



The Agricultural Law Letter

Published by the Law Office of
MCLEOD, WATKINSON & MILLER

Editorial Director: Michael R. McLeod
Editorial Assistant: Mary Carter Hudgins

Volume XV, Number 3

November-December 2000

Randy Green

Congress Passes Sanctions Reform

In recent years, few policies have taken more fire from farm groups than unilateral U.S. economic sanctions. Agricultural advocates have argued that it is unfair and foolish for the United States to prohibit the export of food, feed and fiber to disfavored countries, since our competitors usually are happy to supply these markets if we will not. On the other hand, sanctions advocates argue strongly that sanctions can be an effective means, short of war, for promoting democracy, human rights and the American national interest. The

(Continued on page 2)

Randy Green and Stephen Frerichs

Congress Passes Emergency Aid, Again

Emergency Provisions of H.R. 4461, the 2001 USDA Appropriation Bill

Conferees on H.R. 4461, the fiscal year 2001 agriculture appropriations bill, adopted a range of disaster and economic assistance for agricultural producers and others. The Congressional Budget Office (CBO) estimated the total cost of these items in the fiscal year 2001 to be **\$3.6518 billion**.

(Continued on page 12)

Richard Pasco

Spotlight on Genetically Engineered Foods

Recent discoveries of *Bacillus thuringiensis (Bt)* corn in grocery store taco shells has heightened the scrutiny of how the United States tests, registers, labels, and otherwise regulates genetically engineered products in the food chain. This article will provide an overview of the federal legal framework governing genetically modified organisms (GMOs), highlight some of the most recent actions related to GMO products, identify some of the issues voiced by those who are concerned that GMOs will find their way into a variety of foods, and outline proposed changes to the federal government's oversight of GMOs.

What are Genetically Engineered Foods & Who Regulates Them?

Genetically engineered foods or bio-engineered foods resulting from genetically modified organisms, refers to the use of recombinant DNA and related techniques to alter the genetic makeup of living organisms. These techniques allow scientists to identify and isolate genes of interest from any organism and put them into other organisms. In other words, GMO crops carry new traits that have been inserted through advanced genetic engineering methods. The genetically engineered food crops planted and marketed by U.S. farmers include corn, tomatoes, potatoes, soybeans, canola, and sunflowers. GMO varieties in-

(Continued on page 3)

Randy Green, from Page 1

subject arouses intense emotions, especially when the country in question is Cuba.

The 2001 agriculture appropriations bill awaiting President Clinton's signature (H.R. 4461) will significantly change sanctions policy. The reforms have been highly controversial, both when they were first debated in the House of Representatives and the Senate and when negotiations brokered by the Congressional leadership brought forth a compromise document that subsequently became Title IX of H.R. 4461.

Especially contentious were sections of Title IX that (1) codify restrictions on Americans traveling to Cuba (the limitations have been enforced only by executive order up to now); and (2) prohibit U.S. financial institutions from issuing letters of credit pursuant to commercial sales to Cuba (though they will be permitted to confirm or advise such letters of credit).

The remainder of this article describes the provisions of Title IX, "Trade Sanctions Reform and Export Enhancement."

Restrictions on New Sanctions. The President may not impose a new unilateral agricultural or medical sanction against a foreign country unless he submits a report to Congress within 60 days of imposing the measures *and* Congress subsequently passes a joint resolution approving the sanction. These requirements are not applicable if the sanctions are multilateral or the result of United Nations Security Council action, or in cases of war, military hostilities or imminent hostilities, and the export of certain controlled items.

If the President imposes sanctions, they will automatically sunset in two years unless Congress passes the joint resolution described above.

Existing Sanctions. Title IX requires the President, generally, to terminate existing unilateral agricultural and medical sanctions within 120 days. However, there are important limits on this general requirement, as described below. In addition, the

same exceptions listed for new sanctions (war, etc.) also would void the requirement to end existing sanctions.

Licensing. Title IX requires one-year licenses for agricultural and medical exports to Cuba or countries determined to be state sponsors of terrorism (though Syria and North Korea are specifically exempted). The section includes language that aims to limit how restrictive the licenses can be.

Government Assistance. The new law will contain a general prohibition on U.S. government assistance for exports to Cuba, Iran, Libya, North Korea and Sudan. The President can waive this ban with respect to all the countries except Cuba. The ban refers to "exports" to Cuba, but to "commercial exports" to the other countries. U.S. government assistance is defined to include foreign assistance, export assistance and any credits or guarantees.

Financing Sales. Title IX stipulates that financing for agricultural sales to Cuba can only be carried out by "third country financial institutions." However, the bill says that financing may be "confirmed or advised" by U.S. financial institutions. This means that, in a commercial transaction, a foreign bank would have to issue a letter of credit involved in the sale, although a U.S. bank could advise or confirm it.

Imports from Cuba. The bill restates the existing ban on Cuban imports, specifying that it is unaffected by the sanctions reform legislation.

Travel Restrictions. Title IX requires the Secretary of the Treasury to issue regulations to create a new category of license to travel to Cuba for "the commercial export sale of agricultural commodities." In addition, the legislation codifies existing restrictions on travel to Cuba.

