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Report Highlights:

The EU is a major importer and consumer of agricultural biotechnology products. As the EU falls further behind other countries in approving new events, there is a constant threat to the access of imported animal feed ingredients for the EU livestock and poultry industries, particularly given the EU's zero tolerance for unapproved varieties. There are new initiatives to introduce non-scientific criteria into the EU regulatory process and to completely return some decision making authority to member states or regions. Currently, the EU is reviewing the reauthorization of the only biotech event approved for environmental release, MON 810 corn. The result of this process will have a significant impact on the planting bans implemented by several member states.

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Executive Summary

The EU remains one of the largest consumers of products from agricultural biotechnology, mainly in the animal feed sector. Retailers in most member states continue to be reluctant to sell products carrying a biotech label given consumer attitudes and threats of blacklisting from anti-biotech groups. Area planted with biotech corn in the EU fell in 2009 in line with the reduction in overall corn area. This was primarily the result of the impact of the international credit crisis and corn price expectations on farmers' planting decisions.

The EU's regulatory system for agricultural biotech represents a significant threat to the EU animal feed sector and related industries. The European Commission continues to wrestle with a regulatory structure that is subject to political decision making rather than being based solely on sound science. As a result, the EU animal feed, livestock, and poultry industries are at constant risk of losing necessary access to world oilseed and protein markets. This challenge is growing as the EU falls further behind other countries in research, development, regulation, and commercialization of agricultural biotechnology events.

Some EU member states support formal inclusion of socio-economic criteria into the EU biotech regulatory process. Other member states support completely re-nationalizing or regionalizing regulatory control over environmental release of biotech events. This would pose a serious blow to the EU regulatory framework in all fields and would also run counter to the 2006 WTO report finding that existing Member State bans were in breach of the EU's WTO obligations.

The only approved biotech event for environmental release (MON 810) in the EU is currently undergoing a

required 10-year reauthorization. The European Food Safety Authority has again concluded that MON 810 is as safe for human and animal health and the environment as its conventional counterpart. However, it is unclear how this process will impact Member State planting bans given that the reauthorization decision will ultimately be made at the political level.

The European corn borer is widely established in almost all major EU corn producing areas. It has been successfully controlled by MON 810 varieties, where this choice is freely available to farmers. The corn borer continues to rapidly spread across the EU, with little success at eradication or control through conventional means.

II - Biotech Regulatory System in the EU-27

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:

Authorization for placing on the market of biotech events for food or feed use [2]

An authorization is required for the placing on the EU market (import, distribution, processing) of biotech events. The process to evaluate an authorization application in the EU is well documented.

1. 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 its receipt, and transmits the application to the European Food Safety Authority (EFSA) without delay.
2. EFSA informs the other Member States (MS) and the European Commission of the application without delay, and makes it available to them. EFSA also makes the summary of the dossier available to the public by placing it on the internet.
3. EFSA “**shall endeavor to respect**” a 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.
4. 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.
5. 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 then 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 and Fisheries 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.

6. 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.

^[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, Regulation (EC) No 1829/2003.

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. The following is necessary to obtain written consent.

1. The person wishing to undertake the release must submit a notification [5] to the appropriate national competent authority of the Member State within whose territory the release is to take place.
2. The national competent authority acknowledges the date of receipt of the notification.

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

3. 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.

4. The national competent authority has 45 days to evaluate the MS' 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 adaptation 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 Council of the European Union (typically the 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.

5. If, on the other hand, the MS' 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 adaptation to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organism.*" As in point 4 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 Council of the European Union (typically the 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.

^[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.

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

Safeguard Clause

Where a Member State, 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, may provisionally restrict or prohibit its use on its territory.

In such cases, the Member State immediately informs the Commission and the other MS, giving reasons for its decision and supplying its review of the environmental risk assessment.

Within 60 days of the date of receipt of the information transmitted by the Member State, a decision is taken by the European Commission's Scientific Committee on the Member State's measure.

See also section '**Member State Bans on Biotech Events**' on page 21

Labeling of Food and Feed and Traceability of Biotech Products

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](#) 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 EFSA and a risk management process involving the European Commission and MS through a [regulatory committee procedure](#).

EU food labeling regulations provide for a 0.9 percent threshold for the "**adventitious**", that is, accidental and technically unavoidable, presence of **EU-authorized** biotech event in a non-biotech food or feed. Amounts above 0.9 percent must be labeled as outlined above. In the past, the EU also operated 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. This provision expired in April, 2007.

Cartagena Protocol

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](#).

Regulatory and International Policy developments

Commission Considering Policy on Low Level Presence (LLP) of Unapproved EU Biotech Events

In April 2007, the EU's policy, which allowed a 0.5 percent threshold for genetically engineered material not yet authorized by the EU, but had received a favorable EU scientific assessment, expired. At the time this policy was created, EU policy makers assumed that by the year 2007 the approval process would be functioning in a timely manner. However, that did not occur. Since 2007, there have been instances where agricultural commodities have been recalled, which would not have occurred if the previous policy was still in existence. As a result, the European Commission is considering a new policy regarding the low level presence (LLP) of EU-unapproved biotech events in feed and foodstuffs. This is necessary because the EU livestock feed industry is under constant threat of losing access to the world market for oilseeds and protein. The problem is likely to intensify in coming years as more countries develop and commercialize agricultural biotech events.

Industry and Commission sources indicate that the presence of an EU un-approved biotech event up to a limit of 0.1 percent could possibly be allowed. Some sources also indicate, and the Commission's Services intend, that such a 'technical' solution would not require an amendment of the governing legislation.

So far no formal decision has been made. There are likely to still be requirements regarding the coverage of such a new policy. These include that the EU un-approved event would have to have already been notified to EFSA, and that it would only apply to feed, not food.

Pressure to Allow National Cultivation Bans

The opposition to cultivation of GE crops in many regions of the EU has led to the Netherlands and Austria to make a case for Member States to legitimately opt in or opt out of GE crop cultivation. More precisely, Austria has generated a paper, which asserts that relevant socio-economic aspects could form the basis for individual Member States to prohibit or regulate the cultivation of GMOs on the whole, or certain defined areas, of individual Member States. The principles of subsidiarity and unanimity for decisions on land use (Articles 5 and 175 respectively of the Treaty Establishing the European Community) were invoked as legal justification. During the discussions of the paper at the Environment Council meeting of June 25, 2009, the Commission was urged to put forward a proposal based on the paper. Twelve Member States (including the Netherlands) backed the paper. The Austrian paper (and the Dutch position) should be viewed within the framework of the Environment Council's Conclusions of December 4, 2008. The Conclusions invited MS to collect and exchange information on socio-economic implications of deliberate releases of GMOs by January 2010, with a view to the Commission submitting a report (on the implementation of Directive 2001/18/EC on the deliberate release into the environment of GMOs) by June 2010 for further discussion. (See section "Commission to Report on Socio-Economic Criteria").

According to this concept, the current authorization process for placing on the market of biotech events for food/feed use and for cultivation should remain in place. The Member State would gain the flexibility to

decide for political reasons whether the cultivation of biotech crops will be temporarily or permanently banned in parts of or across its complete territory. In particular, socio-economic criteria are likely to play an influential role in a Member State's decision making process.

While this idea has received significant attention from some MS, other MS are concerned about the precedent this would establish for other "renationalization" decisions. In addition, there would be significant questions regarding this type of policy and its conformity with the EU's obligations under the WTO Sanitary and Phytosanitary Agreement. Further discussions are expected on this topic later in 2009 and in 2010.

Commission 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 on the deliberate release into the environment of genetically modified organisms. The report will include an assessment of socio-economic implications of deliberate releases of agricultural biotech events. MS are to collect, exchange, and submit information on socio-economic implications prior to January 2010. The Commission will submit a report by June 2010 for further discussion. Below are the key conclusions:

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

The Netherlands will host a MS meeting at the end of November in the Hague to develop EU-wide consensus on the role of socio-economic factors. In addition to MS, the Dutch will invite third countries, such as China and some Latin American nations, to speak on their experiences with GMO crops.

