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Report Highlights:
There are seven Member States (MS) commercially producing genetically-engineered (GE) crops, with Spain being, by far, the largest producer. Under the EU policy framework for agricultural biotechnology, MS policy varies greatly. Coexistence frameworks have been set up in most MS or are currently being prepared, and 5 MS continue to maintain national bans. However, the EU is a major consumer of biotech products, mainly soybean meal imported to feed livestock and poultry, with at least 80 percent of EU soy crush estimated to be genetically modified. Finally, agricultural biotechnology research in Europe is declining, mainly due to political pressure.

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Executive Summary

This report consolidates and updates the annual biotechnology reports prepared in 2006 in individual EU Member States (MS).

In the past several years, yield benefits and cost savings of genetically engineered (GE) crops have made them attractive to EU farmers, and the production of biotechnology crops (currently only one corn event) continues to expand in certain Member States. Despite regulatory restrictions and political threat, the area devoted to biotech corn is expected to increase to approximately 110,000 ha in 2009 (mainly located in Spain, the Czech Republic, Portugal, Slovakia and Germany).

Under the EU policy framework for agricultural biotechnology, MS policy varies greatly. Virtually all MS have transcribed EU Directive 2001/18 and implement EU regulations on traceability and labeling. Most MS have set up national coexistence frameworks for biotech and non-biotech crops (Belgium, Czech Republic, Germany, Hungary, Portugal, Romania, Slovakia) or are currently preparing coexistence rules (France, Spain, the United Kingdom). Some MS continue to maintain national bans on genetically-engineered crops (Austria, France, Greece, Hungary and Italy).

The main biotech products used are in animal feed, human food, planting seeds, and the textile industry. They consist of soybeans and products, corn and its derivatives, and cotton. The largest categories of GE products consumed primarily consist of soybean meal, where GE products are estimated to represent 80 to 95 percent, and of corn and corn products (mainly corn gluten feed), in which GE products are estimated to account for 10-25 percent only.

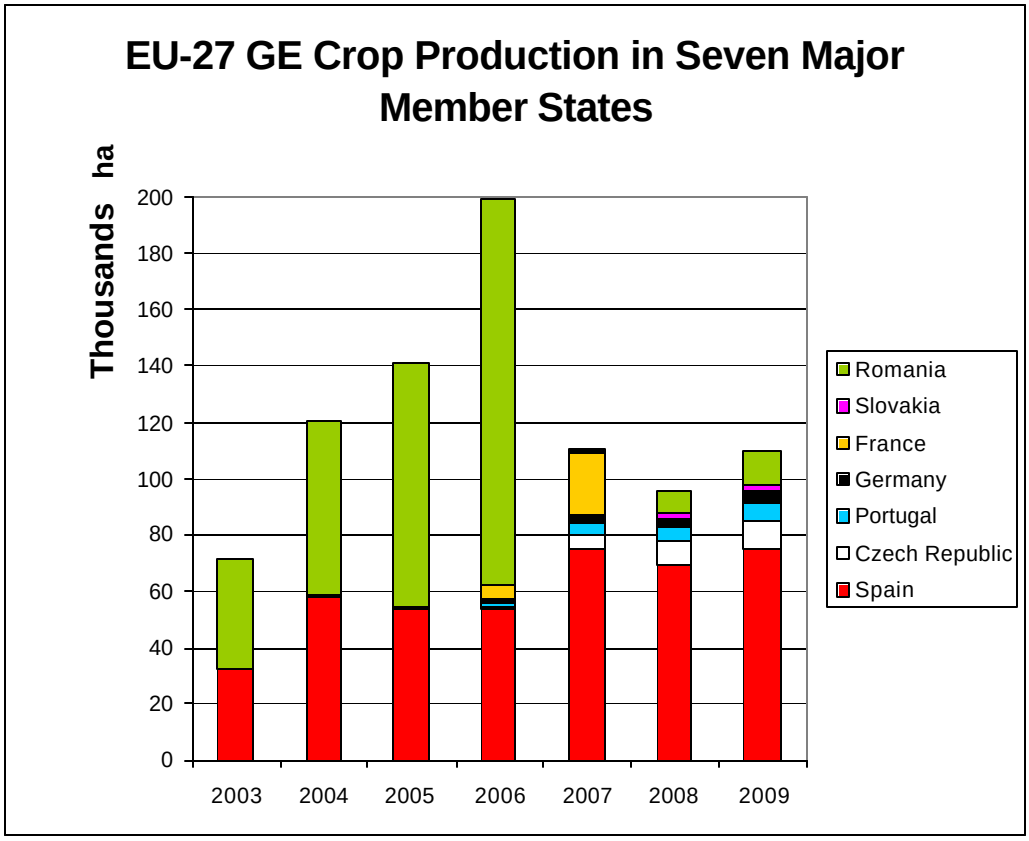
While research in agricultural biotechnology is a stated priority of the European Commission and many MS, in reality, many research scientists have either been forced to drop activities due to political pressure or have moved to institutions (particularly in the United States) where support for such research is undeterred. This reduction in research activities has also

translated into a reduction in field trials, which have also suffered from actions of intimidation by activist groups.

Biotechnology Research, Trade and Production

EU BIOTECH AREA GRADUALLY EXPANDING

Since the approval of the first biotech corn event for planting in the EU, Spain has been the country that has most rapidly adopted its use. Prior to its accession to the EU, Romania was a major producer of biotech soybeans. However, since biotech soybeans are not approved for planting in the EU, this ended in 2007 with its accession to the EU. Interest across farming groups in the EU in the use of agricultural biotechnology continues to expand, particularly as the cost of inputs is increasing. This has made the yield benefits and cost saving especially attractive. As a result, the area devoted to biotech crops (currently only one corn event) continues to expand gradually. However, many growers are constrained by restrictions placed in land rental contracts, threats by neighbors, and intimidation by NGO's. See Annex VIII for biotech crop production in EU member states in 2007 and 2008. In several EU member states (Austria, the Czech Republic, France, Germany, Greece and Romania), farmers producing biotech corn must register their fields with government bodies. The specificity of these registration requirements varies greatly from country to country. See Annex IX for a summary of field registry requirements.



DESPITE POLITICS, EU IS A MAJOR BIOTECH CONSUMER

The main biotech products used in each Member State are in animal feed, human food, planting seeds, and the textile industry. They consist of soybeans and products, corn and its derivatives, and cotton.

The largest category of GE products consumed by Member States consists of soybean meal, which is used in animal feed. The EU-27 roughly consumes 33 million MT of soybean meal annually in animal feed (see EU-27 report E48062 dated 05/30/2008). The bulk of the soybean meal consumed in the EU is imported or produced from imported soybeans, mainly coming from North and South America. GE products are estimated to represent 80 to 95 percent of the total soybean meal used by Member States, i.e., 26 to 31 million MT. Similarly, the EU-27 crushes approximately 14 million MT of soybeans annually, and at least 80 percent is estimated to be GE products, i.e., 11 million MT.

However, there is a niche market for non-GE soybeans and soybean meal used in animal feed, mainly for the poultry sector and other animal production undertaken under the Identity Preservation program or geographical indications, or for human consumption for soybeans (such as in baby food).

Corn and corn products (mainly corn gluten feed) represent the second largest category of GE products used in animal feed. However, the share of GE products out of total corn consumption is generally estimated to be significantly lower (10-25 percent) than for soybean products. This is mainly due to the fact that the EU-27 does not rely as much on imports of corn and corn-derived products as for soybean products.

EU RESEARCHERS SEEK MORE SUPPORTIVE ENVIRONMENTS:

Research into agricultural biotechnology is a stated priority of the European Commission and many of the Member States. However in reality, many research scientists have either been forced to drop activities due to political pressure or have moved to institutions (particularly in the United States) where support for such research is undeterred. This reduction in research activities has also translated into a reduction in the operation of field trials. For several years, researchers and universities were able to implement field trial activities successfully. However, beginning in 2007, activist groups succeeded in intimidating many research stations and universities into dropping field trial work. As a result, the requests for permits to conduct field trials fell dramatically in 2008. In addition, field trial destructions have continued with little or no response from police and judicial authorities in many areas. See Annex X for a summary of field trials in the EU-27.

The situation and policy issues across EU member states vary greatly. Please see Annex I for an overview of the most important issues currently facing agricultural biotechnology in each member state.

Biotech Regulatory System in the EU-27

EU-27 FRAMEWORK FOR ENVIRONMENTAL RELEASE

Europe's regulatory framework for biotechnology was established with the adoption of Council Directive 90/220/EEC "on the deliberate release into the environment of genetically engineered organisms" and Council Directive 90/219./EEC "on the contained use of genetically modified micro-organisms."

The framework was significantly revised by Council Directive 2001/18/EC to strengthen existing rules on the deliberate release of genetically engineered products into the environment. Directive 2001/18/EC is implemented in each EU Member State through national legislation. It sets out procedural guidelines for experimental field trials (Part B Authorization) and commercial introduction into the market (Part C Authorization). Specific measures include:

- environmental risk assessment,
- mandatory post-market (environmental) monitoring,
- mandatory supply of information to the public,
- mandatory labeling and traceability at all stages of placing on the market,
- and the establishment of a molecular register.

Authorizations, which can be renewed, are granted for a maximum period of ten years starting from the date when the authorization is first issued. If a GE product reaches the EU market, the applicant is obliged to ensure that post-market monitoring and reporting is carried out according to the conditions specified in the authorization.

Council Directive 98/81/EC, amending Directive 90/219/EEC, regulates research and industrial work involving the contained use of genetically engineered micro-organisms.

In addition to these Directives, there is a series of EU Regulations which govern the approval and use of genetically engineered products (Note: Unlike EU Directives, EU Regulations do not need to be transposed into national legislation, and therefore are immediately and simultaneously enforceable as law in all EU Member States).

Applications are first submitted to the competent authority in a Member State where the product is to be marketed. The application must clearly define the scope (i.e. for cultivation, for import, etc…), and must also include a monitoring plan, a labeling proposal, and a detection method for the GE product. The national authority informs the European Food Safety Agency (EFSA), and acknowledges receipt of the application within 14 days. After a "completeness check" to ensure all required documentation has been properly submitted, EFSA endeavors to deliver an Opinion within six months. In practice, the "6 month EFSA clock" can stop at any point to request supplemental information from the applicant. During this time, EU Member States can also comment on the pending application. Once EFSA has completed an Opinion, the Commission has three months to draft a proposal for granting or denying authorization. The Commission's proposal can be approved by a qualified majority vote of the Member States in the Standing Committee on the Food Chain and Animal Health. If the Committee is unable to agree on the Commission's proposal, it is then subject to a qualified majority vote by the Council of Ministers. If the Council does not act within 3 months, the Commission adopts the Decision. For more information on EFSA and the EU regulatory process: http://www.efsa.europa.eu/EFSA/Non_Scientific_Document/gmo_factsheet2,0.pdf.

LABELING OF FOOD AND FEED AND TRACEABILITY OF BIOTECH PRODUCTS

Labeling requirements for GE food were first adopted in the Novel Foods Regulation (EC) No 258/97. Specific requirements for GE corn and soybean lines were outlined in Council Regulation (EC) No 1139/98, and were later amended in Commission Regulation (EC) No 49/2000. While maintaining the idea that a GE food or ingredient could not be considered equivalent to its non-GE counterpart (as long as the genetic engineering was detectable), the latter regulation attempted to address the problem of unintended presence of GM by

introducing the concept of a threshold. As long as the GM-derived food ingredient material was below 1 percent of individual ingredients, food stuffs would not be subject to specific labeling requirements. Food additives and flavorings are regulated under Commission Regulation (EC) No 50/2000.

With the introduction of Regulation (EC) No 1829/2003 on '*genetically modified food and feed*', and Regulation (EC) No 1830/2003 on '*the traceability and labeling of genetically modified organisms*', the EU sought to create greater coherence in the regulatory framework for authorization, labeling and traceability. Regulation (EC) No 1829/2003 establishes a "one door, one key" principle, enabling a single application for authorization of release into the environment (according to the criteria set in Directive 2001/18/EC), and the authorization for use as food or feed. The authorization depends on a positive risk assessment by the European Food Safety Authority (EFSA) and a risk management process involving the European Commission and EU Member States through a regulatory committee procedure.

