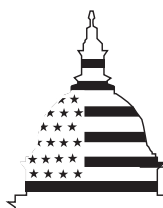


June 2001

INTERNATIONAL TRADE

Concerns Over Biotechnology Challenge U.S. Agricultural Exports



G A O

Accountability * Integrity * Reliability

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Abbreviations

EPA	Environmental Protection Agency
FDA	Food and Drug Administration
EU	European Union
UN	United Nations
USDA	U.S. Department of Agriculture
USTR	U.S. Trade Representative
WTO	World Trade Organization

Contents



United States General Accounting Office
Washington, D.C. 20548

June 15, 2001

The Honorable Charles Grassley
Ranking Minority Member
Committee on Finance
United States Senate

Dear Senator Grassley:

Agricultural biotechnology exports have already encountered disruptions in international markets and are likely to face further challenges. U.S. producers of corn and soybeans, in particular, have become increasingly concerned over the potential adverse effects of regulatory measures that have been adopted or are being considered by the European Union (EU) and other countries that could limit exports. In 1996, crop varieties developed using modern biotechnology techniques, such as genetic engineering, were introduced for commercial production. These crops lowered pest management costs and enhanced yields, and by the end of the decade they had been planted on nearly 100 million acres worldwide. U.S. farmers readily embraced this technology, making the United States by far the largest producer of biotech crops.

We recently briefed your staff on the issues affecting trade in agricultural biotechnology products. Specifically, we (1) summarized developments in key international organizations and among major U.S. trading partners that are likely to affect agricultural biotech trade; (2) identified the principal U.S. commodities most affected by foreign restrictions on biotechnology exports; and (3) described challenges U.S. biotech exporters face in maintaining access to foreign markets. We did not address the appropriateness of U.S. or foreign regulatory measures regarding agricultural biotech products. This report summarizes the content of our briefing. (See glossary for an explanation of the technical terms in this report.)

Results in Brief

U.S. exports of crops with a biotech component are facing restrictions in foreign markets. Since 1998, the EU has effectively blocked approval of new agricultural biotech products. In addition, new regulations and guidelines that may further restrict exports of biotech products, such as requirements for labeling and traceability, or tracking, are being enacted or considered by U.S. trading partners and are being discussed in international organizations. For example, the EU, Japan, and Korea have

enacted mandatory labeling requirements on foods containing or derived from biotech products. Other countries are in the process of enacting similar regulations. The EU is expected to enact requirements for traceability of biotech crops and foods throughout the distribution chain, a measure that could further limit exports. As countries move forward independently with regulatory measures, international organizations are also developing guidelines and rules for biotech products. Multilateral discussions affecting biotech trade are taking place in Codex Alimentarius, which sets international food safety standards, and the Biosafety Protocol, a U.N. environmental agreement. U.S. officials are working to ensure that measures adopted by other countries and international guidelines are consistent with member countries' obligations under various agreements of the World Trade Organization (WTO).

U.S. corn and soybean exports are most threatened by new foreign regulatory measures because of their biotech content. While U.S. soybean exports have not yet experienced disruptions, U.S. corn exports have been largely shut out of the EU market because U.S. farmers are producing some biotech varieties that have not been approved for marketing in the EU. In contrast, only one biotech variety of soybeans is now in general production in the United States, and this variety has been approved in most major markets, including the EU. However, U.S. soybean exports could also encounter difficulties in the future if foreign regulations are adopted that would raise handling costs by ultimately requiring segregation of biotech from conventional varieties.

U.S. agricultural biotech exports face several significant challenges in international markets. First, as the single major producer of biotech products, the United States has been relatively isolated in its efforts to maintain access to markets for these products. Second, in many parts of the world consumer concerns are growing about the safety of biotech foods, which have led key market countries to implement or consider regulations that may restrict U.S. biotech exports. Another challenge is that biotech and conventional varieties are typically combined in the U.S. grain handling system, which relies on the efficiency of mixing crops from multiple sources. U.S. industry contends that segregating biotech from conventional varieties would significantly raise handling costs, and that completely removing traces of biotech grain from bulk shipments may not be possible. Consequently, foreign regulations governing biotech varieties could affect all U.S. exports of these commodities as well as food products containing or derived from biotech crops. Finally, as international discussions in Codex and elsewhere take on greater importance, the U.S.

government faces increasing demands for staff resources and coordination among the multiple agencies involved in biotech trade issues.

Background

Modern agricultural biotechnology refers to various scientific techniques, most notably genetic engineering, used to modify plants, animals, or microorganisms by introducing in their genetic makeup genes for specific desired traits, including genes from unrelated species (see slide 1). For centuries people have crossbred related plant or animal species to develop useful new varieties or hybrids with desirable traits, such as better taste or increased productivity. Traditional crossbreeding, however, can be very time-consuming because it may require breeding several generations to obtain a desired trait and breed out numerous unwanted characteristics. Genetic engineering techniques allow faster development of new crop or livestock varieties, since the genes for a given trait can be readily introduced into a plant or animal species to produce a new variety incorporating that specific trait. Additionally, genetic engineering increases the range of traits available for developing new varieties by allowing genes from totally unrelated species to be incorporated into a particular plant or animal variety.

