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**Date:** 10/17/2018

**GAIN Report Number:** 

# **Poland**

Post: Warsaw

# **Agricultural Biotechnology Annual 2018**

# **Report Categories:**

Biotechnology - GE Plants and Animals Biotechnology and Other New Production Technologies

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### **Report Highlights:**

Poland currently opposes of the use of genetic engineering (GE) in agriculture and prohibits the cultivation of GE crops. On January 01, 2019, a ban on livestock feed and/or feed ingredients derived from GE crops is scheduled to enter into force. Poland's livestock industry is pushing the Government of Poland (GOP) to postpone the ban. The Polish Ministry of Agriculture and Rural Development (MinAg) is preparing new voluntary GE labeling standards for packaged food and feed products.

## **Executive Summary:**

Poland is a major European agricultural producer and European Union (EU) Member State (MS). According to the EU's Principle of Primacy, EU regulations supersede national laws. While most Polish scientists and some commercial farmers understand the benefits of advanced agricultural technologies, biotechnology remains a contentious and politicized topic in Poland. According to public opinion studies, 70 percent of Poles oppose the presence of agricultural biotechnology. Studies also indicate that Polish society's general awareness about biotechnology remains limited. Environmental organizations and consumer groups, some of which receive funding directly from the European Commission, actively spread nonscientific disinformation in Poland about biotechnology, as well as regularly protest its use in agriculture.

On January 28, 2013, Poland issued two regulations which officially banned the cultivation of 235 GE maize varieties, including MON 810, and the (currently unapproved for cultivation in the EU) Amflora potato. Both regulations were subsequent to the adoption of the November 2012 Seed Act, which entered into force on January 28, 2013. Although the current regulatory framework technically allows GE seeds to enter into commerce, the seeds cannot be planted or used for cultivation in any practical way.

Poland's 2006 Feed Act (OJ 2006 No. 144, item.1045), includes prohibitions against processing, marketing, and feeding GE feeds and/or derived ingredients (mostly imported soybean meal) for livestock. On November 4, 2016, Parliament voted in favor of the Act, but in practice, the ban was postponed by the Polish Parliament until January 1, 2019. Polish poultry and livestock producers continue to exert significant pressure on the GOP to further postpone the ban beyond the current January 01, 2019, deadline. Poland remains a major consumer of GE feed ingredients and annually imports over 2.0 million metric tons (MMT) of soybeans, soy meal, and corn for its livestock.

Except for feed ingredients, the Polish public perceives GE crop cultivation in Poland as generally negative. Currently, the issue of GE animal production is not part of Poland's political or civil discourse. Media coverage and public awareness on GE animals remains low. GE animals are used only for research.

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## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE**

## a) Product Development

There are no commercial GE crops produced in Poland. Several institutions conduct research projects under confined conditions, which consist of basic research and development, plant breeding (in few cases in conjunction with foreign companies or laboratories), and experiments measuring the impact of GE plants on the environment.

## **b) Commercial Production**

Poland has approved the "opt-out" EU legislation regarding GE cultivation. On January 28, 2013, the ban on GE-crop cultivation entered into force along with the amended 2006 Seed Act, when 235 maize varieties, including MON 810, and the Amflora potato were prohibited. GE seeds are still technically allowed to enter into legal commerce but cannot be planted or used in any practical way.

## c) Exports

Not applicable.

## d) Imports

Poland imports biotech-derived feed ingredients, although the 2006 Feed Act technically bans biotech livestock feed. The ban was postponed by the Polish Parliament until January 01, 2019, following strong opposition by Poland's livestock and poultry sectors. Poland currently imports upwards of 2.0 MMT of GE soybean meal from Argentina, Brazil, and the United States, most of which is transshipped through Germany and the Netherlands.

In late spring 2018 former Minister of Agriculture Krzysztof Jurgiel informed stakeholders that the 2006 Feed Act would be amended to allow GE-derived feed ingredients through 2024. However, following his resignation in June 2018, and the subsequent appointment of current Minister Jan Krzysztof Ardanowski, MinAg has taken a harder line against soybean meal imports. The earlier amendment to prolong the use of GE feeds through 2024, has since been withdrawn from consideration by Parliament. Commercial stakeholders continue to hope for another extension from the Polish Parliament before the end of December 2018.

#### 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. Poland formally banned biotech livestock feed and derived ingredients under its 2006 Feed Act. As noted above, it suspended enforcement through January 01, 2019, and is currently considering its ban on biotech feed and feed ingredients beyond 2019.

#### **PART B: POLICY**

### a) Regulatory Framework

The June 2001 Law on Microorganisms and Genetically Modified Organisms (O.J. 2007, No 36, pos.233, 2009n No 18 pos. 97, 2015 pos. 277) provides the regulatory basis for requirements applicable to GE products/research, and regulates:

- contained use of GE organisms;
  - o deliberate release of GE into the environment; and
    - introduction of GE products into the market.

On March 22, 2018, the abovementioned 2001 Law on Microorganisms and Genetically Modified Organisms 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 the Biological Security. The 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.