Randy Green is the firm's senior government relations representative. Before coming to McLeod, Watkinson & Miller, he was chief of staff for the Senate Committee on Agriculture, Nutrition and Forestry, and served during 1992 as deputy under secretary of Agriculture for international affairs and commodity programs.

Richard Pasco, from Page 2

clude *Bt* corn, Roundup Ready soybeans, and Flavr Savr tomatoes.

USDA Framework for Regulating GMOs

The USDA is responsible for ensuring that new GMO varieties are safe to grow by regulating the testing of new biotech plants. Prior to a biotech company being able to commercially grow new genetically engineered crops, the USDA has to review what the new plant is and how its growth may potentially impact the environment.

The United States has statutory and regulatory provisions that restrict the introduction of organisms and products altered or produced through genetic engineering, which are either considered plant pests or there is reason to believe are plant pests. USDA's Animal and Plant Health Inspection Service (APHIS) issues field-test permits for new plants that have the potential to create pest problems in domestic agriculture. APHIS regulations provide procedures for obtaining a permit or for providing notification prior to importing, moving interstate, or releasing a "regulated article" in the United States.

The current regulations governing the introduction of organisms and products altered or produced through genetic engineering are found in 7 C.F.R. 340 et seq. These regulations are derived from the statutory authority provided in the Federal Plant Pest Act (7 U.S.C. 150aa et seq.) and the Plant Quarantine Act of 1912 (7 U.S.C. 151-164a, 167), which were recently repealed with the enactment of the new "Plant Protection Act" (7 U.S.C. 7711-7758) on June 20, 2000. While the underlying statute has been repealed, the existing regulations remain operable. One of the effects of the new Plant Protection Act is to significantly increase the penalties for violations of the regulations on genetically engineered products.

Under 7 C.F.R. 340.0, "[n]o person shall introduce any regulated article" unless APHIS is "notified ... or such introduction is authorized by permit." "Any regulated article introduced not in

compliance with" such requirements "shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests" (7 C.F.R. 340.0(c)). Since the underlying statute regulates the movement of plants, plant products, and biological control organisms (7 U.S.C. 7712), GMO products are subject to the procedures and penalties set forth for the discovery of such regulated GMO products.

Any "person", who is defined to include "[a]ny individual, ...corporation, company" is potentially subject to the rules governing GMOs (7 C.F.R. 340.1), if they handle, receive, or import GMO products. Thus, a food company and its employees could be subject to USDA's notice/permit process on GMOs, if it were established that they are responsible for or play a primary role in the introduction of a GMO product into the United States.

Procedures to Notify APHIS of GMOs

GMO notification regulations administered by APHIS require that "performance standards must be met for any introductions" of GMOs (7 C.F.R. 340.3((c))). These "performance standards are as follows:

- 1) Any plants or plant materials that are shipped "must be in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment."
- 2) "When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release."
- 3) "The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained ... when no longer in use."
- 4) "There must be no viable vector agent associated with the regulated article."
- 5) "The field trial must be conducted such that [t]he regulated article will not persist in the environment, and ... [n]o offspring can be pro-

(Continued on page 4)

Richard Pasco, from Page 3

duced that could persist in the environment.”

- 6) “Upon termination of the field test ... [n]o viable material shall remain which is likely to volunteer in subsequent seasons, or ..[v]olunteers shall be managed to prevent persistence in the environment.”

Arguably, the above-mandated performance standards demonstrate that the APHIS notification requirements are directed at the individuals and company that are responsible for introducing the GMO product. Such “person” is required to contact the APHIS Office of Biotechnology Permits (7 C.F.R. 340.3(d)) and provide the following:

- 1) “Name, title, address, telephone number, and signature of the responsible person”;
- 2) “Information necessary to identify the regulated article(s), including...” the scientific and common name of the article, and the designations for the genetic material;
- 3) “The names and locations of the origination and destination facilities for movement or field site location for the environmental release; and the size of the introduction”;
- 4) “The date and, in the case of environmental release, the expected duration of the introduction (release)”;
- 5) “A statement that certifies that the introduction of the article will be in accordance with the” performance standards.

Notification must be submitted to APHIS at least 10 days prior to the day of GMO product introduction, if the introduction is interstate movement. The notice requirement is 30 days in advance of introduction, if the introduction is an importation or an environmental release (7 C.F.R. 340.3(d)(3)).

APHIS Permit Requirement to Introduce GMOs

APHIS regulations provide procedures for obtaining a permit for field testing. To receive a permit, the plant breeder must provide information pertaining to how the plant was developed and the control measures that will be taken during the trials, including field design, monitoring, and report-

ing requirements. If, after a review of the disclosure information submitted by the plant developer, APHIS reaches a “finding of no significant impact,” a field test is permitted.

The permit process begins with the submission of an application to APHIS for a permit to introduce GMOs (7 C.F.R. 340.4(a)). “An application for the release into the environment of a regulated article shall be submitted at least 120 days in advance of the proposed release into the environment” (7 C.F.R. 340.4(b)). In addition, “An application for the interstate movement or importation of a regulated article shall be submitted at least 60 days in advance of the first proposed interstate movement and at least 60 days prior to each importation” (7 C.F.R. 340.4(c)).