To date, the principal biotechnology products marketed have been certain genetically engineered field crops (see slide 2). No genetically engineered animals have yet been approved, and only a modest number of plant products obtained from biotechnology have been marketed. However, for three key crops grown in the United States—corn, soybeans, and cotton—a large number of farmers have chosen to plant varieties derived from biotechnology. In 2000, biotech varieties accounted for about 25 percent of the corn, 54 percent of the soybeans, and 61 percent of the cotton planted in the United States. These crops are the source of various ingredients used extensively in many processed foods, such as corn syrup and soybean oil, and they are also major U.S. commodity exports. The United States accounts for about three-quarters of biotech crops planted globally. Other major producers of biotech crops are Argentina, which produces primarily biotech soybeans, and Canada, whose principal biotech crop is canola.

Several U.S. government agencies are involved in trying to address foreign regulatory measures that affect biotech exports (see slide 3).¹ Some of these government entities, including several agencies within the Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), play a role because of their regulatory expertise in plant and animal health, food safety, or environmental protection.² Other agencies, such as the Office of the U.S. Trade Representative (USTR), USDA's Foreign Agricultural Service, and the Department of State, are involved because of their responsibilities for trade, export facilitation, or diplomatic negotiations.

International Developments Potentially Affecting Exports

Recent developments in countries that are major markets for U.S. agricultural exports and in various multilateral organizations raise concerns about the prospects for U.S. agricultural biotech exports. For example, no agricultural biotech products have been approved in the EU since 1998. In addition, several countries have already passed or are considering regulations mandating labels for foods obtained from biotechnology. Furthermore, in the EU there is an effort to establish regulations requiring documentation to trace the presence of biotech products through each step of the grain handling and food production processes. International organizations, such as Codex, are also developing guidelines or rules affecting agricultural biotech trade (see slide 4).

¹The government's approach for addressing foreign trade measures related to plant, animal, and/or human health issues is complex, involving at least 12 federal trade, regulatory, and research entities. The part various U.S. agencies play in this process is discussed in depth in *Agricultural Exports: U.S. Needs a More Integrated Approach to Address Sanitary/Phytosanitary Issues* (GAO/NSIAD-98-32, Dec. 11, 1997).

²The White House set overall U.S. biotech regulatory policy in 1986, which called for applying the existing regulatory framework for food safety and environmental protection to biotech products.

Approval Processes Vary

Some countries have not approved for marketing certain biotech products that have been approved in the United States (see slide 5). Given the novelty of agricultural biotech products, harmonized regulatory oversight by major trading countries is still a work in progress.³ Indeed, many countries have no approval process for these products at all. Codex is currently developing international guidelines for analyzing the risks of foods derived from biotechnology that countries may use in establishing their own product approval regulations.

The United States and the EU already have in place very different regulatory frameworks for approving new agricultural biotech products or genetically modified organisms.⁴ The United States applies existing food safety and environmental protection laws and regulations to biotech products, and makes decisions on approvals based on the characteristics of products rather than whether they are derived from biotechnology. In order to evaluate new products, U.S. regulators require sufficient evidence to determine their safety or risk. Some of this evidence is developed through testing. Under this approach, the United States has approved most new biotech varieties to date. The EU, on the other hand, has established a distinct regime for regulating biotech products and since 1998 has not approved for marketing any new genetically modified organisms.⁵ Based on a concept the EU calls the “precautionary principle,” the European Commission maintains that approval of new biotechnology products should not proceed if there is “insufficient, inconclusive or uncertain” scientific data regarding potential risks.⁶ U.S. regulators stress that they also consider scientific evidence and exercise precaution in evaluating new products derived from biotechnology. U.S. officials note, however, that the

³In 1995, the Organization for Economic Cooperation and Development established a Working Group on Harmonization of Regulatory Oversight in Biotechnology. This working group issued a report on May 25, 2000—C(2000)86/ADD2—which summarizes various countries’ regulatory regimes.

⁴While U.S. government and industry typically use the term “agricultural biotechnology products,” EU documents generally refer to these products as “genetically modified organisms.”

⁵In February of this year, the EU revised its biotech product approval directive in an attempt to provide for the possibility of new product approvals. However, thus far, this directive has not been implemented because six EU member states are insisting on ancillary regulations on labeling and traceability.

⁶See Commission of the European Communities, Communication from the Commission on the Precautionary Principle (Feb. 2, 2000).

EU's "precautionary principle" may allow product approval decisions to be influenced by political considerations.

Failure of the EU to approve new products is affecting the viability of biotech trade in other parts of the world. For example, given the importance of the EU market, U.S. soybean producers have been reluctant to introduce new biotech varieties that have not been approved for marketing in the EU. Similarly, corn growers in Argentina, who export to the EU, are deferring planting a biotech variety known as "Round-up Ready" corn because the EU has not approved it.