Note: See Annex II for a list of all genetically engineered food and feed events approved in the EU, including those events whose authorizations have expired. Annex III contains products whose applications are pending. Annex IV lists those genetically engineered foods authorized under Regulation (EC) no 258/97. Annex V contains those genetically engineered feeds authorized under Directive 2001/18/EC.Aneex VI contains Applications pending under Directive 2001/18.

INTERNATIONAL TRADE ISSUES CONTINUE

The EU regulatory approach to biotechnology has had a significant impact on international trade. In 2006, the WTO Dispute Settlement Body found that the EU had breached Article 8 of the SPS Agreement by instituting a *de facto* moratorium on the approval of biotech products. The European Commission and the United States have a continuing dialogue on how to normalize trade in products of modern agricultural biotechnology. This dialogue is an effort to address and correct the WTO inconsistent parts of the EU's process. Aside from the WTO case, the EU is facing great challenges in the asynchronous approval of products already legally available in other countries. Trade has been periodically disrupted by products that have been approved for cultivation in other countries, but remain illegal in the EU. For example, U.S. market access for corn gluten feed and distillers dried grains has been effectively lost due to this problem. Such disruptions tend to affect availability and prices. EU labeling regulations provide for a 0.9 percent threshold for the "adventitious", that is, accidental and technically unavoidable, presence of authorized biotech event in a non-biotech food or feed. Amounts above 0.9 percent must be labeled. The EU also temporarily authorized a 0.5 percent threshold for genetically engineered material not yet authorized by the EU, but that had already received a favorable EU scientific assessment. Although the 0.5 percent threshold provision expired in April 2007, discussions are currently under way to re-evaluate the technical definition of "zero tolerance."

The EU is a party to the Cartagena Protocol on Biosafety, and regulates the transboundary movement of genetically modified organisms through Regulation (EC) No 1946/2003.

MEMBER STATES POLICY VARIES GREATLY

Virtually all Member States have transcribed EU Directive 2001/18 and implement regulations on traceability and labeling. Most Member States have set up national coexistence frameworks for organic, biotech, and conventional crops (Belgium, Czech Republic, Germany, Hungary, Portugal, Romania, Slovakia) or are currently preparing

coexistence rules (France, Spain, the United Kingdom). Some Member States continue to maintain national bans on genetically-engineered crops (Austria, France, Greece, Hungary, Italy, and Poland). See Annex VII for detailed information on detailed Member States policies.

New Technologies

As reporting and knowledge about the development of new technologies in agriculture and food production has expanded, many of the same public perception issues have arisen in the EU that have faced agricultural biotechnology over the past 10 years. These include traceability and labeling, advantages for consumers, and regulatory regimes. At the present, there do not appear to be any emerging advocates for these new technologies in the EU. However, it is clear the same EU groups that have actively opposed the timely regulation and adoption of agricultural biotechnology are ready to activate negative campaigns and burdensome regulatory requirements regarding new agricultural or food technologies. For example, the European Commission recently proposed a new novel foods regulation which includes coverage of food products from cloning and nanotechnology. In its current form, many key components of this proposal are ill-defined. In addition, it envisions an onerous pre-market approval process. It could also require products approved under the regulation to carry mandatory labels and to be subject to significant post-market monitoring, even if determined to be substantially equivalent to conventional counterparts.

FOOD PRODUCTS FROM CLONED ANIMALS

Currently, the EU claims that there are no food products in the EU market derived from cloned animals or their progeny.

In December 2007, the European Food Safety Agency (EFSA) provided a draft scientific opinion on food safety and welfare and environmental impact of animals derived from cloning by somatic cell nucleus transfer and their offspring and products obtained from these animals. A report was issued on July 24, 2008. In the draft report EFSA stated that researchers found no difference exceeding the normal variability in the composition and nutritional value of meat from swine and cattle and cow milk between healthy clones or the progeny of clones and their conventional counterparts. The currently available data indicate that food products from cloned cattle and pigs and their progeny are as safe as food products of livestock derived by conventional breeding.

EFSA stated that based on current knowledge there is no expectation that clones or their progeny would pose any new or additional environmental risk compared with conventionally bred animals. The entire report can be accessed at the following address: http://www.efsa.europa.eu/EFSA/DocumentSet/sc_opinion_clon_public_consultation.pdf .

In January 2008, the European Group of Ethics (EGE) published their opinion on ethical aspects of animal cloning for food supply. The EGE has doubts as to whether cloning animals for food supply is ethically justified. Whether this applies also to progeny is open to further scientific research. The entire report can be accessed at the following address: http://ec.europa.eu/european_group_ethics/activities/docs/press_release_opinion23_en.pdf.

NANOTECHNOLOGY

Nanotechnology is a broad field in which the manipulation of matter at the molecular or atomic level occurs. Rapid advances are being made in industrial manufacturing and chemicals (such as food additives and supplements) in Europe. The news media and NGOs have in recent years exaggerated claims about hazards and potential use for this technology. Consumer groups have begun to ask questions about risks of nanoparticle-containing products and processes. They are demanding definitions and nano-specific legislation and post market regulation. Products such as sun creams, cosmetics and textiles containing nanoparticles have raised concerns as these are already available on the market.

The United States and the EU have established a working group focusing on food and agricultural applications of nanotechnology. This research-oriented group continues to discuss advances made in nano-biotechnology, with applications that could directly benefit consumers through better food packaging, spoilage detection and nutrient absorption.

Annexes

ANNEX I: MEMBER STATES INDIVIDUAL SITUATIONS

Austria: Austria remains one of the leading forces within the EU Europe against agricultural biotechnology. Zones restricting the use of biotechnology exist in all nine provinces, and all Austrian provinces are members of the "European Network of GMO-free Regions". National ordinances still effectively prevent the planting of EU approved biotech crops. Responding to consumers' and politicians' anti-biotech attitudes, and NGOs' anti-biotech lobbying, the Austrian retail sector has agreed to refrain from stocking or selling biotech foods. Presently, only biotech feed (soybean meal) can be found in the Austrian market.

Since their inception, the Austrian Government successfully defended national bans on EU approved biotech crops because the European Commission proposals to require their removal were blocked by the EU Council. However, since there was no Council agreement, the European Commission, in May 2008, adopted a decision ordering Austria to lift the safeguard clause on the import and processing ban of MON 810 and T 25 corn events. This decision did not affect Austria's safeguard action on cultivation. While Austria lifted the import and processing bans on MON 810 and T25, it proposed new import bans on MON 863 corn and three oilseed rape lines, Ms8, Rf3 and Ms8xRf3. These new Austrian bans could be implemented by mid July, 2008.

In March 2008, Greenpeace Austria staged a demonstration near the U.S. Embassy in Vienna against potential U.S. retaliatory actions against Austria in response to the WTO Case. In May 2008, FAS Vienna and an American Soybean Producers' (ASA) delegation organized a roundtable discussion to discuss biotech crops with Austrian stakeholders in the food, feed and crop industries. The Austrians were very receptive to the ASA message.

Previous Austria GAIN Reports		
AU7007	Austria fails to win EU support for biotech corn ban	12/18/2007

The Benelux: In 2007, the Benelux region imported approximately US$ 2.4 billion of agricultural and food products from the U.S. A large share of this trade was feed products, which required labeling for biotech content under the European Union's traceability and labeling legislation. The slow approval process of new GM events by the European Union has significantly affected U.S. exports to the Benelux region in particular corn gluten feed (CGF) and Distillers Dried Grains (DDGs). Also exports of U.S. food products such as rice and processed products have declined. Slow EU approval of the new Roundup soybean variety could also limit U.S. soybean exports to the region if placed into commercial market channels before authorization is obtained in the EU.

The Netherlands and the Belgian regions, Flanders and Wallonia, just recently implemented coexistence regulations. Sector sources believe that the combination of restrictions will practically ban the cultivation of biotech events, particularly in the Walloon Region. The Dutch Farmers Organization (LTO) and Belgian Farmers Organization (Boerenbond) are both pragmatic and in favor of using biotech crops. But both organizations point to the resistance of retailers and consumers towards food products containing biotech components, in particular in export markets.

Field trials of biotech crops are almost impossible in the Benelux. In the Netherlands, crop trials are effectively prevented by cumbersome regulations imposed by the government and

by the threat of protests from environmental groups. While the Dutch Government issued over thirty licenses for field trials of biotech crops, only seven were used in 2007. In Belgium and Luxembourg, there have been no licenses issued for field trials since 2004.

Bulgaria: In 2004, Bulgaria passed a major biotech law which de facto prohibited cultivation of biotech events. The law is not fully harmonized with EU regulations. As a result, no research or commercial plots exist in the country. Research conducted prior to 2004 has been terminated.

In April, the law was amended to make some changes to allow research field trials for cotton only. A proposal for such trials was submitted to the Biosafety Commission but there has been no final decision because the dossier was deemed incomplete. Another amendment to allow research trials was proposed in June. The discussions and the vote are scheduled for July. If successful, then some corn field trails could be carried out in 2009.

Czech Republic: The Czech Republic is a pro-biotech country with a pragmatic approach. Czech farmers have grown Bt corn since 2005. From 270 hectares in 2005, the acreage has expanded to almost 10,000 hectares in 2008.

The Ministry of Environment is the competent authority for handling biotech product notifications, and the Ministry of Agriculture is responsible for notifications of biotech food and feed. The Czech Republic's coexistence rules require isolation distances and notifications to the Ministry of Agriculture and the Ministry of Environment. When voting on biotech approvals at various levels in the EU, the Czech Republic takes a case-by-case approach and bases its decision on scientific evidence. The coexistence rules set requirements on information, isolation distances, record keeping and control. The isolation distances were decreased in 2006 from 100 meters for conventional agriculture to 70 meters (or 35 rows of non GM crop as a barrier or a combination of a distance and a buffer zone, in which case 1 row equals 2 meters) and for organic agriculture from 600 meters to 200 meters (or 100 m and 50 rows of non GM crop as a buffer zone).

In terms of food use, some dairy processors refuse to buy milk from farmers who feed their cattle with biotech soybeans or corn. Even though retail chains generally avoid biotech food products, many supermarkets (including Tesco) in the Czech Republic carry items containing biotech components, such as cooking oils, and these products are labeled.

Previous Czech Republic GAIN Reports		
EZ7008	Biotech Conference in Prague	12/10/2007

Finland: In Finland, there is no commercial production of biotech crops. Several seed companies have, however, developed their own GE varieties, including herbicide tolerant rapeseed, herbicide tolerant sugar beet and starch potatoes. In August 2007, the Finnish meat industry publicly abandoned its voluntary ban on biotech animal feed due to rising feed costs. The announcement was met with unexpectedly strong media reaction. As a result, the Finnish Minister of Agriculture, Sirkka-Liisa Anttila, called for voluntary labeling of meat from animals not fed with biotech feed.

France: Prior to 2008, France was the second largest producer of biotech corn in the EU. There was a fourfold increase between 2006 and 2007 to 22,000 ha, due to the favorable

results of the 2006 crop. In addition, the implementation of new a EU regulation on mycotoxin levels for grains spurred French farmer interest.

However, this dramatically changed in 2008 when the current French government, under the lead of the Ministry of Environment, implemented a number of policy initiatives threatening the future of agricultural biotechnology in France. First, France banned MON810 production in January 2008 (pending its no-year reevaluation by EU authorities). Second, the GOF passed a new biotech bill in May 2008 mandating public disclosure of commercial biotech fields at the plot level. The law also reorganized the national authority evaluating genetically-engineered products, to include not only scientists but also a socio-economic committee.

France is actively trying to move its socio-economic evaluation of agricultural biotechnology to the European level through initiatives during its Presidency of the European Union in the second half of 2008.

