!!! F A X !!!

Tel: 301-827-0591 Fax: 301-443-6906 May 19, 1999 Cover + 2 pages

Food and Drug Administration
Office of the Commissioner
Office of Policy, HF-23
5600 Fishers Lane, Rm. 15-74
Rockville, MD 20857 USA
EFlamm@OC.FDA.GOV

To: Tom Freedman
202-456-7431

From: Eric Flamm

Re: BMA Biotech Report

Bill Hubbard asked me to fax this to you. If you have any questions, feel free to contact me or Jim Maryanski, who is the Biotechnology Coordinator for FDA's Center for Food Safety and Applied Nutrition (202-205-4359).

Background and Q's and A's on British Medical Association Press Release of 5/17/99 on GMO's

In the EU in general, and in the UK in particular, there has been growing concern about the safety of foods from genetically engineered plants, and the environmental safety of planting genetically engineered crops and other plants (referred to in Europe as "genetically modified organisms," GMO's, or GM foods and GM crops). This concern was heightened enormously as a reaction to the UK government's handling of "mad cow disease," in which it repeatedly (and incorrectly) assured the public that there was no human health risk whatsoever from eating meat from diseased cows. As a partial consequence, consumers in the UK, and in the rest of Europe, have very little confidence in government regulators and government scientists. Perhaps as part of an attempt to regain consumer confidence, government regulators and scientists have now been taking an extremely cautious approach to bioengineered plants and foods. (It should be noted that no one claims any connection between mad cow disease and biotechnology.)

Three noteworthy events have occurred recently in the UK. In a confidential report, the UK Government's Chief Medical Officer and its Chief Scientific Adviser proposed "the creation of a new unit to monitor the health effects of GMOs, similar to the unit monitoring CJD". It should examine "potential health effects" including "foetal abnormalities, new cancers, and effects on the human immune system." Press accounts of this report appeared on May 2 in the UK. (CJD is the human counterpart to mad cow disease.)

A statement was released about a year ago by a researcher at the Rowett Research Institute in the UK (Dr Arpad Pusztai) that engineered foods were potentially unsafe, based on the results of his studies in which rats were fed potatoes engineered to contain a lectin gene. He was fired from the institute for prematurely announcing preliminary data to the media prior to review within the institute. However, a group of scientists claimed that his work was legitimate and that he was unjustly fired. The media in the UK began running articles claiming that "Frankenstein foods" were being foisted on the public without their consent. The Royal Society of the UK undertook a review of the evidence on the study, and released their findings on May 18, 1999. They concluded that "the data reviewed provide no reliable or convincing evidence of adverse (or beneficial) effects, either of lectins added to unmodified potatoes or of potatoes genetically modified to contain a lectin gene, on the growth of rats or on their immunological function."

On May 17, the British Medical Association issued a report calling for, amongst other things, a moratorium on commercial planting of GM crops in the UK; segregation and labeling of GM foodstuffs, to enable identification and traceability of GM products, and consideration of banning imports that are not segregated and labeled; a ban on use of antibiotic resistance marker genes in plants; and strengthening of the UK disease surveillance systems.

Q: Does the USG believe that GMO foods and crops pose risks to health or the environment?

A: All engineered foods on the market have gone through a consultation process with FDA and FDA has found none to raise any safety concerns that would warrant restricting them from marketing. Before they can be planted, they go through a review process with USDA APHIS, and if they contain certain pesticidal traits, with EPA. We believe that the system in the US provides proper safeguards that no unsafe products are grown or marketed in the US.

Q. What is the USG view of the BMA report?

A. Based on our reading of the report's Executive Summary, we do not believe that it provides any new information or raises any issues that would call into question the safety of US products. We disagree with what seems to be the underlying belief reflected in the report, that engineered crops and foods are so different from traditionally-derived crops and foods that their safety cannot presently be predicted or established. In fact, all engineered food crops marketed to date contain only substances that are commonly found in foods or are substantially similar to substances commonly found in foods, and so do not raise unique or unusual health or safety issues. We do not have any information to indicate that the use of recombinant DNA techniques creates a class of products that differ in quality or safety from those developed using traditional techniques. The US agrees that appropriate cautions should be taken to ensure that agricultural crops and foods pose no risks to human health or the environment, and we believe that our system does take such appropriate cautions.

