NEC HIGH-LEVEL GROUP ON BIOTECHNOLOGY

MEETING AGENDA

September 14, 1999

5:00 – 6:30 p.m.

Roosevelt Room

FOOD
SAFETY -
GMO's

I. Introduction

II. Options

- Improve Public Outreach and Education.
- Modify FDA's Premarket Approval Practices.
- Facilitate Voluntary Informational Labeling Based on Consumers' Right to Know
- Export Labeling to conform with WTO-Consistent Requirements of Foreign Markets.
- Support Legislation requiring Mandatory Right-to-Know Labeling in the U.S.

III. Agency Positions and Next Steps

DISCUSSION PAPER FOR NEC HIGH-LEVEL GROUP ON FOODS MADE THROUGH BIOTECHNOLOGY

September 14, 1999

PURPOSE

To review issues and policy options related to the goals of reinforcing public confidence in the U.S. regulatory system pertaining to agricultural biotechnology products and improving market access for U.S. exports of processed food products and bulk commodities.

BACKGROUND

Modern biotechnology or bioengineering refers to the use of recombinant DNA and related technologies 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 any other organism, as well as to introduce targeted genetic changes in organisms. The practical effect is to open up vast opportunities for developing new foods with beneficial characteristics such as pest and drought resistance, higher yield, enhanced nutrition and better taste. The United States is the acknowledged world leader in the biotechnology industry. Although the use of biotechnology for producing new drugs and vaccines has been widely accepted around the world, the use of the technology in producing foods has been much less well-received.

U.S. Regulatory Framework

In 1986, the Office of Science and Technology Policy published the "Coordinated Framework for Regulation of Biotechnology," in which Federal agencies including the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection (EPA) described their policies for regulating research and products of biotechnology. The underlying premise of the Federal policy was, and remains, that, based on the government's assessment of the science, the regulatory framework that pertains to research and products of traditional genetic manipulation was adequate for research and products of the newer techniques, and that no new laws were needed. In response to the coordinated framework:

- USDA promulgated regulations requiring developers of bioengineered crops to notify USDA before planting such crops in the field. This process was intended to minimize any potential "plant pest" risks that the bioengineered crops might pose to agriculture and the environment. If USDA determined from its review of the resulting data that the crop posed no plant pest risk, it would classify the crop as a non-regulated article and allow it to be planted with no subsequent USDA involvement.

- EPA promulgated rules for the regulation of "intergeneric" microbes, as potentially toxic new chemicals, and for the regulation of pesticidal substances introduced into plants. EPA examines both environmental and human health risks of the microbes and pesticides.

- FDA promulgated no new regulations but did publish a statement of policy describing how the laws and regulations that FDA enforces pertain to foods from new plant varieties. Essentially, the policy said that new substances bioengineered into foods would be subject to premarket approval as food additives if those substances differed significantly from substances commonly found in the diet. However, FDA also said in the policy that most, if not all, substances then being considered for introduction into foods through bioengineering were substantially the same as other substances found in the diet and as such would not need premarket approval. FDA encouraged firms to consult with it on safety issues prior to marketing, and firms have been doing so. If no issues requiring premarket approval are identified during these consultations, firms then could determine that the bioengineered food was "generally recognized as safe," as is the case with nonengineered new varieties of food.

Domestic Concerns

Although Federal regulatory agencies remain assured that bioengineered crops and foods sold in the U.S. are safe, there are increasing numbers of press and media stories questioning the safety of bioengineered foods and crops, and the adequacy of their Federal oversight. While bioengineered corn, soybeans, cotton and canola are widely grown and their products consumed in foods in the U.S., companies are concerned that public acceptance of these foods could be shaken as activist groups charge that the foods pose unknown long-term risks. An example of such concern was the recent announcement by several major baby food manufacturers, in response to pressure from an activist group, that they would remove all bioengineered ingredients from their baby foods sold in the U.S.

Some consumer and environmental groups have argued that bioengineered foods should be required to receive FDA safety approvals before marketing, should be required to be labeled as bioengineered, and that bioengineered crops should have their potential environmental risks better controlled. A group of organizations and individuals filed a lawsuit last year against FDA alleging that it is violating the law by not requiring such labeling and premarket approvals. Another lawsuit has been filed against EPA alleging that its oversight of certain pesticidal substances in bioengineered crops and foods is inadequate.

International Concerns

Biotech firms are facing increasing resistance to their products internationally, particularly in Europe. (See attachment A -- Current picture on foreign market access) The EU requires labeling of bioengineered crops and foods, and is actively working to internationalize these labeling requirements. However, the EU has not issued implementing regulations for their labeling regulation. Other countries around the world are enacting or contemplating labeling requirements for bioengineered foods.

The EU and a number of other countries also have premarket approval requirements for bioengineered crops and foods, although the process in the EU has broken down because of political difficulties brought on by consumer fears and intense opposition from activist groups in a number of EU member states. There have been no new approvals of bioengineered foods in the last year and a half, and there are unlikely to be any new approvals for at least another year or two under the most optimistic scenarios. One result of this breakdown in the EU approval system is that the U.S. can no longer sell corn to the EU, because U.S. corn shipments may contain any of a number of bioengineered varieties that have not yet been approved in the EU. (See attachment B – Economic analysis of market implications of EU standards for GM and non-GM products)

While consumer concerns about the safety of bioengineered foods and crops are most intense in Europe (probably stemming in large part from distrust of scientists and regulators as a result of their handling of the BSE problem in the UK a few years ago and the recent dioxin problem in Belgium), there is some possibility that similar concerns could ultimately cross to the U.S. as well.

Labeling

The U.S. Government (USG) position on labeling of genetically engineered or modified (GMO's) agricultural crops and products has been to oppose any mandatory labeling of such products. This position is based on the Food & Drug Administration (FDA) conclusion that genetically engineered foods are substantially equivalent to their conventional counterparts. However, the FDA requires labeling of food, including GMO's whose composition has been significantly altered, whose nutritional values or intended use is different from conventional food, or which has allergenic properties. While this interpretation and policy is based on sound science, it has failed to quiet consumer demands to require labeling of GMO food. Originally, opposition to GMO food was primarily in European Union (EU) countries but this sentiment is gradually spreading to other countries as well. There are also signs that U.S. consumers are also becoming concerned about GMO's, as is evidenced by an article in the September issue of *Consumer Reports* which advocates labeling of such products.

The USG efforts in international fora have failed to convince critics that labeling of GMO products is not warranted. Since the September 1998 EU announcement requiring labeling of all GMO products, an increasing number of countries are considering whether they should require labeling of GMO products as well. Even in those countries where there is no anit-GMO sentiment, labeling of GMO products is being considered as a "consumer's right to know" issue. Many food and beverage companies, such as Gerber Foods, Kirin, and Iams Company, are sourcing non-GMO commodities to avoid labeling their products. Consequently, a number of companies (e.g. ADM, Staley's, etc.) are requiring segregation of GMO and non-GMO agricultural commodities to meet the demand for identity-preserved non-GMO agricultural commodities.

Industry has not reached a consensus on what direction the U.S. should take to address the problems of labeling and segregation. Food processors and their trade organizations (e.g. Grocery Manufacturers Association, National Food Processors Association) are opposed to the labeling of GMO's for exports mainly because of the increased costs and their fears that eventually they would be required to label domestic GMO food products as well.

The labeling requirements of our trading partners and demands for segregation of agricultural commodities at home have created a near panic among U.S. farmers. Many of our farmers switched to GMO crops in record numbers because of their enhanced traits, reduced costs of pest/disease control, and environmental friendly attributes. However, the recent demand for non-GMO commodities is expected to add costs due to segregation and handling, in the range of 12% to 17% more for non-GMO bulk commodities (see Attachment B). This figure is expected to increase substantially as the threshold for purity approaches zero.

In essence, U.S. exports of GMO products are in serious jeopardy due to lack of approvals in EU countries, the demand for mandatory labeling by many countries, and backlash from consumer rejection. Therefore, a review of policy is appropriate to facilitate consideration of short and long-term solutions to this complex problem.

OPTIONS

1. Improve public (domestic and foreign) outreach and education.

- Establish through agencies public listening sessions and meetings aimed at getting broad public and scientific input on whether additional regulation (for food safety, food labeling, environmental safety) is appropriate. Panels also could be set up to provide a forum for discussing non-scientific (e.g., cultural and social) issues of public concern.

- Engage in greater education of U.S. public.

- Increase activities overseas to explain U.S. regulatory policies and procedures and to work towards more consistent policies internationally.

- Encourage food processors to post on Federal or their own web-sites listings of products containing bioengineered ingredients, with information about their safety and the Federal procedures through which they passed.

  Advantages

  - Reiterates firm position of U.S. scientists that these products do not pose special risks and that the U.S. system of regulatory oversight is adequate and appropriate;

- Could dispel confusion about which agencies are responsible for what aspects of food and crop regulation and provide a coherent and compelling picture of U.S. regulatory system;

- Enables the regulatory agencies to hear public concerns, and to get scientific input, on their separate areas of jurisdiction, which may provide them with information that will lead them to modify their policies and procedures, or seek new statutory authorities;

- Provides a mechanism for the Administration to get public support for modifications of policies or procedures that it considers appropriate;

- Demonstrates Administration openness to outside ideas; and

- May lead to greater international acceptance of U.S. regulatory practices and the safety of U.S. products, and may ease trade disputes.

- Responds to consumers interest in knowing what foods contain bioengineered ingredients, without violating principles of what belongs on a food label;

- May reduce impact of calls for right-to-know labeling; and

Disadvantages

- By itself may not be adequate to meet public concerns; some consumers consider that factors other than science should be considered (e.g., social and cultural issues); and

- Those concerned about the technology and distrustful of the government may not be reassured by scientists and others seen as sponsored by the U.S. government.

- May be dismissed as simply an attempt to avoid right-to-know labeling, and, because companies already can do it, as essentially offering nothing new;

- Companies may not know which of their foods contain bioengineered ingredients;

- May be used as a tool for boycotts of products containing bioengineered ingredients, and may be resisted by industry because of fears of such use;

- If the Administration calls for posting such website information and the industry doesn't respond, the lack of response may be used as additional argument for need for labeling legislation;

- If posted to a website of a Federal regulatory agency, it might be viewed as blurring promotional and regulatory responsibilities; and

- If posted to Federal web-sites, the Federal agencies could be viewed as guarantors of the accuracy of the information, with significant legal, policy and resource implications.

2. Modify FDA's premarket approval practices.

- Require notification to FDA 90 days prior to marketing bioengineered foods (such notification by companies is now voluntary); or

- Sponsor legislation requiring mandatory premarket approval of all bioengineered foods.

Advantages

- Provides an added level of assurance that government is aware of all products marketed and that all regulatory questions are answered prior to marketing;

- Builds public confidence in FDA oversight;

- Answers criticism that current system is an honor system in which industry voluntarily engages FDA in its safety evaluation;

- Accommodates the growing number of foreign markets that require labeling, including (possibly) meeting the requirements of the EU's Novel Foods Directive; and

- Possibly gives us an opening to work in a more cooperative fashion with the Europeans on biotech issues.

