cells to create
	living cells with a new
	combination of
	heritable genetic
	material.

The June 2001 Law on Microorganisms and Genetically Modified Organisms (Law on "GMOs"), with later amendments, provides the regulatory basis for requirements applicable to GE products/research and regulates:

- a) containment of GE crops,
- b) deliberate release of GE into the environment,
- c) introduction of GE products into the market.

On March 22, 2018, the abovementioned *Law on "GMOs"* was amended (O.J. 2018, pos.810) to harmonize Polish law with EU legislation and to provide the legal basis for the National Strategy for Biological Security. This amendment entered into force on July 28, 2018. The amendment enforces the EU directive regulating the "deliberate release of 'genetically modified organisms (GMOs)' into the environment." It also enforces the European Court of Justice's 2014 ruling regarding certain provisions regulating reporting, registration, and notification of GE cultivation to the public. This regulation theoretically allows for GE cultivation; however, its onerous and bureaucratic procedures prevent it on any practical level:

- To register a GE crop, all landowners within a 30-kilometer radius of the field where cultivation is planned must consent.
- Documentation confirming that the cultivation would not negatively affect the environment is required.
- The consent of the local civic council, the county council, and the provincial council (three levels of regional government) are required.
- The area of cultivation cannot be located within 30 km of an established nature conservatory.
- Other details that create additional barriers for GE cultivation.

The amendment introduces fines and possible imprisonment from three months to 12 years, depending on the offenses.

The Act of July 22, 2006, on Feed (OJ 2006 No. 144, item. 1045), along with later amendments, harmonizes Polish law with EU regulations and implements the EU directives; regulates medicated feed production and marketing, establishes feed quality and hygiene

requirements, and regulates feed supervision and official control, including entering commerce.

The Act of August 25, 2006, On Food Safety and Nutrition (Journal of Laws 2006 No. 171, item. 1225), and amendments, defines, among other things, health requirements of food, compliance requirements according to food hygiene principles, regulatory competencies, and official basic procedures and requirements for food controls.

The November 2012 Seed Law Act (OJ 2012 pos. 1512), and amendments, regulates the issues related to seed variety examination and assessment, crop variety production and record keeping, and seed-related trade, assessment, and regulatory control.

Regulations of the Seed Law are as follows:

- Council of Ministers of January 2, 2013 Prohibits Amflora seed potato (OJ 2013 pos. 27)
- Council of Ministers of January 2, 2013 Prohibits maize seed MON 810 (OJ 2013 pos. 39)
- Council of Ministers of May 8, 2013 Amends the Regulation on the Prohibition of Seed Maize MON 810 (OJ 2013 pos. 590)
- Council of Ministers of April 30, 2014 Amends the regulation on the prohibition of seed maize MON 810 (OJ 2014 pos. 641)

On November 18, 2008, the Council of Ministers adopted the Framework for Poland's Position on agricultural biotechnology. The GOP's position opposed allowing GE food and feed into the EU, and the GOP opposes marketing products under Directive 2001/18/ EC. While the GOP opposes GE cultivation and GE field trials, it recognizes the need to obtain environmental risk assessment data by research institutions and universities.

ii. Responsible Government Ministries:

- The Ministry of Climate and Environment (MOE) is the competent authority for regulating and handling notification of any GE cultivation in Poland. The MOE is advised by the Opinion and Advisory Commission of the Minister of Environment, which is an expert advisory panel of scientists, governmental regulators, and non-governmental organizations. The MOE cooperates with the Ministry of Health (MOH) regarding address of potential risks to human health. The MOE is Poland's competent authority regarding the Cartagena Protocol.
- The Ministry of Agriculture and Rural Development (MinAg) is responsible for animal health, crops, livestock feed, and agricultural risks associated with biotechnology. MinAg is Poland's competent authority regarding food and feed enhanced through biotechnology and on rules for coexistence.

iii. Biosafety Committee:

In Poland, the Committee on Biotechnology of the Polish Academy of Sciences was established. More information about its activities can be found at kbiotech.pan.pl.

iv. Political Factors:

Most Polish politicians vote against the use of agricultural biotechnology.