6 mo

-EXECUTIVE OFFICE OF THE PRESIDENT-
COUNCIL ON ENVIRONMENTAL QUALITY

ROOM 360
OLD EXECUTIVE OFFICE BUILDING
WASHINGTON, D.C. 20502

PHONE: (202) 456-6224
FAX: (202) 456-2710

TO: Please see names on List

FROM: Holly Kopack

DATE: 7/16/99 PAGES: 3
(INCLUDING COVER SHEET)

COMMENTS:

Staff Level Biotechnolgy Meeting
July 15, 1999
5:30 PM, Room 476 OEOB

Name	Organization	Phone/Fax	E-Mail
David Sandalow	CEQ/NSC	456-6424/456-2710	
Ian Bowles	CEQ/NSC	" "	
Mary Smith	DPC	456-5571/456-7431	Smith_ML@a1.eop.gov
James Maryanski	FDA/CFSAN	202 205 4359/2024012593	jmaryanski@bangate.fda.gov
B M Hubbard	FDA	301-827-3360	bhubbard@oc.fda.gov
Eric Flamm	FDA	301 827 0591	EFlamm@oc.FDA.GOV
Tom Freedman	DPC	202456-5587/x67493	Freedman_T@A1.EOP.Gov
David Festa	DOC	482 2266/482 4191	dfesta@DOC.GOV
Victoria Greenfield	CEA	395-5040/395-6870	Victoria_A._Greenfield@cea.eop.gov
Nigel Purvis	STATE/G	647-8745/647-0753	
Erik Godwin	OIRA/OMB	202-395-3087/395-7285	Erik_K._Godwin@OMB.EOP.GOV
Steven Galson	EPA/OPPTS	2022606900/401-0849	galson.steven@epa.gov
Michael Schechtman	USDA	202-720-3817/690-4265	michael.g.schechtman@usda.gov
Jamel Celeste	EPA/OGC	202.260.5372/401.1065	
Dave Shark	USTR	202-395-9434/395-4579	d.shark@USTR.GOV
Skip Jones	OMB	202-482-2307/482-5939	SJones@ita.doc.gov
Susan Gordon	State/OES	202 647-3253/647-0191	gordonsc@state.gov
Cathy Enright	State/OES	202 736-7428/736-7351	cenright@State.gov
Brooks Yeager	State/OES	202 647 2232/647 0217	
Bernice Slutsky	USDA/FAS	202 720-4261/690-0677	Slutsky@FAS.USDA.gov
Kenia Wilkinson	STATE/OES	202-647-3966/647-0217	kowilkinson@state.gov
John Payne	USTR	202-395-9558/395-4579	jpayne@ustr.gov
Brian Zuckerman	OMB/OIRA	202-395-5703/395-7285	Brian_L._Zuckerman@oa.eop.gov
Wendy Taylor	OMB	202-395-4815/395-6974	Wendy_Taylor@OMB.EOP.GOV
Margaret Malanoski	OMB	202-395-3122/395-7285	mmalanos@omb.eop.gov
Ina Yoon	EPA/OSCP	202-260-6900/260-0811	

Staff Level Biotechnolgy Meeting
July 15, 1999
5:30 PM, Room 476 OEOB

Name	Organization	Phone/Fax	E-Mail
ISI A. SIDDIQUI	USDA	(202)720-6919 Fax 690-8080	Isi.SIDDIQUI@USDA.G
CLIFF GABRIEL	OSTP	456-6187/6027	Cgabriel@OSTP.EOP.G
MARC BAAS	State/EB	647-3090/647-2302	Lausma@state.gov
Eric Olsen	USDA/OSEC	720-3808/5437	Eolsen@usda.gov
KEITH PITTS	USDA/OSEC	690-2525/690-3662	keith.pitts@usda.gov
Jim Murphy	USTR	395-6127/395-4579	
Anne Pence	E/State	647-7513/647-9763	
Bruce McNamer	NEC	4565363/456 5334	bruce_mcnamer@opd.eop.gov

New Biotech Initiatives at USDA

GMO's

Independent Scientific Review of USDA Regulatory System

USDA is working with the National Academy of Science (NAS) to establish an independent scientific advisory committee to regularly review our regulatory system and to assist in the development of policies and approaches for conducting risk assessments and making regulatory decisions on future biotech products. NAS is working up a proposal; similar committees that have been established in the past have been budgeted at $1 million-1.5 million per year and can complete 5 to 6 major reviews per year.