Disadvantages

- If 90 day notification period is adopted, it does not directly address the principal criticism that bioengineered foods are not subject to mandatory premarket approval;

- Mandatory premarket approval would delay market entry of commercially important new foods for no scientific or public health reason;

- Depending on the specific steps taken, may require additional legislation;

- May provide ammunition to opponents of the technology, who may portray this requirement as evidence that bioengineered foods pose special risks not associated with other foods;

- Could shift focus of debate to other criticisms of the current system, such as adequacy of scientific review;

- Mandatory premarket approval would be extremely resource-intensive for FDA without providing concomitant public health benefits; and

- Depending on how it's implemented, mandatory premarket approval might be strongly opposed by industry.

3. Facilitate voluntary informational labeling based on consumers' right to know.

Under this option, the USG would promote a dialogue with agricultural producers, farming organizations, food processors, consumers, and environmental organizations with the goal of facilitating the voluntary development of informational labeling regarding the GMO content of food products. Consistent with FDA's analysis that mandatory labeling of GMO food is not warranted, the labeling would not be based on health and safety criteria. As such, an agency other than FDA most likely would administer the regime.

New authorizing legislation would be required from Congress. The legislation could be modeled on the National Organic Standards Act of 1990. Labeling pursuant to this Act is not intended to convey whether organic food is better or more healthy than food grown with the help of pesticides and inorganic fertilizers. Instead, it seeks to establish a uniform understanding of the growing and processing procedures that qualify fruits, vegetables, meat, milk, eggs, and cotton for "organic" designation. In a similar vein, the content of voluntary informational labels of engineered products could, for example, track the treatment of bovine growth hormone (BST) on some dairy product labels. Specifically, the label might contain two pieces of information: a representation as to the presence or absence of GMOs as well as a disclaimer as to the health and safety implications of such information.

The role of the USG in such a process could range from simply expressing support for private sector efforts in this regard to proactively coordinating interested parties in the development of criteria for informational labels and procedures for certifying compliance.

Advantages

- Potentially satisfies consumer "right-to-know;"

- Industries that would want to pursue such labeling, in response to consumer demand, would have more specific guidance on how to do so;

- Does not undermine the integrity of the food label by giving Federal support for labeling information not directly relevant to characteristics of the food; and

- May increase credibility of USG with foreign governments when discussing foreign labeling requirements and allow the USG to work with foreign governments in developing fair and reasonable standards.

Disadvantages

- A voluntary label would likely only be used to indicate absence of bioengineered ingredients, and could foster demand for "bioengineered-ingredient-free" products;

- Could spur further effort towards domestic mandatory labeling or could itself become de facto mandatory;

- Despite not being mandatory, might still be thought of as an indication of government support for putting information on a food label that is not related in any way to attributes of the food itself, and that may distract attention from important nutritional and health information present on the label; and

- Could strengthen and legitimize calls for other right-to-know labeling in the U.S., e.g., products produced using pesticides.

4. Provide for export labeling to conform with WTO-consistent requirements of foreign markets.

Under this approach, USG policy on labeling would comply with mandatory GMO labeling requirements of the EU and less stringent labeling requirements of Japan, Australia, and New Zealand, in order to maintain export market access in these countries. USG agencies would assist exporters in meeting the GMO labeling requirements of importing countries, while attempting to negotiate an agreement(s) on biotechnology related trade, bilaterally or in the next round of the WTO. FDA would seek to provide specific guidance on what constitutes a misleading or non-misleading label. Similarly, efforts to expedite and ensure the fairness of the EU rule on labeling would be intensified. This rule should include a reasonable threshold on accidental commingling of GMO products, standardized testing methods and a dispute resolution process. It is important to note that this approach would be primarily focused on maintaining our export markets and thus would not include the labeling of domestic GMO products at this time.

Advantages

- Potentially satisfies consumer "right-to-know" demands in export markets;

- Industries that would want to pursue such labeling, in response to consumer demand, would have more specific guidance on how to do so;

- Does not undermine the integrity of the food label by giving Federal support for labeling information not directly relevant to characteristics of the food;

- May increase credibility of USG with foreign governments when discussing foreign labeling requirements and allow the USG to work with foreign governments in developing fair and reasonable standards;

- Could establish a framework for bilateral and international cooperation on biotechnology regulation that does not now exist; and

- Accommodates the growing number of foreign markets that require labeling, including (possibly) meeting the requirements of the EU's Novel Foods Directive.

Disadvantages

- Could spur further effort towards domestic mandatory labeling or could itself become de facto mandatory;

- Despite not applying to domestic sales, might still be thought of as an indication of government support for putting information on domestic food labels that is not related in any way to attributes of the food itself, and that may distract attention from important nutritional and health information present on existing labels;

- Could strengthen and legitimize calls for other right-to-know labeling in the U.S., e.g., products produced using pesticides;

- Would make Administration appear hypocritical and more sensitive to the demands of foreign consumers than to U.S. consumers, if it did not also support mandatory right-to-know labeling in the U.S.; and

- Segregating (and possibly identity-preserving) and tracking each biotech product through the commercial stream would require superior testing methodologies, manpower, and on-going monitoring capabilities.

5. Support legislation requiring mandatory right-to-know labeling in the U.S. (e.g.,"does contain/may contain").

Advantages

- Responds to one of the most important issue to consumers about bioengineered foods;

- May ultimately be the only way to take the whole issue of bioengineered foods away from opponents of the technology, because it is possible that many consumers will always distrust bioengineered products until they feel that they can choose to eat them or not;

- Because of the number of bioengineered crops already grown in the U.S., many, and soon most, processed foods would need to be labeled, thereby eliminating any special stigma potentially associated with labeled products;

- Administration could have the advantage of being in front of the issue;

- Accommodates the growing number of foreign markets that require labeling, including (possibly) meeting the requirements of the EU's Novel Foods Directive;

- Possibly gives us an opening to work in a more cooperative fashion with the Europeans on biotech issues; and

- Forces Congress to tackle the issue.

Disadvantages

- Undermines the function and utility of the food label, which is to provide information pertinent to characteristics and composition of the food, and distracts attention from important nutritional and health information provided on the label;

- Would delay market entry of commercially important new foods for no scientific or public health reason;

- Could lead food processors to avoid use of engineered ingredients, and consumers to boycott products carrying the label;

- Could foster greater distrust of bioengineered foods, by giving the impression that the products must be different or risky if they warrant special labeling;

- Inconsistent with long-standing government position that biotech foods are as safe as their non-engineered counterparts and as a class have no distinguishing characteristics that would warrant labeling;

- Would be difficult to implement if labeling went any further than "may contain," because it would be difficult to keep track of which processed foods had bioengineered versus non-bioengineered ingredients;

- Would be strongly opposed by industry;

- Experience with irradiation shows that mandatory labeling of a new technology may not contribute to consumer acceptance;

- The Second Circuit Court of Appeals ruled that mandatory "right to know" labeling, without any justification other than satisfying "consumer curiosity," violates the first amendment;

- There would be considerable time lag between the passage of legislation and the promulgation of implementing regulations;

- Changing the U.S. domestic labeling regime unlikely to increase market access in Europe given the obligations of the current and proposed Directive 90/220;

- Segregating (and possibly identity-preserving) and tracking each biotech product through the commercial stream would require superior testing methodologies, manpower, and on-going monitoring capabilities;

- Introducing non-scientific ground for food labeling—particularly of processes—opens the floodgates to labeling foods containing hormones, residue levels of pesticides, etc., affecting billions in U.S. agricultural exports annually; and

- Changing the U.S. labeling policy at this time could undermine important initiatives undertaken in the Codex Alimentarius and OECD, which will be producing reports in Spring 2000 on biotech labeling and food safety.

ATTACHMENT A

U.S. Biotech Product Labeling/
Market Access Considerations (Dept. of State)

Issue: Whether to consider segregation and labeling of biotech products as a means to increase market access abroad.

The Problem:
EU Regulations for Biotech Products
The EU has not granted any biotech approvals since Monsanto biotech corn was approved by the European Commission in April 1998 (and the government of France delayed final approval of the same corn -- destined for sale to Spain and Portugal -- until August 1998). Thirteen biotech products are currently stalled in the EU approval pipeline. On December 11, the French Conseil d'Etat suspended its prior planting approval for three varieties of biotech corn, referring the policy decision to the European Court of Justice as to whether one member state's competence to approve biotech plantings is valid throughout the EU. Several major European supermarkets and baby food producers have announced that they will only carry "GMO-free" products.

On June 25, the EU Environment Council reached a "political agreement" (with France, Ireland, and Italy abstaining) to require that agri-biotech productsbe proven to have no environmental or health risks before being placed on the market, in accordance with the "precautionary principle," and to revise Directive 90/220, including requiring additional procedures for handing biotech seeds and bulk commodities already approved. Ministers announced that the approval process was "suspended" until 90/220 was revised.

The most immediate problem, therefore, are the proposed revisions to Directive 90/220 (originally intended to regulate biotech products for deliberate release into the environment, but which also affects bulk commodity imports). Directive 90/220 allows any import to be blocked on the basis of the "precautionary principle" and any new "scientific" information on a given biotech input (such as the Monarch study). It will require phasing out antibiotic resistance markers, strict identification and "traceability" of each biotech characteristic through the commercial stream, and a lengthy assessment process (with no expedited procedures), including reviews by an Ethics Committee, the European Parliament and, where requested, consumer groups. A new proposed revision mandates additional written consent and public registry requirements, which would further lengthen the approval process before any biotech product could go to market. The relationship of the Novel Foods Directive (EC 1139/98, which regulates labeling of biotech foods, additives and flavorings) and the 90/220 requirements is not clear.

Major importers of U.S. grains and oilseeds:
Japan is the largest importer of U.S. grain and oilseds (followed by Mexico, Canada, Egypt, Netherlands, South Korea, Thailand, China, Hong Kong, Spain, and Saudi Arabia). The Japanese Ministry of Health confirmed that there is no health risk associated with biotech foods. Nonetheless, the Ministry of Agriculture, Fish and Forestry proposed that a select list of 30

processed foods containing biotech inputs be labeled with the word "mixed" ("funbetsu") by 2001 in order to satisfy consumer concerns. Industry informs us that, based solely on the proposed labeling regime, buyers are canceling orders for U.S. biotech products.

Major competitors:
In December 1998, the Australia/New Zealand Food Standards Council directed the Food Authority to amend the foods standards code to require biotech labeling, even if a product is "substantially equivalent" to non-modified food. Australia and New Zealand are exploring ways to inform consumers that foods may have been produced through biotech through fliers and posters in supermarkets, 800-numbers and websites, and other means of consumer education, including an asterisk next to the biotech food product's name on a label (e.g., "soybeans*").

Brazil is drafting biotech regulations, including labeling. In a case filed against Monsanto by Greenpeace and the Brazilian consumers' union, a federal judge suspended in June 1999 the commercialization of approved biotech soybeans until further environmental risk assessments are concluded, possibly to guarantee that Brazil, the second-largest soybean exporter, remains "GMO-free."

U.S. Public
While the biotech issue has been featured on prime time news and in major newspaper and magazine cover stories, the U.S. consumers continue to buy products containing biotech inputs on the grocery shelf. The U.S. public has not yet joined in the European outcry against biotech products, likely because of the high level of confidence in U.S. regulatory agencies, and the option to select organic foods. Greenpeace and other NGOs are planning highly-visible protests against biotech products at the WTO negotiations in Seattle, which will probably bring the issue back to the public's attention.