After several years of field trials, the plant breeder may petition APHIS to release its new plant variety from regulatory requirements through a determination of “nonregulated status.” Before a determination to deregulate is made, USDA requires data on the rationale for development of the plant, the system to transform the genome, the donor genes and regulatory sequences used, genetic analysis and agronomic performance, the environmental consequences of introduction, and the adverse consequences of introduction.

Once APHIS confers nonregulated status, unregulated interstate movement and release of the new plant is allowed. If, however, APHIS determines that the new plant variety poses an environmental risk – for example, if the plant demonstrates a significant potential to cross pollinate with wild relatives and create problems – it has the authority to suspend the field trials and halt further development of the plant.

Upon discovery of “any accidental or unauthorized release of the regulated article”, APHIS must be “[o]rally notified immediately” and “in writing within 24 hours” (7 C.F.R. 340.4(f)(10)(i)). APHIS also must be notified in “writing as soon as possible but not later than 5 working days if the regulated article or associated host organism is found to have characteristics substantially different for those listed on the application for a permit” (7 C.F.R. 340.4(f)(10)(ii)). *(Continued on page 5)*

Richard Pasco, from Page 4

USDA Authority to Implement Measures

USDA is provided with the authority to “prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism” or article ... if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest ... within the United States (7 U.S.C. 7712(a)). “If the Secretary considers it necessary” ... “the Secretary may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of any plant, plant pest,” or article that “is moving into or through the United States” or “is the progeny of any plant” that is moving in violation of the requirements of the statute (7 U.S.C. 7714(a)). In addition, “the Secretary may order the owner of any plant” or article subject to action “to treat, apply other remedial measures to, destroy, or otherwise dispose of the plant” (7 U.S.C. 7714(b)(1)).

However, USDA also is provided with discretion to take less “drastic action that is feasible and that would be adequate to prevent the dissemination of any plant pest ... not known to be widely prevalent or distributed within or throughout the United States” (7 U.S.C. 7714(d)). Furthermore, the owner of any such plant or plant product that is destroyed or otherwise disposed “may bring an action against the United States to recover just compensation for the destruction or disposal of the plant” (7 U.S.C. 7716(a)).

Penalties for Violation of APHIS Notification/Permit Requirements

Under the statute in place before June 20, 2000, any person who “knowingly” violated the GMO notification/permit requirements was subject to a misdemeanor that was punishable “by a fine not exceeding \$5,000, by imprisonment not exceeding one year, or both” (7 U.S.C. 159gg(a)), and a person who did not knowingly violate such requirements could only “be assessed a civil pen-

alty by the Secretary not exceeding \$1,000” (7 U.S.C. 150gg(b)).

Pursuant to the new statute, the criminal sanction remains a misdemeanor, with a discretionary fine “in accordance with title 18, United States Code” and imprisonment “for a period not exceeding 1 year, or both” (7 U.S.C. 7734(a)). However, the civil penalties are increased dramatically in this new statute (see 7 U.S.C. 7734(b)). “Any person that violates” the GMO regulations may “be assessed a civil penalty by the Secretary that does not exceed the greater of –

- (A) \$50,000 in the case of any individual ..., \$250,000 in the case of any other person for each violation” (i.e., a company), “and \$500,000 for all violations adjudicated in a single proceeding; or
- (B) twice the gross gain or gross loss for any violation”

Food Company Action Necessary to Respond to GMO Product Discovery

Generally, any individual person or company, who is handling, receiving, or importing a GMO product is required to contact APHIS in accordance with the above-identified notification procedures. In particular, an individual person or company is subject to reporting requirements, if they are the entity that was responsible for introducing the GMO and had access to field test data and other detailed information about the GMO products. If a GMO product is discovered further down the food chain—in the food supply—the FDA should be contacted to both test such food and to help coordinate a voluntary recall of the food products.

EPA Role in Genetically Engineered Foods

EPA has oversight over all pesticides, and thus all of the GMO plants that are cross-bred or created to produce pesticides. In addition, EPA has to approve the safety of any pesticide-producing plant for consumption.

EPA’s Office of Pesticide Programs, Biopesticides and Pollution Prevention Division

Richard Pasco, from Page 5

regulates “plant pesticides” under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). *Bt* corn is perhaps the most well-known example of a plant modified to produce its own pesticide.

Before submitting an application for field-test approval and registration, the plant breeder consults with EPA scientific staff to decide upon the data requirements that will support the Experimental Use Permit (EUP). An EUP permits the use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit. The studies done under the EUP are used to support the application for registration.

FDA Role in Genetically Engineered Foods

The FDA is generally in charge of all food products for human and animal consumption (with the exception of meat and poultry, which are under the USDA’s jurisdiction). The agency strongly encourages biotech companies to go through a voluntary consultation process prior to putting GMO foods on the market, but does not give a formal approval to GMO products.

The FDA has adopted a risk-based regulatory approach which is consistent with the long history of safe use of genetically-modified plants and the foods derived from them. The FDA’s policies on voluntary consultation and labeling are consistent with the scientific consensus and provide essential public health protection.

Currently, the FDA does not require labeling of foods that contain genetically engineered material. In 1992, the FDA determined that genetically engineered foods pose scientific and regulatory issues that are not substantially different from those of conventional food. However, special labeling may be required if the GMO food product significantly differs from its conventional counterpart, such that the common name would no longer apply, or if it contain allergens. The FDA concluded that it was unnecessary to mandate labeling to indicate the method by which a new vari-

ety of food was developed, so the issue of whether it was genetically engineered was not relevant to labeling requirements, unless the resulting GMO food product was significantly different from existing foods.