While no formal independent scientific review has been conducted on USDA's regulatory system: the NAS conducted a study, and made recommendations to APHIS, on field testing guidelines (1989); a now-defunct advisory committee, the Agricultural Biotechnology Research Advisory Committee, made recommendations that led to the current notification system, an exemptive process, for certain biotech products (1992); and APHIS is currently developing a strategy for the review and approval of modified arthropods.

Regional Centers

See Attached paper.

New Reporting Guidelines

Under the Plant Pest Act, which is used to review and regulate GMO's for release into the environment, USDA does not have legal authority to enforce reporting requirements for unexpected or adverse effects on "deregulated" biotech products. However, in future guidelines and regulatory decisions, APHIS will be requesting biotech developers to report any unexpected or adverse environmental and agricultural impacts to the agency, even after a product has been deregulated.

NEPA Compliance

The current biotech approval process at USDA is technically out of compliance with NEPA. Effective immediately, the Department will be adjusting the approval process to ensure NEPA compliance.

Arm's Length Regulator

The APHIS regulatory approval process is currently staffed by 8 people. These scientists currently must serve USDA's regulatory and trade support and promotion functions for biotechnology, potentially creating conflict of interest and workload concerns. Similar concerns were raised about the Food Safety Inspection Service prior to its reorganization. The Department will be initiating a reorganization effort with APHIS that is similar to what has already happened at FSIS.

Formation of the Advisory Committee on Agricultural Biotechnology

See attached FR Notice.

GMO's

Regional Pest Management Centers

Global markets for food, fiber and grain products demand high quality at competitive prices. American farmers and agribusiness must also satisfy consumer expectations for food safety and environmental progress, a task made more difficult by ever-increasing production costs coupled with decreasing or unstable commodity prices. Added to these contemporary challenges are the implementation of the Food Quality Protection Act of 1996 (FQPA) and rapid advances in agricultural biotechnology.

While the FQPA will help ensure an even higher level of confidence in the safety of the American food supply, it will also impose unprecedented challenges and uncertainty on agricultural producers, both in the short and long term. Several pesticides, including some which have been important components of integrated pest management (IPM) systems, may no longer be available because of potential public health risk stemming from one or more routes of exposure. Also, many of the new tools, while highly effective, do significantly increase the complexity of IPM systems. Hence, there has never been a more critical need, nor more appropriate timing, for USDA to take a proactive role in advancing development and adoption of biologically intensive IPM systems and component technologies.

Prevention-based, multitactic IPM systems are already in place on thousands of farms. Recent scientific advances and the healthy pace of innovation in the agricultural biotechnology and chemicals industries are providing pest managers with new tools and novel tactics to ensure a safe, nutritious, economical food supply for the American public, while maintaining a strong, competitive agricultural economy.

Since crops, pests, and weather patterns differ so greatly from region to region within the United States, no single national public policy, research program, or regulatory approach to pest management will be universally effective across all agricultural regions. It is also not necessary, nor an efficient use of public and private resources, for every state within similar production regions to organize and support repetitive, and often competing and duplicative, pest management program efforts. Accordingly, USDA is committed to the establishment of a network of regional pest management centers focusing on major regional cropping patterns, pests, and environmental challenges. The centers will help foster coordination in program efforts and the identification of research and education priorities. They will be responsible for advancing our ability to measure progress toward biointensive IPM and challenged to quantify the linkages between IPM and attainment of environmental quality goals. Centers will create new mechanisms to seek out and benefit from broad public participation and will use program resources to foster public-private partnerships in setting and achieving pest management and pesticide use goals.

Vision.

The USDA envisions the establishment of Regional Pest Management Centers based on crop production zones similar to EPA Pesticide Residue Field Trial Regions. Centers will be housed at land-grant universities or other appropriate facilities such that

little new infrastructure would be required. Programmatic activities and administrative processes within the Centers will evolve from and integrate, to the fullest extent possible, current state-level IPM program administrative infrastructures. As the new pest management paradigm unfolds, a primary function will be to provide rapid access to information on pest challenges, IPM options, and data on pesticide use patterns. Over time, Centers will also be asked to assume expanded and new roles in the development of regulatory policy on a regional basis and in the administration of competitively awarded research, education and implementation programs, such as the Pest Management Alternatives Program, the Crops at Risk Program, the Risk Avoidance and Mitigation Program and the Methyl Bromide Transition Program.

