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Report Highlights:
Since 1998, the EU has approved nine biotech events in the face of considerable Member State (MS) resistance. Over 35 events are in the pipeline still waiting approval. The pace of approvals has slowed over the last year. The debate on biotechnology in the EU is highly politicized. Few of the contentious issues now confronting the EU are related to human health and environmental safety. Over the last 8 years the EU has implemented a comprehensive regulatory system to guarantee that biotech products are fully evaluated to ensure their safety. In September 2006, the WTO upheld the central claims of the United States, Argentina and Canada that the EU had imposed a de facto moratorium on the approval of biotech products that is inconsistent with WTO rules.

Includes PSD Changes: No
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Biotechnology Trade and Production

Status of Product Approvals

Syngenta's Bt11 sweet corn for human consumption was authorized for marketing in May 2004. This was the first new biotech product approved since the EU imposed an unofficial moratorium in 1998. Over the last 3 years, the EU has approved an additional 8 events (see table below). These are the only new biotech products that the EU has authorized for marketing since 1998. ("Authorized for marketing" means that the product is reviewed and approved for sale for a specific use or uses. Possible uses include for import, cultivation, processing, food, feed and industrial.)

Event	Company	Use
Insect Tolerant Corn Bt11	Syngenta	Food 1/
Herbicide Tolerant Corn NK603	Monsanto	Import, Processing, Food 2/
Herbicide Tolerant Rapeseed Gt73	Monsanto	Import, Processing 3/
Insect Resistant Corn MON863	Monsanto	Import, Processing, Food 4/
Herbicide Tolerant Corn GA21	Monsanto	Food 5/
Insect Tolerant Corn MON863 X MON810	Monsanto	Import, Processing 6/
Herbicide and Insect Tolerant Corn 1507	Pioneer/Mycogen	Import, Processing, Food, Feed

Herbicide Tolerant Hybrid Rapeseed (Ms8Rf3)	Bayer Crop Science	Import, Processing, Food, Feed
Modified Color Carnation Moonlite 123.2.38	Florigene	Import for cut flowers

1/ Approved for import and feed uses prior to 1998.
2/ Authorized for use as feed materials, feed additives and food additives in April 2005 under the "existing products" provisions. See section on Product Authorizations below.
3/ Authorized for use as feed materials, feed additives and food additives in April 2005 under the "existing products" provisions.
4/ Authorized for use as feed materials, feed additives and food additives in April 2005 under the "existing products" provisions. (Food approval pending.)
5/ Authorized for use as feed materials, feed additives and food additives in April 2005 under the "existing products" provisions.
6/ Authorized for use as feed materials in April 2005 under the "existing products" provisions.

Since 1998 no EU regulatory committee made up of the Member States has voted in favor of authorizing the marketing of a product despite consistently positive risk assessments from EFSA.

For all 9 events approved since May 2004, the Commission recommended that the Member States authorize the marketing of these products based on the positive risk assessments issued. Despite this the Member States failed to reach a qualified majority for or against approval and the Commission then asked the Council of Ministers to come to a decision. After three months, the Council also deferred and sent the matter back to the Commission. The Commission then authorized the marketing of the biotech events. Anti-biotech Member States and other groups have accused the Commission of thus "rubber-stamping" the approvals.

The Council of Minister's involvement in the approval process for biotech events is a dramatic departure from normal legislative procedures. Agriculture Ministers meet to approve major CAP reforms or EU trade policy positions in the WTO Doha round. Typically, working level officials drawn from the Member States meet in a regulatory committee to review technical issues and would make decisions on biotech events.

Currently, there are more than 35 biotech events in the pipeline for approval. Those furthest along in the process are presented in the following table. An increasing number of the applications are for cultivation. Since the cultivation of biotech crops is now the most politically-charged aspect of the biotech debate in Europe, the approval process will likely continue at the current leisurely pace.