In France, lack of consumer acceptance of agricultural biotechnology continues, particularly for food products. Food products labeled as containing or derived from biotech are generally not available on the French market. Anti-biotech activists are well organized and work consistently to discourage biotech acceptance. During the summer of 2006 and 2007, activists destroyed two thirds of the open-field test plots. Less visible to the public, but still very effective, is the pressure imposed by these groups on the food and feed industry and retailers. For example, the Greenpeace website has a "blacklist" identifying biotech food products marketed in France. The negative publicity generated by selling a biotech product in a French supermarket has been so detrimental that they are no longer available, and processors have tended to reformulate to avoid labeling.

Previous French GAIN Reports		
FR8008	GOF Action on Biotech – One Year Overview	06/06/2008

Germany: In the past two years, Germany has become one of the most vocal opponents of biotechnology in the EU. In 2007, the current German grand coalition government amended the national genetech law, complicating the cultivation of biotech plants. It increased distance requirements between biotech corn and conventional or organic corn to 150 and 300 meters respectively. As part of the public field registry, farmers must report the exact location of their biotech crop fields. The new law also redefined the term "genetech free" and provided a basis to label livestock products as such if the animals are not fed biotech feed during a certain period prior to slaughter or milking. It is unclear how extensive this labeling option will be used, given the rapidly increasing price non-biotech animal feed.

Despite a high level of public and media opposition against biotech crops, German farmers increased the area planted to Bt corn to 3371 hectares in 2008, up almost 700 hectares from 2007. An additional 36 hectares have been planted as test fields mainly for variety testing of corn. The second most important crop for researchers and breeders is potatoes, which are planted on about ten hectares of test fields. Tests with rapeseed have been discontinued in Germany because of the risk of out-crossing. In the summer of 2007, the western corn root worm diabrotica virgifera was detected for the first time in several locations in Southern Germany. German authorities try to eradicate the pest through conventional methods such as chemical seed treatment and cultivation bans but were unsuccessful.

The German Minister of Agriculture's position on biotech is that cultivation of biotech crops is not needed since current traits provide no benefits to the consumer. The German livestock feed industry and swine producers' organizations are currently calling loudly for an

acceleration of the EU biotech approval process. The industries fear that the importation of soybeans and soybean meal will become more difficult and more expensive when farmers in the U.S. begin to cultivate second generation biotech soybeans.

Outreach activities continue to focus on providing farmers, processors and press contacts information about the practical experiences of U.S. farmers using agricultural biotechnology. These activities have been primarily funded through U.S. Department of State.

Previous German GAIN Reports		
GM7042	Biotech Traces in German Rapeseed Seeds	09/07/2007
GM7052	Biotech Outreach Programs to Germany	11/05/2007
GM8003	Without Biotech Food Label Standard	01/22/2008
GM8006	German Bundestag Passed Amendment of Biotech Law	01/31/2008
GM8014	German Genetech Law Finalized	03/05/2008
GM8022	German Argumentation paper	05/07/2008

Hungary: Hungary has a mixed record with regard to agricultural biotechnology. The GOH introduced the first Act on Biotechnology in 1998. Since then the Act has been amended several times. In November 2006, the last time it was amended, the GOH approved a "Coexistence Regulation" (Act CVII. of 2006). The coexistence regulation is so stringent that it virtually prohibits biotech cultivation because of isolation distances, neighbor liability contracts, etc. The GOH is preparing another amendment to the Act under pressure from opponents of biotechnology in the Parliament. The amendment is to be filed for EU notification later this year. It is unclear what changes will be made.

Hungary's biotechnology legislation reflects the general thinking that the country's current "GM-free" status is a marketing boon. The country is a major seed and feed corn producer in Europe. The general public is rather pragmatic about biotechnology and scientists have a good reputation in Hungary. The country's life science institutes are active participants in international biotechnology research. For example in 2006, pro-biotech institutions and scientists from neighboring countries (with similar ecological conditions) established the "Pannonian" Plant Biotechnology Association to coordinate their activities. Environmental groups and the Ministry of Environment are trying to block the use of the new technology.

Since 2005, Hungary has maintained a moratorium on the planting of the biotech corn variety MON 810. The moratorium is not only inconsistent with EU regulations but is also controversial within the GOH[F3]. The Council of Environmental Ministers has voted down the proposal of the European Commission to lift the ban two times, last on February 20, 2007. EFSA evaluated Hungary's studies in support of its safeguard clause and issued an opinion in July 2008, finding "no new scientific evidence" that would invalidate the previous (EFSA) risk assessments (see at The EFSA Journal (2008) 756, 1-18). It is unclear if the Commission will place a new vote to the agenda and if so, when. It is possible that the 10-year re-evaluation for MON 810 within the EU regulatory regime will affect the Hungarian moratorium.

Ireland: While the Irish government has a policy of science-led decision making on the issue of agricultural biotechnology, a change of government in 2007 resulted in these decisions being changed at the political level. At that time, the Green Party entered the ruling coalition. As part of its Program for Government, the Green Party aspired for a "GM-

free" island of Ireland. This aspiration is undergoing refinement as the difficulties of the implementation of such a policy are now being slowly realized.

Irish farmers rely on imported feedstuffs to supplement the diets of the mainly grass-fed animals. Primary components of these diets are maize by-products such as corn gluten meal and distillers dried grains. However, most if not all of these products now contain genetically engineer derived crops and the implementation of a 'ban' on imports would cause untold economic hardship on Irish farming. With the arrival of new varieties of soybeans, Irish hog and poultry producers could face feed supply difficulties in 2009 and 2010 without EU approval of these new events.

There is no doubt that the cultivation and field trials of biotechnology crops under the present government will not be allowed. Recently, opposition to biotechnology has waned from a media-driven frenzy in the late 1990's to general commentary editorials as the current food and fuel debate rages worldwide.

Italy: Since 2007, there have been no significant developments regarding biotechnology in Italy. However, there are signs that the new Berlusconi Government approach may differ from that of its predecessor.

After the Constitutional Court's decision of 2006, the responsibility for delineating *coexistence* regulations was mandated to the regions. In 2007 a special body (State-Regions Conference) established the guidelines, although not mandatory, that the regions would have to follow when establishing their own coexistence regulations. To date, no Italian region has taken such action. Until these guidelines are established, there will remain a de facto moratorium on planting biotech crops in Italy. Field trails are also blocked due to opposition from the Ministry of the Environment. The approval for field trials must come from a committee of ten (two from the Ministry of Agriculture, two from the Ministry of Environment, and six from the regions). With regard to seeds for planting, Italy applies a "zero tolerance" for adventitious GM presence. The main authority is the Ministry of Agriculture, which also controls registration of seed varieties with the National Register.

Italy has, except for limited cases last year, continued to vote no on the approval of biotech events with in the EU regulatory process. However, there are growing expectations of a possible change in this based upon statements recently made by the new government.

Poland: Since 2006, Poland has maintained an official anti-biotech position and consistently opposes EU approval of new biotech products, and has announced that Poland should be a "GM-free" country. The government banned the sale and registration of biotech seeds in mid-2006 and, passed legislation that was to prohibit import, production and use of animal feed derived from biotech crops by August 12, 2008. Cultivation is still possible, but not the sale of seeds. FAS Warsaw estimates there are about 300 hectares of biotech corn in Poland. EU officials have determined these bans are inconsistent with EU regulations. A new cultivation law is under preparation, but barriers may be set at 1 kilometer with neighbors approving planting. Corn producers lose an estimated $300 million in crop value each year due to losses caused by the European corn borer, which could be prevented by Bt corn. Organic farmers and environmental groups are lobbying hard against relaxing restrictions.

On July 11, 2008, the Senate (upper house of the Polish Parliament) voted to delay introduction of a ban on biotech feed, which had been scheduled to enter into effect August 12, 2008, until December 31, 2012. The proposal was then signed by the Polish President and entered into force. The feed ban would have jeopardized roughly $6.4 billion in pork

and poultry production, plus additional losses for feed compounders. Poland has some of the highest feed prices in Europe and this is one significant reason why Polish pork, beef, and poultry imports are growing due to increasing competition from Western European countries. Many industry associations, scientists, producers, and regional political leaders are calling for changes to biotechnology policy in Poland; and played a key role in delaying the introduction of the proposed feed ban until January 2013.

Previous Poland GAIN Reports		
PL8020	Biotechnology Feed Ban Consequences for Pork and Poultry	06/19/2008
PL8003	EU Overturns Polish anti-GM laws	02/15/2008

Portugal: Total acreage for biotech corn in Portugal for 2008 is expected to reach about 4,700 hectares. This would represent a significant increase over 2007.

Portugal was one of the first EU Member States to implement a coexistence regulation, to evaluate its effects, and to establish rules for declaring biotechnology-free zones. A first-year coexistence compliance monitoring report indicated that currently required buffer zones kept the adventitious presence in surrounding corn crops well below the 0.9 percent threshold required to claim biotechnology-free status. While rootworm-resistant corn is the only agriculture biotechnology crop currently grown in Portugal, many Portuguese farmers are interested in additional biotech crops as potential solutions to other problems.

While root-worm resistant biotechnology corn production is making its mark, the Portuguese Farmers Association has indicated that corn farmers would be even more interested in herbicide resistant corn, as it could be grown on a wider range of Portugal's tillable acreage. Farmers are also looking at ethanol production from biotechnology corn, and other crops in response to Portugal's new biofuels initiative (PO7001).

Previous Portugal GAIN Reports		
PO7011	Biotech Update	12/18/2007
PO7007	Biotech Update	09/13/2007

Romania: Romania continues to be part of the EU group using the opportunity of planting biotech seeds for commercial use. Prior to EU accession, Romania was the only country in Eastern Europe to plant biotech soybeans. The acreage grew 8 fold from 2001 through 2006, reaching 137,000 hectares. This was discontinued in 2007, when Romania acceded to the EU. In 2008, Romanian farmers planted biotech corn for commercial purposes on 7,500 hectares, up from 331 hectares in 2007.

Inspired by the movements of the EU countries opposing biotechnology, the Environment Minister announced in April 2008 that steps towards imposing a moratorium on biotech crops will be taken. In this regard, a new Biosafety Commission was established, with its first task being re-assessment MON 810. The Environment Minister hoped to influence the members of the Biosafety Commission and receive an immediate unfavorable risk-assessment which might have blocked 2008 planting. Nevertheless, the Biosafety Commission proved to be an independent body with rules and organizational principles that led to a proper framework for conducting risk-assessments and taking decisions on biotech events. At the present, it is hard to predict when the Biosafety Commission will complete the risk-assessment (basically a review of the available scientific papers) and when a decision will be taken.

The Environment Minister's initiative to restrict access to biotech crops angered many farmers, who view this as a violation of their right to use any approved technology on their farms. Unlike the Environment Ministry, the Agricultural Ministry has been very supportive of farmers' complaints, claiming that farmers should have access to all three types of agriculture: conventional, organic, biotech.

Green organizations continued to be very active, trying to slow or reverse biotech crop expansion and in misleading consumer groups regarding biotech derived food-products. Their public campaigns have not only targeted crops, but also food, such as soy-based products.

In June 2008, FAS/Bucharest organized a series of events promoting agricultural biotechnology. These were attended mainly by Government officials, members of Parliament, scientists, and media, creating an atmosphere for lively discussions about the current state and future perspectives of agricultural biotechnology in Romania. In the countryside, farmers were the main target and their number and active participation exceeded expectations.

Previous Romania GAIN Reports		
RO8011	Romanian Parliament declines the initiative on biotech labeling	07/14/2008
RO8002	Initiative on biotech labeling rejected by Senate	03/10/2008

Slovakia : Slovak farmers started growing Bt corn in 2006 on 30 hectares. The acreage has been gradually growing, exceeding 1,500 hectares in 2008. Slovakia has fully implemented all EU regulations on biotechnology. The decree administering coexistence came into force in February 2007.