Mission.

The Centers will support the pest management needs of federal and state regulators, extension personnel, and the public through a coordinated effort at the regional level. Each Center will:

A) Address critical pest management needs for the crop commodities within the region,

B) Develop and share national expertise in a specific cross-commodity area such as biological control, biotechnology, invasive species, precision agriculture, resistance management, or information technology, and

C) Maintain an IPM measurement and reporting function to help document the attainment of IPM and environmental quality goals, and to satisfy GPRA and other program evaluation needs.

Each center will provide rapid response to information requests from funding agencies and will actively promote pest management education and implementation in both agricultural and urban environments. Key Center activities will include:

1) Identify and organize pest management expertise within the regions to ensure rapid response capability for pest problems or public information needs,

2) Develop and implement FQPA crop-specific risk mitigation and transition plans,

3) Assess the need for and support development of teaching resources in pest management education for agricultural producers as well as consumers,

4) Provide science-based, regionally-specific input for public policy and regulatory issues,

5) Exercise leadership in promoting and evaluating new agricultural and urban pest management technologies; and

6) Coordinate and report on regional pest management research and implementation projects.

Organization.

Each Center will be composed of a Center Director and staff, an Advisory Board, and an Executive Committee. The *Center Director and staff* will be responsible for establishing center goals, assuring broad-based participation, developing budgets and securing funding, and day-to-day management of programs and activities. The *Advisory Board* will consist of individuals dedicated and willing to work cooperatively toward the goal of promoting adoption of IPM. Boards will include stakeholder and funding agency representatives, IPM innovators in the field, researchers and other technical experts, and consumer and environmental advocates

The *Executive Committee* will consist of the Center Director, Advisory Board Chair and Vice-Chair, Federal Agency Representatives, Land-Grant and 1890 University Representatives from each state in the region, one or more IPM practitioners, including growers, and one or more representatives from the consumer and environmental community. The Executive Committee will make final decisions based on Advisory Board recommendations.

Center Locations.

Centers would be developed in approximately 12 regions of the United States based on similarity of cropping systems, weather patterns, pest problems and geography. These regions would be similar to the field trials regions developed by EPA for use in determining where crop residue studies should come from. It will be necessary to get input from the regions before final boundaries can be defined.

Insect Resistance Management (IRM) in Bt Crops

Management of insect resistance to Bt is important because of the threat insect resistance poses to the high benefits and low risks of using Bt toxins in transgenic crops and in spray formulations. Bt microbial sprays have long been safely used by agronomic, vegetable and fruit farmers as well as foresters to control pests as part of an integrated pest management (IPM) program. Bt toxins expressed in transgenic plants can and have reduced the use of more hazardous insecticides such as organophosphates and pyrethroids for target pests.

However, unique to Bt crops is season long expression of the Bt toxins that will likely increase the risk of resistance development. Therefore, IRM is considered a key to the sustainable use of Bt toxins in both transgenic crops and Bt microbial spray formulations.

EPA and USDA in cooperation with the seed industry and crop commodity organizations have developed a proactive approach to IRM for transgenic crops including the following best management principles:

Increased knowledge of pest biology and ecology,
appropriate high-dose expression strategy,
appropriate refuges composed of non-transgenic crops,
employment of integrated pest management (IPM),
communication and educational strategies on use of Bt crops,
monitoring and reporting of incidents of pesticide resistance development, and
remedial action aimed at elimination of any resistant populations discovered.

As part of its scientific basis for developing IRM recommendations for Bt crops, we have relied on other scientific expert group reports including: the USDA North Central Regional Research Committee NC-205 refuge recommendations, the International Life Sciences Institute/Health and Environmental Sciences Institute (ILSI/HESI) report entitled *"An Evaluation of Insect Resistance Management in Bt Field Corn: A Science-Based Framework For Risk Assessment And Risk Management,"* and the Union of Concerned Scientists' publication entitled *"Now or Never: Serious New Plans to Save a Natural Pest Control."*

Proposed IRM Strategies for Future

In coming years, USDA and EPA seek to continue to improve upon existing IRM recommendations for Bt crops based on the most current understanding of the science and technology while providing flexibility to growers. In addition, we seek to provide a consistent set of IRM recommendations and requirements for similar Bt products, such as Bt field corn, as appropriate, considering regional differences in crop, pest, and weather patterns. We will continue to cooperate with EPA in using a science-based risk assessment and risk management process to evaluate and determine IRM requirements for Bt crops. We will use all information available including the literature, registrant submissions, and expert research groups.

