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EU-27

Biotechnology - GE Plants and Animals

Annual

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Report Highlights:
The European Union (EU) remains a major importer and consumer of biotech products, which primarily consist of soybean and corn products for use in animal feed and human food. Last fall, U.S. shipments of soybeans were blocked at EU ports, due to low level presence of biotech corn events unapproved in the EU. The biotech Amflora starch potato was approved for cultivation March 2010, and is currently grown in three Member States (MS). The European Commission recently released a draft proposal that would allow MS to make final decisions on biotech cultivation in their countries. Animal biotechnology regulation in Europe parallels regulation of plant biotechnology, at both the EU and MS levels. There are no commercial applications of animal biotech in the EU, nor have there been any notifications of food use.

Section I. Executive Summary:

There are currently two biotech products approved for cultivation in the European Union (EU). The first, MON810 corn, was approved in 1998, and its approval is currently subject to renewal. It has been planted on approximately 100,000 hectares (ha) each year since 2005. Estimated at 96,000 ha in 2010, MON810 corn is spread over six Member States (MS), including Spain, the Czech Republic, Portugal, Poland, Slovakia, and Romania. The second product is the Amflora starch potato. It was approved for cultivation in March 2010, and is estimated to be grown on about 225 ha in the Czech Republic, Sweden, and Germany in 2010.

There is interest to grow genetically-engineered (GE) crops among EU farming groups because of the yield benefits and cost savings. Member States with the most pragmatic approach towards plant biotechnology are the Czech Republic, Portugal, Slovakia, and Spain. In Poland and Romania, there is commercial cultivation of biotech crops despite the generally negative image of plant biotechnology.

European farmers face various oppositions to growing biotech crops, which include: (1) In most MS, public field registers with the location of commercially grown biotech crops are compulsory; (2) In Austria, France, Germany, Greece, Luxemburg, and Hungary national cultivation bans are present; (3) For Belgium, the Czech Republic, Germany, Hungary, Portugal, Romania, and Slovakia stringent coexistence measures are in place, and (4) negative publicity, intimidation, and crop destruction by non-governmental organizations (NGOs).

Despite politics, the EU remains a major importer and consumer of GE plant products. The largest category consists of soybean meal, which is used in animal feed as the primary source of proteins for livestock. Most of the soybean meal consumed is imported, roughly 22-23 million metric tons (MT) out of 31-32 million MT annually, as domestic soybean production is marginal. Argentina, Brazil, and the United States are the major suppliers of soybeans and soybean meal to the EU. Corn and corn products (mainly corn gluten feed) represent the second largest category of GE plant products imported and used in the EU in animal feed. The bulk of European corn consumption is supplied by local production rather than imports.

The absence of tolerance by European authorities of biotech events approved and commercially grown outside of the EU, but not approved in the EU, may weaken the EU food chain supply. In fall 2009, due to low level presence (LLP) of biotech corn unapproved in the EU, several soybean shipments were blocked at ports. This issue was resolved when European authorities were forced to accelerate their approval process to meet the demand of the animal feed industry. It is unclear whether the European Commission would present a proposal with a technical solution to this LLP issue in the near future.

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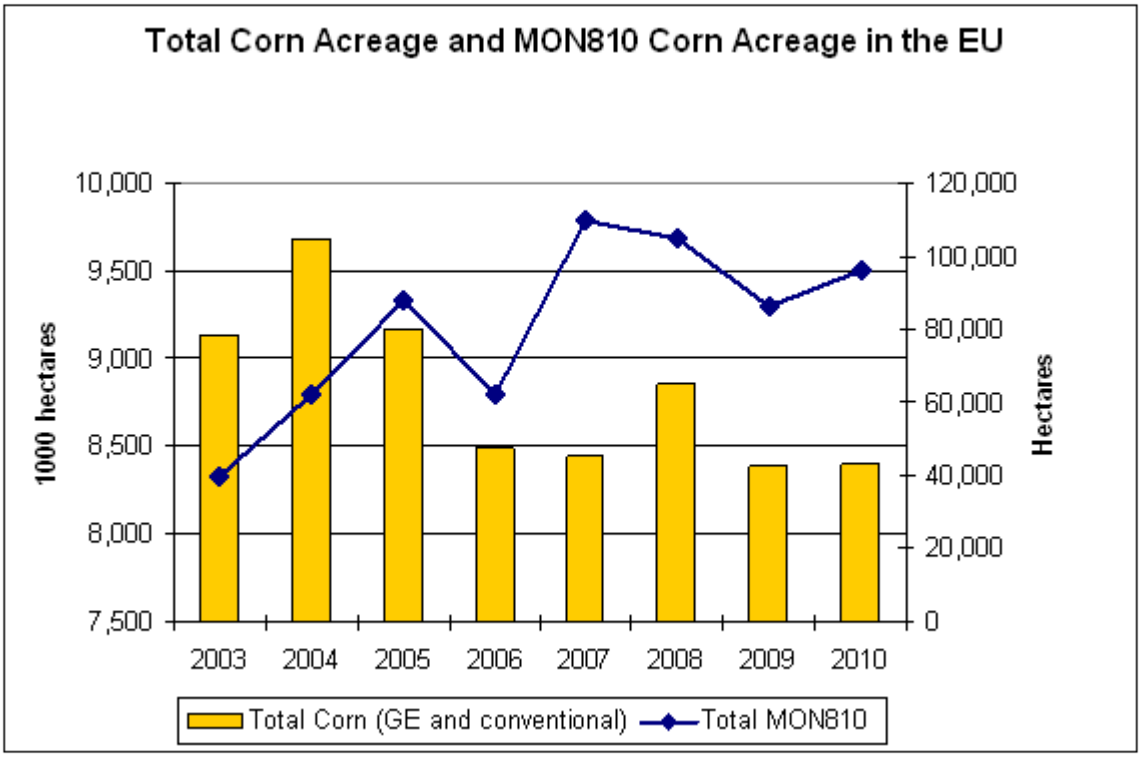
Section II. Plant Biotechnology Trade and Production:

1. Commercial Cultivation

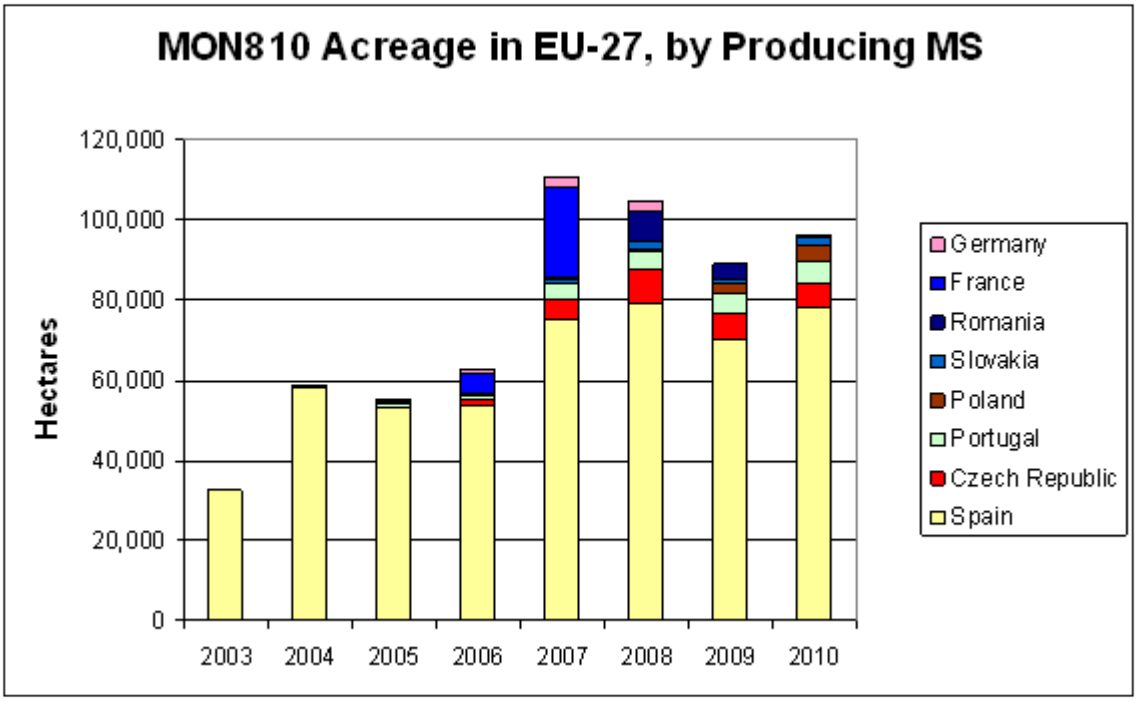
Currently, there are two biotech products approved for cultivation in the EU. The first, MON810 corn, has been approved for cultivation for the past ten years, and the Amflora starch potato, which was approved for cultivation March 2010. The Czech Republic, Germany, and Sweden are the only MS producing the Amflora potato on about 225 hectares (ha).

The MON810 acreage has varied between 86,000 and 110,000 ha, following the fluctuations of total corn (biotech and conventional) acreage in the European Union.



Source: FAS EU Posts

Spain remains the largest producer of MON810, with 81 percent of the total acreage planted in the EU-27 expected in 2010. The Czech Republic and Portugal rank second and third, respectively, with six percent each of the total European MON810 acreage. Poland ranks fourth, with a more recent, but faster, adoption of the technology, with almost four percent of the acreage. Slovakia and Romania are the smallest producers, with 1 to 2 percent of the acreage. France and Germany no longer grow MON810 corn commercially, as a result of their national bans; however, they were major producers from 2006 to 2008.



Source: FAS EU Posts

EU-27 Acreage of MON 810 CORN by Selected Member States (in hectares)								
Member State	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010 (estimate)**
Spain	32,249	58,219	53,226	53,667	75,148	79,269	70,000	78,500
Czech Republic	0	0	250	1,290	5,000	8,380	6,480	6,000
Portugal	0	0	730	1,254	4,199	4,711	5,000	5,500
Poland	0	0	0	100	100	300	3,000	3,500
Slovakia	0	0	0	30	930	1,930	875	1,740
Romania	0	0	0	0	331	7,146	3,400	1,000
France	17	17	500	5,200	22,135	0	0	0
Germany	0	500	342	947	2,685	3,171	0	0
Total MON810 acreage	**39,617**	**62,117**	**87,922**	**62,358**	**109,498**	**104,961**	**86,275**	**96,240**
Total Corn Acreage (GE and conventional)	**9,138,000**	**9,677,000**	**9,169,000**	**8,492,000**	**8,444,000**	**8,854,000**	**8,389,000**	**8,400,000**

Source: FAS EU Posts

Prior to its accession to the EU, Romania was a major producer of biotech glyphosate tolerant soybeans, grown on more than 137,000 ha in 2006. Due to biotech soybeans not approved for planting in the EU, Romania has stopped this production since its accession.

Acreage of Glyphosate Tolerant Soybeans in Romania (in hectares)							
2003	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**

39,600	61,600	86,100	137,300	0

Source: FAS Bucharest

2. Field Register Status

EU farming groups' interest in plant biotechnology use directly results from reported yield benefits and cost savings when growing these crops; yet, farmers in the EU are often discouraged to grow GE crops. This discouragement is due in part to national cultivation bans and stringent coexistence measures, as well as intimidation and crop destructions by non governmental organizations (NGOs).

In Austria, Belgium, Bulgaria, the Czech Republic, France, Germany, Greece, the Netherlands, Romania, Slovakia, and Portugal farmers producing biotech crops must register their fields with governmental bodies. The specificity of these registration requirements varies greatly from country to country, and tends to discourage farmers from growing biotech crops. Austria and Belgium currently have field register statuses; however, no products have been approved or planted. For Bulgaria and Italy, a national field register does not exist. The Czech Republic, Denmark, Germany, Hungary, the Netherlands, and Romania have national field registers.

3. Open Field Experimentation

Agricultural biotechnology research is stated as a priority of the European Commission and many Member States. 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 translated into reduced field trials. For several years, researchers and universities were able to implement field trial activities successfully. However, anti-biotech activist NGOs have succeeded in intimidating research groups (both public and private entities) to drop field trial work, and field destructions have continued with little of no response from police and judicial authorities. As a result, the permit requests to conduct field trials have fallen dramatically since 2007. In Austria, Bulgaria, Greece, Ireland, and Italy field trials are not conducted at this time. However, Belgium, Czech Republic, France, Germany and Slovakia have marginal field trials, ranging from 1 to 25 plots.

4. EU Imports and Consumption

EU plant biotech trade consists of soybean and corn imports for use in animal feed, human food, and planting seeds, as well as cotton products used in the textile industry. The largest category of GE products consumed by MS consists of soybean meal. Soybean meal is the primary source of proteins for livestock, over the past three years, roughly 31-32 million MT was consumed annually (see annual oilseeds report E50028, dated April 2010). Domestic soybean production is marginal. With soybean and soybean meal imports averaging 10 million MT and 23 million MT, respectively, Argentina, Brazil, and the United States are the major suppliers. GE products are estimated to represent more than 80

percent of the total soybean meal use by MS. The remainder mainly consists of identity preserved (IP) and geographical indication sectors. Although rapeseed meal produced from rapeseed grown in the EU-27 partially offset soybean meal in animal feed in the past years, soybean meal remains an excellent ingredient both in terms of price and quality for feed compounders.

Corn and corn products (mainly corn gluten feed) represent the second largest category of GE products used in animal feed. From 2007-2009, European corn consumption from averaged 58-62 million MT annually. It is principally supplied by local production (averaging 55-63 million MT annually), rather than by imports (averaging 2,000-3,000 MT), and the share of GE products out of total corn consumption is estimated to be lower than 25 percent.

The zero tolerance by European authorities of biotech events approved and commercially grown in other countries, but not approved in the EU-27, may weaken the EU food supply chain. Please see the low level presence paragraph in Section III. 7. Several U.S. shipments of soybeans were blocked at EU ports in fall 2009, due to low level presence of biotech corn events unapproved in the EU. This trade issue was finally resolved when European authorities were forced to accelerate their approval process to meet the demand of the animal feed industry. The ample European supply of grains, rapeseed meal, and dried distillers grains are estimated to have temporarily offset the October and November 2009 European soybean meal shortage in animal feed, while supplies were short from South America.

Section III. Plant Biotechnology Policy:

1. EU-27 Biotech Regulatory Framework

Typically, biotech events [1] , either for placing on the market or for release into the environment, are subject to the following regulatory framework:

A. <u>Authorization for placing biotech events on the market for food or feed use [2]</u>

An authorization is required for placing (import, distribution, processing) on the EU market biotech events. To obtain an authorization the following is required:

- An application [3] is sent to the appropriate national competent authority of a Member State. That competent authority acknowledges receipt of the application in writing to the applicant within 14 days of receipt, and transmits the application to the European Food Safety Authority (EFSA).