The competent authority under Directive 2001/18/EC is the Ministry of Environment (MoE). The competencies of the MoE include responsibility to:

- issue consents for the contained use of genetic technologies and GE products; the introduction of GE products into the environment; and the placing of the product on the market
- receive and assess notifications
- receive notices on accidents and on detected changes on deliberate releases
- receive applications for contained uses of genetic technologies and GE products; the introduction of GE products into the environment; and the placing of the product on the market
- keep a record of used genetic techniques
- keep a register of the facilities including the records of users of biotechnologies or GE products, safety committees and heads of the projects

For matters regarding genetic technologies and modern biotechnology, the MoE is the national point of notification to the bodies of the European Union and the national centre for the safety of genetic engineering and modern biotechnology.
Other competencies are covered by the Ministry of Agriculture (food, feed, seed) and the Ministry of Health (community feeding).

Inspection and control authorities include the State Veterinary and Food Administration (food control and inspection) and Central Institute for Supervising and Testing in Agriculture (seeds, coexistence).

Slovenia: In Slovenia, agricultural biotechnology is confined to laboratories and to production facilities. So far, there have not been biotech field trials in Slovenia and there is no commercial production. This might change after the adoption of the Act on Co-existence of Genetically Modified Plants with Other Agricultural Plants in the near future.

In general, Slovenians have a negative opinion of biotech products and, if possible, they would avoid consuming them.

The legislative and administrative framework of biosafety in Slovenia is established in accordance with the legal order of the EU and the international Cartagena Protocol on Biosafety. Special regulations, within the competency of the Ministry of Health and the Ministry of Agriculture, Forestry and Food regulate following issues: medicinal products for the use in human and veterinary medicine, which contain biotech products or are composed of biotech products or their combinations; biotech products used for food, which contains or are composed of biotech products; food made from GE products or containing ingredients made from GE products; GE products used for feed which contains or is composed of GE products, and fodder made from GE products.

Spain: Spain has been and remains the biotechnology "powerhouse" of Europe. In Spain, biotech maize has been commercially grown since 1998, giving it the longest practical experience in cultivating biotech events in the EU. Spanish corn farmers increased biotechnology corn plantings during marketing year 2007 at a near record-setting pace, while total corn planted increased (first time in recent history) only slightly. In 2008, due to excessive rain, farmers experienced some difficulties in corn planting. Initial estimates expect reduction in total acreage, however Bt corn area is expect to remain stable.

Spanish farmers in regions with known corn borer infestations increasingly planted biotechnology corn, while corn farmers in regions where infestations are more inconsistent (weather dependent) are also turning to MON 810 varieties as a means of minimizing risk, increasing productivity and quality, reducing their environmental footprint, and maximizing profit. The biotechnology corn planted and harvested in Spain is used exclusively in the production of domestic compound feeds where it is labeled as containing "genetically modified organisms."

The debate continues on a GOS coexistence decree, the first draft of which was made public in 2004. Spanish corn farmers continue growing biotechnology corn without environmental incident and without a Decree to "protect" organic farmers as demanded by the anti-biotechnology lobby. With each successive successful year the "case" for a Government-imposed national decree becomes increasingly more difficult. However over the years, the terms and conditions of potential co-existence regulations, particularly regarding buffer zones and isolation distances have become more imposing. While nothing has been finalized, it is widely understood that the Environment Ministry is holding out for even more severe conditions that would likely eliminate the possibility of agriculture biotechnology production in Spain.

Previous Spain GAIN Reports		
SP7030	Biotech Update	12/18/2007

Sweden: There is no commercial production of biotech crops in Sweden. Several seed companies have, however, developed their own GE varieties, including herbicide tolerant rapeseed, herbicide tolerant sugar beet and starch potatoes. According to the Swedish Institute for Food and Agricultural Economics (SLI), growing biotech crops in Sweden would

be economically beneficial for Swedish farmers. SLI has concluded that growing biotech crops instead of conventional crops would result in a 4-12% profitability increase. The largest potential benefit is noted for potatoes. Possible costs for co-existence measures such as safety distances between biotech and conventional fields are not considered in the analyses.
Prior to 2006, Sweden did not import biotech products or crops. However since January 2006, when the meat industry lifted its ban on biotech feed, small quantities of biotech soy products have been imported into Sweden. While demand for this product has been limited, there has reportedly been no negative reaction from the Swedish trade. The food processing and retail sectors remain concerned about the possibility of negative consumer reaction and anti-biotech demonstrations.

United Kingdom: The UK government is one of the strongest advocates of agricultural biotechnology in the European Union. Indeed, in June 2008 the UK Environment Minister re-ignited the agriculture biotech debate by suggesting that biotech crops could play a positive role in alleviating global food price rises. In addition, the British Prime Minister is reported to have urged fellow EU leaders to look again at biotech as a way of reducing the cost of food for the world's poorest countries. This action is likely triggered by the current world attention on finding solutions to the global food price issue, sustained pressure from industry for the government to take action over animal feed prices and the recent publication of UK research findings showing positive socio-economic and environmental impacts of GE crops over the last ten years (PG Economics).

The Agricultural Biotechnology Council (ABC which comprised of UK representatives from the major technology providers) provides supporting evidence to the UK government. ABC is calling for an end to the requirement to make biotech crop trials public, a faster regulatory framework and a de-politicization of the genetically engineer crop approval process.

Non-governmental organizations (NGOs) such as Friends of the Earth and Greenpeace are opposed to any such changes, touting their efforts through "GM Freeze". NGOs question the argument for biotechnology as part of the solution to the food price crisis, drawing on the negative findings in the recently published report from the International Assessment of Agricultural Knowledge, Science & Technology for Development (ISAASTD).

In 2004, the UK government declared that there was no scientific case for a blanket ban on the cultivation of biotech crops in the UK, but that proposed uses needed to be assessed for safety on a case-by-case basis. There is still no commercial production of biotech crops in the UK as varieties that are currently approved within the EU are not suited to the growing conditions in the UK. A consultation exercise opened in July 2006 by the Department for Environment, Food and Rural Affairs (Defra) looked at options for managing the coexistence of biotech, conventional and organic crops. The results of the exercise reflected the polarization of the debate with anti-biotech against coexistence in any form, while advocates were largely supportive of the measures proposed.

In response to consumers' lack of enthusiasm for the technology and to avoid EU labeling rules, UK supermarkets and big brand food manufacturers have reformulated their food products to remove biotech ingredients. The number of products that are labeled is very limited. The effective de facto ban on biotech food in the UK, and consequent lack of consumer choice, will remain until supermarkets start to stock more products with a biotech content.

Previous UK GAIN Reports		
UK8011	UK minister re-opens biotech debate	06/25/2008

ANNEX II: COMMUNITY REGISTER OF AUTHORIZED GENETICALLY MODIFIED FOOD AND FEED

Updated versions of this table are available at the following site: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Genetically modified cotton				
Transformation event / Unique ID / Company	**Genes Introduced / Characteristics**	**Authorized use**	**Authorization Expiration Date**	**Details**
Cotton (MON1445) **MON-Ø1445-2** **Monsanto**	Genetically modified cotton that contains: **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Food produced from MON1445 cotton (cottonseed oil)	18/12/2011	
		Food additives produced from MON1445 cotton	Renewal of authorization ongoing	
		Feed produced from MON1445 cotton (feed materials and feed additives)	Renewal of authorization ongoing	
Cotton (MON15985) **MON-15985-7** **Monsanto**	Genetically modified cotton that contains: **cry1Ac** and **cry2Ab2** genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects	Food additives produced from MON-15985-7 cotton	Renewal of authorization ongoing	
		Feed produced from MON 15985 cotton (feed materials and feed additives)	Renewal of authorization ongoing	
Cotton (MON15985 x MON1445) **MON-15985-7 x MON-Ø1445-2** **Monsanto**	Genetically modified cotton that contains: **cry1Ac** and **cry2Ab2** genes inserted to confer insect-resistance highly selective in controlling Lepidopteran insects **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Food additives produced from MON15985 x MON1445 cotton	Renewal of authorization ongoing	
		Feed produced from MON15985 x MON1445 cotton (feed materials and feed additives)	Renewal of authorization ongoing	
Cotton (MON531) **MON-ØØ531-6** **Monsanto**	Genetically modified cotton that contains: **cry1A(c)** gene inserted to confer insect-resistance	Food produced from MON 531 cotton (cottonseed oil)	18/12/2011	
		Food produced from MON 531 cotton (food additives)	Renewal of authorization ongoing	
		Feed produced from MON 531 cotton (feed materials and feed additives)	Renewal of authorization ongoing	
Cotton (MON531 x MON1445) **MON-ØØ531-6 x MON-**	Genetically modified cotton that contains: **cry1A(c)** gene inserted to confer insect-resistance	Food additives produced from MON531 x MON1445 cotton	Renewal of authorization ongoing	

MON-ØØ531-6 x MON-Ø1445-2 **Monsanto**	resistance **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Feed produced from MON 531 x MON 1445 cotton (feed materials and feed additives)	Renewal of authorization ongoing	
Genetically modified maize				
Transformation event / Unique ID / Company	**Genes Introduced / Characteristics**	**Authorized use**	**Authorization Expiration Date**	**Details**
Maize (Bt11) SYN-BTØ11-1 **Syngenta**	Genetically modified maize that contains: **cryIA (b)** gene inserted to confer insect-resistance **pat gene** inserted to confer tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting of or produced from Bt11 maize	18/05/2014 Renewal ongoing	
		Food additives produced from Bt11 maize	Renewal of authorization ongoing	
		Feed containing, consisting of or produced from Bt11 maize (feed materials and feed additives)	Renewal of authorization ongoing	
		Other products containing or consisting of Bt11 maize with the exception of cultivation	Renewal of authorization ongoing	
Maize (DAS1507) DAS-Ø15Ø7-1 **Pioneer and Dow AgroSciences**	Genetically modified maize that contains: **cry1F** gene inserted to confer resistance to the European corn borer and certain other lepidopteran pests **pat** gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Foods and food ingredients containing, consisting or produced from DAS1507 maize (including food additives)	02/03/2016	
		Feed containing or consisting of DAS1507 maize	15/03/2016	
		Feed produced from DAS1507 maize (feed materials and feed additives)	Renewal of authorization ongoing	
		Other products containing or consisting of DAS1507 with the exception of cultivation	15/03/2016	

Maize (DAS59122) **DAS-59122-7** **Pioneer and Dow AgroSciences**	Genetically modified maize that expresses: the Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests such as corn rootworm larvae (Diabrotica spp.) the PAT protein which confers tolerance to the glufosinate-ammonium herbicide	Foods and food ingredients containing, consisting of, or produced from DAS-59122-7 maize (including food additives) Feed containing, consisting of, or produced from DAS-59122-7 maize (feed materials and feed additives) Products other than food and feed containing or consisting of DAS-59122-7 maize for the same uses as any other maize with the exception of cultivation	23/10/2017	
Maize (DAS1507xMON603) **DAS-Ø15Ø7-1xMON-ØØ6Ø3-6** **Pioneer and Dow AgroSciences**	Genetically modified maize that expresses: the Cry1F protein which confers protection against certain lepidopteran pests such as the European corn borer (Ostrinia nubilalis) and species belonging to the genus Sesamia, the PAT protein which confers tolerance to the glufosinate-ammonium herbicide the CP4 EPSPS protein which confers tolerance to the glyphosate herbicide	Foods and food ingredients containing, consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize (including food additives) Feed containing, consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize (feed materials and feed additives) Products, other than food and feed, containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation	23/10/2017	
Maize (GA21) **MON-ØØØ21-9** **Syngenta**	Genetically modified maize that expresses: mEPSPS protein which confers tolerance to herbicide glyphosate	Foods and food ingredients containing, consisting of, or produced from MON-ØØØ21-9 maize (including food additives)	27/3/2018	

