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Report Highlights:
Since 1998, the EU has approved seven biotech events in the face of considerable member state (MS) resistance. About 30 events are in the pipeline still waiting approval. Currently, marketing bans on EU-approved biotech events are in effect in 6 MSs. 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 7 years the EU has implemented a comprehensive regulatory system to guarantee that biotech products are fully evaluated to ensure their safety. The Commission's recent changes to how the European Food Safety Authority conducts risk assessments could further slow the approval process.

Includes PSD Changes: No
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Executive Summary

Since 1998, the EU has approved seven biotech events. About 30 events are in the pipeline waiting approval. Currently, marketing bans on EU-approved biotech events are in effect in 6 member states. 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 7 years the EU has implemented a comprehensive regulatory system to ensure that biotech products are fully evaluated to ensure their safety. However, the Commission's recently implemented changes to how EFSA conducts risk assessments could further slow down the approval process.

The EU and the member states are now 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 ; 2) the development of coexistence measures for biotech, conventional and organic agriculture that equally protect the interests of all farmers; and 3) the lifting of the marketing bans in 6 member states.

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 2 years, the EU has approved an additional 6 events (see table below). These are the only new biotech products that the EU has authorized for marketing since 1998.

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

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. (Food approval pending.)

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 7 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 3 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 consulting in a regulatory committee would make decisions on biotech events.

Currently, there are about 30 biotech events in the pipeline for approval. Those furthest along in the process are presented in the following table.

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

Event	Company	Use	Assessment
Potato, Altered Starch, EH92-527-1	BASF Plant Science	Cultivation and production of starch, food/feed uses	Positive
Herbicide Tolerant Hybrid Rapeseed (Ms8Rf3)	Bayer Crop Science	Import, Processing, Feed	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 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 LL Cotton 25	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 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	Pioneer/ Mycogen	Cultivation, Import, Food/feed	Opinion Pending
Insect and Herbicide Tolerant Corn 59122 X 1507 X NK603	Pioneer	Cultivation, Import, Food/feed	Opinion Pending

Insect and Herbicide Tolerant Corn 59122 X NK603	Pioneer	Cultivation, Import, 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.

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 recommending that the member states authorize 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.

A company can also 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 7 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.

Frustrated by its inability to block approvals, Austria proposed changing the voting procedure to base the outcome on a numerical majority as opposed to a qualified majority. This proposal gained little traction since such a change would require that the EU alter its decision-making procedures (known as comitology) in other policy spheres.

Since EFSA has consistently issued positive risk assessments, the anti-biotech member states and non-governmental organizations (NGOs) have attempted to undermine its credibility. Holding the current presidency, Austria exploited its position to organize a wide-ranging discussion of biotech at the Environmental Council in March and a conference on coexistence in April in Vienna. With the tacit support of Environment Commissioner Dimas and the open support of various NGOs, the Austrians orchestrated an effective campaign against the risk assessment procedures of EFSA.

In response to the criticisms of EFSA, the Commission announced a number of changes to EFSA's procedures. Key changes include:

--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 contend 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 with implications in the WTO.

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 7 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 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 the marketing bans in 6 member states are not 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, in co-operation with 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

Marketing bans for a number of events remain in effect in Austria, Denmark, France, Luxembourg, Germany, and Greece. 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 is 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

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." While it is not clear what the Commission will now do, reportedly some of the products will soon be withdrawn from the market as newer products become available. However, Austria may still face proceedings on two of the products it has banned.

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." Four countries (Germany, Denmark, Portugal, and 6 regions in Austria) have approved measures so far. A complete summary of the proposed rules of other 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, three GM products for cultivation are wending their way through EU's regulatory process (all 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 a 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 0.03 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, a EU institution, 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 traceablity 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 indicating 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 7 biotech events. Currently, the EU has a backlog of about 30 products that are awaiting approval. In view of the unwieldy and less than transparent process for application and approval, we do not expect this backlog to 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. In February 2006, the WTO released a confidential copy of the panel's findings to the parties to the case. Press reports have indicated that the WTO has preliminarily found that the EU has had a de facto moratorium on agricultural biotechnology products that is inconsistent with WTO rules. The panel report is expected to be released to the public in September 2006.