- EFSA informs other MS and the European Commission of the application without delay, and makes it available. EFSA also makes the summary of the dossier available to the public via the internet.

- EFSA is obliged to respect the time limit of six months from its receipt of a valid application to give its opinion. This six month limit is extended whenever EFSA (or a national competent authority through EFSA) requests supplementary information from the applicant.

- EFSA forwards its opinion on the application to the European Commission, the MS, and the applicant. EFSA also makes its opinion available for public comment within 30 days from publication.

- Within three months after receiving the opinion from EFSA, the European Commission presents its Standing Committee on the food chain and animal health (composed of representatives of the MS) with a draft decision reflecting EFSA's opinion. The Standing Committee votes on the draft decision. In the case of no qualified majority (qualified majority being 255 votes out of 345) in favor of the draft decision, the European Commission submits it to the Council of the European Union (typically the Agriculture Council) without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission.

- Authorizations granted are valid throughout the EU for a period of ten years. They are renewable for ten year periods on application to the European Commission by the authorization holder at the latest one year before the expiry date of the authorization. This application for renewal of authorization must include *inter alia* any new information which has become available regarding the evaluation of safety and risks to the consumer or the environment. Where no decision is taken on the renewal before the authorization's expiry date, the period of authorization is automatically extended until a decision is taken.

B. Authorization for deliberate release into the environment of biotech events [4]

The standard authorization procedure requires written consent of the appropriate competent authority to be given before the deliberate release into the environment (cultivation for which no specific containment measures are used) of a biotech event. To obtain written consent the following applies:

- The person wishing to undertake the release must submit a notification [5] to the appropriate national competent authority of the MS within whose territory the release is to take place.

- The national competent authority acknowledges the date of notification receipt.

- The national competent authority sends to the European Commission, within 30 days of receipt, a scientific opinion on each notification received.

- The European Commission, at the latest 30 days following receipt, forwards the opinion to the other MS which may, within 30 days, present observations through the Commission or directly.

- The national competent authority has 45 days to evaluate the MS's observations. If these observations are in line with the national competent authority's scientific opinion, that opinion is sent to the European Commission which, in turn, presents a draft decision reflecting the opinion to its Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms. The Committee votes on the draft decision. In the case of no qualified majority in favor of the draft decision, the European Commission submits it to the EU Agriculture Council without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission.

- If, on the other hand, the MS's observations are not in line with the national competent authority's scientific opinion, the matter is passed to EFSA for its scientific opinion. EFSA's opinion is then sent to the European Commission which presents a draft decision reflecting EFSA's opinion to the Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms. As in point B.5., above, the Committee votes on the draft decision. In the case of no qualified majority in favor of the draft decision, the European Commission submits it to the EU Environment Council without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission.

Please see Annex I for authorized products and Annex II for products pending authorization.

[1] In the EU commonly referred to as Genetically Modified Organisms (GMOs)

[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council

[3] The application is accompanied by *inter alia*:

- name and address of the applicant;
- designation of the food, and its specification, including the transformation event(s) used;
- a copy of the studies which have been carried out and any other available material to demonstrate no adverse effects on human or animal health or the environment;
- methods for detection, sampling and identification of the event;
- samples of the food;
- where appropriate, a proposal for post market monitoring;
- a summary of the dossier in standardized form.

A complete list of accompanying information is provided in Article 5 (3) for food use, and Article 17 (3) for feed use of Regulation (EC) No 1829/2003.

[4] Directive 2001/18/EC of the European Parliament and of the Council

[5] The notification includes *inter alia*:

- a technical dossier supplying the information necessary for carrying out an environmental risk assessment;
- the environmental risk assessment and the conclusions, together with any bibliographical reference and indications of the methods used.

Complete details are provided in Article 6 (2) of Directive 2001/18/EC.

2. Implementation of EU Policy and National Coexistence Rules

Nearly all MS have transcribed EU Directive 2001/18 and have implemented EU traceability and labeling regulations 2003-2010. Some MS such as Austria, Finland, Germany and Sweden have fully implemented EU biotech regulations and their regional authorities 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 and the United Kingdom).

3. Safeguard Clause: National Bans in Six Member States

Where a MS, as a result of new information, has detailed grounds for considering that an approved biotech event constitutes a risk to human health or the environment, the MS may impose a safeguard clause on the biotech product, i.e., may provisionally restrict or prohibit its use on its territory. The Member State shall ensure that in the event of a severe risk, emergency measures (such as suspension or termination of the placing on the market) shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

A decision shall be taken on the matter within 60 days by a Regulatory Committee (composed of the representatives of the Member States and chaired by a representative of the Commission). For the purpose of calculating the 60 day period, any period of time during which the Commission is awaiting requested further information or is seeking the opinion of the Scientific Committees shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committees consulted shall not exceed 60 days.

If the measures envisaged are not in accordance with the opinion of the Committee, the Commission submits a proposal to the Council without delay and informs the Parliament. The Council has a maximum period of three months from the date of referral to the Council to adopt or oppose the proposal. If on expiry of that period the Council has neither adopted nor opposed the proposal, the Commission adopts it.

National Bans Currently in Force

Country	Event Banned	Scope	Date of Ban
Austria	Syngenta Bt176 corn,	Cultivation	1997 (Amended 2008)
	Bayer T25 corn,	Cultivation	2000 (Amended 2008)
	Monsanto MON 810 corn	Cultivation	1999 (Amended 2008)
	Monsanto GT73 rapeseed	Import/Processing	2007 (Amended 2008)
	Monsanto MON 863 corn	Import/Processing	2008

	Bayer Ms8 rapeseed	Import/Processing	2008
	Bayer Rf3 rapeseed	Import/Processing	2008
	Bayer Ms8XRf3 rapeseed	Import/Processing	2008
	BASF EH92-527-1 potato	Import/Processing	2010
France	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Bayer MS1XRf1 rapeseed	Import/Processing	1998
	Monsanto MON 810 corn	Cultivation	2008
Germany	Syngenta Bt176 corn	Cultivation	2000
	Monsanto MON 810 corn	Cultivation	2009
Greece	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2001
	Bayer T25 corn	Import/Processing	1997
	Bayer MS1XRf1 rapeseed	Import/Processing	1998
Luxemburg	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2009
Hungary	Monsanto MON 810 corn	Cultivation	2005

Source: FAS EU Posts

Based on EFSA opinions asserting that there was no scientific basis for the MS bans, the European Commission recommended lifting these bans. In meetings of the Environment Council, the MS' Ministers for the Environment voted against the European Commission proposal so that these bans remain in place. The events banned are presented in the following table. The European Commission had approved these products for marketing based on positive risk assessments issued by EU scientific committees.

Three of the nationally banned biotech products' EU approvals were withdrawn March 2007, when the Commission and MS voted to withdraw approvals for five biotech products no longer in commercial use.

Three of the products withdrawn were cited in the WTO case brought by the United States, Argentina and Canada against the EU: Bt-176 (Syngenta corn); and 2 Bayer rapeseed events (Topas 19/2 and Ms1XRf1). The other products withdrawn were Monsanto's MON810 X GA21 corn and Bayer's Ms1Rf2 rapeseed.

