

GMOs

## Foodstuff

# 'Genetically Modified' On the Label Means ... Well, It's Hard to Say

## Attempt at Clarity in U.K. Brings Much Confusion; FDA Studies the Issue 'Non-GM' Isn't 'GM-Free'

By STEVE STECKLOW

Staff Reporter of THE WALL STREET JOURNAL

LONDON—It seems simple enough: Let consumers know when they're buying bioengineered food by requiring a label. It's an idea being promoted heavily in the U.S. by groups such as Greenpeace and Friends of the Earth, and even by some members of Congress.

But a trip up and down the supermarket aisles of Britain, which has required such labeling since March, shows the new law hasn't exactly made things easier for discerning shoppers. Rather, it has spawned a bewildering array of marketing claims, counterclaims and outright contradictions that only a food scientist possibly could unravel.

Take cheese. One supermarket chain here labels its cheese as being "made using genetic modification," the European catchword for bioengineering. But other supermarket chains, whose cheese is made exactly the same way, haven't changed their labels, saying the cheese itself contains no genetically modified ingredients.

Then there's Birds Eye frozen beef burgers. The label on a box purchased last week states that one ingredient, soya protein, is "produced from genetically modified soya." But a spokesman for maker Unilever PLC insists that the soya isn't genetically modified. The company has reformulated the product, he explains, but has yet to replace the box.

### Yes or No?

Confused yet? Then scan over the small print on a Haagen-Dazs chocolate-covered ice-cream bar. No genetically modified ingredients listed there. But consumers who question the company about it are sent a letter stating that the bar's chocolate coatings, in fact, contain soya oil that "may have been derived from genetically modified soya, but it is identical to any other soya oil and therefore does not contain any genetically modified material." The letter adds, "We are, however, investigating whether there are suitable alternative oils."

All of this may seem puzzling to American shoppers, who so far aren't up in arms over whether the food they buy includes ingredients that have been tinkered with in a laboratory. After all, that's already the case with many U.S. products. But European consumers, who have lived through such recent food scares as beef linked to "mad cow" disease, salmonella-contaminated eggs and dioxin-tainted animal feed, are taking no chances, even though there's no proof that bioengineered foods pose any health risks.

### Monster Mash

The result has been a biotech backlash that at times borders on hysteria. In Britain, tabloid newspapers routinely refer to genetically modified products as "Frankenstein food." One prisoner even went on a hunger strike demanding that no genetically modified food be served to inmates.

Critics say bioengineered foods offer consumers no obvious benefit and that despite industry and government assurances, not enough research has been done to assure they are safe. Environmental groups have expressed concern that genetically modified plants could have unintended side effects, including killing beneficial insects and, through the spread of pollen, promoting growth of herbicide-resistant "super weeds" and antibiotic-resistant "super bugs." Others fear genetically modified foods could cause dangerous allergic reactions in some people.

In response to widespread consumer outcry, the European Union last year approved legislation that required its 15 member countries to begin labeling all foods that contain genetically modified ingredients, namely corn and soybean in which new genes have been added to provide traits such as insect resistance.

### American Reverberations

While no such plans have been announced in the U.S., the Food and Drug Administration said last week that it plans hearings around the country this fall to gauge public opinion on the issue. Already, several American health-food companies have begun slapping labels on their products declaring that they contain no genetically modified ingredients.

But before America leaps into mandatory labeling, the government, retailers and consumer groups might want to take a look at the far-reaching impact such a law has had in Britain.

When the European Union introduced its legislation last year, Britain's agriculture minister called it "a triumph for consumer rights to better information." Britain went on to enact the toughest labeling standards in Europe, requiring even restaurants, caterers and bakers to list genetically modified ingredients. Violations are punishable by fines of as much as \$6,000, and the government says it intends to conduct surveillance, including independent lab testing.

"This is not a health issue in any way," says J. R. Bell, head of the government's additives and novel-foods division, adding that his ministry believes the latest bioengineered products are safe. "This is a question of choice, of consumer choice."

But, in fact, as a direct result of the labeling law, there's hardly any choice now at all. That's because Britain's new law sparked a mad rush by manufacturers, retailers and restaurant chains to rid their products of any genetically modified ingredients so they wouldn't have to alter their labels and risk losing sales. Even some pet-food manufacturers are claiming their products contain no genetically modified ingredients.

Among the thousands of products sold in Britain that now claim not to contain any GM ingredients are Pillsbury UK Ltd.'s Green Giant vegetables and Old El Paso Mexican food, Kellogg cereals and Unilever's Van den Bergh Foods Beanfeast line. A spokesman for McDonald's Restaurants Ltd., which operates 1,000 restaurants in the United Kingdom, says, "We do not use any genetically modified products or ingredients that contain genetically modified material." He adds, however, that some ingredients, such as soya oil used in hamburger buns, "could have come from a source which itself is genetically modified at some point."

The rush to keep products from being branded as bioengineered is hardly surprising. When J. Sainsbury PLC, a supermarket chain, began selling a bioengineered tomato puree under its own brand in 1996, sales initially exceeded other, more expensive brands by 30%, though the product's label volunteered that it was genetically modified. But as the GM controversy heated up, sales slowed and, by the end of last year, "absolutely fell through the floor," says Alison Austin, Sainsbury's

environmental manager. The product has since been taken off the market by its creator and distributor, Zeneca Plant Science, a unit of AstraZeneca PLC.

Having gotten the message that consumers don't want bioengineered foods, Sainsbury's and other supermarket chains, as well as food manufacturers that sell in Britain, launched extensive, month-long reviews of their product formulations. They began changing recipes to eliminate soya and corn derivatives and ordered their suppliers to find new sources of non-bioengineered raw materials in places such as South America and Asia.

"We poured over something like 5,000 ingredients... and made changes to 1,600 recipes as part of this process," says Bob Mitchell, manager of food technical policy at Marks & Spencer PLC, which operates specialty food shops. "It was a colossal task."

Supermarkets soon began declaring in advertising that their own house brands, which in Britain can constitute more than half of all sales, no longer contained genetically modified ingredients.

