

Marketing and Cultivation of Genetically Modified (GM) Products in the EU

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The regulation of genetically modified (GM) plants in Europe is complex. The European Union's system of checks and balances and the need to secure agreement among the EU's 27 Member States, where opinions on GM safety and ethics vary widely, creates a deliberative process that considers the safety of GM foods. Major GM-producing countries, agribusinesses, biotech companies and the World Trade Organisation relentlessly pressure the European Union to lower regulatory standards and allow more cultivation of GM foods. The tension between an aggressive and well-funded agribusiness lobby and the European public's opposition to genetically modified organisms (GMOs) creates a constantly changing legal and political landscape. Here is an overview of EU regulation of GMO cultivation and sales as of Summer 2011.

GM crops can be approved in the European Union for two purposes: marketing and cultivation. The EU has approved about 30 GM products for marketing, primarily GM soy and maize for animal feed.¹ Only two GM crops have been approved for cultivation, Monsanto's MON810 insect-resistant maize and BASF's industrial starch Amflora potato.²

Europe's Falling GMO Production

Total EU GM cultivation dropped by half from 2006 to 2009 and is continuing to fall. In 2009, only 0.05 percent of European fields were growing GM crops.³

In 1998, the EU approved MON 810 insect-resistant maize for cultivation.⁴ This crop is currently grown in six EU countries but cultivation fell 15 percent from 2008 to 2010.⁵ Spain is the leading EU producer of this GM crop, growing 76,575 hectares in 2010.⁶ France, Germany, Austria, Greece, Hungary, Bulgaria, and Luxembourg now ban MON810 cultivation.⁷

The second GM crop approved for cultivation in the EU was BASF's Amflora potato, which produces industrial starch.⁸ Austria, Luxembourg and Hungary banned Amflora because it contains an antibiotic resistance marker (ARM) gene, the use of which is banned by EU's Deliberate Release Directive to protect the efficacy of human and veterinary medicines.⁹ In 2010, its first year of production, the crop was only grown in Sweden, Germany

and the Czech Republic.¹⁰ Soon after planting, BASF found 47 incidences of contamination with a different, unauthorised GM potato, affecting 16 hectares.¹¹ Amflora plantings collapsed to just 17 hectares in Germany and Sweden in 2011.¹²

EU GMO Regulation

Authorisation for the cultivation of GM crops is regulated by the deliberate release directive 2001/18/EC of the European Parliament and Council.¹³ Under this regulation, the environmental risks of GM crops are evaluated on a case-by-case basis.¹⁴ Member States must follow the precautionary principle, which suggests if a path of action could result in potential health risks, known or unknown, the action should not be taken.¹⁵

In 2003, the EU approved (EC) No. 1829/2003, regulation governing the market approval of GM food and feed.¹⁶ It requires that all foods and feed containing GMOs must be labelled. The law provides for so-called "adventitious presence," or unintentional contamination, up to 0.9 percent in cases of accidents where the company can demonstrate its presence was "technically unavoidable."¹⁷

GM products considered "processing aids," like GM enzymes used to make cheese, are exempt from labelling.¹⁸ The resulting meat, milk and eggs from these animals does not currently require a label, although some EU

Member States have voluntary labelling schemes in place to show consumers where GM feed is used.¹⁹ In this way, the majority of GM use, including soybean and maize imports, is hidden from consumers in unlabelled meat and milk from GM-fed livestock. European consumers, who have widely opposed GM foods, are unable to make an informed choice and are in fact unwittingly supporting the GM industry.²⁰

Under EU regulation, the European Food Safety Authority (EFSA), EU's primary health and safety organization, assesses the health risks of GM crops and products and makes a recommendation on authorisation to the Commission—EU's executive arm.²¹ EFSA's competence has been called into question by civil society, Member States, politicians and independent scientists, with the Council calling for reinforcement of regulations and independent scientific assessment as far back as 2008.²²

The Commission makes a recommendation to grant or deny the GM authorisation and sends it to the Standing Committee on the Food Chain and Animal Health—made up of Member State representatives—to make a decision.²³ If the Committee does not achieve a qualified majority, 255 votes out of 345, the Commission takes its proposal to the European Council (comprised of Ministers from Member States) who vote on whether or not to approve the GM product.²⁴ A qualified majority against may reject the GMO, so the Commission must choose its timing carefully when putting proposals to the vote if it does not want to lose.²⁵ In the absence of a qualified majority here, the Commission of unelected officials makes the final decision.²⁶

Genetic Modification and the World Trade Organisation

The EU had approved 18 GM products for marketing by June 1999, when five EU Member States (Denmark, France, Greece, Italy and Luxembourg) declared a *de-facto* moratorium on new authorizations until the Commission introduced legislation for traceability and labelling.²⁷ Austria, Belgium, Finland, Germany, Netherlands, Spain and Sweden did not apply a moratorium but invoked a “thoroughly precautionary approach” and urged the Commission to rapidly deal with traceability and labelling regulations.²⁸

In response, the United States, Canada and Argentina filed a complaint with the World Trade Organisation's Dispute Settlement Body in 2003. In 2006, the WTO ruled that the EU “undue delay” in its approval process for 24 GM products from 1999-2003 constituted a *de facto* moratorium on GM that was inconsistent with WTO rules.²⁹ It also ruled that national GM bans violate trade rules and are unjustified when the countries had not provided or considered adequate risk assessments.³⁰ The ruling did not prohibit the EU from applying its own standards and laws, including restricting GM crop approvals, provided the rules were implemented properly. Although the ruling narrowed the substance of the question, the WTO's GM decision was another attack on the right of countries to ensure food safety and protect the environment.



