# Biotechnology Facts

***Office of the United States Trade Representative*** ***www.ustr.gov***
**September 2006**

# *Agricultural Biotechnology: WTO Case on Biotechnology*

**Background**

- Since the late 1990s, the European Union has pursued policies that undermine the development and use of agricultural biotechnology.

- In the late 1990s, six member states (Austria, France, Germany, Greece, Italy and Luxembourg) banned imports of biotech corn and rapeseed approved by the European Union. Although these actions were inconsistent with EC approvals, the European Commission refused to challenge the national bans.

- After 1998, the EC adopted an across-the-board moratorium under which no product application was able to reach the final stage of approval.

- This moratorium effectively prohibits exports of many U.S. agricultural products to Europe, including most corn and corn products. The United States, based on the belief that the moratorium appeared to breach World Trade Organization (WTO) rules, brought a challenge under the WTO dispute settlement mechanism.

- Under the WTO Agreement, members are free to establish approval procedures for new agricultural products in order to examine risks to health, safety, and the environment. Decisions are to be based on scientific principles and evidence, and must be made without undue delay.

- But the EU moratorium on new biotech products and the member State product bans were not based on scientific evidence. To the contrary, the products covered by the EU measures are safe, as recognized for many products by the EU's own scientific committees.

- By not allowing its approval system to operate, the EU is imposing undue delays on biotech approvals, resulting in extensive delays and preventing the marketing of many crops grown in the United States.

- The United States simply wants the EU to apply a scientific, timely, rules-based review and approval process to agricultural biotech product applications, as required both under the WTO Agreement and the EU's own laws.

- The U.S. case is not an attempt to "force" acceptance of biotech foods on European consumers. It is the EU's actions, without any scientific, health or environmental basis, that deprive consumers of choice.

**U.S. Legal Arguments**

- The United States argued in the WTO case that the EU has adopted a general moratorium on all new biotech products, and separate product-specific moratoria on each new biotech product. Under these moratoria, the EU has not implemented its own regulations to allow for review of biotech applications to take place – it could have taken decisions on the product applications currently being reviewed, but did not do so.

- The WTO Agreement requires that approval decisions be made without "undue delay." The United States argued that the moratoria violate this obligation by imposing undue delay on the more than 25 products in the EU's regulatory review pipeline, some having languished with little movement since 1998.

- Likewise, the Member State bans are not supported by scientific evidence and are thus illegal under WTO rules. Those measures were taken by Austria, Luxembourg, France, Italy, Greece, and Germany under Article 16 of Directive 90/220, also known as the "Safeguard clause."

**Findings of the WTO Panel:**

- The WTO Panel upheld the central U.S. claims.

  - The Panel found that the EU adopted a moratorium on the final approval of biotech products, starting in 1999 up through the time the panel was established in August 2003.

  - The Panel found that the EU had presented no scientific or regulatory justification for the moratorium, and thus that the moratorium resulted in "undue delays" in violation of WTO rules.

  - The Panel also identified specific, WTO-inconsistent "undue delays" with regard to 24 of the 27 pending product applications that were listed in the U.S. complaint.

  - With respect to each of the EU member state bans on biotech crops approved by the EU prior to the adoption of the moratorium, the Panel upheld the United States' claims that, in light of positive safety assessments issued by the EU's own scientists, the member state bans were not supported by scientific evidence and were thus inconsistent with WTO rules.

**Recent EU Approvals**

- Recent EU approvals of a few biotech products – made after, and perhaps in response to, the United States' filing of its WTO case – do not mean that the EU has lifted the moratorium.

- Many safe, proven biotech products remain stalled in the EU's complex approval procedures.

- In addition, even the few products that were approved had to go through an extraordinary process involving needless delays, and approval by the EU Commission over the objections of many EU member States.

- The EU will not have lifted the moratorium until decisions are based on scientific principles and evidence – not politics – and until each biotech product application is processed without undue delay.