- v. For information on the following topics, please see the current EU Agricultural Biotechnology Annual Report, which can be found in the <u>FAS GAIN Report Database:</u>
 - Distinctions of GE Plant Products Containing DNA in Final Product
 - Distinctions of the Approval for Food, Feed, Processing, and Environmental Release
 - Legislation with the Potential to Affect U.S. Exports
 - Timeline for Approvals
 - If No Regulation in Place Discussion
 - Additional Product, Seed Registration Beyond GE Plant Approval
 - Pre-Registration Requirements
 - Approval/Authorization Limits

b) APPROVALS/AUTHORIZATIONS

Approval of GE products for food, feed, and cultivation is subject to EU procedures. A list of GE products approved by the EU can be found in the <u>FAS GAIN Report Database</u>. However, as noted above, Poland does not cultivate GE products.

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

Poland implements EU legislation for stacked events. For more information, please refer to U.S. Mission to the European Union's (USEU) Office of Agricultural Affairs' <u>FAS GAIN Report Database</u>.

d) FIELD TESTING

Poland has not conducted any GE field trials since 2015.

e) INNOVATIVE BIOTECHNOLOGIES

There is no specific, current legislation regarding new breeding techniques (NBT) in Poland. Polish legislation does not recognize NBT from GE techniques.

f) COEXISTENCE

MinAg implemented coexistence regulations into the national law with the Act of March 22, 2018 (O.J.2018, pos.810), amending the 2001 Law on GMMs and GMOs. The Act requires isolation zones between GE crops of 500 and 1,000 meters between conventional and organic crops, respectively.

g) LABELING AND TRACEABILITY

Poland implements EU regulations for GE food labeling. Packaged foods and feed derived from and/or containing GE enhanced ingredients must be labeled when GE ingredients are present at over 0.9 percent per ingredient. "Contains GMOs" is a typical example of a product label statement found in the Polish market. Labeling is enforced by local authorities and follows EU labeling standards. For more information on EU biotechnology and labeling requirements, see FAS USEU's <u>Agricultural Biotechnology EU Report</u>. To date, no national labeling requirements

exist for products derived from GE animals or products produced from animals fed with GE feed.

In 2019, the Polish Parliament issued the Act of July 13, 2019, on *Genetically Modified Organisms Free Product Labelling*, published in the Polish Journal of Laws, Item 1401. The Act introduces labeling voluntary standards for food products free from GE, including for animal products derived from livestock not fed with GE feeds and/or products. The standard includes a "non-GMO" label. The purpose of the Act is to standardize the labels for food and feed produced without GE ingredients, as well as to standardize the rules for labeling products of animal origin. According to MinAg, the labeling scheme will raise the credibility of Polish labeling rules and increase the competitiveness of Polish foods in the domestic market.

1. Draft label for GE-free plant origin foods, single or multi-component, and for GE-free feeds:



2. Graphic Template for labeling food products of animal origin, certifying that no GE feed or other GE ingredients were used during production:



h) MONITORING AND TESTING

Poland implements EU legislation regarding monitoring and testing (see FAS USEU's Agricultural Biotechnology EU Report). The GOP allows imports of GE food only when it is clearly labeled and without any further processing in Poland. The MOH and MinAg are the competent authorities regarding food and feed enhanced through biotechnology and on rules for coexistence. Poland actively tests for GE traits in imports on a risk assessment basis. The competent authority for imports of food is the Polish Sanitary Inspectorate. If an unapproved product is detected, further procedures depend on the specific nature of the situation. Sometimes, providing additional and/or completing documentation may be enough to obtain market access.