But a close examination of stores' claims, based on interviews with supermarket executives, shows that one chain's definition of removing genetically modified ingredients isn't necessarily the same as another's.

Sainsbury's, for example, says on its Web site that it is "the first major U.K. supermarket to eliminate genetically modified ingredients from its own-brand products." Does that include food additives, such as sweeteners and flavorings, which may be genetically modified? Alison Austin, the company's environmental manager, replies, "To be honest, we have focused in on major ingredients" such as soya and maize proteins and oils, as well as lecithin, an emulsifier. As for other bioengineered ingredients, she says, "It takes time for the supply chain to provide alternatives."

### 'We Mean Zero GM'

Tesco PLC, Britain's leading supermarket chain, says it makes no distinction between major and minor genetically modified ingredients. As a result, 150 of its house-brand products are still labeled as containing GM ingredients. "When we say zero GM, we mean zero GM," says Simon Softe, a Tesco spokesman.

Maybe so, but laboratories that test for genetically modified ingredients say it is almost impossible to guarantee that a product line contains absolutely no genetically modified ingredients. Many growers don't segregate bioengineered and nonbioengineered soybeans and corn. Moreover, genetically modified materials in highly processed additives or oils often can't be detected in testing. "If there's no way to test, then people are going to bend the rules and they're going to bend the truth," says Bruce Ferguson, president of EnviroLogix Inc., an environmental-testing company in Portland, Maine.

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Some inconsistencies in supermarket claims can be attributed to the labeling law itself. At the moment, the European Union and British regulations require labeling only if genetically modified material is detectable in DNA or protein. Additives and flavorings are exempt.

#### Cheese-Making

That has led to some strange labeling dilemmas in items as simple as cheese. Traditionally, cheese was set using an enzyme called rennet, taken from the lining of calves' stomachs. But to appease vegetarians, many European cheese makers in recent years switched to an enzyme called chymosin that is produced from genetically modified bacteria.

There's no evidence that any genetically modified ingredient remains in the cheese after production. Still, one supermarket chain, Co-Op, decided to place labels on its cheese that say "made using genetic modification and so free from animal rennet." "It's a question of whether the retailer is honest or open in labelling it," says a Co-Op spokesman.

Meantime, Iceland, a small but scrappy convenience-store chain whose chairman coined the term "Frankenstein food," says it has switched to making its cheese with another enzyme that doesn't come from animals and isn't produced from genetically modified bacteria. "We've done them one better," says Bill Wadsworth, the chain's technical director.

European Union officials say they are hoping to clear up some of the confusion in the marketplace. Last week, a panel of government representatives voted to extend the labeling law to cover additives and flavorings, a change that is expected to take effect next year and could force many manufacturers and fast-food restaurants

to either change recipes, switch suppliers or begin labeling.

The EU also decided to address the problem of products "contaminated" with trace amounts of genetically modified material despite the best intentions of manufacturers. In a controversial decision, the panel recommended that products don't require labeling if each of the ingredients contains 1% bioengineered material or less. Consumer groups had argued that the limit should be one-tenth of that.

In the future, the EU may also try to define when a retailer or manufacturer may claim that a product is "GM-free," a phrase that already has sprung up in some advertising and promotional material. Many retailers, such as Marks & Spencer, instead use the term "non-GM," which they insist is different. "We would never call it GM-free because you could never guarantee that," Mr. Mitchell says.

And thornier labeling issues loom. In their competitive frenzy, some British supermarkets have begun introducing raw and frozen chicken that they claim was raised on feed containing no genetically modified ingredients—even though there isn't evidence that bioengineered material ends up in the meat. To accomplish this, Iceland convenience stores say they now buy their chickens in Brazil, instead of Britain. Marks & Spencer says it is about to introduce a new line of free-range, non-GM poultry, egg and pork products.

Salisbury's has yet to join the non-GM chicken and pork parade, but Mrs. Austin says it's probably "inevitable" and adds it may only be a first step. "We are utterly adamant that if you wish to claim you are GM-free, then you are ultimately going to have to go as far as GM-free veterinary medicines," she says.

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# Group Sows Seeds of Revolt Against Genetically Altered Foods in U.S.

By LUCETTE LAGNARD  
Staff Reporter of THE WALL STREET JOURNAL

BLUE MOUNTAIN LAKE, N.Y.—It was, by all appearances, a typical corporate retreat.

Top officials from several multinational enterprises jetted in last week from six continents to a secluded camp in the Adirondack Mountains. For six days, they strolled along babbling brooks, huddled before roaring fires and mapped out how to crack the hard-to-penetrate American market.

But these were no CEOs. At the Blue Mountain Center in upstate New York, the 22 participants from 12 countries descended on this sylvan setting to plot the first all-out assault on the U.S. biotech-food industry.

Several of the activists, attorneys and scientists on hand helped orchestrate previous campaigns against food made from genetically modified crops in continental Europe, the U.K. and elsewhere. Penny Haerlin, for one, is the international coordinator for Greenpeace in Berlin. He is credited with directing a campaign in western Europe that left major companies scared and scrambling to yank baby food and other genetically engineered groceries from store shelves last year.

With public opposition galvanized abroad, the group is now setting its sights on the U.S. High on its agenda: gearing public sentiment against genetically modified organisms (GMO) and picking corporate targets.

The U.S. food industry has been tense about this. Half the nation's soybean crop and a third of its corn crop contain transplanted genes. Those crops, in turn, are used in countless food products: the syrup for Coke, McDonald's hamburger buns, Heinz ketchup and General Mills' Betty Crocker

cake mixes, to name a few.

While some U.S. food companies have recently begun switching ingredients, a backlash of the magnitude seen in Europe hasn't materialized here. One reason: there is little evidence now that genetically modified crops are even hazardous.

While opponents concede that any real risks to people are unknown, they argue that the biotech industry is treating people as guinea pigs by failing to conduct long-term studies first. Some say it's possible genetically modified foods could trigger deadly, if rare, allergies. They also think genetically altered crops raise environmental concerns and cite the monarch butterfly, whose larvae have died in the laboratory when exposed to pollen from genetically altered corn.