When new data, such as measurements of resistance gene frequency and gene expression, show that smaller refuges are adequate, the size of existing structured refuges may be reduced. Similarly if new data such as larval and adult movement or ovipositional and mating behavior suggest the location or size of a structured refuge should be changed, the requirements for certain refuge options will be changed. In addition, we believe the Regional Pest Management Centers, once they are operational, may provide information for regionally-specific implementation of IRM plans including structured refuges.

Regional Pest Management Centers

Because crops, pests, and weather patterns differ from region to region within the United States, a single, national approach to pest management across all the agricultural regions is not effective. It is also not economically efficient to have redundant pest management program efforts in all states with similar production regions. Recently, the USDA proposed the development of Regional Pest Management Centers based on similarity of cropping patterns, pest problems and environmental conditions. The regional centers would provide a forum for dialogue on pest management issues, would also assist in the development and establishment of appropriate regional resistance management strategies for Bt crops, and other monitoring issues related to bioengineered crops.

Notices

Federal Register
Vol. 64, No. 108
Monday, June 7, 1999

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Advisory Committee on Agricultural Biotechnology

AGENCY: Research, Education, and Economics, USDA.

ACTION: Notice of intent to establish the Advisory Committee on Agricultural Biotechnology

SUMMARY: The U.S. Department of Agriculture proposes to establish the Advisory Committee on Agricultural Biotechnology (ACAB). The Secretary of Agriculture is requesting nominations for qualified persons to serve as members of the ACAB.

DATES: Written nominations must be received on or before July 7, 1999.

ADDRESSES: Nominations should be sent to Michael Schechtman, Designated Federal Official; Office of the Deputy Secretary, USDA, 202B Jamie L. Whitten Federal Building, 14th and Independence Avenue, SW, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Michael Schechtman, Designated Federal Official, telephone (202) 720–3817; fax (202) 690–4265; email *michael.g.schechtman@usda.gov*. To obtain form AD–755 ONLY please contact Dianne Harmon, Office of Pest Management Policy, telephone (202) 720–4074, fax (202) 720–3191; email *dharmon@ars.usda.gov*.

SUPPLEMENTARY INFORMATION:

Advisory Committee Purpose

The Secretary of Agriculture is establishing the Advisory Committee on Agricultural Biotechnology (ACAB) to advise the Secretary of Agriculture on the broad array of issues related to the expanding dimensions and importance of agricultural biotechnology. USDA has complex and crucial roles in protecting public health and safety, the natural environment, and a competitive, vibrant, and diverse farm economy; ensuring the quality and availability of our food and fiber supply; and maintaining the competitive position of American agricultural products in the international marketplace. These topics are of critical concern in the conduct of agricultural biotechnology research, regulation, and commercialization. Some of the topics that the Secretary of Agriculture has identified for the ACAB's initial consideration include: effects of industry concentration and consolidation on farmers; intellectual property rights and grower autonomy; effects of biotechnology on small farmers; ways to maximize or encourage potential benefits of biotechnology in different agricultural sectors; and USDA's role in assuring that farmers have an array of choices for future agricultural technology and practices. The ACAB will meet in Washington, DC, up to four (4) times per year.

Task Force Membership

The ACAB will consist of 25 members of whom no more than five (5) will be federal employees. Members of ACAB should have recognized expertise in one or more of the following areas: Recombinant-DNA (rDNA) research and applications using plants; rDNA research and applications using animals; rDNA research and applications using microbes; food science; silviculture and related forest science; fisheries science; ecology; veterinary medicine; the broad range of farming or agricultural practices; weed science; plant pathology; small farm advocacy; biodiversity issues; applicable laws and regulations relevant to agricultural biotechnology policy; risk assessment; consumer advocacy and public attitudes; public health/epidemiology; occupational health; ethics, including bioethics; human medicine; biotechnology industry activities and structure; intellectual property rights systems; and international trade. Members will be selected by the Secretary of Agriculture in order to achieve a balanced representation of viewpoints to address effectively USDA biotechnology policy issues under consideration.

Nominations for ACAB membership must be in writing and provide the appropriate background documents required by USDA policy, including background disclosure form AD–755. Neither the form nor the information it contains may be released to the public, except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C.552a).