Consideration of Socio-Economic Criteria by Member States	
Member States	Approach of Socio-Economic Criteria
Austria	The Austrian Government is in favor of including socio-economic criteria. Small scale, environmental-friendly, and organic agriculture are likely to play an important role in the Austrian position.
Belgium	The Belgian Government is preparing its point of view regarding the socio-economic criteria. They will lead the discussions during their Presidency beginning in July 2010 .
Bulgaria	So far the Bulgarian Government has not expressed any official position on this issue due to upcoming elections. It was expected that the socio-economic criteria would be highly politicized and current officials prefer to leave this issue to the next government which will likely be in place in late July/August.
Czech Republic	The Czech Republic is against including the socio-economic criteria in the decision-making process on GE products, because it would significantly weaken the position of science in the decision-making process.
Finland	The Finnish government is in favor of including socioeconomic criteria in the approval process and believes that it would be useful. It is, however, concerned about practical issues in implementing these criteria.
France	<p>In December 2008, EU Environment Ministers unanimously-adopted conclusions recognizing the importance of appraising socio-economic benefits and risks, pointing out that the Commission is 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, and inviting MS to collect and exchange information on socio-economic implications by January 2010 with a view to the Commission submitting a report by June 2010 for further discussion in the Council and the Parliament.</p> <p>New French Biotech Authority has a Socio-Economic Wing: On April 22, 2009, the French Minister for Ecology announced the formation of the new High Council for Biotechnology (HCB) to evaluate environment and public health risks and benefits on a wide range of biotech products and advise the Government of France (GOF). HCB has a unique dual assessment component composed of two committees, one focusing on scientific elements and the other on economic, ethical, and social issues. The previous authority, composed solely of scientists, was disbanded by the GOF in lieu of a process that gives social stakeholders a voice. One of the GOF's top priorities for this committee is to recommend that a similar structure for biotech evaluation be adopted at the EU level.</p>
Germany	German politicians are split on the role of socio-economic criteria in the approval of biotech events for environmental release. The Minister of Research is a supporter of research and application of modern scientific knowledge in plant breeding. In contrast, the Minister of Agriculture and the Minister for the Environment have repeatedly stated that the currently approved biotech events do not provide benefits to the consumers and to German farmers. These latter ministers have frequently cited private opinion poll results indicating that about 70 to 80 percent of the German population opposes the cultivation of biotech crops.
Hungary	The Government of Hungary (GOH) supports the proposal to consider socio-economic effects of agricultural biotechnology when evaluating approvals.
Italy	The Italian government has not expressed , thus far, any official position on this issue and seems reluctant to weaken the role of EFSA, despite the pressure from anti-biotech groups.
Netherlands	The Dutch Government supports the use of socio-economic criteria for the approval of producing GE products. As such, national regulations should be conclusive, applying socio-economic criteria. Productivity and sustainability of the variety are mentioned as the main criteria. For the import of GE products, the current EU harmonized regulations should apply. According the Dutch Government, the discussion about the use of such importing

	criteria should be held on an international level.
Poland	Socio-economic criteria are mostly studied by representatives of the Polish University faculty and some scientists. Limited attention to this issue is placed by the Committee on biotechnology , an advisory body to the Minister of Environment, which concentrates mostly on environmental aspects of the technology. Political parties use this resource only when they can obtain results that can justify “anti-GMO” campaigns.
Portugal	Portugal has not, yet, expressed an official position. Portugal would support a review of the current legislation.
Romania	There is no official decision at the government level on the opportunity of introducing socio-economic implications in the assessment of new biotech varieties. Some of the players disagree with this initiative considering that the approval process would be prolonged and that these criteria have a relatively low degree of relevance, weakening the role of science.
Slovakia	Slovakia has not expressed an official position on this issue yet. Ministry contacts say that this issue in Slovakia has been highly political.
Spain	Spain’s Government has not expressed any official position on this issue, but according to sources, Spain is not interested in including socioeconomic criteria in the approval process.
Sweden	The Swedish government is hesitant to start a process to develop new criteria in the risk assessments of GE products, mainly because of possible trade implications. It believes that new criteria should be implemented using current regulations.
United Kingdom	The UK government does not have a firm position on this. The European Commission is due to send out a questionnaire to all EU Member States to get their views on the matter, and the UK will develop and release its position in response to that.

Reauthorization of MON810 Maize Initiated

MON 810 maize, the only biotech event currently authorized in the EU-27 for cultivation under Directive 2001/18, is under consideration for reauthorization by EU authorities. This is required after ten years. The event remains approved until the reauthorization process is finalized. In June 2009, EFSA adopted its supportive scientific opinion on MON 810. **“The EFSA GMO panel considers that the information available for maize MON 810 addresses the scientific comments raised by Member States and that maize MON 810 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 MON 810 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.”**

The EFSA opinion was the first step of many in the process to obtain the approval to reauthorize MON 810, which, as indicated in the above Regulatory Framework paragraph, MS would then vote on at the regulatory committee, and at the EU Council, which are both unlikely to approve or reject it by qualified majority. As often in votes on biotech products, the European Commission is likely to be the final decision maker. It is important to note that in its evaluation process, EFSA reviewed all the available studies on MON 810 including those used by the different MS that have implemented national cultivation bans. The final decision is not expected before the end of 2009, and will depend on a number of political factors including the

composition and agenda of the new European Commission, to be reappointed in late 2009. However, until a final decision is adopted, it is unclear what action the European Commission will take against the existing bans in France, Germany, Austria, Hungary, Greece and Luxembourg.

US-EU WTO Dispute

The EU regulatory approach to biotechnology has had a significant impact on U.S. exports to the EU. 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. 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 GE 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 availability and prices of protein-rich feed ingredients.

III - Member States Policy Varies Greatly

Individual Situations

Member State	Situation
Austria	<p>Austria remains one of the leading forces within the EU 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 non-governmental organizations' (NGO') 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.</p> <p>Since their inception, the Austrian Government has successfully defended its national bans on EU-approved biotech crops because the European Commission proposals to require their removal were blocked by the Council of the European Union. 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 issued two new ordinances in July 2008 to ban the import of MON 863 corn and three oilseed rape lines, Ms8, Rf3 and Ms8xRf3. The import ban on oilseed rape GT 73 which was issued in 2006 has been extended until the end of 2010. A further Commission attempt to lift those import bans was rejected by MS in February 2009.</p>

<p>The Benelux</p>	<p>In 2008, the Benelux region imported approximately US\$ 2.6 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 GE 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). Exports of U.S. food products such as rice and processed products have also been denied access into the region.</p>
<p>Bulgaria</p>	<p>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 2008, 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 2008. The amendment was subject to discussions in the fall of 2008 and was finally voted positively by the Agricultural Commission in the Parliament in February 2009. The Environmental Commission in the Parliament discussed the same amendment in May 2009 and voted negatively. Thus, the amendment will not be considered in the current Parliament due to upcoming elections in July 2009. In the meantime, the EC started infringement procedure against Bulgaria under 90/219/EC.</p>
<p>Czech Republic</p>	<p>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 over 8,000 hectares (ha) in 2008. In 2009, Czech farmers planted 7,000 ha of Bt corn due mainly to the credit crunch – farmers choose less expensive seeds or farm seeds and less expensive inputs in general.</p> <p>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 GE 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 GE crop as a buffer zone).</p> <p>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.</p> <p>In the first half of 2009, the Czech Republic held the Presidency of the EU. During their presidency, Czechs remained rather silent about the issue of biotechnology, since it was a highly politicized topic and its highlighting usually leads to rather controversial outcomes.</p> <p>As a consequence of recent policy developments and the unfavorable situation in the EU towards GE products, Czech scientists prepared a White Paper on Biotechnology that will probably be presented in Summer 2009. The aim of this initiative is to emphasize the importance of the science and rationally based decision-making process for GE products</p>

	approvals in the EU.
Finland	<p>The Finnish government's views on agricultural biotechnology are, to a large extent, based on science. Finland has voted positively on almost all applications since the restart of the approval process in 2004 and is considered to be one of the 'GE-positive' member states within the EU. In the past couple of years, however, the political influence in biotech policy issues seems to have increased. For example, the Finnish government is advocating labeling of GE-free products and is also very positive to give member-states the right to decide on national GE-free regions.</p> <p>There is no commercial production of biotech crops in Finland. 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.</p>
France	<p>Prior to 2008, France was the second largest producer of biotech corn in the EU, with 22,000 ha in 2007. 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: MON 810 production was banned in January 2008, and 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. Formed in April 2009, the new biotech authority has a unique dual assessment component composed of two committees, one focusing on scientific elements and the other on economic, ethical, and social issues. It will advise the GOF on risk assessments methodologies for the environment and public health in a wide range of biotech issues, including GE products, genetic therapy studies, and use of veterinary drugs derived from biotechnology.</p> <p>Defining non-biotech: The new French biotech authority's first priority is to work and provide recommendations to the GOF on non-biotech definition and labeling. This recommendation, expected in 2009, will be based on the advisory body National Council for Consumption (CNC) report released in May 2009 recommending two types of non-biotech labeling: one based on the detection threshold and the other for animal products derived from animals fed on less than 0.9 percent biotech feed.</p> <p>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.</p>
Germany	<p>In the past several years, political leadership in the German Federal Ministry of Agriculture has become one of the most vocal opponents to biotechnology in the EU. This led to a cultivation ban for MON 810 corn varieties in April 2009. The cultivation ban also applies to coexistence research projects for MON 810. This ban generated a very heated discussion between groups of leading German scientists and politicians. It also revealed disputes within individual political parties proving that the difference of opinion about agricultural biotechnology is not along party lines in Germany. The outcome of the federal elections in September 2009 offers the opportunity to revisit Germany's positioning on plant biotechnology.</p>

