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Agricultural Biotechnology Annual

Annual

Approved By:
Lashonda McLeod
Prepared By:
Marie-Cecile Henard, Lashonda McLeod, and the group of FAS biotech specialists in the European Union

Report Highlights:
Due to the diversity of industry needs and public perceptions, Member States (MS) approach to biotechnology can be identified as the following: MS producing biotech crops; MS ready for adoption; MS with restrictive legislation and hostile public opinion, but supportive farmers and industry; and MS with the strongest opposition. The European Union (EU) is dependent on imports of feed ingredients (mainly soybean and corn products) for its livestock and poultry industries, and its suppliers are also major producers of genetically engineered (GE) corn and soybean. No GE animal is commercially produced in the EU; and GE animals are used for research purposes in medical and pharmaceutical applications.

Section I. Executive Summary

Despite the unified regulatory approach of biotechnology by authorities in the European Union (EU), Member States (MS) address this issue in multiple ways both in terms of policy and marketing. This is due in part to the diversity of industry needs (especially for feed products) and public opinions within the Member States.

Four Categories of MS According to their Approaches to Biotechnology

1. **GE producing** MS include the Czech Republic, Poland, Portugal, Romania, Slovakia and Spain. They are all producers of GE crops, and farmers and industry welcome the technology;
2. MS **ready for adoption** due to the positive perception by the industry and the non-opposition by the public opinion are the Benelux, Denmark, Estonia, Finland, Lithuania, Sweden, and the United Kingdom (UK). However, in this group no GE crop is cultivated, as those authorized in the EU are not relevant for these markets;
3. MS with **restrictive legislation and hostile opinion, but supportive farmers and industry** are Bulgaria, France, Germany, Ireland, Latvia and Slovenia. These countries do not produce GE crops; however, France and Germany did produce GE corn in the past;
4. MS with the **strongest opposition** are Austria, Greece, Hungary, and Italy. In these countries, biotechnology has a negative image in the public opinion, national policies are restrictive, and the industry is not open to the technology.

Imports meeting the needs of the animal feed industry, but hampered by trade barriers

The EU policy on imports of GE products is less restrictive than that on GE crop cultivation, as it faces some market realities: the EU is dependent on imports of feed ingredients (mainly soybean and corn products) for its livestock and feed industry, and EU suppliers (principally the United States, Brazil and Argentina) of these products are also major producers of GE corn and soybeans. The largest category of GE products consumed in the EU consists of soybean meal, with roughly 30 million metric tons consumed annually in the EU. The second largest category of GE products consumed in the EU is Dried Distillers Grains (DDGs), which are corn products. EU imports of DDGs are booming in 2011, and the United States is the EU's leading supplier. EU imports of GE products are, however, hampered by several types of trade barriers, including the national bans imposed on specific GE crops and the asynchronous approval between the EU and its suppliers. In February 2011, MS endorsed an EC proposal providing for a 'technical solution' designed to harmonize the implementation of the zero tolerance policy on non-authorized GE material in feed, and defining the lowest level of GE presence considered by the EU Reference Laboratory when validating detection methods as 0.1 percent.

Policy is changing and completed by national measures

EU policy on biotech crop cultivation is based on a regulatory framework that is criticized as lengthy and countered by national bans imposed by seven MS on EU-approved products. In July 2010, the European Commission (EC) presented a package aimed at allowing MS to decide whether or not to cultivate approved biotech crops on their individual territories. Most MS oppose the proposal due to the disruption of the single internal market and potential WTO issues.

Coexistence rules between biotech and non-biotech production are regulated by national authorities. The socio-economic aspects of biotech crop cultivation are a growing concern. In April 2011, the EC presented a report to the European Parliament and the Council demonstrating the current limitations in assessing the socio-economic implications of biotech crop cultivation in the EU. This complex, changing, two-layered policy framework on GE crop cultivation has resulted in only two products approved for cultivation.

GE Animals – Some Research, No Commercial Production

There are no GE animals commercially produced in the EU. GE animals are principally used for research purposes for medical or pharmaceutical applications. Animal biotechnology regulation in Europe parallels regulation of plant biotechnology and some MS do have specific regulations on animal biotechnology.

The report represents a group effort from the following FAS analysts:

Stefano Baldi	FAS/Rome
Ornella Bettini	FAS/Rome covering Greece
Mila Boshnakova	FAS/Sofia
Monica Dobrescu	FAS/Bucharest
Jolanta Figurska	FAS/Warsaw covering Poland, Latvia, Lithuania, and Estonia
Bob Flach	FAS/The Hague covering the Benelux Countries
Marta Guerrero	FAS/Madrid
Marie-Cecile Henard	FAS/Paris
Roswitha Krautgartner	FAS/Vienna covering Austria and Slovenia
Diogo Machado	FAS/Madrid covering Portugal
Jana Mikulasova	FAS/Prague covering the Czech Republic and Slovakia
Ferenc Nemes	FAS/Budapest
Yvan Polet	FAS/USEU/Brussels
Piotr Rucinski	FAS/Warsaw covering Poland, Estonia, Latvia and Lithuania
Paul Spencer	FAS/Berlin
Asa Wideback	FAS/Stockholm covering Sweden, Denmark and Finland
Barrie Williams	FAS/USEU/Brussels
Jennifer Wilson	FAS/London covering the United Kingdom and Ireland

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Section II. Plant Biotechnology Trade and Production

A. Imports of Biotech Plant Products

EU plant biotech trade consists mainly of soybean and corn products imported for use in animal feed, human food, and planting seeds, as well as cotton products used in the textile industry. Current conditions indicate that EU production of feed grains will have some difficulties in meeting the feed demand from the livestock and poultry industry in 2011/12, which are likely to increase imports of feed ingredients, namely, soybean, and corn products. **Poland** bans GE seed trade, and plans to implement a ban on GE feed by January 2013. Agricultural experts are of the opinion that the actual implementation of the ban will be prevented before its due date. In **Bulgaria**, a new law in 2010 effectively prohibits trade in biotech seeds, even for research and development purposes.

Soybean Products

The largest category of GE products consumed by MS consists of soybean meal, which is the primary source of proteins for livestock. As the EU lacks adequate supplies of vegetable protein used in animal feed, meat producers are dependent on imports of soybean and soybean meal from the United States and South America. Exports of these commodities from the United States to the EU have declined significantly since 1997. More specifically, U.S. exports of soybeans and soybean meal to the EU have

averaged around $1 billion annually since 2006. Exports were up by almost 20 percent in the first three months of 2011.

Over the past three years, 30-32 million metric tons (MT) of soybean meal were consumed annually (see annual EU-consolidated report on oilseeds dated April 7, 2011) in the EU. Domestic soybean production is marginal. With soybean and soybean meal imports averaging 12 and 22 million MT, respectively, Argentina, Brazil, and the United States are the major suppliers. The largest users of soybean meal, **Germany**, **Spain**, and **France** are also the major producers of livestock and poultry, with more than 40 percent of total EU consumption. GE products are estimated to represent more than 80 percent of the total soybean meal use by MS. The remainder consists of identity preserved (IP) and geographical indication sectors. Soybean meal remains an excellent ingredient both in terms of price and quality for feed compounders and livestock breeders.