Industry Position
While there are several different industry positions, it is clear that any proposed voluntary or mandatory U.S. domestic labeling regime will encounter strong opposition from the domestic food and feed industry, which would prefer not to label unless there is a strong consumer demand for it. For the relatively small amount of processed foods that are sold to Europe, many in industry are willing to comply with the EU labeling rules and/or use non-biotech inputs. For Asia, where processed foods account for over half the exports, the industry wants any labeling regimes to be reasonable, transparent, practical and non-discriminatory. One major grain and oil seed producers (Cargill) has not confirmed its previous willingness to segregate biotech products destined for the EU. ADM announced it would stop taking deliveries of high fructose corn syrup because ADM cannot guarantee to its buyers that it is GMO-free.

If We Agree to Domestic Labeling and Segregation, Are We Likely to Gain Market Access?

The USG could boost its bona fides by showing that we are being proactive in providing information to consumers and a choice for them in the market place. Segregation and labeling could overcome some European consumer perceptions that the only U.S. priority is promoting large agribusiness firms. Given our excellent track record on food safety, the Europeans should

have some confidence that an identity-preservation/labeling regime would be administered responsibly and effectively. We could credibly argue that refusals to accept U.S. exports under these conditions would constitute an unacceptable trade barrier.

ATTACHMENT B

CEA/USDA Preliminary Analysis: Do Not Cite or Quote
August 20, 1999

EU Standards for GM and Non-GM Products
Possible Market Implications

This paper evaluates the possible market implication of EU standards for GM and non-GM products on international and domestic markets. The analysis proceeds in three parts. First, we estimate the costs of non-GM product segregation in the United States. Next, we evaluate the effects of existing EU standards for corn and finally, we consider the short and long run impacts of an (as yet unspecified) EU standard for soybeans.

We reach two principal conclusions:

First, the long-run costs of segregation and production are sensitive to the standards that are adopted. If the standards allow for reasonable GM tolerance levels, the additional costs of segregation and production could be less than 12 percent of the projected farm price of corn for 1999/00 and less than 17 percent of the projected farm price of soybeans. However, if the standards require extremely strict identity preservation (IP), the costs of segregation and production could approach, or even exceed, 66 percent of the projected farm price of corn for 1999/00 and 54 percent of the projected farm price of soybeans.

Second, the costs to the United States are greater, the more suddenly the standards are invoked and the smaller the supply of non-GM products available on world markets. If promulgated without prior notice, a non-GM standard for soybeans, for which available non-GM supplies are less than EU demand, could be highly disruptive, particularly in the short term. The immediate response would be an increase in the price of non-GM products and a reduction in prices of GM and non-segregated non-GM products. Over time, however, as the supply system responds, non-GM prices would decline and GM prices would rise until the price differential converged to a non-GM premium which reflected additional production, segregation, and transportation costs. The current impasse on approvals of GM corn varieties, by contrast, probably has little effect on the EU or the United States, because trade can be rerouted.

1. Estimates of Additional Costs for non-GM Products

Estimates of additional handling costs for specialty crops provide a basis for estimating the additional segregation costs for non-GM corn and soybeans. Using survey data, Bender et al. report the additional costs of handling specialty corn and soybeans, consisting of high-oil corn (HOC), Synchrony Treated Soybeans (STS), and various food corns and soybeans.[1] Their report provides ballpark figures for current discussions about product segregation and IP in other arenas, such as non-GM corn and soybeans. However, the analogies are imperfect. For example, the estimates in Bender et al. pertain to niche-market products. Additional handling costs could be substantially lower for relatively high-volume products, owing to economies of scale. Other factors, as discussed below, could nudge the estimates upward.

The costs of segregation depend, in part, on the level of tolerance established for deliverable products. For example, if a purchaser were to set a strict zero tolerance level for GM varieties, it could be very costly for suppliers to segregate sufficiently to meet the standard -- particularly for corn where the potential for cross-contamination from other fields, conveyances, and storage facilities is high. Generally, the more stringent the

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1. See Karen Bender, Lowell Hill, and others at the University of Illinois, Urbana-Champaign in, *Alternative Market Channels for Specialty Corn and Soybeans* (AE-4726, Feb. 1999).

standard, the higher the cost of segregation. As used in this analysis, IP is defined as a rigorous form of segregation, associated with a very low tolerance threshold. Under IP, segregation by variety would be done strictly throughout the entire handling and distribution system. Shipment might be done by container, as in the case of tofu-grade food soybeans exported to Japan.

A. Estimates of Segregation Costs for Corn and Soybeans

Estimates of additional segregation costs for non-GM corn range from 10 percent to 63 percent of the projected price for 1999/00. For a single point in the distribution chain, Bender et al. report additional costs ranging from 6 cents per bushel for HOC to 39 cents per bushel for various types of food corn.[2] If these costs recur at two other points in the chain, e.g., the sub-terminal or export elevator, the total additional costs would range from 18 cents per bushel to $1.17 per bushel. The cost at the high end of the range may be reflective of a greater degree of stringency afforded to certain kinds of food crops, akin to IP. For HOC, the total additional cost would amount to about 10 percent of the average projected farm price of $1.85 per bushel of corn for 1999/00.[3] For food corn, the additional cost would amount to about 63 percent of the average projected farm price.

Estimates of additional segregation costs for non-GM soybeans range from 13 percent to 43 percent of the projected price for1999/00. For a single point in the distribution chain, Bender et al. report additional costs ranging from about 18 cents per bushel for STS, to about 61 cents per bushel for various kinds of food soybeans. If these costs recur at two other points in the chain, e.g., the sub-terminal or export elevator, the total additional costs would range from 54 cents per bushel to $1.83 per bushel. As above, the cost at the high end of the range may be reflective of a greater degree of stringency afforded to certain kinds of food crops, akin to IP. For STS, the total additional cost would amount to about 13 percent of the average projected farm price of $4.30 per bushel of soybeans for 1999/00. For food soybeans, the additional cost would amount to about 43 percent of the average projected farm price.

Cost estimates provide rough indicators. The actual costs of segregation could be lower or higher. Several competing considerations come into play. First, the total additional costs are derived from a simple multiplication of the costs for a single point in the distribution channel, often the first handler. This approach may overstate the total, because the costs of segregation may decline after the initial separation. Second, high-volume non-GM transactions could convey significant economies of scale. These two considerations suggest that the costs could be lower, but other factors could offset some of these reductions. Third, USDA notes that all GM-testing methods available to date are geared to a specific protein level or DNA sequence. Thus, separation requires one test for each specific genetic modification. Such testing costs may be higher than those identified in Bender et al. Fourth, for corn, a two-tier segregation process could result in higher handling costs.

B. Estimates of other costs in the distribution chain

Additional costs also arise at the farm level. The overall costs to the farmer of planting non-GM varieties are the foregone benefits of adopting GM varieties and any additional costs of segregating products. For early adopters, net cash returns from Roundup Ready soybeans have been estimated anecdotally, at $10 to $25 more per acre than from non-GM varieties. Based on an approximate yield of 50 bushels per acre, producers would have to receive cash prices for non-GM varieties of 20 cents to 50 cents per bushel higher than for GM varieties to consider switching. From a slightly different perspective, Dupont-ADM reported a farm-level price premium of 18 cents per bushel for STS soybeans in 1999 and Consolidated Grain reported a premium of 5 cents per bushel for

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2. As presented here, in section (A), the reported additional costs arise primarily from storage, handling/segregation, risk management, transportation, analysis/testing, and marketing. Bender et al. also reports purchasing costs, including price premiums. These premiums are potentially reflective of the additional costs accruing at the farm level. These costs are addressed separately in section (B) below.

3. For price projections, see USDA, *World Agriculture Supply and Demand Estimates*, July 12, 1999.

non-GM corn.[4] In a highly competitive and well-established market, the price premium would just offset the additional farm-level costs, but in a thin and newly established market it is more difficult to interpret the figures precisely.

Other costs may arise after export. Another potentially important consideration is the degree to which exports can be certified at origin to meet a specified delivery standard and that certification recognized and honored by the importing country. Testing at the port of entry can lead to substantial costs because of potential demurrage charges incurred while the shipment awaits the results of the test and the potential losses if the shipment were to be rejected. The net effect would depend, in part, on when the buyer takes possession and the risk-sharing arrangements specified in purchase contracts.

2. Analysis of Corn Markets

Production and trade. The United States accounts for a significant share of world production and exports (see Table 1). In 1998/99, the United States produced an estimated 248 mmt of corn, amounting to about 42 percent of total world production. GM varieties may account for as much as 35 percent of U.S. corn acreage, but planting decisions can be altered from year to year. The United States is also the single largest corn exporter in the world market. In 1998/99, the U.S. exported an estimated at 49 mmt of corn, amounting to about 67 percent of total world exports. The United States is also a significant producer and exporter of corn gluten and meal. Other major suppliers of bulk corn include Argentina, which grows only EU-approved biotech corn or non-GM varieties. Argentina produced about 14 mmt of corn in 1998/99, of which it exported almost 9 mmt. The EU, which produced an estimated 34 mmt of corn in 1998/99, engages in trade as both an importer and exporter. On net, however, EU imports typically account for only a small fraction of total world imports. For 1998/99, the EU=s net imports of corn are estimated at less than 3 mmt.

EU policies probably have little net effect on corn markets. Until recently, the United States accounted for a significant share of the EU's net corn imports.[5] In 1997/98, U.S. exports to the EU dropped precipitously because of marketing difficulties arising over the slow pace of the EU=s approvals of GM corn. In the absence of U.S. supplies, however, the EU imports >acceptable= corn from other sources, such as Argentina and Eastern Europe. Re-routing probably results in slightly higher transportation costs, but likely has little net impact on the volume of trade. Because the EU has many potential alternative sources for feed grains, it is unlikely that non-GM corn will carry much premium to GM varieties.

Some corn products may be at risk. Corn gluten feed is a by-product of the wet milling process used to make products such as high fructose corn syrup and ethanol. The United States is expected to wet mill about 1.3 billion bushels of corn in 1999/00, yielding an estimated 7.4 mmt of corn gluten feed. Of this, more than 70 percent is typically exported to the EU. To date, the EU has imposed no restrictions on corn gluten feed imports. Earlier this spring, however, two large corn processors, A.E. Staley and ADM, announced that they would not accept GM corn varieties that had not been approved in the European Union. The market for corn gluten feed and meal is more problematic than the market for bulk corn because these products are feed substitutes. If the EU market were closed to U.S. corn gluten feed exports, it is likely that most of the U.S. corn gluten feed would be fed domestically and would compete with other protein feed stuffs, thus driving down domestic prices.

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4. Bender et al. report farm-level price premium of 12 cents per bushel for high-oil corn, 35 cents per bushel for food corn, 15 cents per bushel for STS soybeans, and $1.07 dollars per bushel for food soybeans.

5. As part of the compensation for their accession to the EU in the mid-1980s, the EU established a tariff rate quota for corn exports to Spain and Portugal of 2.5 million tons. The tariff rate quota is offered on a most favored nation basis, but its operation by the EU has historically favored the United States. The EU typically opened the tariff rate quota in late November and December. Since Argentine supplies were usually exhausted by the early fall, the United States was the main beneficiary of the quota.