		Feed containing, consisting of, or produced from MON-ØØØ21-9 maize (feed materials and feed additives)		
		Products other than food and feed containing or consisting of MON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation		
Maize (MON810) **MON-ØØ81Ø-6** **Monsanto**	Genetically modified maize that contains: **cryIA (b)** gene inserted to confer resistance to lepidopteran pests	Foods and food ingredients produced from MON810 (including food additives)	Renewal of authorization ongoing	
		Feed containing or consisting of MON810 maize	Renewal of authorization ongoing	
		Feed produced from MON810 maize (feed materials feed additives)	Renewal of authorization ongoing	
		Seeds for cultivation	Renewal of authorization ongoing	
Maize (MON863) **MON-ØØ863-5** **Monsanto**	Genetically modified maize that contains: a trait gene **cry3Bb1** inserted to confer insect- resistance **nptII** gene inserted as a selection marker	Food containing, consisting of, or produced from MON 863 maize	12/01/2016	
		Food additives produced from MON 863 maize	Renewal of authorization ongoing	
		Feed containing or consisting of MON 863 maize	12/02/2016	
		Feed produced from MON 863 maize (feed materials and feed additives)	Renewal of authorization ongoing	
		Other products containing or consisting of MON863 with the exception of cultivation	12/02/2016	
Maize (MON863 x NK603) **MON-ØØ863-5 x MON-**	Genetically modified maize that contains: **nptII** gene inserted as a selection marker	Food additives produced from MON863 x NK603 maize	Renewal of authorization ongoing	

MON-ØØ863-5 x MON-ØØ6Ø3-6 **Monsanto**	a trait gene **cry3Bb1** inserted to confer insect- resistance **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Feed produced from MON863 x NK603 maize (feed materials and feed additives)	Renewal of authorization ongoing	
Maize (MON863 x MON810) **MON-ØØ863-5 x MON-ØØ81Ø-6** **Monsanto**	Genetically modified maize that contains: **cryIA (b)** gene inserted to confer resistance to lepidopteran pests **cry3Bb1** gene inserted to confer resistance to certain coleopteran pests, principally corn rootworm **nptII** gene inserted as a selection marker	Feed materials produced from MON863 x MON810 maize	Renewal of authorization ongoing	
Maize (NK603) **MON-ØØ6Ø3-6** **Monsanto**	Genetically modified maize that contains: **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Food containing, consisting of, or produced from NK603 maize	02/03/2015	
		Food additives produced from NK603 maize	Renewal of authorization ongoing	
		Feed containing or consisting of NK603 maize	17/10/2014	
		Feed produced from NK603 maize (feed materials and feed additives)	Renewal of authorization ongoing	
		Other products containing or consisting of NK603 with the exception of cultivation	17/10/2014	
Maize (NK603 x MON810) **MON-ØØ6Ø3-6 x MON-ØØ81Ø-6** **Monsanto**	Genetically modified maize that expresses: the **CP4 EPSPS** protein which confers tolerance to glyphosate herbicides and the **Cry1Ab** protein which confers protection against certain lepidopteran insect pests (Ostrinia nubilalis, Sesamia spp.)	Foods and food ingredients containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize (including food additives)	23/10/2017	
		Feed containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize (feed materials and feed additives)		

		Products other than food and feed containing or consisting of MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize for the same uses as any other maize with the exception of cultivation		
Maize (T25) **ACS-ZMØØ3-2** **Bayer**	Genetically modified maize that contains: **pat** gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Food and food ingredients produced from T25 maize	Renewal of authorization ongoing	
		Feed containing, consisting of, or produced from T25 maize (feed materials and feed additives)	Renewal of authorization ongoing	
		Seeds for cultivation	Renewal of authorization ongoing	

Genetically modified microorganisms

Transformation event / Unique ID / Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Bacterial biomass **(pCABL- Bacterial biomass)** **Ajinomoto Eurolysine SAS**	Bacterial protein, by-product from the production by fermentation of L-Lysine HCl obtained from (Brevibacterium lactofermentum) the recovered killed microorganisms. The source is the Brevibacterium lactofermentum strain SO317/pCABL	Feed produced from GMO bacteria: " bacterial biomass"	Renewal of authorization ongoing	
Yeast biomass **(pMT742 or pAK729-Yeast biomass)** **NOVO Nordisk A/S**	NOVO Yeast Cream is a product produced from genetically modified yeast strains (Saccharomyces cerevisiae) cultivated on substrates of vegetable origin. The source is the Saccharomyces cerevisiae strain MT663/pMT742 or pAK729	Feed materials produced from GMO yeast: "yeast biomass"	Renewal of authorization ongoing	

Genetically modified oilseed rape

Transformation event / Unique ID / Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Oilseed rape (GT73) **MON-ØØØ73-7** **Monsanto**	Genetically modified oilseed rape that contains: **cp4 epsps** and **goxv247** genes inserted to confer tolerance to the herbicide glyphosate	Food produced from GT73 oilseed rape (refined oil and food additives)	Renewal of authorization ongoing	
		Feed containing and consisting of GT73 oilseed rape	20/02/2017	

		Feed produced from GT73 oilseed rape (feed materials and feed additives)	Renewal of authorization ongoing	
		Other products containing or consisting of GT73 with the exception of cultivation	20/02/2017	
Swede-rape (MS8, RF3, MS8xRF3) **ACS-BNØØ5-8ACS-BNØØ3-6ACS-BNØØ5-8 x ACS-BN003-6** **Bayer**	Genetically modified oilseed rape that contains: a **bar (pat)** gene inserted to confer tolerance to herbicides based on glufosinate ammonium **barnase** gene inserted to lead to lack of viable pollen and male sterility **barstar** gene inserted to lead to lack of viable pollen and male sterility	Food produced from MS8, RF3, MS8 x RF3 swede-rape (processed oil)	Renewal of authorization ongoing	
		Feed containing or consisting of MS8, RF3, MS8 x RF3 swede-rape	24/05/2017	
		Feed produced from MS8, RF3, MS8 x RF3 swede-rape	Renewal of authorization ongoing	
		Other products containing or consisting of MS8, RF3, MS8 x RF3 swede-rape with the exception of cultivation	24/05/2017	
Oilseed rape (T45) **ACS-BNØØ8-2** **Bayer**	Genetically modified oilseed rape that contains: **pat** gene inserted to confer tolerance to the herbicide glufosinate-ammonium	Food additives produced from T45 oilseed rape	Renewal of authorization ongoing	
		Feed materials produced from T45 oilseed rape	Renewal of authorization ongoing	

Genetically modified soya

Transformation event / Unique ID / Company	Genes Introduced / Characteristics	Authorized use	Authorization Expiration Date	Details
Soya (MON40-3-2) **MON-Ø4Ø32-6** **Monsanto**	Genetically modified soya that contains: **cp4 epsps** gene inserted to confer tolerance to the herbicide glyphosate	Food containing, consisting of, or produced from MON 40-3-2 soybean (including food additives)	Renewal of authorization ongoing	
		Feed containing or consisting of MON 40-3-2 soybean	Renewal of authorization ongoing	
		Feed produced from MON 40-3-2 soybean (feed materials and feed additives)	Renewal of authorization ongoing	

		Other products containing or consisting of MON 40-3-2 soybean with the exception of cultivation	Renewal of authorization ongoing	

Genetically modified sugar beet				
Transformation event / Unique ID / Company	**Genes Introduced / Characteristics**	**Authorized use**	**Authorization Expiration Date**	**Details**
Sugar beet (H7-1) **KM-ØØØ71-4** **KWS SAAT and Monsanto**	Genetically modified sugarbeet that expresses: a CP4 EPSPS protein confers tolerance to glyphosate containing herbicides	Foods and food ingredients produced from KM-ØØØH71-4 sugar beet Feed produced from KM-ØØØH71-4 sugar beet	23/10/2017	

Products subject to Commission Decisions on withdrawal from the market

Transformation event / Unique ID / Company	Withdrawal	Details
Maize (Bt176) **SYN-EV176-9** **Syngenta**	The period of authorization for the cultivation and the placing on the market of SYN-EV176-9 maize and its derived products in the Community ended on 18/04/2007. A decision (2007/304/EC) was adopted on 25 April 2007. In order to ensure effective withdrawal from the market of seeds from inbred lines and hybrids derived from SYN-EV176-9 maize for the purpose of cultivation the notifier shall comply with the measures set out in the Decision Annex. The presence of material which contains, consists of or is produced from SYN-EV176-9 maize in food or feed products notified under Article 8(1) and Article 20(1) of the Regulation shall be tolerated until 5 years after the date of notification of this Decision: (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9pct.	
Maize (GA21 x MON810) **MON-ØØØ21-9 x MON-ØØ81Ø-6** **Monsanto**	The period of authorization for the cultivation and the placing on the market of MON-ØØØ21-9xMON-ØØ81Ø-6 maize and its derived products in the Community ended on 18/04/2007. A decision (2007/308/EC) was adopted on 25 April 2007. The presence of material produced from MON-ØØØ21-9xMON-ØØ81Ø-6 maize in food or feed products notified under Article 8(1)(b) and Article 20(1)(b) of the Regulation shall be tolerated until five years after the date of notification of this Decision: (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9 %.	
Swede-rape (MS1, RF1, MS1xRF1) **ACS-BNØØ4-7** **ACS-BNØØ1-4** **ACS-BNØØ4-7xACS-BNØØ1-4** **Bayer**	The period of authorization for the cultivation and the placing on the market of ACS-BNØØ4-7xACS-BNØØ1-4 hybrid oilseed rape and its derived products in the Community ended on 18/04/2007. A decision (2007/305/EC) was adopted on 25 April 2007. In order to ensure effective withdrawal from the market of seeds of hybrid oilseed rape ACS-BNØØ4-7xACS-BNØØ1-4 for the purpose of cultivation the notifier shall comply with the measures set out in the Decision Annex. The presence of material which contains, consists of or is produced from ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ1-4 oilseed rape in food or feed products notified under Article 8(1)(a) and Article 20(1) of the Regulation shall be tolerated until five years after the date of notification of this Decision: (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9 %.	
Swede-rape (MS1, RF2, MS1xRF2) **ACS-BNØØ4-7**	The period of authorization for the cultivation and the placing on the market of ACS-BNØØ4-7xACS-BNØØ2-5 hybrid oilseed rape and its derived products in the Community ended on 18/04/2007. A decision (2007/306/EC) was adopted on 25 April 2007. In order to ensure effective withdrawal from the market of seeds of hybrid oilseed rape ACS-BNØØ4-7xACS-	

ACS-BNØØ2-5 **ACS-BNØØ4-7xACS-BNØØ2-5** **Bayer**	BNØØ2-5 for the purpose of cultivation the notifier shall comply with the measures set out in the Decision Annex. The presence of material which contains, consists of or is produced from ACS-BNØØ4-7, ACS-BNØØ2-5 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ2-5 oilseed rape in food or feed products notified under Article 8(1)(a) and Article 20(1) of the Regulation shall be tolerated until five years after the date of notification of this Decision: (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9 %.	
Swede rape (TOPAS19/2) **ACS-BNØØ7-1** **Bayer**	The period of authorization for the cultivation and the placing on the market of ACS-BNØØ7-1 oilseed rape and its derived products in the Community ended on 18/04/2007. A decision (2007/307/EC) was adopted on 25 April 2007. The presence of material which contains, consists of or is produced from ACS-BNØØ7-1 oilseed rape in food or feed products notified under Article 8(1)(a) and Article 20(1) of the Regulation shall be tolerated until five years after the date of notification of this Decision: (a) provided that this presence is adventitious or technically unavoidable; and (b) in a proportion no higher than 0,9 %.	

Last update: 6-11-2007

ANNEX III: GENETICALLY MODIFIED FOOD AND FEED PENDING AUTHORIZATION

Updated versions of this table are available at the following address: http://www.efsa.europa.eu/EFSA/ScientificPanels/GMO/efsa_locale-1178620753812_GMOApplications.htm.

A yellow background color means that this application was updated.

