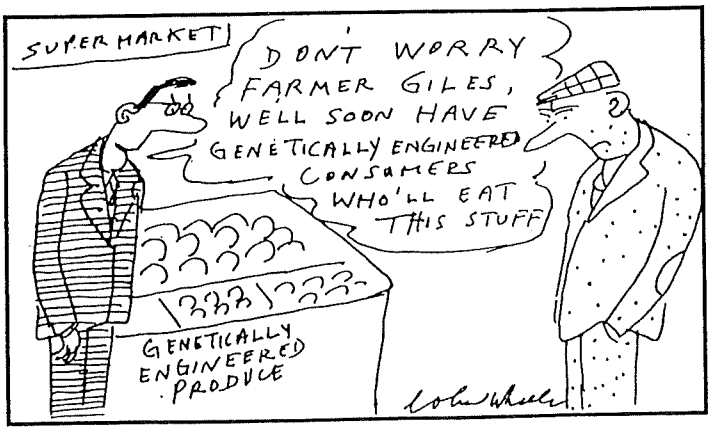
Changes in US Government and Industry Tactics on Biotechnology Diplomacy

The US diplomatic offensive to facilitate trade in foods derived from biotechnologies faced several challenges during the month of June. These challenges have resulted in a change of US tactics away from, in effect, forcing consumers in the European Union (EU) to eat genetically engineered foods or face trade war retaliations, towards plans for consumer education on the "benefits" of genetically engineered (GE) food and for an US-EU pilot project to fast track approval of GE foods in the EU regulatory system.

Hugo Paemon, EU Ambassador to the United States, remarked on two facets of rhetorical decorum in US biotechnology diplomacy in an interview at the US-EU Summit, June 21 in Bonn: "We are quite regularly impressed by the difference in tone of our American interlocutors when they talk privately and when they talk publicly - particularly when they are on Capitol Hill" (the site of the US Congressional buildings). A regular visitor to Capitol Hill, Peter Scher, U.S. Trade Representative special negotiator for agriculture, acknowledged at the Group of 8 meeting in mid-June in Bonn that the disputes with the EU over biotechnology "were as much a consumer issue as a trade issue" and that the US needed to focus more on consumer education about GE food. The following overview is indicative of how the US government and biotechnology industry have responded to resistance to GE food trade.

Industry Strategises For Next WTO Round

On June 10, the Advisory Committee on Trade Policy and Negotiations (ACTPN), a private sector committee that advises the President and US Trade Representative (USTR), met to begin developing a position and strategy on biotechnology for the next round of World Trade Organization (WTO) negotiations. The ACTPN debated on whether to obtain US government and industry objectives for GE food trade through renegotiating the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures or to propose a "stand-alone" WTO agreement for agricultural and pharmaceutical biotechnology.



A confidential ACTPN discussion guide for the June 10 meeting premised that "[a]ll currently marketed products of modern biotechnology have been shown to be not materially different from the predecessors in structure, function or human safety profile." This premise is being challenged in a lawsuit filed against the US Food and Drug Administration (FDA) on May 27, 1998, in the US Federal District Court in Washington, DC. The premises of the lawsuit were outlined by Steven Druker, an attorney and executive director of the lawsuit's lead plaintiff, the Alliance for Bio-Integrity, in a June 17th meeting in Washington DC. According to Druker, 44,000 pages of FDA documents produced thus far during the discovery phase of the lawsuit show that criticisms by FDA scientists of GE food approvals were ignored or overruled by FDA's top echelon.

Square Peg In Round Hole

In response to the US doctrine of "equivalency" between GE foods and food produced by traditional breeding practices, Dr. Linda Kayl, an FDA compliance officer, wrote that the FDA was "trying to fit a square peg into a round hole" by concluding that "there is no difference between foods modified by genetic engineering and foods modified by traditional breeding practices." A memo from the FDA's Division of Food Chemistry and Technology stated that "every transformant [i.e. genetically transformed substance] should be evaluated before it enters the marketplace", rather than the current practice of allowing industry to determine which "genetic events" are significant enough to warrant regulatory review. Of these documents, attorney Druker stated "[e]ven though the FDA knew that genetically engineered foods are not even uniformly recognized as safe by its own scientists - let alone by a consensus within the scientific community - it declared them to be generally recognized as safe."

