Appendix B: Background on EU regulatory process and regulations

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References used in this section:

Current state of regulations and approvals: http://ec.europa.eu/food/food/biotechnology/gmfood/

Texts of regulations: search by regulation number of subject area in http://eur-lex.europa.eu

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Background on EU regulatory process and regulations

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Several European Union institutions have a role in the regulation of genetically modified foods. The EU Commission, the supranational body of individual administrators in charge of policy proposals and implementation, is the executive branch of the European Union. The Commission currently consists of one commissioner from each of the EU's 27 member states, but will be reduced to a number of members equivalent to two-thirds the number of member states effective in 2014. Commissioners serve a five ear term coinciding with the five year term of members of Parliament. The President of the Commission is selected by the EU Council while other commissioners are selected by member governments in consultation with the incoming commission president. President and members are then confirmed in office by the European Parliament. The Commission drafts proposals for consideration by the EU Council of Ministers and European Parliament, and supervises the EU bureaucracy. In its executive branch role, the Commission exercises more direct control over the regulation of GM foods than either of the EU's two legislative bodies. Its task is to look out for the general public interest, rather than the interests of specific member states or domestic constituencies within them.

Before developing rules addressing a specific GM organism or product, the Commission secures a risk assessment of that GM organism or product from the European Food Safety Authority (EFSA), an independent agency governed by a fifteen member Management Board of experts appointed by the EU Council. The EFSA's Panel on Genetically Modified Foods consists of appointed members with a scientific background, provides the risk assessment and advises on whether to approve the sale of foods consisting of or made with ingredients derived from GM plants.

The Commission also has an important legislative task: it alone has the right to propose new Directives and Regulations ("European laws"). Final legislative authority, including adoption of laws and the EU budget, is shared by two bodies, the Council of Ministers (EU Council) and the European Parliament. The Council is an intergovernmental body consisting of the head of government (premier, chancellor, or prime minister), or relevant department head (minister) of each member state's national government. Which official attends a particular Council meeting is determined by the issue on the agenda, and the name of the ministry involved is attached when the Council meets at the ministerial level. Thus, ministers of the environment ("the Environment Council") deal with pollution and other environmental concerns while ministers of agriculture ("the Agricultural Council") deal with farming. Issues raised by GM technology are considered by both the Environment Council (which tends to be more skeptical of it) and the Agriculture Council (which tends to be more accepting of it). Except in particularly sensitive areas like taxation, immigration, foreign policy and security policy, on which unanimity is required, the Council makes decisions by a qualified majority. Each member state is assigned a number of votes based roughly on population on a formula giving some extra votes to the smaller countries so they do not feel overwhelmed by the larger. The exact requirements for a qualified majority have shifted as the number of EU member states has increased. During the period of greatest contention on biotechnology policy discussed in the case on GM foods, the Council's Qualified Majority Voting rules required that Council members from at least half of the member states having at least 62% of the total EU population and casting 255 of the 345 total votes (approximately 74% of the total). In practice, however, the Council continues to seek consensus, which works well when issues are not contentious and leads to prolonged stalemate when they are.

The EU's second legislative body, the 785-member European Parliament, is the only EU body in which the members are chosen directly by voters in the member states. Besides sharing authority to adopt European laws and the EU budget, it can also exercise some control over the executive by dismissing the whole European Commission. If it does, the whole commission must be replaced. This is a severe measure which the Parliament does not consider very often; yet a serious threat to do so usually induces the Commission to stop doing whatever the Parliament finds so objectionable.

The EU Court of Justice, the judicial branch, resolves disputes between EU agencies and member state governments. Member governments can challenge acts of the Commission on grounds they exceed Commission authority or are inconsistent with the basic EU treaties or an EU directive; and the Commission can ask the court to require a member state taking no action or only very slow action to fulfill its obligations to implement or enforce European laws. The courts of member states also refer questions about the correct interpretation of European laws to the EU Court of Justice and use its judgments to make their own rulings in particular cases where lawsuits within a country involve EU laws.

Thus the Commission has the primary role in developing EU regulations on use of GM technology or sale of plants, feeds, and foods containing GM ingredients: it proposes Directives, adopts supplementary, and manages the consultations with national governments required under the current regulations. The Council offers broad direction while the Council and Parliament together adopt any Directives needed. The EU Court of Justice gets involved if there are disputes between the Commission and one or more member governments.

