"The U.S. Request for a WTO Panel on the EC Biotech Moratorium: Why Now and With What Result?"

Steve Suppan, Institute for Agriculture and Trade Policy
ssuppan@iatp.org

GMO-Food Aid to Africa: Crime Against the Hungry or Defense against an unfair Attack?
Humboldt University
3 September 2003

First, I'd like to thank the organizers of this meeting, particularly my sponsor, the German Church Development Service (EED), for giving me an opportunity to speak with you today. Our meeting is a Side-Event of the International Workshop, "Defining the Role of Food Aid in Contributing to Sustainable Food Security," hosted by the Federal Government of Germany. Despite a long day at the International Workshop, several government delegates, including representatives from the government of my country, the United States, have come for this evening meeting and we are grateful for their participation.

As you may know, on May 13th, the United States requested consultations with the European Commission concerning the so-called EU moratorium on regulatory review of applications to commercialize genetically modified organisms. In a mid-May speech, U.S. President George Bush justified the dispute by stating, "By widening the use of new high-yield bio-crops, and unleashing the power of markets, we can dramatically increase agricultural productivity and feed more people across the continent [of Africa]. Yet our partners in Europe have impeded this effort. They have blocked all new bio-crops because of unfounded, unscientific fears. This has caused many African nations to avoid investing in biotechnologies, for fear their products will be shut out of European markets."[1]

This rhetorical justification for launching the dispute has been backed financially by U.S. government and foundation joint ventures with genetic engineering firms that promise to bring genetically modified organisms (GMOs) to Africa without the great costs of intellectual property royalties. For example, the Rockefeller Foundation, together with DuPont, DowAgroSciences, Syngenta and Monsanto and the U.S. Agency for International Development have set up the Africa Agricultural Technology Foundation in Nairobi to provide new technologies to Africa's farmers.[2]

Earlier today, Dan Maxwell of Care International commented that a food shortage crisis was an inopportune moment to launch a dispute about the validity of EU rules on GMOs.[3] I agree, but the Bush Administration has chosen to make food aid delivery into a subject of GMO controversy, and I have been asked to comment about this policy choice.

The Bush Administration and the biotech industry have tried to make the case that not only are its interests in genetically engineered (GE) food aid primarily humanitarian, but that opposition to GE food has no scientific grounding. The Bush Administration's distortion of scientific

[1] Cited in Robert Weissman, "Biotech Food Fight," MULTINATIONAL MONITOR (June 2003), 6.
[2] Hannah Hoag, "Biotech firms join charities in drive to help Africa's farms," NATURE, vol. 422 (20 March 2003), 246.
[3] Maxwell's presentation and all International Workshop documents can be consulted at http://www.foodaid-berlin2003.de

evidence has been widely documented.[4] For example, contrary to what the President's statement implies, the GE technology attached to a hybrid seed is not the prime determinant of yield in most cases – the hybrid vigor resulting from cross-breeding with landraces is the prime determinant of yield, weather, other conditions being equal. It takes a large pest or weed problem that GE crops target for the GE technology to have decisive yield impact and such infestations are not the norm. Nonetheless, the United States chose to make GE food aid a high profile issue in its overall GE campaign for a variety of reasons, some rebutted by European Commission officials and some not.

Much of the controversy on GE food aid has focused on political declarations assuring the public of the "safety" of GE food. Therefore, it is important to point out that the primary focus of the U.S. regulation of GE food and feed is not safety. Rather, the U.S. regulatory framework builds a bureaucratic justification for why U.S. regulatory agencies do not need to require independent pre-market safety testing of GMOs, but may rely on the voluntary provision of company summaries of company testing to approve commercialized GE products.