In Europe, just the possibility of health or environmental threats—a spark fanned by Greenpeace, among other environmental and leftist groups—has forced food makers, supermarkets and restaurants to go non-GMO.

Companies such as Novartis AG say that, while fears are so far largely unfounded, biotech agriculture already has many proven benefits. Among them are "a major reduction in pesticide use, a major reduction in soil erosion, a major reduction in water pollution and a major increase in yield," says Steve Briggs, director of Novartis Discovery Agricultural Institute in San Diego, a research arm of the Novartis Foundation. Of the detractors, he adds, "They distort the truth."

Monsanto Co. and DuPont Co. likewise say they are committed to biotech foods, but are willing to discuss concerns raised by opponents. Charles O. Holliday, chairman and chief executive of DuPont, deliv-

ered a speech in September at the Chief Executives Club of Boston extolling the virtues of biotechnology. Citing the potential to solve world health problems and increase agricultural productivity, he said, "I have great passion and excitement for biotechnology."

The Blue Mountain retreat was organized by a group of American activists who felt the moment was ripe for a U.S. campaign. Activists from all over the globe—India, Brazil, Zimbabwe, Australia, Europe and the Philippines—flew in for the unpublicized meeting.

Pat Mooney, a Canadian who runs the Rural Advancement Foundation International, brought his 10-year-old stepdaughter, Kelsey. Mr. Mooney is credited with coining the phrase "terminator" to describe an experimental gene technology that Monsanto would access through its pending acquisition of a Mississippi cottonseed company. The technique creates sterile seeds.

At one point, he enlisted Kelsey's help to lay out the debate in stark terms. Is 'terminator' good or bad?" he asked her Thursday night, in front of other activists.

"Bad," the child replied, after a pause. "Is Monsanto good or bad?" Mr. Mooney asked.

"Bad," she replied, without missing a beat. Mr. Mooney smiled.

It's not at all given that the ferocity of Europe's biotech-food sentiment will spread here, but resistance may have begun to take root. A couple of months ago, under pressure from Greenpeace, Novartis's U.S.-based Gerber division said it would eliminate genetically modified ingredients from its baby food. H.J. Heinz Co. is taking similar steps. Last week, bowing to public pressure, Monsanto announced it wouldn't market the controversial seed.

Today at Rockefeller Center in New York City, the Blue Mountain activists have scheduled a press conference to present a global front against biotech foods. Next step: U.S. activists will reach out to public-health associations, women's groups and college-student organizations. Already, they say, the movement is stirring up interest on university campuses across the country.

An international network—with regular

communications and Internet strategy sessions—was formally created at Blue Mountain to link activists as they take on multinational corporations. When the World Trade Organization meets in Seattle next month, there will be an antibiotech "teach-in" to influence trade officials and the public.

And, following the big tobacco company lawsuits, there is discussion of slapping biotech-food companies with "massive litigation from people suffering from genetic pollution of crops," says Andrew Kimbrell, a public interest attorney who runs the International Center for Technology Assessment, in Washington. His group last year sued the U.S. Food and Drug Administration in federal district court in Washington to demand that foods containing genetically altered ingredients be labeled as such.

Fund raising is a priority for the U.S. groups. Chris Desser, the coordinator of the Funders Working Group on Biotechnology, San Francisco, says she has reached out to the Ford, Rockefeller and other mainstream foundations. Funding for last week's retreat came from the HKH Foundation, which endows the Blue Mountain mansion, and from Britain's JMG Foundation, which has financed groups opposed to biotech food in the U.K. and France.

Lounging on pillow-strewn sofas and sipping red wine from plastic cups, the Blue Mountain activists discussed their next corporate targets. Monsanto has already been "clobbered," declared Mr. Mooney. Marty Teitel, executive director of the Council for Responsible Genetics, Cambridge, Mass., said he's discontinuing the column, "MonsantoWatch," which appears in his group's newsletter. Next up, he says: a column called "NovartisWatch" or maybe just "CorporateWatch."

In India, says Vandana Shiva, protests are already aimed at U.S. companies and "the biotech crops they want to dump." She is a physicist and founder of the anti-GMO Research Institute for Science, Technology and Ecology, in New Delhi. And she compares the Indian demonstrations, in which fields of cotton have been set afire, to Mahatma Gandhi's efforts to end British colonial rule.

"The problems of the entire world have been created in the U.S.," she says, "so we have to bring these issues back home."

THE WALL STREET JOURNAL  
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# Raytheon Hits Snags on Pentagon Work

Cost and Schedule Problems  
Plague Over 12 Contracts  
Valued Above \$2 Billion

By ANNE MARIE SQUED

Staff Reporter of THE WALL STREET JOURNAL  
Raytheon Co., long viewed as a successful example of defense-industry consolidation, is over cost or behind schedule on more than a dozen of its Pentagon fixed-price contracts, according to people familiar with the programs.

Raytheon already disclosed in September that it was having some problems in its defense-electronics and construction units that will result in reporting a pretax charge of \$350 million to \$450 million. The company is expected to give details of the charge to financial analysts tomorrow at meetings in New York and Boston.

Some of those Pentagon contracts are included in the charge, which will be posted for the third quarter, but others aren't.

Among the fixed-priced contracts that are running over cost are Raytheon's lucrative Tomahawk cruise missiles, P-3 Orion patrol aircraft and RC-135 reconnaissance aircraft programs, said those familiar with the matter. Also having troubles are the shoulder-held Javelin missile, the Navy Extremely High Frequency Satellite Communications program, and the conversion of a military plant in Umatilla in northern Oregon for commercial use, they said.

Exceeding preset contract amounts on these contracts leaves the Lexington, Mass., company responsible for the difference unless the Pentagon agrees to a contract change. At least some of the issues were discussed two weeks ago when Pentagon officials met with Raytheon executives

to discuss the company's various contracts as part of the agency's broader review of all of its contractors, those familiar with the situation said.