Labeling Requirements Being Considered, Adopted

In advance of international guidelines, the EU, Japan, and Korea have already passed regulations requiring labels for food and food ingredients derived from biotechnology (see slide 6). These three countries are all significant markets for U.S. agricultural exports. Several other countries, including Australia, New Zealand, and Mexico, are also taking action to adopt such labeling requirements.⁷ U.S. officials have raised concerns that such regulations, depending on how they are crafted, could significantly increase production costs and disrupt trade.⁸ U.S. producers argue that a label identifying foods as derived from biotechnology is likely to be construed by consumers as a warning label, inhibiting demand for these products. Ultimately, if food producers seeking to avoid such labels reject biotech-derived ingredients, grain handlers may be compelled to separate conventional products from biotech varieties, which would raise handling and documentation costs considerably.

Labeling requirements also raise questions about threshold levels for biotech ingredients in food. It would not be possible for many foods to avoid labeling requirements that set a zero tolerance for the presence of biotech ingredients, according to U.S. officials. This is primarily because of the comingling of conventional and biotech varieties in the U.S. grain handling system. In the case of Japan, at least, USDA believes that U.S.

⁷Australia and New Zealand have enacted labeling requirements for biotech foods that will take effect in December 2001. The Mexican Senate has passed legislation calling for mandatory labeling of biotech products, but there has been no further action to date.

⁸The United States does not require special labeling for foods derived from biotechnology. Biotech foods are subject to the same labeling requirements that apply to foods in general; any significant difference from their traditional counterparts, such as the presence of an allergen, must be disclosed on the label.

products will be able to comply with its new labeling rules because foods containing less than a 5-percent threshold of biotech ingredients do not require labeling. More highly processed products, such as seed oils, are exempt from Japan's labeling requirement because they have no detectable trace of genetic modification.

The Codex Food Labeling Committee is currently in the process of developing international guidelines for countries that choose to establish mandatory labeling of food and food ingredients obtained through biotechnology. The U.S. delegation has supported a Codex guideline for mandatory labeling only when biotech-derived foods differ significantly from corresponding conventional foods in composition, nutritional value, or intended use. Draft language under consideration in the committee also includes an option for mandatory labeling based on the method of production, even if there is no detectable presence of DNA or protein in the end product resulting from the genetic modification. The U.S. delegation, led by FDA, has opposed this language. The committee remains deadlocked on this issue and has been for several years.

Traceability Through Each Step of Production

“Traceability” is a concept that forms the basis for a proposed EU regulation of agricultural biotech products that could affect U.S. exports (see slide 7). This regulation would require documentation tracing biotech products through each step of the grain handling and food production processes. Currently, no countries have enacted traceability requirements.

The European Commission is expected to adopt new regulations on both traceability and labeling requirements for foods and animal feed that contain biotech ingredients or are derived from biotechnology later in 2001.⁹ Under these proposed rules, margarine made from soybean oil, for example, would require documentation to identify whether it contains or was derived from a conventional or biotech soybean variety. If the oil was obtained from a biotech soybean variety, the margarine would have to be labeled, even though the oil may not contain detectable traces of modified DNA or protein. After the Commission adopts the regulations, it will

⁹The EU's stated objectives for requiring traceability of biotech products are to facilitate (1) the withdrawal of products in the event of an unforeseen risk to human health or the environment, (2) monitoring of potential health or environmental effects, and (3) control and verification of labeling claims.

forward them to EU legislative bodies for final approval, a process that may take up to a year or more.

The EU has also pushed for traceability rules to be included in Codex guidelines and in the Biosafety Protocol's pending rules for documentation of bulk commodity grain shipments.¹⁰ The U.S. government has opposed the inclusion of traceability requirements for biotechnology products in these multilateral discussions. U.S. government officials maintain that traceability requirements could significantly disrupt trade while having no compelling public health benefit. Moreover, U.S. industry groups are concerned about the burden these new regulations would place on the U.S. grain handling and food production systems because of the associated documentation requirements and the need to segregate biotech from conventional crop varieties.

Certain Commodity Exports May Be Limited By Foreign Regulations

Corn and soybeans are the principal U.S. commodity exports most threatened by foreign regulations governing biotech products (see slide 8). While exports of both crops are mainly destined for animal feed, these crops face notable differences in overseas markets. Corn exports have already experienced significant losses. From average annual sales of about \$300 million in the mid-1990s, U.S. corn exports to the EU have dropped to less than \$10 million in recent years. This decline is primarily because new biotech corn varieties have been introduced into production in the United States that have not been approved in the EU. Since it is possible that traces of biotech varieties not approved for marketing in the EU could be present in any shipment of U.S. corn, exporters have opted to discontinue most corn exports to Europe.

While the EU has never accounted for more than 5 percent of the world market for U.S. corn, Asian and Latin American countries purchase more than three-quarters of U.S. corn exports. Recently some of the largest markets in these regions—Japan, Korea, and Mexico—have taken action to enact regulatory measures that would require labeling of biotech foods and food ingredients. U.S. industry representatives note that labeling

¹⁰The Biosafety Protocol, signed in January 2000, is an agreement under the 1993 U.N. Convention on Biological Diversity. The protocol applies to the transboundary movement, transit, handling, and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity. The protocol will go into effect after it has been ratified by 50 countries, which is expected to occur within the next 2 years.

requirements in these countries may adversely impact the marketability of products with a biotech component and present additional difficulties for U.S. corn exports.