As a U.S. National Academy of Science's review of the U.S. GE regulatory system stated in April 2000: "In the regulation of recently approved transgenic pest-protected plant products (that is plant products with Bt and viral coat proteins), the emphasis has not been on detailed assessments of safety for humans or domestic animals. Rather, it has been on exploring the scientific basis for why there is probably not appreciable risk and justifying the tests which are required."[5] U.S. regulatory agencies require that companies submit evidence of their studies only in very limited cases, such as when there is likelihood of allergenic reactions to GE foods. Nonetheless, an ABC news poll of 1,024 U.S. adults reported in July that 46 percent of them considered GE food safe, though 92 percent wanted GE food to be labeled, and 55 percent said they would avoid foods carrying a GE label.[6]

In the remainder of my remarks, I will not focus on the GE food aid controversy in terms of food aid policy or the nutritional ethics of sending whole grain GE corn for the malnourished, rather than other more nutritionally balanced food aid. Instead, I want to take these few minutes to outline the U.S. case against the EU genetic engineering regulatory system, why the case is being launched now and what evidence the WTO dispute panel is likely to consider in judging for or against EC and EU member state regulation of GMOs.

On August 18, the United States, Canada and Argentina requested the formation of a WTO dispute settlement panel to review the WTO legality of the so-called moratorium. In the U.S statement announcing the request, U.S. Ambassador Linnet Deily stated "The Agreement on the Application of Sanitary and Phytosanitary Measures recognizes that Members may adopt approval procedures for crops and food products, including biotech products, in order to protect health and the environment. EC legislation sets out such procedures, and those procedures, as written are not the focus of the U.S. complaint. The United States only asks that those procedures be permitted to proceed to their normal conclusion."[7] For the U.S., the "normal conclusion" would be approval to commercialize GMOs, the conclusion of almost all U.S. regulatory reviews. (By comparison, under the standards of the Norwegian Gene Technology

---

[4] E.g. see David Malakoff, "Democrats Accuse Bush of Letting Politics Distort Science," SCIENCE, Vol. 301 (15 August 2003), 901. The basis of the article is a report that can be consulted at http://www.house.gov.reform/min/politicsandscience

[5] *Genetically Modified Pest-Protected Plants: Science and Regulation*, Section 2.5 "Potential Health Effects," (April 2000), 64.

[6] "Most in U.S. Would Shun Labeled Biotech Foods," REUTERS, 15 July 2003.

[7] The statement and related documents are at http://www.ustr.gov

Act, four of 31 commercialization applications received as of July 2001 from EU companies had been approved, with eight denied and 19 applications still pending.[8])

This focus on the moratorium, and not on the EU labeling and traceability directives, was made after a two-year debate among industry and government officials and their academic advisors. Given the ferocity of opposition to the EU directives by U.S. agribusiness firms,[9] it is very likely that the U.S. will launch a subsequent dispute against the traceability and labeling directives, since, as one industry official stated, "removal of the moratorium is 'utterly useless' if it is replaced by traceability and labeling rules."[10]

Both Commission officials and U.S. trade officials had hoped that the moratorium would be lifted at the March 2002 EU Summit in Barcelona,[11] in advance of the EU Parliament revisions of the draft directives. Instead Commission officials presented "Life sciences and biotechnology: A Strategy for Europe," about which I will have a few concluding remarks at the end of this talk.

Why launch the dispute, now when the Commission has done so much towards commercializing GMOs in Europe, including taking EU Member States to the European Court of Justice for not transposing EU biotech directives to national legislation?[12] There are at least three reasons, two of which are relatively short term and opportunistic, and one which has to do with the longer term relations of regulating for consumer protection vs. the deregulatory trend to enhance competitiveness.

Senator Charles Grassley of Iowa insisted upon launching the GE dispute now, and reportedly threatened to hold up President Bush's most cherished piece of legislation, his massive tax cut, if the U.S. did not take the EU to dispute settlement.[13] Since the failure of both the 1996 and the 2002 U.S. Farm Bills to raise market-derived farm income,[14] politicians desperately need a way to explain this failure. Grain trader sales allegedly lost due to EU rules on GE corn and soy diverts attention from the broader failure of U.S. agricultural policy to support fair market prices for agricultural raw materials. Furthermore, these politicians needed a story during the 2003-2004 election season (e.g. U.S. fights the EU) to give hope to farmers from states such as Iowa, where agriculture revenues form a large but plummeting share of the economy. The prospect of defeating EU GE rules is held out as an opportunity to improve U.S. farmgate income by making up in volume of exports what is lacking in depressed prices for corn and soy, the principal GE exports targeted for EU member states.