	<p>In 2007, the 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. In addition, several Laender (states) in Germany require separation distances of 800 to 1,000 meters for biotech corn to nature reserves. As part of the public field registry, farmers must report the exact location of their biotech crop fields. Farmers have to inform all neighbors about their intention to cultivate biotech corn. This includes the owners of forest land. As a general good agricultural practice, German rules do not allow planting of conventional corn after biotech corn for one year.</p> <p>Despite a high level of public and media opposition against biotech crops, increasing number of German farmers have expressed interest and registered fields for the planting of Bt corn. In 2008, farmers planted 3,171 hectares to MON 810 corn varieties, up almost 500 hectares from 2007. Until the announcement of the cultivation ban in late April 2009, farmers had registered about 3,500 hectares.</p> <p>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 have tried to eradicate the pest through conventional methods such as chemical seed treatment and crop rotation requirements but they were unsuccessful. Biotech corn varieties controlling the pest are not available to farmers in the EU.</p> <p>While supported by the Federal Minister of Agriculture, there is no Government-wide agreement on amending the current EU regulatory system to allow the individual member states to decide about cultivation approval for biotech crops.</p> <p>An amended biotech labeling law 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. Despite this option, there are only a handful of food processors in Germany using the new labeling scheme.</p> <p>With regard to applications for EU-approval of biotech traits for import and processing, Germany in general takes a more business friendly position. Driven by intensive educational work by the German animal feed industry and the swine producers’ organizations, Germany has so far supported the approval of 2nd generation soybean events.</p>
Hungary	<p>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, liability concerns, 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 in 2009.</p> <p>Hungary is a major seed and feed corn producer in Europe and its biotechnology legislation reflects the general thinking that the country’s current “GE-free” status is a marketing boom. 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.</p>

	<p>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. The Council of Environmental Ministers twice voted down the proposal by the European Commission to require Hungary to lift its ban. The last vote occurred on February 2009. 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 on the agenda. It is possible that the 10-year re-evaluation for MON 810 within the EU regulatory regime will affect the Hungarian moratorium.</p>
Ireland	<p>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. During this period, 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 still holds, but the difficulties of the implementation of such a policy are now being 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 GE 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 the short-term without EU approval of new events.</p> <p>There is no doubt that the cultivation and field trials of biotechnology crops under the present government will not be allowed. However, opposition to biotechnology has waned compared to the negative media-driven frenzy in the late 1990's.</p>

<p>Italy</p>	<p>Since the new Berlusconi Government was seated (May 2008), there have been no significant developments regarding biotechnology in Italy. The general attitude remains confusing, although many key Ministers have often reiterated their favorable support. Nonetheless, the Minister of Agriculture remains opposed to biotech, supported by the leading farmers' organization, Coldiretti.</p> <p>The Constitutional Court confirmed that the competence for coexistence lies in the hands of the Regions. In late 2007 a special body (State-Regions Conference) established "suggested", not mandatory, guidelines that the Regions should follow when implementing their own coexistence regulations. However, no Italian Region has so far issued any legislation on this subject, thus making it impossible to plant any biotech crop in Italy. Several appeals against this de facto moratorium have been filed with the local courts by biotech companies, as well as individual farmers willing to plant biotech corn, but with no success. Nor has progress been reached for the resumption of biotech field trials, after a hiatus of more than 10 years. The Minister of Environment approved the testing protocols last summer, but the Minister of Agriculture has not yet signed the final decree. With regard to planting seeds, Italy still applies a "zero tolerance" for adventitious GE presence. The main authority is the Ministry of Agriculture, which also controls registration of seed varieties with the National Register.</p> <p>The only partially positive development comes from the votes for the approval of new biotech events, as Italy, after many years of a negative approach, has abstained on a few occasions. This is due to pressure of Italian stakeholders, particularly in the feed industry. These groups have become more outspoken in their demand for more proactive steps on biotechnology.</p>
<p>Poland</p>	<p>Since 2006, Poland has maintained an official anti-biotech position and consistently opposed EU approval of new biotech products. It also 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 2008.</p> <p>In July 2008, the Senate (Upper House of the Polish Parliament) voted to delay introduction of a ban on biotech feed until December 31, 2012. Many industry associations, scientists, producers, and regional political leaders are calling for changes to biotechnology policy in Poland. Cultivation is still possible, but not the sale of seeds. There are about 3,000 ha of biotech corn in Poland. EU officials have determined these bans are inconsistent with EU regulations. A new cultivation law is under preparation, but isolation distances may be set at 1 kilometer. Corn producers lose an estimated \$1.5 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.</p> <p>Opponents to the technology have never been as active in Poland as during the second part of 2008 and the beginning of 2009. Supporters of "GMO free Poland" have been writing petitions to Ministers of Agriculture and Environment and organizing demonstrations (some with hunger strikes). On May 20, 2009 the Polish Association of Corn Growers (PZPK) issued a statement in support of biotechnology.</p>
<p>Portugal</p>	<p>Total acreage for biotech corn in Portugal for 2009 is expected to reach about 5,000 hectares – representing a 6-percent increase over 2008.</p> <p>Portugal was one of the first EU Member States to implement all EU regulations regarding "GMOs". In 2005, Portugal implemented a coexistence regulation and established rules for</p>

	<p>declaring biotechnology-free zones. A coexistence compliance monitoring report following the first year of implementation indicated that required buffer zones kept adventitious presence in surrounding corn crops well below the 0.9 percent threshold required to claim biotechnology-free status.</p> <p>The fact that rootworm is a problem only in certain areas of Portugal limits the area planted to MON 810 corn. Consequently, Portuguese farmers are interested in the potential of other biotech crops with properties such as herbicide tolerance.</p>
Romania	<p>Romania continues to be part of the EU group using biotech seeds for commercial use. In 2008, Romanian farmers planted biotech corn for commercial purposes on 7,146 hectares, up from 331 hectares in 2007. Nevertheless, the cultivated area is expected to decline to less than half (3,400 ha) in 2009, as a result of several factors, such as difficulties in selling the harvest at competitive price, specific requirements for separate storage, and the price of seeds. On the other hand, the amount of biotech seeds subject to field testing increased significantly in 2009, as did the research area.</p> <p>In 2008, the Ministry of Environment invoked the Safeguard Clause option provided by Directive 2001/18 and requested the newly established Biosafety Commission to conduct a risk-assessment on MON 810 corn. The Biosafety Commission conducted a risk assessment and reviewed the scientific papers published regarding the above transformation event, and issued a favorable decision for MON 810.</p>
Slovakia	<p>Slovak farmers started growing Bt corn in 2006 on 30 hectares. The acreage has been gradually growing, reaching almost 2,000 hectares in 2008. Slovakia has fully implemented all EU regulations on biotechnology. The decree administering coexistence came into force in February 2007.</p> <p>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, 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, keep a record of used genetic techniques, and keep a register of the facilities including the records of users of biotechnologies or GE products, safety committees and heads of the projects.</p> <p>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, and 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).</p> <p>In 2009 Slovak farmers planted less than half of the Bt corn acreage compared to previous year. The reason has not only been the credit crunch situation but also problems with selling the GE crop to processors. Even though the Bt corn would serve better as a raw material for many processors, they refuse it because of the additional costs and administrative procedures that are connected to its labeling and separation from a conventional product. Biotechnology in Slovakia has been a political issue. In general, Slovakia applies a case-by-case approach. Slovak authorities, farmers and consumers face pressure by NGOs that have lead anti-biotech campaigns.</p>
Slovenia	<p>In Slovenia, agricultural biotechnology is confined to laboratories and to production</p>

	<p>facilities. So far, there have been no 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.</p> <p>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 <u>Ministry of Health</u> and the <u>Ministry of Agriculture, Forestry and Food</u> regulate <u>medicinal products</u> 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.</p>
Spain	<p>As the biotechnology “powerhouse” of Europe, Spain grows about 80 percent of all MON 810 corn sown within the EU-27. Strong support for biotech corn is a reflection of Spain’s high domestic demand for livestock feed. Spain is the EU’s number two pork producer and number one corn importer.</p> <p>Bt corn has been commercially grown in Spain since 1998 -- the longest practical experience in cultivating biotech events in the EU. Biotech corn plantings increased significantly in marketing year 2007, while total corn planted increased only slightly. In 2008, MON 810 corn area increased at a pace of 5%. For 2009, a slight decrease in acreage is expected – reflecting the general decline in area planted to cereals. Lower cereal prices during the sowing season made feed corn less interesting than other crops.</p> <p>While Spanish farmers in regions with known corn borer infestations have increasingly planted Bt corn, corn farmers in regions where infestations are more inconsistent are also turning to MON 810 varieties as a means of minimizing risk, increasing productivity and quality, reducing their environmental footprint, and maximizing profit. Bt corn planted and harvested in Spain is utilized exclusively for the production of domestic compound feed and is labeled as containing “genetically modified organisms.”</p> <p>When voting on biotech issues, Spain has historically based its decisions on science. There are two institutions which weigh-in on Spain’s biotechnology decision-making process: the National Biosecurity Commission focuses on the scientific side while the Inter-ministerial Council, composed of representatives from relevant Ministries, takes a technical approach.</p> <p>The debate continues on a Government of Spain (GOS) coexistence decree, the first draft of which was made public in 2004. Nevertheless, Spanish farmers continue to grow biotech corn without any 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 coexistence decree becomes increasingly more difficult. However, the situation is different at the regional level.</p> <p>The Basque Parliament, one of 17 regional parliaments in Spain, passed a stringent biotech coexistence regulation in April 2009, which could force farmers to halt planting of MON 810. The Basque Country, together with the Canary Islands and Asturias, are regions which have declared themselves GMO-free. Since there is no Bt corn planted in these regions, these declarations have not affected total plantings of MON 810 in Spain. However, on February 5, 2009, an initiative was proposed within the Catalonia Regional Parliament to also declare that region “GM-free”. About 30 percent of Spain’s MON 810 corn is grown in Catalonia.</p>