3. Analysis of Soybean Markets

Production and trade. The United States accounts for a significant share of world production and exports (see Table 2). In 1998/99, the United States produced an estimated 75 mmt of soybeans, amounting to about 48 percent of total world production. GM varieties may account for as much as 50 percent of U.S. soybean acreage, but planting decisions can be altered from year to year. The United States is also the single largest soybean exporter in the world. In 1998/99, the U.S. exported an estimated at 21 mmt of soybeans, amounting to about 54 percent of total world exports.[6] The United States is also a significant, though less prominent, producer and exporter of soybean meal. Other major suppliers of soybeans and soybean meal include Argentina, which has approved GM soybeans, and Brazil, where GM soybeans are being currently considered for approval. Argentina produced about 18 mmt of soybeans in 1998/99 and Brazil produced another 31 mmt. The EU, which does not produce substantial quantities of bulk soybeans, is expected to import about 16 mmt of soybeans in 1998/99. Roughly 40 percent of the EU=s imports originates in the United States.

Advance warning is important. A stringent standard could be highly disruptive, especially in the short term. As a practical matter, it might block exports from countries that produce both GM and non-GM varieties. Without adequate notice, the United States and Argentina would likely divert exports to other markets, but hold some production in storage until the next marketing year. Brazil, Eastern Europe, and other non-GM suppliers could step in to fill some EU demand, but substantial re-routing may be unrealistic on short notice. On balance, trade would likely diminish. However, with adequate notice, GM and non-GM suppliers might be able to shift their trade routes more fully. Brazil currently produces about twice as much soybeans as the EU imports, but consumes about 70 percent of its crop domestically.[7] If Brazil and other non-GM suppliers were to increase their production and exports, they could satisfy EU demand, but the shift would be substantial. With this shift, there would be enough >acceptable= non-GM soybeans to meet EU demand -- even without segregation in the U.S. or other distribution systems. However, if Brazil were to approve GM technologies, segregation could become necessary, as there might not be enough >acceptable= soybeans to meet EU demand. To the extent that re-routing alone did not suffice to meet EU demand, neither the United States nor Argentina could likely develop segregation systems rapidly enough to service the EU in the near term. Uncertainty about an EU standard could further complicate the adjustment.

Initially, U.S. prices would fall. Table 3 shows possible effects in the United States of a substantial decrease in soybean exports. If U.S. exports were to fall by 25 percent, prices could fall by as much as 30 percent. However, as discussed above, some re-routing would likely occur -- even in the short term. Brazil could increase its exports to the EU, thus leaving other markets for the United States and Argentina to fill. Because of these substitution effects, a halt in EU imports of U.S. and Argentine soybeans would likely result in a smaller drop in total exports. Even with a 10 percent decline in exports, U.S. market prices for GM soybeans could fall by as much as 14 percent or about 60 cents per bushel.

At the same time, prices would rise in the EU. Table 3 does not incorporate the effect of the standard -- and the attendant market disruption -- on prices in the EU, but this effect could be significant. If Brazil and other non-GM suppliers cannot meet EU demand, as seems likely on short notice, the price of oilseeds in the EU will rise. EU consumers would lose, because of higher prices, and non-GM suppliers would gain.

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6. Roughly 30 percent of U.S. exports go to the EU, amounting to about 6.4 mmt of soybeans.

7. Brazil currently exports about 30 percent of its production. If it were to increase this share to 50 percent it would offset EU demand. As Brazil would likely need to import some soybeans from GM suppliers to meet domestic demand, it could be difficult for Brazil to prove that GM and non-GM products had not been co-mingled.

Eventually, markets would adjust, at least partially. Markets would respond to the EU=s >price premium.= In the long term, prices would reflect any additional transportation costs, and possibly some additional production and handling costs. If GM and non-GM suppliers can re-route their trade to meet EU demand, the costs of transportation would rise, but there would be no other significant market effects. The overall impact on trade would be small. If re-routing were not sufficient, segregation might occur -- if the price premium were large enough to offset any additional production and handling costs. To the extent that segregation did occur, EU consumers would absorb some of the additional costs in the form of higher prices, but -- after the market adjusted -- the difference in the price of GM and non-GM soybeans would be no greater than the difference in production and handling costs.

U.S. farm programs could interfere with market adjustment. At present, U.S. soybean producers would be largely insulated from a drop in soybean prices. The marketing loan provisions of the 1996 Farm Bill allow producers to place their crop under loan and repay at world prices. Because prices are now under the loan rate, producers would have little incentive to switch to non-GM varieties. As prices rise above the loan rate, however, some or all of the price difference between GM and non-GM varieties would be transmitted to U.S. producers. If the premium for non-GM varieties were sufficiently large, i.e., to compensate for any differences in production and handling costs, U.S. grain and oilseed handlers could develop segregated distribution channels for EU exports.

Table 1. World Corn Supply and Use, 1998/99
(Estimates in Million Metric Tons)

	Production	Imports	Exports	Net Exports*
World	592.53	73.35	72.71	n/a
United States	247.94	0.51	48.9	48.39
Total foreign	344.58	72.85	23.81	-49.04
Major exporters	20.3	0.85	8.7	7.85
Argentina	13.8	0	8.5	8.5
South Africa	6.5	0.85	0.2	-0.65
Major importers	93.43	48.16	11.04	-37.12
EU-15	34.49	11.16	8.61	-2.55
Japan	0	16.5	0	-16.5
Mexico	17.5	5.25	0.05	-5.2
Southeast Asia	15.65	2.5	0.2	-2.3
South Korea	0.08	7.75	0	-7.75
Other	25.71	5	2.18	-2.82
Selected other				
China	124	0.25	2.5	2.25
FSU-12	5.29	0.7	0.45	-0.25
Russia	0.8	0.65	0	-0.65

*Negative numbers indicate net importer

Source: USDA, *World Agriculture Supply and Demand Estimates*, July 12, 1999

Table 2. World Soybean Supply and Use, 1998/99
(Estimates in Million Metric Tons)

	Production	Imports	Exports	Net Exports*
World	157.19	39.95	39.62	n/a
United States	75.03	0.11	21.36	21.25
Total foreign	82.16	39.84	18.26	-21.58
Major exporters	52.4	1.5	15.1	13.6
Argentina	18.3	0.9	3.1	2.2
Brazil	31	0.6	9.5	8.9
Other	3.1	0	2.5	2.5
Major importers	17.28	31.24	1.51	-29.73
EU-15	1.54	17.12	1.34	-15.78
Japan	0.16	4.7	0	-4.7
China	13.8	3.6	0.18	-3.42
Other	1.78	5.82	-0.01	-5.83

*Negative numbers indicate net importer

Source: USDA, *World Agriculture Supply and Demand Estimates*, July 12, 1999

Table 3 B Possible Effect of a Decrease in Soybean Exports, 1999/00 Crop Year

Item	Unit	Reduction in Exports		
		0 percent	10 percent	25 percent
Exports	Million bushel	930	837	698
Total use	Million bushel	2,744	2,674	2,564
Price	$ per bushel	4.30	3.70	3.00
Value of production	$ million	12,620	10,860	8,805
Marketing loan outlays	$ million	3,150	4,820	6,584
Gross income	$ million	15,770	15,680	15,389
Cash expenses	$ million	9,543	9,543	9,543
Net income	$ million	6,227	6,137	5,846
Change in net income	$ million	0	-90	-381

Source: USDA analysis using Data from *World Agriculture Supply and Demand Estimates*, July 12, 1999.

September 13, 1999

MEMORANDUM FOR: Lael Brainard

FROM: Peter Scher

SUBJECT: Views on Biotech Labeling

Per your request, this is to provide our views on the State Department paper on labeling, which was apparently cleared interagency.

We face two key problems on ag-biotech. The most immediate problem is the roughly $200 million of annual sales of corn grain we are losing in the EU. These are sales into quotas for Spain and Portugal which were established to compensate the U.S. at the time of the accession of those two countries into the EU. We lost those sales in 1998, are losing them in 1999, and will continue to lose them until the EU's approval process is operating again which could be another 2 or 3 years according to the EU Commission. You recall that we outlined this problem in the letter from the POTUS to Prodi. We are losing these sales because we have several corn varieties commingled in our exports which are not yet approved in the EU. Labeling does not address this problem.

The second problem is that the approval process for agricultural biotech products in the EU has collapsed. No new products have been approved since April 1998, and the EU Commission has told us it will likely be 2 or 3 years before it is operating again.

The State paper correctly notes as its first "con" that labeling will not provide access for U.S. products. The EU is not basing its moratorium on science but on politics. In essence, what EU leaders are saying is that until the public can be convinced that ag-biotech products are safe, they have no intention of taking on this issue. Revision of EU Regulation 90/220, which the EU has been promising for over four years, will not occur until the EU leadership believes that it is politically safe to do so. This is clear from the current EU Environmental Council's criteria for ag-biotech products – proof of no health or environmental risk – and the way none of the incoming Commissioners has been willing to take responsibility for this issue.

Labeling – either mandatory or voluntary – will not resolve this issue by itself at this time for at least three reasons. First, in the UK retailers have been removing GMO-containing products from their shelves whether or not they are labeled. Clearly the problem in the UK has gone

beyond labeling. Second, while the EU enacted regulations last year mandating labeling, they have never agreed on the implementing regulations. They need to set a threshold level above which labeling would be required and they need to specify acceptable testing methodologies. In the absence of implements regulations, members states are not enforcing labeling. Third, the U.S. distribution system is not now capable of segregating and testing most biotech products. Therefore, U.S. attempts to label products now would neither achieve U.S. goals of market access nor be effective.

The beef hormone dispute provides ample evidence of the EU's approach. Despite decades of research (including EU) showing such products to be safe and U.S. offers to label such products, the EU leadership declares that the ban will never be lifted (and concocts "evidence" to prove its case).

It is worth noting that the labeling issue is very likely a temporary problem. As the industry moves to the next phase of products with direct consumer benefits, they will of course label these products to attract consumer attention.

What should we do?

First, we should continue to work in international organizations, such as CODEX and the OECD. This work could be useful in developing an internationally agreed approach.

Second, we should work with other countries which pursue labeling to assure that any labeling requirements are consistent with international obligations, especially the TBT Agreement.

Third, we should engage EU officials, particularly new President Prodi. We need to stress that we want to work constructively and cooperatively, but that we cannot just wait and hope that the European public will someday accept these products.

Fourth, we should not interfere with private sector decisions to segregate products. That is, to some extent, the market is sorting out the problem in the short-term. These private sector decisions may weaken resistance to labeling.

Fifth, we should demonstrate to the EU and to others that the EU's criterion for ag-biotech products ("no risk) is impossible for this or other products. We could demonstrate that this criterion applied to other products (e.g., eggs, poultry, pigs, tomatoes) would mean that the EU public should not eat anything.

