Commercial, Safety, and Trade Implications

Raised by Importation of:

Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed or Processing

Proceedings from a roundtable hosted by the Pew Initiative on Food and Biotechnology, Sept. 7-8, 2006, Washington D.C.

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Introduction

For more than a decade, the United States has led the world in developing and cultivating genetically engineered (GE) plants for agricultural applications. The use of genetically engineered organisms (GEOs) in farmed crops, almost all of which are intended for food or animal feed, has been controversial in some markets. As a result, some of America's key trading partners—chief among them Japan and the nations of the European Union—have developed detailed policies that set specific standards for handling imports of GE crops, whether they arrive as raw shipments of commodity crops such as corn or soybeans or as ingredients in processed or finished foods.

However, in the U.S., GE imports have not been a high priority issue. Given that the U.S. is the world's major producer of GE plants, trade issues have focused more on export challenges. But that could change. Around the world, many countries, including developing countries such as China and India, are creating new varieties of GE plants that soon could be widely cultivated. While the main motivation in these countries is to use biotechnology to improve production and nutrition for their own populations, in a world where there is significant trade in agricultural and food products, there is at least a possibility that GE crops developed abroad could end up in the U.S. in some form or another.

The prospect of novel GE crops coming into the U.S. as food, feed, or processing imports adds a new dimension to the U.S. experience with agricultural biotechnology. The U.S. currently receives some GE crops from abroad, but those are varieties of crops that have already passed through the U.S. regulatory system. It remains to be seen what level of scrutiny novel GE crops will receive. Also unclear is what federal regulators should be doing to assure consumers that imported GEOs are as safe as what is produced at home.

In September 2006, the Pew Initiative on Food and Biotechnology convened a two-day roundtable discussion entitled *"Commercial, Safety and Trade Implications Raised by Importation of Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed or Processing."* (Given time and logistical constraints, the group confined its discussion to imports of GE plants and plant products and did not consider imports involving GE animals or animal products.) The meeting involved people from all sides of the issue, including federal regulators, representatives from food and agribusiness concerns, an expert in GEO testing services, and representatives of public interest groups.

The forum was not intended to reach consensus. Rather, the goal was to articulate the many issues that could arise should GE imports become more commonplace and to consider how various stakeholders, particularly federal regulators, would or should respond. The result was a wide ranging and at times complex exchange that should be of benefit in defining various challenges created by imports of GE plants and help initiate a process for considering the best way to address them.

Michael Fernandez
Executive Director
Pew Initiative on Food and Biotechnology

Executive Summary

The United States is currently the world's foremost developer, producer and exporter of genetically engineered feed and food products, but many other countries are narrowing that lead with increasing GE crop production and research. As more and more acreage is devoted to GE crop production worldwide, the U.S. may find itself increasingly importing GE food and feed products. Though many other countries already grow GE crops, virtually all of these crops are simply different varieties of those grown in the U.S. and previously reviewed by U.S. regulators, so their presence in imported food or feed has not posed new problems for U.S. regulators. A significant number of countries, however, are also developing new varieties of transgenic plants with characteristics which may not have been previously reviewed for safety by U.S. regulators. As these crops move into commercial cultivation, there is a chance they could end up in the U.S. as food or feed imports. At this time, it is not clear whether the U.S. regulatory system or food industry is fully prepared for their arrival.

In September 2006, in order to clarify the challenges raised by novel GE imports, the Pew Initiative on Food and Biotechnology convened a two-day roundtable discussion entitled *"Commercial, Safety, and Trade Implications Raised by Importation of Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed or Processing."* The forum provided an opportunity for people involved in various aspects of the issue—including food processors, growers, government regulators, public interest groups and international trade experts—to discuss what it would mean for the U.S.—which is now almost exclusively an exporter of GE food and feed products—to become an importer as well.

According to presentations at the conference, there are a number of countries, including developing countries led by China, working on GE varieties of crops such as corn, cotton, rice, potatoes, papayas and tomatoes. These crops are being researched for domestic markets and will likely not be intended for export, but because of the huge volume of international trade in food and feed goods, it is plausible that some of these products will end up on the global market.

There was general acknowledgement that the risks posed by GE imports may be more to business interests than consumer health. For example, the inadvertent presence of GE crops developed abroad in the U.S. food supply might, due to consumer concerns, harm food sales even if there is no scientific evidence that they pose a health threat. There was debate but no consensus about the extent to which government regulators should act if the risk involves mainly commercial, not health, concerns.

Participants noted that accidental mixing of GE with non-GE products may become more common as more countries begin cultivating transgenic food crops. Some participants pointed out that simply having more players in the game will increase the chances of unwanted GE products ending up in what are intended to be conventional foods. Today, U.S. exporters satisfy customer demand for GE-free products by adopting comprehensive “identity preservation” or IP, systems. It was acknowledged, however, that such systems may prove too costly or unworkable in many countries now poised to introduce GE plants into commercial production.

A key issue discussed was whether there are technical and regulatory systems in place that would make it easier to detect GE food and feed products entering U.S. markets and, furthermore, determine whether or not the imports might pose any risks.

As for technical challenges, a representative from a company that tests food and feed products for the presence of GE organisms (GEOs) said accurate detection methods require extensive information on the process used to create the transgenic plant. If past experience is any guide, that information is often difficult to obtain because GE plant developers are reluctant to divulge what they view as confidential business information.

On the regulatory front, discussions focused on the fact that government agencies that conduct oversight of food and feed products may have difficulty identifying GE imports and, upon determination that a product is GE, the ability of the agency to act will depend on the product involved.

For example, representatives from the U.S. Department of Agriculture (USDA) noted that, while they have clear authority to regulate imports of GE plants intended for cultivation, they have little authority to police imports that are intended as food unless they pose a danger of accidentally propagating. Meanwhile, the agency with the biggest role in monitoring food safety, the U.S. Food and Drug Administration (FDA), does not require that GE foods, imported or domestic, undergo a safety review before being sold to consumers.

An FDA official said the agency has created a voluntary review process for considering the safety of GE food products, and U.S. producers are participating as if it were mandatory. He said the agency is trying to make it easier for foreign firms to participate and believes they will see a benefit to engaging FDA before commencing sales of GE food products in the U.S.

Several participants said they remain concerned that the FDA process is voluntary and hence, in some instances, GE food products could be legally imported and sold in the U.S. without any regulatory notification or review.

A review of how countries such as Japan and the nations of the European Union address public demands to ascertain whether U.S. food and feed imports contain GEOs revealed that while it can result in cumbersome procedures, our trading partners have managed to accommodate their marketplace demands. But discussions also illustrated that there can be a fine line between conducting oversight of GE imports and instituting policies that restrict trade.

Ultimately, there was general agreement that the situation demands more dialogue with emerging GE producer countries before their new agricultural biotech innovations reach the market. Some worried that even with more regulatory vigilance, there may still be significant risks for food and agricultural trade.

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Why Should We Be Concerned About GE Imports?

A fundamental question for the entire two days of discussion was simply: why should anyone be concerned about the U.S. importing grains, whole foods (such as fruits or nuts) or manufactured foods that might contain GEOs developed and grown in other countries? For Nick Hether, a food safety consultant who spent 20 years as Director of Product Safety and Regulatory Science at Gerber Food, the reason is simple: GE imports are likely to be "unique relative to what we have in this country."

"At least we know about our crops in this country," he said. "If (GE) crops are being grown in other countries, we don't necessarily know about them. They haven't been approved. They haven't gone through our (regulatory review) process."

Hether said even if GE crops developed in other countries turn out to be perfectly safe, it's important that all involved—particularly U.S. regulators charged with monitoring the safety of GEOs—are aware of what other countries are developing and are prepared for the possibility that foreign GEOs will end up here. He believes the sudden and unexpected appearance in the U.S. market of imported GE plants that have not been examined by U.S. experts would leave regulators looking inept and expose food companies to significant financial losses.

Hether pointed out that regulatory agencies have "immense credibility with consumers" and a more active role in monitoring GE imports could go a long way toward addressing consumer concerns about safety. He said without clear direction from the regulatory authorities about how they will deal with GE imports, particularly safety concerns related to their unintended presence in U.S. food products, many U.S. companies will seek to protect themselves by putting severe restrictions on certain types of imports, and the credibility of the food supply safety system will be eroded unnecessarily.

"Those things are not inconsequential," he said.

But Thomas Redick, who represents the U.S. Soybean Export Council on biosafety issues, wondered if it was time to start looking at genetic modification as just another process for developing food that may or may not pose risks and "stop obsessing so much about DNA." He would rather the focus be placed on food safety issues in general, not GEOs in particular.