<p>Sweden</p>	<p>The Government of Sweden is positive but cautious towards GE food, feed and crops. At the EU level, Sweden often plays a mediator role in helping Member States come to consensus on GE legislation and approvals. Sweden has voted positively on almost all applications since the restart of the approval process in 2004. The major issues concerning agricultural biotechnology in Sweden today are related to the environment. The general view within the scientific community is that the health issue is no longer of major concern. 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 analysis.</p> <p>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. 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.</p>
<p>United Kingdom</p>	<p>The UK government is one of the strongest advocates of agricultural biotechnology in the European Union. Over the last year, the UK government has consistently stated that there is a need to consider the possibilities offered by agricultural biotechnology for helping to tackle some of the challenges of food security and agricultural stresses caused by climate change. In the EU approval process, the UK continues to vote on the basis of scientific evidence on a case-by-case basis.</p> <p>Despite this relatively positive political climate, there is no commercial production of biotech crops in the UK. The varieties that are currently approved for cultivation within the EU are not suited to the growing conditions in the UK. As far as research and development of relevant applications goes, the UK undertakes fairly extensive laboratory-based research into agricultural biotechnology. However, much of this work flounders at the development stage as the locations of field trials are publicly available and have previously been prone to vandalism. In the absence of imminent commercial production, the UK has not formalized its co-existence measures, but it has undertaken extensive consultation and research in this area.</p> <p>Devolved governments in Northern Ireland, Scotland, and Wales have some jurisdiction over agriculture, fisheries, and food policy in their region. Scotland and Wales are countries with a high proportion of Less Favored Areas under EU definitions and they trade heavily on their 'pristine environment' image. Currently, the political leadership of Scotland and Wales is seeking the most restrictive policies possible on agricultural biotechnology, including the set up of "GM-free zones". Similarly, Northern Ireland joined forces with the Republic of Ireland to call for Ireland to become a "GM-free zone" in September 2008. These political leaders take the position that there is a risk of damage to the reputation of produce from Scotland, Wales and Ireland by growing biotech crops that outweighs any benefits that agricultural biotechnology might bring.</p> <p>At least 70 percent of soybean meal utilized in UK poultry and red meat production is thought to be biotech in origin. However, there is a large market for non-biotech fed animals for private-label poultry and pork in major supermarket chains. This is reported to be rapidly becoming less economically viable as the price and the pressure on availability of non-biotech animal feed increases. The UK's Department for Environment, Food and Rural Affairs will release a report</p>

	<p>late in 2009 that analyzes the economics of animal feed and the affect that asynchronous and slow approvals by the EU will have on the livestock sector.</p> <p>Consumer attitudes on food issues tend to mirror the mainstream media reporting of the day. Biotech has slipped in importance and the fewer negative column inches devoted to it recently is a reflection of that. When stirred, basic consumer skepticism about the technology continues. However, despite reported distrust of politicians' views on food issues, it is interesting to note that a survey by the Institute of Grocery Distribution in 2008 reported statistics that seemed to indicate that the positive statements made by national politicians over the last year have gained some traction. In this survey, a sizeable proportion of consumers agreed that using genetic engineering could help to protect crops against disease and extreme weather (47 percent), and have a role to play in improving output to feed a growing world population (52 percent).</p>
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Source: FAS Posts

Implementation of EU Policy and National Coexistence Rules

Virtually all MS have transcribed EU Directive 2001/18 and implemented EU regulations on traceability and labeling. Some MS or 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, the United Kingdom).

Member States Policy

Member State	National Competent/ Relevant Authorities	Implementation of EU policy	National Coexistence rules
Austria	Federal Ministry of Health	Austria has fully implemented EU regulations on biotechnology Biotech food and feed	The European 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. In July 2008, Austria issued new import bans on corn MON 863 and three oilseed rape lines Ms8, Rf3 and Ms8xRf3. The import ban on oilseed rape GT73 issued in 2006 has been renewed. A further attempt to lift those import bans was rejected by a February 2009 European Council vote.
	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	GE-free 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."
Bulgaria	Ministry of Agriculture and Foods, Ministry of Environment and Waters	Bulgaria has a GMO Act passed in 2004 which is not fully	The GMO Act establishes certain isolation distances between crops but they can not be applied due to the general restriction for

	and Ministry of Health Care	harmonized with the EU legislation. It is more restrictive than the EU directives. The requirement for a 30km separation zone makes any planting impossible. In mid-2009, EC started an infringement procedure against Bulgaria under 90/219	30 km separation zones.
Belgium	Federal Government Department for Health, Food Chain Safety and Environment	2001/18 implemented in 2005	<p>-The two Belgian Regions, Flanders and Wallonia, are responsible for formulating and implementing a coexistence policy.</p> <p>-In March 2007, the Flemish Government decided upon a framework for the coexistence regulations, enforced in May 2009. The regulations reportedly guarantee free choice for the farmer to plant GE crops, and include a liability fund. The conditions for compensation are not yet agreed upon. The border zone for corn is 200 meters.</p> <p>-In February 2006, the Walloon Government approved coexistence regulations, enforced in August 2008.</p> <p>-According to the Walloon Government, the regulations on cultivating GE crops 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 GE crops. The "GMO-free" zone is not yet defined, but is expected to be 300-600 meters for corn. Sector sources believe that the combination of restrictions will practically ban the cultivation of GE crops in Wallonia.</p>
Czech Republic	Ministry of Agriculture	Transposition of the 2001/18 in 2004 in Act no. 78/2004 (Act 441/2005 amending the Act on Agriculture and Decree 89/2006 on more detailed requirements for cultivation of genetically modified variety)	<p>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 GE crop as a buffer zone).</p> <p>No genetech-free zones managed by the decree.</p> <p>No constraint for biotech crops with regard to nature conservation districts.</p> <p>There is a new decree prepared that will simplify administrative procedures related to GE crop growing. The decree is waiting</p>

			for approval and will not affect farmers in 2009.
Czech Republic (continued)	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	
Finland	Finnish National Food Administration (EVIRA), under the Ministry of Agriculture and Forestry	Finland has fully implemented EU biotech regulations.	The Finnish government has prepared a proposal for national regulations on coexistence but it has not yet been proposed to the Finnish Parliament. Expectations are that national legislation will be implemented this fall, but might be postponed further.
France	French Ministries of Environment and Agriculture	France transposed EU Directive 2001/18 in the biotech bill adopted in Spring 2008	The 2008 biotech bill created 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 French Minister of Ecology announced the formation of the new biotech authority (High Biotech Council - HCB) on April 22, 2009. Coexistence does not make the HCB's priority list, suggesting biotech cultivation in France (which is effectively banned) is not likely in the near term.
France (continued)	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 German Federal Ministry of Food, Agriculture and Consumer Protection	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. Several German Laender (states) implemented specific distance requirements for GE corn neighboring nature protection areas of 800 meters or 1000 meters. 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/bundeslandStatistic.do?year=2008

			GE-free zones have been established in many German regions. Their numbers are growing. 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.
		German Genetech-Free Labeling Law, last amended 2008	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.
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 EFET is in charge of enforcement in cooperation with GOG Ministry of Agriculture	The European Commission adopted a decision ordering Greece to lift the safeguard clause 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, the Greek Government prevents the planting of EU approved biotech crops. The whole country is a "GMO-free" 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 wide 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 GE	

		insect resistant corn (MON 810) by invocation of safeguard clause, on January 18 2005.	
	Ministry of Agriculture (together with other Ministries such as M. of Environment, Economy, Health)	Several Orders (application rules) setting the role of lower level institutions, fees and fines etc. concerning the enforcement of above Acts	
Ireland	Department of Agriculture, Fisheries and Food	SI 424 (2004): transposes the Feedstuffs elements of the EU Regulations	
	Department of Health and Children	In relation to the food elements of the regulations	Has not yet transposed the elements of EU legislation in relation to food
	Department of the Environment and Local Government	Directive 2001/18 transposed in SI500/2003 on the deliberate release. Directive 90/219 transposed in SI73 (2001) on containment	
Italy	Regions for coexistence		Although the guidelines for coexistence have been approved by a special State/Regions body in late 2007, no coexistence regulations have yet been issued by any of the 20 Italian regions. As a result, a de facto moratorium on GE crop planting continues to exist.
	Ministry of Environment is responsible for the approval of new events for planting, while the approval of new events for imports are under the authority of the Ministry of Health. The Ministry of Agriculture, also has a major role, as in both cases, the approval process includes discussions among the involved Ministries.	2001/18 was implemented in 2003	
	Ministry of Health	Food & Feed, Labeling and Traceability	
Netherlands	-Ministry of Public Health, Welfare and Sport	-2001/18 implemented in 2003	-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.
	-Ministry of Housing, Regional Planning and	-1829/2003 and 1830/2003 are by EC	