Event	Company	Use	EFSA Risk Assessment
Insect Tolerant Corn Bt11	Syngenta	Cultivation	Positive
Insect and Herbicide Tolerant Corn 1507	Pioneer/ Mycogen	Cultivation	Positive

Potato, Altered Starch, EH92-527-1	BASF Plant Science	Cultivation and production of starch, food/feed uses	Positive
Insect and Herbicide Tolerant Corn MON863 X NK603	Monsanto	Import, Processing, food/feed	Positive
Insect and Herbicide Tolerant Corn NK603 X MON810	Monsanto	Import, Processing, food/feed	Positive
Insect and Herbicide Tolerant Corn MON863 X MON810 X NK603	Monsanto	Import, Processing, feed/ food	Positive
Insect and Herbicide Tolerant Corn 1507 X NK603	Pioneer/ Mycogen	Import, Food/Feed	Positive
Herbicide Tolerant LL Cotton 25	Bayer Crop Science	Import, Processing, Food/ Feed	Positive
Herbicide Tolerant Sugar Beet H7-1	Monsanto	Import, Processing, Food/ Feed	Positive
Insect and Herbicide Tolerant Corn 59122	Pioneer/ Mycogen	Import, Processing, Food/feed	Positive
Insect and Herbicide Tolerant Corn 59122	Pioneer/ Mycogen	Cultivation	Opinion Pending
Herbicide Tolerant Rapeseed (T45)	Bayer Crop Science	Import, Processing	Opinion Pending
Herbicide Tolerant Rice Liberty Link 62	Bayer Crop Science	Import, Processing, Food/ Feed	Opinion Pending
Herbicide Tolerant Soybean A27014-12	Bayer Crop Science	Import, Processing, Food/ Feed	Opinion Pending
Insect Tolerant Corn MIR604	Syngenta	Import, Processing, Food/Feed	Opinion Pending
Herbicide Tolerant Corn NK603	Monsanto	Cultivation	Opinion Pending
Insect and Herbicide Tolerant Corn NK603 X MON810	Monsanto	Cultivation	Opinion Pending
Herbicide Tolerant Corn GA21	Syngenta	Import, Processing, Food/feed	Opinion Pending
Corn, Altered Composition (ethanol) 3272	Syngenta	Import, Processing, Food/feed	Opinion Pending

Insect and Herbicide Tolerant Corn 1507 X NK603	Pioneer/ Mycogen	Cultivation	Opinion Pending
Insect and Herbicide Tolerant Corn 59122 X 1507 X NK603	Pioneer	Cultivation, Import, Food/feed	Opinion Pending
Herbicide Tolerant Soybean 40-3-2	Monsanto	Cultivation	Opinion Pending
Herbicide Tolerant Soybean A2704-12	Bayer Crop Science	Import, Processing, Food/ Feed	Opinion Pending
High Lysine Corn LY038	Renessen LLC	Import, Processing, Food/ Feed	Opinion Pending

Biotechnology Policy

Regulatory Framework

Technology providers can file an application for the authorization of agricultural biotech products under two EU regulations. Under Regulation (EC) No 1829/2003, a company can file a single application for the biotech event and all its uses (known as the "one door, one key "principle). The company submits the application to the competent authorities of the Member State where the product will first be marketed. Within 14 days, the Member State must forward the application to the European Food Safety Authority (EFSA) for review. The review conducted applies to all EU Member States.

EFSA conducts a single risk assessment and a single authorization can be granted for an event and all its uses (cultivation, importation, processing into food, feed or industrial products). While EFSA attempts to issue an opinion within 6 months, they may request additional information from the applicant thus lengthening the time frame. If EFSA issues a positive risk assessment, the application is forwarded to the European Commission, who has responsibility for risk management.

The Commission will then present a proposal to the Member States recommending that they authorize marketing of the product. The Commission may impose certain conditions (e.g., harvesting, transport, and monitoring) concerning the product. The Commission has 3 months to draft the proposal. The Member States then review and vote on the proposal in a regulatory committee. A qualified majority (QM) is required to approve or defeat the proposal. If the proposal fails to obtain a QM, the proposal then goes to the Council of Ministers for review. The Council has three months to make a decision. If the Council fails to reach a decision, the Commission may then authorize the marketing of the product. (See also the report AGR E47043 on the FAS Website for additional information on the decision-making procedure.)

Alternatively, a company can file an application under Directive 2001/18/EC for the purpose of marketing a biotech event for cultivation, importation and processing into different products. While the procedure under this directive resembles that of Regulation (EC) No 1829/2003, there are some differences. When the application is submitted in the Member State, that country's competent authorities perform an assessment. Should they issue a negative assessment, the applicant's only option is to submit the file in another Member State. However, if the Member State does issue a favorable assessment, then the results are shared with the Commission and all other Member States who may approve the event for

marketing within the EU or raise objections. Should objections be raised, then the Commission will ask EFSA to conduct a study. From this point on, the approval procedure resembles that of Regulation (EC) No 1829/2003.