Drafted by: R.Ives/9-13-99

FYI

Tom will talk to you about

GMOs- Multilateral Trade & Biosafety Protocol Strategy
Deputies Meeting
July 30 1999, 11:30 a.m.
Roosevelt Room

Agenda

I. Review Options for Strategic Approach to Multilateral Trade Talks

- APEC
- WTO
- FTAA

II. Current Strategy/Posture for Biosafety Protocol Negotiations

III. Review of Agencies' Public Outreach on Biotechnology

FOOD SAFETY - GMO's

SENSITIVE - PRE-DECISIONAL

BIOTECHNOLOGY AND TRADE: THE NEXT STEPS

Summary:

This paper summarizes recent discussions on biotechnology and trade and initiates further discussion with respect to biotechnology in APEC, the FTAA, and the WTO.

Background:

Recent NEC Deputies meetings have addressed several aspects of biotechnology and trade. As has been identified in recent papers for those meetings, there are serious concerns for the immediate trade problems facing U.S. exports to Europe because: (1) the approval process is stalled and decisions are not being reached by the responsible governmental bodies (with no new GMO products approved in the European Community (EC) since April1998), and (2) uncertainty exists regarding compliance with Europe's broad, mandatory labeling requirements.

In early June, the NEC Deputies discussed a paper prepared by the SPS Steering Group which presented a series of options for addressing U.S. export losses resulting from the collapse of the EU's approval system for agricultural biotech products and the EU's labeling regulation for biotech products. At that meeting the Deputies agreed that these issues were best addressed in a broad food regulatory context, because of the integrated nature between food regulation, labeling, education, etc., in providing consumer confidence in food safety.

Recently, NEC Deputies also discussed updates on additional significant developments. Those included the assignment for OECD to undertake a study of biotechnology and other aspects of food safety and to report their findings to the next G-8 Summit in 2000. The Deputies took note of the recent spate of negative press for biotechnology spawned by the reporting of the Cornell University study indicating that pollen from Bt corn is toxic to Monarch butterflies in the larval stage.

At the most recent meeting of the Deputies on the issue of biotechnology and trade, the Deputies discussed both short term and longer term initiatives to address the specific trade issues with Europe where the U.S. is losing corn sales to Spain and Portugal under quotas established to compensate the U.S. for the accession of these countries to the EU. At current corn prices, the value of U.S. losses is $200 million annually. The EC also has enacted mandatory labeling requirements for foods containing genetically modified corn and soybeans but has never established implementing regulations specifying the threshold level above which products must be labeled, acceptable testing methodologies, and a possible negative list of exempted products.

The USG will need to continue to consult widely with both industry and representatives of U.S. consumer-based organizations as we develop strategies on biotechnology and trade. However,

discussions to date with the industry indicate that they have not reached consensus on what direction the U.S. should move. The industry obviously is frustrated by the lack of movement on approvals in the EU and would like the USG to find a way to address that problem. When potential scenarios for hypothetical strategies are raised for discussion, the potential for loss of control of the issue in emotional debate is often a concern raised by industry whether the forum for the hypothetical strategy is WTO, or one of the other trade fora.

Consumer and Environmental Groups want to be assured that any new disciplines that would apply to biotechnology would neither constrain the U.S. regulatory agencies from maintaining high standards in protecting health, safety, and the environment in general, nor would they prevent the U.S. from carefully and thoroughly reviewing the safety of the products of biotechnology.

We expect that in the next several years, GMO products that offer direct benefits to consumers (such as nutritional improvements or reduced fat characteristics) will come onto the market. This may begin to lessen opposition from some consumers in the EU and other parts of the world. Between now and then, however, we can expect an increasing number of countries trying to come to grips with consumer acceptance, labeling and approval processes.

In this paper we raise the issues of strategy within the contexts of APEC, FTAA, and the WTO. The arena of the Biosafety Protocol is not addressed in this paper because it has been discussed separately by the Deputies.

BIOTECHNOLOGY AND APEC

Key Dates: Aug. 5-13 Senior Officials Meeting (SOM) and related meetings

Sept. 9-14 APEC Leaders/Ministers meetings

Discussion:

In the Asia Pacific Economic Cooperation (APEC) biotechnology has been the subject of several initiatives. In the 1997 Ministerial in Vancouver, the following statement was issued: " Recognizing the vital contribution that biotechnology can make toward expanding agricultural and food production, Ministers encouraged the Agricultural Technical Cooperation (ATC) Experts Group to intensify science-based approaches to the introduction and use of bio-technology products." This initiative has led to an extensive series of increasingly substantive technical exchanges. Under this umbrella, organizational meetings were first held in Australia with Chinese Taipei as Co-chair, followed by workshops involving scientific exchange on biotechnology risk assessment in Hawaii, Malaysia, and Japan. The tenor of these workshops has been positive and focused with the oft repeated refrain, "let's keep the focus on scientific

assessment and not politicize this the way it has been in Europe."

In addition to the 1997 Ministerial Statement of the Vancouver Summit and the good technical work initiated by it, biotechnology might be factored in in several other areas of the work of APEC. The APEC Food Systems (AFS) initiative also offers some possibilities. An ABAC (APEC Business Advisory Council) report on AFS contains some useful language on food safety.

Recently Ambassador Carla Hills has been retained by a group of companies with interest in biotechnology to work toward international support for biotechnology in multilateral settings. The work undertaken by industry may strengthen international interest in finding solutions to current trade problems and concerns with biotechnology.

Points for Discussion:

Preliminary interagency staff discussion has surfaced the potential for several initiatives:

- Several activities are already underway in APEC that could serve as a spring board for the biotech issue. The governmental report on AFS will be finalized at the August SOM; we should ensure that it contains the same type of positive language that was included in the 1997 Vancouver Minister's Declaration.

- USTR is working with USDA and State to develop a strategy for getting a positive statement on biotech in the Leaders/Ministers Declaration in September, possibly combined with the launch of a higher visibility work program in APEC that would be supportive of a science-based approach to biotech.

- Once an approach is agreed with State and USDA (which should be before the August SOM), we should recommend to Hills and company that they build this into their industry presentations in the Asian area. In broad terms, we need to develop some strong biotech supporters among the developing APEC countries (especially ASEAN), solidify the position of like-minded countries like New Zealand and Australia, and pull Japan back from its current drift towards the EU position.

- A stand-alone task force has been proposed to focus more on the policy aspects of biotechnology not currently addressed by the ACT workshops. Pro: it would bring additional visibility to biotechnology; Con: it might take the discussion away from science-based approaches where it has been, to biodiversity, intellectual property concerns, and ethical issues, which have not been the focus of the discussion in APEC.

BIOTECHNOLOGY IN THE FTAA

SENSITIVE - PRE-DECISIONAL

Key Dates: Sept. 1999 Ag Group concludes annotated outline

Nov.3-4,1999 FTAA Ministerial

Nov.1999 EU-Mercosur Senior Negotiators meeting

Jan. 2000 Ag negotiations resume

Discussion:

Given that there has been no discussion of biotechnology within the Negotiating Group on Agriculture or the Negotiating Group on Market Access, it is not feasible to introduce biotech into the annotated outline. This does not preclude introducing it into the negotiations in 1999. However, as we have learned with E-Commerce, it takes substantial time and educational effort to develop a consensus on a U.S. high-tech topic that is not well-understood by the Latins; their initial reaction is suspicion that we are pushing an initiative that will give us even greater advantages in dominating the region's economy.

For the same reasons that it is not feasible to include biotech in the annotated outline, it is not possible to include biotech in the Ministerial Declaration. Trying to cram Declaration language down the throats of our trading partners will only make it more difficult to bring them to our side of the debate.

Industry initiatives to explore solutions in multilateral trade instruments (see discussion in APEC background above) may provide a tool for private diplomacy to augment the efforts of the government in seeking multilateral solutions, including in the FTAA.

Points for Discussion:

- We could recommend to industry representatives that they should begin laying the groundwork on biotech among the principal like-minded Latin American countries, especially the larger agriculture producing countries (e.g., Brasil, Argentina, Chile). These countries are concerned that their agricultural products will be shut out of the EU if they use genetically-engineered materials. They need to be convinced first of the safety and much greater productivity of using biotech products; then we have an opportunity to enlist them on the side of open trade for biotech products and the agricultural output from such products. We also should stress that a receptive trade policy position on biotech will be an essential ingredient in attracting research efforts on developing products suitable to local agricultural conditions.

- The USG could also start raising this issue bilaterally with the larger agricultural

producing countries. Argentina has already staked its position that biotechnology trade issues should be addressed through current rules in TBT, and when appropriate SPS, and they have made it clear that they do not support raising the issue in FTAA or the WTO in the upcoming negotiations.

BIOTECHNOLOGY IN THE WTO

Key Dates:	July 28 - 29	Papers submitted to WTO General Council
	September	Ag portion of Ministerial Communique "teed-up"
	Oct. - Nov.	Further discussion/negotiation of Ministerial Statement
	Nov. 29 - Dec 3	WTO Ministerial - Seattle

Discussion:

At the WTO General Council meeting this week, the U.S. tabled a paper that sets out an objective for the next round that the negotiations address disciplines to ensure trade in agricultural biotechnology products is based on transparent, predictable and timely processes.

The paper further notes that production and trade of agricultural biotechnology products have increased dramatically in recent years as new technologies have reduced costs, increased yields, and enhanced beneficial characteristics of food and fiber products. This trend will continue as more biotechnology products with more beneficial characteristics are commercialized, and as the reduction in protection and support increases trade in agricultural products. It is critical that decision-making for these products be transparent, predictable, and timely to meet the long-run objective of a fair and market-oriented agricultural trading system as well as helping ensure sufficient agricultural production to meet the world's needs.

The U.S. paper further notes that while extensive trade in agricultural biotechnology products is a relatively new characteristic of international trade, the basic issues related to this trade are already covered under the WTO framework. For example, the Agreement on Agriculture identifies the long-term objective "to provide for substantial progressive reductions in agricultural support and protection sustained over an agreed period of time, resulting in correcting and preventing restrictions and distortions in world agricultural markets" and establishes specific disciplines on non-tariff measures. More generally, the WTO agreements are predicated on reducing trade restrictions in agriculture and on ensuring all measures are transparent and do not create unnecessary or arbitrary barriers to trade. These goals are in the interests of producers (to have fair competition in the marketplace) and consumers (to ensure

transparency and protection against identified hazards.)

Other papers with reference to biotechnology may be tabled this week by other delegations. If this occurs the shape of the debate may come into clearer focus. Other Members have at least floated ideas or positions on the margins of other multilateral and bilateral discussions. For instance, representatives of Canada have talked up the idea of a "Working Party on Biotechnology" (but with very little in the way of specifics). Representatives of Argentina have made clear their position that it would be a mistake to raise biotechnology for substantive negotiation in the WTO, given the very negative position of the Europeans. Rather they argue it would be better to apply the current disciplines of TBT and SPS and ride out the current wave of negative public opinion. They argue that any actions suggesting we are forcing products on consumers against their will are counterproductive. Rather, we should expedite the introduction of products which have perceived direct benefit to consumers and let the market right itself.

Points for Discussion:

* Some have proposed a "Biotechnology Working Party or Task Force" in WTO. This would presumably include both the aspects of reviewing the application of current obligations and disciplines as well as identifying perceived gaps in the current disciplines. In some iterations of this idea it has been suggested that the group could function in some ways as a negotiating group to initiate solutions to perceived gaps in coverage of current disciplines. It may not be possible to keep such a group focused on the problem at hand. Such an independent group might wish to address IPR issues, including discussions of access of have-nots to the technology. The perennial issues raised by some of linkage of biotechnology to bio-diversity and ethics concerns will inevitably be raised in such a forum.