Products Subject to Commission Decisions on Withdrawal from the Market since April 18, 2007	
Transformation	**Withdrawal Commission Decision**
Maize (Bt176) Syngenta	2007/304/EC
Maize (GA21 x MON810) Monsanto	2007/308/EC
Swede-rape (MS1, RF1, MS1xRF1) Bayer	2007/305/EC
Swede-rape (MS1, RF2, MS1xRF2) Bayer	2007/306/EC
Swede rape (TOPAS19/2) Bayer	2007/307/EC

4. Proposal to Give Member States a Choice to Cultivate Biotech Crops

In his political guidelines for the current European Commission, Commission President, José Manuel Barroso, referred to the principle of subsidiary and stated, "In an area like GMOs (genetically modified organisms) it should be possible to combine a Community authorization system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory." Health and Consumer Policy Commissioner, John Dalli, reiterated this announcement at the May 4, 2010, European Parliament's Agriculture and Rural Development Committee by stating that the Commission would make a proposal on the freedom to cultivate by the end of June 2010.

The reason underlying the freedom to cultivate proposal is that the authorization system for commercial cultivation of biotech crops does not work in the way intended by the governing legislation. Currently, in six Member States there are safeguard measures, as well as total bans, against the cultivation of MON810. This demonstrates MS's dissatisfaction with the authorization of biotech crops for cultivation procedures, and the MS limited power to decide whether or not to cultivate. The objective of the proposal is to give MS the freedom to decide whether to cultivate biotech crops, while maintaining an EU-wide science-based authorization system. Reportedly, the Commission would prefer to propose a solution that does not imply significant legislative amendments, while maintaining an appropriate degree of legal certainty. At the time of this report, it appears that possible policy options could include the following: (1) Limiting applications to specific countries or territories; (2) Revision of the co-existence guidelines to provide Member States with more room of maneuver; (3) Consideration of socio-economic factors; or (4) A combination of the options.

5. March 2010 Amflora Potato Cultivation Approval, Reauthorization of MON810 Initiated

EU Approved Biotech Potato for Cultivation

For the first time since 1998, the European Commission approved a new biotech event for cultivation in the EU. Developed by the German BASF company, the Amflora potato produces predominantly amylopectin starch (98 percent) and is mainly used for industrial purposes. The EU approval covers also the use of the potato pulp as animal feed. Traces of Amflora in food are only permitted accidentally or technically unavoidable to a maximum content of 0.9 percent. The Amflora is viewed as controversial by anti-biotech NGOs, because it contains an antibiotic marker gene. A group of 40 anti-biotech organizations, predominantly from German speaking Europe, filed a legal claim against the Amflora approval at the European Court of Justice demanding that the cultivation approval be withdrawn.

To date, 15 hectares of Amflora have been planted in Germany, 80 hectares in the Czech Republic, and 150 hectares in Sweden. Cultivation in Sweden and Germany is only for seed multiplication. Production in the Czech Republic will be used for industry tests. The Government of Austria banned Amflora cultivation. Specific coexistence regulations for the cultivation of the Amflora potato, such as distance rules, have not yet been developed. Member States are expected to draft such rules by the end of 2010.

Reauthorization of MON810 Corn Initiated

MON810 corn is under consideration for reauthorization by EU authorities, as EU approvals for biotech events require reauthorization after ten years. The event remains approved until the reauthorization process is finalized. EFSA made the following public opinion on MON810 adopted on June 15, 2009:

"The EFSA GMO panel considers that the information available for maize MON810 addresses the scientific comments raised by Member States and that maize MON810 is as safe as its conventional counterpart with respect to potential effects on human and animal health. The EFSA GMO panel also concludes that maize MON810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target Lepidoptera. Moreover, the EFSA GMO panel advises that pest resistance management strategies continue to be employed."

In its evaluation process EFSA reviewed all available new studies on MON810, including those used by the different MS to invoke national cultivation bans. However, until the proposal is adopted, existing bans in France, Germany, Austria, Hungary, Greece, and Luxembourg are very likely to remain.

The EFSA finding was the first step of many in the renewal of MON810, which MS will vote on at the regulatory committee, and then at the EU Council. It is unlikely that both the committee and council would approve or reject MON810 renewal by a qualified majority. As often in votes concerning biotech products, the European Commission is likely to be the final decision maker. It is probable that the final decision will not be taken until after the Commission's proposal on allowing Member States to choose whether or not to cultivate biotech crops on their territory is reached, which is expected by the end of June 2010, has been implemented (see Section III. 4.).

6. Food and Feed Labeling and Biotech Traceability

Labeling requirements for genetically engineered 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 GE by introducing the concept of a threshold. As long as the GE-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 regarding "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.

7. Policy on Low Level Presence

Traces of biotech events deregulated for commercial use in food and feed in the United States and other countries, but not yet authorized in the EU were detected in not only U.S. shipments, but also shipments from other countries to the EU. The EU's policy of zero tolerance implies that shipments containing low level presence (LLP) of EU unapproved events are not allowed into the European Union. The previous Commissioner for Agriculture and Rural Development, Mariann Fischer Boel, warned the EU Agriculture Council on September 7, 2009, that Member States must stop blocking biotech import authorizations if they wish to secure their required feed supplies in the absence of a new threshold for LLP of biotech events as yet unapproved in the EU.

As the EU is protein deficient, it is highly dependent on soybean and meal imports, and exports from the United States to the EU have declined. The value of U.S. exports to the 27 EU Member States stood at $2.8 billion in 1997, $1.8 billion in 1998, $1.1 billion in 2007, and $1.9 billion in 2008 (source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics). A significant proportion of this decline can be attributed to the EU's complex and administratively burdensome biotechnology approval process. The process relies heavily on the individual, sometimes non-science-based stances of its 27 Member States, which ironically, often come after the European Food Safety Agency (EFSA) has issued its scientific opinions stating that the products are safe. This results in the deregulation of biotechnology events occurring earlier in the United States than the granting of authorization in the EU, taking about 15 months and 40 months, respectively (asynchronous approval).

It is understood that the European Commission's Services have developed a technical solution which would allow a threshold of 0.1 percent (or up to 0.3 percent at the discretion of the individual Member State to allow for statistical error) applying to feed and possibly food. The scope of this solution would include events that have the following: (1) already been approved outside the EU, (2) a file in EFSA which has passed the completeness test, and (3) a validated detection method.

Although a formal proposal on LLP has yet to be made, intelligence suggests that it is unlikely- but possible- that the Commission will do so before the end of 2010. It seems that the Commission's priority issue for biotechnology policy is to give Member States the choice to cultivate biotech crops on their territory (see Section III., 4.). The unclear position of certain Member States on the inclusion of food within the scope of the LLP "technical solution" coupled with the reportedly unwelcomed high

profile reaction to the Commission's March 2010 approval on cultivation of the biotech potato variety Amflora make a later date for a proposal on LLP more probable.

8. European Commission and EU MS to Report on Socio-Economic Criteria

The December 4, 2008, Environment Council meeting unanimously adopted conclusions on socio-economic benefits and risks of agricultural biotechnology. The Commission is to submit a specific report on the implementation of Directive 2001/18/EC regarding the deliberate release into the environment of genetically modified organisms. The report is to include an assessment of socio-economic implications of deliberate releases of agricultural biotech events. During the beginning of 2010, MS collected, exchanged, and submitted information on socio-economic implications prior. Below are the following key conclusions:

1. Appraising socio-economic benefits and risks: The Commission is called upon to submit a specific report on the implementation of Directive 2001/18/EC on the deliberate release into the environment of GE products, including an assessment of the socio-economic implications.