Unlike corn, U.S. soybean exports have not yet experienced disruptions. As noted above, U.S. soybean exports to the EU are primarily intended for animal feed. The European market is much more important for U.S. soybean exports than it is for corn. U.S. soybean producers have been more restrained about introducing biotech varieties that have not been approved in the EU. Currently, only one biotech variety of soybeans is in general production in the United States, and it has been approved in the EU and most other major markets. However, U.S. officials note that regulations on labeling and traceability now being considered in Europe may pose a threat to future soybean exports even if no new biotech varieties are introduced. This is because for the first time these regulations are expected to apply to animal feed as well as to food meant for human consumption.

Challenges Facing U.S. Biotech Exports

The United States faces a number of challenges to maintaining access to markets for biotech crops and foods containing or derived from agricultural biotechnology products (see slide 9). Among these challenges are the EU's moves to establish labeling and traceability requirements and gain recognition of the "precautionary principle" in various international organizations. U.S. and industry representatives are concerned that some developing countries may use the EU regulatory framework as the basis for their own regulations on agricultural biotechnology products. They also fear that some foreign governments' lack of experience regulating this new technology may lead them to impose rules that would restrict trade in a manner inconsistent with their WTO obligations. The United States is relatively isolated on biotech trade issues since currently only a few other countries produce or export these commodities. According to U.S. officials, other countries tend to view biotech as primarily a bilateral trade problem between the United States and the EU. Furthermore, since the United States is not a party to the U.N. Convention on Biological Diversity, U.S. participation will be limited in future Biosafety Protocol discussions, including those regarding bulk commodity shipments.

Growing consumer concerns, particularly in Europe, about the safety of biotechnology underlie actions taken by foreign governments that may restrict biotech trade. EU and U.S. officials note that recent food safety scares involving "mad cow" disease and dioxin and the ineffective response to these incidents by certain EU member governments have undermined

European consumers' confidence in their food safety regulatory system. Consequently, according to these officials, consumers in Europe question the capacity of regulatory authorities to ensure food safety, and even though these scares were not associated with biotechnology, European attitudes toward biotech foods have been adversely impacted. Some consumer groups contend that there are uncertainties about the risks and benefits of biotech foods, and they are not satisfied with existing U.S. health and environmental safety regulations. Moreover, the first generation of biotech products has primarily provided benefits for producers (such as lower pest management costs and enhanced yields)—not consumers. Recognizing this, the agricultural biotech industry is now promoting the potential benefits to consumers of the next generation of products, particularly improved nutritional content. However, such products have yet to be marketed and may not be for a number of years. Thus, the potential benefits to consumers are not yet well defined.

The difficulty grain handlers encounter in trying to completely separate biotech from conventional varieties poses an additional challenge.¹¹ This problem was highlighted by last year's discovery in U.S. supermarkets of foods containing a biotech corn variety known as StarLink. StarLink had been approved in the United States only for animal feed but found its way into processed foods, as well as into grain shipments to Korea and Japan where the product was not approved. According to industry representatives, the competitive advantage of the U.S. grain handling system results from the comingling of bulk commodity crops, including conventional and biotech varieties. Any regulatory measure that would ultimately lead to segregation or traceability would raise handling costs and potentially undermine the efficiency and competitiveness of this system, they maintain. While growers generally support biotechnology, some actors in the agricultural sector, notably exporters, have been critical of biotech companies for marketing varieties in the United States that have not yet been approved in major market countries.

Another challenge is the ability of U.S. government agencies to address other countries' new biotech regulations as they arise and protect U.S. interests in multilateral organizations in matters affecting biotech trade.

¹¹Some unintentional mixing of biotech grains with non-biotech grains can occur even when different varieties are not comingled, such as through the spread of pollen from a biotech plant to a non-biotech plant, or by inadequate cleaning of storage or shipping facilities that contained biotech grains.

Given the numerous international discussions in Codex committees and elsewhere, the U.S. government must contend with an increasing demand for staff resources devoted to biotech trade issues. U.S. officials have also highlighted the need for greater outreach to countries participating in these talks or considering their own biotech regulations. Such outreach efforts place an additional burden on agency resources. Finally, the number of U.S. trade and regulatory agencies with biotech-related roles, both domestically and internationally, creates a challenge for effective coordination. For example, there are several different U.S. government agencies representing U.S. interests in international organizations on biotech issues and working with other countries bilaterally, including USTR, USDA, FDA, and State. Their efforts require extensive interagency coordination in order to develop and carry out consistent U.S. positions on these issues.

Agency Comments and Our Evaluation

We obtained oral comments on a draft of this report from the Office of the U.S. Trade Representative, including the Director for Sanitary and Phytosanitary Affairs. We also obtained oral comments from the Department of Agriculture's Foreign Agricultural Service. The agencies provided technical comments that we incorporated as appropriate.