Hong Chen, with the Canadian Food Inspection Agency, said she is often asked whether there is something qualitatively different about a food import that contains GEOs. Her response is that it is legitimate to single out GE imports, because, unlike GE plants produced domestically, the plants involved are likely to be less familiar to national regulatory officials, particularly when it comes to an equivalent understanding of their safety profile. Imports also would be of particular concern, she said, if they enter the country without advance notice and domestic authorities lack a test that could detect their presence.

Margaret Mellon, with the Union of Concerned Scientists, a group that is not opposed to GE foods but believes they need to be strongly regulated, said she believes predictions that a steady flow of GE crops from many countries will soon be entering the world market—and with varying degrees of safety assessments—are contributing to a sense that oversight of agricultural biotechnology is "spinning out of control." For U.S. industry, she believes a proliferation of unexpected and unexamined GE imports will exacerbate the challenge of convincing consumers that GE plants are safe to grow and eat.

Gary Drimmer, a consultant for international grain trading concerns, asked Mellon whether there is any GE food or feed being developed abroad that appears to be unsafe. Mellon noted that nobody knows of any, but neither has there been much research that would identify hazards. Also, she noted that today there only a few GE traits—mainly insect and herbicide resistance traits—in the food system. While we believe they are safe, she said, that does not mean people should be comfortable with "throwing tens or hundreds of new traits into the food system."

Greg Jaffe, with the Center for Science in the Public Interest, said there are so many questions about what's being developed in other countries and how U.S. regulators will grapple with them that it would be foolish to simply wait and see what happens.

"It's better to be thinking about these questions now than to think about them in crisis management mode, when things are either at our doorstep or already in our food supply," he said.

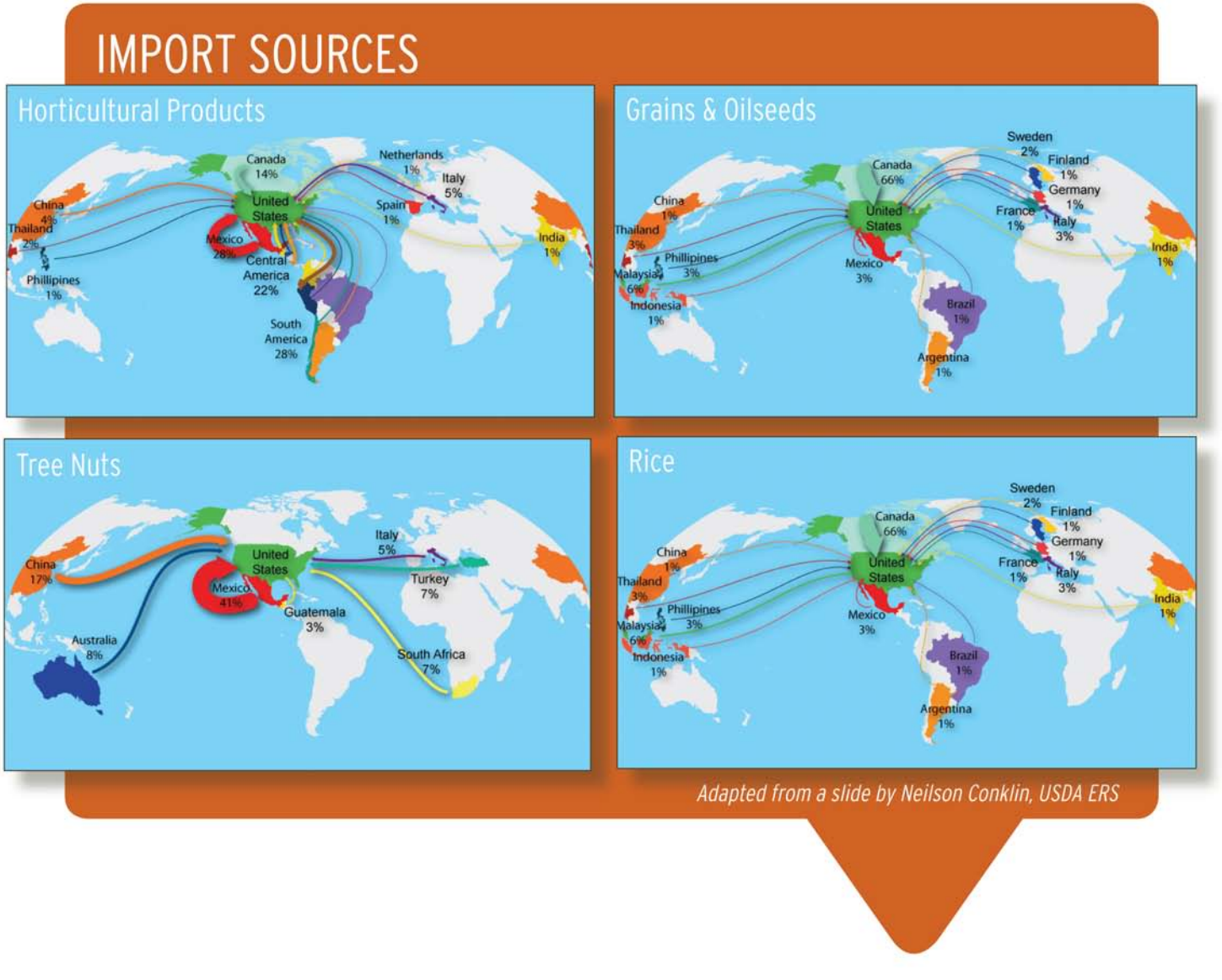
GE Crops and the Global Farmer's Market

One reason to anticipate that transgenic agricultural products cultivated abroad might end up in the U.S. is that large volumes of farmed goods from around the world regularly cross our borders.

According to Neilson Conklin, director of the Market and Trade Economics Division at the U.S. Department of Agriculture's (USDA's) Economic Research Service, U.S. agricultural imports are growing rapidly. Some of that growth is due to a sharp rise in imports of items that fall into a broad and somewhat vague category known as horticultural products, which can include everything from flowers and beer and wine imports to trade in "essential oils."

Fruit imports also are on the rise as more and more grocery stores stock their shelves in the off-season with produce grown in the southern hemisphere, where seasons are the opposite of what they are in the U.S. While food and feed grains are generally thought of as a major export commodity, Conklin said grain imports are on the uptick as well, rising from 3.5 million metric tons in 1990 to more than 7 million in 2005.

Paralleling the import increase has been a steady expansion of America's agricultural trading partners. Conklin's data show that today, the feeding of America involves trade interactions that are literally all over the map, whether it is getting rice from Pakistan, India and Thailand, tree nuts from Mexico, China and South Africa, or grains and oilseeds from Sweden, Canada, and Argentina.



"As you can see, our agricultural imports really do come from all over the world," he said.

Conklin cautioned that the government's trade data is not collected in a way that would reveal whether or not any of the agricultural products flowing into the U.S. are genetically engineered. In fact, there is no evidence anywhere that GE farm products developed in other countries and not reviewed by U.S. regulators are being shipped to the U.S., but that could change as more and more countries explore agricultural biotechnology.

Agricultural Biotechnology Moves Beyond the Industrialized World

Joel Cohen, who studies international GE crop research as principal director for the consulting firm Science, Technology and Education Associates, said it's clear that many of our agricultural trading partners, particularly those in the developing world, are experimenting with GE crops, though at the moment the focus is not on creating innovations for export.

Cohen said his research indicates there are now about 46 GE crops under development in publicly supported projects in 16 developing countries. China and India appear to be the countries mounting the strongest efforts. But many other Asian countries, along with a few African nations (including Kenya and South Africa) and several Latin American countries (Brazil, Argentina, Costa Rica and Mexico) also are interested in developing transgenic crops. Plants being studied for modification include the relatively narrow assortment of crops in the U.S.—corn, cotton, soybeans and canola—but also of interest, Cohen said, is creating new GE varieties of rice, potatoes, papayas, and tomatoes.

Cohen said foreign developers are focused on creating new crop varieties with many of the same types of traits—such as herbicide tolerance and insect resistance—that have been incorporated into transgenics produced in the U.S. Crops also are

Initial regulatory packages completed: **indicators of progress**

Public GM events with regulatory package:

BRAZIL: soybean

COSTA RICA: rice

KENYA: sweet potato; maize

MALAYSIA: papayas

PAKISTAN: cotton

SOUTH AFRICA: maize; strawberry; apples

EGYPT: wheat; cotton, maize

Next Harvest data

Adapted from a slide by Joel Cohen, Science, Technology, and Education Associates

being developed that use biotechnology to improve nutritional content or endow plants with genes that allow them to survive in harsh conditions, such as drought.

Many of the GE plants developed in other countries have yet to move to widespread cultivation. Cohen said several countries are engaged in production of (GM) cotton, maize, rice and soybean, but they are not yet entering world markets. (Also, at the moment, virtually all of the commercial production of GE commodities outside of the U.S. involves varieties that were first developed, tested, approved and cultivated in the U.S.).