The Commission's Directorate General for Health and Consumer Protection--known by the French acronym SANCO--handles applications that are submitted under Regulation (EC) No 1829/2003. Typically, the Agriculture Council of Ministers reviews Commission proposals under this legislative authority when the Member States are deadlocked. The Directorate General for the Environment handles applications submitted under Directive 2001/18/EC with the Environment Council of Ministers reviewing Commission proposals when the Member States fail to reach a QM.

Commission Reform of EFSA's Risk Assessment Procedures

Spearheaded by Austria, a number of Member States have complained that the Commission has been obliged to approve all 9 events since May 2004. In all cases, the Member States failed to muster a qualified majority in favor or against approval as required under community law. (Qualified majority gives more votes to the most populous Member States.) Most Member States have preferred to abstain rather than risk alienating key political constituencies.

In response to criticisms of EFSA, the Commission announced a number of changes to EFSA's procedures in mid-2006. Key changes included:

--EFSA will work more closely with national scientific bodies, with a view to resolving possible diverging scientific opinions with Member States.
--EFSA will provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities.
--EFSA will clarify the specific protocols that should be used by applicants to carry out scientific studies (for example regarding toxicology) demonstrating safety.
--Applicants and EFSA will also be asked to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs.
--If after EFSA has issued a positive opinion and the Commission or a Member State raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer back the question for further consideration.

Environment and Sanco Commissioners Dimas and Kyprianou contended that these changes will make the approval process more transparent, allay Member States' concerns, and thus compel them to vote for or against approval instead of abstaining.

Other Commissioners reportedly are less sanguine, commenting that these new requirements could result in undue delays in the authorization procedure. To date, the latter concerns appear justified. Over the last year, the number of new product approvals has dropped dramatically and the backlog of applications at EFSA has increased.

Political Factors

The debate concerning biotechnology in the EU is highly politicized. Few of the contentious biotech issues now confronting the EU are related to human health and environmental safety. Over the last 8 years the EU has implemented a comprehensive regulatory system to ensure that biotech products are fully evaluated to ensure their safety. The European Food

Safety Authority (EFSA) and the Member State competent authorities have the final scientific say before a product is authorized for release on the market.

Now the EU and the Member States are deadlocked over a number of issues that are based on economic considerations, and not safety: 1) the on-going search for seed labeling legislation for biotech events approved by EFSA and 2) the development of coexistence measures for biotech, conventional and organic agriculture that equally protect the interests of all farmers. Similarly, the EU Commission has stated that Member State marketing bans have not been based on legitimate safety concerns.

Product Authorizations

Please refer to the link below for a list of biotech food products that were approved under the Novel Food Regulation (EC) No 258/97:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec_authorised_en.pdf

The Novel Food Regulation (EC) No 258/97 has since been superseded by Regulation (EC) 1829/2003.

Please refer to the link below for a list of biotech feed products that were approved under the Directive No 2001/18/EC:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec_authorised_en.pdf

On April 18 2005, the Commission published a list of 26 biotech products that have been legally on the EU market since before the new legislative framework was introduced in April 2004 for authorizing biotech food and feed had entered into effect. These so-called "existing products" were either approved under former EU legislation, or did not require approval at the time that they were put on the market. They have been added to a specific section of the Community register of biotech food and feed in order to clarify exactly which products can be sold in the EU.

Since the entry into force of Regulation 1829/2003 on biotech food and feed in April 2004, all biotech products seeking to enter the EU market as food or feed have to undergo a thorough authorization procedure, including a scientific safety assessment by EFSA. However, there are certain biotech food and feed products that can be legally sold in the EU according to the rules in place before Regulation 1829/2003.