Individual EU member states began developing regulations on use of GM technology or sales of foods and feeds containing GMOs in the early 1980s, before their 1986 agreement to create a Single Internal Market by standardizing regulations covering a large number of industries. The first European Union regulations on GMOs were adopted in 1990 out of concern that divergent national approaches would hobble efforts to create a Single Internal Market.[1] EU Directive 90/220, also known as the Deliberate Release Directive, established a European-wide regulatory approach for approving commercial growing of GM food crops and also required member states to ensure that the GMOs would not cause "adverse effects". Directive 90/220 had a procedure for approving GM foods similar to the USA's "substantial equivalence" approach. The Novel Foods Regulation, 258/97/EC, extended EU regulations to any foodstuff containing GM products and also introduced the requirement that products containing GM material must be explicitly labeled as such.

Internal challenges to this initial EU position on GM foods first arose in the late 1990s. In February 1997, Austria invoked Article 16, the "safeguard clause," of Directive 90/220 to justify banning cultivation of Bt-176 maize (Novartis). Article 16 allows any member government to ban the sale in their country of products previously approved by the EU if the banning government believes the product poses a threat to the country's environmental safety. Austria's act opened up the floodgates as opponents of GM products in other member states began invoking Article 16 to ban crops previously approved by the EU.

The invocations of Article 16 highlighted the combination of knowledge uncertainty and ethical concern about the environmental impact of GM foods driving public opinion on the issue. Public and member government opposition was sufficient to inspire the EU Commission to extend a moratorium on authorizing

[1] Internet links to the official texts of all the EU Directives and Regulations mentioned in this appendix are provided at the end.

new GM products for sale that had been in place since October 1998 after the EU Environmental Council declared at its meeting on 15 June 1999 that it would not authorize new GM products for commercial sale until new regulations were adopted. The firm public stance against further approvals of GMOs taken by five member countries – Denmark, France, Greece, Italy, and Luxembourg – indicated there was an effective blocking minority under the qualified majority voting rules and brought application of the 1990 Directive to a halt. Looking to the future, the Environment Council also maintained the rule that products containing GMOs must be explicitly labeled, and agreed that future approvals of GM products would be valid only for ten years, after which their sale would have to be re-authorized. Formal rules on the reauthorization process for already approved products would be codified later in Regulation 1829/2003/EC, which simplified the process by essentially guaranteeing the products' reauthorization unless the competent national authority can find new evidence that demonstrates the GM products are unsafe.

This "general de facto moratorium," as it was called later in the WTO trade dispute proceedings, was not accompanied by any EU regulation formally imposing a moratorium or by any statement expressly declaring GM products to be unsafe. The EU Commission explained it was simply deferring action on applications until it could complete further study of the safety of the GM products before their use had become widespread and EU regulations could be revised as needed based on the results of that study. The EU had to take this indirect approach because either an explicit moratorium or a blanket ban of all GMO organisms could be challenged by other countries through the WTO dispute settlement procedure as being contrary to the EU's and its members' commitments under the General Agreement on Trade and Tariffs (GATT) and its related Agreement on Sanitary and Phytosanitary Measures (SPS Agreement).

Most of the EU Environment Council's June 1999 decisions were incorporated into the new EU Directives adopted in 2001 and 2003. In March 2001, Directive 90/220 was repealed and replaced by Directive 2001/18/EC. It established more stringent criteria for approval of a GM product, including specific protections against "risk to human health and the environment, whether direct or indirect, immediate or delayed." The 2001 rules also required companies wishing to grow GM products to submit their plans for monitoring the product's effects on the environment.

Directive 2001/18/EC required explicit approval before a GM product is "released into the environment" (planted in outdoor fields) or is sold anywhere within the EU, and mandates prior assessment of the potential environmental consequences of introducing a new GM product. It applies to all GM products whatever their country of origin, to all plants and/or seeds considered "organisms", which the Directive defines as anything that "may reproduce in the environment and cross national frontiers thereby affecting other Member States."

Under Directive 2001/18/EC, a company wishing to introduce a new GM product into the environment (use a GM organism in plants grown on outdoor fields) must obtain prior written authorization to do so. Article 6 specifies the procedures for securing authorization. Rather than turn matters over to an EU-level regulatory agency, member states agreed that authorization decisions will be taken by individual member governments. However, the process is coordinated regionally. In the initial version specified in Regulation 2001/18, the regulatory process started with a preliminary determination at the national level.