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
FR-2008-59	*PT73 Escherichia coli* (TM) dried killed bacterial biomass	Feed	Under completeness check	More info
UK-2008-58	MON15985 x MON1445 Cotton	Food, feed import and processing	Under completeness check	More info
UK-2008-57	MON15985 Cotton	Food, feed import and processing	Under completeness check	More info
UK-2008-56	Bt11 x MIR604 x GA21 Maize	Food, feed import and processing	Under completeness check**	More info
DK-2008-55	B12 with recombinant human intrinsic factor	Food produced from GM plants or containing ingredients produced from GM plants (Arabidopsis thaliana)	Under completeness check	More info
CZ-2008-54	MON88017 Maize	CULTIVATION	Under completeness check	More info
UK-2008-53	98140 Maize	Food, feed import and processing	Under completeness check**	More info
NL-2008-52	A5547-127 Soybean	Food, feed import and processing	Under completeness check	More info
NL-2008-51	GHB614 Cotton	Food, feed import and processing	Valid application	More info
UK-2007-50	Bt11 x MIR604 Maize	Food, feed import and processing	Valid application**	More info

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
UK-2007-49	Bt11 x GA21 Maize	Food, feed import and processing	Valid application**	More info
UK-2007-48	MIR604 x GA21 Maize	Food, feed import and processing	Valid application**	More info
NL-2007-47	305423 x 40-3-2 Soybean	Food, feed import and processing	Valid application	More info
NL-2007-46	T25 Maize	Food, Feed import and processing CULTIVATION	Valid application	More info

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
NL-2007-45	305423 Soybean	Food, feed, import and processing	Valid application**	More info
FR-2007-44	PT73 Escherichia coli (THR) dried killed bacterial biomass	Feed	Valid application**	More info
UK-2007-43	356043 Soybean	Food, feed import and processing	Valid application**	More info
UK-2007-42	MON88913 x MON15985 Cotton	Food, feed import and processing	Valid application**	More info
UK-2007-41	MON88913 Cotton	Food, feed import and processing	Valid application**	More info
FR-2007-40	PL73 Escherichia coli (LYS) dried killed bacterial biomass	Feed	Valid application**	More info

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
NL-2007-39	MON 89034 x MON 88017 Maize	Food, feed import and processing	Valid application**	More info
NL-2007-38	MON 89034 x NK 603 Maize	Food, feed import and processing	Valid application	More info
NL-2007-37	MON 89034 Maize	Food, feed import and processing	Valid application**	More info
NL-2006-36	MON 89788 Soybean	Food, feed import and processing	Valid Application	More info
NL-2006-35	LLCotton25 x MON 15985 Cotton	Food, feed produced from GM plants (derived products)	Under completeness check**	More info
UK-2006-34	Event 3272 Maize	Food, feed import and processing	Valid application**	More info
CZ-2006-33	MON 88017 x MON 810 Maize	Food and feed import and processing	Valid application**	More info
NL-2006-32	LY038 x MON810 Maize	Food and feed Import and processing	Valid application**	More info
NL-2006-31	LY038 Maize	Food and feed import and processing	Valid application**	More info
UK-2006-30	59122 x 1507 x NK603 Maize	Food, feed import and processing CULTIVATION	Valid application**	More info

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
UK-2006-29	59122 x NK603 Maize	Food, feed import and processing CULTIVATION	WITHDRAWAL OF THE APPLICATION BY THE APPLICANT ON 3 January 2007	More info
NL-2005-28	1507 x 59122 Maize	Food, feed import and processing CULTIVATION	Valid application**	More info
CZ-2005-27	MON 88017 Maize	Food, feed import and processing	Valid Application**	More info
NL-2005-	NK603 x MON810	CULTIVATION	Valid Application**	More info

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
26	Maize			
UK-2005-25	T45 Oilseed rape	Food, feed import and processing	EFSA overall opinion published	More info
NL-2005-24	40-3-2 Soybean	CULTIVATION	Valid application**	More info
NL-2005-23	59122 Maize	Food, feed import and processing CULTIVATION	Valid application**	More info
NL-2005-22	NK603 Maize	Food, feed import and processing CULTIVATION	Valid application** Validation method reports published	More info
UK-2005-21	59122 x 1507 x NK603 Maize	Food, feed import and processing	Valid application**	More info
UK-2005-20	59122 x NK603 Maize	Food, feed import and processing	Valid application**	More info

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
UK-2005-19	GA21 Maize	Food, feed import and processing	EFSA Overall opinion published	More info
NL-2005-18	A2704-12 Soybean	Food, feed, import and processing	EFSA overall opinion published	More info
UK-2005-17	1507 x NK603 Maize	Food and feed, import and processing, CULTIVATION	Valid application**	More info
NL-2005-16	281-24-236 x 3006-210-23 Cotton	Food, feed	Valid application** Validation method reports published	More info
NL-2005-15	1507 x 59122 Maize	Food, feed import and processing	Valid application** Validation method reports published	More info
UK-2005-14	Amylopectin Potato event EH92-527-1	Food, feed	EFSA overall opinion published	More info
NL-2005-13	LLCotton25	Food, feed import and processing	EFSA overall opinion published	More info
NL-2005-12	59122 Maize	Food, feed import and processing	EFSA overall opinion published	More info
UK-2005-11	MIR604 Maize	Food, feed import and processing	Valid application**	More info
UK-2005-10	MON 15985 and MON 15985 x MON 1445 Cotton	Food, feed produced from GM plants (derived products)	Valid application**	More info

GMO Applications

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
UK-2005-09	MON 531 x MON 1445 Cotton	Food, feed produced from GM plants (derived products)	Valid application**	More info
UK-2004-08	H7-1 Sugar Beet	Food, feed produced from GM plants (derived products)	EFSA overall opinion published	More info

EFSA-GMO-No	Event/Species	Application Scope	Status	Document Link
BE-2004-07	MON863 x MON810 x NK603 Maize	Food, feed import and processing	EFSA overall opinion published	More info
UK-2004-06	MON863 x NK603 Maize	Food, feed import and processing	EFSA overall opinion published	More info
UK-2004-05	1507 x NK603 Maize	Food, feed import and processing	EFSA overall opinion published	More info
UK-2004-04	LLRICE62 Rice	Food, feed import and processing	EFSA overall opinion published	More info
DE-2004-03	MON863 x MON810 Maize	Food, feed	EFSA overall opinion published	More info
NL-2004-02	1507 Maize	Food	EFSA overall opinion published	More info
UK-2004-01	NK603 x MON810 Maize	Food, feed	EFSA overall opinion published	More info

ANNEX IV: REGULATION (EC) NO 258/97, GENETICALLY MODIFIED FOOD AUTHORIZED (UNTIL JANUARY 17, 2006)

This table is available at the following address:
http://ec.europa.eu/food/food/biotechnology/authorisation/258-97-ec_authorised_en.pdf

GENETICALLY MODIFIED (GM) FOODS AUTHORISED IN THE EUROPEAN UNION UNDER THE NOVEL FOOD REGULATION (EC) 258/97

	EVENT	CROP	APPLICANT	TRAIT	POTENTIAL FOOD USES	DATE	LEGAL BASIS
1	GTS 40/3/2	Soybean	Monsanto	Insect protection and herbicide tolerance	Soy foods. Soy foods include soy beverages, tofu, soy oil, soy flour, lecithin.	03.04.1996	Dir. 90/220/EEC Art. 13
2	Bt 176	Maize	Ciba-Geigy	Insect protection and herbicide tolerance	Maize foods. Maize foods include kernels, oil, maize flour, sugar, syrup.	23.01.1997	Dir. 90/220/EEC Art. 13
3	TOPAS 19/2	Oilseed rape	AgrEvo	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may include fried foods, baked products and snack foods.	24.06.1997	Reg. (EC) 258/97 Art 5
4	MS1 / RF2	Oilseed rape	Plant Genetic Systems	Herbicide tolerance		24.06.1997	Reg. (EC) 258/97 Art. 5
5	MS1 / RF1	Oilseed rape	Plant Genetic Systems	Herbicide tolerance		24.06.1997	Reg. (EC) 258/97 Art. 5
6	GT 73	Oilseed rape	Monsanto	Herbicide tolerance		21.11.1997	Reg. (EC) 258/97 Art. 5
7	MON 810	Maize	Monsanto	Insect protection	Maize derivatives. These may include maize oil, maize flour, sugar and syrup. Products made with maize derivatives may include snack foods, baked foods, fried foods, confectionary and soft drinks.	06.02.1998	Reg. (EC) 258/97 Art. 5
8	T 25	Maize	AgrEvo	Herbicide tolerance		06.02.1998	Reg. (EC) 258/97 Art. 5
9	Bt 11	Maize	Novartis	Insect protection		06.02.1998	Reg. (EC) 258/97 Art. 5
10	MON 809	Maize	Pioneer	Insect protection		23.10.1998	Reg. (EC) 258/97 Art. 5

GENETICALLY MODIFIED (GM) FOODS AUTHORISED IN THE EUROPEAN UNION UNDER THE NOVEL FOOD REGULATION (EC) 258/97

11	Falcon GS 40/90	Oilseed rape	Hoechst / AgrEvo	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may include fried foods, baked foods and snack foods.	08.11.1999	Reg. (EC) 258/97 Art. 5
12	Liberator L62	Oilseed rape	Hoechst / AgrEvo	Herbicide tolerance		08.11.1999	Reg. (EC) 258/97 Art. 5
13	MS8/RF3	Oilseed rape	Plant Genetic Systems	Herbicide tolerance		26.04.2000	Reg. (EC) 258/97 Art. 5
14	1445	Cotton	Monsanto	Herbicide tolerance	Cottonseed oil. Products made with cottonseed oil may include fried foods, baked foods and snack foods.	19.12.2002	Reg. (EC) 258/97 Art. 5
15	531	Cotton	Monsanto	Insect protection		19.12.2002	Reg. (EC) 258/97 Art. 5
16	pRF69/pRF93	Bacillus subtilis	F. Hoffmann - La Roche	Riboflavin	Vitamin B2	23.03.2000	Reg. (EC) 258/97 - Art. 5
17	Bt11	Maize	Syngenta	Insect resistance	Sweet corn from Bt11	19.05.2004	Reg. (EC) No. 258/97 Art. 7
18	NK603	Maize	Monsanto	Herbicide tolerance	Food and food ingredients derived from NK603 maize	26.10.2004	Reg. (EC) No. 258/97 Art. 7
19	GA21	Maize	Monsanto	Herbicide tolerance	Foods and food ingredients produced from GA21 maize	13.01.2006	Reg. (EC) No. 258/97 Art. 7
20	MON 863	Maize	Monsanto	Insect protection	Food and food ingredients derived from MON 863 maize	13.01.2006	Reg. (EC) No. 258/97 Art. 7

ANNEX V: GENETICALLY MODIFIED FEED AUTHORIZED UNDER DIRECTIVE 2001/18/EC

Updated versions of this table are available at the following address: http://ec.europa.eu/food/food/biotechnology/authorisation/2001-18-ec_authorised_en.pdf.