In order to cover these GM products, Regulation 1829/2003 stipulated that operators who wished to continue marketing an "existing product" had to notify the Commission and submit detailed information on the biotech event before October 18, 2004. Non-notified products will no longer be allowed on the EU market. The Commission and its research agency the Joint Research Center, examined the validity of the notifications it received and agreed to enter 26 biotech products into a specifically created section of the Community register of genetically modified food and feed. Once one of these "existing products" is on this register, it can legally be sold in the EU for a set period of between 3-9 years, after which it has to resubmit an application for the renewal of the authorization. For the register of biotech "existing products", see:

EUROPA - Food Safety - Biotechnology - Authorisation - Community Register of GM Food and Feed

Specific legislation governing these products can be found at the following link:

http://europa.eu.int/comm/food/food/biotechnology/gmfood/reg641_2004_en.pdf

Member State Marketing Bans of Biotech Products

Starting in 1997, Austria, Denmark, France, Luxembourg, Germany, and Greece invoked national safeguard measures (Directive 2001/18/EC, Article 23) in order to ban the marketing of a number of biotech products. In November 2004, EU Member States met in a regulatory committee to review the Commission's proposal recommending the lifting of the bans. The Commission based its recommendation on EFSA opinions asserting that there was no scientific basis for the Member State bans. Nevertheless, the regulatory committee failed to reach a decision and the Commission referred the matter to the Council.

On June 24, 2005 the Environment Council, consisting of the Environment Ministers of the Member States in the European Union, voted against the Commission proposal to lift the bans or restrictions imposed on biotech products. The Council voted against all eight Commission proposals. A number of these eight safeguard clauses include bans or restrictions on cultivation, while others include bans on imports and use in food and feed. This was the first time that the Council reached a qualified majority against a Commission proposal on biotech since 1998.

The events banned are presented in the following table. The Commission had approved these products for marketing based on positive risk assessments issued by EU scientific committees.

Country	Event Banned	Date of Ban
Austria	Syngenta Bt176 Corn, Bayer T25 Corn, Monsanto MON810 corn	1997, 2000, 1999
France	Bayer Rapeseeds Topas 19/2 and MS1XRf1	1998 for both
Germany	Syngenta Bt176 corn	2000
Greece	Bayer Rapeseed Topas 19/2	1998
Luxembourg	Syngenta Bt176	1997
Hungary	MON810 corn	2005

On April 12, 2006, EFSA once again reaffirmed the safety of the banned biotech products, stating that "there is no reason to believe that the continued placing on the market of the 5 products is likely to cause any adverse effects for human and animal health or the environment." In the light of the EFSA opinion, the Commission proposed two draft Council decisions requesting Austria to repeal its measures concerning MON810 and T25 maize. In December 2006, the Council rejected the proposals of the Commission to lift the national marketing bans. The Commission has now three options according to EU comitology rules: to

submit amended proposals to the Council; re-submit the same proposals or present legislative proposals through co-decision procedure.

In 2007, the companies that developed three of the banned products (Bt176, Ms1Rf1 and Topas 19/2) notified the Commission that they no longer wished to market these products. The companies didn't plan to file applications to renew EU licenses for these three products (plus two others) before the products' authorization expired on April 18. The Commission stated that "if the companies responsible for these GMOs wanted to continue marketing them in the EU after that date, they had to submit an application to the Commission. For the 5 GMOs affected ... no applications for renewal are expected. This is due to the fact that they are no longer being used and the companies no longer have any commercial interest in them."

In March 2007, the Commission and Member States voted to withdraw 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 Ms1Rf1). The other products withdrawn were Monsanto's MON810 X GA21 corn and Bayer's Ms1Rf2 rapeseed. The Commission's decisions concerning these products can be viewed at the following sites:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_117/l_11720070505en00140016.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_117/l_11720070505en00170019.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_117/l_11720070505en00200022.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_117/l_11720070505en00230024.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_117/l_11720070505en00250026.pdf

In January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 corn. The Commission submitted the information provided by Hungary to EFSA for its evaluation. In June 2005, EFSA concluded that this information did not invalidate the initial risk assessment of MON 810. On September 18, 2006, a Sanco regulatory committee made of Member State officials failed to reach a qualified majority either in favor or against any of these proposals. Under these circumstances, and in accordance with EU comitology procedures, the proposals were transmitted to the Council. On February 20, 2007, the Council rejected the proposal of the Commission to lift the national safeguard clauses. The Commission now has three options according to EU comitology rules: to submit amended proposals to the Council; re-submit the same proposals or present legislative proposals through co-decision procedure.

Coexistence

Commission officials have stated on numerous occasions that coexistence is an economic and marketing issue, and not a safety issue. Coexistence rules and practices apply only to biotech events that have been authorized for marketing by the Commission and have received a positive risk assessment from EFSA.