Individuals or companies that wished to sell foods and feeds containing GM ingredients or to grow plants based on GM organisms would apply to the national regulatory agency in a particular state first, then submit an application ("issues a notification" in the particular jargon of the Directive) to the relevant national

agency of their own country. The application must include the person's or company's own risk assessment for the new GMO, and Annex II specifies that this risk assessment must include "identification of characteristics which may cause adverse effects; evaluation of the potential consequences of each adverse effect, if it occurs; evaluation of the likelihood of the occurrence of each identified potential adverse effect; estimation of the risk posed by each identified characteristic of the GMO(s); application of management strategies for risks from the deliberate release or marketing of GMO(s); determination of the overall risk of the GMO(s)." The national agency then considered the application and accompanying materials and issued a report of its findings. What happened next depended on whether the assessment report is favorable (suggests the cultivation should be allowed) or unfavorable (suggests the cultivation should be prohibited).

If the national agency issued a favorable report, that state informs the other EU states via the European Commission. The governments of other member states then had the opportunity to list observations on or objections to the report. The next steps in the regulatory process depended on whether there were objections:

> If no other member state objected, the relevant national agency of the initially petitioned state authorizes selling products containing the GM organism or growing plants bred with it, and this approval is good throughout the EU for the maximum allowable period of ten years;
>
> If any of them objected, the European Commission, the notifying state, and all other member states enter into a conciliation process. If questions and objections are resolved, the relevant national agency of the initially petitioned state authorizes selling the product or growing the plants throughout the EU for ten years.
>
> If discussions in the conciliation phase failed to satisfy the objecting states' demands, the European Commission took charge of the regulatory process. It first secured an opinion on the GM product or plant from the European Food Safety Authority, then considers that advice and presents a draft decision (either to authorize sale or to withhold authorization) to the Standing Committee on the Food Chain and Animal Health, a body made up of food regulators from the member states. The European Commission's draft became a binding decision if the Standing Committee adopted it. If the Standing Committee did not, the question went to the Council of Ministers, where a unanimous vote was needed to block approval.
>
> If the national agency initially petitioned issues an unfavorable report, then the company could submit a notification to the relevant national agency of another EU state, where the process would begin anew.

This ability to apply in a second state means that GM organisms prohibited as food ingredients or as crops in one EU country could be accepted in another. However, the objection process means that a government previously prohibiting the GM organism could step in and at least delay the second country's approval. Maintenance of the safeguard clause allowing individual member countries to ban particular GM products or crops thus creates an exception to the usual Single Internal Market rule that items approved for sale in any one EU country may be sold in all others.

Directive 2001/18/EC was followed by Regulation 1829/2003/EC, the Food and Feed Regulation, covering GM products used as ingredients in human foods and animal feeds that are not "organisms" because they lack the ability to self-reproduce in the environment. Regulation 1829 specifies that a company wishing to market a GM product must first obtain written permission, in accordance with Article 6 of Directive 2001/18/EC, and must include in its application a monitoring plan, a labeling proposal, and a detection method. The monitoring plan must certify that assumptions included in the environmental risk assessment are accurate, and specify how the seller will look for unforeseen consequences that could pose a risk to human health or the environment. The labeling plan requires that any GM food, food product, or animal feed delivered to consumers must also be clearly labeled as containing GM organisms. Article 47 of Regulation 1829 outlines the detection method and also limits accidental or incidental mixing of GM in non-GM foods or feeds to 0.5 percent of the product. To qualify as "accidental or incidental" the GMO presence (called "contamination" in the Regulation) must also meet the following requirements:

a) the process by which GM ingredients enter the non-GM product is "adventitious or technically unavoidable,"

b) the particular GMO involved has been accepted as safe by the EU Scientific Committee or the European Food Safety Authority before Regulation 1829 went into effect,

c) application to sell or crow the GM ingredient was not formally rejected by EU authorities, and

d) detection methods are publicly available.

Regulation 1829 also altered the regulatory process. Companies desiring to sell foods and feeds containing GM ingredients still notify a national food agency, but it immediately forwards the file to the European Food Safety Authority of the application and supplies it with any supplementary information it requests. EFSA circulates the application and supplementary material to the member states and the EU Commission, and also releases a summary to the public. EFSA then performs scientific risk assessments and has six months to reach an opinion on the application. It reports its findings and opinion on the particular GM variety to the European Commission. The European Commission uses the opinion to develop a draft decision which is then referred to the Standing Committee on the Food Chain and Animal Health.

If the Standing Committee on the Food Chain and Animal Health approves the European Commission's draft decision by qualified majority vote, then the Commission adopts the decision. A decision to accept the initial application places the products into the Public Register of GM food and feed, and authorizes its sale for ten years. If the Standing Committee does not approve the Commission's draft, the draft goes to the Council of Ministers. If the Council of Ministers approves the decision by qualified majority vote, fails to reach a qualified majority vote on either approval or rejection of the draft, or does not act within three months, then the Commission adopts (in the words of the Regulation "shall adopt") the draft as a decision on its own.