The prospect of large-scale market openings for agricultural export commodities and inputs as a result of a successful dispute settlement for the U.S. is furthermore reckoned to be a "good story"

---

[8] Anne Ingeborg, "Precaution, Context and Sustainability: A study of how ethical values may be involved in risk governance of GMOs" (Thesis submitted for the degree of doctor scientarium, University of Tromsø, 2002), 4-5.
[9] E.g. "U.S. Ag, Biotech, Food Groups Sound Alarm Over EU Biotech Rules," INSIDE U.S. TRADE, 1 June 2001.
[10] "U.S. Looking At Special DSB Session For First Biotech Panel Request," INSIDE U.S. TRADE, 1 August 2003.
[11] Chris Rugaber, "EU Barcelona Summit in March Could Include Biotech Decision, Officials Say," INTERNATIONAL ENVIRONMENT REPORTER, 16 January 2002.
[12] EC Moves To Defuse Possible U.S. WTO Biotech Challenge," INSIDE U.S. TRADE, 18 April 2003 and Joe Kirwin, "EU Commission Takes 11 States to Court For Failing to Implement GMO Legislation," INTERNATIONAL ENVIRONMENT REPORTER, 16 July 2003
[13] "Grassley Sets Deadline For Administration Decision on EU Biotech Case," INSIDE U.S. TRADE, 9 May 2003.
[14] E.g. Alan Guebert, "A midsummer review of the numbers," FARM AND FOOD FILE, for the week beginning 17 August 2003 and "Rethinking U.S. Agricultural Policy: Changing Course to Secure Farmer Livelihoods Worldwide," AGRICULTURAL POLICY ANALYSIS CENTER (September 2003) at http://www.agpolicy.org/blueprint.html.

that boosts biotech company share prices on Wall Street. Such "stories" help biotech companies attract venture capital and more favorable terms for loans. The launch of the dispute can be thought of in terms of a "policy investment" with far greater projected worth than such federal grants as the $6 billion over ten years that President Bush has called for to use biotechnology to combat bio-terrorism.[15]

However, the longer-term U.S. goal of this dispute is not simply to gain trade sanctions or market openings, but to discourage rigorous EU member state regulation of GMOs and support the kind of company-driven, voluntary system of regulatory review that prevails in the United States. I'll describe some of the failings of the U.S. regulatory model and why the EU should avoid developing a biotechnology strategy driven by the notion that the EU needs to speed approvals of GMOs in order for European biotech companies to become competitive with U.S.-based transnational biotech companies. First let's look at the Commission's response to the filing of the dispute.

Despite the European Commission's pro forma temporary blocking of the formation of a dispute panel, authorization for forming a panel was given when the WTO Dispute Settlement Body met on August 29. The dispute settlement process, including the expected appeal, is expected to continue at least through 2004. According to WTO Secretariat notes of the DSB meeting, the European Commission "expressed surprise and disappointment at the panel requests."[16]

However, there is and has been a great deal of sympathy among the Commissioners for GE agriculture. Consider, for example, remarks by Commissioner David Byrne to a panel at the industry's Bio-Vision Conference on 10 April in Lyon, France: "The issue of GMOs is among the most striking and indeed high profile examples of exaggerated risk perception within European society. There is no known case of mortality from eating a GMO product – yet suspicion, paranoia and even outright hostility remains." After pointing out that his Commission is organizing a "stakeholder forum" in risk perception to take place this December, the Commissioner concludes that "We need to learn the lessons of the GMO debate and ensure that citizens do not feel alienated from future advances in the field of biotechnology."

So what are the lessons of the GMO debate? Are there grounds for the suspicion that Commissioner Byrne points to or are skeptics of the promises of genetic engineering paranoid, i.e. experiencing feelings of persecution without any rational basis?

I think that there is sufficient evidence to be skeptical about the biotech company supplied summaries of company studies that U.S. government regulators use to declare GE varieties to be generically safe. A detailed analysis of a commercialization application is not possible within the limits of this talk. However, even the way in which the U.S. Food and Drug Administration (FDA) formulates its approval of applications to commercialize GMOs gives cause for concern. FDA letters of approval to biotech companies never state that a product is safe. Instead they state that the FDA understands that the applicant for commercialization, according to information supplied voluntarily by the applicant, believes the GM application to be safe.