The new regulation--in theory—allows for GE cultivation, but the onerous and bureaucratic procedures required practically prevents it

- To register a GE crop, the registration requires the consent of all land owners within a 30 kilometer radius from the external borders of the plot where cultivation is planned.
- Documentation confirming that the cultivation would not negatively affect the environment is required.
- The consent of the local civic council, the poviat council, and the voivodeship council (three levels of regional self-government) are required.
- The area of cultivation cannot be located less than 30 km from the established nature conservatories.
- Other details which create additional barriers for GE cultivation.
- The amendment introduces fines and imprisonment sentences from three months to 12 years, depending on the offenses.

The Ministry of Environment (MOE) is the competent authority handling the notification and regulation of agricultural biotechnology use in Poland. The MOE is advised by the Opinion and Advisory Commission of the Minister of Environment on genetically modified microorganisms (GMM) and GMO, an expert advisory body consisting of scientists, representatives from administrative authorities and non-governmental organizations. MOE cooperates with the Ministry of Health (MOH) regarding address of potential risks to human health. The MOE is the Competent Authority in reference to the Cartagena Protocol.

The MinAg is responsible for animal health, crops, feeds, and agricultural risks associated with biotechnology. The MinAg is the Competent Authority in reference to food and feed enhanced through biotechnology and on rules for co-existence.

There are numerous specific acts and regulations on GE legislation which build on the basic 2001

Law on Genetically Modified Organisms:

- 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 the production and use of medicated feed and marketing; establishes quality and hygiene requirements for feed, and establishes the means for entering into commerce; and regulates supervision and official control of feed.
- The Act of August 25, 2006, On Food Safety and Nutrition (Journal of Laws 2006 No. 171, item. 1225), and amendments. The Act defines, among others, health requirements of food, requirements for compliance with the principles of food hygiene, materials and articles intended to come into contact with food and the competences of authorities and basic procedures and requirements of official food controls.
- Act of November 2012, Seed (OJ 2012 pos. 1512), and amendments. The Act regulates the issues related to the examination and assessment of varieties for registration, record keeping crop varieties and production, trade, assessment and control of seed.

Regulations to the Seed Law are as follows:

- Council of Ministers of January 02, 2013. Prohibits Amflora seed potato (OJ 2013 pos. 27).
- Council of Ministers of 2 January 2013. Prohibits maize seed MON 810 (OJ 2013 pos. 39)
- Council of Ministers of 8 May 2013. Amends the Regulation on the Prohibition of Seed Maize MON 810 (OJ 2013 pos. 590)
- Council of Ministers of 30 April 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 Genetically Modified Organisms. The GOP's position opposed allowing GE food and feed into the EU Community. The GOP opposes marketing of products under Directive 2001/18/ EC. The GOP also opposes GE for cultivation and release of GE into the environment for experimental purposes. However, it recognizes the need to perform experiments aimed at obtaining data on GE's effect on the environment in the Polish climatic conditions, carried out by research institutions and universities.

#### b) Approvals

Poland bans all GE crops, including those approved by the EU Commission, for cultivation, except for scientific research. Poland adopted the EU "opt-out" for cultivation legislation.

## c) Stacked or Pyramided Event Approvals

Poland implements EU legislation regarding stacked events, for more information please refer to the EU-28 Biotechnology Report available at

https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx

## d) Field-Testing

In 2015, two GE plants underwent field tests in Poland, namely poplar and flax.

## e) 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 innovative technologies (genomic editing, etc.), Polish authorities are cautious vis-à-vis their current position.

### f) Coexistence

The MOA drafted coexistence implementing regulations that require isolation zones between GE crops of 500 and 1,000 meters between conventional and organic crops, respectively.

## g) Labeling

Poland implements EU regulations for GE food labeling. Packaged foods and feeds derived from and/or containing GE enhanced ingredients must be labeled when GE-derived ingredients exceed 0.9 percent of ingredients. "Contains GMOs" is a typical example of a product label statement found on the Polish market. Labeling is enforced by local authorities and follows EU labeling standards. For more information on EU biotechnology, labeling requirements see the EU 28 Biotechnology Report available at <a href="https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx">https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx</a>. To date, no national labeling requirements exist for products derived from GE animals, or products produced from animals fed with GE feed.

The MinAg issued new draft 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 draft standard would include a "non-GMO" label. MinAg plans to submit the draft legislation to the Upper Chamber of the Polish Parliament (Sejm) in fall 2018.

### h) Monitoring and Testing

Poland implements EU legislation regarding monitoring and testing, for more information please refer to the EU 28 Biotechnology Report available at

https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx. The GOP allows imports of GE food only when it clearly marked and without any possibility of further processing in Poland. The MOH and MOA are the Competent Authorities in reference to food and feed enhanced through biotechnology and on rules for co-existence. Poland actively tests for GE traits in imports. The competent Authority for imports of food is Sanitary Inspectorate in Poland. Tests are conducted on risk assessment basis. If a product is unapproved the further procedure depends on the nature of unlawfulness. Sometimes completing documentation is enough to obtain entrance permission.