	Environment -Ministry of Agriculture, Nature and Food Quality	law directly enforced in entire EU	- 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 (meters): <table border="1"><thead><tr><th></th><th colspan="2">The Netherlands</th></tr><tr><th></th><th>C</th><th>O</th></tr></thead><tbody><tr><th>Potato</th><td>3</td><td>10</td></tr><tr><th>Sugar beet</th><td>1.5</td><td>3</td></tr><tr><th>Maize</th><td>25</td><td>250</td></tr></tbody></table> C = distance from conventional production O = distance from organic production		The Netherlands			C	O	Potato	3	10	Sugar beet	1.5	3	Maize	25	250
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Sugar beet	1.5	3																
Maize	25	250																
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. In December 2008, Poland submitted the proposed regulation to European Commission for approval. The regulation included the possibility to create “GMO-free” zones, contradicting general EU regulations, and proposing restrictions that could prevent planting GMO crops in many parts of Poland. In March 2009, the European Commission returned the draft requesting changes. Work is currently in progress and the Polish Government is expected to complete work on the new regulation by the end of 2009.															
Portugal	Environment Ministry/ Ministry of Agriculture	Transposition of the 2001/18 in 2003 by decree-law 72/2003.	The GOP published a coexistence decree in September 2005 (decree-law 160/2005). 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, Forests and Rural Development; National Veterinary and Food Safety Authority; Ministry of Public Health; National Guard for Environment.	<ul style="list-style-type: none"> - <u>Directive 2001/18</u> transposed through Emergency Ordinance 43/2007 (June 2007) - <u>Directive 90/219</u> transposed through Emergency Ordinance 44/2007 (June 2007) - Regulation 1829/2003 transposed through Government Decision 256/2006 (Feb 2006) - Regulation 1830/2003 transposed through Government Decision 173/2006 (Feb 2006) - Biosafety Commission (Since April 2008) - Emergency Ordinance 164/2008 for environment protection modifying Ordinance 195/2005 approved through Law 265/2006 	<ul style="list-style-type: none"> - According to national regulations issued by the Ministry 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 commingling GE seed with organic or conventional seeds through separate storage. - It is mandatory that biotech farmers notify in writing, both land owners and land users of nearby plots, about their intention to cultivate biotech plants. - According to Emergency Ordinance (EO) 164/2008, any activity for obtaining, planting, storing, processing and trading “genetically modified organisms” inside natural protected areas is prohibited. This is an extension of the previous provision which stated “planting and testing”. Amendments on EO 164/2008 are expected. - In 2009, the legislation on seeds certification was changed to establish thresholds for “GMO-free” seeds. These are 0.3% on laboratory testing in the case of cross-pollinated varieties and hybrids (syngamy), and 0.5% in the case of self- pollinated varieties (autogamy); seeds with GM content exceeding these thresholds will not be certified as GMO-free.
Slovakia	Ministry of Environment	<ul style="list-style-type: none"> -Act on the Use of Genetic Techniques and Genetically Modified Organisms (Act on GMOs) no. 151/2002 from April 1, 2002, amended by the Act no. 77/2005 and recently amended by the Act no. 100/2008. Decree no. 399/2005 administering the Act on GMOs (contained use etc.) was recently amended by the Decree no. 312/2008 	<p>The new amendments to the Act and Decree on “GMOs” mainly simplify the administrative procedure of registration for contained use of “GMOs”.</p> <p>The Ministry of Environment has been also preparing a document National Policy on Biosafety (formerly known as the National Biosafety Strategy). The document is expected to be finished in September 2009.</p>
	Ministry of Agriculture	Act no.184/2006 on	The minimum isolation distances for

		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 GE crops	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 Rural, Environmental and Marine Affairs /Autonomous Regions Authorities	Transposition of 2001/18 (by National Law 9/2003 – 25, April 2003)	The first draft of national coexistence legislation was made public in 2004. No developments have occurred at the national level so far as the GOS would prefer coexistence legislation at the EU level. At the regional level, the Basque Parliament passed stringent biotech coexistence regulation, which would likely force farmers to halt planting of MON 810 due to strict compliance issues. As the Basque region does not grow Bt corn, this is would not negatively impact MON 810 plantings.
Spain (continued)	Health and Consumer Affairs Ministry	Monitors and enforces labeling requirement compliance	
Sweden	Swedish Board of Agriculture (feed and seed) and the National Food Administration (food), both under the Ministry of Agriculture	EU policy is fully implemented in Swedish national legislation.	The Swedish government adopted its framework for coexistence measures in May 2007. In June 2008, detailed rules were decided: - Farmers who plan to cultivate GE crops must notify owners/users of neighboring land, one year before planting, at the latest. - Farmers must notify authorities within two weeks after planting. Registration fee SEK 200 (EURO 22). - Distance requirements: Corn 50 meters, potato 3 meters. Shorter distances are allowed if agreed between the parties. - Detailed rules only include potato and corn, since these are the GE crops in question for possible cultivation in Sweden

			in coming few years.
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 has not finalized the UK national policy. The devolved governments of Northern Ireland, Scotland and Wales are exploring setting their own co-existence requirements.
	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).	
United Kingdom (continued)	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).	

Source: FAS Posts

Member State Bans on Biotech Events

During the past twelve years several EU MS invoked national safeguard measures (Directive 2001/18/EC, Art. 23) in order to ban the marketing or cultivation of certain biotech events. 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.

Country	Event Banned	Scope	Date of Ban
Austria	Syngenta Bt176 corn,	Cultivation	1997 (Amended
	Bayer T25 corn,	Cultivation	2008)
	Monsanto MON 810 corn	Cultivation	2000 (Amended
	Monsanto GT73 rapeseed	Import/Processing	2008)
	Monsanto MON 863 corn	Import/Processing	1999 (Amended
	Bayer Ms8 rapeseed	Import/Processing	2008)
	Bayer Rf3 rapeseed	Import/Processing	2007 (Amended
	Bayer Ms8XRf3 rapeseed	Import/Processing	2008)
France	Bayer Rapeseed Topas	Import/Processing	1998
	19/2	Import/Processing	1998
	Bayer MS1XRf1 rapeseed	Cultivation	2008
Germany	Syngenta Bt176 corn	Cultivation	2000
	Monsanto MON 810 corn	Cultivation	2009
Greece	Bayer Rapeseed Topas	Import/Processing	1998
	19/2	Cultivation	1997
	Syngenta Bt176 corn	Cultivation	2001
	Monsanto MON 810 corn	Import/Processing	1997
	Bayer T25 corn	Import/Processing	1998
Luxembourg	Bayer MS1XRf1 rapeseed		
	Syngenta Bt176 corn	Cultivation	1997
Hungary	Monsanto MON 810 corn	Cultivation	2009
		Cultivation	2005

Status of Biotech Events no Longer in Commercial Use

In March 2007, the EU withdrew the approval 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.

The Commission decisions on withdrawal lay down that the presence of material which contains, consists of or is produced from the withdrawn events shall be tolerated until five years after the date of notification provided that this material is adventitious or technically unavoidable and in a proportion no higher than 0.9

percent. After April 25, 2012, adventitious presence of traces of the withdrawn events is no longer permitted.

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

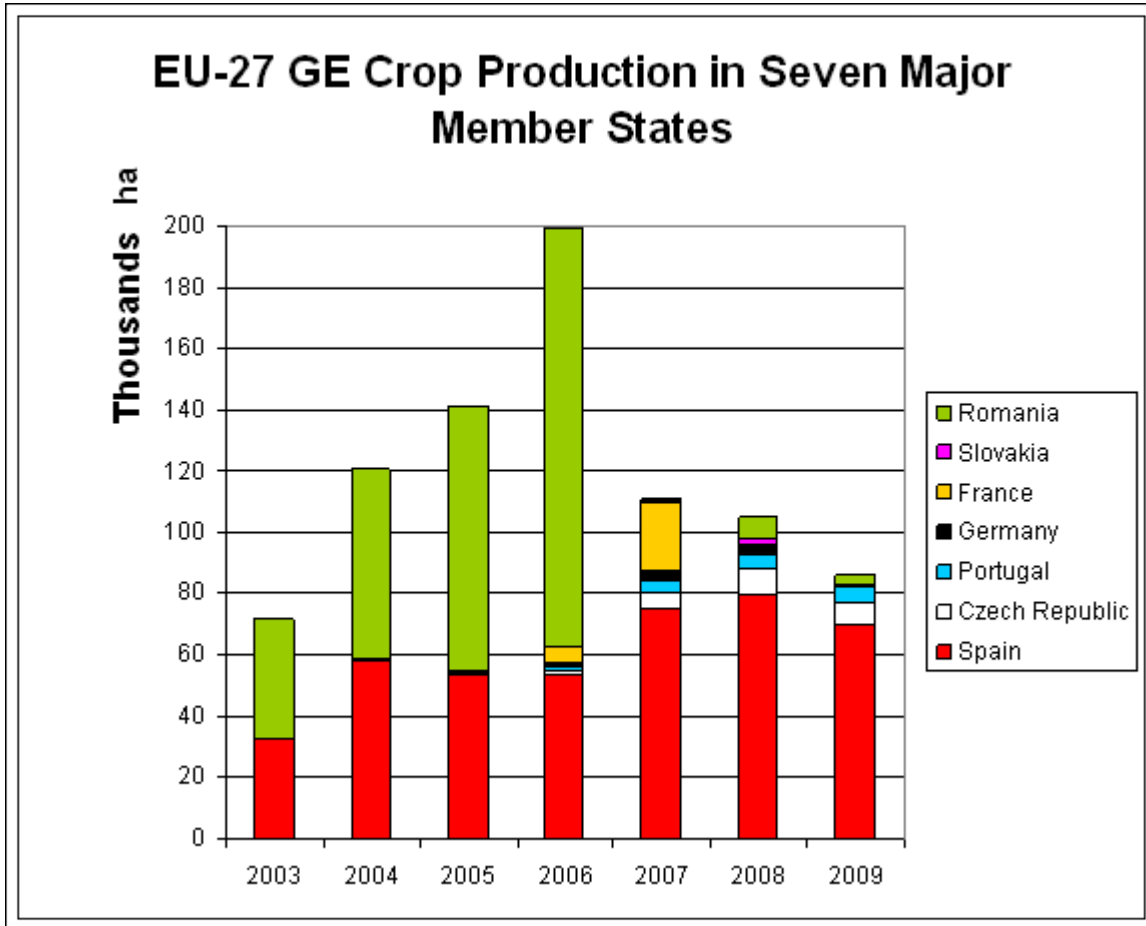
IV - Biotechnology Production, Trade and Research