Corn Products

Corn and corn products, mainly Corn Gluten Feed (CGF) and Dried Distillers Grains (DDGs), represent the second largest category of GE products used in animal feed. In the past three years, the EU corn consumption averaged 60-63 million MT annually; principally supplied by local production (averaging 55-59 million MT annually), rather than by imports (averaging 3,000-6,000 MT). The share of GE products out of total corn consumption is estimated to be lower than 25 percent.

EU imports of DDGs doubled in the first ten months of marketing year (MY) 2010/11 (July/April). The United States is the leading supplier with 88 percent market share. The slow approval process of new GE events by the European Union has significantly impacted U.S. exports of CGF and DDGs to the Benelux region; however, there imports have recovered. There is also great potential for increasing DDG exports to France.

Seeds for Planting

The percentage of biotech corn out of the total corn grown in the European Union is limited. The leading producers of corn seeds for planting in the EU are **France** and **Hungary**. There is also production in **Bulgaria** and **Romania**. In 2011, Romania produced its own biotech corn seeds for planting, while in Bulgaria, non-biotech corn seeds are imported from other EU MS, Turkey, and the United States. **German** seed companies provide biotech seeds to U.S. farmers. These seeds, however, are not produced in Germany due to political opposition concerning the environmental release of GE crops. **Portugal** sources GE corn seed directly from the United States and Chile, but the majority is U.S. produced seed imported after repacking. **Spain**, the leading EU biotech corn producer, sources its GE seeds from South Africa, Romania**,** and Chile. The United States is not a source of biotech planting seeds because of the low of tolerance for adventitious presence of unapproved events in planting seeds.

B. Commercial Planting

The two GE crops authorized for cultivation in the EU are as follows: MON810 GE corn and the Amflora potato. Since 2007, the EU acreage of GE corn has remained relatively stable, with fluctuations between 93,000 and 110,000 hectares (ha). **Spain** remains the leading GE corn producer

with 85 percent of the total acreage. In 2011, Spain's production is anticipated higher, triggered by last year's high pressure of the corn borer, and with the overall increase of area planted to corn.

Other producers are **Portugal**, the **Czech Republic**, **Poland, Slovakia** and **Romania**. In Portugal, planting intentions for 2011 have risen by about 50 percent to 7,300 ha due to a rise in the overall corn area (although the rise in GE corn area is proportionally higher) and corn borer attacks during the previous season. Farmers in Romania recognize the benefits of biotechnology, but several factors, such as specific requirements for separate storage and additional costs generated by implementing all specific EU rules negatively influence their planting decisions. In the Czech Republic, the decline in GE corn acreage results from the demand for non-biotech products from neighboring countries like Austria.

GE corn is principally grown for domestic animal feed in Spain and Portugal. While in the Czech Republic and Slovakia, GE corn is used for feeding animals in small scale, as feedstock for biogas stations.

GE Corn Cultivation by Selected Member States (in hectares)									
Member States	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011 (est.)**
Spain	32,249	58,219	53,226	53,667	75,148	79,269	79,706	76,575	80,200
Portugal	0	0	730	1,254	4,199	4,856	5,094	4,869	7,300
Czech Republic	0	0	250	1,290	5,000	8,380	6,480	4,678	4,000
Poland	0	0	0	100	100	300	3,000	3,500	3,900
Slovakia	0	0	0	30	930	1,930	875	1,281	1,000
Romania	0	0	0	0	331	7,146	3,400	822	590
Germany	0	500	342	947	2,685	3,171	0	0	0
France	17	17	500	5,200	22,135	0	0	0	0
Total GE corn acreage	32,266	58,736	55,048	62,458	110,528	105,052	98,555	91,725	96,990
Total Corn Acreage (1,000 ha)	9,138	9,677	9,169	8,492	8,444	8,854	8,284	8,000	8,600

Source: FAS Posts

GE potato production is estimated to remain marginal in 2011 (20 hectares), and all located in **Sweden**. The cultivation of the Amflora potato will be significantly lower in 2011, due to the discovery of an unapproved GE potato last year. This resulted in stricter control measures for cultivating Amflora, thus making it practically impossible to cultivate larger areas. The Czech Republic and Germany reduced their production of GE potato to zero in 2011 as a result of efforts aimed at focusing more on planting material in the next years.

EU-27 acreage on GE Potato by Selected Member States (in hectares)		
Member State	**2010**	**2011 (estimate)**
Sweden	150	20
Czech Republic	147	0
Germany	15	0
Total Amflora Potato Acreage	225	20

Source: FAS Posts

C. Research and Development - Field Trials of GE Crops

Agricultural biotechnology research is a stated priority of the European Commission and many Member States. Previously, researchers and universities implemented successful field trial activities. However, anti-biotech activists have succeeded in intimidating research groups (both public and private entities) to drop field trial work. Field destructions have continued with little or no response from police and judicial authorities. As a result, permit requests to conduct field trials have fallen dramatically since 2007. Some research scientists were forced to drop activities due to political pressure or have moved to institutions where support for such research is undeterred.

Due to strict regulations and hostile public opinion, there are no field trials in **Austria, Belgium, Bulgaria, Greece, Ireland, Lithuania, Estonia, Latvia, Italy** and **Slovenia,** and a limited number in **Denmark, France**, **Germany**, **Slovakia** and **Sweden**. In the **Czech Republic** (virus-resistant plum trees), the **Netherlands** (potatoes), **Poland** (coexistence studies), **Portugal** (corn), **Romania** (corn), **Spain** (corn, sugar beet, cotton, potatoes), and the **United Kingdom** (nematode-resistant and blight-resistant potatoes) open field test plots are conducted at a larger scale.

D. Confined Research

With less strict regulations and little or no visibility for public opinion, there is confined research conducted by public entities. In **Austria**, for example, the University of Natural Resources and Life Sciences is working on a project that investigates biotech fruit trees under contained conditions. **France's** National Institute for Research in Agriculture partners with private entities in research programs on crop genomics, a variety selection program of corn with high yields and limited needs in water and chemicals, as well as a variety selection program of wheat with high yields and quality, but stress tolerant. In **Germany**, four big research organizations (Max-Planck-Society, Leibniz Association, Helmholtz Association, Fraunhofer-Gesellschaft), universities, technical colleges, and non-academic research institutes play a central role in biotech development. In **Hungary**, the main research institutes belong to the Hungarian Academy of Science, the Ministry of Rural Development, and universities. For **Poland**, plant biotechnology research is conducted by several research institutes, in

some cases in cooperation with foreign companies or laboratories. There is also confined research reported in **Portugal**, **Slovenia, Spain,** and in the **United Kingdom**.