* Some have floated a proposal intended to address the specific problem of access by the U.S. to Europe because of the failure of timely product approvals by the E.C. That proposal would build on the current disciplines of the TBT and SPS, but would seek an understanding or clarification of Annex C of the SPS Agreement, which states that: "1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products." In particular, it is suggested that it might be possible to negotiate a more precise understanding of the term "completed without undue delay" that would constrain the E.C. from its current failure to complete timely approvals for new biotech products. Clearly, any proposed language would need careful consideration to maintain the necessary authority of our regulatory agencies to fulfill their obligations under U.S. law with its administrative procedures for public involvement.

* Some have suggested rather than making a very specific proposal for textual changes or

formal understandings, that the U.S. should insist that the issue of biotechnology and other new and emerging technologies be considered and accommodated in the next round in all appropriate contexts. Under this approach the U.S. might wish to highlight the new technologies and state specific objectives for the negotiations as has been done for biotechnology, but not too quickly choose a vehicle for meeting the objective that might forestall other options.

* It will be essential to carefully review any other papers referencing biotechnology submitted this week to the WTO General Council to understand the initial positions of our trading partners on biotechnology. Out of that should come more specific proposals for U.S. positions which would be vetted through the TPSC and other interagency processes. Some of the potential courses of action suggested by other Members may bear additional scrutiny.

Drafted: Payne 395-9558 7/28

SENSITIVE - PRE-DECISIONAL

ATTACHMENT

UPDATE ON FOLLOW-UP ACTIVITIES ON BIOTECHNOLOGY AND TRADE

Below is a brief status summary of follow-up activities from previous NEC Deputies meetings that build on current U.S. policy. (After each activity, lead agencies or suggested lead agencies are indicated.)

Responding to Immediate Trade Losses to Europe:

1. Ambassador Barshefsky will follow-up on her June 1998 letter to Sir Leon Brittan regarding the loss of U.S. corn sales to Spain and Portugal. As a concession to corn exporters upon the entry of Spain and Portugal into the European Union, the EC negotiated corn quotas for Spain and Portugal in 1987. Although established on an MFN basis, the quotas were negotiated to open at a time when the United States is the predominant exporter. Since 1998, U.S. exporters have been unable to compete fully in import tenders because of the EC's failure to approve certain GMO corn varieties that have received approval in the United States. Given the results of the Environmental Council, it's likely that GMO approvals in the EU will be suspended for several years. The United States should therefore, in consultation with the U.S. corn industry, consider a renegotiation of this concession since U.S. corn exports look to be effectively shut out of the Spanish and Portugese markets for the foreseeable future. (USTR)

2. The USG will ask EU President-designate Romano Prodi to meet, or to designate his chef de cabinet to meet, with appropriate USG officials to consult on the point above. We would also seek Prodi's commitment to defining an overall Commission approach to biotechnology and, in particular, to removing the political blocks to products sown in the United States but currently stuck in the 90/220 pipeline. Seven products – five corn varieties and two cotton varieties – have received scientific clearances but are not moving to the next step in the approval process because of political sensitivities. (USTR, State)

3. Intensify work with U.S. domestic producers to ensure they are making realistic planting decisions concerning GMO crops with an eye towards market and regulatory conditions in overseas markets. (USDA, USTR)

Emphasis on Science & Consumer Education:

4. Implement the pilot project under the TEP Biotechnology Group as agreed to at the U.S.-EU Summit. The pilot project is designed to engage the EU on its regulatory processes for biotech approvals with a view to underpinning and strengthening

transparency and the importance of independent scientific credibility. The first phase of the pilot project – a comparison of certain environmental review processes in the U.S. and the EU that have already been carried out on bioengineered plant varieties – is targeted for completion in March 2000. (USTR)

5. Redouble efforts to assure that credible scientific information is reaching consumers in major trading markets, such as posting timely information on the basis for U.S. regulatory decisions on Internet web sites. (APHIS, EPA, FDA)

6. Continue the dialogue, started as a result of the Glickman/Scher meeting with the French Minister of Agriculture, to enlist the assistance of France to simplify and reform the EU's regulatory approval process for biotech plant varieties and also to seek clarification on France's position on labeling and traceability. (USDA, USTR)

7. Develop a communication strategy to educate consumers about the safety of GMO crops and products, with emphasis on opinion leaders with credibility with EU consumers. (State)

8. Continue to encourage and support establishment of a science-based European Food Safety Agency. Offer support from our own experts on food regulatory regimes and reforms. (State, USTR)

9. At the G-8 Summit, leaders tasked the OECD to undertake a study of biotechnology to report their findings to the next G-8 Summit in 2000. (State, FDA, USDA, EPA, USTR)

10. Propose to Mr. Prodi and the new Finnish presidency that the U.S. National Academy of Sciences and an equivalent group in the EU cooperate to conduct a study on the impact of biotechnology on agriculture and the development of new foods. (OSTP, State)

Work in International Organizations:

11. At the Codex Commission meeting (June 23 - July 3), the an ad hoc Working Group on Biotechnology was established to develop food safety assessment guidelines. The U.S. will work with the host country, Japan, to facilitate the work of the group to support science-based regulatory processes in the Members of Codex. (US Codex)

12. Continue to pursue in the Codex Committee on Food Labeling, and other fora, a discussion of labeling policies that promote "truthful and non-misleading" consumer labeling. (US Codex, FDA)

13. Continue to support the work of the OECD experts group on biotechnology, particularly in light of the charge to the OECD from the G-8 Summit. (USDA)

14. Table in Geneva, the interagency cleared position on objectives for new agricultural technologies (including biotechnology) and work to have it included in the content of the Seattle Ministerial declaration regarding the objectives of the WTO negotiations. (USTR)

Labeling:

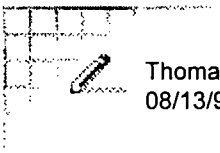
15. Work with industry to explore the feasibility of an industry sponsored voluntary labeling scheme with marketing tools such as logos and consumer information, all targeted for the European market. (USDA, FDA)

16. Focus discussion of labeling with the EU on developing appropriate criteria (*e.g., de minimis* levels) and standards for testing and validation that are workable. Raise with appropriate countries, uniform enforcement of truthful labeling where claims are made of " GMO free" status. (FDA, USDA, USTR, State)

17. The USG will continue to work in international fora for science-based labeling similar to that instituted in accordance with the Federal Food, Drug, and Cosmetic Act; and to oppose new mandatory labeling schemes for food and food products solely on the basis of products being derived through modern biotechnology. (US CODEX, FDA)

Updated: Payne 395-9558 (USTR) 7/27/99

FOOD SAFETY - GMO'S



Thomas L. Freedman
08/13/99 11:23:17 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP@EOP, Eric P. Liu/OPD/EOP@EOP

cc: Mary L. Smith/OPD/EOP@EOP
Subject: FW: Biotechnology and foods policy

This is a confidential note from a senior FDA guy that I think makes some sense as a proposal for dealing with genetically modified foods. (The note also lays out the history of the issue in as solid a way as I've seen). I'm just as happy to have NEC deal with this issue -- it has large USTR implications, but this is the path I'll push unless you disagree. Again, he'll appreciate us not circulating this.

---------- Forwarded by Thomas L. Freedman/OPD/EOP on 08/13/99 11:18 AM ----------

WHUBBARD@OC.FDA.GOV
08/12/99 11:10:00 PM

Record Type: Record

To: Thomas L. Freedman@eop

cc:
Subject: FW: Biotechnology and foods policy

Please let me know if you got this.

> -----Original Message-----
> From: Hubbard, William K
> Sent: Friday, August 06, 1999 4:45 PM
> To: 'freedman_t@a1.eop.gov'
> Subject: Biotechnology and foods policy
>
> You asked for more information about the food biotechnology issue, in
> order respond to my call to you about the request from many food companies
> for a meeting on the issue. Here's some background.
>
> The United States is the acknowledged leader in the biotechnology
> industry. Although biotechnology for producing new drugs and vaccines has
> been widely accepted around the world, the use of the technology in
> producing foods has been much less well received. Because such new
> products were being developed for marketing in the early 1990s, FDA, EPA,
> and USDA developed policy statements about how those products would be
> regulated. Essentially, the policy enunciated by FDA for the safety of
> foods produced from biotechnology said that companies did not need to seek
> FDA premarket approval if there was no new food additive involved; thus,
> the firm could "self determine" that it was safe. However, FDA encouraged
> firms to "consult" with FDA on the safety of the food. The policy laid

> out a decision tree for helping the company ensure that it did not need to
> seek FDA approval and that the product was safe (e.g., things like "Is
> there a possibility that an allergic substance is being created?") The
> policy was announced in 1992 with substantial praise by the industry, and
> firms planning to market biotech foods began consulting with FDA as the
> policy said they should. Many consumer groups were critical, saying that
> FDA should require substantial premarket testing and a premarket approval
> by FDA.
>
> USDA's role was to ensure that the development of new seeds from
> biotechnology do not have a negative impact on agriculture, and EPA's was
> to regulate any new pesticides (or environmental impacts) created from
> biotechnology (e.g., the so-called Bt corn that kills certain insects that
> normally consume corn). In developing its policy, FDA said that its
> policy did not need to do an enviromental impact analysis, as required by
> the National Environmental Policy Act (NEPA), because FDA was relying on
> the fact that USDA's oversight of the seed development adequately took
> into account any such impact that FDA would have done. Such analyses can
> be lengthy and costly. [This is why any suggestion by USDA that its
> program may not be NEPA compliant is of concern to FDA, who is being sued
> re: its biotech policy.]
>
> Although FDA and other Federal scientists remain assured
> that the system overseeing biotechnology is adequate, biotech firms are
> having increasing doubts raised about the safety of their products,
> particularly in Europe. Allegations include that the products should be
> labeled, that the U.S. regulatory system is a voluntary "honor" system,
> and that long-term safety of biotech foods has not been established. The
> European attitude could be influenced by several factors (low confidence
> in their regulatory agencies, the fact that the biotech industry is
> dominated by American firms, fallout from the BSE and dioxin scares in
> Europe, historical governmental financial support for an inefficient
> agricultural system that does not favor high yield technology such as that
> introduced by U.S. firms, and perhaps a desire to find an excuse to deny
> imports into Europe of U.S. foodstuffs that compete with European foods).
>
> The Europeans (and many American activists) argue
> that biotech foods should be labeled as being genetically modified
> organisms (GMOs). FDA has said that it has no authority to require
> labeling unless there's a "reason," that is, unless the change in the food
> is a "material fact." But unless the food contains an allergen or some
> other reason to label, no such material fact exists, and FDA cannot
> require labeling that just tells consumer what they "want to know."
>
> After issuing its policy statement on the
> development of biotech foods in 1992, FDA then drafted a proposed
> regulation early in the Clinton Administration to require that biotech
> firms "notify" the FDA of their intent to market a new biotech food. This
> was intended to ensure that firms did indeed consult with FDA before
> marketing such foods. But the industry objected at the time to
> "unnecessary" regulation and the proposal never cleared HHS.
>
> Now, however, the industry is concerned that it is
> increasingly faced with buyer resistance to GMO foods and fears that the