Market Conditions and National Bans Affect EU Biotech Corn Area

Since the approval of the first biotech corn event for planting in the EU, Spain has been the EU 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 EU farming groups in the use of agricultural biotechnology remains stable, particularly as the cost of inputs is increasing. This has made the yield benefits and cost saving especially attractive. In contrast, MS' cultivation bans and stringent coexistence measures restrict farmers in most MS from taking advantage of the modern seed varieties. Many growers are constrained by restrictions placed in land rental contracts, threats by neighbors, and intimidation by NGOs.

In 2009, EU farmers reduced overall area planted to corn (both conventional and biotech) because of the market outlook and weather conditions. The overall impact of market conditions on corn area was far greater than the impact of the new planting ban in Germany.

EU -27 Production of GE Crops by Member State (hectares)							
Member State	2003	2004	2005	2006	2007	2008	2009
Czech Republic	0	0	250	1,290	5,000	8,380	7,000
France	17	17	500	5,200	22,135	0	0
Germany	0	500	342	947	2,685	3,171	0
Portugal	0	0	730	1,254	4,199	4,711	5,000
Romania	39,600	61,600	86,100	137,300	331	7,146	3,400
Slovakia	0	0	0	0	930	1,930	875
Spain	32,249	58,219	53,226	53,667	75,148	79,269	70,000
Total with Romania	71,866	120,336	141,148	199,658	109,498	104,961	86,275
Total without Romania	39,617	62117	87,922	62,358			



In several EU MS (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, and tends to discourage farmers from growing biotech crops.

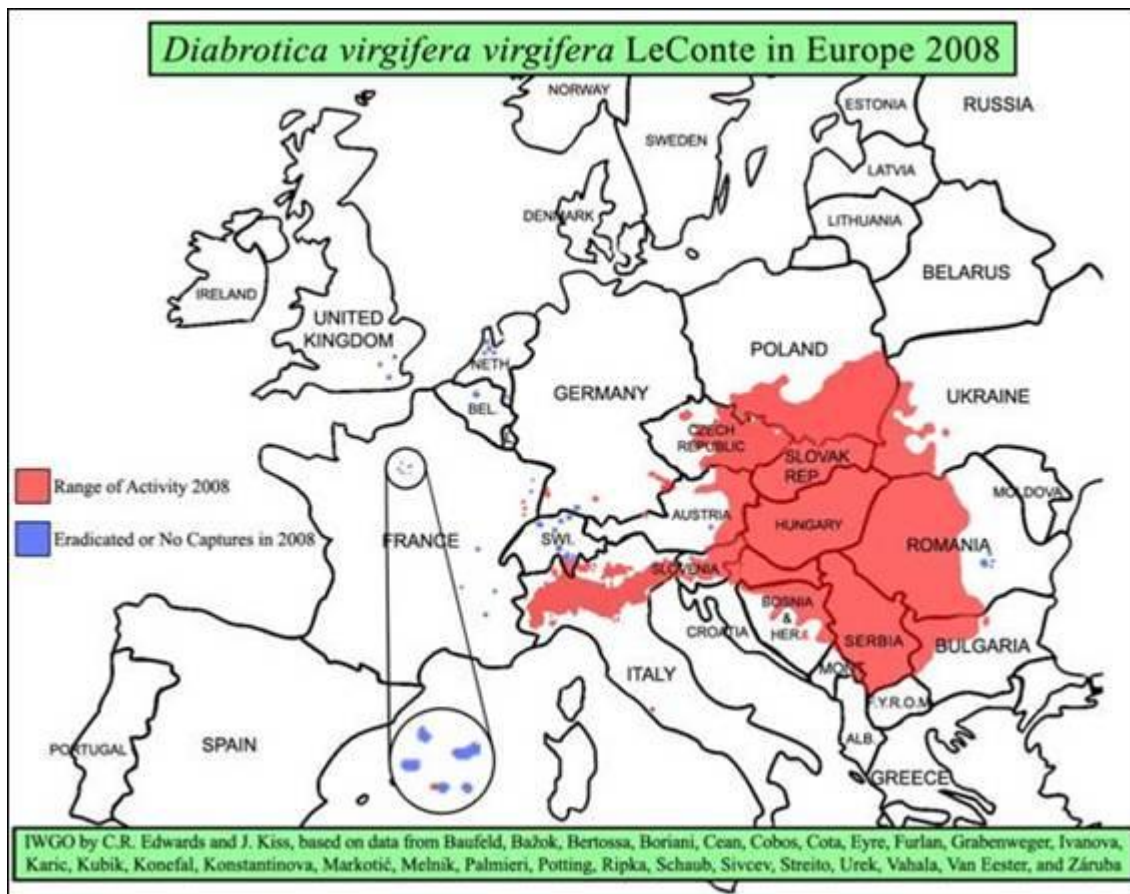
Field Register Status by EU Member State	
Member States	Field Register
Austria	An Austrian field register table theoretically exists. The Gene Technology Act 1994 (latest amendments in 2005) earmarks a gene technology register. Part III of the register includes approved field releases, whereas Part IV 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.
Belgium	In Belgium, a national field register exists and is directly accessible at: https://portal.health.fgov.be/portal/page?_pageid=56,512563&_dad=portal&_schema=PORTAL Of the commercial biotech plantings, the region of the location is reported. There are, however, no plantings of commercial biotech crops. Of field trials, the exact location is given.

Bulgaria	None
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. Registration was made compulsory in spring 2008. However, there has been no commercial plantings in France in 2008 and 2009, as a result of the national ban on MON 810 corn.
Finland	None
Germany	Farmers have to report the exact location and size of their biotech plantings to a national field register administered by the Federal Office for Consumer Protection and Food Safety (BVL), which is accessible to the general public. BVL also provides a fairly detailed map about the locations of the commercial plantings of biotech crops. The commercial planting intentions have to be reported to the field register at the latest three months prior to actual planting. http://194.95.226.237/stareg_web/bundeslandStatistic.do
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 by crop, variety and acreage on what they intend to cultivate, for each category.
Hungary	When a field release application is approved in Hungary for experimental purposes (as commercial production of biotechnology plant varieties is banned) the details of the approval are published in the Official Gazette of the Ministry of Agriculture and Rural Development. The location of the experiment is a part of the information package.
Ireland	None
Italy	No field registers are in place, due to the lack of any coexistence legislation at regional level.
Netherlands	In the Netherlands, a national field register exists and is directly accessible at: http://www.vrom.nl/ggo-vergunningverlening It provides detailed information about the location of commercial biotech crop cultivation. There are, however, no plantings of commercial biotech crops. Of field trials, the region of the location is reported.
Poland	None
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 and number of farms 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 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 GE 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 Environmental and Rural and Marine Affairs web page. No farmer or plot register is published. Of field trials, the municipality location is given.
Portugal	The localization of farms where biotech crops are produced must be registered.
Sweden	None
UK	None

Extent of Pests In the EU Controlled with GE Corn Varieties

In corn production, European farmers are confronted with intensive corn borer infestation and rapidly growing presence of the western root worm. The corn borer is not a quarantined insect and infests most of the major EU corn-producing regions south of a line from Northern France into Poland. While some farmers have adopted biotech varieties to fight this pest, most farmers continue to use crop rotation, plowing and insecticide applications.

The western root worm is a new pest to the EU since the late 1990s. So far it has been primarily found in Hungary and the surrounding areas including the Po valley region of Northern Italy. Since 2007, the root worm has also spread into Southern Germany. Primary control measures are crop rotation, seed treatment, and insecticide application. GE corn varieties controlling the root worm are currently not available to EU farmers.



Despite Politics, the EU is a major Biotech Consumer

The main biotech products used in the EU 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, undertaken under the Identity Preservation program or geographical indications, or for human consumption of soybeans (such as in baby food).