Recent Discoveries in Food Products

Recent public disclosures concerning the discovery of millions of bushels of genetically engineered corn approved only for animal use in the human food supply chain have heightened the sensitivity of this issue not only for government officials and the food industry, but for the public, who may fear that such products will trigger allergic reactions. Over the last few months, a major supermarket chain voluntarily recalled its house brand taco shells, which followed a similar action by a major food manufacturer and comes after the developer of a GMO corn announced that its seed would no longer be sold. In the aftermath of the discovery of GMO corn in the food supply, the biotech company that developed the GMO seed, the food industry and federal officials have worked cooperatively to find the GMO corn before it is made into more taco shells and other corn-based food products.

Although the corn found in the taco shells was not approved for human consumption because of fears it might trigger allergic reactions, federal officials do not believe the presence of the GMO corn in food poses an imminent health risk. However, this development raises questions about whether GMO products can be kept segregated from conventional ones in the nation’s food system.

Developments Related to StarLink Corn

The StarLink variety of yellow corn became more prominent in the public eye on Sept. 22. On that date, Taco Bell Home Originals taco shell products, which are sold nationwide in supermarkets and other retail grocery outlets, were voluntarily recalled by Kraft Foods. Tests performed by an expert independent laboratory had indicated the presence in certain samples of a variety of corn

(Continued on page 7)

Richard Pasco, from Page 6

Kraft had not specified for the product and which had not been approved for use in food. As soon as Kraft learned of the possibility of a product ingredient problem, the company began immediate consultations with the FDA and with its supplier. FDA confirmed the presence of StarLink corn in the taco shells through independent testing, and the agency issued a Class II voluntary recall, which means a potential health risk.

Thereafter, the USDA and Aventis Crop-Science, the developer of the GMO corn (and a subsidiary of Aventis S.A.), began buying back the StarLink variety of corn grown on farms. Aventis is working with grain elevators, flour mills and processors to identify commingled corn and removing it from the food chain. The Starlink corn now on farms is under an agreement with USDA that Aventis will buy back the corn at a 25-cent bonus over USDA's Oct. 2 posted county price. The corn is being isolated under USDA supervision and sold only for livestock feed or industrial use, which is primarily for ethanol. Aventis also is paying to test commingled corn in many grain elevators, and will buy any corn in storage that has even a small amount of StarLink in it.

The food recalls also triggered a series of investigations by federal regulators and Aventis to determine how the corn had gotten to a Texas corn flour miller, who had inadvertently used the corn from last year's crop to make taco shells. While the investigations continue, Aventis says the corn from this year's corn crop was apparently sold by farmers to several grain elevators across the country, which unknowingly distributed it to millers and processors for use in manufacturing food.

The gene-spliced Starlink variety corn was engineered with a gene that produces a protein lethal to the corn borer, a common pest that devastates crops. StarLink corn is the only genetically modified variety of corn that was approved by the EPA for animal feed use, but not for human consumption. Aventis has identified about 350,000 acres that were planted with StarLink by approximately 2,200 producers – mostly in the Midwest and upper Midwest. Another 168,000 acres of

buffer crops were planted to protect against pollen spread from this biotech corn. While none of the StarLink corn was supposed to enter the human food supply, some farmers did not know that the corn was only approved for animal or industrial use; some farmers knew the restrictions but forgot them; some corn was grown on a small section of larger farms and farmers just harvested it together; some farmers did not advise the grain elevators of the restrictions; and some farmers did not know that the corn had been planted near their crops, which were in the official buffer zone.

It is estimated that USDA has isolated about 88% of the StarLink corn, which was either being stored on farms or used for animal feed. Aventis is in the process of tracking down and buying back when they can, the other 12% of the StarLink corn -- or 9 million bushels -- that already left farms this year. Some analysts have estimated that the cost will approach \$100 million.

Recently, the Kellogg Co. stopped production at one of its plants because it was concerned about the possible presence of StarLink corn. Kellogg noted that it could not guarantee that the corn used in its Memphis, Tennessee plant was not StarLink corn. Apparently, the plant only endured a minor production disruption.

Tyson Foods Inc. also recently stopped purchasing StarLink corn for its chickens. Tyson is believed to be the first food company to stop the purchase of StarLink corn as an animal feed, in a precautionary move to avoid confusion among consumers, even though there has been no evidence of the GMO corn transferring to food products. A Tyson representative commented that the company did not plan to carry out independent testing, but will leave to its suppliers to ensure that the corn it purchases is free of StarLink.

In another development, the EPA announced that Aventis agreed to cancel its registration of StarLink corn at the urging of EPA. This voluntary agreement provides a means to remove StarLink corn from being planted for any agricultural uses. This corn was recalled because StarLink corn is currently only approved for livestock

Richard Pasco, from Page 7

feed and industrial use, and not for human consumption.