Scope and Methodology

To meet our objectives of (1) summarizing developments in key international organizations and among major U.S. trading partners that are likely to affect agricultural biotech trade; (2) identifying principal U.S. commodities most affected by foreign regulations on biotechnology exports; and (3) describing challenges U.S. biotech exporters face in maintaining access to foreign markets, we studied official documents from various U.S. federal agencies and foreign governments. We did not, however, independently review all foreign government rules or regulations affecting biotech imports. We examined statements by industry groups and nongovernmental organizations, as well as academic studies that addressed agricultural biotechnology trade issues. We interviewed U.S. officials from relevant agencies, including USTR, USDA, FDA, EPA, and the Departments of State and Commerce. We also met with USTR, USDA, and State Department officials in Brussels and Geneva. We met with a cross-section of industry groups, including representatives of growers, processors, exporters, food manufacturers, and biotech companies. In addition, we attended three conferences on agricultural biotechnology issues, and met with agency officials assigned to U.S. delegations to Codex.

Our focus was on challenges encountered by U.S. agricultural biotech exports. Pharmaceutical products derived from biotechnology were not part of our review. Moreover, we did not address the appropriateness of U.S. or foreign regulatory measures regarding biotech products. We conducted our work from October 2000 through May 2001 in accordance with generally accepted government auditing standards.

We are sending copies of this report to the Honorable Ann Veneman; Secretary of Agriculture; the Honorable Robert B. Zoellick, U.S. Trade Representative; the Honorable Colin L. Powell, Secretary of State; the Honorable Tommy Thompson, Secretary of Health and Human Services; and the Honorable Christine Todd Whitman, Administrator, Environmental Protection Agency. Copies will be made available to other interested parties upon request.

If you or your staff have any questions concerning this report, please call me at (202) 512-4347. Additional GAO contacts and staff acknowledgments are listed in appendix V.

Sincerely yours,

A handwritten signature in black ink that reads "Loren Yager". The signature is written in a cursive style with a large initial "L" and "Y".

Loren Yager, Director
International Affairs and Trade

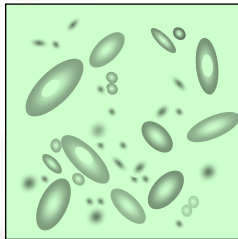
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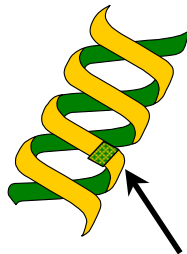
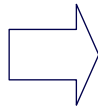
What is Agricultural Biotechnology?

Agricultural biotechnology is a collection of scientific techniques, such as genetic engineering, used to modify plants, animals, or microorganisms by introducing in them desired traits, including characteristics from unrelated species. For example, traits may be introduced to facilitate pest management and improve yield or nutritional value.

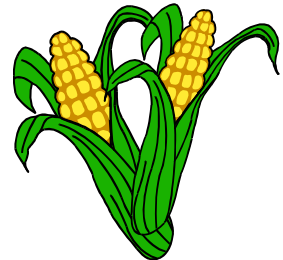
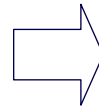
Example of Agricultural Biotech Process



The microorganism *Bacillus thuringiensis* (Bt) produces an insecticidal substance.



Bt gene is inserted into corn (maize) DNA.



The resulting corn variety (Bt corn) produces its own insecticide, reducing the need for farmers to spray pesticides.



Major Biotech Crops and Producers

To date the principal biotech products marketed have been certain genetically engineered field crops. The United States is by far the world's largest producer of biotech crops.

Major U.S. Biotech Crops

(Percentage represents biotech share of overall crop)*



Corn: 25%



Soy: 54%

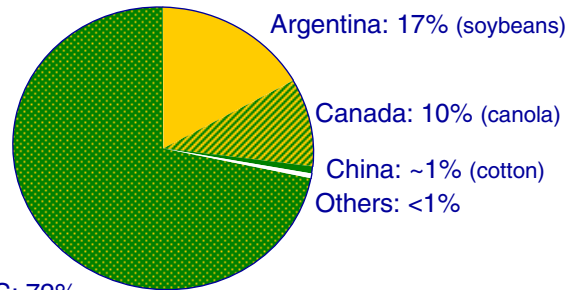


Cotton: 61%

*Based on USDA National Agricultural Statistical Service's June 2000 *Acreage* Report. Photo source: USDA.