Here is a quote from the 29 May 1998 letter approving the StarLink corn variety for commercialization: "Based on the safety and nutritional assessment that you have conducted, it is our understanding that AgrEvo has concluded that corn grain and forage derived from the new

[15] e.g. Erika Check, "Share slump bring biotech firms to government's door," NATURE, Vol. 423 (26 June 2003), 908.
[16] Ian Elliott, "EU blocks WTO panel request in biotech dispute," FEEDSTUFFS, 25 August 2003.

variety are not materially different in composition, safety, or other relevant parameters from corn, grain or forage currently on the market, and that they do not raise issues that would require pre-market approval . . . As you are aware, it is AgrEvo's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements."

What the FDA and other U.S. agencies in charge of reviewing applications actually judge are not studies by independent scientists or even by companies scientists, but summaries of such studies as the company wishes to make available to the government.[17] The U.S. Administrative Procedures Act governing regulatory procedures allows regulators the discretion to determine what commercial applicants may retain as "confidential business information," even in matters of public and environmental health, in each commercialization application.[18]

One consequence of the U.S. voluntary and company selected submission of scientific evidence is a situation in which companies and the U.S. government assume the other to be responsible for ensuring the safety of GMOs. According to FDA regulator James Maryanski, "Foods are not required to undergo pre-market approval by FDA. So new varieties of corn, for example or soybeans, do not necessarily, do not come [*sic*] to the FDA for approval." Instead, the legislative authority for the FDA, according to Maryanski, "places the legal responsibility for the safety of these products on the developer, on the purveyor of the product."[19]

However, according to Monsanto's director of corporate communications, "Monsanto should not have to vouchsafe the safety of biotech food . . . Our interest is in selling as much of it as possible. Assuring [*sic*] its safety is the FDA's job."[20]

Why does each party seek to abjure its legal responsibility for the safety of GMOs? Part of the answer lies in "risk management" in a Wall Street, rather than food safety sense of the term, i.e. to minimize a company's exposure to criminal and civil liability. But more broadly, the careful obfuscation of responsibility for the safety of GMOs considered to be safe by the company is a symptom of the inability of regulatory dogma to take into account new scientific information and regulate according to the specific risks posed by genetic engineering.

Perhaps the chief dogma, alluded to in the StarLink approval letter, is the assumption of "substantial equivalence" between traditional plant breeding and breeding through genetic engineering. Corollary to this dogma is the FDA doctrine that only the products derived from genetic engineering, and not the process of the transgenic event, may be reviewed in determining the safety of a GMO. Both these doctrines were controversial in 1992, when the FDA issued its fundamental policy on GMO regulation, a policy that still governs U.S. regulatory review of GMOs.

FDA compliance official Linda Kahl, in a comment on the draft FDA policy, wrote, in January 1992: "The processes of genetic engineering and traditional breeding are different, and according to the technical experts in the agency, they lead to different risks. There is no data that addresses the relative magnitude of the risks – for all we know the risks may be lower for genetically

---

[17] Bill Freese, "Genetically Engineered Crop Health Impacts Evaluation – GAPS Analysis," FRIENDS OF THE EARTH, July 2003.
[18] "Administrative Procedures Act," U.S. Code: Title 5, Section 552, subsection F, paragraph b4) at http://www.4law.cornell.edu/uscode/5/552.text.html
[19] Cited in Kathleen Hart, *Eating in the Dark: America's Experiment with Genetically Engineered Food* (Pantheon Books, 2002), 85.
[20] Ibid., 85.

engineered foods than for foods produced by traditional breeding. But the acknowledgment that the risks are different is lost in the attempt to hold to the doctrine that the product and not the process is regulated."[21]

FDA scientist Louis Pribyl, in his March 6, 1992 comments on the draft framework for FDA regulation of genetic engineering products, began "What has happened to the scientific elements of this document? Without a sound scientific base to rest on, this becomes a broad, general `what do I have to do to avoid trouble' type document. The examples do not supply the scientific rationale that is needed. A scientific document is needed because there is very little (even when things are called scientific) scientific information supplied."[22]