Of course, the next logical question and a core issue for the conference is, will the GE crops developed by other countries eventually end up in the U.S. market?

Cohen said part of the answer to that question will depend on what U.S. consumers want and whether domestic production can meet their demands.

For example, at least for the foreseeable future, he said, imports of GE soybeans developed abroad are unlikely because American farmers produce soybeans in abundance. However, the U.S. markets currently depend on foreign producers to satisfy growing consumer demand for a range of so-called "specialty crops,"—a category that includes fruits and vegetables. That demand eventually could drive imports of GE specialty crops.

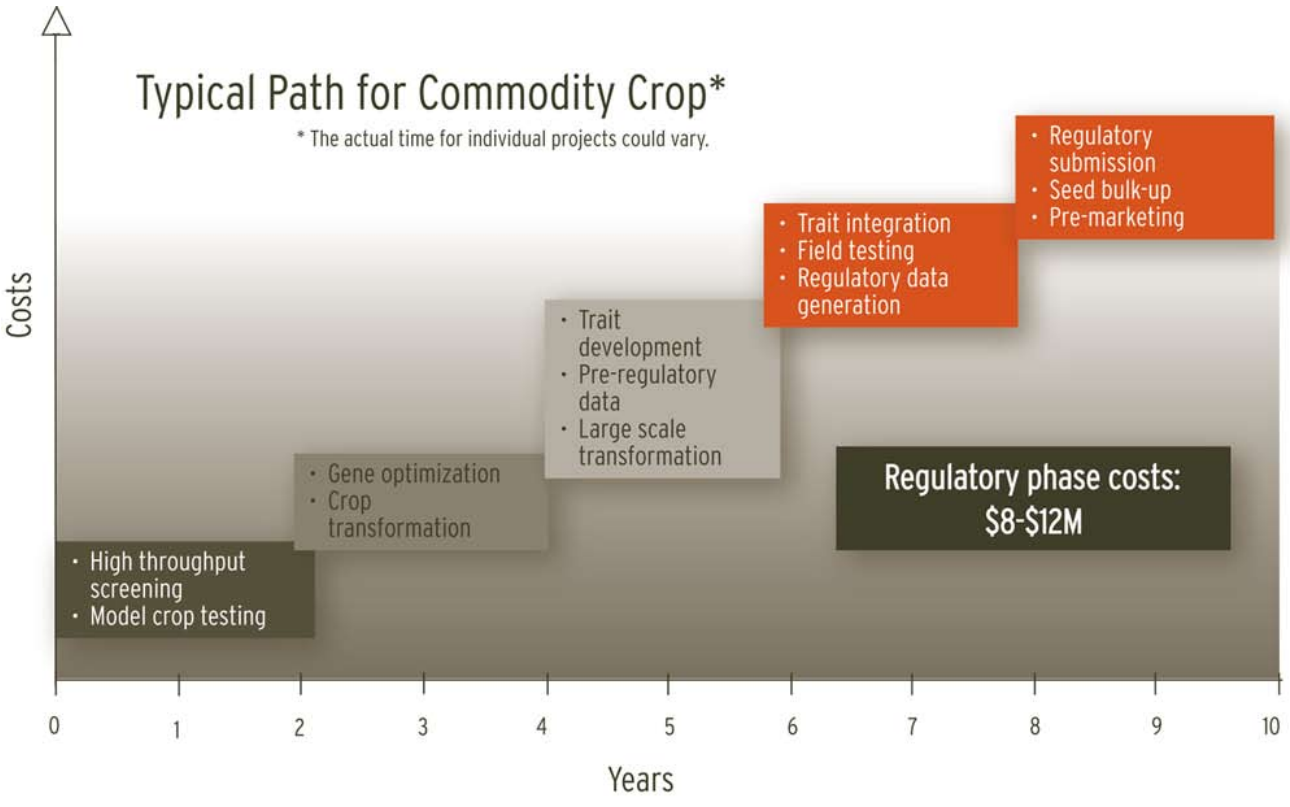
Jerry Hjelle, the global head of regulatory sciences and regulatory affairs for Monsanto Company, echoed Cohen's observation that there are many developing countries interested in GE plants, particularly if the technology can provide crops

that can better withstand harsh conditions and repel plant pests or offer more nutritious food for humans or better feed for animals. But for the most part, he said, developing countries pursuing GE plants appear to be chiefly motivated by the technology's potential to help farmers meet internal food and feed needs. He said developing countries do not appear to be eyeing new GE crop varieties as a way to improve their competitiveness in global agricultural markets.

Hjelle and Cohen felt that tensions are likely to arise between the safety standards that should be applied to GE plants that are being cultivated to meet domestic food needs and not for export, and those GE plants intended for international trade.

For example, Hjelle believes that if a crop is clearly destined for the U.S., then it should be held to the same safety standards as those applied to a U.S.-grown GE crop. However, he acknowledged that many of the developing countries interested in GE crops may lack the expertise and resources required to conduct the kind of rigorous laboratory work, field trials and environmental and food safety assessments that U.S. agencies demand. For example, he said doing the work required to obtain U.S. regulatory approval for a GE crop variety can cost between $8 and $12 million.

Cohen remarked that for crops not intended for export, pressuring developing countries to conduct certain costly scientific assessments of new GE crops could be seen as inhibiting their efforts to achieve food security and avoid hunger. But on the other hand, he said, allowing safety assessments to fall short of what is now demanded in industrialized countries could be seen as advocating a global double standard for ensuring the safety of GE plants.



Identity Preservation Under Pressure as GE Crops Go Global

Today, U.S. growers and food producers have adapted to a complex market in which many U.S. farmers grow GE crops but certain buyers of U.S. farm commodities and food products—chiefly European buyers—want nothing to do with GEOs. To satisfy demands for non-GE products, companies adopt procedures known as "identity preservation systems" (IP) that keep track of a particular farm commodity—such as a field of non-GE corn—as it moves from seed to farm to fork to make sure it is not unintentionally co-mingled with GE crops.

For the most part, these systems are put in place not because scientists believe the GEOs are unsafe to eat, but rather, because the customer simply does not want them.

Sometimes IP farm products are sold raw, in bulk, to buyers in Japan or Europe. Other times they are sold to U.S. food manufacturers who need IP ingredients for non-GE finished food items they will export to Europe and Japan.

It is difficult enough to keep things separated in a world where only a few countries are widely producing GE crops. But many participants in the conference stated that maintaining the integrity of IP systems is likely to become much harder as more countries begin adopting agricultural biotechnology.

For example, a key challenge for today's IP systems is the unintentional co-mingling, or "adventitious presence," of GEOs in what is supposed to be a GEO-free product. Clearly, an increase in GE food crops produced around the world will expand opportunities for accidental mix-ups, particularly as international food companies seek to lower operating costs by "sourcing" ingredients from an array of suppliers around the globe.

Gary Drimmer, an expert in the international grain trade, described a global trading environment in which there are multiple opportunities for GEOs and non-GEOs to end up in the same shipment.

He said it is important to understand that in today's market, farm products, particularly grains, move around the world in huge vessels capable of hauling up to 200 thousand tons each. Each vessel's cargo does not come from one farm or one village. It comes from many locations within the exporting country, or could include products from a variety of countries all mixed together. The bottom line, he said, is that today a shipment of farm products from one country to another usually represents the aggregation of many growers' harvests, and thus introduces a host of opportunities for the kind of co-mingling that is anathema to IP systems.

This kind of aggregation isn't a problem for bulk shipments that don't require identity preservation, but for those shipments that do, that bulk system can create

challenges. Drimmer pointed out that with bulk shipments aggregating grains from a large number of sources, the only way to impose some type of IP system on imports is to use "smaller shipments and shipping containers where you are going from one producer through one handling system—and handling it only once—and not going through a multitude of mixing and handling systems." For example, he noted that U.S. companies that supply non-GEO farm commodities to foreign buyers reduce the opportunity for co-mingling by transporting their products in relatively small, individual shipping containers that can be loaded on a barge and then offloaded on to trucks or rail cars.

"The advantage of using containers," he said, "is that you can load them from one grain elevator and ship them to one destination."

Nick Hether, the former Gerber product safety specialist, observed that U.S. companies exporting feed and food products have developed an understanding of the need to separate different kinds of crops to meet customer demands, and have instituted IP systems their customers have come to trust. But he wondered whether a similar level of appreciation for IP exists in Asia or other places that may soon be producing GE crops at relatively high levels.

Drimmer acknowledged that it's fair to question whether the rigorous practices developed in the U.S. to satisfy customers demanding GEO-free products will be applied elsewhere.

"It will be an educational process at the very best," he said.