The financial impact of the cost overruns is unclear. But the total value of the programs is upwards of \$2 billion. The Javelin program, which Raytheon shares with Lockheed Martin Corp., totals at least \$745 million, while the Tomahawk program alone exceeds \$300 million.

A Raytheon spokeswoman declined to comment on details of the Pentagon meeting or the coming investor conferences. But a company statement noted that Raytheon has more than 6,000 contracts of varying size and complexity, and so "it is not unusual that issues may arise on a few that require attention."

A Pentagon spokeswoman declined to comment. A Lockheed Martin spokesman said he isn't aware of any problems with the Javelin program that could lead to a charge.

Raytheon's problems are causing con-

cern on Wall Street, which had viewed Raytheon as the rare case of a defense company that had appropriately managed its acquisitions. The wave of consolidation that swept through the U.S. defense industry after the Cold War ended in 1989 caused prolonged problems for a number of giant aerospace and defense companies including Lockheed Martin and Boeing Co.

Raytheon, though, appeared to take a different approach to its acquisitions of the defense-electronics businesses of Texas Instruments and Hughes Electronics Corp. Analysts said Raytheon aggressively set out to create a homogenous entity, moving to consolidate its missile and related operations in Tucson, Ariz.

"People had looked at Raytheon as a strong performer," said ING Barings analyst Sam Pearlstein. Now, "there's general uncertainty about the ongoing earnings potential and outlook for this company."

Raytheon stock fell 37.5 cents to \$42 in

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## Raytheon Over Cost Or Behind Schedule On Pentagon Work

Continued From Page A3

New York Stock Exchange composite trading yesterday. The stock has fallen about one-third from the day before the charge was announced.

With the exception of work on the Umatilla plant, which is run by Raytheon's Engineers & Constructors unit, the programs are the domain of Raytheon Systems Co. Raytheon executives have said the charge announced Sept. 16 was related to these two units, with the majority attributable to Raytheon Systems. Raytheon Systems, which includes both the company's defense and commercial electronics systems, accounts for \$14.8 billion in annual revenue, or about three-quarters of the company's \$20 billion total.

Raytheon Engineers & Constructors has experienced problems over the years with the highly competitive, often-political market to build power plants and other large-scale industrial projects. Raytheon executives have considered shedding or spinning off the unit, but are in the process of getting its costs in line before that happens, analysts said. The unit's revenue totaled \$2.1 billion in 1988.

Separately, Raytheon announced the restructuring of its commercial-electronics business, which is part of Raytheon Systems. In doing so, the company combined some of its commercial and defense-electronics businesses and appointed Delbert Lippert as vice president of the newly formed business. Mr. Lippert, who was serving as the unit's acting head, will report directly to Chief Executive Daniel Burnham.

November 10, 1999

GMOs

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM:

REF: **Decision on Agricultural Biotechnology Issues**

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**Purpose:** A vigorous debate is under way 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 policy options.

**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 this policy was that, based on the government's assessment of the science, the regulatory framework pertaining to traditional genetic manipulation remains adequate for research and products of these newer techniques, and that no new laws were needed. As a result:

- USDA promulgated regulations requiring developers of bioengineered crops to notify it 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.
- FDA promulgated no new regulations but did publish a statement of policy indicating 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. It went on to

note, however, that most, if not all, substances being considered for introduction into foods through bioengineering were substantially the same as other substances found in the diet and therefore would not need premarket approval. FDA encouraged firms to consult with it on safety issues prior to marketing, which firms have been doing.

- 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.

Federal regulatory agencies remain confident that bioengineered crops and foods sold in the U.S. are safe. Bioengineered corn, soybeans, cotton and canola are widely grown and consumed in foods here, and American consumers retain a generally benign view of the technology. Nevertheless, companies are increasingly concerned that public acceptance could erode in the face of media questions and activists' representations that the technology poses unknown long-term risks. And they fear that international resistance to the products, especially in Europe, could eventually spill over into the US market.

International Considerations. The EU is proving increasingly problematic, in part due to recent food safety scares unrelated to biotechnology as well as preliminary research indicating that some biotech corn pollen may harm Monarch butterflies. Last June, the EU Environment Council decided to require that agri-biotech products be proven to have no environmental or health risks before being placed on the market and that the EU Directive regarding biotechnology regulation (90/220) be revised to include additional procedures for handling already-approved biotech seeds and bulk commodities. US producers are being adversely affected by this effective moratorium on regulatory approvals of bioengineered products. With seven pending applications for new corn varieties, corn growers are losing at least \$200 million per year in exports. US producers are concerned that additional countries, such as Japan, Korea, Australia, and New Zealand, are following the EU's lead in mandating labeling of biotech foods, as foreign food retailers and processors are beginning to demand GMO-free foods to protect their brand image and avoid loss of market share. This is generating uncertainty among American farmers and concern about the added segregation and testing costs. As a result, the Administration is working to promote fair market access for US exports on several fronts, including:

- Technical cooperation and information sharing in the OECD and Transatlantic Economic Partnership in projects initiated at this past June's G-8 and US-EU Summits as well as through the National and Royal Academies of Science;
- A high-level US-EU governmental dialogue that was initiated in your recent meeting with EU Commission President Prodi for the purpose of securing more predictable regulatory approval processes in Europe and resolution of outstanding market access issues, including blocked US corn exports; and
- Preparation of US negotiating objectives for the Seattle WTO Ministerial aimed at focusing any discussion about biotechnology in the new trade round on ensuring the continuing application of existing trade disciplines to biotech trade and promoting greater predictability to regulatory approvals based on sound science.