2. Strengthening environmental assessment and monitoring arrangements: The report is to include impacts on non-target species; long-term effects and ecological impacts of GE products in affected regions were identified as areas where more MS involvement is needed.

3. Making better use of expertise: Broader involvement is encouraged in considering specific national or regional characteristics and a broadening of disciplines (e.g., ecology) in risk assessment.

4. Sensitive or protected areas: Emphasis is needed to consider specific regional and local characteristics of value in terms of biodiversity. Also, the Environmental Council underscored the legitimacy of establishing biotech-free zones based on the precautionary principle and freedom of choice.

Currently Austria, Hungary, Netherlands and Slovakia's policies favor including socio-economic criteria. Belgium and the United Kingdom are in the reviewing stages regarding their position, while the Czech Republic is against including the socio-economic criteria in their GE-products decision making. Germany's politicians are split on this issue, and Sweden is hesitant to start a process to develop new criteria in the risk assessments of GE products because of possible trade implications.

9. International Trade Issues Continue

The EU regulatory approach to biotechnology has had a significant impact on U.S. exports to the EU. In 2006, the World Trade Organization's (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. As a result, the European Commission and the United States implemented an ongoing 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. Market access has been denied for 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 the availability and prices of protein-rich feed ingredients.

EU food 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.

Section IV. Plant Biotechnology Marketing Issues:

1. Member States' Approach to Biotechnology and Marketing Issues

The MS can be grouped according to their approach towards biotechnology as the following:

Group #1. Negative image and no cultivation: Austria, Bulgaria, France, Germany, Greece, Hungary, Ireland, and Italy

Group #2. Pragmatic and no cultivation: The Benelux, Denmark, Finland, Slovenia, Sweden, United Kingdom

Group #3. Cultivation despite negative image of biotechnology: Poland, Romania

Group #4. Pragmatic and cultivation: Czech Republic, Portugal, Slovakia, Spain

Undoubtedly, for Group #1, the image of plant biotechnology has been damaged principally by activists. The industry is discouraged to produce and use GE products, thus resulting in an official cultivation ban, and little to no research.

2. March 2010 Eurobarometer Survey

While it is often believed that biotechnology has a negative image among the public, results of a poll

conducted by Eurobarometer published March 2010, called "Europeans, Agriculture, and the Common Agricultural Policy." Interestingly, one of the report's findings suggests that 77 percent of the respondents agree that the EU should encourage farmers to take advantage of progress in biotechnology.

Section V. Plant Biotechnology Capacity Building and Outreach:

USDA Foreign Agricultural Service (FAS) offices in EU Member States and the U.S. Mission to the European Union regularly conduct outreach activities relative to plant biotechnology. These activities, which include meetings, visits, and conferences for U.S. visitors (government, industry, research, farmer organizations) with European officials, aim to facilitate bilateral information flow and understanding. We routinely facilitate exchanges for European officials (policy makers, industry, farmer groups, media, universities, scientific researchers) who have expressed an interest in U.S. plant biotech issues. USDA FAS offices regularly provide up-to-date information on the plant biotechnology situation (policy, scientific research, and economics) in the United States to local contacts, e.g., the FAS Paris biannual biotech newsletter.

USDA'S Global Agriculture Information Network (GAIN) provides timely information on the agricultural economy, products, and issues in foreign countries that are likely to have an impact on United States agricultural production and trade. FAS Europe-based posts have regularly reported on agricultural biotechnology in Member States (http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx).

Previous Reports Prepared by Member States			
Member State	**Date**	**Report Number**	**Title**
Bulgaria	02/10/2010	BU1001	Amendments to the GMO Law
Italy	03/31/2010	IT1020	The Minister of Agriculture Rejects the Request to Plant GM Corn
	03/05/2010	IT1016	Italy Again Complains about EU GMO Approvals
	02/10/2010	IT1011	The Financial Cost to Corn Growers of Italy's Ban on Biotechnology
	02/04/2010	IT1008	Italy, One Step Closer to Biotech Cultivation
	02/01/2010	IT1006	The Widespread Use of Biotechnology in Italy
	01/11/2010	IT1003	How to Influence EU Public Opinion about Agricultural Biotechnology
	12/29/2009	IT9034	Biotech Update
	12/29/2009	IT9033	Italy MINAG Vocal Against GMO's
France	11/16/2009	FR9032	High Biotech Council – Defining Biotech-Free Production

	11/13/2009	FR9031	Science or Political Science – Workshop Explores Societal Concerns
	10/2/2009	FR9027	Biotech-Friendly Voices in France – Farmers, Food, and Feed Industry
	9/25/2009	FR9025	Attack on Transgenic Rootstock Vines Destroys Research
Germany	12/04/2009	GM9043	German Position on Barosso Initiative and MON810
	10/15/2009	GM9039	German Farmers Launched an E-Postcard Activity pro Biotech
	10/09/2009	GM9038	LLP of Biotech Corn Traces Less Damaging to EU Livestock
	06/15/2009	GM9026	Biotech Field Destructions Continue
	03/30/2009	GM9016	Bavrian Parliamentarians have to Admit 'A Cow Remains a Cow'
	03/12/2009	GM9012	German Biotech Industry and Researchers Kick Back
Hungary	05/25/2010	HU1003	Hungarian Safeguard Measures Against Production of Amflora Potato
	02/03/2009	HU9001	Biotechnology Update
Netherlands	2/8/2010	NL0005	Dutch Proposal on GMO Approvals and Socio-Economic Factors
	10/19/2009	NL9031	The Search for GMOs by the Dutch VWA
	10/9/2009	NL9029	The GMO Approval Process and Socio-Economic Factors
	9/1/2009	NL9023	Dutch Sector Lobbies for a Solution to LLP Issue
	8/5/2009	NL9019	U.S. Exports of Soya to the EU on Hold
	7/28/2009	NL9017	Netherlands Feed Industry Expects Higher Soy Prices
Poland	03/06/2009	PL9005	Problems with the Draft Cultivation Law and Poland Votes Against New GMOs
	03/03/2009	PL9006	Deficiencies in Draft Cultivation Law; Poland Votes No on New GMO Corn
Romania	09/17/2009	RO9004	Amendments in Biotech Legislation

Section VI. Animal Biotechnology:

Animal biotechnology regulation in Europe parallels regulation of plant biotechnology, at both the EU and MS levels. Reports indicate that there are no commercial applications of animal biotech in the EU, nor have there been any notifications of food use. MS approaches to research vary widely, with most permitting laboratory projects for medical or pharmaceutical applications. Several Member States are conducting research with potential for agricultural applications, mainly in the area of resistance to animal diseases.

The FAS 2009 comprehensive survey on EU biotechnology in animal production is available at: http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx. Substantial changes have not been reported during the past several months, but the following is an addendum:

Under the 7th Framework Program (FP), the European Commission is funding an integrated project, titled Pegasus, which aims to provide policy support regarding development, implementation, and commercialization of GM animals, derivative foods, and pharmaceutical products. The Pegasus project includes eight Work Packages.

The Work Packages include:

- WP 1 Public perception of transgenic animals, food and pharmaceutics
- WP 2 Foresight of GM animal technology developments
- WP 3 Production chain context
- WP 4 Life science dimension
- WP 5 Ethical issues: Analysis of stakeholders positions and ethical judgments
- WP 6 Policy implementation and development
- WP 7 Public engagement
- WP 8 Project management and dissemination

More information about the Pegasus project is available at: http://www.pegasus.wur.nl/UK/

Section VII. Author Defined:

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

Note: In the following table, products authorized since last year's agricultural biotechnology report are highlighted in orange, while the only product authorized for seeds cultivation is highlighted in green.