In March 2006, the Commission released a report reviewing the experiences of the 25 Member States in the implementation of coexistence measures for organic, conventional and biotech crops. The Commission concluded that harmonized, EU-wide rules on coexistence

are not justified at the moment because of a lack of experience in implementing national measures.

Agriculture Commissioner Fischer-Boel stated that, "growing conditions are very varied from country to country and experience with GM crops is still limited in Europe. It therefore does not seem appropriate to propose unified EU rules at this time." Fifteen countries have notified the Commission of their draft national rules so far. A complete summary of the proposed rules of the Member States can be viewed at the Commission website.

Initiated by Austria, the Commission organized a conference on coexistence in Vienna in April 2006. EU Agriculture Commissioner Fischer Boel again reiterated that EU-wide rules on coexistence are not justified at present in view of the limited experience with the cultivation of biotech crops and the fact that the process of introducing national coexistence measures has not yet been completed. "Whatever our personal views may be, the use of GM technology is spreading, as is the use of GM crops," she said. "It is already completely legal to grow certain GM crops within the European Union and the list of permitted crops will almost certainly become longer if we look years ahead. GM farming has arrived," she told the conference.

At the conference, EU Environment Commissioner Dimas again expressed his misgivings on a number of aspects of biotech. According to him, there is still no satisfactory scientific assessment of the long-term impact of biotech crops. He also stated that biotech products used for cultivation presented a "whole series of possible risks to the environment, notably potential longer-term effects that could impact on biodiversity." Currently, 8 GM products for cultivation are wending their way through EU's regulatory process (of which 3 have already gotten positive risk assessments). Dimas encouraged continued research to improve conventional varieties. "We must, therefore, persist in looking at the means to continually improve these varieties. We should not ignore the use of upgraded conventional varieties as an alternative to GM crops, particularly where similar characteristics can be introduced without genetic modification," he said.

Austria, Denmark, and Italy have taken the lead in pressing the Commission to adopt an EU-wide regulation for the coexistence of biotech crops and conventional and organic agriculture. Along with Germany, each of these countries has drafted coexistence laws that are extremely restrictive in terms of what farmers of biotech crops are required to do. Faced with such challenges, farmers will likely not run the risk of planting biotech crops. Moreover, certain aspects of these laws would appear to violate the internal market rules of the EU which guarantees "free circulation", and is reiterated in Article 22 of Directive 2001/18/EC which regulates the deliberate release into the environment of genetically modified organisms.

Labeling

The EU's labeling requirements are intended to address consumer concerns, and are not related to safety. Before a product can be labeled as biotech, the Commission must review its safety and authorize the marketing of it. Similarly, the EFSA must issue a positive risk assessment.

Labeling regulations for products containing or consisting of GMOs are presented in Regulation (EC) No 1830/2003, article 4B. In general, these labeling regulations apply to bulk agricultural commodities such as whole grains and oilseeds. The scope of GMO products covered is defined in Directive 2001/18.

Labeling regulations for food and feed products that are produced from GMOs are presented in Regulation (EC) No 1829/2003, articles 12-13 for food and articles 24-25 for feed. These products have undergone varying degrees of processing.

In general, all food and feed products containing/consisting of GMOs and/or produced from GMOs, including products that no longer contain detectable traces of GMOs, must be labeled. The allowable adventitious presence level for EU-approved varieties of GMOs for use in food and feed is set at 0.9 percent. Above this level, all products must be labeled. For GM varieties, which are not yet formally approved but which have received a positive EU risk assessment, the adventitious presence level is set 0.5 percent. This provision will expire after 3 years. Above this threshold, the product is not allowed on the EU market. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

The regulation does not require labeling of products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

An Example of to How to Label for Food Produced from GMOs

Article 13 of Regulation 1829/2003 specifies the wording to be used on the label as follows:
(a) Where the food consists of more than one ingredient, the following wording must follow immediately after the ingredient concerned, in brackets: "genetically modified" or "produced from genetically modified [name of ingredient]. A compound ingredient with a constituent X which is produced from a GMO Y must be labeled "contains X produced from genetically modified Y.
Example: a biscuit containing soy flour derived from GM-soy must be labeled "contains soy flour from genetically modified soy".
(b) Where the ingredient is designated by the name of a category, the following wording must be used in the list of ingredients: "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]".
Example: for vegetable oils containing rape oil produced from genetically modified rape, the reference "contains rape oil from genetically modified rape" must appear in the list of ingredients.
(c) Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of organism]" must appear clearly in the labeling.
Example 1: "a spirit containing caramel produced from genetically modified corn".
Example 2: "genetically modified sweet corn"
(d) If the product consists of or contains a GMO e.g. sweet corn in a Mexican salad, the label must state "genetically modified sweet corn"
The designations in (a) and (b) may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