EPA acknowledges that it has no evidence that food containing StarLink corn will cause any allergic reaction in people, and that the risks, if any, are extremely low. While the food and biotech industry supports a petition just submitted to EPA by Aventis that provides human health data to support a conclusion that the StarLink variety of corn is safe for human consumption, it has been reported that EPA is not planning on granting any sort of temporary approval of StarLink for human use, and will take several weeks to solicit public comments to provide a thorough scientific review and to examine whether there is enough evidence available to determine if StarLink can cause allergic reactions.

On Oct. 25, Aventis offered new evidence to EPA for its case that the key protein in StarLink corn is not an allergen. The company found that the protein known as Cry9C did not elicit reactions when tested on the blood of people particularly susceptible to food allergies. Aventis also presented data showing that the protein would be destroyed by stomach acids more quickly than thought. Aventis further points out that even if the protein is a potential allergen, there is so little in the food supply that people would not be exposed enough to cause reactions.

A chronological summary of events relevant to the issues raised by StarLink corn are outlined as follows:

- May 22 – EPA issues/publishes the StarLink exemption from a feed tolerance, thus approved it for animal feed use
- August 9 – EPA announces that it will conduct a comprehensive scientific review of its current approvals for corn and cotton that have been genetically modified to produce *Bt*
- Sept. 22 – Kraft Foods voluntarily recalls its Taco Bell Home Originals taco shells
- Sept. 26 – Aventis CropScience announces that StarLink seed would no longer be sold
- Oct. 11 – Safeway Stores voluntarily recalls its

- house brand taco shells
- Oct. 11 – Sen. Dick Durbin introduces legislation that directs FDA to conduct mandatory pre-market reviews of all genetically engineered foods and authorizes FDA to test products already on the market for the presence of unapproved biotech ingredients
- Oct. 12 – Western Family Foods issues a recall of all of its brand name taco products after reading news reports about the detection of StarLink in corn food products
- Oct. 12 – Aventis CropScience voluntarily withdraws the StarLink registration to provide additional assurance that StarLink would not be planted again until food approval was received
- Oct. 18? – Kellogg Co. stops production at one of its plants because of concerns about the possible presence of StarLink corn
- Oct. 20 – Tysons Foods stops purchasing StarLink corn for its chickens
- Oct. 20 – European Commission questions whether U.S. regulations are adequate to stop bio-engineered grain from getting into exports to countries in Europe
- Oct. 24 – The Genetically Engineered Food Alert sends a letter to President Clinton urging him to make sure EPA does not give StarLink corn clearance for human consumption
- Oct. 25 – Aventis petitions EPA with new scientific data in an effort to have StarLink corn approved as a safe ingredient for human food use, stating that there “was reasonable certainty of no harm”

Anti-Biotech Groups Push for Increased Government Oversight

The discovery of Starlink corn in taco shells has triggered a chain of events that caught the attention of consumer and environmental groups, the media, and government agency officials with oversight over biotechnology. Although the FDA is testing a variety of corn products for the presence of unapproved corn, a coalition of consumer and environmental groups, called the Genetically Engineered Food Alert

(Continued on page 9)

Richard Pasco, from Page 8

(GEFA), is now demanding increased testing of food products by the FDA. Specifically, they are calling for FDA to test all food products made with No. 2 yellow corn. GEFA wants the FDA to pre-market test GMO food, label GMO products, and force the biotech companies to accept all liability for problems with their goods. In addition, anti-biotechnology protesters are continuing to push USDA, EPA and FDA to publish their list of farmers who grew StarLink.

GEFA also is attempting to persuade food companies to remove genetically engineered ingredients from their food products. GEFA includes Friends of the Earth, the National Environmental Trust, the Center for Food Safety, and the Organic Consumers Association. These groups have announced that they intend to deluge certain companies with letters, e-mails, and telephone calls.

On Sept. 29, the U.S. District Court for the District of Columbia granted a motion for summary judgment against a lawsuit brought by a coalition of anti-biotech groups and individuals, who sought to compel the FDA to conduct safety testing and require labeling of all genetically engineered foods. The court held in favor of FDA in determining that genetically modified foods need not be labeled "because they do not differ 'materially' from nonmodified foods." Similarly, the same district court dismissed an earlier suit by Greenpeace alleging that the EPA acted negligently in approving *Bt* crops.

Nevertheless, the anti-biotech advocates continue to suggest that widespread use of plants engineered with built-in protection against insect and viral pests could accelerate the development of pesticide-resistant insects or could have a negative impact on populations of beneficial insects, such as the Monarch butterfly. It also has been argued that the use of herbicide-tolerant plants could increase herbicide use and that "superweeds" could be developed through cross-pollination between GMO plants and nearby weeds.

International Concern About GMOs in Foods

The European Commission has questioned whether U.S. regulations are adequate to stop bio-engineered grain from getting into exports to countries in Europe who are concerned about genetically modified foods. The new concerns were raised following the recall of taco shells and flour containing StarLink corn. Great Britain, France, Italy, and more than two dozen other countries around the world prohibit the sale of foods containing biotech ingredients unless they are clearly labeled for consumers. The use of StarLink corn for human or animal consumption has not been approved within the European Union.

More recent reports from a consumer group in Japan claim that StarLink corn was found in tests on imported meal, which provides the first indication that the corn has spread overseas. A Japanese consumer group asked the health and agriculture ministries to recall this food product, and seeks a suspension of imports of GMO crops. In response, the Japanese Ministry of Health and Welfare has said the National Institute of Health Sciences would conduct its own test on the "Home Baking" product, which is used to make scones and other baked goods. StarLink is not approved in Japan even for animal feed use.