Since 2005, annual audits have been conducted to monitor conventional rapeseed, corn, and mustard seed (2010) for the presence of GE. Seed samples marketed and produced in Poland, other EU Member States, or in third countries are collected by the State Inspectorate for Plant and Seed Protection (SIPSP) in accordance with the methodology of the International Seed Testing Association (ISTA). The audits are conducted in the Central Laboratory of the Main Inspectorate for SIPSP in Toruń. The tests are performed using polymerase chain reaction (PCR) qualitative analysis and real-time PCR quantitative analysis. SIPSP also audits fields for compliance with the ban on MON 810 corn. To date, there are no indications of GE crop production in Polish fields.

i) LOW LEVEL PRESENCE (LLP) POLICY

Although the EU does not have an LLP Policy, it does have a "technical solution" of a 0.1 percent allowance (a definition of zero) for products with applications submitted to the EU. Poland has been open to imports of commodities meeting the technical solution threshold. Despite its official anti-GE position, Poland supports an EU-level resolution to LLP.

j) ADDITIONAL REGULATORY REQUIREMENTS

None

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Polish IPR legislation follows EU requirements (see FAS USEU's <u>Agricultural Biotechnology EU Report</u>). The main national IPR legislation related to plant breeding is the Act of June 26, 2003, on the Legal Protection of Plant Varieties.

1) CARTAGENA PROTOCOL RATIFICATION

In Poland, the provisions of the Cartagena Protocol have been in force since March 9, 2004. The Minister for the Environment is responsible for implementing the provisions of the Protocol regarding biological safety.

m) INTERNATIONAL TREATIES AND FORUMS

Poland is a member of the International Plant Protection Convention (IPPC) and actively participates in its discussions related to phytosanitary issues. Poland opposes GE technology in agriculture, both in internal policy and in international fora.

n) RELATED ISSUES

None

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

According to national polls, nearly 70 percent of Poles oppose the use or cultivation of GE crops and products. Studies indicate low general awareness of agricultural and food biotechnology in Polish society.

Anti-GE organizations are active in Poland and include Greenpeace, the International Coalition to Protect the Polish Countryside, Stop GMO, Friends of the Polish Countryside, the Greens/European Free Alliance in the European Parliament, Friends of the Earth, and the Association of Ecological Farmers.

b) MARKET ACCEPTANCE/STUDIES

Recent retail studies show that most Polish customers tend to make food purchases based on price versus ingredients. Feed containing GE-derived ingredients are not generally called into question.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Research on GE farm animals remains limited but is conducted in several research centers in Poland. Each research project must be approved by the MOE.

MOE holds the public registers of approvals for closed use of GE organisms

, which is understood as subjecting organisms to genetic modification or cultivation of GE cultures, their storage, transportation within a genetic engineering facility, destruction, disposal or use in any other way, during which safeguards are applied to effectively limit contact of GE organisms with humans or the environment and ensure a high level of their protection.

MOE also holds the public registers of approvals for operation of GE establishment

, which includes premises, buildings, laboratories, or their complexes, adapted and intended to carry out closed use of GE microorganisms or closed use of GE organisms.

While Polish scientists are interested in genome editing and other innovative technologies, they operate in a restrictive legal framework. The main objectives of research on GE animals are:

- The production of proteins, enzymes, and other substances in the pharmaceutical industry.
- Immunization of livestock for diseases.
- Increase productivity and efficiency of animals and thus obtain the desired animal traits for breeding; and
- Production of material for xenotransplantation, which produces organs used for transplants from cloned animals. This is the only use of animal cloning currently authorized apart from research projects.

Information about cloned animals in laboratory research is very limited.

b) COMMERCIAL PRODUCTION

There are no commercial applications of animal cloning or GE animals in Poland.

c) EXPORTS

Not applicable

d) IMPORTS

According to information from the Polish Federation of Dairy Cattle Breeders and Milk Producers (PFDCBMP), which evaluates imported bovine semen, occasionally semen imported from the United States originates from cloned bulls. They recognize those bulls by the extension of their name containing ETS, ETN, or ETM. According to information received from MinAg, there are currently no regulations banning genetic imports derived from cloned animals or offspring of cloned animals.

e) TRADE BARRIERS

There are no additional trade barriers beyond EU legislation on animal biotech and cloned products.