## Domestic Perspectives

- Government. The U.S. Government (USG) position on labeling of genetically engineered or modified agricultural crops and products has been to oppose any mandatory labeling of such products. This position is based on the Food & Drug Administration's conclusion that genetically engineered foods are substantially equivalent to their conventional counterparts. However, the FDA requires labeling of food, including that which is bioengineered, 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 not entirely succeeded in quieting consumer demands for labels and other information about the bioengineered content of food.
- Consumers. Although US consumer perceptions of agri-biotech products remain largely positive, the situation is fluid. In its September 1999 edition, *Consumer Reports* magazine advocated labeling of bioengineered food products. And US advocacy groups are intensifying media and public education campaigns. Some contend that bioengineered foods should be subject to formal FDA safety approval before being marketed, labeled as bioengineered, and examined more thoroughly for potential environmental risks. A number of them 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.
- Industry. For its part, 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. However, they have recently begun quietly suggesting that some degree of greater engagement by the government would be desirable, including additional public education, a requirement that companies notify FDA of new bioengineered products before marketing them, and work by USDA and FDA to help farmers, companies, and consumers determine what constitutes a non-biotech product.
- Farmers. Perhaps the most pressing aspect of the issue is the uncertainty facing farmers, who fear development of a two-tier price system with discounts for biotech crops and a shortage of conventional seeds next spring. Many of our farmers in recent years switched to bioengineered crops because of their enhanced traits, reduced costs of pest/disease control, and environmentally friendly attributes. However, growing 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. This figure could increase substantially if very stringent thresholds were adopted by countries and companies (e.g., the EU has recently proposed that any product containing more than 1% of bioengineered product be considered bioengineered), suggesting that the US has a major commercial stake in how such decisions are made.
- Environment. Finally, agricultural genetic engineering could have significant environmental impacts, both good and bad. Potential benefits include reduced pressure to clear tropical rainforests for farmland (due to enhanced agricultural productivity), quicker, more effective clean-up of oil spills

(with genetically engineered plants and microorganisms) and less use of harmful pesticides. Risks include the development of “super-weeds” (if genetically modified plants hybridize with wild relatives), adverse impacts on non-target species (such as the monarch butterfly) and disruption of ecosystems (for example, by the unintended release of “super-growth” salmon into the marine environment). In several recent cases, agencies have identified environmental risks from GMOs and responded accordingly. In 1997, EPA expressed concern about hybridization of certain genetically-modified cotton crops with wild relatives in certain parts of Florida and Hawaii, and denied approval for planting in those areas. EPA is currently considering guidelines to protect monarch butterflies in the planting of Bt corn. In other cases, the regulatory authorities for addressing environmental impacts of GMOs may be less clear. FDA, for example, is currently considering applications for the approval of genetically-modified salmon that grow faster and larger than native species. Although FDA is considering the ecosystem impacts of an unintentional release of the modified salmon as part of a NEPA review, it is not clear that FDA’s legal authorities would allow the agency to deny approval based on adverse ecosystem impacts if any were found.

## **Options**

An NEC High-Level Group on Biotechnology was created last spring to assess these developments and consider their implications for public policy. Principals, Deputies and staff have met and conducted outreach with the producer and NGO communities. Following are policy options that have emerged from this process for your consideration:

### **1. Enhancing Public Education and Outreach to Strengthen US and Foreign Consumer Confidence**

- Domestically, engage in greater outreach to emphasize the scientific basis of US regulation and convene public sessions and meetings for the purpose of soliciting 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.
- Encourage US 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.
- Intensify international educational, cooperative scientific, diplomatic, and technical assistance activities to explain US regulatory policies and work toward more consistent policies.

These activities would enable the regulatory agencies to hear public concerns, receive scientific input, dispel inaccurate information, and influence regulatory decisions in foreign markets. All agencies are supportive of these steps, and many, including USDA, FDA, and State, are undertaking them presently.

### **2. Maintaining and Strengthening Confidence in the US Regulatory Framework**

a) Require Companies to Notify FDA 90 Days before Biotech Products Are Introduced into Commerce. In 1992, FDA issued a policy statement to provide industry with guidance on Federal

requirements that must be met before feed and food products derived through recombinant DNA techniques can be introduced into commerce. This policy statement did not mandate pre-market notification or approval, but encouraged consultations between industry and FDA. To date, all new feed/food products have gone through this voluntary consultative process; however, critics point to the voluntary nature of this process to make the claim that FDA's oversight of GMO food is based on an honor system. In an attempt to address this criticism, FDA has launched a series of public listening sessions over the next month in part to explore the possibility of requiring pre-market notification.

This step would provide an added level of assurance that government is aware of all products marketed and that all regulatory questions are answered prior to marketing. It would build public confidence in FDA oversight, responding to criticism that current system is an honor system in which industry voluntarily engages FDA in its safety evaluation, and possibly provide an opening to work in a more cooperative fashion with the Europeans on biotech issues. At the same time, it would not directly address the principal criticism that bioengineered foods are not subject to mandatory premarket approval and 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.

All agencies are generally supportive; however, FDA believes that any policy change in this regard should be based on and follow a process of public outreach, such as its three public sessions scheduled over the course of the next month.

b) Direct CEQ to Organize an Interagency Process to Examine the Adequacy of Federal Environmental Monitoring Activities and Regulatory Authorities with Respect to Agricultural Biotechnology. This proposed process would look at the adequacy of our environmental monitoring activities and capabilities as well as the sufficiency of the existing regulatory authorities and framework. Analysis would begin with case studies of how the existing system applies to different transgenic organisms. Work would be designed to identify strengths and weaknesses of the current system and, in combination with scientific information, establish a foundation for future recommendations. New directions might include recommendations for additional environmental monitoring and risk assessment activities. Initial recommendations would be likely within six months. This policy option would help address questions about the environmental implications of agricultural biotechnology and bolster public confidence that the federal government is taking them seriously. It is supported by all agencies.