Transformation Event	Characteristics	Authorized Use	Authorization Expiration Date/Ongoing
Cotton			
Cotton (MON1445) Monsanto	Tolerance to glyphosate	Food	18/12/2011
		Food additives	Ongoing
		Feed	Ongoing
Cotton (MON15985) Monsanto	Lepidopteran insect-resistance	Food additives	Ongoing
		Feed	Ongoing
Cotton (MON15985 x MON1445)	Lepidopteran insect-resistance and tolerance to glyphosate	Food additives	Ongoing
		Feed	Ongoing

Monsanto			
Cotton (MON531) **Monsanto**	insect-resistance	Food	18/12/2011
		Food,food additives + Feed	Ongoing
Cotton (MON531 x MON1445) **Monsanto**	insect-resistance tolerance to glyphosate	Food additives	Ongoing
		Feed and feed additives	Ongoing
Cotton (LLCotton25) **Bayer**	tolerance to glyphosinate-ammonium herbicide	Foods	28/10/2018
		Feed	
		Other Products	
Maize			
Maize (Bt11) **Syngenta**	insect-resistance and tolerance to glufosinate-ammonium	Foods and food ingredients	18/05/2014 Renewal ongoing
		Food additives produced	Ongoing
		Feed	Ongoing
		Other products	Ongoing
Maize (DAS1507) **Pioneer and Dow AgroSciences**	resistance to the European corn borer and certain other lepidopteran pests tolerance to glufosinate-ammonium	Foods and food ingredients	02/03/2016
		Feed	15/03/2016
		Feed	Ongoing
		Other products	15/03/2016
Maize (DAS1507xMON603) Pioneer and Dow AgroSciences	• protection against certain lepidopteran pests such as the European corn borer Sesamia • tolerance to glufosinate-ammonium • tolerance to glyphosate	Foods	
		Feed	23/10/2017
		Other Products except cultivation	
		Foods and food ingredients	07/09/2018
		Feed	
		Products other than food and feed except cultivation	
Maize (DAS59122) **Pioneer and Dow AgroSciences**	- protection against certain coleopteran pests such as corn rootworm larvae - tolerance to glufosinate-ammonium	Foods + Feed	23/10/2017
		Products other than food and feed except cultivation	
Maize (GA21) **Syngenta**	tolerance to glyphosate	Foods + Feed	27/3/2018
		Products other than food and feed except cultivation	
Maize (MON810) **Monsanto**	resistance to lepidopteran pests	Foods + Feed	Ongoing
		Seeds cultivation	Ongoing
Maize (MON863)	insect- resistance, selection marker	Food	12/01/2016
		Food additives	Ongoing

Monsanto		Feed	12/02/2016
		Feed	Ongoing
		Other products except cultivation	12/02/2016
Maize (MON863 x NK603) **Monsanto**	selection marker, insect- resistance, tolerance to glyphosate	Food additives	01/03/2020
		Feed	
Maize (MON863 x MON810) **Monsanto**	resistance to lepidopteran pests, resistance to certain coleopteran pests (principally corn rootworm), selection marker	Feed materials produced from MON863 x MON810 maize	01/03/2020
Maize (NK603) Monsanto	tolerance to glyphosate	Food	02/03/2015
		Food additives	Ongoing
		Feed	17/10/2014
		Feed produced	Ongoing
		Other products except cultivation	17/10/2014
Maize (NK603 x MON810) **Monsanto**	tolerance to glyphosate, protection against certain lepidopteran insect pests (Ostrinia nubilalis, Sesamia spp.)	Foods + Feed	23/10/2017
		Other Products except cultivation	
Maize (T25) **Bayer**	tolerance to glufosinate-ammonium	Food + ingredients + Feed	Ongoing
		Seeds f.cultivation	Ongoing
Maize (MON88017 Monsanto	protection against coleopteran pests tolerance to glyphosate	Foods + Feed	29/10/2019
		Other products except cultivation	
Maize (MON89034) Monsanto	protection against lepidopteran pests	Foods + Feed	29/10/2019
		Other products except cultivation	
Maize (59122 x NK603) Pioneer	protection against coleopteran pests tolerance to glufosinate-ammonium tolerance to glyphosate	Foods + Feed	29/10/2019
		Other products except cultivation	
Maize (MIR604) Syngenta	protection against coleopteran pests selection marker	Foods + Feed	29/10/2019
		Other products except cultivation	
Maize (MON863xMON810xNK603) Monsanto	protection against coleopteran pests protection against lepidopteran pests tolerance to glyphosate selection marker	Foods + Feed	01/03/2020
		Other products except cultivation	
MICROORGANISMS			
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.	Feed	Ongoing
Yeast biomass	produced from genetically modified yeast strains (Saccharomyces	Feed	Ongoing

NOVO Nordisk A/S	cerevisiae) cultivated on substrates of vegetable origin.		
RAPESEED			
Oilseed rape (GT73) **Monsanto**	tolerance to glyphosate	Food	Ongoing
		Feed	20/02/2017
		Feed	Ongoing
		Other products except cultivation	20/02/2017
Swede-rape (MS8, RF3, MS8xRF3) **Bayer**	tolerance to herbicides based on glufosinate ammonium, lack of viable pollen and male sterility	Food	Ongoing
		Feed	24/05/2017
		Feed	Ongoing
		Other products except cultivation	24/05/2017
Oilseed rape (T45) **Bayer**	tolerance to glufosinate-ammonium	Foods and food	09/03/2019
		Feed	
		Products other than food and feed	
POTATO			
Starch potato (EH92-527-1) BASF	Amylopectin expression	Feed	01/03/2020
		Food, no higher than 0.9%	01/03/2020
		Cultivation	31/03/2020
SOYBEAN			
Soybean (MON40-3-2) **Monsanto**	tolerance to glyphosate	Food	Ongoing
		Feed	Ongoing
		Other products except cultivation	Ongoing
Soybean (A2704-12) **Bayer**	tolerance to glyphosinate-ammonium	Foods	07/09/2018
		Feed	
		Other Products except cultivation	
Soybean (MON89788) **Monsanto**	tolerance to the herbicide glyphosate	Foods + Feed	03/12/2018
		Other Products except cultivation	
SUGARBEET			
Sugar beet (H7-1) **KWS SAAT + Monsanto**	tolerance to glyphosate	Foods	23/10/2017
		Feed	

Updated information is available at the following site:
http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

ANNEX II: GENETICALLY MODIFIED FOOD, FEED, AND CULTIVATION - PENDING AUTHORIZATIONS

EFSA ID*	Product	Company	Trait	Scope of Application	EFSA Evaluation Status
UK-2004-01	NK603 x MON810 Maize	Monsanto	Insect Resist	Food Feed	Opinion Adopted
NL-2004-02	1507 Maize	Pioneer HiBred	Insect Resist	Food	Opinion Adopted
DE-2004-03	MON863 x MON810 Maize	Monsanto	Insect Resist	Food Feed	Opinion Adopted
UK-2004-05	LLRice62	Bayer	Herb Tol	Food / Feed	Opinion Adopted
UK-2004-05	1507 x NK603 Maize	Pioneer HiBred	Insect Resist	Food Feed Processing	Opinion Adopted
M-2004-0135	Liberty Link 62 Rice (LLRice62)	Bayer	Herb Tol	Feed Processing	Withdrawn
UK-2004-40	LLRICE62 Rice	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted
UK-2004-06	MON863 X NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed Import Processing	Opinion Adopted
BE-2004-07	MON863 x MON810 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed Processing	Opinion Adopted
UK-2004-08	H7-1 Roundup Ready® Sugar beet	KWS Monsanto	Herb Tol	Food Feed	Opinion Adopted
UK-2005-09	MON531 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested

UK-2005-10	MON15985 Cotton and MON15985 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Withdrawn
M-2005-0030	Phytase SP 1002 for piglets, pigs for fattening, sows, chickens for fattening, turkeys and laying hens	DSM	Feed Additive	Feed	Opinion Adopted
NL-2005-12	59122 Maize	Pioneer HiBred	Insect Resist	Food Feed Processing	Opinion Adopted
UK-2005-11	MIR604 Maize	Syngenta	Insect Resist	Food Feed	Additional data requested
NL-2005-13	LLCotton25 Cotton	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted
M-2005-0059	Phyzyme® XP for chickens for fattening	Danisco Animal Nutrition	Feed Additive		Opinion Adopted
UK-2005-14	EH92-527-1 Amylopectin Potato	BASF	Starch Composition	Food Feed	Opinion Adopted
M-2005-0109	3-phytase (Natuphos) for piglets, pigs for fattening, chickens for fattening, laying hens, turkeys for fattening.	BASF	Feed Additive		Opinion Adopted
NL-2005-15	1507 x 59122 Maize	Dow Agro Science Pioneer HiBred	Insect Resist Herb Tol	Food Feed Processing	Opinion Adopted
NL-2005-16	21-24-236-3006-210-23 Cotton	Dow Agro Science	Nsect Resist Herb Tol	Food Feed	Additional data requested
NL-2005-18	A2704-12 Soybean	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted
UK-2005-	1507 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed Processing	Additional data

17				Cultivation	requested
M-2005-0176	Biogalactosidase (alfa-galactosidase) for pigs for fattening	Kerry BioScience	Feed Additive		Additional data requested
UK-2005-19	GA21 Maize	Syngenta	Herb Tol	Food Feed Processing	Opinion Adopted

UK-2005-20	59122 x NK603 Maize	Pioneer HiBred	Insect Resist Herb Tol	Food Feed Processing	Opinion Adopted
NL-2005-26	NK603 x MON810 Maize	Monsanto	Insect Resist Herb Tol	Cultivation	Additional data request
CZ-2005-27	MON88017 Maize	Monsanto	Insect Resist Herb Tol	Food Feed Processing	Opinion Adopted
M-2005-0208	Rovabio PHY AP/LC. (3-Phytase) for chickens for fattening, laying hens, weaned piglets and pigs for fattening	Adisseo	Feed Additive		Opinion Adopted
UK-2005-21	59122 x 1507 x NK603 Maize	Pioneer HiBred	Insect Resistant Herb Tol	Food Feed Processing	Opinion Adopted
NL-2005-22	NK603 Maize	Monsanto	Herb Tol	Food Feed Cultivation	In progress
NL-2005-23	59122 Maize	Pioneer HiBred Dow	Insect Resist	Food Feed Cultivation	Additional data requested
NL-2005-24	40-3-2 Soybean	Monsanto	Herb Tol	Cultivation	Additional data requested
NL-2005-28	1507 x 59122 Maize	Mycogen Dow Pioneer HiBred	Insect Resist Herb Tol	Food Feed Cultivation	Additional data requested

UK-2005-25	T45 Oilseed rape	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted
UK-2006-30	59122 x 1507 x NK603 Maize	Pioneer HiBred	Insect Resist Herb Tol	Food Feed Cultivation	Additional data requested
UK-2006-29	59122 x NK603 Maize	Pioneer HiBred	Insect Resist Herb Tol	Food Feed Cultivation	Withdrawn
NL-2006-32	LY038 x MON810 Maize	Renessen Europe	Insect Resist Lysine	Food Feed	Withdrawn
NL-2006-31	LY038 Maize	Renessen Europe	Lysine	Food Feed	Withdrawn
CZ-2006-33	MON88017 x MON810 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	In progress

M-2006-0023	Quantum Phytase 5000 L and 2500D (6-phytase) for chickens, ducks and turkeys for fattening, laying hens and piglets (weaned)	Syngenta	Feed Additive		Opinion Adopted
UK-2006-34	3272 Maize	Monsanto	Altered Composition	Food Feed	Additional data request
NL-2006-35	LLCotton25 x MON15985 Cotton	Bayer	Insect Resist Herb Tol	Food Feed	Withdrawn
M-2006-0101	Danisco Xylanase (Endo-1,4beta-xylanase) for chickens for fattening, laying hens, ducks for fattening	Finnfeeds	Feed Additive		Opinion Adopted
NL-2006-36	MON89788 Soybean	Monsanto	Herb Tol	Food Feed Processing	Opinion Adopted
M-2007-	Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin and alpha-	Finnfeeds Danisco	Feed Additive		Additional data

0020	amylase) for chickens for fattening and ducks for fattening				requested
NL-2007-37	MON89034 Maize	Monsanto	Insect Resist	Food Feed Processing	Opinion Adopted
NL-2007-38	MON89034 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
NL-2007-39	MON89034 x MON88017 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
FR-2007-40	PL73 Escherichia coli (LYS)(dried killed bacterial biomass) for feed	Ajinomoto Eurolysine	Feed Additive		Withdrawn
UK-2007-41	MON88913 Cotton	Monsanto	Herb Tol	Food Feed	Additional data requested
UK-2007-42	MON88913 x MON15985 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
UK-2007-43	356043 Soybean	Pioneer Overseas	Herb Tol	Food Feed	Additional data requested
FR-2007-44	PT73 Escherichia coli (THR) (dried killed bacterial biomass)	Ajinomoto Eurolysine	Feed Additive		Withdrawn
M-2007-0097	Econase XT L and Econase XT P (endo-1,4-beta-xylanase) for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned)	Roal Oy Finland	Feed Additive		Opinion Adopted
NL-2007-45	305423 Soybean	Pioneer HiBred	Altered Composition	Food Feed	Additional data requested
M-2007-0110	Ronozyme NP (6-phytase) for chickens for fattening	DSM Nutritional Products	Feed Additives		Opinion Adopted

NL-2007-46	T25 Maize	Bayer	Herb Tol	Food Feed Cultivation	Additional data requested
UK-2007-48	MIR604 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food Feed	Additional data requested
UK-2007-49	Bt11 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food Feed	Additional data requested
UK-2007-50	Bt11 x MIR604 Maize	Syngenta	Insect Resist	Food Feed	Additional data requested
NL-2007-47	305423 x 40-3-2 Soybean	Pioneer HiBred	Altered Composition Herb Tol	Food Feed	Additional data requested
M-2007-0953	L-Valine for all species	Ajinomoto Eurolysine	Feed Additive		Opinion Adopted
M-2008-0013	Natugrain TS (endo-1,4-ß-xylanase and endo-1,4-ß-glucanase) for piglets (weaned), laying hens, chickens and turkeys for fattening and ducks	BASF	Feed Additive		Opinion Adopted
NL-2008-51	GHB614-glyphosate tolerant Cotton	Bayer	Herb Tol	Food Feed	Opinion Adopted
M-2007-0953	L-Valine for all species	Ajinomoto Eurolysine	Feed Additive		Opinion Adopted