Corn and corn products (mainly **corn gluten feed**) represented the second largest category of GE products used in animal feed until 2007. 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 on soybean products. Nonetheless, EU domestically produced corn from GE varieties is consumed without issue by feed compounders.

EU Biotech Research

An EU-Wide Research Program - Coextra - is Now Completed

Coextra (www.coextra.eu) was a five-year research program, with a budget of 22 million euros funded by the European Commission, and conducted in 18 different countries inside the EU and outside the EU (Brazil, Russia and Argentina). The stated objectives of the program was to study and validate biological containment methods, forge supply chain organizations, and provide practical tools and methods for implementing co-existence between “GMO-based” and “no-GMO-based” supply chains. The conclusions of this program were presented in June 2009 in Paris. Coextra’s experimental and economic work (for example on modeling pollen flow) favored the least costly programs for coexistence and traceability. Coextra reportedly developed new strategies and detection methods for stacked genes and non-authorized biotech events.

Coextra’s conclusion paper pointed out that there is a difference between the regulatory threshold of 0.9% and the threshold used by operators: generally 0.1%. Because of this highly constraining de facto threshold, Coextra concluded that coexistence among farmers is only possible if significant attention will be put on the definition isolation distances or if certain production areas will be dedicated to GE crops. This is based on the results of the models developed in the European program SIGMEA. Coextra underlined that the

scientific, technical, and legal definitions of such dedicated production areas still need to be made and that bio-confinement methods could contribute to coexistence.

Also of interest, Coextra stated that planting seeds purity is essential to assure coexistence in the fields, and recommended the adventitious presence (AP) threshold for biotech in seeds be lower than the labeling threshold of 0.9%. Coextra concluded that the purer the seed, the lower the AP in the harvest and the easier it will be to successfully achieve coexistence in fields.

The Coextra project and results reportedly have no legal standing within the EU. However, given that coexistence provisions are currently completely regulated at the Member State level, some organizations may use the results to reintroduce this issue at the EU level.

Increasing Difficulty to Conduct Open-Field Trials

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, continuing in 2009. In addition, field trial destructions have continued with little or no response from police and judicial authorities in many areas.

Extent of Field Releases of GE Crops by Member State							
	2003	2004	2005	2006	2007	2008	2009
Austria							0
Belgium							1 plot with 448 poplars
Bulgaria							0
Czech Republic	0	0	1 plot, 624 m ² (potatoes)	5 plots 9,500 m ² (potatoes, corn)	17 plots 92,200 m ² (potatoes, corn, flax, prunus)	8 plots 13,500 m ² (potatoes, corn, flax)	15 plots 52.6 ha (potatoes, corn, prunus /plum tree/, flax, tobacco)
Finland	Since 1995, 21 field trials have been conducted in Finland, including rapeseed, oats, barley, potato, birch, carrot, cabbage, tomato, and strawberries.						
France	17 ha 56 plots (Coffee, rapeseed, grass, corn,	7 ha 48 plots (Coffee, rapeseed, grass, corn,	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.)	Marginal: a few plots of corn, poplar and vine	Marginal: a few plots of vine and poplar

	poplar, tobacco)	poplar)					
Germany	0	0	25 ha (corn, potatoes, rapeseed, peas)	8 ha (corn, potatoes, winter wheat, rapeseed, spring barley, peas)	68 ha (corn, sugarbeet, potatoes, winter wheat)	36 ha (corn) (corn, sugarbeet, potatoes, winter wheat)	29 ha (potatoes, corn, sugarbeet, winter wheat)
Greece	0						
Hungary	Corn, wheat, potato, tobacco	Corn, wheat, potato, tobacco	Wheat, corn	Corn, wheat, potato, tobacco	Corn, wheat, potato, barley	Barley, Wheat	Corn, wheat
Ireland	0						
Italy	0						
Netherlands					14 ha (apples, potatoes)	24 ha (apples, potatoes, corn)	25 ha (potato, corn)
Poland	0	0	0	100 ha	100 ha	300 ha (corn)	3000 ha (corn)
Romania	Potato, sugarbeet, corn,	Corn	Corn	Corn	Corn, Soybean, Plum tree	435 Kg seeds (corn)	704.5 kg corn seeds 45.36 kg soybean seeds 400 sqm of plum trees
Slovakia	0	0	0	0	4 plots 0.64 ha (corn)	23 plots 65 ha (corn)	3 plots 92 ha (corn)
Spain	n/a	n/a	n/a	n/a	Potatoes, cotton, orange. Various plots	Cotton, corn, sugar beet, and oranges	Potatoes, Corn, Sugar beet, oranges, Cotton
Portugal	n/a	n/a	n/a	n/a	n/a	corn	corn
Sweden		Thale cress, aspen, potato, rapeseed, sugarbeet, apple root stock	Thale cress, flax, potato, rapeseed, sugarbeet, apple root stock	Thale cress, corn, potato, rapeseed, apple root stock	Thale cress, potato, rapeseed, sugarbeet, apple root stock	Corn, potato, sugarbeet, apple- and pear root stock, rapeseed, aspen, thale cress	Corn, potato, sugarbeet, apple- and pear root stock, aspen, thale cress
United Kingdom	n/a	n/a	n/a	n/a	0.1 ha, 1 plot (potatoes)	2 ha, 1 plot (potatoes)	

Previous reports:

For specific information on biotech situations in MS, please find the following GAIN Reports at:

<http://www.fas.usda.gov/scripts/AttacheRep/default.asp>

Previous Reports Prepared by Member States			
Member State	Date	Report Number	Title
Italy	May 27, 2009	IT9014	The Unexpected potential of Organic-Biotech Production
Poland	March 11, 2009	PL9005	Problems with the draft cultivation law and Poland votes against new GMOs
Germany	March 9, 2009	GM9008	Mixed Reactions to the Aigner Warning Group on Biotech Corn Cultivation Ban
Germany	February 23, 2009	GM9007	German AgMinister Considers Cultivation Ban for MON810
France	February 17, 2009	FR9003	French Biotech Policy Measures Bogged Down
Germany	February 12, 2009	GM9005	Separation Distance to Environmentally Sensitive Areas
Germany	March 5, 2009	GM004	"Without Genetech" Food Label in Germany Misunderstood by Consumers
Greece	April 26, 2007	GR7005	Greece continues to ban GM corn for planting
Poland	January 5, 2009	PL8037	Potential Benefits to Crops
Italy	December 16, 2008	IT8041	Annual Update on Biotech Issues
UK	December 10, 2008	UK8019	Purple Tomatoes – Biotech Gets Colorful
Czech Republic	December 9, 2008	EZ8007	Moving ahead, slowly but surely
Italy	December 8, 2008	IT8039	Italy approves GM Field Trials
Poland	December 4, 2008	PL8032	Poland's Framework Position on GMO's – They say no, again.
Poland	December 3, 2008	PL8029	Update: Introduction of Feed Ban Extended ; GM Cultivation Law
Italy	November 5, 2008	IT8031	Attack on the "Anti-Cancer" Tomatoes
Germany	September 30, 2008	GM8044	"Without Genetech" Labeled Foods in the German Retail Market
Sweden	September 12, 2008	SW8009	Annual Report
Poland	August 27, 2008	PL8026	Poland Publishes New Draft Law on Cultivation
Germany	August 18, 2008	GM8033	Biotech Outreach Program for Germany
Romania	August 8, 2008	RO8011	Romanian Parliament declines the initiative of biotech labeling
Hungary	February 26, 2008	HU8001	Biotechnology Update
Hungary	February 3, 2009	HU9001	Biotechnology Update

Annexes

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

Updated information of this table is available at the following site:

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm.

Note: In the following table, products authorized since last year's report are highlighted in **orange**, while the only product authorized for seeds cultivation is highlighted in **light 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) Monsanto	Lepidopteran insect-resistance and tolerance to glyphosate	Food additives	Ongoing
		Feed	Ongoing
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 glyphosate-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	Foods and food ingredients	02/03/2016
		Feed	15/03/2016
	tolerance to glufosinate-ammonium	Feed	Ongoing
		Other products	15/03/2016
Maize (DAS1507xMON603) Pioneer and Dow	<ul style="list-style-type: none"> protection against certain lepidopteran pests such as the 	Foods	
		Feed	23/10/2017
		Other Products	