Despite the revelations of apparent regulatory negligence in declaring GE foods to be safe, the ACTPN is advising President Clinton and the US Trade Representative to resist those who would negotiate more demanding sanitary and phytosanitary standards in the WTO SPS agreement. After taking into account the ACTPN's deliberations, on June 24th, US Trade Representative Charlene Barshefsky told the US Senate Agriculture Committee that the US would not reopen the SPS Agreement for negotiation, but would defend

(continued on p.4)

(Biotech: from Page 3)

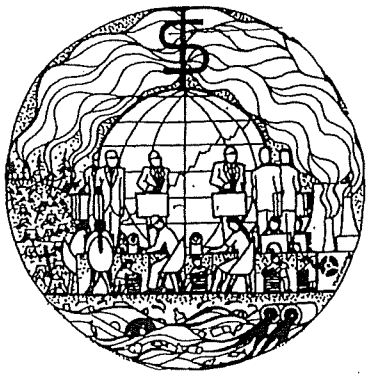
the existing agreement "at all costs." Instead, the USTR will likely adopt the proposal of the US Ag Biotech Forum, a biotechnology industry group, to file "interpretative statements" about the SPS Agreement, in order to advance the US trade objectives on GE foods. Such "interpretative statements" have been used by US diplomats to give quasi-legal import to the US interpretation of international agreements referenced in bilateral negotiations.

While the US government and biotech industry groups are satisfied with the "integrity" of the SPS Agreement, President Jacques Chirac of France gave the Agreement and its implementation at the WTO a vote of no confidence. At the Group of 8 leading industrialized countries meeting in Germany in mid-June, President Chirac proposed a global "High Scientific Council for Food Safety" that would be independent from the WTO. The US and Canada immediately characterized the proposal as protectionist. The other members of the G-8 countered by proposing to commission the Organization for Economic Cooperation and Development (OECD) Working Group on the Harmonization of Regulatory Oversight of Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds to study the food safety implications of GE foods.

US Talks Tough on EU GE Foods Position

While the consultations for the OECD study will take months to develop, on Capitol Hill US officials had more pressing concerns expressed in more bellicose language. On June 24, US Trade Representative Barshefsky told a hearing of the US Senate Agriculture Committee that she was contemplating "WTO-related remedies" to discipline EU refusal to approve GE foods for commercialization. At the same hearing, US Department of Agriculture (USDA) Secretary Dan Glickman told Senator Tom Harkin that the EU does not have a food safety system "worth a damn" and that EU supermarket chains were de facto regulators of GE foods. Secretary Glickman then left for Paris to confer with officials about President Chirac's proposal and about new EU proposals for review of GE foods announced at a June 24-25 EU policy council meeting. Glickman told reporters that he was going to Paris to "deal with what looks like an impending train wreck between the United States and Europe on biotechnology."

At the end of June, in the face of unrelenting diplomatic and scientific opposition, the US proposed to the Codex Alimentarius Commission meeting in Rome that no international standard be adopted for genetically engineered bovine growth hormone (rBST), which is used to increase cow's milk production. Codex Alimentarius standards are regarded as international terms of reference by the WTO and may be used to help settle trade disputes. The approval of an international standard for rBST would have been a major victory for Monsanto, the major producer of rBST, and for US commercial diplomacy. However, the Commission approved the creation of an intergovernmental task force to fast track the elaboration of standards for foods derived from biotechnology, so that standards will be adopted by 2003.



Though the US quietly withdrew its proposal for rBST approval at Codex Alimentarius, rather than risk repudiation, on June 21st at the US- EU Summit, an ambitious initiative was announced that would fast track all GE food product reviews in the EU. The Transatlantic Economic Partnership (TEP) Biotechnology Group, following the recommendations of the Transatlantic Business Dialogue Biotechnology Group, announced a pilot project to facilitate more rapid approval of GE foods in the EU. The pilot project is an initial stage in working toward a Mutual Recognition Agreement in biotechnology products based on the assumption of "equivalency" in product standards.

The TEP Biotechnology Group "Pilot Project Outline" states that it will "kick off" activities at a September 13 meeting in Brussels, which will work towards a March, 2000 target date for producing a document to be reviewed by "interested parties" for comment prior to submission of a final report to the TEP Steering Committee. The first project has been designed by the USDA and its Animal and Plant Health Inspection Service and the EU's "Director General XI (and other relevant services)." The first activity of the project will be to compare the US and EU molecular genetic characterization component, "one of the most fundamental parts of the [GE food] application dossier." Val Giddings, former USDA official and a vice president of the Biotechnology Industry Organization, said the pilot project "is definitely very good news" but that "it has a long fuse."

On July 2, at a US Trade Representative's briefing for US non-governmental organizations, the US head of the TEP Biotechnology Group, US Assistant Trade Representative for agriculture James Murphy, said that the Food and Drug Administration, and the Environmental Protection Agency, both responsible for GE food approvals, would be brought into the pilot project process at a later date.

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