Section III. Plant Biotechnology Policy

A. Commercialization

1. EU -27 biotechnology regulatory framework

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

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

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

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

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

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

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

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[1] In the EU, biotech events are commonly referred to as Genetically Modified Organisms (GMOs)
[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council
[3] The application is accompanied by inter alia:
- name and address of the applicant;
- designation of the food, and its specification, including the transformation event(s) used;
- a copy of the studies which have been carried out and any other available material to demonstrate no adverse effects on human or animal health or the environment;
- methods for detection, sampling and identification of the event;
- samples of the food;
- where appropriate, a proposal for post market monitoring;
- a summary of the dossier in standardized form.
A complete list of accompanying information is provided in Article (5) 3 for food use, and Article 17 (3) for feed use of Regulation (EC) No 1829/2003.

- Within three months after receiving the opinion from EFSA, the European Commission presents its Standing Committee on the Food Chain and Animal Health (SCoFCAH - composed of representatives of the MS) with a draft decision reflecting EFSA's opinion. The Standing Committee votes on the draft decision. For draft decisions prior to March 1, 2011, in the case of no qualified majority (qualified majority being 255 votes out of 345) in favor of the draft decision, the European Commission submits it to the Council of the European Union (typically the Agriculture Council) without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. Draft decisions after March 1, 2011, are subject to the procedural rules resulting from the Lisbon Treaty. Under these rules, in the case of no qualified majority in favor of the draft decision, the Commission may either submit an amended draft to the Committee or submit the original draft to the Appeal Committee (comprised of senior officials from the Member States). If the Appeal Committee has neither adopted the draft decision nor opposed it by qualified majority within two months from the date of referral, it may be adopted by the European Commission. It should be noted that the post-Lisbon procedural rules give more discretion to the Commission – whereas before Lisbon the Commission was obliged to adopt the draft decision, after Lisbon the Commission has the choice whether or not to adopt the draft decision.

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

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

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

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

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

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

[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.

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

- The national competent authority has 45 days to evaluate the MS's observations. If these observations are in line with the national competent authority's scientific opinion, that opinion is sent to the European Commission which, in turn, presents a draft decision reflecting the opinion to its Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms (GMOs). The Committee votes on the draft decision. In the case of no qualified majority in favor of the draft decision, the European Commission submits it to the EU Agriculture Council without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. Those draft decisions that have been put to the Committee after March 1, 2011, are subject to the procedural rules resulting from the Lisbon Treaty (as described in section A above).

- If, on the other hand, the MS's observations are not in line with the national competent authority's scientific opinion, the matter is passed to EFSA for its scientific opinion. EFSA's opinion is then sent to the European Commission which presents a draft decision reflecting EFSA's opinion to the Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms. The Committee votes on the draft decision. In the case of no qualified majority in favor of the draft decision, the European Commission submits it to the EU Environment Council without delay. If the Council has neither adopted the draft decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. Draft decisions after March 1, 2011, are subject to the procedural rules resulting from the Lisbon Treaty (as described in section A above).

2. Proposal for MS to be allowed to decide on cultivation of biotech crops on their territories

Commission Proposal

On July 13 2010, the Commission presented a package aimed at allowing MS to decide whether or not they cultivate approved biotech crops on their individual territories. The package consists of a 'fast solution' and a proposal for a legislative amendment to the governing legislation and a proposal for a legislative amendment to the governing legislation. The 'fast solution' essentially implies new guidance on isolation distances recommended to ensure co-existence between biotech and traditional crops. Those MS that do not wish to cultivate biotech crops are, in practice, able to use the new guidance to impose isolation distances which would effectively preclude the possibility of biotech cultivation. As this does not imply legislative amendments, the Council and the European Parliament are not required to approve the measure which was applicable immediately. At the time of this report, it is understood that no MS has used this facility.

The proposal for legislative amendment would allow a MS to formally 'opt out' of biotech crop cultivation and requires approval by the Council and the Parliament. It is understood that the Commission would be prepared to withdraw the proposal for legislative amendment if it were to encounter significant opposition.

The report on the Commission's proposal made by the European Parliament's Committee on the Environment, Public Health and Food Safety (Lepage report) was voted July 2011. *Inter alia*, the Lepage report adds environmental grounds as a justification for banning or restricting the cultivation of biotech crops.

The Council has not reached a common position on the Commission's proposal. As no deadline is imposed on the Council for reaching one and it is not certain that the incoming Polish Presidency of the Council of the European Union will treat the issue as a priority. It seems unlikely that a common position will be reached in the medium term. As such, the Commission's proposal will be frozen until the Council reaches a common position.

Reactions of the Member States

Several MS are also opposed to the Commission proposal because of disruption of the single internal market and potential WTO issues.

France continues to request for the implementation of the Environment Council of December 4, 2008 under the French Presidency of the EU to reinforce the environmental impact assessment and EFSA's independence. **Germany** does not support the European Commission proposal.

The government of the **Netherlands** opposes a study for the marketing approval for GE products by the Member State, in addition the study of the EFSA. According the Dutch government, the discussion about the use of such criteria should be held on an international level. **Spain** has reacted cautiously to the Commission's proposal. Spain's concerns are the compatibility with the common internal market and the compliance with WTO rules.

The **UK** government is cautious about renationalization of cultivation approvals as there is potential for fragmentation of policy. Scotland, Wales and Northern Ireland have authority over cultivation on their soil. From the start, the UK government questioned the legal status of the renationalization concept, and the viability of attaining robust socio-economic criteria.

Austria is in favor of the GE opt-out" clause to allow individual member states to decide on cultivation. While the current **Estonian** government is using a science based approach to biotech products, it is not supportive of planting GE crops. One hundred percent of Estonian Members of the European Parliament (MEP) voted for the proposal. Ninety-one percent of **Lithuanian** MEP voted for the proposal

The **Latvian** government is openly against plant biotechnology, including planting. According to the current Law on Circulation of Genetically Modified Organisms a local government may already determine a prohibition by issuing binding rules for the cultivation of genetically modified crops in

the relevant administrative territory or in a particular territory thereof upon its own initiative or on the basis of a proposal of a person. Over 88 percent of Latvian counties already declared themselves as biotech-free territories. One hundred percent of Latvian MEP voted in favor of the European Commission's proposal.

The **Polish** Minister of Agriculture declared that this move, which transfers the decision making on GE cultivation in MS from EU/Brussels to MS, could disrupt "the single internal market." Ninety percent of Poland's MEP voted for the proposal.