Earlier, on April 20, StarLink corn (in chicken feed) and another variety of corn that was not approved in Japan were found in a test conducted by a Japanese anti-biotech group. Japan imported 15.4 million tons of U.S. corn in 1998-1999 marketing year, which accounts for \$1.5 billion of the \$5 billion in total corn exports from the United States (for both food and feed use). In fact, Japan is the largest market for U.S. corn, importing 60% of U.S. corn exports and 6% of its total corn crop.

The Administration's Approach to GMO Foods

On August 9, the EPA announced that it will conduct a comprehensive scientific review

Richard Pasco, from Page 9

of its current approvals for corn and cotton that have been genetically modified to produce *Bt* (a naturally-occurring pesticide). This review is intended to ensure that the registrations for these crops are based on the most current health and ecological data. The EPA said that it will publish its risk assessment for public comment and present it to the EPA Scientific Advisory Panel for review. Meanwhile, an EPA study released in September concludes that *Bt* corn poses little risk to the monarch butterfly or other non-target species.

In addition, the Clinton Administration released a plan on May 3 that would increase federal oversight of genetically modified foods by moving toward a regulation that would make FDA consultations for GMO food mandatory, while continuing to allow voluntary labeling. Biotech companies would have to notify the FDA at least 120 days before marketing a new genetically modified food, and provide FDA and the public with research results that affirm the new food's safety. Specifically, FDA would require that specific information be submitted to help determine whether food products pose any potential safety, labeling or adulteration issues. After reviewing a submission, the FDA would issue a letter to the company describing its conclusion about the regulatory status of the food.

According to Agriculture Secretary Dan Glickman, USDA's role would be to help develop testing procedures and quality assurance programs designed "to differentiate non-biotech commodities." USDA would become directly involved in validating new scientific tests that aim to detect the presence of gene-altered ingredients.

The FDA also would create a regulatory mechanism, so for the first time, foods could be labeled as being free of gene-altered ingredients. This initiative, however, does not require the labeling of foods that contain GMOs. Labeling would continue to be voluntary, but the FDA would provide labeling guidance to companies that want to label bio-engineered products. Critics of GMOs argue that these proposed steps are

insufficient, while food industry groups generally praise the Administration's approach. The FDA's proposed biotech guidelines on labeling and the mandatory consultation process will soon be published in the Federal Register.

The View in Congress of the Current Regulatory Approach to GM Foods

Rep. Nick Smith (R-MI), the chairman of the Subcommittee on Basic Research, of the House Committee on Science, released an informational report entitled "Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology," on April 13. This report, which is based on a series of hearings held by the subcommittee, generally endorses FDA's regulatory regime for genetically engineered crops and foods, but recommends changes in USDA and EPA regulations. The report states: "Years of research and experience demonstrate that plant varieties produced using biotechnology and the foods derived from them, are just as safe as similar varieties produced using classical plant breeding, and they even may be safer."

In February, Sen. Barbara Boxer (D-CA) introduced the "Genetically Engineered Foods Right-to-Know Act" (S. 2080), which mandates the labeling of GMOs. In noting that Congress already required labeling of foods containing artificial colors and flavors as well as chemical preservative and artificial sweeteners, Sen. Boxer, commented that American families should have the right to decide whether they want to eat genetically engineered food. Similarly, Rep. Dennis Kucinich (D-OH) introduced a bill (H.R. 3377) last October that requires labels for genetically engineered food.

In response, the food industry has informed Congress that such new mandatory labeling requirements could lead to higher food costs and result in consumer confusion. It has argued that foods containing GMOs have been proved safe by FDA, USDA, and EPA, and that such products would not be allowed on the market, if they had not met the highest U.S. safety standards.

Richard Pasco, from Page 10

Rep. Kucinich also introduced legislation (H.R. 3883) which would have all genetically engineered foods considered "food additives." The food additive designation would require FDA approval of the foods for safety prior to marketing. The Senate companion bill for this measure is S. 2315, introduced by Sen. Patrick Moynihan (D-NY) on March 29.

More recently, Sen. Dick Durbin (D-IL) introduced the "Genetically Engineered Foods Act," which directs FDA to conduct mandatory pre-market reviews of all genetically engineered foods and authorizes the agency to test products already on the market for the presence of unapproved biotech ingredients. While most of this bill mirrors changes FDA has already announced, the bill also requires FDA, EPA, and USDA to improve tests used to determine genetic varieties in food.

Additionally, Sen. John Ashcroft (R-MO) introduced "Advancing the Global Opportunities for Biotechnology in Agriculture Act of 2000" (S. 2106), legislation to increase internationally the exchange and availability of biotechnology information and to coordinate a federal strategy in order to advance the benefits of biotechnology, and particularly in agriculture.

Biosafety Protocol for GMOs

The Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD), adopted in January 2000, addresses the safe handling, transfer, and trade of biological organisms. The Protocol, which was adopted by the 176 countries that are parties to the CBD, sets forth procedures and rules concerning trade in biological products, including GMOs. While the United States has not ratified the CBD, these rules are key to U.S. economic interests in agriculture, including those who develop biotechnology.