GMOs AUTHORISED FOR FEED USE IN THE EUROPEAN UNION IN ACCORDANCE WITH DIRECTIVES 90/220/EEC AND 2001/18/EC

	Product	Notifier	Date of Commission Decision[1] / Member State Consent[2]
1.	Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1) Uses : breeding activities	Plant Genetic Systems C/UK/94/M1/1	06.02.96
		Plant Genetic Systems C/F/95/01/A	06.06.97 (not finally approved by F)
2.	Soybean 40-3-2 tolerant to glyphosate Uses : import and processing	Monsanto C/UK/94/M3/1	03.04.96
3.	Bt-maize tolerant to glufosinate ammonium (Bt-176)	Ciba-Geigy C/F/94/11-03	23.01.97
4.	Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2)	Plant Genetic Systems C/F/95/05/01/B	06.06.97 (not finally approved by F)
5.	Swede rape tolerant to glufosinate ammonium (Topas 19/2) Uses : import and processing	AgrEvo C/UK/95/M5/1	22.04.98
6.	Maize tolerant to glufosinate ammonium (T25)	AgrEvo C/F/95/12/07	22.04.98
7.	Maize expressing the Bt cryIA(b) gene (MON 810)	Monsanto C/F/95/12-02	22.04.98
8.	Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11) Uses: import and processing	Novartis (formerly Northrup King) C/UK/96/M4/1	22.04.98

[1] Where objections were raised by Member State authorities
[2] In the absence of objections by Member State authorities

GMOs AUTHORISED FOR FEED USE IN THE EUROPEAN UNION IN ACCORDANCE WITH DIRECTIVES 90/220/EEC AND 2001/18/EC

	Product	Notifier	Date of Commission Decision[1] / Member State Consent[2]
9.	NK603 Maize, tolerant to glyphosate herbicide Uses: Import and use in feed and industrial processing	C/ES/00/01 Monsanto	Commission Decision 2004/643/EC of 19.07.04
10.	MON 863 maize, resistant to corn rootworm Uses : import and use of grain and grain products	C/DE/02/9 Monsanto	Commission Decision 2005/608/EC of 08.08.05
11.	GT 73 oil seed rape, herbicide resistant Uses : import and uses in feed and industrial processing	C/NL/98/11 Monsanto	Commission Decision 2005/635/EC of 31.08.2005[3] See also Commission recommendation 2005/637/EC of 16.08.2005
12.	1507 Maize, herbicide and insect resistant Uses: : import and uses in feed and industrial processing	C/NL/00/10 Pioneer/Mycogen Seeds	Commission Decision 2005/772/EC of 03.11.2005[4]

[3] The Commission Decision does not apply before a detection method specific to the GT73 oilseed rape is validated by the Community reference laboratory

[4] The Commission Decision does not apply before the date of application of a Community Decision authorising the placing on the market of the product for uses as or in food and including a method, validated by the Community reference laboratory, for detection of that product.

ANNEX VI: PENDING AUTHORIZATIONS UNDER DIRECTIVE 2001/18

Updated versions of this table are available at the following address: http://ec.europa.eu/food/food/biotechnology/authorisation/2001-18-ec_pending_en.pdf.

FEED CONSISTING OF OR CONTAINING GMOS NOTIFIED UNDER DIRECTIVE 2001/18/EC
PENDING AUTHORISATION IN THE EUROPEAN UNION,
WITHOUT PREJUDICE OF THE APPLICATION OF ARTICLE 20 OF REGULATION (EC) NO 1829/2003 (1)

Notification under Directive 2001/18/EC Product notification details	Notification/Company	Approval required under Directive 2001/18/EC	Approval required under Regulation (EC) No 1829/2003 Transformation into application under Regulation 1829/2003/EC required
1. NK603 x MON810 maize	C/GB/02/M3/03 Monsanto	Yes	
2. Potato with altered starch composition	C/SE/96/3501 Amylogene	Yes	
3. Ms8, Rf3 oilseed rape	C/BE/96/01 Bayer	Yes	
4. Glufosinate tolerant soybeans	C/BE/98/01 Bayer		Yes
5. Glufosinate tolerant oilseed rape (Falcon)	C/DE/96/5 Bayer		Yes
6. Glufosinate tolerant oilseed rape (Liberator)	7. C/DE/98/6 8. Bayer		Yes
9. Roundup Ready sugar beet (H7-1)	C/DE/00/8 KWS SAAT AG/Monsanto		Yes
10. MON863 and MON863 x MON810 maize	C/DE/02/9 Monsanto	Yes	
11. Glufosinate tolerant oilseed rape (T45)	C/GB/04/M5/4 (replacing C/GB/99/M5/2) Bayer		Yes

(1) Feed produced from those GMOs may be notified as existing products in case that they have been lawfully placed on the market prior 18 April 2004

ANNEX VII: MEMBER STATES POLICIES

Member State	National Competent/ Relevant Authorities	Implementation of EU policy	National Coexistence rules
Austria	Federal Ministry of Health, Family and Youth	Austria has fully implemented EU regulations on biotechnology Biotech food and feed	The EU Commission adopted a decision ordering Austria to lift the safeguard clause in place on the import and processing of the two biotech corn lines MON 810 and T 25.
	Federal Ministry of Agriculture, Forestry, Environment and Water Management	Planting of biotech crops	National ordinances still effectively prevent the planting of EU approved biotech crops.
	Provincial Governments	Precautionary Bills	GMO restricting zones have been established in all of the nine provinces of Austria and all Austrian provinces are members of the "European Network of GMO-free Regions."
Belgium	Federal Government Department for Health, Food Chain Safety and Environment	-2001/18 implemented in 2005 -1829/2003 and 1830/2003 are by EC law directly enforced in entire EU	-The two Belgian Regions, Flanders and Wallonia, are responsible for formulating and implementing a coexistence policy. -In March 2007, the Flemish Government decided upon a framework for the coexistence regulations for Flanders. -The regulations reportedly guarantee free choice for the farmer to plant GMOs, and include a liability fund. The conditions for compensation are not yet agreed upon. For border zones see table below. -In February 2006, the Walloon Government approved coexistence regulations. -According to the Walloon Government, the regulations on cultivating GMOs are as restrictive as possible within the scope of the harmonized EU regulations. The regulations contain possibilities to impose GMO free zones, and a liability fund paid by the farmer planting GMO crops. For border zones see table below. -Sector sources believe that the combination of restrictions will practically ban the cultivation of GMOs.
Czech Republic	Ministry of Agriculture (Act 441/2005 amending the Act on Agriculture and Decree 89/2006 on more detailed requirements for cultivation of genetically modified variety)	Transposition of the 2001/18 in 2004 in Act no. 78/2004	Distance requirements: The isolation distances were decreased in 2006 from 100 meters for conventional agriculture to 70 meters (or 35 rows of non-GM crops as a barrier or a combination of a distance and a buffer zone, in which case 1 row equals 2 meters) and for organic agriculture from 600 meters to 200 meters (or 100 m and 50 rows of non GM crop as a buffer zone). No genetic-free zones managed by the decree. No constraint for biotech crops with regard to nature conservation districts.

	Ministry of Environment	- Act 78/2004 on genetically modified organisms and genetic products - Decree 209/2004 on detailed conditions for the use of genetically modified organisms and genetic products	- Act 78/2004 on genetically modified organisms and genetic products - Decree 209/2004 on detailed conditions for the use of genetically modified organisms and genetic products
France	French Ministries of Environment and Agriculture	France transposed EU Directive 2001/18 in the biotech bill adopted in spring 2008	- The GOF initiated a safeguard clause freezing cultivation of MON810 in January, 2008. -The 2008 biotech bill creates a new biotech authority, establishes technical conditions for producing biotech crops through a new coexistence framework, and sets harsher penalties for biotech crop destruction. The decrees implementing the bill will have to be prepared and published in the French Official Journal. Of high interest will be the decrees detailing biotech and non-biotech crop coexistence measures.
	Fraud Control Office, French Ministry of Economy (DGCCRF)	Biotech traceability and labeling is under the responsibility of DGCCRF, and EU regulations on NF/NF and T&L have been implemented since April 2004	
Germany	Bundesamt f. Verbraucherschutz und Lebensmittelsicherheit	Germany has fully implemented EU regulations on biotechnology: German Genetech Law, last amended in February 2008	To date, Germany has only established distance requirements for corn production. 150 meters to conventional corn fields, 300 meters to organic corn fields
	On the regulatory side the German Federal Ministry of Food, Agriculture and Consumer Protection has prime responsibility for biotechnology.	German Genetech-Free Labeling Law, last amended 2008	Farmers must report their intention to cultivate biotech seeds three months before planting to a national register. This field register is publicly accessible on the internet. http://194.95.226.237/stareg_web/bundesandStatistic.do?year=2008
			Liability: Biotech farmers remain liable to their conventional or organic farming neighbors even if they adhered to all good management rules. Farmers have to prevent any level of out-crossing.
			Effective July 2008, the German food processing industry has the option of labeling livestock products genetech-free if the animals have not been fed biotech feeds for a certain period prior to slaughter and milking.
			GMO restrictive zones have been established in many German regions. Their number is growing.

Greece	Ministry of Environment for new crop approvals and Ministry of Agriculture with EFET (Hellenic Agency for Food Control) on food ingredient and food item approvals.	Greece has fully implemented EU regulations on biotechnology Biotech food and feed but serious problems are reported in enforcing the regulations. EFET is in charge of enforcement in cooperation with GOG Ministry of Agriculture but there is lack of funds and personnel.	The EU Commission adopted a decision ordering Greece to lift the safeguard clause it had in place on the import and processing of the two biotech corns, MON 810 and T 25. GOG does not comply with EU decisions in adopting a coexistence system in a certain period of time using numerous ways to justify the delay. The constraints are political.
	Ministry of Agriculture, And Local Authorities at Prefecture and Municipality Levels	Planting of biotech crops	To date, they prevent the planting of EU approved biotech crops. The whole country is a GMO restricted zone (see also 2007 map of such regions: http://genet.iskra.net/)
Hungary	Hungarian Parliament	Act. No. XXVII. Of 1998 On Biotechnology Activities	
		Act. No. LXVII. Of 2002 On the Amendment of the Act No. XXVII. Of 1998	
		Act. No. CVIII. Of 2006 On the Amendment of the Act No. XXVII. Of 1998	This Act (amendment) contains the so called “Coexistence Regulation.” The most debated provisions are the prior written consent requirements of all landowners and land users of the neighboring parcels, and the big isolation distances required between biotech and conventional or organic crop fields. The latter is 400 meters for corn, more than double that of the distance used in hybrid seed propagation worldwide and much larger than the required isolation in Member States already producing biotech crops.
	The Government of Hungary	Implemented moratorium on production of genetically modified (GM), insect resistant corn (MON 810) by invocation of safeguard clause, on January 18 2005.	

<table>
<tr><td></td><td>Ministry of Agriculture (together with other Ministries such as M. of Environment, Economy, Health)</td><td>Several Orders (application rules) setting the role of lower level institutions, fees and fines etc. concerning the enforcement of above Acts</td><td></td></tr>
<tr><td rowspan="3">Ireland</td><td>Department of Agriculture, Fisheries and Food</td><td>SI 424 (2004): transposes the Feedstuffs elements of the EU Regulations</td><td></td></tr>
<tr><td>Department of Health</td><td>In relation to the food elements of the regulations</td><td>Has not yet transposed the elements of EU legislation in relation to food</td></tr>
<tr><td>Department of the Environment and Local Government</td><td>Directive 2001/18 transposed in SI500/2003 on the deliberate release. Directive 90/219 transposed in SI73 (2001) on containment</td><td></td></tr>
<tr><td rowspan="3">Italy</td><td>Regions for coexistence</td><td></td><td>Coexistence regulations have not yet been issued by any of the 20 Italian regions. As a result, a de facto moratorium on GM crop planting continues to exist.</td></tr>
<tr><td>Ministry of Environment. For the approval of new events, however, other Ministries are responsible: Health, Welfare, Agriculture, Economic Development, Education. (see our IT7016)</td><td>2001/18 was implemented in 2003</td><td></td></tr>
<tr><td>Ministry of Health</td><td>Food & Feed, Labeling and Traceability</td><td></td></tr>
<tr><td>Netherlands</td><td>-Ministry of Public Health, Welfare and Sport
-Ministry of Housing, Regional Planning and Environment
-Ministry of Agriculture, Nature and Food Quality</td><td>-2001/18 implemented in 2003

-1829/2003 and 1830/2003 are by EC law directly enforced in entire EU</td><td>-On November 2, 2004, the Dutch agricultural sector and NGOs jointly presented their coexistence agreement to the Dutch Ministry of Agriculture, Nature and Food Quality.
- The Dutch sector still needs to reach agreement on the scope of a compensation fund for possible damage to conventional and organic crops, and a monitoring system in the field. For border zones see table below: proposed border zones in the Benelux (meters):
<table>
<tr><th></th><th colspan="2">The Netherlands</th><th>Flanders</th><th>Wallonia</th></tr>
<tr><th></th><th>C</th><th>O</th><th></th><th></th></tr>
<tr><td>Potato</td><td>3</td><td>10</td><td>-</td><td>-</td></tr>
<tr><td>Sugar beet</td><td>1.5</td><td>3</td><td>-</td><td>-</td></tr>
<tr><td>Maize</td><td>25</td><td>250</td><td>200</td><td>50</td></tr>
</table>
C = distance from conventional production
O = distance from organic production

