Appendix A: Chronology

M.J. Peterson Version 4, Revised June 2010

Appendix Contents:

1.) GMO Chronology

References used in this section:

US Joint Agency Website: usbiotechreg.nbii.gov

Dispute settlement page of WTO website: www.wto.org

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The timeline below documents important events associated with the regulation of Genetically Modified Organisms, Plants, Feeds, and Foods.

Key

Orange Public controversies about food safety or GMO

containing plants or foods

Dark Blue EU regulatory measures Red US regulatory measures

Purple International negotiations or decisions

1978

EU Commission withdraws proposed directive requiring prior notification and authorization of GMO research; later adopts more permissive rules.

1986

US government adopts Coordinated Framework for Regulation of Biotechnology assigning GM regulation tasks to US Department of Agriculture, US Food and Drug Administration, and US Environmental Protection Agency on basis of existing US law. This also establishes the baseline for subsequent US regulation by declaring GM plant varieties to be "substantially similar" to conventionally-bred varieties.

1990

EU adopts Directives 90/219 on laboratory work with GM organisms and 90/220 on field trials and approval for sale of GM foods and crops. Its main procedures are similar to the US "substantial equivalence" guidelines, but Article 16 of 90/220 allows member countries to block the import of varieties of GM food if they determine the imports would be detrimental to the nation as a whole.

1992

US Food and Drug Administration issues guidance on approval of GM crops and foods adopting the product-based approach outlined in the 1986 Coordinated Framework.

First US approval of a GM crop (Calgene's Flavr Savr tomato).

1995

Nov

First meeting of the Transatlantic Business Dialogue in Seville, Spain. Recommends to the intergovernmental US-EU Transatlantic Economic Project (TEP) that participating governments promote liberalization and synchronization of trade regulations on both continents.

1996

Mar

Pathogens causing bovine spongiform encephalopathy (BSE or "mad cow disease") found in beef in UK and then in beef exported from UK to other EU countries. This inspires massive public doubt regarding the adequacy of food safety regulation in EU countries.

First US approval of a GM soybean variety (Monsanto's RoundupReady soybeans, bred for pesticide resistance).

1997

Jan EU adopts Novel Foods Regulation. It includes mandatory labeling of products containing GM material.

EU Commission authorizes sale of a variety of GM maize, Bt176 developed by Novartis.

Feb Austria invokes Article 16 of Directive 90/220 and bans import or sale of Bt176 maize. Five other EU countries – France, Germany, Greece, Italy, and Luxembourg – ban a total of eight GM varieties of plants in following months.

To stem further invocations of the safeguard clause, the European Commission announces it will propose amendments to Directive 90/220 to address concerns of EU member states.

1998

Nov

May TEP creates a biotechnology working group that attempts to create a process for simultaneous regulation of GMOs in both the US and EU.

Nov EU approves GM plant authorizations under Directive 90/220 but suspends their application while policy revision proceeds. Commission also decides to defer consideration of additional applications until the new regulations are in place.

1998-1999 Controversy over prospect of developing "terminator technology" that would make seeds from GM plants infertile, with critics charging this was another way major firms were trying to dominate global food supplies. Controversy ends with Monsanto and other firms stating publicly that they will not develop the technology.

1999

US Food and Drug Administration holds extensive public hearings on adequacy of US regulation of GM plants.

Public controversy in US and EU after one scientific study finds link between Bt corn and harm to monarch butterfly larvae; additional studies do not confirm the finding.

Renewed public outcry about adequacy of food safety regulations in EU after dioxin contamination is discovered in animal feeds in Belgium and sewage contamination is detected in animal feeds in France.

Jun EU announces it will not authorize additional GM plant varieties for cultivation or inclusion

in food products until more stringent regulations are adopted.

The TEP abandons its GM regulatory synchronization project.

2000

Jan Cartagena Protocol on Biosafety adopted.

EU issues White Paper on Food Safety.

Oct Starlink corn (Aventis), approved for animal feed but not for human consumption, is found in tacos sold to the public in the USA. Aventis has to recall the corn; the incident raises doubts about the adequacy of US food regulation, especially in Europe.

US Food and Drug Administration issues guidelines on voluntary labeling of GM foods.

Amended Plant Protection Act specifically extends, consolidates, and expands US system of regulating matters related to plant pests and diseases. GM varieties defined as "potential plant pests." GM-based varieties found to be plant pests after field testing will continue to be regulated; those found not to be plant pests are "deregulated" and therefore available for cultivation and sale.

2001

US Environmental Protection Agency asserts authority over GM plants incorporating GM-based pest resistance traits.

Mar EU Directive 2001/18 on deliberate release of GMOs, replacing Directive 90/220. It substitutes much more stringent criteria for monitoring and approving the commercial growing of GM products.