Labeling for Genetically Modified Microorganisms (GMMs) and "Processing Aides"

The Commission stated on September 24, 2004 that "food and feed (including food and feed ingredients such as additives, flavorings and vitamins) produced by fermentation using a GMM which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation (EC) No. 1829/2003. These food and feed products have to be considered as having been produced with the GMM, rather than from the GMM."

Therefore, these products don't have to be labeled like products produced from agricultural biotechnology. This was contrary to the original position taken by the Commission in April 2004 when the Commission had proposed that these products be labeled (see point 2D, Fermentation Products).

Likewise in the case of GMMs such as yeast used in alcoholic beverages, the Commission doesn't require labeling if the GMM is not present in the final food. Like vitamins, the EU justifies its stance on the basis that the "…resulting food is considered to have been produced with a GMM, but not from a GMM". This is also true of cheese that has been produced "with" the use of chymosin, an enzyme that is genetically modified. Such processing aides don't fall within the scope of the labeling regulations.

Status of Seed Labeling Legislation

While the former Prodi College of Commissioners had intended in September 2004 to propose a seed labeling amendment for the presence of GM seeds commingled with conventional seed, the different directorate generals (DG) couldn't reach agreement. Reportedly, DG Environment and DG Agriculture pressed for a maximum AP of 0.3 percent for corn whereas DG Health and Consumer Protection favored 0.5 percent. There was agreement of 0.3 percent for rapeseed. Faced with this impasse, the Prodi Commission called for additional research to determine the economic impact of different thresholds on farmers and seed producers before taking any further action. The Commission has been trying to develop a policy on seed labeling since 2001 when the Scientific Committee on Plants presented recommendations on AP levels for a number of biotech seeds (corn—0.5 percent; soybeans—0.7 per cent; and rapeseed – 0.3 percent).

In the absence of a EU seed labeling regulation for the presence of biotech seed, the Commission has stated that since no thresholds for the AP of GMOs in conventional seed lots have been established, any seed lot containing GM seed authorized for the cultivation has to be labeled as containing GMOs. Seed lots containing GM seeds that are not authorized for cultivation can not be marketed in the EU.

Some members of the new Barroso Commission appear to favor setting AP thresholds at the level of detection--0.1 percent. Environment Commissioner Stavros Dimas has voiced support for 0.1. Likewise, Agriculture Commissioner Mariann Fischer-Boel, one of the architects of Denmark's tough coexistence law and a strong proponent of organic agriculture, also reportedly favors very low thresholds.

In February 2006, the Joint Research Center, released a report demonstrating how farmers can reduce the adventitious presence of biotech material in non-biotech crops, and in general supported higher thresholds than reportedly proposed by the Directorate Generals of Environment and Agriculture. "The report concludes that conventional (non-GM) seed production in Europe with adventitious GM presence not exceeding 0.5% is feasible with few (maize) or no changes (sugar-beet and cotton) of current seed production practices. For maize seed production, such changes would build on existing practices (namely the implementation of larger isolation distances than those currently used to separate maize seed and maize crop production fields). In addition, lowering the seed threshold to 0.3 % would require additional measures (for example arranging GM and non-GM seed plots in the farm in a way that takes into account dominant winds). Finally, guaranteeing that maize seeds will contain no more than 0.1 % adventitious GM presence is not possible if co-existence measures are limited to action on individual farms or coordination between neighboring farms."

Traceability

The EU's traceability requirements are intended to address consumer concerns, and are not related to safety. Before a product can be sold in the EU, the Commission must review its safety and authorize the marketing of it. Similarly, the EFSA must also issue a positive risk assessment.

Under the rules for traceability in Regulation (EC) No 1830/2003, business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market. Information concerning the presence of GMOs must be transmitted throughout the commercial chain and must be retained for five years. The regulation covers all products, including food and feed, containing or derived from GMOs that received an EU authorization, e.g. GM seeds, GM grain, tomato paste and ketchup derived from a GM tomato or starch, oil or flour produced from a GM maize.