The United States has not only pioneered the use of biotechnology, but it is the world's leading producer of GMO crops. Thus, most U.S.

analysts consider the current Protocol language a victory for GMO product trade, even though they agree that the future impact of the Protocol on trade is difficult to gauge because so many key aspects are still to be decided.

Evaluation of the Science

On April 5, the National Research Council released a report entitled "Genetically Modified Pest-Protected Plants: Science and Regulation." This report emphasized that there is no evidence that genetically engineered foods are unsafe to eat. However, it also noted that given the current level of public concern over these foods, the federal agencies must make some regulatory changes and conduct more research to reduce the concern about potential harm to human health and the environment.

Extensive scientific evaluation worldwide has produced no evidence to support the claims of the anti-biotech proponents. Far from causing environmental and health problems, GMOs have tremendous potential to reduce the environmental impact of farming, provide better nutrition, and help feed a growing world population. Crops designed to resist pests and to tolerate herbicides and environmental stresses, such as freezing temperatures, drought, and high salinity, will make agriculture more efficient and sustainable by reducing synthetic chemical inputs and promoting no-tillage agricultural practices.

Richard Pasco is an attorney in the firm specializing in legislative, agricultural, food safety, and trade law.

Green and Frerichs, from Page 1

Many of the provisions respond to weather-related disasters, and several were not part of either the House or the Senate version of H.R. 4461, but were added by the conferees. A significant number of the provisions amend or override major authorizing statutes, including the 1996 farm bill, illustrating the degree to which annual appropriations bills have become a preferred vehicle for changing agricultural policy.

This article summarizes, in tabular form, the provisions of Title VIII of H.R. 4461, in which most of the emergency provisions are contained. The costs listed in the table are one-year costs for FY 2001. Where amounts were specified in the legislation, those amounts are listed. Where no amount was specified, the numbers given are CBO estimates of budget authority (BA) and are marked with an asterisk (*).

In a few cases, provisions that have an impact over more than one year will have a substantially greater cost than is reflected from the one-year BA estimates. CBO's estimates of five-year costs are provided in these cases. Combining these costs with the 2001 spending, Title VIII's full five-year price tag is **\$5.3248 billion**.

Subject	Amount	Description
Information Technology	\$19.5 million	Additional funding for USDA's common computing environment in field offices
Small Business Advocacy	\$200,000	Transfer to SBA for impact review of disasters on small businesses
FSA Salaries & Expenses	\$50 million	Increased FSA salaries to administer emergency aid
Emergency Conservation Program	\$80 million	Added funds for program that restores conservation structures, fences, etc.
Crop Insurance	\$13 million	Make up funding shortfall for 1999 crops
Watershed and Flood Prevention	\$110 million	Repair of damage to waterways and watersheds, including floodplain easement purchase and snow telemetry equipment
Rural Community Advancement Program	\$200 million	Grants to depressed communities, areas with high energy costs, communities affected by major disasters, community facility loans and grants, etc.
Sec. 801. Conservation Technical Assistance	\$35 million	Funds for technical assistance under CRP and WRP
Sec. 802. Livestock Assistance Program	-0-*	Extend period of eligibility for program
Sec. 803. Livestock Definition	-0-*	Conforms definitions in two different livestock program

(Continued on page 13)

Green and Frerichs, from Page 12

Subject	Amount	Description
Sec. 804. Miscellaneous Disaster Payments	\$19 million*	Discretionary authority for payments on damage from (a) Mexican fruit fly; (b) plum pox virus; (c) Pierce's disease (wine grapes); (d) watermelon sudden wilt disease; (e) grasshoppers and Mormon crickets
Sec. 805. Dairy Assistance	\$473 million*	Requires payments on 35% of reduction in milk price from 5-year average, with payment limits per producer
Sec. 806. Livestock Losses	\$490 million	Extends 1999 Livestock Assistance Program to losses in 2000, with several earmarks
Sec. 807. Nursery Stock Losses	-0-*	Compensates 1999 nursery stock losses
Sec. 808. Wetlands Reserve Program	\$117 million*	Authority for additional enrollment in Wetlands Reserve Program, overriding provision of the 1985 farm bill and CCC Charter Act
Sec. 809. Sheep Losses	\$2.4 million	Compensation for certain Vermont sheep destroyed for public health reasons
Sec. 810. Citrus Canker	\$58 million	Compensation for citrus and lime trees removed to control citrus canker
Sec. 811. Apple and Potato Payments	\$138 million	Compensation for lost apple markets (\$100 million) and quality losses for potatoes and apples (\$38 million)
Sec. 812. Honey Price Supports	\$20 million*	Non-recourse marketing loan and loan deficiency payments for honey at \$0.65/lb.; conversion of outstanding honey loans to non-recourse
Sec. 813. Livestock Indemnities	\$10 million	Compensation for disasters, including fire and anthrax
Sec. 814. Wool and Mohair Payments	\$20 million	Payments to wool and mohair producers at \$0.40/lb.
Sec. 815. Production and Quality Losses	\$1,627 million*, of which - \$500 mil. quality \$1,100 mil. quantity \$15 mil. salt water intrusion \$2 mil. pecans \$10 mil. nursery	mandates payments for quantity, quality and economic losses in 2000 crops, under guidelines similar to corresponding programs for earlier crop years, with new formulas for quality losses