For example, Drimmer said, that in today's market, there are only a handful of companies that promise to separate conventional grains from GE grains. These are relatively large companies with deep pockets. Drimmer said these companies have imposed highly disciplined IP processes on their purchasing systems, prompting their customers to trust their GEO-free assurances. Drimmer sees the growing use of GE crops abroad as likely to bring more smaller players into the IP business. As a result, he believes assurances of separation are likely to mean "less and less and less."

More Needles, Bigger Haystack: Imports and the GE Testing Conundrum

Over the past few years, the desire to keep GE crops out of certain foods has produced a relatively new type of service provider: companies that, for a fee, will test anything from raw ingredients to a finished food—such as a pie or pizza—for the presence of GEOs. These services have become an important component of IP systems, particularly when selling in the European market where even trace amounts of a GEO could result in consumer or regulatory rejection.

Lulu Kurman, manager of Food Safety Systems for GEO testing firm Eurofins GeneScan, said companies involved in food production are increasingly interested in the financial advantages of obtaining ingredients or finished food products from abroad. But they need to monitor quality and today, she said, it is not unusual for a company to include, as part of its quality control procedures, tests that can determine whether imported foods—be they "bags or corn" or a "whole cheesecake"—have any GE content.

"The main question is going to be 'Is a genetically engineered organism present?'" she said. "Is the (GE) protein present in the food or ingredient?"

Right now, she said, testing is mainly conducted for firms exporting food and feed products from the U.S. to Europe. Kurman said Eurofins GeneScan has yet to conduct a GEO test on food or feed destined for the U.S. She attributes the absence of testing to the fact that there is very little cultivation of GE crops outside of the U.S. that were not first developed and approved in the U.S.

If, as expected, global development and production of GE crops increases, Kurman believes it is reasonable to anticipate a growing interest in testing U.S. agricultural imports for the unintended presence of GEOs. The testing could be motivated by a concern about the safety of a particular GE crop—such as one intended to produce industrial or pharmaceutical substances—or by a fear that, safe or no, U.S. consumers simply will not want it in their food.

But wanting to test and being able to test are two different things. Kurman pointed out that detecting a particular GE plant requires two things that, in the future, may not always be there.

First, there needs to be a public disclosure or some other general industry awareness that a particular GE crop is now in production and it is either openly sold for food or feed on the global market or at least has the potential to show up in imports.

"No one is ever going to send anything in for testing unless they believe there is a potential for (a GMO) to exist," she said.

Second, once they know it's out there, to develop a reliable test, laboratories such as Eurofins GeneScan need specific information on the genes and the transforma-

"No one is ever going to send anything in for testing unless they believe there is a potential for (a GMO) to exist." –Lulu Kurman, *Eurofins GeneScan*

tion process that were used to create the plant. A certain amount of basic information is required to detect the GEO at all, Kurman said. To make testing financially feasible for the customer, she said, companies like Eurofins GeneScan need considerably more information and getting it can be a challenge.

“It is absolutely critical to have open communication and collaboration in order for us to meet our end of the bargain,” she said.

But what concerns some people is that as more producers get involved, the more likely it is for a GE crop to arrive on the market without forewarning and without any information describing how to devise a test to detect it.

Canice Nolan, who focuses on food safety, health and consumer affairs for the Delegation of the European Commission to the USA, said testing is critical for keeping consumers satisfied that government regulators can monitor GEOs coming into their country and reject food containing either unapproved varieties or those deemed as unsafe. But he said two incidents in 2006 have shown that tests can be hard to come by.

One involved the unexpected presence in Europe of a U.S.-developed GE rice called Liberty Link 601 that, while eventually deemed safe by U.S. regulators, had not been approved for European consumption. The other involved allegations from the environmental group Greenpeace that it had found unapproved GE rice, developed in China, in European food products.

In the Liberty Link situation, Nolan said that even after it was clear that the unapproved GE rice was in Europe, EU regulators faced stiff resistance when they asked officials from the company that developed the rice to make a detection method publicly available.

“We had to do a lot of arm-twisting until we said, ‘OK, we are going to put it (the test) on our web site and if you want to, sue us’,” he said. “Just before we did it, they agreed.”

Similarly, he said it has been difficult to substantiate claims by Greenpeace that GE rice developed in China is present in foods sold in the EU because “we don’t have access to the testing methods.”

“Testing methods should be available to everybody,” he said.

Stealth GEOs: Identifying What's Out There

As was noted often during the conference, without specific knowledge concerning the amount and type of GE plants other countries are developing and cultivating, it will be very difficult to institute the safeguards—including regulatory oversight, IP systems and testing services—that could help pre-empt problems and assure that imports do not threaten U.S. food safety, consumer acceptance or food exports.

While there are certainly strong indications of what various countries are developing, there does not yet appear to be in anyone's possession a definitive list of GE crops that are being tested and cultivated abroad. Also, even when a project is identified, there may be little, if any, disclosure about where it is in the production pipeline or information about the genetic construct and transformation process used to produce the plant.

For example, it long has been common knowledge that China is aggressively developing an agricultural biotechnology industry. But Thomas Redick said a recent presentation by a Chinese law professor at an international biosafety meeting drew gasps from the audience when the professor matter-of-factly discussed the large number of GE crops now under development in China.

"No one had any idea of how far ahead of the rest of the developing world China had gone," he said. "They were quietly innovating about 70 different rice varieties, three different wheat varieties, 20 soybeans and the list goes on and on."

The fact that the Redick's colleagues, all closely involved with international agricultural issues, had little knowledge of the breadth of China's agricultural biotechnology program points to a major challenge: how will various stakeholders—including government regulators, food companies, grain handlers and consumers—have any confidence that they know what's being grown outside of the U.S., much less whether the GE crops are being imported into the U.S.?

Redick pointed out that a recently negotiated international agreement that addresses trade in GEOs, the Cartagena Protocol on Biosafety, has a provision in which sig-

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natories to the treaty are supposed to disclose any GE plants currently under cultivation in their country, whether in field trials or commercial production. (The U.S. has not signed the treaty but is participating in efforts to implement it.)

But the disclosures are voluntary and it is not clear how many countries will participate. For example, China has signed on to the Biosafety Protocol but has not offered up a comprehensive a list of its GE plants. It is also not clear precisely what countries will be asked to disclose to the data base and whether the information will be sufficient to 1) alert trading partners that the GE plant could end up in their food supply and 2) allow them to develop a test for its presence.

Also, Redick said building such a database so it is not used by some countries as a tool for blocking agricultural imports from certain countries is going to be "very, very tricky."

For example, one controversial area of research involves genetically engineering food crops so that they can produce ingredients needed for pharmaceuticals. Redick said European companies that have developed "plant-made pharmaceuticals" are looking to cultivate these plants in certain areas of South Africa where they believe they would be less likely to co-mingle with food plants. But he said public disclosure of pharma plant cultivation in South Africa could end up having a chilling effect on South Africa's agricultural exports in general.

"The question is going to be 'What do we do if we get South African shipments in the future and they have a history of growing plant made pharmaceuticals?'" Redick said.

Imports May Expose Holes in the Regulatory Safety Net

Greg Jaffe, Biotechnology Director at the Center for Science in the Public Interest, believes the U.S. regulatory system is already struggling to properly assess the safety of homegrown GE crops. His concern is that what he views as the regulatory system's current inadequacies will be even more exposed when it comes to conducting oversight of GE imports.

For example, he noted that while there are three agencies regulating agricultural biotechnology—USDA, FDA and the Environmental Protection Agency (EPA)—none have implemented any measures for monitoring whether a GE plant or plant product developed abroad, and yet to be reviewed by U.S. regulators, has entered the country. He pointed out that there are no plans for developing testing procedures for such detection, no questions at the border that ask whether a particular shipment contains GE products, and no import certifications (among the many certifications required for food and agricultural products) mandating a disclosure that a plant or a food import contains GEOs.

"Generally, we've set up a system in which it is very hard to identify if there are any imported biotech products, be they seeds or plants or foods," he said. "And I think that is something that needs to be thought about in our system as it moves forward, especially when products are coming in from countries like China and others that are planting and growing different kinds of biotech crops."

Jaffe sees problems even if foreign producers want to openly announce that they are exporting GEOs to the U.S. and would like to comply with U.S. law. He said such notifications will earn foreign producers an encounter with a regulatory system that is "complex and hard to understand."

For example, Jaffe noted that the authorities exercised by USDA, FDA and EPA vary considerably depending on the product involved and where it is in the production process. For example, USDA does not regulate finished food containing GEOs, only GE plants intended for cultivation or possibly raw foods, such as raw corn, that could, if spilled on the ground, grow into a plant. EPA would be involved only if the GE crop in question has been engineered with a gene that confers pesticidal proteins. Finally, FDA has a process for conducting pre-market safety reviews of food containing GEOs, but the process is voluntary and focuses only on data supplied by the food maker.

Furthermore, and perhaps most important, Jaffe said that regardless of whether they have the authority to do anything about them, he does not believe U.S. regulators have put much thought into dealing with imports.