This process centralized and streamlined the preliminary stages of the approval process, but left intact the provisions for direct member state involvement in decisions at the end and made it easier for member states to block approvals. It also imposed some limits on individual member state bans of approved GM

varieties by requiring that these be justified on grounds of serious threat to human or animal health or the environment. Thus the EU could consider factors like consumer preferences in making approval decisions, but individual member states could not do so when imposing their own bans of an EU-approved GM variety.

Regulation 1830/2003/EC covers pre-packaged products containing GM products. It mandates that pre-packaged goods any single ingredient of which contains more than 0.9 percent of any authorized GM product, have labels which explicitly state "This product contains genetically modified organisms." For example, in a cereal with 15 ingredients the 0.9% limit applies to each of the 15 separately. Thus, presence of a GM ingredient amounting to 0.91% of an ingredient which itself amounted to 5% of the total mix would trigger the labeling requirement. It also provided a 0.5 percent threshold for GM varieties certified as safe by the EFSA but not yet approved for sale by the EU Commission for a three year period. If approval did not follow within three years, the non-approved GM variety would be subject to a zero trace level requirement. This threshold went into effect on several GM varieties in April 2007, and caused severe complaint from the US and other exporters to the EU because of the extreme difficulty of separating out different varieties of grain in bulk shipment.

The traceability requirements in Regulation 1830 were supplemented by Regulation 2004/65/EC, which added a requirement that each GMO present in the product have a unique alphanumerical identifier assigned to it upon its approval for commercial sale in the EU. Companies or individuals engaged in product transfers along the distribution chain from food processor to final consumers that receive foodstuffs or animal feeds produced from GMOs must be given written confirmation from the previous entity in the distribution chain of each food ingredient that is produced from GMOs in excess of 0.9 percent of the total amount, as well as each food additive produced from GMOs. They are required to maintain the records of each transaction involving GM products for five years.

Regulations 1829 and 1830 allow two exceptions to the labeling requirements. The first covers foods derived from animals fed with genetically modified feed or treated with genetically modified medicinal products. Thus, beef from cattle or milk from cows fed a GM maize variety would not have to be labeled, nor would eggs from chickens fed GM feed varieties. The second covers genetically modified processing aids – such as the enzymes used in cheese-making – that are used solely in production and do not appear in the resulting food.

The EU's "de facto general moratorium" ended in May 2004 when Regulation 1829 went into effect for the entire European Union. Soon afterward, the European Food Safety Authority allowed a new variety of sweet corn containing *Bacillus thuringiensis-11*, a pest resistant trait developed by Swiss biotech company Syngenta, onto the market. It determined that Bt-11 sweet corn did not pose any greater risk to the environment than the introduction of a new strain of corn developed by traditional plant hybridization methods. Neither the EU Council of Ministers nor the EU Commission objected.

The Council or the Commission could have objected. While required by EU rules to defer to the EFSA's determinations on knowledge issues, they retain the right to review the benchmarks defining "acceptable risk." With Bt-11, they accepted the EFSA's use of a "no greater risk than posed by new varieties produced in traditional ways" and the EFSA's implicit selection of a standard for burden of proof indicating that absence of evidence for additional risk was sufficient. Logically, they could have insisted on a lower risk, but this would be difficult since the risks of already-accepted products tend to form the regulatory baseline.

They could also have insisted on imposing a greater burden of proof by requiring GM breeders to show positive evidence that no additional harm would be posed. This alternate burden of proof would be very hard because of the difficulty of proving there will be no harmful effects before a GM organism has had an opportunity to interact with other organisms under natural conditions.

Internet links to official texts:

EU Directive 90/220 (Deliberate Release Directive; repealed): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0220:EN:HTML

Regulation 258/97/EC (Novel Foods Regulation; repealed): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997R0258:EN:HTML

Directive 2001/18/EC (in effect): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML

*Regulation 1829/2003/EC (Food and Feed Regulation; in effect)***:**
http://ec.europa.eu/environment/biotechnology/pdf/regu1829_2003.pdf

Regulation 1830/2003/EC (in effect):
http://ec.europa.eu/environment/biotechnology/pdf/regu1830_2003.pdf

Regulation 2004/65/EC (in effect): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0065:EN:HTML

Current Information:
http://ec.europa.eu/food/food/biotechnology/gmfood/index_en.htm

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