The **Portuguese** government has been in favor of the Commission's proposal following the orientation of the Ministry of Environment that was, until now,the responsible body for regulating cultivation. A reviewed position, however, is possible in the near future as a new Government has just been elected and there is now one single Ministry for Agriculture and the Environment. Agriculture has traditionally been against the Commission's proposal fearing the effects of the pressure from anti-biotech NGOs and the media if such a proposal were to be approved. The Portuguese Autonomous Region of Madeira has become the first Region of the EU to declare itself a zone free of the cultivation of genetically modified organisms since the European Commission made its proposal. The Regional Government of Azores is also preparing the submission of a request to the Commission for the same purpose. GE corn is cultivated in the Azores for the first time this year.

3. National coexistence rules

Some MS have set up national coexistence frameworks for organic, biotech, and conventional crops. **Austria** has no federal coexistence law but all nine provinces implement precautionary bills that include coexistence regulation. The **Czech Republic** recently updated coexistence rules to remove administrative duplicities and add rules for future situations, such as growing GE soybeans. In 2005, **Denmark** was the first EU MS to impose coexistence rules. **Portugal** was one of the first countries to create legislation that recognizes the right of farmers to voluntarily associate and establish both GE Production Zones (PZ) and GE-Free Zones (FZ). In GE production zones farmers are still mandated to fulfill all legal obligations related to farming GE varieties, namely completing training requirements and notifying the State and adjacent farmers about their GE crop farming intentions. Except for limit zones, farmers in PZ are exempt from applying measures to minimize the accidental presence of GE material, be it through pollen contamination or mechanical mix. In 2010, twenty-one production zones were active, accounting for 46 percent of total biotech corn planted area.

Germany's approach to coexistence between biotech and conventionally grown and organic crops is complex and changing. German federal and local governments have put into place an assortment of planting bans, segregation distances, and other requirements. In December 2010, a scientific policy advisory board for the German Ministry of Food, Agriculture, and Consumer Protection published additional recommendations on coexistence. While not binding, the recommendations, which call for economically unrealistic segregation and cultivation measures, underscore how coexistence regulations can be used to discourage farmers' adoption of biotech crops.

Several MS are currently preparing coexistence rules. The **French** biotech authority, the High

Council on Biotechnology (HCB), is expected to release coexistence recommendations within the next few months in 2011. This will be based on its recent recommendations on the definition of "non-biotech" and on the obligation of declaration of GE crop producers. A decree on the "non-biotech" definition is currently being reviewed by French government, to be published in the Official Journal. **Poland** is proposing restrictive coexistence measures on the crops under new legislation, which is expected to be completed by early 2012.

While Spain remains the leading GE crop producer in the EU, no developments regarding coexistence have been made due to the lack of consensus among the interested parties. To date, coexistence has been managed following the good agriculture practices promoted by the National Association of Seed Breeders (ANOVE), which are published on a yearly basis. Similarly, there are no coexistence rules in the **United Kingdom**.

4. Field register status

In **Austria, Belgium, Bulgaria, the Czech Republic, Denmark, France, Germany, Greece, the Netherlands, Romania, Slovakia, and Portugal** farmers producing biotech crops must register their fields with governmental bodies. The specificity of these registration requirements varies greatly from country to country, and tends to discourage farmers from growing biotech crops. The implementation of a commercial GE plots register is being discussed in **Spain**.

5. Evaluation of the EU legislation framework in the field of cultivation and marketing

In December 2008, the Commission launched a technical evaluation of a) the regulatory framework of the cultivation of biotech crops under Directive 2001/18/EC on the deliberate release into the environment of biotech events and b) Regulation (EC) No 1829/2003 on biotech food and feed and the marketing of their other uses under the Directive. The aim of the evaluation is to assess the extent to which the legislative framework on the cultivation and marketing of biotech products and if its implementation have achieved its objective of protecting human and animal health, the environment and consumers' interest, while ensuring the effective and efficient functioning of the internal market. The evaluation will cover topics such as risk assessment, management and communication, authorization procedures, national safeguard measures, inspections and controls and confidentiality rules.

The contractor of this exercise is GHK, member of the European Policy Evaluation Consortium (EPEC) consortium. Within the framework of its task, it will analyze the biotech legislation, documents, reports, and studies related to its implementation. Moreover, it will consult stakeholders, including the MS' Competent Authorities under the biotech legislation, professional associations, biotech industry and civil society organizations involved in biotechnology issues. Commission sources suggest that the results of this work are to be released during 2011.

6. Environmental risk assessment guidance

Directive 2001/18/EC provides that the potential adverse effects on human health and the

environment are accurately assessed on a case-by-case basis. This assessment shall be conducted jointly by MS and EFSA in accordance with the principles of the Directive 2001/18/EC and the supplementary guidelines. Following a specific mandate of the Commission to EFSA in March 2008, supported in the Environment Council Conclusions of December 2008, an updated version of the current environmental risk assessment (ERA) guidance was published by EFSA on November 12, 2010. In parallel, EFSA delivered an opinion to address the evaluation of potential impact of biotech plants on non-target organisms (NTOs). The Commission is continuing the discussion on ERA guidance with MS to clarify the specific aspects of this guidance before being transformed into a legal text. This guidance will be the basis for applicants when submitting applications for biotech authorization and for MS and EFSA when assessing the environmental risk of biotech plants.

7. Updated guidance for food and feed risk assessment of biotech plants – EFSA

On May 24, 2011, EFSA published updated guidance for the risk assessment of food and feed derived from biotech plants**.** The document expands on previous EFSA guidance and reflects scientific developments in areas such as assessment of allergenicity and selection of the conventional comparator plant against which the biotech plant is compared. It also establishes a new statistical methodology aimed at strengthening the risk assessment of biotech plants. The European Commission has announced that it will move ahead with a Regulation capturing and imposing this more stringent EFSA guidance.

8. New Plant Breeding Techniques

Directive 2001/18/EC provides for a general definition of GMOs. The Directive includes annexes which give additional information regarding the breeding techniques that may or may not result in genetic modification, or that result in genetic modification but yield organisms that are excluded from the scope of the Directive.

As agreed by a meeting of the MS' Competent Authorities, in October 2007, the Environment Directorate of the European Commission established an expert Working Group on new breeding techniques (Directive 2001/18/EC) and GMOs under contained use (Directives 90/219/EEC and 98/91/EC). The aim of this exercise is to harmonize MS' interpretation on whether or not newly applied techniques result in a GMO or not.

The Working Group is evaluating the following new breeding techniques in light of the most recent scientific data:

- Zinc Finger Techniques (ZFN)
- Oligonucleotide-directed Mutagenesis (ODMG)
- Cisgenesis
- RNA-dependent DNA-methylation
- Grafting
- Reverse Breeding
- Agroinfiltration

- Synthetic Biology

The Working Group aims to:

a. Classify current technologies and ascertain whether they fall under the current definition of a GMO as defined in Directive 2001/18/EC;
b. Check if some techniques may be exempted for technical or practical reasons.

During the spring of 2010, the Commission's Health and Consumers Directorate took over the coordination of the Working Group from the Environment Directorate. To date, the Working Group has met nine times and is currently finalizing a technical report that will be presented at a meeting of the MS' competent Authorities.