M-2008-0013	Natugrain TS (endo-1,4-ß-xylanase and endo-1,4-ß-glucanase) for piglets (weaned), laying hens, chickens and turkeys for fattening and ducks	BASF	Feed Additive		Opinion Adopted
NL-2008-51	GHB614-glyphosate tolerant Cotton	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted

M-2008-0073	Ice Structuring Protein (ISP) as novel food ingredient	Unilever		Food	Opinion Adopted
NL-2008-52	A5547-127 Soybean	Bayer	Herb Tol	Food Feed	Additional data requested
GMO 2008-53	98140 Maize	Pioneer HiBred	Herb Tol	Food Feed	Additional data requested
CZ-2008-54	MON88017 Maize for cultivation	Monsanto	Insect Resist Herb Tol	Cultivation	Additional data requested
DK-2008-55	B12 Vitamin with recombinant human intrinsic factor (rhIF). from Arabidopsis thaliana	Cobento	Vitamin		Under Consideration
UK-2008-56	Stacked Bt11 x MIR604 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food Feed	Additional data requested
M-2008-0150	Finase L and P (phytase) for laying hens, turkeys for fattening, sows, ducks for fattening, pheasants and other game birds	Roal Oy	Feed Additive		Additional data requested
UK-2008-57	MON15985 Cotton	Monsanto	Insect Resist	Food Feed	Additional data requested
UK-2008-58	MON15985 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
FR-2008-59	PT73 Escherichia coli (TM)	Ajinomoto Eurolysine	Feed Additive		Additional data requested
M-2008-0419	Ronozyme® WX (Endo-1,4-ß-ylanase) for poultry, piglets (weaned) and pigs for fattening	DSM Nutritional products	Feed Additive		Additional data requested
Uk-	GA21 Maize	Syngenta	Herb Tol	Food / Feed	Additional data

2008-60					requested
FR-2008-61	d PL73 Escherichia coli (LM)	Ajinomoto Eurolysine	Dried killed bacteria biomass	Feed	Additional data requested
CZ-2008-62	MON89034 x 1507 x MON88017 x 59122 Maize	Dow Monsanto	Insect Resist Herb Tol	Food / Feed	Additional data requested
DE-2008-63	H7-1 Sugar beet	Monsanto	Herb Tol	Food / Feed Cultivation	Under Consideration

M-2008-0431	Ronozyme ProAct (serine protease)	DSM	Feed Additive	Chickens for fattening	In progress
DE-2009-64	BPS-CV127-9 Soybean	BASF		Food / Feed	Under Consideration
NL-2009-65	MON89034 x 1507 x NK603 Maize	Dow Monsanto	Insect Resist Herb Tol	Food / Feed	Under Consideration
NL-2009-68	281-24-236 x 3006-210-23 x MON88913 Cotton	Mycogen Seeds Dow	Insect Resist Herb Tol	Food / Feed	Waiting for full dossier
M-2009-0061	L-isoleucine for all animal species	Ajinomoto Eurolysine	Feed Additive		Additional data requested
DE-2009-66	Bt11 x MIR162 x MIR604 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food / Feed	Under Consideration

* Events listed with their mandate number M-200*-** have been applied for under EC regulation 1831/2003*

Biotech Events notified under EU Directive 2001/18

EFSA ID *	Product	Company	Trait	Scope of Application	EFSA Evaluation Status
C/NL/00/10	1507 Maize	Pioneer HiBred	Insect Resist	Import / Processing	Opinion Adopted

C/F/96/05/10	BT11 Maize	Syngenta	Insect Resist	Cultivation Feed Ind.Processing	Opinion Adopted
C/ES/01/01	1507 Maize	Pioneer HiBred	Insect Resist	Import Feed Processing Cultivation	Opinion Adopted
C/SE/96/3501	GM EH92-527-1 Potato with altered starch composition	BASF	Starch Composition	Cultivation	Opinion Adopted
C/GB/02/M3/3	GM NK603 x MON810 Maize	Monsanto	Insect Resist Herb Tol	Import Processing	Opinion Adopted
C/NL/04/02	Carnation Moonlite 123.2.38	Florigene	Colour	Import	Opinion Adopted
C/BE/96/01	GM Ms8, Rf3 and Ms8 X Rf3 Oilseed rape	Bayer	Herb Tol	Import, processing, cultivation	Opinion Adopted
C/NL/04/01	GM 281-24-236/3006-210-23 Cottonseed	Dow Agro Science	Insect Resist Herb Tol		Opinion Adopted
C/NL/06/01	GM Carnation Moonaqua 123.8.12 for import only	Florigene	Colour	Import	Opinion Adopted

Applications Seeking Renewal of Existing Authorization

EFSA ID*	Product	Company	Trait	Scope of Application	EFSA Evaluation Status
RX-40-3-2	40-3-2 Soybean	Monsanto	Herb Tol	Food Feed	Additional data requested
RX-40-3-2	40-3-2 Soybean	Monsanto	Herb Tol	Food Feed	Additional data requested
RX-MON1445	MON 1445 cotton	Monsanto	Herb Tol	Food Feed	Additional data requested
RX-1507	1507 Maize	Pioneer HiBred	Insect Resist	Feed Feed Additives	In progress
RX-15985	MON15985 Cotton	Monsanto	Insect Resist	Feed Feed Additives	Additional data requested
RX-Bt11	Bt11 Maize	Syngenta	Insect Resist	Food Feed	Completed
RX-GA21	GA21 Maize	Syngenta	Herb Tol	Food Feed Processing	Completed
RX-GT73	GT73 oilseed rape	Monsanto	Herb Tol	Food	Additional data requested

RX-GT73	GT73 Oilseed rape	Monsanto	Herb Tol	Feed	Additional data requested
RX-MON810	MON810 maize	Monsanto	Insect Resist	Food Feed	In progress
RX-MON531	MON531 Cotton	Monsanto	Insect Resist	Food Feed	In progress
RX-MON531XMON1445	MON 531 x MON 1445 cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
RX-MON810	MON810 Maize	Monsanto	Insect Resist	Food Feed Cultivation	In progress
RX-MON810	MON810 Maize	Monsanto	Insect Resist	Food	In progress
RX-T45	T45 oilseed rape	Bayer	Herb Tol	Food Feed Processing	Completed
RX-T25	T25 Maize	Bayer	Herb Tol	Food Feed	Additional data requested
RX-pMT742/pAK729	GMO yeast pMT742 or pAK729, "yeast biomass"	Novo Nordisk		Feed	Waiting for full dossier
RX-PL73	GMO bacteria "Brevibacterium lactofermentum strain S0317/pCABL" "PL73".	Ajinomoto Eurolysine		Feed	Additional data requested
RX-NK603xMON810	NK603 x MON810 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Withdrawn
RX-MS8xRF3	MS8/RF3 oilseed rape	Bayer	Male Sterility Herb Tol	Food Feed	Additional data requested
RX-MON15985xMON1445	MON15985 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
RX-MON863xMON810	MON863 x MON810 Maize	Monsanto	Insect Resist	Feed	Additional data requested

RX-MON863xNK603	l MON863 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data requested
RX-MON863	MON863 maize	Monsanto	Insect Resist	Food Feed	Additional data requested
RX-NK603	NK603 maize	Monsanto	Herb Tol	Food Feed	Additional data requested

Information has been compiled from the following website:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2

This information is also available at following address:
http://www.gmo-compass.org/eng/gmo/db/