AgroSciences	European corn borer <i>Sesamia</i>	except cultivation		
		• tolerance to glufosinate-ammonium	Foods and food ingredients	07/09/2018
		• tolerance to glyphosate	Feed	
			Products other than food and feed except cultivation	
Maize (DAS59122)	- protection against certain coleopteran pests such as corn rootworm larvae	Foods + Feed	23/10/2017	
Pioneer and Dow AgroSciences	- tolerance to glufosinate-ammonium	Products other than food and feed except cultivation		
Maize (GA21)	tolerance to glyphosate	Foods + Feed	27/3/2018	
Syngenta		Products other than food and feed except cultivation		
Maize (MON810)	resistance to lepidopteran pests	Foods + Feed	Ongoing	
Monsanto		Seeds cultivation	Ongoing	
Maize (MON863)	insect- resistance, selection marker	Food	12/01/2016	
Monsanto		Food additives	Ongoing	
		Feed	12/02/2016	
		Feed	Ongoing	
		Other products except cultivation	12/02/2016	
Maize (MON863 x NK603)	selection marker, insect- resistance, tolerance to glyphosate	Food additives	Ongoing	
Monsanto		Feed	Ongoing	
Maize (MON863 x MON810)	resistance to lepidopteran pests, resistance to certain coleopteran pests (principally corn rootworm), selection marker	Feed materials produced from MON863 x MON810 maize	Ongoing	
Monsanto		Food	02/03/2015	
		Food additives	Ongoing	
		Feed	17/10/2014	
		Feed produced	Ongoing	
Maize (NK603 Monsanto)		Other products except cultivation	17/10/2014	
Maize (NK603 x MON810)	tolerance to glyphosate, protection against certain lepidopteran insect pests (<i>Ostrinia nubilalis</i> , <i>Sesamia</i> spp.)	Foods + Feed	23/10/2017	
Monsanto		Other Products except cultivation		
Maize (T25)	tolerance to glufosinate-ammonium	Food + ingredients + Feed	Ongoing	
Bayer		Seeds cultivation	Ongoing	
MICROORGANISMS				
Bacterial biomass	Bacterial protein, by-product from the production by fermentation of L-Lysine HCl obtained from (<i>Brevibacterium</i>	Feed	Ongoing	
Ajinomoto				

Eurolysine SAS	lactofermentum) the recovered killed microorganisms.		
Yeast biomass NOVO Nordisk A/S	produced from genetically modified yeast strains (<i>Saccharomyces cerevisiae</i>) cultivated on substrates of vegetable origin.	Feed	Ongoing
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	
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

Annex II: Genetically Modified Food, Feed, and Cultivation - Pending Authorizations

Information of this table has been compiled from

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>

A different presentation of this information is provided at the following address:

<http://www.gmo-compass.org/eng/gmo/db/>

EFSA ID *	Product	Company	Trait	Scope of Application	EFSA Evaluation Status
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UK-2004-01	NK603 x MON 810 Maize	Monsanto	Insect Resist	Food Feed	Opinion Adopted
NL-2004-02	1507 Maize	Pioneer HiBred	Insect Resist	Food	Opinion Adopted
DE-2004-03	MON 863 x MON 810 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	MON 863 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	MON 531 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
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 request

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	Insect Resist Herb Tol	Food Feed	Additional data request
NL-2005-18	A2704-12 Soybean	Bayer	Herb Tol	Food Feed Processing	Opinion Adopted
UK-2005-17	1507 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed Processing Cultivation	Additional data request
M-2005-0176	Biogalactosidase (alfa-galactosidase) for pigs for fattening	Kerry BioScience	Feed Additive		Additional data request
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 MON 810 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 Resist 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 request
NL-2005-24	40-3-2 Soybean	Monsanto	Herb Tol	Cultivation	Additional data request
NL-2005-28	1507 x 59122 Maize	Mycogen Dow Pioneer HiBred	Insect Resist Herb Tol	Food Feed Cultivation	Additional data request
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 request
UK-2006-29	59122 x NK603 Maize	Pioneer HiBred	Insect Resist Herb Tol	Food Feed Cultivation	Withdrawn
NL-2006-32	LY038 x MON 810 Maize	Renissen Europe	Insect Resist Lysine	Food Feed	Withdrawn
NL-2006-31	LY038 Maize	Renissen Europe	Lysine	Food Feed	Withdrawn
CZ-2006-33	MON 88017 x MON 810 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
	Danisco Xylanase (Endo-				Opinion Adopted

M-2006-0101	1,4beta-xylanase) for chickens for fattening, laying hens, ducks for fattening	Finnfeeds	Feed Additive		
NL-2006-36	MON 89788 Soybean	Monsanto	Herb Tol	Food Feed Processing	Opinion Adopted
M-2007-0020	Avizyme 1505 (endo-1,4-beta-xylanase, subtilisin and alpha-amylase) for chickens for fattening and ducks for fattening	Finnfeeds Danisco	Feed Additive		Additional data request
NL-2007-37	MON 89034 Maize	Monsanto	Insect Resist	Food Feed Processing	Opinion Adopted
NL-2007-38	MON 89034 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
NL-2007-39	MON89034 x MON 88017 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
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 request
UK-2007-42	MON88913 x MON15985 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
UK-2007-43	356043 Soybean	Pioneer Overseas	Herb Tol	Food Feed	Additional data request
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 request
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 request
UK-2007-48	MIR604 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food Feed	Additional data request
UK-2007-49	Bt11 x GA21 Maize	Syngenta	Insect Resist Herb Tol	Food Feed	Additional data request
UK-2007-50	Bt11 x MIR604 Maize	Syngenta	Insect Resist	Food Feed	Additional data request
NL-2007-47	305423 x 40-3-2 Soybean	Pioneer HiBred	Altered Composition Herb Tol	Food Feed	Additional data request
M-2007-0953	L-Valine for all species	Ajinomoto Eurolysine	Feed Additive		Opinion Adopted
M-2008-0013	Natugrain TS (endo-1,4- β -xylanase and endo-1,4- β -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- β -xylanase and endo-1,4- β -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 request

GMO 2008-53	98140 Maize	Pioneer HiBred	Herb Tol	Food Feed	Additional data request
CZ-2008-54	MON 88017 Maize for cultivation	Monsanto	Insect Resist Herb Tol	Cultivation	Additional data request
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 request
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 request
UK-2008-57	MON15985 Cotton	Monsanto	Insect Resist	Food Feed	Additional data request
UK-2008-58	MON15985 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
FR-2008-59	PT73 Escherichia coli (TM)	Ajinomoto Eurolysine	Feed Additive		Additional data request
M-2008-0419	Ronozyme® WX (Endo-1,4-β-ylanase) for poultry, piglets (weaned) and pigs for fattening	DSM Nutritional products	Feed Additive		Additional data request
Uk-2008-60	GA21 Maize	Syngenta	Herb Tol	Food / Feed	Additional data request
FR-2008-61	d PL73 Escherichia coli (LM)	Ajinomoto Eurolysine	Dried killed bacteria biomass	Feed	Additional data request
CZ-2008-62	MON 89034 x 1507 x MON88017 x 59122 Maize	Dow Monsanto	Insect Resist Herb Tol	Food / Feed	Additional data request
DE-2008-63	H7-1 Sugar beet	Monsanto	Herb Tol	Food / Feed Cultivation	Under Consideration
	Ronozyme ProAct (serine			Chickens for	In progress

M-2008-0431	protease)	DSM	Feed Additive	fattening	
DE-2009-64	BPS-CV127-9 Soybean	BASF		Food / Feed	Under Consideration
NL-2009-65	MON 89034 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 MON 88913 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 request
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 Ingredient 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
	GM Ms8, Rf3 and Ms8			Import, processing,	Opinion Adopted

C/BE/96/01	X Rf3 Oilseed rape	Bayer	Herb Tol	cultivation ?	
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 request
RX-40-3-2	40-3-2 Soybean	Monsanto	Herb Tol	Food Feed	Additional data request
RX-MON1445	MON 1445 cotton	Monsanto	Herb Tol	Food Feed	Additional data request
RX-1507	1507 Maize	Pioneer HiBred	Insect Resist	Feed Feed Additives	In progress
RX-15985	MON15985 Cotton	Monsanto	Insect Resist	Feed Additives	Additional data request
RX-Bt11	Bt11 Maize	Syngenta	Insect Resist	Food Feed	Finished
RX-GA21	GA21 Maize	Syngenta	Herb Tol	Food Feed Processing	Finished
RX-GT73	GT73 oilseed rape	Monsanto	Herb Tol	Food	Additional data request
RX-GT73	GT73 Oilseed rape	Monsanto	Herb Tol	Feed	Additional data request
RX-MON810	MON 810 maize	Monsanto	Insect Resist	Food Feed	In progress
RX-MON531	MON 531 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 request
RX-MON810	MON 810 Maize	Monsanto	Insect Resist	Food Feed Cultivation	In progress
RX-MON810	MON 810 Maize	Monsanto	Insect Resist	Food	In progress
RX-T45	T45 oilseed rape	Bayer	Herb Tol	Food Feed Processing	Finished
RX-T25	T25 Maize	Bayer	Herb Tol	Food Feed	Additional data request
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 request
RX-NK603xMON810	NK603 x MON 810 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Withdrawn
RX-MS8xRF3	MS8/RF3 oilseed rape	Bayer	Male Sterility Herb Tol	Food Feed	Additional data request
RX-MON15985xMON1445	MON15985 x MON1445 Cotton	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
RX-MON863xMON810	MON 863 x MON 810 Maize	Monsanto	Insect Resist	Feed	Additional data request
RX-MON863xNK603	MON 863 x NK603 Maize	Monsanto	Insect Resist Herb Tol	Food Feed	Additional data request
RX-MON863	MON863 maize	Monsanto	Insect Resist	Food Feed	Additional data request
RX-NK603	NK603 maize	Monsanto	Herb Tol	Food Feed	Additional data request