Percent of Global Land Area Planted in Biotech Crop Varieties - by Country

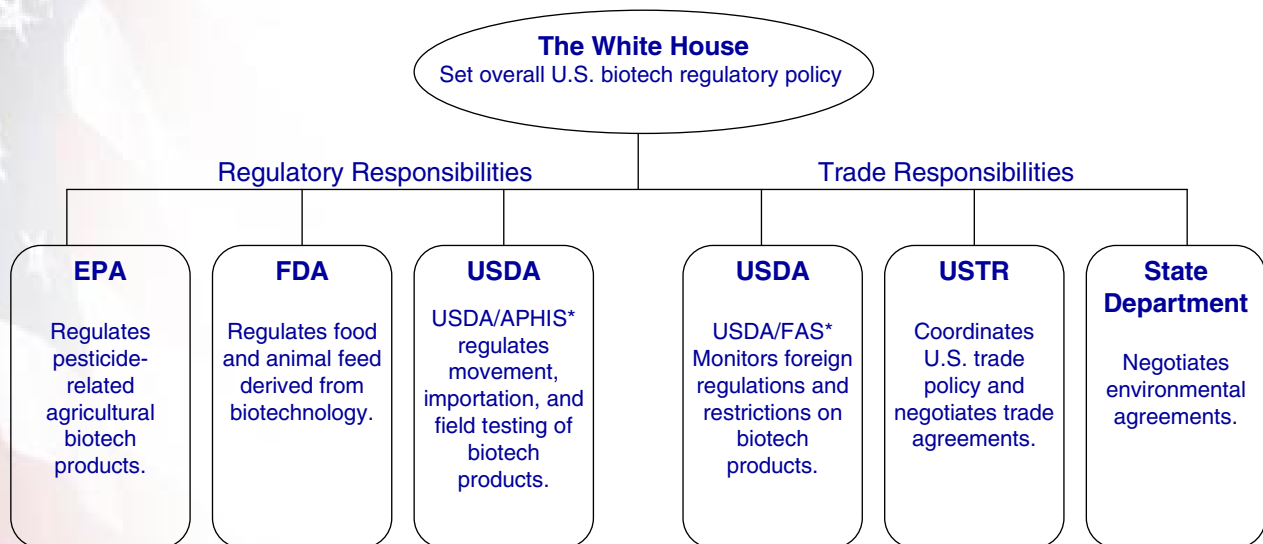
1999 total global land area: 98.6 million acres



Source: International Service for the Acquisition of Agri-Biotech Applications, "Global Status of Commercialized Transgenic Crops: 1999."



Agricultural Biotechnology and the U.S. Government



*APHIS: Animal and Plant Health Inspection Service; FAS: Foreign Agricultural Service.

USDA, FDA, EPA, State, and USTR all play a role in agricultural biotechnology trade.

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International Organizations Addressing Agricultural Biotechnology Issues

Discussions on biotechnology are taking place in Codex Alimentarius and the Biosafety Protocol. U.S. seeks to ensure guidelines set by these organizations are consistent with WTO disciplines.



Codex: Sets international food safety standards recognized under the WTO Sanitary and Phytosanitary (SPS) agreement. Active discussions related to biotech are taking place in several Codex committees. USDA manages overall U.S. participation in Codex. USDA and FDA lead U.S. delegations to Codex committees.



Biosafety Protocol: Environmental agreement under the U.N. Convention on Biological Diversity, covering the transshipment and use of living modified organisms. Protocol takes effect upon ratification by 50 countries. The United States has not ratified the Convention nor signed the Protocol. State Department represented U.S. interests at Biosafety Protocol negotiations.



WTO: Provides institutional framework for multilateral trade. Trade disciplines established under the SPS and Technical Barriers to Trade (TBT) agreements and the General Agreement on Tariffs and Trade (GATT) are related to biotech trade issues. USTR represents U.S. interests at WTO.



International Developments Affecting Trade: Approval Process

ISSUE

Some foreign countries have not approved for marketing certain biotech products that have been approved in the United States. Resistance to new product approvals in the EU has affected U.S. exports and biotech trade in other parts of the world.

U.S. POSITION

Product approval regulations must be clear, transparent, timely, science-based, and predictable. U.S. regulators have concluded that approved biotech foods on the market now are as safe as their conventional counterparts.

Ongoing Developments

- European Commission efforts to resume new biotech product approvals effectively blocked by six member states
- EU pushing for “precautionary principle” in various international organizations, including Codex and Biosafety Protocol
- Codex Ad Hoc Task Force on Biotechnology developing guidelines for analyzing risks of biotech foods



Photo source: USDA.

8/29/2000

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International Developments Affecting Trade: Labeling Requirements

ISSUE

Strict labeling requirements could impact U.S. exports because they could reduce consumer demand and increase costs.

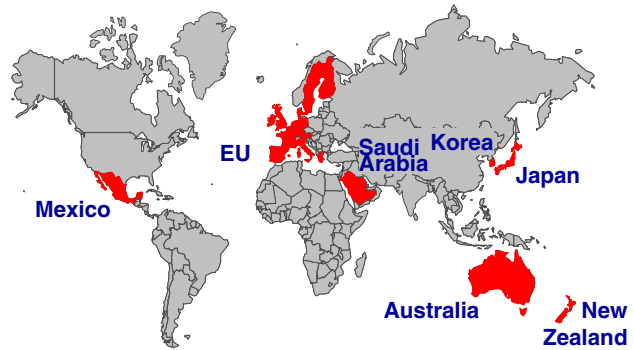
U.S. POSITION

Mandatory labeling should only be implemented when the new biotech product represents a significant change from the conventional variety or poses a threat to consumer safety. FDA has recently proposed voluntary labeling guidelines.

Ongoing Developments

- Various countries have taken action to enact mandatory labeling requirements (shaded areas on map)
- Codex Labeling Committee developing mandatory labeling guidelines
- Codex Ad Hoc Task Force on Animal Feeding considering biotech labeling for feed

Potential Markets Affected



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International Developments Affecting Trade: Traceability Requirements

ISSUE

EU is pushing for traceability requirements to track biotech products throughout the production and distribution chains. However, the implementation cost to producers may be prohibitive.