Summaries of the MS coexistence regulations can be found on: http://www.gmo-safety.eu/en/coexistence/513.docu.html</td></tr>
</table>

Poland	Food products: approval -Chief Sanitary Inspectorate, lab testing - National Sanitary Inspectorate working under the Ministry of Health Feeds: Ministry of Agriculture and Rural Development, Veterinary Inspection (testing, labeling issues) Legal regulations on Planting/ Coexistence: Ministry of Environment	2001/18 – implemented in May 2003. -implementation of 1829/2003 – April 18, 2004 and 1830/2003 – April 25, 2004.	Work on new regulations for Genetically Modified Organisms, including the coexistence rules is currently in progress within the Ministry of Environment. It is expected to be completed by the end of 2008 (this date was officially presented to EC by Poland's GOV). On July 11, 2008, the Senate (upper house of the Polish Parliament) voted to delay introduction of a ban on biotech feed, which was scheduled to enter into effect August 12, 2008, until December 31, 2012; the proposal was then signed by the Polish President and entered into force. New regulations on Genetically Modified Organisms, including the coexistence rules is currently in progress within the Ministry of Environment. It is expected to be completed by end of 2008.
Portugal	Environment Ministry/ Ministry of Agriculture	Transposition of the 2001/18 in 2003 by law 9/2003.	The GOP published a coexistence decree in September 2005. Farmers are required to implement 200-meter isolation zones between biotechnology and traditional corn crops, and 300-meter zones between biotechnology and organic corn production. This distance may be replaced by a 24-row conventional-seed buffer zone, or by combining a 50-meter isolation zone with a 28-row conventional-seed buffer zone. In the case of insect resistant varieties, producers need to create "refuge" zones equal to 20 percent of field area, which must be populated with conventional corn varieties. The current coexistence decree effectively restricts biotechnology-seed use in most corn growing districts, because of the prevalence of small properties making it difficult, if not impossible, to meet the isolation zone requirements.
Romania	Ministry of Environment Ministry of Agriculture and Rural Development; Veterinary and for Food Safety National Authority; Ministry of Public Health; National Guard for Environment.	- Directive 2001/18 transposed through Emergency Ordinance 43/2007 (June 2007) - Directive 90/219 transposed through Emergency Ordinance 44/2007 (June 2007) - Regulation 1829/2003 transposed through Government Decision 256/2006 (Feb 2006) - Regulation 1830/2003	According to national regulations issued by the Min. of Agriculture, biotech farmers have to avoid cross-contamination by setting a minimum isolation distance between the biotech and conventional fields, according to the general regulations on seeds certification. The farmers should also establish a "buffer zone" and carefully plan the sowing season. In case of biotech corn, the minimum isolation distance is 200 meters. During the harvesting, transportation and storage process, farmers have to avoid

		transposed through Government Decision 173/2006 (Feb 2006) - Biosafety Commission (Since April 2008)	commingling GM seed with organic or conventional seeds through separate storage, through cleaning of machinery for sowing and conditioning, cleaning transportation means, according to specific legislation on certified seeds. It is mandatory that biotech farmers notify in writing both land owners and land users with plots nearby about their intention to cultivate biotech plants. Planting biotech crops inside the natural protected areas is forbidden, but there are no limits set for the area around these protected areas.
Slovakia	Ministry of Environment	-Act on the Use of Genetic Techniques and Genetically Modified Organisms no. 151/2002 from April 1, 2002, amended by the Act no. 77/2005 that came into force on February 3, 2005 Decree no. 399/2005 administers the Act on GMOs 77/2005 (contained use etc.)	Ministry of Environment is about to prepare a new National Biosafety strategy by the end of this year.
	Ministry of Agriculture	Act no.184/2006 on Growing of GM Crops in Agriculture Decree 69/2007 implementing the Act no. no.184/2006 and providing details on technical measures, isolation distances and handling GM crops	The minimum isolation distances for conventional crops is 200 meters for corn, 400 meters for rapeseed, 50 meters for sugar beets, 20 meters for potatoes. For organic production the isolation distances are 300, 600, 50, and 20 meters respectively.
Slovenia	Ministry of Environment and Spatial Planning	-Management of Genetically Modified Organisms Act (Official Gazette of the RS 67/02) (reflects Directives 90/219, 98/81, 2002/18 and some provisions of the CPB) -Management of Genetically Modified Organisms Act (Official Gazette of the RS 23/2005)	Act on Co-existence of Genetically Modified Plants and Other Agricultural Plants currently under discussion.

Spain	Ministry of Environment& Agriculture/Autonomous Regions Authorities	Transposition of 2001/18 (by National Law 9/2003 – 25, April 2003)	The debate continues on a GOS coexistence decree, the first draft of which was made public in 2004. Coexistence liability could be managed from the new Environmental Responsibility Law (rules currently under development) without the need of a specific regulation for coexistence.
	Health and Consumer Affairs Ministry	Monitors and enforces labeling requirement compliance	
United Kingdom	Department for Environment, Food & Rural Affairs (Defra)	Directive 2001/18 is implemented by the Environmental Protection Act and (in England) the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (similar regulations have been implemented in Northern Ireland, Scotland and Wales).	No coexistence measures finalized. Public comment period in 2006 generated very polarized feedback between pro- and anti-biotech supporters. Since no commercial production is expected in the UK in the short term, Defra is not moving forward on this issue at present.
	Department for Environment, Food & Rural Affairs (Defra)	Regulation 1829/2003 is implemented in England through the Genetically Modified Food (England) Regulations 2004 and the Genetically Modified Animal Feed (England) Regulations 2004 (similar Regulations have been implemented in Northern Ireland, Scotland and Wales).	
	Department for Environment, Food & Rural Affairs (Defra	Regulation 1830/2003 has been implemented in England by way of the Genetically Modified Organisms (Traceability and Labeling) (England) Regulations 2004 (similar Regulations have been implemented in Scotland, Northern Ireland and Wales).	

ANNEX VIII: EU -27 PRODUCTION OF GE CROPS BY REGION

Member State	Producing Region	2006 (Hectares)	2007 (Hectares)	2008 (Hectares)
Czech Republic	**Total**	**1,290**	**5,000**	**9,000**
France	Midi-Pyrenees		16,117	0
	Aquitaine		5,061	0
	Poitou-Charentes		516	0
	Rhones-Alpes		271	0
	Other		170	0
	Total	**5,200**	**22,135**	**0**
Germany	Eastern Germany		2,654	3,340
	Southern Germany		14	17
	Northern Germany		17	14
	Western Germany		0	0
	Total	**947**	**2,685**	**3,371**
Portugal	Alentejo		2,306	2,069
	Lisboa/Vale do Tejo		1,291	1,154
	Norte		62	146
	Centro		490	1,292
	Algarve		51	51
	Total	**1,254**	**4,199**	**4,711**
Romania	North-east and south-east		65	n/a
	South		226	n/a
	Southwest and west		40	n/a
	Total	**137,300**	**331**	**7,500**
Slovakia	**Total**		**930**	**1,930**
Spain	Aragon		35,860	33,000
	Catalonia		23,013	21,000
	Extremadura		6,460	6,000
	Navarra		5,327	5,300
	Castilla-La Mancha		3,659	3,700
	Others		829	1,000
	Total	**53,667**	**75,148**	**70,000**
Grand Total		**199,658** (with Romania) **62,358** (without Romania)	**109,498**	**94,582**

ANNEX IX – FIELD REGISTER STATUS BY EU MEMBER STATE

Member States	Field Registry
Austria	An Austrian field register table theoretically exists. The Gene Technology Act 1994 (latest amendments in 2005) earmarks a gene technology register. Part III of the register includes approved field releases, whereas Part IV deals with the planting of approved biotech crops. To date, there have been no approved field releases or plantings of biotech crops. According to the law the register is public.
Benelux	n/a
Czech Republic	A national field register exists but it is not directly accessible to the public. The information about locations of GM crops can be obtained by a special official written request to the Ministry of Environment.
France	A national register exists and each commercially-grown biotech plot must be listed. Made compulsory in spring 2008.
Germany	Farmers have to report the exact location and size of their biotech plantings to a national field register, which is accessible to the general public.
Greece	Field register tables exist at prefecture level which is supposed to be developed and revised annually, and is only for conventional crops. The Greek Ministry of Agriculture's decentralized stations at the prefecture level (named KEPYELs) receive farmer's declarations annually per crop, variety and acreage on what they intend to cultivate, per category. EU approved biotech crops are not grown in Greece based on numerous Ministerial Decisions. Coexistence system applications have never progressed in Greece. The GOG finds multiple ways to postpone implementation of coexistence practices.
Hungary	n/a
Ireland	n/a
Italy	n/a
Poland	n/a
Romania	Data on farmers authorized to plant biotech crops for commercial use is recorded in the National Registry of Biotech Farmers. The county office of the Ministry of Agriculture keeps and updates the County Register with full information about farmers: acreages planted with biotech crops, seeds source, the varieties sown, harvested production and its purpose of use. Subsequently, this information is inserted in the National Registry of Biotech Growers. The legislation is not clear to what level the content of the registry may become public information. So far, the Ministry of Agriculture has published information on total area planted with biotech crops at the level of each county, without publishing the location of the biotech fields. According to the national regulations, it is mandatory for biotech farmers to inform, in writing, all the legal owners of the neighboring plots within the limit set for co-existence (200 m for corn) as well as the city/community hall about their intention to plant biotech crops. Further, the legislation states that when farmers prove to have a legitimate interest in preventing potential cross-contamination with organic or conventional plots, the local agricultural offices will make available information about the type of agriculture practiced by the

	neighbors of those farmers.
Slovakia	A national field register exists but it is not directly accessible to the public. The information about locations with GM crops is kept by the Central Controlling and Testing Institute in Agriculture (UKSUP).
Spain	Information on area by region is publicly available at the Ministry of Agriculture web page. No farmer register is published.
Portugal	
UK	n/a

ANNEX X - EXTENT OF FIELD RELEASES OF GE CROPS

	2003	2004	2005	2006	2007	2008
Austria	0	0	0	0	0	0
Benelux (Netherlands)					14 ha (apples, potatoes)	24 ha (apples, potatoes, corn)
Czech Republic	0	0	1 plot, 624 m2 (potatoes)	5 plots 9,500 m2 (potatoes, corn)	17 plots 92,200 m2 (potatoes, corn, flax, prunus)	8 plots 13,500 m2 (potatoes, corn, flax)
France	17 ha 56 plots (Coffee, rapeseed, grass, corn, poplar, tobacco)	7 ha 48 plots (Coffee, rapeseed, grass, corn, poplar)	23 ha 80 plots (Grass, poplar, corn, vine)	3 ha 30 plots (Grass, corn, poplar, tobacco, vine)	4 ha 28 plots (Poplar, corn, tobacco, vine.)	Corn, poplar, vine
Germany	0	0	19 ha (corn)	81 ha (corn)	47 ha (corn) 21 ha (sugarbeet, potatoes, winter wheat)	25 ha (corn) 11 ha (sugarbeet, potatoes, winter wheat)
Greece	0	0	0	0	0	0
Hungary	Corn, wheat, potato, tobacco	Corn, wheat, potato, tobacco	Wheat, corn	Corn, wheat, potato, tobacco	Corn, wheat, potato, barley	n/a
Ireland	n/a					
Italy	n/a					
Poland	0	0	0	100 ha	100 ha	300 ha
Romania	Potato, sugarbeet, corn,	Corn	Corn	Corn	Corn, Soybean, Plum tree	435 Kg seeds (corn)
Slovakia	0	0	0	0	4 plots 0.64 ha (corn)	23 plots 65 ha (corn)
Spain	n/a	n/a	n/a	n/a	Potatoes, cotton, orange. Various plots	Cotton, corn, sugar beet, and oranges
Portugal	n/a	n/a	n/a	n/a	n/a	corn
United Kingdom	n/a	n/a	n/a	n/a	0.1 ha, 1 plot (potatoes)	2 ha, 1 plot (potatoes)