In parallel to this exercise, the Joint Research Center (JRC) has recently finalized a report focusing on those breeding techniques entitled, "New Plant Breeding Techniques: Adoption and Impact of Policy Options." The JRC is organizing a closed international policy meeting in Seville on September 12-13, 2011 to which government representatives from Argentina, Australia, Canada, Japan, South Africa and the United States will be invited. The aim of the meeting will be to improve understanding of those countries' classification policy. Clearly, if a product were not to be classified as GM in the United States but were to be in the EU for example, U.S. trade would be significantly impeded.

B. Trade Barriers

1. Safeguard clause

Where a MS, as a result of new information, has detailed grounds for considering that an approved biotech event constitutes a risk to human health or the environment, the MS may invoke a safeguard clause on the biotech product; its use would be provisionally restricted or prohibited on its territory. The MS must ensure that in the event of a severe risk, emergency measures (including suspension or termination of the placing on the market, and provision of appropriate information to the public) are applied. The MS must immediately inform the Commission and the other MS of actions taken and give reasons for its decision. The MS must provide its review of the environmental risk assessment, indicate whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

In an effort to dissuade MS from abusing the safeguard clause system and to comply with its role as 'Guardian of the Treaties,' the European Commission has developed a package aimed at allowing MS to decide on whether or not to cultivate EFSA approved biotech crops on part or all of their respective territories.

Detailed Safeguard Clause by MS and by Event Banned			
Country	**Event Banned**	**Scope**	**Date of Ban**
Austria	Bayer T25 corn,	Cultivation	2000 (Amended 2008)
	Monsanto MON 810 corn	Cultivation	1999 (Amended 2008)

	Monsanto GT73 rapeseed	Import/Processing	2007 (Amended 2008)
	Monsanto MON 863 corn	Import/Processing	2008
	Bayer Ms8 rapeseed	Import/Processing	2008
	Bayer Rf3 rapeseed	Import/Processing	2008
	Bayer Ms8XRf3 rapeseed	Import/Processing	2008
	BASF EH92-527-1 potato	Cultivation	2010*
Bulgaria	Monsanto MON810	Cultivation	2010*
France	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Bayer MS1XRf1 rapeseed		
	Monsanto MON 810 corn	Import/Processing	1998
		Cultivation	2008
Germany	Syngenta Bt176 corn	Cultivation	2000
	Monsanto MON 810 corn	Cultivation	2009
Greece	Bayer Rapeseed Topas 19/2	Import/Processing	1998
	Syngenta Bt176 corn		
	Monsanto MON 810 corn	Cultivation	1997
	Bayer T25 corn	Cultivation	2001
	Bayer MS1XRf1 rapeseed	Import/Processing	1997
	Monsanto MON810 corn	Import/Processing	1998
		Cultivation	2010*
Hungary	Monsanto MON 810 corn	Cultivation	2005
	EH92-527-1 Amflora Potato	Cultivation/Feeding	2010*
Luxemburg	Syngenta Bt176 corn	Cultivation	1997
	Monsanto MON 810 corn	Cultivation	2009

Source: FAS Posts
*Most recent bans

In **Austria** and **Greece**, all EU approved biotech crops are banned for cultivation. Greece maintains a zero-tolerance policy for GE cotton seeds for planting, requiring laboratory certification prior to shipment from the United States. **Bulgaria**'s 2010 biotech law mandates that the Minister of Agriculture initiate a safeguard clause whenever another EU Member State decides to apply a safeguard clause for that same crop on its own territory.

The draft law introduced in Parliament in May 2010, which intends to prohibit biotech crops planting in **Romania** for 5 years, is still under debate. On June 18, 2009, **Latvia** modified its Law on Circulation of Genetically Modified Organisms to allow local municipalities self-determination on the cultivation of bioengineered crops within their jurisdiction. Since then, eighty-eight percent of Latvian municipalities have either banned or are in the process of banning cultivation of bioengineered crops in response to consumer activism and tacit support from the Ministry of Environment.

Hungary amended the legislation governing seed imports in March 2011. Under the new Order of

the Minister of Rural Development, each seed lot imported from non-EU countries has to be tested. The former legislation ordered random testing only. For biotech content Hungary declared zero tolerance. The official laboratory of the Central Agricultural Office (MgSzH) declared several corn seed samples positive for biotech DNA content. The Ministry has recently ordered the destruction of 950 hectares of corn and soybean fields planted with the seeds of concern.

Italy appears likely to invoke the safeguard clause. For the past decade, Italy has maintained a *de facto* ban on the cultivation of biotech crops by failing to develop necessary regulations. Observers speculate that Italy will provide some type of evidence to support its request not to cultivate EU-approved biotech crops and that the European Commission will not reject the request even though EFSA has determined that the crops are safe.

2. Policy on Low Level Presence (LLP)

Asynchronous approval has resulted in the detection in U.S. shipments to the EU trace amounts of events that have been deregulated for commercial use in food and feed in the United States but not authorized in the EU. The EU's policy of zero tolerance implies that shipments containing low level presence (LLP) of EU unapproved events are not allowed into the European Union. Although the most significant impact has been on U.S. soy, other products (notably rice and corn products) have also been affected.

On February 22, 2011, Member States at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) endorsed a Commission proposal providing for a 'technical solution' designed to harmonize the implementation of the zero tolerance policy on non-authorized genetically engineered material in feed. The proposal aims at addressing uncertainty faced by EU operators when placing on the market feed based on imports of raw materials from non-EU countries.

This technical solution defines the lowest level of GE presence that is considered by the EU Reference Laboratory when validating detection methods, as 0.1 percent. It is limited to GE feed material authorized for commercialization in a non-EU country and for which an EU authorization request for the biotech event in question has been lodged with EFSA for at least three months or of which the authorization has expired. Feed will be considered non-compliant with EU legislation when the presence of this GE feed material is, after due consideration of the margin of error, above the technical zero of 0.1 percent. This draft regulation was subject to the scrutiny of the European Parliament and of the Council for three months following their formal receipt of the draft. In the absence of opposition to the draft from either of those institutions within that time period the draft was adopted (Commission Regulation (EU) No 619/2011) and entered into law from, July 20, 2011.

The EU farmer association, COPA-COGECA, had pressed for an end of the EU's zero tolerance policy prior to the decision to accept the 0.1 percent tolerance threshold. The association is reported

to have underlined that, given the bulk handling of grains in international trade, compliance with a zero tolerance policy is impossible. The new rules are still too restrictive. Additionally, it is not possible in practice to separate biotech-based animal feed from biotech seeds and food. As such, zero tolerance could be replaced by a practical tolerance threshold in all three areas.