**3. Facilitating Voluntary Informational Labeling of Non-Biotech Products (i.e., defer to the private sector on product segregation and labeling but engage with it to lend order to the process and reduce uncertainty and confusion for farmers, companies, and consumers).**

Although there is general confidence in and out of government that bioengineering *per se* does not pose unique health risks in food products requiring FDA-approved labeling, consumer preferences abroad and, to a lesser extent, in the US are prompting some commodity firms and food companies to segregate and voluntarily label non-bioengineered crops and products. Competing producers have an interest in ensuring that such claims are not false or misleading. Consumers have an interest in ensuring that information voluntarily disclosed on products is accurate, reliable, and comparable to

information found on other products, as illustrated by the current confusion of supermarket shoppers in the UK. Finally, farmers and elevator operators have an interest in ensuring that steps they take to test and maintain the segregated identity of non-biotech crops will be reliable and generally recognized as valid by commodity firms. Accordingly, this option would launch a process of public outreach and technical research through USDA and FDA to support an orderly process of voluntary product segregation and labeling to the extent one emerges in the private sector.

a) USDA process on testing, tolerances, and quality assurance. USDA would initiate a comprehensive process of public outreach to determine the feasibility of establishing standardized testing protocols, maximum-biotech content tolerances, and quality assurance programs to support voluntary non-biotech product segregation and claims. This process would take into account both consumer demands and production and handling factors such as pollen drift and commingling. It would involve public meetings, specific stakeholder group consultations, and the issuance of an Advanced Notice of Proposed Rulemaking (ANPR). It might most usefully be initiated following next year's harvest after the industry has had more experience with segregating and testing commodities. Once a certification process were established, the GMO status of a given commodity would become a key component of industry-developed "chain of custody" programs, which might facilitate voluntary labeling of consumer products. This USDA process would also inform and support USG efforts to influence foreign regulatory decisions about non-biotech tolerance levels and preserve fair market access opportunities for US farm exports. Should domestic industry choose to use such labels, FDA would need to determine whether the labels were truthful and not misleading.

b) FDA process to develop guidance for voluntary informational labels.

The Food and Drug Administration (FDA) has already initiated a Federal Register notice announcing three hearings on November 18 and 30 and December 13. The purpose of these hearings is to share the agency's approach regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information on the most appropriate means of providing information to the public about these products. Under current Federal Food, Drug, and Cosmetics Act (FFDCA) authority, companies currently can use product labels to indicate whether their products contain genetically engineered ingredients. However, the labels must meet the standard of being truthful and non-misleading, as interpreted by the FDA. Building on the current FDA hearings, this policy option would create a process by which the agency would develop guidance on the elements of a truthful and not misleading label for non-GMO food products in order to inform the design of any such claims voluntarily made by companies.

USDA and other agencies support these options, with the exception of HHS, which believes that even limited governmental involvement in activities related to biotech labeling would implicitly bless and energize the actions of those who oppose the products and call for their mandatory labeling, thereby undermining public confidence in them. HHS is also concerned that adding information on food labels on matters unrelated to the safety or fundamental characteristics of the product would undermine the function and utility of food labels, in part by adding clutter and distracting consumers from core nutritional information.

#### **4. Supporting Mandatory Pre-Market Approval and Product Labeling**

The Administration could adopt the EU posture of requiring pre-market regulatory approval and labeling of products with bioengineered content above a certain threshold. It could do so by sponsoring or endorsing legislation in Congress.

a) Mandatory approval of new products (as distinguished from mandatory pre-market *notification* in Option 2a above) would allow FDA itself to vouch for safety of bioengineered foods based on in-depth reviews, as it now does for food additives. This would satisfy demands of at least some consumer groups by providing an additional assurance of safety, removing the criticism that the current system depends on the good faith of biotech companies. However, such a change in policy would be opposed by industry on the grounds that it could undermine public confidence by suggesting that the federal government has serious concerns about the safety of the technology. It could also create significant period of "regulatory limbo" between the time of the proposal and enactment, delaying market entry of commercially important new foods despite the longstanding Federal view that bioengineered foods do not raise scientific or safety issues warranting such oversight.

b) Mandatory labeling of bioengineered food products may ultimately be the only way to cease being on the defensive about bioengineered foods, because many consumers may decide to distrust the technology until they feel that they have the capacity to choose it or not. In light of the number of bioengineered crops grown in the U.S., many processed foods would need to be labeled, thereby potentially eliminating any stigma associated with labeled products. By taking this posture, the Administration might be able to get in front of the issue, forcing stakeholders to work with Congress to develop a solution. This option would afford the maximum degree of information to consumers. With access to information readily available, their concerns over the technology might well be lower in the long run than in the absence of a regime of mandatory product disclosure.

On the other hand, mandatory food labels for biotech content could undermine the function and utility of the food label, whose purpose is to provide information pertinent to characteristics and composition of the food. As such, it could distract attention from important nutritional and health information now on food labels and trigger additional calls for consumer "right to know" labeling on other issues. In addition, an abrupt policy shift of this nature could foster greater distrust of bioengineered foods by giving the impression that they must be different and riskier than other products, leading food processors to avoid their use and consumers to boycott their purchase. Since industry is currently interested most of all in having the federal government clearly and repeatedly vouch for the safety of the products, it would undoubtedly be highly critical of this policy and consider fundamentally 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.

No agency supports these options, reflecting the concern, shared by industry and farmers, that such a major policy shift might alarm consumers and create a disorderly shift in their purchasing behavior that would not be warranted by our scientific understanding of the issue. The top priority of industry and farmers is for the USG to take steps to reinforce the generally strong level of consumer confidence that

still prevails in the US. They perceive that these steps would work at cross purposes to this objective.

## RECOMMENDATION

### Approve

Option #1 -- Enhancing Public Education and Outreach to Strengthen Consumer Confidence.

Option #2 -- Maintaining and Strengthening Confidence in the US Regulatory Framework by:

- a) requiring companies to notify FDA 90 days before biotech products are introduced into commerce; and
- b) directing CEQ to organize an interagency process to examine the adequacy of federal environmental monitoring activities and regulatory authorities with respect to agricultural biotechnology.

Option #3 -- Facilitating Voluntary Informational Labeling of Non-Biotech Products by initiating:

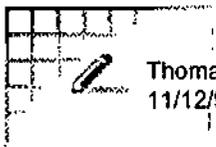
- a) USDA process on testing, tolerances, and quality assurance; and
- b) FDA process to develop guidance for voluntary informational labels.