Unfortunately, this kind of documentation will not be admitted in the WTO dispute settlement process, unless the panel decides to accept amicus, or friend of the court, briefs that seek to discredit the regulatory systems of the plaintiff. The status of amicus briefs is extremely controversial at the WTO, since many developing countries view the admission of amicus briefs as giving the NGOs filing the briefs rights that most developing country members cannot afford to exercise. Indeed, the authority of the Appellate Body to initiate procedural changes not contemplated in the Dispute Settlement Understanding is calling into question the legitimacy of Appellate Body rulings.[23]

There are at least three kinds of evidence that the U.S. will use against the EU and that will likely be admitted by both the Dispute Settlement panel and the Appellate Body that will also almost certainly rule on the case.

First, (not in terms of importance or priority) is whatever standards or guidance documents from the Codex Alimentarius that the U.S. believes will support its case. The Codex Alimentarius Commission is among the intergovernmental bodies whose standards are assumed to conform with WTO agreements, particularly the agreement on the application of sanitary and phytosanitary measures (SPS Agreement). The U.S. will be able to avail itself of the recently approved "Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms," "Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA- Plants," and an annex to those guidelines on the assessment of allergenicity. The EU's defense of its moratorium will also be able to invoke these guidelines.

The "Statement by six member States in Response to Amendment of Directive 90/220/EC, not to lift the EU Moratorium" begins "Considering the principles of prevention and precaution" in EU law.[24] However, it is unlikely that the EU will choose to use the Precautionary Principle as an element of its legal defense of the moratorium. The most that the recently adopted "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" allow for precaution is this: "Precaution is an inherent element of risk analysis." (Codex Alimentarius

---

[21] "Memo from Linda Kahl, FDA Compliance Officer to James Maryanski, FDA Biotechnology Coordinator, dated January 8, 1992" in *The Litigation Against Unregulated, Unlabeled Genetically Engineered Foods: FDA Internal Documents Released Through Discovery* at CENTER FOR FOOD SAFETY (www.centerforfoodsafety.org) and at www.biointegrity.org

[22] "Memo from Louis Prybl, FDA Scientist, to James Maryanski, FDA Biotechnology Coordinator, dated March 26, 1992" in *The Litigation Against Unregulated, Unlabeled Genetically Engineered Foods: FDA Internal Documents Released Through Discovery"*

[23] Chakravarthi Raghavan, "AB and DSU functioning getting curiouser and curiouser," NORTH SOUTH DEVELOPMENT MONITOR (Email edition), No. 5211, 14 October 2002.

[24] Annex C in Thomas Schweiger et al., "EU Enlargement: The Intorudction of GMOs by the Back Door of EU Accession?" FRIENDS OF THE EARTH and ANPED (May 2003).

Commission, Report of the 26th Session (30 June to 7 July 2003), ALINORM 03/41, Appendix IV, para. 11). Furthermore, these Codex risk analysis principles are not to be applied by member governments of the Codex Alimentarious Commission, but only by Codex Committees and the Commission in their own work. Principles to be applied by governments that could invoke precaution are still in debate at Codex and at least one industry group, the Grocery Manufacturers Association, has argued that Codex should develop no guidance for governments on risk analysis.[25] Both the formula for the mention of precaution in the working principles and the split in the scope of application of the principles came from the United States, and after fierce and long debate, were agreed to by European Union delegates to Codex.

Secondly, the U.S. will seek to gain a judgment against the EU by reference to the other WTO agreements cited in its complaint, in the event that the reference to the SPS Agreement (Articles 2, 5, 7, and 8 and Annexes B and C) fails. These Agreements include GATT 1994 (Articles I, III, X and XI), the Agriculture Agreement (Article 4) and the TBT Agreement (Articles 2 and 5).[26] The United States and other plaintiffs reserve their right to modify the grounds for its complaint as the case proceeds, so it is not unlikely that more grounds will be adduced for the complaint.

Finally, the U.S. will invoke the statements of EU officials that that the moratorium violates WTO rules. Since such statements were made to the press, and are not official EU documents , it is not clear what standing such statements will have as evidence. Certainly, the statements cannot help the EU defense. More damaging to the EU will be the decisions and opinions of scientific review panels, and of the European Court of Justice concerning GMOs. Future opinions and decisions by the European Safe Food Authority might also be adduced as evidence against the moratorium or a subsequent dispute against the traceability and labeling directives.