> Europeans may completely close off a major market on the excuse that GMO
> foods are not assured of safety--remember the allegation of a U.S. "honor"
> system. Complicating the situation is that fact that biotechnology "took
> off" much faster in the U.S. than anticipated, and many grain crops are
> now 1/2 or more GMOs. Many grains get so intermingled with non-GMO foods
> that they cannot be sold easily as "non-GMO," so hundreds of millions of
> dollars worth of grain that would normally be exported to Europe goes
> unsold (which is one of the reasons that USDA is so worried about
> biotechnology).
>
> Some options that have been suggested: One is to
> label foods as GMO when they contain products of biotechnology. Such
> consumer "right to know" labeling has been opposed by food processors but
> the biotech industry seems to be reconsidering--ie., that it might be a
> good idea. A second is a "blue ribbon" committee of wise old experts who
> could study and opine that this technology is as safe as the U.S. govt.
> has been saying it is. (But Europeans may dismiss it as "whitewash by
> obviously conflicted U.S. experts") Another is to strengthen the U.S.
> regulatory system.
>
> A way to strengthen the U.S. system would be to dust
> off the 1993 premarket notification proposal that was never published.
> The FDA and Administration could say that there is certainty that all
> biotech foods receive govt. scrutiny under such an approach, which could
> address the vountary honor system allegation. It appears that the food
> processors would now endorse such as reg, and the biotech industry might
> as well (Monsanto, the largest U.S. company, says it would endorse this
> approach already.) It would be necessary, however, to describe why such a
> requirement is necessary now yet wasn't 5 years ago. [Of course, if a
> firm goes to market with a biotech food and doesn't consult with FDA
> under the current policy, all Hell may break loose that it is "proof" that
> the honor system doesn't work.] Obviously, further strengthening of the
> U.S. regulatory system is possible, such as greater study and premarket
> approval by FDA, but the industry would not likely support such a costly
> approach.
>
In any event, a number of major media
stories are about to come out on this issue, so it would be beneficial to
get out ahead of those with some sort of strategy.

August 16, 1999

FOOD SAFETY - GMO's

To: Tom Freedman, DPC

Fr: Keith Pitts, USDA

Re: GMO Labelling

After two years of immersion in the biotechnology and a lot of serious thought concerning agricultural biotechnology, the Secretary's thinking has evolved from being a very high profile OPPONENT of GMO labelling to being a PROPONENT of GMO labelling. The issue is, as you know, very complicated and cannot be dispatched with quickly—e.g. whether to approach this from a "GMO-free" perspective or from a "Contains GMO Corn/May Contain GMO Corn" method has not yet been resolved in our ongoing internal discussions. Before laying out what we are doing to be more capable of understanding, considering and finalizing internal discussions, within USDA, on this issue, let me raise a few points on why the Secretary has become more vocal about the future of ag-GMOs and the need to promote labelling.

1) Many important trading partners, competitors and markets are either mandating GMO labelling (the EC) or have stated their intentions to require GMO labelling (Australia, New Zealand, Brazil, Japan and South Korea—many of which are major ag-biotech developers)

   Without a doubt, US exports will be labelled to comply with these foreign market requirements. USDA sees no plausible explanations that we can provide to US consumers about the lack of labelling at home when we are doing it to comply with foreign market regulations. We strongly believe any differentiation between domestic and export markets would very easily be used to fan concerns/suspicions about the US regulatory system—e.g. "Is the government trying to hide something from me by refusing to endorse GMO labelling, while their doing it for US exports?"

1) Consumer right to know—even though we're absolutely, positively and scientifically backed in our assessments that existing products are safe for human consumption, some US consumers for deeply held, personal beliefs will be strongly opposed to this technology and its use in food production. In our opinion they deserve information and options to support their decision not to support the technology. Our assessments concerning long term environmental impacts are not quite as unequivocal. As you know, issues do continue to "pop" up—e.g. insect resistance, Monarch butterflies, and the regulatory system needs to better quantify, and where necessary mitigate, these complex concerns. Some consumers will also want to "choose" on the basis of these concerns. We're going to be hearing a lot more about GMOs from domestic consumer groups—the US will not remain totally immune to the happenings in Europe.

1) Our current negotiating posture of very limited GMO labelling really prevents the US government from shaping the outcome of what will inevitably be a international GMO labelling scheme—right now the EC, with Australia, New Zealand, Brazil, Japan and South Korea soon behind are shaping this debate. There is growing concern at USDA that important decisions about how information can be accurately conveyed; about how GMO thresholds and detection methods can be best established (and enforced), and about how to maintain smoother channels of trade for both GMO and non-GMO crops can be developed are being made or ignored without meaningful US input. We've either got to find a happ(ier) medium with the EC or file a trade disupute regarding GMOs at the WTO—USDA would pick the former over the latter. Fish or cut bait, I guess.

The key to labelling will be providing accurate information that cannot be (readily and easily) used to unfairly disparage GMO products—and this will be tricky. It will probably be a combination of 1) taking "high profile" steps to bolster public confidence in the objectivity and scientific underpinnings of our regulatory system—e.g. some of the Glickman-speech initiatives fit this bill , 2) intensive outreach by pertinent regulatory agencies about our decisions related to GMO products and why they are "safe," and finally, and perhaps most importantly, 3) industry actively quantifying and promoting GMO product benefits actively quantifying and promoting GMO benefits rather than hiding behind the US government regulatory system and somewhat nebulous "sound science" arguments.

To gear up for these discussions, we've quietly started some projects at USDA for our own edification: 1) OSEC has asked USDA Economic Research Service to expand the current NEC/ERS study on the cost-benefit of market segregation to do a similar analysis for c-b analysis for some GMO labelling options—Susan Offut, ERS Administrator, recently did a very good presentation on other labelling schemes (nutritional, dolphin safe, organic) for the cage, and believes the underlying information used to do the market segregation study could readily support a c-b analysis for GMO labelling scheme(s). 2) OSEC has asked the Undersecretary for Marketing and Regulatory Programs (APHIS, Federal Grain Inspection Service, Agricultural Marketing Service, etc...) to develop a white paper on how to approach, both scientifically and programmatically, an appropriate "threshold of regulation" for GMO traits—whether for trade, honest marketing for growers, organic produce contamination, etc...as you know, countries that have chosen the mandatory labelling route continue to struggle over this particular problem with GMO labelling. And, finally, 3) an FY2001 budget crosscut on biotechnology to adequately explore and articulate resource needs for the technology—particularly some of the newly announced USDA initiatives on biotech.

In a nutshell, USDA believes we're stuck in a rut on this technology—and without stepping into new directions that can demonstrably build public confidence in the

technology and the systems used to regulate it, we could very easily lose it as a tool for the immediate future—a tragedy in our estimation. There's a lot of room to explore between voluntary labelling and mandatory labelling—the same holds true for the current US posturing vs. the EC posturing. We vote for exploring that middle ground. Unfortunately, if the rumored Biosafety Protocol meetings (this Septemeber) are used by the EC and others to jam us on the basis of our current labelling position, the US will be greatly hampered in shaping the debate leading up to the Seattle WTO. I'm a bit afraid we're a day late and a dollar short under this scenario. Let me know if you need more information. Please use carefully, I haven't had an opportunity to speak with Greg Frazier about this memo to you, but it is an accurate portrayal of the current thinking and discussions in the Cage.

MEMORANDUM ON FOODS MADE THROUGH BIOTECHNOLOGY

PURPOSE

A vigorous debate is under way, both in the U.S. and around the world, about how governments should most appropriately regulate foods and crops made using biotechnology. This memorandum is intended to present the issues surrounding the current debate and provide options for Administration action in this area.

BACKGROUND

Modern biotechnology or bioengineering refers to the use of recombinant DNA and related technologies 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 any other organism, as well as to introduce targeted genetic changes in organisms. The practical effect is to open up vast opportunities for developing new foods with beneficial characteristics such as pest and drought resistance, higher yield, enhanced nutrition and better taste. The United States is the acknowledged world leader in the biotechnology industry. Although the use of biotechnology for producing new drugs and vaccines has been widely accepted around the world, the use of the technology in producing foods has been much less well-received. Indeed, some consumer activists have alleged that these foods are unnatural, calling them "Frankenfoods."

In 1986, the Office of Science and Technology Policy published the "Coordinated Framework for Regulation of Biotechnology," in which the Food and Drug Administration, the U.S. Department of Agriculture, the Environmental Protection Agency, the Occupational Safety and Health Administration, and the National Institutes of Health described their policies for regulating research and products of biotechnology. The underlying premise of the Federal policy was, and remains, that, based on the government's assessment of the science, the regulatory framework that pertains to research and products of traditional genetic manipulation was adequate for research and products of the newer techniques, and that no new laws were needed.

USDA promulgated regulations requiring developers of bioengineered crops to notify USDA before planting such crops in the field. This process was intended to minimize any potential "plant pest" risks that the bioengineered crops might pose to agriculture and the environment. If USDA determined from its review of the resulting data that the crop posed no plant pest risk, it would classify the crop as a non-regulated article and allow it to be planted with no subsequent USDA involvement.

EPA promulgated rules for the regulation of "intergeneric" microbes, as potentially toxic new chemicals, and for the regulation of pesticidal substances introduced into plants. EPA examines both environmental and human health risks of the microbes and pesticides.

FDA promulgated no new regulations but did publish a statement of policy describing how the laws and regulations that FDA enforces pertain to foods from new plant varieties. Essentially, the policy said that new substances bioengineered into foods would be subject to premarket approval as food additives if those substances differed significantly from substances commonly found in the diet. However, FDA also said in the policy that most, if not all, substances then being considered for introduction into foods through bioengineering were substantially the same as other substances found in the diet and as such would not need premarket approval. FDA encouraged firms to consult with it on safety issues prior to marketing, and firms have been doing so. If no issues requiring premarket approval are identified during these consultations, firms then could determine that the bioengineered food was "generally recognized as safe," as is the case with nonengineered new varieties of food.

DOMESTIC CONCERNS

Although Federal regulatory agencies remain assured that bioengineered crops and foods sold in the U.S. are safe, there are increasing numbers of press and media stories questioning the safety of bioengineered foods and crops, and the adequacy of their Federal oversight. While bioengineered corn, soybeans, cotton and canola are widely grown and their products consumed in foods in the U.S., companies are concerned that public acceptance of these foods could be shaken as activist groups charge that the foods pose unknown long-term risks. An example of such concern was the recent announcement by several major baby food manufacturers, in response to pressure from an activist group, that they would remove all bioengineered ingredients from their baby foods sold in the U.S.

Some consumer and environmental groups have argued that bioengineered foods should be required to receive FDA safety approvals before marketing, should be required to be labeled as bioengineered, and that bioengineered crops should have their potential environmental risks better controlled. A group of organizations and individuals filed a lawsuit last year against FDA alleging that it is violating the law by not requiring such labeling and premarket approvals. Another lawsuit has been filed against EPA alleging that its oversight of certain pesticidal substances in bioengineered crops and foods is inadequate. Despite repeated assurances by Federal agencies that the current system of regulation is adequate to assure food and environmental safety, some in the public appear to be putting greater faith in the protestations of the opponents of the technology.