U.S. POSITION

A costly and onerous traceability system is not justified because biotech products are not inherently less safe than other foods. U.S. officials have opposed traceability requirements in Codex.

Ongoing Developments

- EU developing new regulations on traceability and labeling for food and feed in conjunction with revised directive on biotech product approvals
- Codex Ad Hoc Task Force on Biotechnology divided on traceability guidelines
- Biosafety Protocol negotiations on documentation requirements may address traceability issue for bulk shipments



Photo source: USDA.

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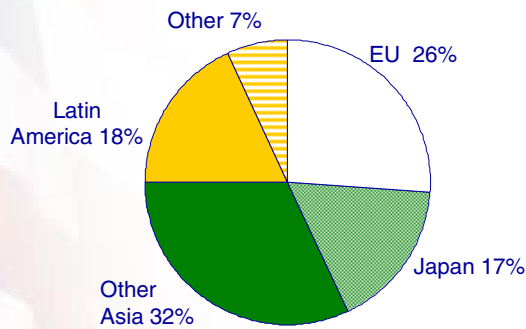


Major Exports Potentially Affected By Foreign Regulations

Corn and soy exports are most threatened by foreign regulations on biotech products. Because the U.S. grain handling system comingles biotech and conventional products, restrictions on biotech varieties affect nearly all exports of these commodities.

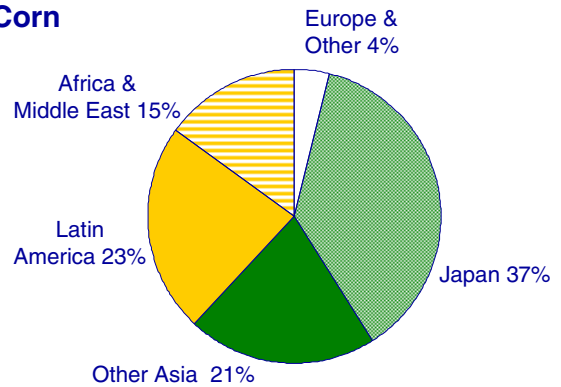
U.S. Soy and Corn Export Markets

Soybeans



Total 1999 exports: \$4.5 billion
Exports as percent of production: 29%

Corn



Total 1999 exports: \$4.9 billion
Exports as percent of production: 18%

Source: USDA, Economic Research Service.

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Challenges Confronting U.S. Agricultural Biotech Exports

FOREIGN GOVERNMENTS

- Persistent opposition of the EU and some of its members
- Relatively isolated U.S. position
- Lack of knowledge about biotech issues in developing countries

U.S. GOVERNMENT

- Coordination required among numerous agencies
- Increased resource demands for biotech-related activities

U.S. INDUSTRY

- Comingled nature of U.S. grain handling process
- Different perspectives within industry heightened by StarLink crisis

CONSUMERS

- Potential consumer resistance in major markets
- Benefits to consumers not well defined



Photo source: USDA.

8/29/2000

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Important Dates in Biotechnology Trade

1998	October	EU approvals for agricultural biotech products come to a halt
1999	Nov/Dec	Ministerial Conference of World Trade Organization in Seattle -- U.S. and Canada propose a working group on biotechnology
2000	January	Agreement reached on Biosafety Protocol in Montreal
	March	1 st meeting of Codex Ad Hoc Task Force on Biotech in Japan
	April	Codex Committee on General Principles meeting in France on risk analysis
	May	Codex Committee on Food Labeling meeting in Canada
	September	StarLink corn found in taco shells sold in the United States; delegation of U.S. agricultural and biotech companies visits Geneva to encourage discussions on biotech in WTO
	December	1 st meeting of the interim intergovernmental committee for the Biosafety Protocol in France
2001	March	2 nd meeting of Codex Ad Hoc Task Force on Biotech; 2 nd meeting of Codex Ad Hoc Task Force on Animal Feeding; special session of WTO agriculture negotiations
	April	Codex Committee on General Principles meeting in France on risk analysis; labeling guidelines in Japan take effect
	May	Codex Committee on Food Labeling meeting in Canada
	June	G-8 Economic Summit; U.S.-EU Summit; special session of WTO agriculture negotiations
	July	Labeling guidelines in Korea take effect
	October	2 nd meeting of the interim intergovernmental committee for the Biosafety Protocol in Canada
	November	WTO Ministerial in Qatar
2002	Summer	Mid-term report of Codex Ad Hoc Task Force on Biotech due
2003	Summer	Final reports of Codex Ad Hoc Task Forces on Biotech and Animal Feeding due

Source: GAO Analysis.