The Cartagena Protocol: Offering a Window to the World of GE Imports?

The Cartagena Protocol on Biosafety is an international agreement designed to limit any potential risks that "living modified organisms" or LMOs, as the Protocol calls them, might pose to biological diversity. It establishes a Biosafety Clearing House or BCH. While the U.S. is not a signatory to the agreement, U.S. officials are actively involved in discussions about how to implement the many facets of the Protocol and set-up a viable BCH.

Countries are to use the BCH to provide detailed, publicly accessible information about GM plants that "may be subject to transboundary movement for direct use as food or feed or for processing." The disclosures are supposed to include, among other things, a "description of the gene modification, the technique used, and the resulting characteristics of the living modified organism," in addition to an assessment of any risks posed by the plant.

"If a developer or an importer does want to comply with the system, I don't think the system has really told them how it is going to address their applications," he said.

The biggest gap, according to Jaffe, lies within the FDA. While the USDA deals with agricultural products, FDA has the principle role of assuring that the food for sale in the U.S. is safe to eat. Jaffe, and many other observers as well, believe that the first encounters in the U.S. with GEOs produced abroad will not involve seeds or plants destined for a farm, but food headed to market.

Jaffe acknowledged that the FDA has a system for assessing the safety of GEOs in foods. But he reiterated their compliance is voluntary and that he does not believe there is anything legally preventing any company from selling to U.S. consumers food that contains a GEO that has not been reviewed by FDA.

He noted that FDA officials assert that U.S. firms treat the voluntary review as if it were mandatory because they want the FDA to sign-off on their food safety assessment before putting a product on the market. But Jaffe said producers in other countries might decide to take the FDA review at face value: as a voluntary process that they don't have to engage.

Jaffe contrasted this approach to Europe's where the law says you cannot market a biotech food without getting it approved.

"The reality is that a voluntary system does not make importing these products illegal," he said.

Jaffe sees the reason the majority of American consumers currently have no qualms about eating biotech products is because they trust government regulators have determined they are safe. But he said the system as now constructed means that imported GE foods can be sold in America "and nobody in the U.S. (regulatory agencies) can stand up and say they are safe."

Jason Dietz, a science policy analyst with FDA's Center for Food Science and Applied Nutrition, said it's wrong to view FDA as powerless in the face of GE imports. For example, he said if FDA has reason to suspect that a food coming

Furthermore, the Protocol also institutes new documentation requirements intended to alert countries that there might be GE content in certain imported farm commodities. Specifically, if there is reason to believe there might be LMOs in a particular farm export, the importer is to be formally notified that the shipment "may contain" LMOs.

However, it remains to be seen whether the Protocol will provide the kind of information required to adequately monitor global movement of GE food and feed products.

Skeptics note that compliance with the Clearing House notification requirements is voluntary. Also, because it is not a formal signatory to the treaty, it's not clear how the U.S. would use the Protocol's commodity shipment documentation requirements to gain advance knowledge that a particular import might contain LMOs.

There is also the issue that export disclosures are confined to *living* modified organisms. In other words, countries are under no obligation to provide advance notice of exports involving GE plants used in processed foods.

into the country contains an unapproved food additive or is unsafe—and that could include a GEO—the import could be detained or refused entry.

"Under the law, a food that appears to be illegal can be refused entry," he said.

Margaret Mellon agreed with Jaffe's view that that the prospect of GE imports is highlighting flaws in the U.S. regulatory approach, particularly FDA's decision to make consultations on bioengineered foods voluntary.

Dietz clarified that while participation in FDA's consultation procedures is voluntary, it is mandatory that GE foods comply with the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act). GE foods–whether domestic or imported–are held to the same high safety standards as all other foods regulated by FDA. Those foods–genetically-engineered or conventional, domestic or imported–that do not meet the safety and legal standards of the Act may be the subject of regulatory action. Also, under the Act, it is incumbent on manufacturers to ensure that the foods they offer for sale are safe and legal. Participation in FDA's consultation procedures affords firms the opportunity to ensure that their foods meet the safety and legal standards of the Act before offering their products for sale.

Mellon expressed the view that the power of the voluntary consultations to protect consumers is entirely dependent on the FDA's close relationships with U.S. based food producers, relationships the agency does not have with foreign producers.

"I think by advocating such a weak regulatory system in the U.S., we've put ourselves in a difficult position to assure our own folks that what's going to come from outside is going to be stringently regulated," she said.

Furthermore, she said, if regulators do find a way to apply an equivalent level of oversight to GE imports, it's not clear whether many of the countries now pursuing GE plants—which include developing countries that may lack strong regulatory institutions—are prepared to provide the kind of safety assurances American consumers have come to expect.

"I think by advocating such a weak regulatory system in the US, we've put ourselves in a difficult position to assure our own folks that what's going to come from outside is going to be stringently regulated." –Margaret Mellon, *Union of Concerned Scientists*

Food Companies Eager for Agency Guidance on GE Imports

Nick Hether, the food safety expert and former Gerber executive, said industry will be looking to government regulators for help in developing a rational approach to identifying and dealing with the safety concerns and market disruptions that could be caused by GE imports.

"We don't have the resources, for example, to develop databases of what crops are available or what genes to look for," he said.

Hether also noted that when GE plants developed abroad are known to be circulating in the global market, Hether said government experts could set a "threshold" for how much would be considered safe to eat and thus help industry avoid costly problems caused by inadvertent GE presence in U.S. food products.

Overall, the key for food companies is knowing as soon as possible what kind of GE plants other countries are growing. Then, he said, companies at least theoretically have the option—whether motivated by safety concerns or the need to satisfy customer preference—of instituting tests and other measures designed to keep them out of their products.

But he said if companies don't know what crops are out there or don't know how to test for their presence, then chances are GE imports will move into the U.S. food supply and no one will know they are there until products already are on the market. Hether said that food companies operate in an environment in which unintended co-mingling of agricultural products is a regular occurrence, and there is no reason to expect it won't happen with GE crops grown in other countries.

"Soybeans with corn is very common," he said. "I have seen sweet potatoes with carrots. I have seen walnuts with peaches. The nature of the agricultural system in the U.S. and the rest of the world is we cannot preclude this from happening. So the problem for food companies is that if we don't know this stuff is out there, we would be buying ingredients and not know what to exclude. Somebody could discover it and suddenly, if the regulatory agencies have not approved it, you have a potential food safety problem. You would certainly have consumer perception disasters."

Are U.S. Officials Ready for GE Imports?

Representatives from several U.S. agencies discussed whether tools they currently have for addressing safety concerns related to agricultural biotechnology are sufficient for handling a potential surge in GE imports. It's a discussion that takes one into the somewhat complicated world of the multi-agency "Coordinated Framework for the Regulation of Biotechnology" that has, at times, struggled to define a coherent vision for reviewing the safety of domestically developed GE plants and is now confronting the issue of how to deal with imports.

The discussion of how U.S. regulatory officials might review GE imports quickly reminded participants that the federal agencies involved—USDA, EPA and FDA—have never sought new authority specifically designed to deal with safety issues related to GE plants, domestic or imported. Rather, they have endeavored to conduct oversight of this new technology by applying authorities that existed long before the arrival of agricultural biotechnology. This approach apparently will continue when it comes to examining GE imports, as there was no indication that anyone is contemplating seeking new authority to help agencies evaluate GE imports.

At USDA, Oversight for Commodity Imports, including GEOs

For the lay person, it can be difficult to understand how existing authorities have been interpreted to apply to GE plants.

Shirley Wager Pagé oversees commodity import analysis and operations staff in the Plant Protection and Quarantine (PPQ) Program at USDA's Animal and Plant Health Inspection Service (APHIS)[1]. Terri Dunahay is team leader for international policy for APHIS Biotechnology Regulatory Services (BRS). Together, their com-

1 It should be noted that BRS regulates commodities that are developed domestically and abroad; the Commodity Import Analysis and Operations staff review the risk associated with imported commodities.

GE Imports and the Broader Challenge of Food Safety

Monitoring the safety of food imports is nothing new for either the public or private sector. So one way to look at GE imports, said participants in the discussion, is that any threats they may pose to humans, animals or the environment will be dealt with as effectively—or, according to some participants, as ineffectively—as any other food safety threats coming from abroad.

Greg Jaffe with the Center for Science in the Public Interest noted that overall, with conventional products, there already is a considerable discrepancy between the way the U.S. screens domestically produced foods for safety versus imported products. For example, he noted that a USDA inspector is on site every day at U.S. meat packing plants. Contrast that to seafood imported into the U.S., he said, where a very small percentage of what comes in from other countries is subject to inspection. Yet in terms of a food safety threat, he said, one could argue that imported seafood probably poses more risks to consumers than "meat that is being slaughtered in Iowa."