--for GMOs intended for deliberate release into the environment: operators must transmit specified information on the identity of the individual GMO(s) a product contains;

--for GMOs intended for food, feed or for processing: business operators may either transmit the specified information or transmit a declaration that the product shall only be used as food or feed or for processing together with the identity of the GMO(s) from which the product was derived;

--for food and feed produced from GMOs: operators must inform the next operator in the chain that the product is produced from GMO(s).

On January 14, 2004, the European Commission published Commission Regulation 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs. A unique identifier is assigned to each GMO as a means of tracking its presence and reflecting the specific transformation event covered by the consent or authorization for placing that GMO on the market.

Cartagena Biosafety Protocol

The EU is a signatory to the biosafety protocol. To align its regulatory framework with the provisions of the Protocol, the EU has implemented a Regulation on transboundary movements of GMOs that addresses in particular exports of living modified organisms. The regulation was approved by the Council of Ministers on 13 June and entered into force in September 2003.

Trade Barriers

The current EU regulatory system and approval process for biotech products is a barrier to trade. Since 1998, the EU has approved only 9 biotech events. Currently, the EU has a backlog of about 35 products that are awaiting approval. In view of the unwieldy and less than transparent process for application and approval, it is unlikely that this backlog will be reduced significantly in the short term.

In May 2003, the United States announced that it would initiate a WTO dispute settlement process focused on the EU's de facto moratorium on approvals of biotechnology products, and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. In March 2004, the WTO formed a panel to consider the

challenge of the United States, Argentina and Canada to the EU's moratorium on the approval of new agricultural biotech products. The panel hearing the dispute delivered its interim report in February 2006 and published the final report on September 29, 2006.

The panel upheld the central claims of the United States and the other complainants that the EU had imposed a de facto moratorium on agricultural biotechnology products that is inconsistent with WTO rules. The European Commission has not yet indicated how it plans to implement the panel's decision.

On April 18, 2004, the EU's newest regulations (EC No 1829/2003 and EC No 1830/2003) concerning the labeling and traceability of biotech food and feed products went into effect. These new regulations were intended to address the Member States' concerns about protecting consumer and environmental interests. Despite the passage of these regulations, the Member States continue to thwart the approval of new biotech products that have received favorable risk assessments from the European Food Safety Authority and the support of the EU Commission. In addition, Austria and Hungary continue to maintain illegal marketing bans on approved biotech events.

Regulations 1829/2003 and 1830/2003 are frequently difficult to understand and comply with and have had an adverse impact on trade. The Commission has been slow to provide guidance documents to help exporters interpret these new regulations. In particular, exporters have had difficulty determining if their product (s) are subject to the new labeling requirements. Finally, Sanco and the Member States decided that products (such as beer, wine and cheese) that are produced with genetically modified "processing aids" are not subject to these regulations. This is inconsistent with the intent of the new regulations.

In accordance with DG Agriculture's guidance document on the coexistence of biotech and conventional crops, which recommended a regional approach to coexistence issues, a number of Member States, including Denmark, Germany, and three regions in Austria, have drafted new coexistence laws. These laws have taken a maximalist approach, requiring extensive liability systems be put in place and mandating extremely low thresholds for adventitious presence. Once enacted, the European Commission may initiate infringement proceedings against a Member States' coexistence law if it is judged to be incompatible with EU law. However, there is no time limit on how quickly the Commission must act.

Marketing Issues

The breakdown in the EU's approval process for products made from biotechnology has blocked most U.S. exports of corn and hinders trade in other products. Many food processors and exporters have either reformulated or sought out non-biotech sources in response to the implementation of mandatory traceability and labeling requirements in April 2004. Consumer-ready products have been particularly hard hit. Most European retailers' own-store brands are non-GM, while they may consider carrying private supplier brands containing biotech ingredients. Since labeling hasn't been required for animal products such as meat and dairy, biotech feed ingredients have generally fared better. Reportedly, about 2/3 of the animal feed consumed in the EU is currently labeled as genetically modified. However, some consumer groups are pressuring retailers to carry meat and dairy products produced from non-biotech feed ingredients. Agricultural biotechnology continues to be more of a political than a scientific issue in Europe and the prospects for improvement remain dim.