Option #4 -- Supporting Mandatory Pre-Market Approval and Product Labeling

### Attachments

Tab A      Memorandum to NEC High-Level Group Principals

GMOs



Thomas L. Freedman  
11/12/99 05:47:46 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP@EOP, Eric P. Liu/OPD/EOP@EOP  
cc: Mary L. Smith/OPD/EOP@EOP  
Subject: BIOTECH NEC POTUS PAPER

NEC is still drafting new versions of its memo but it is basically these 4 options. I've said I thought Bruce would want to be on record for recommending options 1,2 and 3, you agree? (That is we support steps towards voluntary labeling but not mandatory labeling.)

**1. Enhancing Public Education and Outreach to Strengthen US and Foreign Consumer Confidence**

- Domestically, engage in greater outreach to emphasize the scientific basis of US regulation and convene public sessions and meetings for the purpose of soliciting 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.
- Intensify international educational, cooperative scientific, diplomatic, and technical assistance activities to explain US regulatory policies and work toward more consistent policies.

These activities would enable the regulatory agencies to hear public concerns, receive scientific input, dispel inaccurate information, and influence regulatory decisions in foreign markets. All agencies are supportive of these steps, and many, including USDA, FDA, EPA and State, are undertaking them presently.

**2. Maintaining and Strengthening Confidence in the US Regulatory Framework**

Yes

a) Require Companies to Notify FDA 90 Days before Biotech Products Are Introduced into Commerce. In 1992, FDA issued a policy statement to provide industry with guidance on Federal requirements that must be met before feed and food products derived through recombinant DNA techniques can be introduced into commerce. This policy statement did not mandate pre-market notification or approval, but encouraged consultations between industry and FDA. To date, all new feed/food products have gone through this voluntary consultative process; however, critics point to the voluntary nature of this process to make the claim that FDA's oversight of GMO food is based on an honor system. In an attempt to address this criticism, FDA has launched a series of public listening sessions over the next month in part to explore what if any modifications to its policies might be warranted.

This step would provide an added level of assurance that government is aware of all products marketed and that all regulatory questions are answered prior to marketing. It would build public confidence in FDA oversight, responding to criticism that current system is an honor system in which industry voluntarily engages FDA in its safety evaluation, and possibly provide an opening to work in a more cooperative fashion with the Europeans on biotech issues. At the same time, it would not directly address the principal criticism that bioengineered foods are not subject to mandatory premarket approval and 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.

All agencies are generally supportive; however, FDA has noted that going forward with mandatory premarket notification would require development of a legal rationale that does not undercut the US government's scientific assessment that foods from bioengineered plants are not inherently different from or less safe than foods from conventionally derived plants.

*Yes*  
b) Direct CEQ/OSTP to Organize an Interagency Process to Examine the Adequacy of Federal Environmental Monitoring Activities and Regulatory Authorities with Respect to Agricultural Biotechnology. This proposed process would look at the adequacy of our environmental monitoring activities and capabilities as well as the sufficiency of the existing regulations. It would build on the the outreach processes already underway by USDA and EPA, through the creation of an independent standing committee of experts under the aegis of the National Academy of Sciences and the establishment of regional pest management centers. Analysis would begin with case studies of how the existing system applies to different transgenic organisms. Work would be designed to identify strengths and weaknesses of the current system and, in combination with scientific information, establish a foundation for future recommendations. New directions might include recommendations for additional environmental monitoring and risk assessment activities. Initial recommendations would be likely within six months. This policy option would help address questions about the environmental implications of agricultural biotechnology and bolster public confidence that the federal government is taking them seriously. It is supported by all agencies; however, some concern was expressed that care would have to be taken to avoid the impression the Administration did not have complete confidence in the U.S. regulatory system or had concerns about biotechnology.

**3. Facilitating Voluntary Disclosure of Consumer Product Information through Non-Biotech Labeling and Other Means** (i.e., defer to the private sector on product segregation, tolerance-setting, and choice of mechanism for providing consumer information, including non-biotech labeling, but engage with it to lend order to the process and reduce uncertainty and confusion for farmers, companies, and consumers).

Although there is general confidence in and out of government that bioengineering *per se* does not pose unique health risks in food products that would require mandatory FDA labeling, consumer preferences abroad and, to a lesser extent, in the US are prompting some commodity firms and food companies to segregate and voluntarily label non-bioengineered crops and products. Competing producers have an interest in ensuring that any such claims are not false or misleading. Consumers have an interest in ensuring that information voluntarily disclosed on products is accurate, reliable, and

comparable to information found on other products, as illustrated by the current confusion of supermarket shoppers in the UK. Finally, farmers and grain elevator operators have an interest in ensuring that steps they take to test and maintain the segregated identity of non-biotech crops will be reliable and generally recognized as valid by commodity firms. It should be noted that industry is more comfortable with negative, or "non-biotech," labeling than it is with affirmative, or "contains GMOs," labeling, which it fears could unduly raise the profile of the issue for consumers given the widespread presence of bioengineered corn, soy and other ingredients in products on US supermarket shelves.

As noted above, FDA has already announced three hearings, the purpose of which is to share the agency's approach regarding safety evaluation and labeling of food products derived from bioengineered plant varieties, solicit views on whether FDA's policies or procedures should be modified, and gather information on appropriate means of providing information to the public about these products. Building on these activities, this option would create a process of public outreach and technical research through USDA and FDA to support an orderly process of voluntary product segregation and non-biotech labeling to the extent one emerges in the private sector.

a) USDA process on testing, quality assurance and tolerances for non-biotech products. USDA would initiate a comprehensive process of public outreach to determine the feasibility of establishing standardized testing protocols, quality assurance programs, and tolerances for voluntary non-biotech product segregation and claims. This process would take into account both consumer demands and production and handling factors such as pollen drift and commingling. It would involve public meetings, specific stakeholder group consultations, and, for development of quality assurance procedures and tolerances, the issuance of an Advanced Notice of Proposed Rulemaking (ANPR). It might most usefully be initiated following next year's harvest after the industry has had more experience with segregating and testing commodities. Once a certification process were established, the GMO status of a given commodity would become a key component of industry-developed "chain of custody" programs, which might facilitate voluntary labeling of consumer products. The process could inform and support USG efforts to influence foreign regulatory decisions about where to set non-biotech tolerance levels, thereby potentially helping to preserve fair market access opportunities for US farm exports. Should domestic industry choose to use this information to develop labels, FDA would need to determine whether they were truthful and not misleading in order to ensure that no unwarranted inferences would be drawn by consumers concerning human health considerations.