"Our society has not really allocated resources from a regulatory point of view and a safety

ments underscored the fact that the agency uses its long-standing authority to regulate potential plant pests as its basis for conducting oversight of GE crops.

APHIS/PPQ oversees importation into the United States of plants for planting, and agricultural commodities. The focus on preventing entry of unwanted pests and disease, or weedy or invasive species, that may accompany these shipments. Any GE plants or commodities would also be subject to this oversight. In addition, APHIS/BRS regulates varieties of GE crops to ensure that the new gene or trait does not increase the potential for that plant itself to pose a risk to U.S. agriculture, as compared to the non-engineered variety. For example, APHIS BRS wants to know whether the GE traits could increase the likelihood that the plant, or its wild relatives, could become weedy or invasive, or have unintended harmful effects on beneficial insects. APHIS requires all GE plants intended for cultivation on U.S. soil, regardless of whether they were developed domestically or abroad, to undergo agency review.

Thus, when it comes to GE plants that would be grown on a farm, either experimentally or commercially, APHIS' regulatory authority is relatively well established and exercised. But as Wager Pagé and other USDA officials noted, the concerns of most participants in the discussion were more focused on what USDA would do about GE imports that might involve grains and fresh produce intended only for food. In this area, USDA authority to regulate GEOs is less clear, as the likelihood of environmental exposure, and thus potential harm to agriculture, would be significantly reduced.

Wager Pagé noted that, under PPQ regulations, the presence of GEOs in farm products intended only for use as food, is not a factor in determining whether that product might present a risk to U.S. agriculture from pests associated with that crop in the exporting country. She noted that the agency already has evaluated the potential pest threat posed by a large number of farm products coming into the United States from a variety of countries. Their import status in PPQ would not change should one of those products become available in a GE variety; however, the product may still be subject to BRS oversight.

point of view to really address the biggest risks out there," he said.

Andy LaVigne with the American Seed Trade Association, said he believes food quality control in both the public and private sector is getting better and better and that progress should provide some measure of confidence that any safety issues involving GE imports would be detected and addressed.

"We are never going to be able to catch 100 percent of the problems that come into this country but we've seen a process put into place over the last 20 years, whether it involves recalls of beef or melons or strawberries, that gets to them very quickly," he said.

LaVigne said private sector companies in the U.S. also are focusing more intently than ever on controlling the quality of products they buy from foreign suppliers. For example, they insist foreign suppliers follow certain processes designed to ensure product safety and if they don't, then they lose the contract.

Tom Redick, representing the U.S. Soybean Council, said U.S. companies can preempt problems with GE imports by showing developing countries now entering the world of agricultural biotechnology how the U.S. has handled the issue and encouraging them to be open about publicly discussing the details of GE plants they will release for commercial cultivation.

For example, Wager Pagé noted that an earlier presentation had mentioned the possibility that developing countries may produce new GE varieties of sweet potato and cassava, a plant used in many ethnic dishes. Imports of raw GE sweet potatoes would be banned, she said, but *only* because all sweet potatoes, conventional or GE, are prohibited from coming into the United States as a fresh commodity [due to concerns they could introduce plant pests]. Cassava imports from many countries, on the other hand, are allowed. If one of those countries were to develop a variety of biotech cassava, she said, the product would not be subject to additional review by PPQ; however, the product would be subject to review by BRS.

Terri Dunahay talked about some of the gray areas that BRS is grappling with when it comes to considering how to deal with GE imports. She noted that imports of GE plants headed for cultivation would require close scrutiny from BRS, while finished or highly processed foods containing GE ingredients lie outside its purview. But Dunahay said the agency is less certain about what kind of review should be applied to raw products coming in only for food, feed and processing, such as raw corn or soybeans, or fruits and vegetables for fresh market consumption, that, theoretically, have the ability to propagate.

"The question is what sort of environmental risk assessment needs to be done for products that are not intended to go into the environment," she said. "It's a very different level of risk and we want to make sure our procedures are appropriate for that."

She said available options range from requiring a full environmental assessment for every product coming in that might have the ability to propagate, to continuing with the status quo, which is to determine if a full assessment is needed for such imports on a "case by case basis." But she noted that distinctions likely would need to be made that focus on the risk that the GE import would inadvertently produce plants.

For example, whole GE corn that is destined for a feed lot where it could spill on to the ground and grow a corn plant might deserve more scrutiny than whole corn that's headed straight to a processing plant.

Offering a window into the agency's thinking on GE imports is a new standard now being developed by the North American Plant Protection Organization (NAPPO) for handling trade in GE plants between Canada, the United States and

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–Terri Dunahay, *USDA APHIS BRS*

Mexico. Dunahay said discussions on drafting this standard have focused on the kind of distinctions mentioned earlier, such as a qualitatively different level of review for importing GE seedless grapes (not that there are any currently on the market) versus bringing in a GE apple (again there are none currently on the market) which, of course, has seeds. A draft standard is expected to be available for public comment sometime in 2007.

Dunahay said that the U.S. to date has primarily been a producer and exporter of GE crops, and GE imports have not been a major issue for BRS. She said most of the requests for import approvals have been for "small amounts" of GE organisms intended for laboratory research or field trials. Dunahay could recall only one instance of BRS considering the importation of a farm commodity intended to be used for food. It was a request several years ago to import GE canola developed and produced in Canada for processing into oils in the U.S. The request was granted, she said, following a review by the agency concluding that the canola imported for this purpose would not pose a risk to plants in the U.S.

Dunahay said that as part of a broad, ongoing review of how the agency regulates agricultural biotechnology, USDA is interested in taking a fresh look at how it should handle GE imports intended only for food use. But she said that so far very few stakeholder comments about the agency's review process have mentioned GE imports.

EPA and GE Imports: A Narrow Focus on Pesticides

As part of the interagency "coordinated framework" by which the federal government regulates agricultural biotechnology, the EPA is charged with monitoring issues related to pesticides and pesticide residues. That charge limits EPA's role in dealing with domestically produced GE plants and it is likely to limit its involvement in conducting oversight of GE imports.

Stephen Howie, an environmental scientist at EPA who handles biotech and transboundary issues, explained that EPA does not have much to do with the "majority of genetically modified traits that are put into crops because the number of modifications for pesticide use are small."

The majority of GE plants with pesticide properties currently on the market are those that have been engineered to incorporate one or more of the insecticidal proteins from *Bacillus thuringiensis,* or Bt. The agency looks at whether the pesticide, which the agency calls a "plant incorporated protectant" or PIP, is safe for humans, animals and the environment.

EPA has issued exemptions from tolerances for certain Bt proteins in PIPs. These would only apply to any GE import involving the same Bt protein in a food plant for which a tolerance exemption exists.

Howie said that like domestic producers, anyone seeking to import and cultivate a plant engineered with pesticide properties would need to get an experimental use permit or registration from EPA. A person intending to import a pesticide must notify EPA of such intent prior to the arrival of the pesticide in the United States. Just as with USDA regulators, he said EPA may grapple with identifying when an import of a GE plant is intended for cultivation and when it is intended for food, as there is not a clear mechanism for making that distinction when a product arrives at the border.

FDA and GE Food Imports

Much of the discussion of regulatory authority at the conference focused on FDA, since there is a widespread sense that GEOs developed abroad are most likely to make their initial appearance in the U.S. as food products, not as plants intended for cultivation. FDA is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through bioengineering.[2]

According to FDA's Jason Dietz a consumer safety officer, FDA has the power to monitor any food under its regulatory purview,[3] domestic or imported, GE or conventional, for safety problems and can take food deemed to be harmful off the market or, in the case of imports, seize potentially unsafe products at the border.

Dietz said concerns about food security that flowed in the wake of the 9/11 terrorist attacks have prompted the U.S. Congress to beef-up the agency's authority to monitor food imports. For example, there are now in place stricter rules requiring FDA to receive advance notification that a food shipment is coming into the country. While there is not a requirement for flagging the GE content of the shipment, Dietz said that the notifications now mean that if the agency suspects a problem with a specific country's exports, including whether there is a safety concern related to an imported GE food, officials can "target that shipment for inspection when it gets into port."

2 EPA also has a hand in food and feed safety regulation as EPA sets tolerance limits for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug and Cosmetic Act.

3 Meat, poultry, and egg products are under the regulatory purview of the United States Department of Agriculture.

The FDA has the authority to issue an "import alert" if it believes an unsafe product may be on its way to the U.S. For example, there was an import alert issued for rice sticks and rice vermicelli made in China believed to have been contaminated with filth. But simply because a food is GE or contains a GE ingredient, even if the content is inadvertent or unexpected, is not sufficient to trigger an import alert.