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, 5 member states continue to maintain illegal marketing bans on a number of 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, the EU has 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.

In a Eurobarometer poll on the environment, Europeans responded that the impact of chemicals (41 percent) and biotechnology (40 percent) were the two areas in which they

most lacked information. 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.

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E36050	USEU	European Commission Report on Coexistence	4/26/06
E35183	USEU	GMO trials on wine given go-ahead in France	10/7/05
E35158	USEU	GMO Warnings Issued to three Member States	08/8/05
E35154	USEU	EFSA Says GM Maize Hybrids are Safe, MON863 Dossier Passed to Council	08/3/05
E35152	USEU	EFSA Launches Public Consultation on Post-Market Environmental Monitoring	08/3/05
EU35074	USEU	Register of Existing GM Food and Feed Products Published by the Commission	08/3/05
EU35126	USEU	Environment Council votes No to Lifting Biotech Bans	08/2/05
EU35091	USEU	Annual Biotechnology Report	06/13/05
EU35075	USEU	Register of Existing GM Food and Feed Products Published by the Commission	04/22/05
FR6012	Paris	French Reactions to WTO Preliminary Conclusions on Ag Biotechnology	03/7/06
FR6008	Paris	French Biotech Bill Progresses	02/27/06
FR5088	Paris	Despite Obstacles French Corn Growers Will Plant Biotech Corn	01/24/06
FR5084	Paris	Exploring Coexistence	01/24/06

FR5061	Paris	French Corn Growers Show Strong Support for Biotech crops	09/20/05
FR5060	Paris	500 to 1,000 ha of GM corn in France in 2005	10/07/05
FR5051	Paris	Annual	08/30/05
GM5041	Berlin	Three Bt Corn Seed Varieties Registered in Germany	01/24/06
GM5027	Berlin	Annual	08/30/05
GM5013	Berlin	Marginal Improvement on Biotech Regulations in Germany	03/22/05
IT6017	Rome	Coexistence Legislation in Italy - The Court Steps In	04/26/06
IT6004	Rome	Italian Scientists ask the Political Leadership for a Positive Stand on GMOs	02/27/06
IT5301	Rome	FAO AND BIOTECHNOLOGY	02/14/06
IT5026	Rome	Annual	06/28/05
IT5003	Rome	Italy's Coexistence Law - English Text	02/03/05
NL5028	The Hague	Annual Agricultural Biotechnology Report	10/28/05
DA5010	Copenhagen	Denmark Expected to Vote for Approval of GM Corn Event	10/28/05
DA5007	Copenhagen	Annual	09/16/05
DA5002	Copenhagen	Danish Advisory Committee Call for Consumer Acceptance of Biotechnology.	01/18/05
AU5029	Vienna	Austria to Lead GMO Debate	01/24/06
AU5022	Vienna	European Court of Justice Rules Against Upper Austria's GMO-free Zones	10/28/05
AU5019	Vienna	Survey Shows Only 11% of Consumers Willing to Buy Biotech Foods	10/07/05
AU5004	Vienna	Organic Farmers' Association Starts New Anti-Biotech Campaign	08/17/05
AU5012	Vienna	Annual	08/30/05
SP5034	Madrid	Biotechnology Update	10/28/05
PO5021	Lisbon	Report	10/28/05
PO5017	Lisbon	Annual	09/15/05
PL6007	Warsaw	Polish Reaction to WTO Biotech Case	03/24/06
PL5034	Warsaw	International GMO Protest in Poland	01/26/06
PL5014	Warsaw	Annual	08/12/05
UK5013	London	Annual	08/30/05

SW5016	Stockholm	Swedish Farmers Lift GM Feed Ban	12/15/05
SW5010	Stockholm	Annual	08/12/05
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