Equally important to the prospect for a dispute settlement that will allow EU member states to establish a rigorous and independent scientific review of GMOs, rather than to emulate the U.S. voluntary submission of summaries of evidence by companies, is the political will of the Commission to fight the case. The Commission's rhetorical defiance notwithstanding,[27] there are elements of the Commission's "Life sciences and biotechnology – A Strategy for Europe"[28] that echo the "deregulation for the sake of improved competitiveness" argument that determined the framework of U.S. biotech regulatory policy in the late 1980s, what U.S. skeptics call "regulation lite."

Indeed, deregulation for the sake of competitiveness arguments were invoked in Germany in the early 1990s in order to stimulate venture capital investment in biotech firms.[29] The "Strategy," by constantly touting the "potential" of biotechnology, rather than analyzing its performance comparatively, reads like a Wall Street investment bank report for a public stock offering to raise

---

[25] "GMA urges halt to Codex risk advice to governments," FOOD CHEMICAL NEWS, 11November 2002.

[26] These articles are cited in the May 13, 2003 letter requesting consultations from the U.S. Mission to the World Trade Organization to the European Commission Delegation to the WTO. The United States may choose to accuse the EU of having violating other articles and even agreements in the case.

[27] "European Commission Regrets U.S. Decision To File WTO Case on GMOs As Misguided and Unnecessary," (IP/03), EUROPEAN COMMISSION, 13 May 2003.

[28] "Communication from the Commission to The Council, The European Parliament, The Economic and Social Committee and the Committee of the Regions: Life Sciences and biotechnology – A Strategy for Europe," EUROPEAN COMMISSION (COM (2002) 27), 23 January 2002.

[29] Arthur Daemmrich, Biotechnology, Competitiveness and The Regulatory State," in *Reversal of Fortune?: Assessment of the German Biotechnology Sector in Comparative Perspective*, ed. Stephen J. Silvia, Economic Studies Program Series, Vol. 5, American Institute for Contemporary German Studies, The Johns Hopkins University (1999), 33-48.

capital. While the "Strategy" is a political document with no legal authority for EU Member States, the Commission's enthusiasm for GE technologies may lead to a less than robust defense of the EU regulatory framework for GMOs.

Missing from the Commission's analytic framework for its GE "Strategy" is any opportunity costing of using GE technologies vs. other technologies to achieve a given objective. Indeed, the agency that would do such comparative technology assessment , the President's Office for Technology Assessment, has been dismantled.

The examples of lost opportunities for the development of more cost effective and technically efficient technologies than GE make for disheartening reading. Dr. Charles Benbrook, the former director of agricultural research for the National Academy of Science, remarked on the U.S. government's abandonment of Integrated Pest Management (IPM) first in the mid-1980s and then at the beginning of the Clinton Administration, in order to wait for the more expensive and riskier GE corn and soy technologies some ten years later. Benbrook wrote in 1999: "Stepping back from today's public debates and tensions surrounding biotechnology, I suspect that one of the largest social costs of the `biotech era' will be a long list of opportunities and options – lost. Clearly the just released ERS [Economic Research Service] report on IPM makes a strong case for adding `IPM during the Clinton era' to the list of `opportunities lost.'"[30]

I would encourage you to read the Commission's biotech strategy report closely and ask whether the black or white "options" that it presents are adequate technology options assessment. The implementation of this strategy, if unrevised, could be far more influential for European agricultures and foods than the result of the U.S. case against the EU regulatory system. If the Commission emulates the United States and designs a regulatory system for GE products whose framework is to ensure competitiveness with the United States, then the U.S. case against the EU regulation of GE foods, food ingredients, feed and seed could be a moot point or at best a footnote in trade history.

Thank you for your attention to these remarks. I look forward to your questions.

[30] Charles Benbrook, "Important New USDA Report on IPM," email, 17 October 1999. Benbrook's Ag BioTech InfoNet at www.biotech-info.net is indispensable.