In addition to its enforcement powers, the FDA is encouraging anyone importing food with GE foods to participate in the agency's voluntary "consultation procedures" for reviewing safety and legal concerns, Dietz said. The process allows FDA experts to review company-generated data attesting to the safety and legality of GE foods. If the FDA is satisfied that all safety and legal issues have been addressed, it issues a letter to the firm saying that the agency has no further questions at this time.

"The consultation procedures are a way that firms importing bioengineered food into the United States can ensure that their products are safe and legal," he said. "The procedures are open to foreign and domestic firms."

Dietz said that any firm, including a foreign firm, may speak with FDA officials via phone in order to facilitate participation in the voluntary consultation procedures. Dietz added that the consultation procedures are working well and firms continue to use the process.

What Would Trigger FDA Action on GE Imports?

Dietz was questioned as to what might prompt the agency to proactively monitor food imports for the presence of GE materials that were developed in other countries and had not been reviewed for safety in the U.S. For example, Margaret Mellon pointed to allegations from Greenpeace that products made from a variety of GE rice developed in China that has never been examined by U.S. regulators is showing up in Europe. She suggested that FDA could conduct tests that might reveal whether any GE rice developed in China is present in the U.S. food system.

Dietz said the possibility that GE rice from China has penetrated U.S. markets was a new development and that the agency is monitoring the situation, but was not currently testing. Mellon said she understood why the agency might be reluctant to probe for the rice, but she said the fact that no regulatory authorities are on the lookout for the GE variety, despite reports that it might be in circulation, "does not create a lot of consumer confidence about untested or insufficiently tested GE products."

Nick Hether said the U.S. food industry is uncomfortable with the fact that there is little information being generated from the FDA or other agencies that would help companies understand whether rice from China or GE products from other countries may already be on the market, even though their presence has not been officially announced.

"How am I supposed to make business decisions absent information from FDA or others about what might be regarded as approved and what we should avoid?" he said.

Dietz responded that ultimately it is a food company's responsibility to "ensure that the products it is offering are safe" and that firms need to work to make sure that the foods and ingredients they use–whether domestic or imported–are safe and legal.

Hether said that U.S. food producers are aware that quality is their responsibility, but when it comes to the unintended presence of GEOs, they need to know what they should be looking for and for FDA to determine what levels are appropriate should there be accidental co-mingling. With the allegations swirling about unapproved Chinese GE rice, Hether said food companies are lacking on both counts: no information about whether it really is circulating in U.S. markets, and no information on whether it is safe to eat, at least in trace amounts.

That's a key concern of Jane DeMarchi of the North American Millers Association

"If it's something that's not deemed safe, what will we do?" she asked.

Hether agreed that as long as industry doesn't know what's out there in the supply chain and, if it does, whether FDA would find it safe, "it is going to be a very, very uncertain situation."

Mellon noted that even with all of FDA's authority to police foods, both imported and domestically produced, she is still concerned that there is no requirement that a company consult with FDA before putting a GE product, domestic or imported, on the market.

But Dietz said foreign firms, like their domestic counterparts, likely will understand that they have a strong incentive to discuss safety and legal issues with FDA before a GE product is made available to consumers. If it turns out the product is unsafe or otherwise illegal, he said, they could face punitive action from FDA and lawsuits from their customers. "Participating in the consultation program helps firms avoid this situation," he said.

But Canice Nolan with the European Delegation said no one should confuse FDA's examination of a company's safety data with a formal, independent agency review of product safety. He said when FDA signs off on the safety of a GE product, the agency is basically saying "we have seen your safety assessment and we have no more questions" as opposed to "FDA has assessed this (product) and we say it's safe."

"The consultation procedures are a way that firms importing bioengineered food into the United States can ensure that their products are safe and legal. The procedures are open to foreign and domestic firms." –Jason Dietz, *FDA*

"That's problematic in the sense you would like regulators (from different countries) to talk together, to trust each other and to use each other's assessments, because this is not an FDA assessment," he said.

Robin Churchill with the Canadian Food Inspection Agency, said Canadian officials would be very interested in learning whether or not GE rice or other GE products from China are coming into Canada. But she said it's not clear how to test for it, what types of rice to probe for its presence and, if it is found, what to do about it?

"You can't just go chasing after each rumor and not know what you're testing for," she said.

The GE Imports: Health Risks Versus Commercial Risks

Craig Thorn, an agricultural trade expert at DTB Associates, said before the U.S. or Canada allocates what is a finite amount of resources on inspecting and testing imported food for the presence of GEOs, they need to determine if the potential threat to food safety is sufficient to warrant the investment of time and money.

"I think that testing and inspection needs to be proportionate to the risk that's presumed," he said.

Jane DeMarchi of the North American Millers Association, agreed that the regulatory approach should be "commensurate with the risk."

"If there isn't any real obvious safety concern, then how much time and energy should the government put into testing?" she said.

But Gary Drimmer an expert in the international grain trade, said that there are two kinds of potential risks that could be caused by GE imports and regulators could have a role in mitigating both: risks to human health and risks to commercial ventures. For example, when GE grains have unintentionally co-mingled with conventional grains, there has been no evidence that anyone's health was put in jeopardy. But, Drimmer said, these situations have had "tremendous" financial consequences for U.S. firms.

He said the problem several years ago of StarLink, a GE corn variety approved only for animal feed, getting into the food supply and, more recently, the problem with a GE variety of Liberty Link rice co-mingling with exports to Europe, where it has not been approved, has cost U.S. farmers "billions of dollars" in lost exports to customers demanding GEO free commodities. Those losses occurred even though there were no health problems caused by the co-mingling and the amounts involved were minimal.

"Even without a health risk there is a tremendous potential for commercial risk," he said.

Drimmer's comments were viewed as highlighting yet another challenge: what is the government's responsibility if the risk posed by the GE import is almost purely to commercial ventures, not human health?

Margaret Mellon of the Union of Concerned Scientists, asserted that regulators routinely focus on food issues that are not "explicit threats to human health." For example, she said FDA sets standards for the amount of insect parts that may inadvertently co-mingle with food products because people just don't want them there, not because they pose a health threat.

Jane DeMarchi said food companies would like FDA to give "consideration" to taking similar action with imported GEOs: setting levels for how much could accidentally end up in food products but be considered harmless.

"While the government has limited resources on what it can test and what it can spend money on, we cannot have the commercial system having to make up for a weak regulatory system," she said. "So the decisions need to be made by the government and regulations set in place so that we're not just having to totally rely on a commercial system to do all the testing."

How Other Countries Handle GE Imports

The discussion of what the U.S. should do about GE imports presumes a future when a large number of countries around the world would be cultivating and exporting GE crops either, intentionally or unintentionally. At the moment, however, the U.S. is the world's leading producer and exporter of GE crops. As such, a

"While the government has limited resources on what they can test and what they can spend money on, we cannot have the commercial system having to make up for a weak regulatory system." –Jane DeMarchi, *North American Millers Association*

significant issue confronting U.S. exporters is that many countries have yet to approve many of the GE products being exported. In some instances, countries may be in the process of developing a regulatory system, while in others no regulatory system exists to approve GE products. Therefore, one way to consider how the U.S. should respond to GE imports is to consider the regulatory systems our various trading partners have created to import agricultural commodities produced using genetic engineering. (Strictly speaking, policies imposed in many countries targeting GE commodities are not necessarily import-specific, as many of the requirements could also apply to domestically-produced agricultural goods as well. However, it's clear that for the most part they are a response to GE imports, as the most restrictive regulations—such as those adopted by the EU—are in countries where there is almost no domestic commercial cultivation of GE crops.)

The European Union, for example, requires anyone growing, storing, transporting or processing GE products destined for EU markets to be able to track them at every step of the marketing chain, from farm to fork, and to maintain these "traceability" records for five years. EU regulators say they need to be able to trace GE food products back to their origin should questions arise about their safety. Furthermore, the EU requires that products must be labeled as containing GEOs if their GE content is greater than 0.9 percent.

Liz Jones, who works in the Biotech Group at USDA's Foreign Agricultural Service, said regulations governing GE imports vary widely from country to country and are driven by national priorities. In China for a major importer of U. S. GE crops, she said, the government priority is to meet domestic consumption needs, and those needs—coupled with nascent consumer concern about eating foods produced through genetic engineering—appear to influence a rather pragmatic, albeit still very much developing and not without impediment, regulatory policy toward GE imports. That could change should China's agricultural biotechnology innovations lessen the need for imports.

In other countries—Japan and South Korea are good examples—regulatory policy toward GE plants appears designed to balance substantial food and feed import needs with consumer concerns about GE products. Jones explained that in Japan, for example most U.S. exports of raw plants and finished foods intended for human consumption are handled in a way that "preserves" their identity as conventional or "non-GE." If a product has more than five percent GE content, it

must be labeled as having GE content. There are some nuances to Japan's approach to GE feed and food products. For example, there is no labeling requirement for cooking oils made from U.S. grown GE soybeans. However, tofu made from these same GE soybeans would have to be labeled. Therefore, soybeans imported from the U.S. destined to become cooking oil usually are GE varieties, while those destined for tofu are not.