The draft regulation includes a recital stating that the *"... rules should be adapted if this becomes necessary to take account of new developments in particular as regards their impact on the internal market and on food and feed operators."* As such, the Commission has explicitly acknowledged the possibility of including food within the scope of the measure in the future. The Commission's services have indicated that after the threshold for feed is adopted, the scope will be extended to include food at a later stage. The absence of food within the scope of the new rules clearly implies *inter alia* that trade in U.S. rice to the EU will continue to be subject to a system of absolute zero tolerance where zero equals zero, and that normal trade levels will be compromised.

3. Socio-Economic aspects of biotech cultivation

Commission Report

On April 15 2011, in response to the Conclusions of the Environment Council of December 2008, the Commission presented a report to the European Parliament and the Council demonstrating the current limitations in assessing the socio-economic implications of biotech crop cultivation in the EU. More specifically, the report (based on information principally provided by MS) demonstrates that the existing information is often statistically limited and is based upon preconceived ideas about biotech crop cultivation. In the report, the Commission presents an analysis of the socio-economic dimensions of biotech cultivation as reported in the international scientific literature and in the conclusions of research projects funded under the European Framework Program for Research.

Since the EU represents only a fraction of global surface dedicated to biotech crops, European experience in the matter is limited. The report asserts that the contributions from MS: *"…highlight that the present or future socio-economic impacts of (biotech crop) cultivation in Europe, across the food chain and the society as a whole, are often not analyzed in an objective manner."*

As such, the Commission views the report as a starting point for the MS, the Commission, the European Parliament and all interested parties to deepen their reflection on the issue. It considers that discussions should shift from the polarized perceptions documented in the report to a more tangible and objective basis. Therefore, the Commission recommends defining a set of factors and indicators to capture the socio-economic consequences of biotech crop cultivation across the EU and along the food chain. The Commission also suggests initiating a reflection on the potential use of the improved understanding of the socio-economic dimension in the management of biotech crop cultivation.

MS Individual Situations on Socio-Economic Criteria

France is the only MS with a biotech regulatory framework that includes a socio-economic review of biotech products, in addition to the scientific review. The High Council on Biotechnology, created by the 2008 law on biotechnology, includes both a social, ethical and economic committee and a scientific committee.

The governments of **Austria, Estonia, Finland, Hungary**, **Latvia, Lithuania, the Netherlands, Poland, Slovakia** and **Sweden** favor the use of socio-economic criteria for the approval of GE products. Sweden is interested in keeping the indicative list of grounds to restrict or ban biotech crop cultivation outside the legal act since it believes that many of the grounds are not WTO-compatible.

Section IV. Plant Biotechnology Marketing Issues

A. Market Acceptance Issues Relating to the Sale of Biotechnology Products

There are four categories of MS according to their domestic policy, farmer and industry approaches, and public opinion on biotechnology:

GROUP 1 - GE producing MS are the most open to the technology - Czech Republic, Poland, Portugal, Romania, Slovakia and Spain

All are producers of GE crops, and farmers and industry welcome the technology. In this group, **Poland** and **Romania** are, however, facing potential policy changes towards more restrictive measures, while the other MS have a more pragmatic approach. The Parliament in **Poland** initiated a restrictive legislative proposal pertaining to agricultural biotechnology. The proposed requirements are expected to prevent planting of modified crops on a commercial scale. New legislation is expected to be completed by early 2012. The livestock sector depends on feed imports from third countries, mainly soybean meal, which in most cases, is genetically modified. Animal producer groups see the need for maintaining the import of feed with biotech content in order to compete within the EU market. Many scientists promote the technology, but are also attacked for their views. There is no resistance from consumers, as this meat produced with GE feed does not have to be labeled. The public opinion is very negative. Very active, well funded, anti-biotech movements exist. Political parties are cautious, being rather on a negative side.

Farmers in **Romania** have difficulty in finding markets for their biotech production. They have to offer it at a significant discount, so that customers will cover expenses they incur in complying with traceability rules (supplementary documents, separate storage, etc). In this way the farmers' profitability is affected. There was once commercial production of GE soybeans before accession to the EU. The current government has, in general, an open attitude towards biotechnology, as well as on decisions being adopted based on scientific opinions and standpoints released by the academic institutions.

The **Czech Republic** recently updated regulations to alleviate the constraints imposed on farmers,

especially in terms of notification of their cultivation of GE crops. The manual that explains the rules and changes is available at the following link: http://eagri.cz/public/web/file/48548/AM_03_2010_Zmena_pravidel.pdf. In the **Czech Republic** and **Slovakia**, most of the GE corn is used as a feedstock for biogas stations. Milk and meat buyers require a statement that the animals were not fed on GE corn. This is not consistent with the fact that the main protein source in feeds in the Czech Republic is soy, which is mainly imported and biotech.

Portugal's perspective on the growing of GE varieties has been traditionally moderate. As a net importer of soybeans and corn for feed, poultry, pork, and feed associations are in favor of increasing imports of GE feed materials. There, however, are organized anti-biotech NGOs with a presence in the media and influence in the Former Environment Ministry, now merged into one with Agriculture, Forests, and Fisheries. Some corn producers with supply contracts with food companies are reticent to the use of biotech varieties because of the complicated and hard to implement segregation measures.

Spain, which was traditionally one of the most open MS to biotechnology, abstained in recent votes on biotech products at the EU level. Most of Spain's farmer associations are in favor of planting biotech crops. Spain is one of the major livestock producers within the EU; its structural shortfall of grains and oilseeds makes its trade, feed and livestock sectors traditional supporters of biotech. Meat produced with GE feed does not have to be labeled, thus there is not a strong reaction from retailers or meat consumers.

Sweden did not import biotech products or crops. Since January 2006, however, when the meat industry lifted its ban on biotech feed, small quantities of biotech soy products have been imported. While demand for this product is limited, there is reportedly no negative reaction from the trade. The food processing and retail sectors remain concerned about the possibility of negative consumer reaction and anti-biotech demonstrations. The **Finnish** meat industry followed the Swedish example and abandoned its ban on biotech feed in 2007.

GROUP 2 - MS **ready for adoption** (positive perception by the industry and the non-opposition by the public opinion) - Benelux, Denmark, Estonia, Finland, Lithuania, Sweden, and the United Kingdom

In this group, no GE crop is cultivated to date. These countries have a pragmatic approach and other GE crops, which are more appropriate to local markets and natural conditions could be adopted.

The **Benelux** livestock sector depends on feed imports from third countries, mainly soybean meal, which is mainly genetically modified. There is no resistance by consumers as the meat produced with GE feed does not have to be labeled. The Dutch Farmers Organization (LTO) and Belgian Farmers Organization (Boerenbond) are both pragmatic and in favor of planting biotech crops. Both organizations point to the resistance of retailers and consumers towards food products containing biotech components, in particular in export markets such as Germany.