Exports of Bt10 Corn

On March 22, 2004 Commission officials were advised that the company Syngenta had inadvertently marketed the biotech corn Bt10 in the United States from 2001-2004. Since Bt10 had not been authorized for marketing in the EU, the Commission introduced emergency inspection measures to identify the presence of Bt10 in exports of corn gluten feed and distiller's dried grain to the EU. The inspection system went into effect on April 18, 2005, and was to remain in place for 6 months at which time a review would be conducted to determine whether it was still necessary. In October 2005, Member States voted to extend the measures. In 2003/04, the United States shipped about 3.4 million tons of corn gluten feed, a pelletized feed ingredient valued at about $340 million, to the European Union as a feed ingredient used in compound animal feed.

On January 16, 2007, the Commission and Member States voted in favor of lifting the emergency inspection measures for corn gluten feed and distiller's dried grain. The Commission decision repealing the measures went into effect on March 7, 2007.

Exports of U.S. Long Grain Rice

On August 18, 2006, U.S. Secretary of Agriculture, Mike Johanns announced that the U.S. Department of Agriculture (USDA) and U.S. Food and Drug Administration had been notified by Bayer Crop Science that the company had detected trace amounts of a biotech rice known as Liberty Link 601 in samples taken from commercial long grain rice. At the time of the announcement, LL601 was not approved for marketing in the United States nor the EU. The EU is a major export destination for U.S. long grain rice. In CY2005, U.S. exports of rice to the EU-25 equaled $86.5 million, the bulk of which was long grain.

Since LL601 had not been authorized for marketing in the EU, the Commission introduced emergency measures on August 23 to identify the presence of LL601 in exports of U.S. long grain rice. The measures required that all exports of long grain rice be accompanied with an analytical report stating that the product doesn't contain LL601. The USDA and Bayer Crop Science developed and validated a methodology to test for the presence of LL601 in U.S. long grain rice exported to the EU. Upon receipt of reference material from Bayer Crop Science, the Joint Research Center of the Commission validated this detection method. Under the emergency measures, the Commission instructed Member States to use this detection method to carry out random sampling and analysis.

The Commission reported on September 11 that Dutch authorities detained a 20,000 ton shipment consisting of 23 barges of rice. Three barges tested positive for LL601 while 20 barges tested negative. Dutch and Commission authorities ordered the rice to be returned to the United States or destroyed. Over the following weeks, other Member States detected traces of LL601 in bulk shipments and processed products resulting in numerous cases of product rejections and returned shipments. Because of the heightened financial risks of product rejection, U.S. exports of rice all but stopped.

While all U.S. rice shipments were required to be accompanied by an analytical reports attesting to the absence of LL601, the testing protocols employed in the United States at origin and in the EU at destination yielded divergent results. (Testing at destination was at this point at the discretion of Member State authorities, and not mandatory.) In response, the U.S. government began intensive talks with Commission officials to establish a common protocol for the sampling and analysis of rice shipments in an effort to avoid mandatory testing at destination. These talks failed to produce an agreement and the Commission with Member State support introduced mandatory testing at destination on October 23, 2006. This had the effect of continuing the effective embargo on trade in long grain rice from the United States.

Coincident with the U.S. government's notification to the EU of the presence of LL601 in long grain rice, Greenpeace and the Friends of the Earth reported the week of September 4, 2006 that they had found evidence of a biotech rice in products imported from China. Since that time, Member States have notified the Commission on 12 separate occasions concerning the positive detection of unauthorized GM rice and processed rice products from China. The most recent notification occurred on May 10, 2007.

To date, the Commission has not imposed emergency measures mandating the inspection of Chinese rice products at origin in China nor at destination in the EU. All sampling and analysis that has been conducted by Member State authorities has been at their discretion. Moreover, Commission officials are still working---nearly 9 months later--to validate with Chinese officials a method for the detection of unauthorized Chinese biotech rice exports. U.S. officials presented to their EU counterparts a validated methodology on August 23, 2008, 4 days after they notified the EU of the detection of LL601.

To review the Commission and MS deliberations concerning unauthorized Chinese biotech rice, please click on the following links:

March 2, 2007 Sanco Standing Committee Report

January 16, 2007 Sanco Standing Committee Report

October 23, 2006 Sanco Standing Committee Report

September 11, 2006 Sanco Standing Committee Report

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