INTERNATIONAL CONCERNS

Biotech firms are facing increasing resistance to their products internationally, particularly in Europe. The EU requires labeling of bioengineered crops and foods, and is actively working to internationalize these labeling requirements. Many other countries around the world are enacting or contemplating labeling requirements for bioengineered foods.

The EU and a number of other countries also have premarket approval requirements for bioengineered crops and foods, although the process in the EU has broken down because of political difficulties brought on by consumer fears and intense opposition from activist groups in a number of EU member states. There have been no new approvals of bioengineered foods in the last year and a half, and there are unlikely to be any new approvals for at least another year or two under the most optimistic scenarios. One result of this breakdown in the EU approval system is that the U.S. can no longer sell corn to the EU, because U.S. corn shipments may contain any of a number of bioengineered varieties that have not yet been approved in the EU.

While consumer concerns about the safety of bioengineered foods and crops are most intense in Europe (probably stemming in large part from distrust of scientists and regulators as a result of their handling of the BSE problem in the UK a few years ago and the recent dioxin problem in Belgium), there is some possibility that similar concerns could ultimately cross to the U.S. as well.

ISSUES FOR CONSIDERATION

Is the current Federal regulatory scheme over bioengineered crops and foods adequate to ensure safety of these products?

Yes, the responsible Federal agencies, based on their scientific determination, are confident that the regulatory system in place is adequate to assure safety. However, critics of biotechnology allege otherwise, arguing that the current food safety system safety is inadequate because it is an "honor" system that does not guarantee safety and does not provide for special labeling, and that the oversight of bioengineered crops does not adequately address long-term environmental risks. Many other countries around the world, particularly in Europe, have decided on, or are moving toward, a system of premarket approval for bioengineered foods; this is in contrast with the U.S. position of not treating these products as inherently different from any other foods.

Will this issue remain (or become more) controversial?

Although the current regulatory position is scientifically sound, the opponents of the technology are making headway in their efforts to convince the public that these foods and crops pose safety risks. Several articles in major periodicals (e.g., Washington Post, Consumer Reports, NBC News) have been or are about to be released that give opponents opportunities to raise doubts about the products and the government's oversight of them. Thus, this issue is likely to remain an active one.

Should the Administration take a more active stance in supporting the safety and marketing of foods and crops made from biotechnology?

These products comprise research and production investments in the hundreds of millions of dollars, with sales in the billions of dollars, and the technology that produces them is an area in which U.S. firms are the clear leaders. A large volume of U.S. exports are at risk if foreign countries refuse entry of American goods based on a spurious claim that they are unsafe. Thus far, the Administration has taken the position that these products deserve support, both for their economic benefits as well as for their potential societal advantages.

Is there a need to enhance public confidence in the products themselves and the process by which the government assures their safety?

The available signs suggest that there is such a need, based on increasing skepticism about these products overseas as well as indications that American consumers may also be becoming more concerned about the food and environmental safety of bioengineered foods and crops. The biotechnology and food production industries certainly believe that such a need exists, as do the agencies involved in the regulation of these products.

OPTIONS TO INCREASE PUBLIC CONFIDENCE IN BIOENGINEERED FOODS AND TO ADDRESS TRADE ISSUES ASSOCIATED WITH SUCH FOODS

(Note: The ordering of the following options is not meant in any way to imply an order of preference, but rather the amount of required change to existing policy and law.)

1. Agencies set up public listening sessions and meetings aimed at getting broad public and scientific input on whether additional regulation (for food safety, food labeling, environmental safety) is appropriate. Panels also could be set up to provide a forum for discussing non-scientific (e.g., cultural and social) issues of public concern.

Advantages:

- Enables the regulatory agencies to hear public concerns and get scientific input on their separate areas of jurisdiction, which may provide them with information that will lead them to modify their policies or seek new statutory authorities;

- Provides a mechanism for the Administration to get support for modifications of policies or procedures that it considers appropriate;

- Demonstrates Administration openness to outside ideas.

Disadvantages:

- By itself may not be adequate to meet public concerns.

2. **Engage in greater education of U.S. public, having the regulatory agencies explain their complementary but distinct roles, emphasizing the scientific basis of U.S. regulation, summarizing the record over the past decade of the U.S. experience with review of food and agricultural products of this technology, and describing the interrelated factors that contribute to ensuring that all such food is as safe as traditionally-derived food and that the environmental risks of bioengineered crops are adequately and appropriately addressed. Complementary to this effort could be convenings of scientists, consumers, industry representatives and "wise people" to discuss safety issues posed by engineered food and environmental issues posed by engineered crops.**

Advantages:

- Reiterates firm position of U.S. scientists that these products do not pose special risks and that the U.S. system of regulatory oversight is adequate and appropriate;

- The meetings of blue ribbon scientists and other public meetings could dispel some of the widely-circulating misinformation about the safety of these products;

- Could dispel confusion about which agencies are responsible for what aspects of food and crop regulation and provide a coherent and compelling picture of U.S. regulatory system.

Disadvantages:

- By itself may not be adequate to meet public concerns; replays decade-old efforts that appear to be losing ground; some consumers consider that factors other than science should be considered (e.g., social and cultural issues)

- Those concerned about the technology and distrustful of the government may not be reassured by scientists and others seen as sponsored by the U.S. government.

3. **Increase activities overseas to explain U.S. regulatory policies and procedures and to work towards more consistent policies internationally.**

Advantages:

- May lead to greater international acceptance of U.S. regulatory practices and the safety of U.S. products, and may ease trade disputes.

Disadvantages:

- By itself is unlikely to be sufficient.

4. Encourage food processors to post on Federal or their own web-sites listings of products containing bioengineered ingredients, with information about their safety and the Federal procedures through which they passed.

Advantages:

- Responds to consumers interest in knowing what foods contain bioengineered ingredients, without violating principles of what belongs on a food label;

- May reduce impact of calls for right-to-know labeling;

- Consistent with approach used by Administration to inform the public about potential Y2K-related product/system failures.

Disadvantages:

- May be dismissed as simply an attempt to avoid right-to-know labeling, and, because companies already can do it, as essentially offering nothing new;

- Companies may not know which of their foods contain bioengineered ingredients;

- May be used as a tool for boycotts of products containing bioengineered ingredients, and may be resisted by industry because of fears of such use;

- If the Administration calls for posting such website information and the industry doesn't respond, the lack of response may be used as additional argument for need for labeling legislation;

- If posted to a website of a Federal regulatory agency, it might be viewed as blurring promotional and regulatory responsibilities;

- If posted to Federal web-sites, the Federal agencies could be viewed as guarantors of the accuracy of the information, with significant legal, policy and resource implications.

5. **Actively support voluntary labeling by having FDA develop more specific guidance on misleading and non-misleading labeling on food products containing bioengineered ingredients.**

Advantages:

- Can be done without new legislation;

- Industry that would want to pursue such labeling would have more specific guidance on how to do so;

- Does not undermine the integrity of the food label by giving Federal support for

labeling information not directly relevant to characteristics of the food.

Disadvantages:

- Would likely only be used to indicate absence of bioengineered ingredients, and could foster demand for "bioengineered-ingredient-free" products;

- Could be portrayed as an attempt to divert discussion from mandatory labeling;

- Could spur further effort towards mandatory labeling or could itself become de facto mandatory;

- Despite not being mandatory, might still be thought of as an indication of government support for putting information on a food label that is not related in any way to attributes of the food itself, and that may distract attention from important nutritional and health information present on the label.

6. **Announce acceptance by trade agencies of mandatory labeling requirements in other countries, and would work with them in developing workable rules.**

Advantages:

- Will allow U.S. to help ensure that foreign rules are fair and reasonable;

- Could establish a framework for bilateral and international cooperation on biotechnology regulation that does not now exist.

Disadvantages:

- Could strengthen and legitimize calls for right-to-know labeling in the U.S.;

- Would make Administration appear hypocritical and more sensitive to the demands of foreign consumers than to U.S. consumers, if it did not also support right-to-know labeling in the U.S.

7. **Sponsor legislation requiring mandatory right-to-know labeling in the U.S.** (e.g.,"does contain," "may contain").

Advantages:

- Responds to one of the most important issue to consumers about bioengineered foods;

- May ultimately be the only way to take the whole issue of bioengineered foods away from opponents of the technology, because it is possible that many consumers will always distrust bioengineered products until they feel that they can choose to eat them or not;

- Because of the number of bioengineered crops already grown in the U.S.,

many, and soon most, processed foods would need to be labeled, thereby eliminating any special stigma potentially associated with labeled products;

- Administration could have the advantage of being in front of the issue;

- Forces Congress to tackle the issue.

Disadvantages:

- Undermines the function and utility of the food label, which is to provide information pertinent to characteristics and composition of the food, and distracts attention from important nutritional and health information provided on the label;

- Could lead food processors to avoid use of engineered ingredients, and consumers to boycott products carrying the label;

- Could foster greater distrust of bioengineered foods, by giving the impression that the products must be different or risky if they warrant special labeling;

- Inconsistent with long-standing government position that bioengineered foods are as safe as their non-engineered counterparts and as a class have no distinguishing characteristics that would warrant labeling;

- Would be difficult to implement if labeling went any further than "may contain," because it would be difficult to keep track of which processed foods had bioengineered versus non-bioengineered ingredients;

- Opens door to other consumer "right-to-know" situations;

- Would be strongly opposed by industry;

- Experience with irradiation shows that mandatory labeling of a new technology may not contribute to consumer acceptance;

- One State court has ruled that such labeling violates the First Amendment right not to speak.

8. **Require notification to FDA 90 days prior to marketing bioengineered foods.**

Advantages:

- Provides an added level of assurance that government is aware of all products marketed and that all regulatory questions are answered prior to marketing;

- Builds public confidence in FDA oversight;

- Answers criticism that current system is an honor system in which industry

voluntarily engages FDA in its safety evaluation;

- May garner some industry support.

Disadvantages:

- Does not directly address the principal criticism that bioengineered foods are not subject to mandatory premarket approval;

- May require additional legislation, particularly if the agency's scientific assessment of these products remains unchanged;

- Absent additional legislation, not judicially enforceable and would rely on threat of adverse publicity; this could invite further criticism of notification as inadequate;

- May provide ammunition to opponents of the technology, who may portray this requirement as evidence that bioengineered foods pose special risks not associated with other foods;

- Could shift focus of debate to other criticisms of the current system, such as adequacy of scientific review.

9. **Sponsor legislation requiring mandatory approval of all bioengineered foods.**

Advantages:

- Addresses honor system criticism;

- Would allow FDA itself to vouch for safety of bioengineered foods, as it can for food additives based on an in-depth review;

- Satisfies demands of at least some consumer groups by providing additional assurance of safety.

Disadvantages:

- May not "solve" issue but only shift focus of critical debate (especially for that element of the consumer block that is opposed to biotech on a social value basis);

- Enactment highly unlikely, thus raising specter that special regulation was needed but did not exist;

- Would create significant period of "regulatory limbo" between time of proposal and any enactment;

- Would delay market entry of commercially important new foods for no scientific

or public health reason;

- Extremely resource-intensive for FDA without providing concomitant public health benefits;

- Would be strongly opposed by industry;

- Is in direct contradiction to long-standing Federal position that bioengineered foods do not raise scientific or safety issues warranting such oversight.