(Continued on page 14)

Green and Frerichs, from Page 13

Subject	Amount	Description
Sec. 816. Cranberries	\$20 million	Requires purchase of cranberry juice concentrate and frozen fruit out of previously committed funds (\$30 million), and direct grower payments (\$20 million)
Sec. 817. Vegetative Cover	-0-*	Waives a 1985 farm bill requirement for vegetative and water cover in cases of excessive moisture
Sec. 818. Shared Appreciation	\$2 million* (\$6 million 2001-03)	Recapture payments required of producers with certain farm loans; can be amortized over up to 25 years, amending 1990 farm bill
Sec. 819. Grain Fund	\$2.5 million	Matching grant to South Carolina to capitalize a grain dealers' indemnity fund
Sec. 820. Wildlife Habitat Incentives Program	\$6 million*	Added funds for technical assistance to producers
Sec. 821. Puerto Rico Stamp Block Grant	Authorization	Reauthorizes program through 2002
Sec. 822. Hawaiian Sugar Transportation Cooperative	\$7.2 million	Requires a payment to Hawaii, to be used to assist the state's sugar transportation cooperative
Sec. 823-826, 828, 831. Emergency Watershed Program Funds	\$14 million	Financial aid earmarks for projects in Utah, Arkansas, Minnesota, Illinois, North Carolina (2)
Sec. 827. Oyster Payments	-0-*	Allows oyster producers in Connecticut to keep payments made to them by USDA
Sec. 829. Crop Insurance	-0-*	Technical change to allow funds to be obligated, rather than expended by a date certain
Sec. 830. Emergency Conservation Program	-0-*	Allow alternate uses for unexpended funds appropriated in a previous supplemental bill
Sec. 832. Transfer of Farm Loan Funds	-0-*	Authority to transfer funds among farm ownership and operating direct and guaranteed emergency accounts
Sec. 833. Chicken House Loans	-0-*	Authority to make emergency loan to poultry producers and rebuild chicken houses
Sec. 834. Value-Added Agricultural Products Development Grants	\$10 million	Added funding for existing grant program
Sec. 835. Business and Industrial Guaranteed Loans	\$10 million	Added funds for existing loan program

(Continued on page 15)

Green and Frerichs, from Page 14

Subject	Amount	Description
Sec. 836. Sugar Program	-0-*	Amends 1996 farm bill to make all sugar loans non-recourse, eliminating previous import-related trigger for recourse loans.
Sec. 837. Higher Payment Limitation	-0-*	Amends the 1996 farm bill to raise cap on 2000-crop loan deficiency payments from \$75,000 to \$150,000
Sec. 838. Rice Loan Extension	-0-*	Extends by 60 days loan maturity on certain rice
Sec. 839. Fire Control Agreements	-0-*	Authority for agreements with livestock producers to control buildup of grasses and other natural fuels on rangelands
Sec. 840. Issuance of Regulations	Not applicable.	Requires prompt regulations under several sections of Title VIII
Sec. 841. Tobacco Payments	\$3 million	Previously-mandated tobacco payments to be made without regard to whether tobacco was produced on the farm in 2000
Sec. 842. Administrative Offset	-0-*	Exempts Title VIII appropriations from administrative offset requirements
Sec. 843. Compensation for Cooperative Insolvency	\$20 million	Payments to tomato, pear, peach and apricot producers injured by insolvency of a California farm cooperative
Sec. 844. Burley Tobacco Forfeitures	\$50 million* (\$250 million 2001-05)	Allows forfeiture of 1999-crop burley tobacco regardless of quality, and prohibits charging any resulting losses against the No Net Cost Account
Sec. 845. Marketing Assistance Loans and Loan Deficiency Payments	\$5 million*	Excludes marketing loans and LDPs from a general ban on federal assistance to certain debtors
Sec. 846. Food Stamp Excess Shelter Expense Deduction	\$15 million* (\$510 million 2001-05)	Revises 1996 welfare reform provisions, increasing eligibility for Food Stamp benefits
Sec. 847. Food Stamp Vehicle Allowance	\$25 million* (\$999 million 2001-05)	Revises 1996 welfare reform provisions, increasing to \$4,650 the value of vehicle that may be owned by individuals qualifying for Food Stamps

Stephen Frerichs is an economist specializing in budgetary issues that relate to agricultural programs. Before coming to McLeod, Watkinson & Miller, he was a budget analyst at the Office of Management and Budget for eight years. Mr. Frerichs currently represents crop insurance companies.

The Agricultural Law Letter is published to highlight recent changes and developments in the law and public policy. As with any publication of this type, it is essential that before any action is taken based upon this information, competent, individualized, and professional advice should be obtained. Copy-right 2000 by McLeod, Watkinson & Miller. Reproduction in part or in whole is permitted with per-mission from McLeod, Watkinson & Miller. Contact Mary Carter Hudgins at (202) 842-2345, or write to One Massachusetts Avenue, N.W., Suite 800, Washington, D.C. 20001. Subscriptions are \$25 per year.



The Agricultural Law Letter

MCLEOD, WATKINSON & MILLER

ONE MASSACHUSETTS AVENUE, N.W.

SUITE 800

WASHINGTON DC 20001

(202) 842-2345