US Department of Agriculture adopts new regulations on use of Organic Food label that exclude use of GM plants and organisms.

2002

Apr

Jan Establishment of European Food Safety Authority.

2003

Jul

Mar USA, Argentina, and Canada invoke WTO Dispute Settlement System to complain about European treatment of GM crops and foods.

Establishment of Dispute Settlement Panel to consider the US, Argentine, and Canadian complaints established after initial consultations between the governments fail to produce an agreed settlement.

Sep EU Regulation 1829/2003 on Genetically Modified Food and Feed.

EU Regulation 1830/2003 on traceability of GMOs adopted.

These replace the 1997 Novel Foods Regulation. Regulation 1829 establishes strict guidelines to prevent the unauthorized mixture of GM food with non-GM food. Regulation 1830 requires strict labeling and tracing procedures for GM products in pre-packaged foodstuffs.

2004

May EU Council approves growth and sale of Bt-11 maize, breaking the de facto moratorium.

Jun WTO Dispute Settlement Panel begins hearing oral arguments.

2005

Mar Swiss firm Sygenta notifies US and EU authorities that approximately 1000 tons of its not yet authorized Bt-10 corn had been distributed in the US, mixed in with shipments of the Bt-11 variety already approved for sale in US and EU.

US authorities later determine that Bt-10 was safe and authorize its sale in US.

EU Commission deplores the release and requires all shipments of corn (used for feed and brewing) from the US be tested and certified as free of Bt-10.

May EU Commission decides to challenge national GMO bans.

> EU Council rejects Commission proposal to overturn the 8 existing national bans on particular GMOs.

2006

US authorities announce detection of unauthorized GM variety LL601 rice (Bayer CropSciences) in shipments of rice to be exported. EU Commission and Japanese authorities require all rice imported from the US be tested for presence of LL 601.

Mar EU Commission rejects calls for EU-level regulations on coexistence of GM and conventional crop cultivation on grounds the lack of much cultivation experience and diversity of agricultural environments in Europe make such regulations premature.

Jan-Jun Austria uses its term as EU president to press for more restrictions in GMOs.

WTO Dispute Settlement Panel releases preliminary report in EC-Biotech Dispute.

Responding to member state criticisms, the EU Commission adopts regulatory guidelines "inviting" the European Food Safety Agency to pay more attention to national regulatory agency objections to particular GM varieties, explain the rationale for not accepting national-level scientific objections, and addressing long-term effects and biodiversity concerns in its risk assessments.

Jun

Jun

Feb

Jun

Sep

WTO Panel Final Report ruling in EC-Biotech Dispute. Panel concludes that the EU's premarket approval system as applied so far violates the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) because the process is subject to unnecessary delays, and permits member states to ban GMO-containing plants and products without undertaking a scientific assessment as required for an SPS measure limiting trade.

Later discussions with complainants establish a mutually agreed deadline for EU to comply with the ruling.

2006-2007 EU Commission approves 10 additional GM plant varieties for sale as food and feed ingredients but not cultivation under the rule permitting it to do so if there is deadlock in the Council. Anti-GMO groups and some member states condemn the decisions.

2007

Apr

EU "zero tolerance" policy takes effect. No food or feed product in the EU may contain any trace amounts of a GMO not authorized for sale in the EU (even if the ESFA has issued a favorable scientific risk assessment on it). This puts strong pressures on exporters to strictly separate growth, processing, and shipping of GM plant varieties approved by the EU from others.

Nov

WTO deadline for the EU to bring its policies into compliance with the Panel ruling.

In defiance, Austria maintains its ban on sale or cultivation of two varieties of GM maize, Mon810 and T25, which had previously been approved by the EU. EU thus vulnerable to trade retaliation from the complaining states.

Argentina and Canada agree to extension of compliance deadline; US initiates, then agrees to suspend, process of securing WTO authorization to adopt retaliatory restrictions on EU imports.

2008

May

EU Commission delays approval of applications to authorize 7 GM crops.

EU Commission informs Austria that it will challenge Austrian bans on sale of foods and feeds containing Mon810 and T25 maize, (but not its ban on cultivation inside Austria).

Jun

Austria agrees to lift its ban on importing and processing Mon810 (Monsanto) and T25 maize.

Jul

Austria announces a ban on another variety of GM maize, Mon863 (Monsanto).

Jul-Dec

France uses its term as president of EU to create a committee to propose ways of further tightening EU regulations on GMOs.

EU Commission exploring various ways of breaking the impasses over GMO regulations.

Jul

Canada settles its WTO complaint against the EU by accepting ongoing consultations regarding GM regulations.

2010

Mar Argentina settles its WTO complaint against the EU by accepting ongoing consultations regarding GM regulations.

Jun

EU Commission circulates draft of new GMO regulations that would permit member states to maintain bans on particular GM varieties but ease EU-level approval process.

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