Every year since 2005, audits have been conducted to monitor studies of conventional rapeseed, maize, and mustard seed (2010) for the presence of admixtures of genetically modified seeds. Samples of seed marketed in Poland, produced in Poland, other EU Member States or in third countries are collected by PIORiN inspectors in accordance with the methodology of the International Seed Assessment Association (ISTA). The research is carried out in the Laboratory of Identity Identification and Analysis of "GMO" Central Laboratory GIORiN in Toruń. The tests are performed using PCR (qualitative analysis) and Real-Time PCR (quantitative analyzes).

## i) Low level Presence (LLP) Policy

Poland follows EU regulations. Although the EU does not have an LLP Policy, it does have a "technical solution" of at 0.1 percent allowance (a definition of zero) for products with applications submitted to the EU. Poland has been open to imports of commodities holding a low-level presence of bioengineered events in general. Despite its official anti-GE position, at the EU level Poland supports a resolution of the issue.

## j) Additional Regulatory Requirements

Not applicable

## k) Intellectual Property Rights (IPR)

There is IPR legislation in Poland and Poland adheres to EU-based IPR requirements. For more information on EU biotech-related IPR see the EU 28 Biotechnology Report available at <a href="https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx">https://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx</a>. The main national IPR legislation related to plant breeding is Act of 26 June 2003 on the legal protection of plant varieties.

## 1) Cartagena Protocol Ratification

Poland signed the Cartagena Protocol in May, 2000, and ratified it on December 10, 2003.

## m) International Treaties and Forums

Poland is a member of the International Plant Protection Convention, and actively participates in all discussions related to phytosanitary issues, except of GE plants. Poland has not taken any significant position in international fora, (*e.g.* at the Codex Alimentarius) related to GE.

#### n) Related Issues

none

## **PART C: MARKETING**

## a) Public/Private Opinions

According to national polls, nearly 70 percent of Polish society opposes the use or cultivation of GE crops and products. Studies also indicate that the general awareness in Poland about science in support of genetic engineering is low.

Anti-GE organizations are active in Poland and include Greenpeace, 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 Association of Ecological Farmers. These groups are very vocal and employ Polish celebrities as a means of attracting media coverage. Consistent with their marketing strategy in other countries, these organizations rely on nonscientific innuendos, debunked and/or pseudoscientific studies, and other forms or propaganda.

## b) Market Acceptance/Studies

Recent retail studies show that purchase decisions of the majority of Polish customers are determined by price of the product versus ingredient lists.

Promotional media campaigns sometimes include "GMO" free mozzarella and eggs. Public opinion studies show that 70 percent of respondents oppose buying/eating food derived from GE crops. Feeds containing GE-derived ingredients are not generally called into question, mostly

due to lack of awareness.

#### **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

#### PART D: PRODUCTION AND TRADE

## a) Product Development

In Poland GE animals are used for basic research and pharmaceutical studies. As in any EU countries, Poland does not allow GE animals for human consumption.

Research on GE animals remains limited. Three research centers in Poland, chiefly the Institute of Animal Breeding in Balice (Krakow), the Institute of Animal Genetics in Jastrzebiec (Warsaw), and the Agricultural University (Poznan) conduct some research. Each research project must be approved by the MOE. While Polish scientists are interested in innovative technologies (genomic editing, etc.,) Polish authorities are cautious vis-à-vis their current position.

The main objectives of research on GE animals are:

- Use in 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 animals traits for breeding;
- Production of material for xenotransplantation. This technology uses cloning for multiplication of animals with organs used for transplantations. It is the only use of animal cloning currently implemented apart from research projects.

## b) Commercial Production

In Poland GE animals are used for basic research and pharmaceutical studies. Likewise, there are no commercial applications of animal cloning.

### c) Exports

Not applicable

## d) Imports

Not applicable

#### e) Trade Barriers

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

### **PART E: POLICY**

## a) Regulatory Framework

As noted above the legislation on GE animals is based on the 2001 Polish Law on Genetically Modified Organisms (updated May 21, 2003). This legislation mainly addresses GE plants. There is no legislation regarding cloning of animals.

The Polish Parliament is working on a new biotechnology law (see Plant Section of the report).

The MOE is responsible for oversight of existing biotechnology regulations.

The MOH is responsible for regulation of food originating from GE animals. These foods are considered "novel foods."

According to the General Veterinary Inspectorate of the Ministry of Agriculture there are no regulations in Poland which are specific to GE animals.

## b) 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 innovative technologies (genomic editing, etc.,), they remain cautious vis-à-vis their current position.

## c) Labeling and Traceability

Poland has been following the 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.

## d) Intellectual Property Rights

Not applicable

## e) International Treaties and Forums

Not applicable

#### f) 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 general public into two distinct opinion groups, who opt for, or against GE development. Biotechnology in general in Poland remains a much 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.