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Glossary

Bacillus thuringiensis (Bt)	A bacterium commonly found in soil, lethal to certain insects. It has been marketed for control of many plant pests. A gene from this organism has been spliced into the genetic material of various crops to protect them from specific pests.
Biosafety Protocol	An environmental agreement completed in January 2000 under the U.N. Convention on Biological Diversity. The protocol applies to the transboundary movement, transit, handling, and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity.
Codex Alimentarius	The joint food standards program for the U.N. Food and Agriculture Organization and the World Health Organization established in 1962. Its objectives are to help protect the health of consumers and facilitate trade through the establishment of international food standards, codes of practice, and other guidelines. The WTO Sanitary and Phytosanitary Agreement cites Codex standards and guidelines as the preferred international measures for facilitating trade in food.
Comingling	The practice of combining crops from multiple farms in the grain distribution system of the United States, including grain elevators and bulk commodity shipments. Consequently, biotech and conventional varieties are typically combined. Comingling enables the efficient handling and shipment of large quantities of bulk grain.
Dioxin	A class of chemical compounds shown by studies of highly exposed human populations to produce adverse developmental effects and increases in cancer, and to possibly affect immune and endocrine functions.
DNA (Deoxyribonucleic acid)	The genetic or hereditary material of all cellular organisms. It carries the information needed to direct the replication of cells.
European Commission	A body of the European Union that among other things exercises the EU's executive functions for implementing and managing policy and makes proposals for all new legislation. The Commission has recently revised the approval process for genetically modified organisms.
Gene	The basic unit of heredity found in all living organisms.

General Agreement on Tariffs and Trade (GATT)	Multilateral arrangement established in 1947 until the advent of the World Trade Organization in 1995. It provided the legal framework for international trade. Its primary mission was the reduction of trade barriers.
Genetic Engineering	A modern scientific technique used to modify plants, animals, or microorganisms by introducing in their genetic code genes for specific desired traits, including genes from unrelated species.
Genetically Modified Organism	A plant, animal, or microorganism produced by genetic engineering.
Hybrid	A plant or animal that is the result of crossbreeding between different varieties or species.
Identity Preservation	Strict separation of one crop from another, typically involving shipping in separate containers, to preserve a product's unique characteristics. Identity preservation is generally used for marketing value-enhanced products such as food-grade corn and soy, which command higher prices.
Living Modified Organism	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
Mad Cow Disease	A degenerative brain disease of cattle technically known as Bovine Spongiform Encephalopathy (BSE). A number of studies have confirmed that BSE in cattle can be transmitted to humans causing a form of Creutzfeldt-Jakob disease, a fatal brain disease in human beings.
Modern Biotechnology	A collection of scientific techniques, such as genetic engineering, used to modify plants, animals, or microorganisms by introducing in their genetic code genes for specific desired traits, including genes from unrelated species.
Organization for Economic Cooperation and Development	Multilateral organization founded in 1961 to coordinate the economic policies of industrialized nations. It has issued several studies on various aspects of biotechnology.
Precautionary Principle	A general concept contained in EU legislative texts. According to the EU, the precautionary principle covers circumstances “where scientific evidence is insufficient, inconclusive or uncertain and . . . there are reasonable grounds for concern” about a product's “potentially dangerous effects on the environment, human, animal or plant health.”

Round-Up Ready	The trade name for biotech crops modified to tolerate the use of a specific herbicide known as Round-Up.
Sanitary and Phytosanitary Measures	Sanitary measures pertain to human and animal health and safety. Phytosanitary measures pertain to protecting plants from pests and diseases.
Species (Plant or Animal)	A group of plants or animals possessing traits or characteristics in common that distinguish them from other groups. Members of the same species may interbreed and reproduce their traits in their offspring.
StarLink	A trademark for several corn hybrids obtained through biotechnology. StarLink hybrids contain a plant pesticide protein that kills certain destructive pests. The EPA approved StarLink for animal feed only, not for use in food intended for human consumption.
Threshold	The level for content of a regulated substance below which a regulatory measure would not be triggered. For example, a biotech food labeling requirement with a 5 percent threshold would not be triggered if a food or food ingredient has less than 5 percent biotech content.
Tolerance	Maximum limit for the amount of content or residue of a regulated substance in food or feed. A regulatory measure that sets a “zero tolerance” is triggered by any detectable presence of the regulated substance.
Traceability	A concept serving as the basis for a proposed regulation in the European Union that would require the identification and tracking of biotech or biotech-derived products at all stages of the production and distribution chain in the food and feed sectors.
Transgenic	A plant or animal variety that contains genes from a different species transferred using genetic engineering techniques.
U.N. Convention on Biological Diversity	A convention whose principal aims are the conservation and equitable and sustainable use of biological diversity. The convention entered into force in December 1993.
Variety (Plant or Animal)	A group of plants or animals forming a subdivision of a species consisting of naturally occurring or selectively bred individuals sharing certain traits or characteristics.

World Trade Organization (WTO)	International trade organization established in January 1995 to provide the institutional framework for the multilateral trading system. It administers rules for international trade and provides a forum for resolving trade disputes and conducting trade negotiations.
WTO Sanitary and Phytosanitary (SPS) Agreement	An agreement under the WTO establishing disciplines on member countries' measures to protect human, animal, or plant life or health. Under the agreement, such measures must be based on an assessment of risk and science and should not be applied arbitrarily or in a way that constitutes a disguised restriction to trade.
WTO Technical Barriers to Trade (TBT) Agreement	An agreement under the WTO establishing disciplines on member countries' technical regulations and standards for protection of human, animal, or plant life or health, or the environment not specifically within the scope of the SPS Agreement. Under the agreement, such regulations and standards cannot be more trade-restrictive than necessary to fulfill a legitimate objective.

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