The **Danish** meat industry has long been using GE feed in its animal production. Denmark imports 70 percent of its soybean meal from Argentina. The Ministry of Agriculture in **Lithuania** appears moving in direction of a science-based policy by its efforts to attract scientific seminars, source scientific publications, and arrange educational opportunities for young professionals in the United States. Additionally, rapeseed producers are vocal supporters of the Ministry's efforts.

In the **Netherlands**, the government is pragmatic as a significant share of the economy is based on imports. The government differentiates biotech policy for imports and for domestic production. Dutch farmers are generally not in favor of cultivating GE crops. For **Sweden**, the government is generally considered to be more open to biotechnology than the industry.

The **UK** approach remains pragmatic and science-based with the new government coalition, although not identified as a top priority. Private label dominates the supermarket sector and all retailers have a similar non-biotech policy for their goods. However, given the labeling derogation for animals reared on biotech feed, the majority of soy meal incorporated into swine rations is biotech in origin. Until recently, all private label poultry was fed non-biotech. Asda (Walmart) took the decision to source from members of the Round Table on Responsible Soy and have made sustainability the main factor in sourcing their soy, not non-biotech feed. Other retailers, such as Tesco, are reportedly following suit, incorporating sustainability as part of the normal food chain sourcing protocol. The increasing lack of availability and rising price premiums for non-GE are strong drivers for putting sustainability at the heart of retail sourcing as opposed to the question of GE or non-GE.

GROUP 3 - MS with **restrictive legislation and hostile opinion, but open farmers and industry -** Bulgaria, France, Germany, Ireland, and Latvia

These countries do not produce GE crops, but farmers are generally open to the technology.

In addition to the extremely restrictive biotech law of 2010, **Bulgaria** has two other regulations (amendments to the Food Law) that impose extreme requirements on the labeling and ban on sales of foods containing GE products in schools, kindergartens, and nurseries. The ban is valid for all GE products regardless of whether or not they are approved by the European Commission. The Bulgarian livestock sector depends entirely on feed imports from third countries, mainly soybean meal. Since the local livestock industry and consumers are very price sensitive, all imports are genetically modified. There is no resistance by consumers, as this meat produced with GE feed is not labeled. Poultry and Pork Producers Associations are in favor of importing biotech crops as long as this is done quietly and will not hurt animal products sales. However, the public opinion is very negative, and import restrictions are supported by all green and consumer organizations. The media is vocal and does not publish anything in support of biotechnology. Political parties do not support biotechnology and farmer organizations are not united.

In the past few years, **France** has taken various steps to prevent biotech crop cultivation, including the incorporation of the precautionary principle into its Constitution, the Ministry of Ecology taking the lead on biotechnology issues, the incorporation of socio-economic perspectives as part of the official biotech dossiers review, and the national ban on MON810 corn. The industry is divided on the biotechnology issue. The feed and livestock industry is pragmatic and imports biotech soybean and corn derived products, for which demand is high. The public opinion and retailers have significant demands for non-biotech sectors, such as organic and high-end products marketed under Geographical Indications. Most French farmers favor the technology and some consider the national ban on GE corn is affecting their competitiveness.

Germany also imposes a national ban on MON810 corn, mainly driven by the Green political forces.

The Ministry of Agriculture, however, is open to dialogue with the biotech industry. There is little prospect for near or medium-term acceptance of biotech crops, either from a regulatory or marketing perspective. A whole generation of Germans has grown up under the assumption – echoed by major political parties, NGOs, and the media – that biotech crops are bad. Among the political class, biotech crops are recognized 'third rail' that in any political calculus is not counterbalanced 'pro-biotech' forces. The food retail sector is concentrated and reluctant to support biotech policies that might be considered anti-consumer by either NGOs or competitors. The public arguments against biotech crops are shifting, border on urban myth, and are often mixed with anti-capitalist sentiment.

The Government of **Latvia** is openly negative towards biotechnology and encourages local municipalities to consider banning cultivation of crops enhanced through this technology. The agrarian sector is attempting to counter this activism. The livestock industry realizes it needs better access to animal feed, and currently gained approval to import U.S. origin soybeans into the market (after a break of several years due to the country's zero biotech tolerance policy). Only biotech feed can be found on the **Slovenian** market.

GROUP 4 - MS with the **strongest opposition -** Austria, Greece, Hungary, and Italy

In these countries, biotechnology has a negative image in the public opinion, national policies are restrictive, and the industry is not open to the technology. In these MS, the image of plant biotechnology was damaged principally by the binary approach by activists and the industry. The industry was discouraged to produce and use GE products, thus resulting in an official cultivation ban, and little to no research.

Austria remains one of the leading forces within the EU against agricultural biotechnology. The Gene Technology Act, its amendments, and pertaining orders represent the core of Austrian biotech regulations. Although some private labels promote the production of animals and animal products by "biotech-free" feed, the livestock industry is heavily dependent on biotech soybean meal. Most consumers are only concerned about biotech food directly deriving from biotech crops but not about animals and animal products from animals fed by biotech feed. There is high resistance from consumers and politicians regarding food which has to be labeled "biotech" according to EU regulations, such food cannot be found in the Austrian market.

The government of **Hungary,** elected in 2010 and include Greens, fundamentally renewed the Constitution of the country in 2011, expressing its negative stance on genetic engineering and insisting on the necessity to preserve biological diversity.

Several vocal NGOs and lobbying groups lead the charge against domestic development of biotechnology in **Italy**, which strongly influenced politicians and consumers' opinion. Italy must strike a balance between the productive, economic and environmental implications of the technology and its position under its "made in Italy" campaign and its role as a leading organic crop producer. The main farmer organizations have been split in their support of biotechnology. As for the food retail sector, the uncertainty around biotech national policy and the strong opposition from the public opinion, sharply affect supermarket chain marketing strategies. One supermarket chain and several brand names have consistently, and successfully, marketed themselves as GE-free.

Section V. Plant Biotechnology Capacity Building and Outreach

In the European Union, FAS offices believe it is crucial to facilitate mutual knowledge and understanding between the United States and Member States by maintaining a close dialogue with public authorities, farmers, and industry groups.

In **Austria, Bulgaria, the Czech Republic, France, Hungary, Latvia, the Netherlands, Poland, Romania, Slovakia**, and **Sweden**, country-specific activities conducted by FAS offices over the past two years included a number of outreach activities relative to plant biotechnology. The meetings, visits, and seminars for U.S. visitors (government, industry, research, farmer organizations) with European officials aimed at facilitating bilateral information flow and understanding. For example, the FAS/Paris office maintains presentations of official visitors on biotechnology at: http://www.usda-france.fr/biotechnology-en.htm. FAS Posts in Europe routinely facilitate exchanges for European visitors (policy makers, industry, farmers groups, media, universities, scientific researchers) who have expressed an interest in U.S. plant biotech issues.