b) FDA process to develop guidance for voluntary informational labels for non-biotech products. Under current Federal Food, Drug, and Cosmetics Act (FFDCA) authority, companies currently can use product labels to indicate whether their products contain genetically engineered ingredients. However, the labels must meet the standard of being truthful and non-misleading, as interpreted by the FDA. Building on the current FDA hearings, this policy option would create a process by which the agency would develop guidance on the elements of a truthful and not misleading label for non-GMO food products in order to inform the design of any such claims voluntarily made by companies. Such guidance would likely include a recommendation that GMO-free labels include a disclaimer indicating that

bioengineered foods do not differ in safety or qualify from other foods. FDA recommended use of a similar disclaimer in its guidance on labeling of milk from cows not treated with rbST.

c) FDA process to develop appropriate mechanisms, other than through the food label, for providing information to consumers. Building on the current FDA hearings, and on the experience FDA gained from developing a web-site listing the Y2K compliance status of thousands of medical devices, this policy option would create a process by which the agency would develop guidance on the listing of GM and GM-free food products on Federal or company web-site or on making such information available through 800-numbers.

USDA and other agencies support these options, with the exception of HHS and USTR, which do not support sub-options (a) and (b) because they believe that even limited governmental involvement in activities related to biotech labeling would implicitly bless and energize the actions of those who oppose the products and call for their mandatory labeling, thereby undermining public confidence in them. HHS is also concerned that adding information on food labels on matters unrelated to the safety or fundamental characteristics of the product would undermine the function and utility of food labels, in part by adding clutter and distracting consumers from core nutritional information. USTR believes the marketplace will sort these issues out without the help of government programs. Commerce supports sub-options (a) and (c) but not (b), for the same reasons as those attributed to HHS.

#### **4. Supporting Mandatory Pre-Market Approval and Product Labeling**

The Administration could adopt the EU posture of requiring pre-market regulatory approval and labeling of products with bioengineered content above a certain threshold. It could do so by sponsoring or endorsing legislation in Congress.

a) Mandatory approval of new products (as distinguished from mandatory pre-market *notification* in Option 2a above) would allow FDA itself to vouch for safety of bioengineered foods based on in-depth reviews, as it now does for food additives. This would satisfy demands of at least some consumer groups by providing an additional assurance of safety, removing the criticism that the current system depends on the good faith of biotech companies. However, such a change in policy would be opposed by industry on the grounds that it could undermine public confidence by suggesting that the federal government has serious concerns about the safety of the technology. It could also create significant period of "regulatory limbo" between the time of the proposal and enactment, delaying market entry of commercially important new foods despite the longstanding Federal view that bioengineered foods do not raise scientific or safety issues warranting such oversight.

b) Mandatory labeling of bioengineered food products may ultimately be the only way to cease being on the defensive about bioengineered foods, in part because many consumers may end up harboring misgivings about the technology absent greater assurance that they will have control over the decision to consume foods derived from it or not. Moreover, in light of the range of bioengineered crops grown in the U.S., the scale of the processed foods that would have to be labeled might actually serve to reduce any stigma associated with labeled products. The

Administration might be able to get in front of the issue in this fashion, forcing stakeholders to work with Congress to develop a solution. And by affording the maximum degree of information to consumers, mandatory labeling in the long run might well lead to lower consumer concerns regarding the technology than would otherwise be the case.

On the other hand, mandatory food labels for biotech content could undermine the function and utility of the food label, whose purpose is to provide information pertinent to characteristics and composition of the food. As such, it could distract attention from important nutritional and health information now on food labels and trigger additional calls for consumer "right to know" labeling on other issues. In addition, an abrupt policy shift of this nature could foster greater distrust of bioengineered foods by giving the impression that they must be different and riskier than other products, leading food processors to avoid their use and consumers to boycott their purchase. Since industry is currently interested most of all in having the federal government clearly and repeatedly vouch for the safety of the products, it would undoubtedly be highly critical of this policy and consider fundamentally 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. Finally, shifting away from science-based labeling could reduce the Administration's credibility with U.S. science-based societies and industries. Pharmaceutical and Genomics industries are already concerned about spill-over of anti-science sentiment from agriculture to medicine, and abandoning science-based policy in this area could reduce the Administration's ability to enlist and maintain support for science-based standards and requirements in various international fora and negotiations.

No agency supports these options, reflecting the concern, shared by industry and farmers, that such a major policy shift might alarm and confuse consumers and create a disorderly shift in their purchasing behavior that would not be warranted by our scientific understanding of the issue. The top priority of industry and farmers is for the USG to take steps to reinforce the generally strong level of consumer confidence that still prevails in the US. They perceive that these steps would work at cross purposes to this objective.

## RECOMMENDATION

With the exception of HHS, USTR and Commerce, all agencies support Options 1, 2, and 3. (HHS and USTR support all but sub-Options 3a and 3b, whereas Commerce supports all but sub-Option 3b. In addition, HHS believes strongly that implementation of Option 2a should follow conclusion of its current outreach process.)

Option #1 -- Enhancing Public Education and Outreach to Strengthen Consumer Confidence.

Option #2 -- Maintaining and Strengthening Confidence in the US Regulatory Framework by:

a) requiring companies to notify FDA 90 days before biotech products are introduced into commerce;  
and

b) directing CEQ/OSTP to organize an interagency process to examine the adequacy of federal environmental monitoring activities and regulation with respect to agricultural biotechnology.

Option #3 -- Facilitating Voluntary Disclosure of Consumer Product Information through Non-Biotech Labeling and Other Means.

- a) USDA process on testing, quality assurance and tolerances; and
- b) FDA process to develop guidance for voluntary informational labels.
- c) FDA process to develop appropriate mechanisms, other than through the food label, for providing information to consumers.

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Approve Recommendation

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Disapprove Recommendation

Attachments

Tab A            Memorandum to NEC High-Level Group Principals