Canada settled its dispute and dropped its complaint against the EU in 2009, followed by Argentina in 2010, leaving the United States as the only party to the complaint.³¹ The United States is aggressively trying to force trading partners to overturn their GE prohibitions. The U.S Trade Representative (USTR) is lobbying trading partners to remove “unjustified import bans and restrictions to U.S. biotech products.”³² USTR is even pressing countries to eliminate GM labelling requirements.³³

Relaxation of Zero Tolerance Policy

Until recently, the EU only permitted approved GM feed for livestock and prohibited any GM content that had not passed the EU's safety assessment procedures.³⁴ This zero tolerance policy was designed to prevent risky traits from entering EU's food supply, but biotechnology companies and agribusinesses have pushed to relax the EU's “zero tolerance” policy of unapproved GM traits in animal feed in order to open up the EU's GM market. These groups have lobbied for an unhindered supply of soy for animal feed, which they claim will ensure the viability of EU livestock production.³⁵

The zero tolerance policy was overturned in June 2011 when the European Commission adopted regulation allowing animal feed to contain up to 0.1 percent unapproved GM material.³⁶ This policy relaxation will not affect zero tolerance safeguards for food, although some are pressing for this.³⁷ However, even this low threshold opens the door to unapproved GMOs, exposes Europe to potentially risky experimental GM crops and advances agribusiness power.

“GMO-Free Regions”

By September 2010 the EU had 292 regions and provinces and 4,713 local governments that were GMO-free.³⁸ These bans, however, are not legally binding. In 2007, the ECJ ruled that GM-free regions should not limit farmers' freedom of choice as long as they establish accountability conditions.³⁹ These GMO-free regions are an expression of the will of citizens facing unsympathetic



and unresponsive lawmakers and many farmers support them as a protection against loss of markets, contamination and associated legal ramifications.

National Bans on GM Foods, Products, Crops

A “safeguard clause” under the EU’s Deliberate Release Directive allows EU Member States to restrict or prohibit GM use or sale providing there is evidence that the crop poses significant risks.⁴⁰ Several EU countries have implemented marketing and cultivation bans on GM products, despite agribusiness and WTO pressure. Currently, nearly a quarter of EU Member States operate bans on GM products: Austria, Bulgaria, France, Germany, Greece, Hungary, and Luxembourg.⁴¹ Additionally, some regions of Italy have a de facto ban until supporting regulations are in place.⁴²

Austria has banned GM maize cultivation since 1997 and marketing GM animal feed imports since 2007.⁴³ In May 2008, Austria lifted its marketing ban on GMOs under pressure from the Commission, but the cultivation ban remains.⁴⁴ Austria also bans cultivation of the GM potato Amflora.⁴⁵ Large supermarkets have a voluntary agreement not to offer GM-derived food products and manufacturers may use a non-GM-fed label for meat.⁴⁶

Bulgaria banned cultivation of three Monsanto maize varieties in February 2010.⁴⁷

France banned MON810 maize cultivation in 2008, but EFSA challenged the ban for lacking sufficient scientific basis.⁴⁸ Despite this evaluation, the French government has maintained its ban. In March 2011, the European Court of Justice issued a non-binding opinion that the ban is illegal, indicating the likely outcome of any Commission case against France.⁴⁹ In 2010 the EU’s largest food retailer, Carrefour, launched a non-GM-fed label in its French stores.⁵⁰

Germany banned MON810 maize cultivation in 2009 and although EFSA determined there was insufficient scientific evidence to justify the ban, the German Agricultural Ministry has upheld it.⁵¹ In October 2008, Campina—one of the world’s largest dairies—launched its non-GM-fed label in Germany, which led to a 10 per cent rise in sales in 2009.⁵²

Greece banned MON810 maize cultivation in 2005, and the ban remains despite negative pressure from the Commission.⁵³

Hungary banned MON810 maize cultivation in early 2005, and despite several Commission attempts to lift the ban, it remains in effect.⁵⁴ Hungary also bans cultivation of the GM potato Amflora.⁵⁵

Italy has not prohibited GM cultivation, but a de facto ban has been in effect while Italian regions negotiated coexistence regulations. In May 2010, Italy’s regional farming

heads unanimously called on the Agriculture Minister to implement an official ban of GM maize and potato cultivation.⁵⁶

Luxembourg banned MON810 maize cultivation in 2009 and Amflora potato cultivation in 2010.⁵⁷

Poland forbids marketing of GM seeds and enacted a total ban on GM feed in 2006.⁵⁸ The GMO feed ban was scheduled to take effect in 2008 but the implementation was postponed until 2013.⁵⁹ The Commission challenged the ban and in March 2011 referred Poland to the European Court of Justice (ECJ) for “failing to fulfil its obligations under EU law.”⁶⁰

Romania became GM-free in 2007 despite widespread cultivation of GM soy before joining the EU.⁶¹

Devolution of National Cultivation Decisions

Current Commission proposals to devolve decisions on cultivation of GMOs to Member States are struggling to gain acceptance. In countries without bans, farmers are permitted to grow EU-authorized GMOs as long as they comply with co-existence rules, which help keep GM and non-GM crops segregated to prevent contamination and associated noncompliance and labelling problems.⁶² The EU acknowledges that co-existence can lead to contamination of organic and conventional crops, and economic damage to their producers, but liability remains unclear.⁶³ The Commission initially attempted to extract a concession for the right to ban GM crops, which was clearly an offer to exchange the right to ban for positive votes on individual GM authorisations.⁶⁴ The language of this concession was removed in subsequent documents following publication of unfavourable legal opinions and publicity from civil society.⁶⁵

There is considerable debate concerning the legal certainty offered by the Commission’s new proposals and fear that Member States may be sued by biotech companies for invoking bans.⁶⁶ Some Member State leaders question whether the proposals could be challenged as breaches of both the single market and international trade law.⁶⁷

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