Because GE labeling is not required for animal feed, a majority of U.S. commodity exports, which include GE varieties, are directed to animal feed. But regardless of the end consumer, a human or an animal, Japan requires all genetically engineered products in food or feed to be reviewed for safety.

South Korean policies on genetic engineering, similar to Japan's, attempt to balance food and feed needs with consumer concerns. For example, the U.S. supplies 28 percent of South Korea's bulk corn imports—2.5 million metric tons were shipped in 04-05—most of it transgenic. But since South Korea requires labeling for foods containing GE products—which might prompt them to be rejected by consumers—a majority of South Korea's corn imports from the U.S. are directed to animal feed. Any corn imports destined for food use must carry documents to confirm its identity as conventional or "non-GE."

By contrast, Jones said, in Mexico there is little consumer concern about GEOs in foods and relatively unfettered demand for U.S. grown corn and soybeans, conventional and GE. Mexico has approved imports of U.S. grown GE corn, canola and soybeans for food and feed use. Mexico does not require GE products to be labeled. Jones noted, however, that Mexico is in the process of reviewing its biotech and bio-safety regulatory procedures, which could change the way it deals with GE imports.

One widely noted area of concern with respect to biotechnology relates to Mexico's position as a center of origin for corn. Much of the debate in Mexico has focused on the potential impact of biotechnology on both bio-diversity and on the role corn plays in Mexico's national heritage.

Jones said that, overall, despite the complicated mix of regulatory systems for GE products worldwide, there continues to be significant market demand for agricultural commodities from the United States, particularly for non-food use. In other words, while countries' bio-safety regulatory policies are often controversial and viewed by some as inhibiting trade, many countries have found ways to balance concerns about GE products with market requirements.

GE Import Policies and International Trade Obligations

Developing a national policy for controlling GE imports must be done with an eye toward international agreements or a country could end up facing sanctions from its trading partners. Craig Thorn with DTB Associates noted that, in general, the World Trade Organization (WTO) requires any controls placed on agricultural imports to be rooted in scientific assessments of risks to humans, animals and plants.

However, Thorn said, that rule is not iron clad, as the WTO has created exceptions for when countries can halt an import in the absence of clear scientific evidence of safety problems. He said WTO members can at least "temporarily restrict" an import if they are concerned about a potential problem, but must act expeditiously to provide scientific support for their action.

The U.S. has used the WTO as a forum to charge that certain EU regulations of GE imports violate the EU's WTO commitments. Thorn said a WTO panel reviewing the complaint issued a narrow ruling, finding that EU delays in approving imports of U.S.-grown GE products violated WTO rules. But the panel was silent about other charges raised by the U.S., such as whether WTO rules allow the EU to require pre-market approvals for GE imports or whether the EU's "traceability" standards are consistent with its WTO commitments.

Overall, Thorn believes it remains unclear as to what precisely countries can do to regulate GE imports without violating WTO obligations. For example, it's not clear whether, in the absence of scientific support for potential safety threats, WTO rules allow countries to institute pre-market approval processes and traceability standards that target only GE plants.

"I think that's probably going to be an area of future litigation, because we have seen how labeling and traceability rules can be so disruptive commercially and it's questionable whether or not countries have a valid scientific basis," he said.

In addition to WTO rules, Thorn said, global trade in GE plants and foods derived from them will be affected by how countries that are part of the international Biosafety Protocol interpret their obligations under that treaty.

Thorn said there are ample opportunities for conflict between the protocol and WTO rules. He said the biggest issue is that the protocol requires signatories to enact policies for monitoring trade in GE plants regardless of whether there are safety concerns with a particular product. In other words, under the protocol, it is the genetic modification process, not the end product, that is the primary trigger for action. By contrast, he said, in general WTO wants member countries to enact policies that "focus on the characteristics of the end product rather than the production process."

"I do believe it is possible to implement a biosafety regime based on the biosafety protocol that is also WTO consistent," Thorn said. "But it is not automatic. There are plenty of pitfalls."

A De Facto Welcome Mat for GE Food Imports?

To illustrate some of the questions and concerns that GE imports into the U.S. might raise, participants discussed a couple of scenarios where a country might be free to sell foods derived from GE crops developed abroad with little or no U.S. review.

One hypothetical scenario involved GE rice engineered with a Bt gene—that could be sold immediately in the U.S. without running into legal problems. If the GE import involved a bag of rice or a rice cake for consumption, USDA would have no authority since the import would not pose the likelihood of propagating or of otherwise introducing a potential plant pest. Meanwhile, if the rice were engineered to produce a Bt protein for which a tolerance exemption in rice already exists, neither EPA nor FDA would have cause to act since they have already determined that the protein is safe.

But while some people might say that is exactly how the regulatory system should work—no harm, no foul—others pointed out that food companies and consumers might have a different reaction.

Jaffe suggested changing the scenario slightly. What if, he said, the Bt protein from China is substantially different from the protein found in Bt crops approved for U.S. cultivation, different enough that one could argue that regulators could not be sure that the plant-incorporated protectant is safe to eat?

EPA's Melissa Kramer said in a situation where officials decide that the safety of a pesticide has not been determined, its regulatory status is clear.

"If you have a pesticide residue without a tolerance or tolerance exemption in a food product, the food is adulterated and may be subject to seizure," she said.

But Nick Hether said what U.S. food companies fear is that, in such a scenario, the GE import will inadvertently co-mingle with one their products before anyone knows it's here or has determined it's safe. For example, because there is no requirement for a pre-market review or notice that a food import contains a GEO, the rice could easily be mistaken for conventional rice and used as an ingredient in a U.S.-manufactured food product. And when it comes to light that the GEO is in the country, he said, food companies would be "left hanging" while regulators decide whether the imported GEO fits the first scenario—a protein known to be safe—or the second—one whose properties are sufficiently vague that the rice and anything it has co-mingled with should be pulled from the market.

Just one confusing situation like that would be sufficient to cause major problems, he said. If there are several such scenarios involving a series of GE food imports, Hether believes the market disruption would be immediate and profound.

For example, he said that even if U.S. regulators eventually decide that certain GE imports that have unexpectedly entered the U.S. food supply are safe, other countries might not be so quick to agree. He noted that in Japan and Europe, there is a "zero tolerance" for unapproved GEOs in food or feed. And if these coutries have evidence that an unapproved GEO (by virtue of imports), is circulating freely in the U.S. food supply, they might act to widely restrict U.S. feed and food imports, forcing U.S. companies to enter uncharted territory: developing IP systems designed to exclude GEOs that could be originating from multiple countries.

Hong Chen with the Canadian Food Inspection Agency said it's important for governments not to just wait for a GEO import to arrive and then try to decide what it is and how it should or should not be regulated.

When a non-approved product is at your border, it's almost too late to do anything about it, she said. For example, she said that, because China is a major trading partner and appears to be on the verge of becoming a major producer of biotech crops, Canada is now conferring with China's regulators about how they are conducting safety reviews of GE plants intended for commercial production.

"Hopefully we will get to a point where we will have a good regulator to regulator relationship so that, in the future, we can deal with issues arising from trade in biotech products," she said.

Andy LaVigne of the American Seed Trade Association said industry needs to realize that waiting for national regulatory agencies or the WTO review bodies to assert their authorities will not solve the challenges raised by GE imports.

"If we wait...we're always going to be chasing the problem instead of getting ahead of it," he said.

Further, he said, the only way to deal with the array of concerns in various quarters is to do as Chen suggested and forge stronger relationships with the emerging producer countries like China and others, and discuss how they are going to proceed and where they might need assistance.

"We can all do what we want to domestically, but I don't think we will get any additional level of confidence or security unless we have those folks (regulators and producers from countries like China) around the table," he said. "Because of the increased volume of trade, there is no way we could put the resources at our borders to check everything coming in today. All you're going to do is put a further burden on people who already are complying."

Jane DeMarchi, with the North American Millers Association, said that it's important to remember that the reason we are likely to see GEOs imported into the United States is that the technology is becoming more widely used and the potential applications are growing.

She noted that in the next few years, it will not be just countries outside of the U.S. who will be expanding the variety of GE plants under commercial cultivation. U.S. producers, DeMarchi said, also will be continuing to develop new GE plants and will have a growing interest in seeing a rational international system emerge that can accommodate the presence of a diversity of GEOs in the global market.

"So it's not just about being static and trying to figure out how will we import these products," she said, "It is how can we keep global trade in these products moving forward" wherever they come from.

Participants

Commercial, Safety, and Trade Implications Raised by Importation of Genetically Engineered Ingredients, Grain or Whole Foods for Food, Feed, or Processing hosted by the Pew Initiative on Food and Biotechnology

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