USDA's Global Agriculture Information Network (GAIN) provides timely information on the agricultural economy, products, and issues in foreign countries that are likely to have an impact on United States agricultural production and trade. FAS Europe-based posts have reported on agricultural biotechnology this year:

Reports Prepared by Member States Within the Past Year			
Member State/EU	**Date**	**Report Number**	**Title**
EU	4/15/2011	E60023	EU Novel Foods Proposal failed to win Approval
	2/3/2011	E60005	The European Food Safety Authority
	1/31/2011	E60004	Proposed Novel Foods Regulation could impede Animal Products Exports
France	7/13/2011	FR9072	Innovation and Plant Biotechnology to Address Food Security
	5/17/2011	FR9067	Chief USDA Scientist Gets Scientific View of Biotechnology
Hungary	3/25/2011	HU1102	Scientific Community Promotes Plain Facts on GMOs
Italy	7/6/2011	IT1127	Italy Intends to Invoke Safeguard Clause
	6/28/2011	IT1125	Biotechnology in Italy 2011
Poland	1/25/2011	PL1105	Draft GMO legislation returned to Parliamentary Sub-Commission
UK	1/31/2011		The UK's forthright Foresight Report

FAS GAIN reports are available at:
http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx

Section VI. Animal Biotechnology

A. Use of Genetic Engineering – Research and Production

In several MS genetic engineering is not used in animals, while for the other MS, genetic engineering is used for medical or pharmaceutical applications. There is no GE animal commercially produced in the EU. In **Belgium,** GE animals are authorized for use as laboratory animal for medical research at universities and academic hospitals. In **Denmark**, transgenic pigs have been developed at Aarhus University to be used in research on Alzheimer's disease. The pigs have been genetically modified to function as animal models for Alzheimer's disease. Thereafter, the pigs are cloned with the use of these somatic cells.

In **France**, INRA conducts research in animal breeding on various livestock species in order to supply phenotypes (biomedical models) to study the genetic determinism of characters and gene regulation network. For example, INRA conducts research on the genetic resistance to infectious diseases in sheep. In 2010, INRA collaborated to the characterization of the gene and mutation responsible for a hair character in rabbits, used high debit genome analysis to assess genetic potential of dairy bulls, and studied the genetic factor of some hereditary genetic disorder in dogs. In **Germany**, animal biotechnology is made only on basic science level, in "closed system" laboratories.

GE animals are authorized for use as laboratory animal for medical research at universities and academic hospitals. In the **Netherlands**, 15 to 20 licenses are granted annually. The largest group of genetically modified animals is mice. The livestock sector does not keep genetically modified animals nor do agricultural research institutes for research purposes. Genetic engineering for the development of farm animals is not being used in the **Nordic countries**.

Genetic engineering of farm animals is still at the development stage in **Poland**. Research on GE animals is very limited. It is carried out in three research centers: Institute of Animal Breeding in Balice (Krakow), Institute of Animal Genetics in Jastrzebiec (Warsaw) and Agricultural University (Poznan). The leading animal GE laboratory of the National Institute of Animal Breeding in Balice near Krakow concentrates on production of animal (swine) for xenotransplantations. Most of the work concentrates on reduction of species-specific immunological difference and decrease of risk of xenograft rejection. Polish scientists from Balice produced a transgenic boar, TG 1154.

In **Spain,** there is no known research of development of GE animals for the food market. The Ministry of Environment and Rural and Marine Affairs keeps track of the GE animals used in confined facilities and publishes a complete list on their website. GE animal research since 1992 consists on mice, hogs or fish for medical purposes. Research in this field is carried out by both public and private research centers. In the **UK,** the universities of Cambridge and Edinburgh announced in early 2011 that they had created a biotech chicken that will not pass on the avian influenza virus to other birds, thereby preventing outbreaks spreading through poultry flocks. The researchers also claim that if introduced into commercial poultry flocks, the trait has the potential to increase the production of poultry meat and eggs by protecting the health of the birds. The study was published in the journal *Science*, and publicly funded by the Biotechnology and Biological Sciences Research Council (BBSRC).

B. Regulation

Animal biotechnology regulation in Europe parallels regulation of plant biotechnology, at both the EU and MS levels. **Denmark**, the **Netherlands**, and **Sweden**, however, do have specific regulations on animal biotechnology. In the past year, no changes occurred to EU biotech legislation. The European Food Safety Authority (EFSA) is working on guidelines for applications for risk assessments in view of the approval of GE animals in the EU market. Such risk assessments include several aspects as there are risk assessments on the food, feed, environmental safety assessment, and animal health and welfare (AHAW) aspects of GE animals.

EFSA is pursuing two different approaches for the food and feed safety issues, animal health and welfare issues, as well as environmental safety issues. The first approach includes creating two Working Groups (WG) within EFSA:

1. WG of the biotech Panel that is developing guidance for the molecular characterization and the food and feed safety assessment of products derived from GE animals, and
2. WG from the AHAW Panel that is developing guidance for animal health and welfare aspects.

For the environmental safety issues, EFSA tendered third party expert reports to define the criteria to be considered for the environmental risk assessment (ERA) of GE fishes, insects, mammals, and birds. These reports will serve as a basis for the development of EFSA biotech Panel guidance on the ERA of GE animals. During 2010, separate final reports for GE fishes and GE insects were published on EFSAs webpage, whereas work on the report for GE mammals and birds is still ongoing. EFSA has created webpage on Genetically Modified Animals that keeps track of the progress of the work on GE animals, as well as provides relevant documents and reports. To date, EFSA has not received any applications on GE animals.

Under the 7th Framework Program (FP), the European Commission is funding an integrated project, titled Pegasus, which aims to provide policy support regarding development, implementation, and commercialization of GE animals, derivative foods, and pharmaceutical products. The Pegasus project includes eight Work Packages. More information about the Pegasus project is available at: http://www.pegasus.wur.nl/UK/.

The government entities regulating biotech animals in MS are the Ministries of Environment (**France, Poland, Romania** and **Spain**), Agriculture (**Austria, Bulgaria, France, Germany, the Netherlands, Poland, Portuga**l, and **Sweden**), Rural Development (**Hungary**), Health (**Bulgaria, Czech Republic,** and **Slovakia**). Specific Committees are also in charge of this regulation. The Service of Biosafety and Biotechnology in **Belgium**; the Board for Gene Technology in **Finland**; the High Council on Biotechnology (HCB) and the National Agency for Health Safety in Food, Environment and Work (ANSES) in **France**; the National Authority on Food Safety in **Romania**; and the National Biosecurity Commission and the Inter-ministerial Council in **Spain.** Currently, there is no discussion regarding new regulation and policy of biotech animals in MS.

C. Public Opinion

In a majority of MS, animal biotechnology is currently a non-issue, and is expected to remain as such,

as long as genetic engineering is used in animals for medical and pharmaceutical purposes to treat diseases. An exception is the **Netherlands**, where the genetically modified bull, Herman, sparked a debate on the desirability of the technology in animals, leading to the introduction of legislation to regulate the application of biotechnology.