PART E: POLICY

a) REGULATORY FRAMEWORK

The legislation on GE animals is based on the June 2001 *Law on Microorganisms and Genetically Modified Organisms* (latest amendment O.J. 2022, No 546). This legislation pertains to GE plants, animals, and microorganisms. It establishes the rules for the closed use of genetically modified microorganisms; closed use of genetically modified organisms; deliberate release of genetically modified organisms into the environment; marketing of genetically modified products; cultivation of genetically modified plants.

With limited use of GE animals, the legislation mainly addresses GE plants. There is no specific legislation regarding cloning of animals.

The responsible government ministries and their roles in the regulation of products of animal biotechnology and/or livestock clones, regarding food safety, animal welfare, and environmental safety issues are as follows:

- The MOE is responsible for oversight of existing biotechnology regulations.
- The Chief Sanitary Inspectorate (CSI) under the MOH is responsible for the regulation of food originating from GE animals. These foods are considered 'novel foods.'

According to the General Veterinary Inspectorate of the MinAg, there are no regulations in Poland that are specific to animal welfare of GE animals.

b) APPROVALS/AUTHORIZATIONS

As throughout the EU, cloned animals are not allowed for human consumption. There are no GE animals approved for import or production in the EU.

c) INNOVATIVE BIOTECHNOLOGIES

There is currently no special legislation on innovative biotechnologies in Poland. To date, these techniques are treated as GE. While Polish scientists are interested in genome editing and other innovative technologies, Poland remains cautious vis-à-vis its current policies.

d) LABELING AND TRACEABILITY

Poland follows EU regulations in this area. To date, no national labeling requirements exist for products derived from GE animals or products produced from animals fed with GE feed.

e) ADDITIONAL REGULATORY REQUIREMENTS

There are no additional regulatory requirements beyond EU legislation on animal biotech and cloned products.

f) INTELLECTUAL PROPERTY RIGHTS (IPR) Not applicable.

g) INTERNATIONAL TREATIES AND FORUMS

Poland is a member of IPPC, the World Organization for Animal Health, and the UN's Food and Agriculture Organization and actively participates in all discussions related to animal breeding and sanitary issues. Currently, Poland does not have an active public policy for or against cloning technology in animal breeding.

h) RELATED ISSUES

None

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS

To date, there have been discussions on the topic of GE animals or cloning that would divide the public into two distinct opinion groups, those for genetic engineering or against the use and development of GE products. Biotechnology, in general in Poland, remains a highly politicized issue.

b) MARKET ACCEPTANCE/STUDIES

FAS/Warsaw is not aware of any market studies or activities related to the marketing of products derived from cloning or GE animals.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Information regarding the commercial production of food ingredients derived from microbial biotechnology is not available.

b) EXPORTS

Information regarding exports of food ingredients derived from microbial biotechnology is not available.

c) IMPORTS

Information regarding imports of food ingredients derived from microbial biotechnology is not available.

d) TRADE BARRIERS

Poland applies EU legislation (see FAS USEU's Agricultural Biotechnology EU Report).

PART H: POLICY

a) REGULATORY FRAMEWORK

As noted above, the legislation on GE plants and animals is based on the June 2001 Law on Microorganisms and Genetically Modified Organisms (O.J. 2007, No 36). This legislation mainly addresses GE plants.

b) APPROVALS/AUTHORIZATIONS

Please refer to CHAPTER 1: PLANT BIOTECHNOLOGY.

c) LABELING AND TRACEABILITY

Please refer to CHAPTER 1: PLANT BIOTECHNOLOGY.

d) MONITORING AND TESTING

Please refer to CHAPTER 1: PLANT BIOTECHNOLOGY.

e) ADDITIONAL REGULATORY REQUIREMENTS

Please refer to CHAPTER 1: PLANT BIOTECHNOLOGY.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Please refer to CHAPTER 1: PLANT BIOTECHNOLOGY.

g) RELATED ISSUES

Not applicable

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Polish society is not widely informed about the role of microbial biotech for food ingredients or nutritional purposes. It is hard to assess the public or private perception.

b) MARKET ACCEPTANCE/STUDIES

FAS/Warsaw is not aware of market acceptance studies.

Attachments:

No Attachments