No member may serve on the ACAB for more than three (3) consecutive terms. Nominees will initially serve for terms of 1 or 2 years for purposes of continuity.

Members of the ACAB and its subcommittees shall serve without pay, but with reimbursement of travel expenses and per diem for attendance at ACAB and subcommittee functions for those ACAB members who require assistance in order to attend the meetings. While away from home or their regular place of business, those members will be eligible for travel expenses paid by REE, USDA, including per diem in lieu of subsistence, at the same rate as a person employed intermittently in the government service is allowed under section 5703 of Title 5, United States Code.

Submitting Nominations

Nominations should be typed and include the following:

1. A brief summary of no more than two (2) pages explaining the nominees suitability to serve on the ACAB.
2. A resume or curriculum vitae.
3. A completed copy of form AD–755.

Nominations should be sent to Michael Schechtman at the address listed above, and be post marked no later than July 7, 1999.

USDA is actively soliciting nominations of qualified minorities, women, persons with disabilities and members of low income populations through outreach to minority-focused media outlets, Historically Black Colleges and Universities, including Clark Atlanta University, the Hispanic Association of Colleges and Universities, the National Congress of Native American Indians, the Intertribal Agriculture Council, Gallaudet and Purdue Universities, and the Rural Coalition. To ensure that recommendations of the ACAB take into account the needs of underserved and diverse communities served by the USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent

minorities, women, and persons with disabilities.

I.M. Gonzalez,

Under Secretary for Research, Education, and Economics.

[FR Doc. 99-14308 Filed 6-4-99; 8:45 am]

BILLING CODE 3410-03-P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Request to Extend a Currently Approved Information Collection

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Research Service's intent to request an extension of a currently approved information collection, the Continuing Survey of Food Intakes by Individuals (CSFII) 1999–2002.

DATES: Comments on this notice must be received August 11, 1999 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Alanna J. Moshfegh, Research Leader, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, U.S. Department of Agriculture, 4700 River Road, Unit 83, Riverdale, MD 29737, (301) 734–8457.

SUPPLEMENTARY INFORMATION:

Title: Continuing Survey of Food Intakes by Individuals (CSFII) 1999–2002.

OMB Control Number: 0518–0023.

Expiration Date of Approval: October 31, 1999.

Type of Request: Extension of a currently approved information collection, the Continuing Survey of Food Intakes by Individuals (CSFII).

Abstract: USDA has been conducting nationwide food surveys since the 1930's as one means of fulfilling its responsibility to ensure the health and well-being of Americans through improved nutrition. USDA food consumption surveys measure the levels and shifts in the food and nutrient content and the nutritional adequacy of U.S. diets over time, and provide other information pertinent to understanding diets and their determinants.

The Continuing Survey of Food Intakes by Individuals (CSFII) is a major component of the National Nutrition Monitoring and Related Research Program (NNMRRP), established by the National Nutrition Monitoring and Related Research Act of 1990 (P.L. 101–445). The CSFII addresses the requirement of the 1990 Act for continuous monitoring of the dietary and nutritional status of the U.S. population and trends with respect to such status by obtaining information on food intakes by individuals. Another component of the NNMRRP, the Diet and Health Knowledge Survey (DHKS), is included in the CSFII. The DHKS is the first national survey designed so that data on individuals' attitudes and knowledge about nutrition and health can be linked directly to data on their food and nutrient intakes.

The primary public policy applications of USDA's food consumption survey data include evaluating the adequacy of American diets in relationship to scientific and Federal dietary recommendations and goals. Applications include monitoring the dietary status of at-risk population subgroups including children, the elderly, low-income, etc; assessing the nutritional impact of Federal food assistance programs; estimating exposure to pesticide residues, food additives, and contaminants; and monitoring and evaluating food use across the population specifically as it relates to food safety issues. Under the Food Quality Protection Act of 1996, the CSFII provides food consumption data for use in improving the accuracy and quality of EPA dietary risk assessments. Other applications include developing food fortification, enrichment, and labeling policies and assessing the nutritional impact of those policies; and assessing demand for agricultural products.

Accurate and timely food consumption data in an electronic, user-friendly format is a goal essential for meeting the information needs of these applications. The CSFII 1999–2002 interviews will use a computer-assisted telephone mode of collection. A newly developed USDA multiple-pass 24-hour recall method will be used to collect the dietary information. The sample will be drawn through a list-assisted random-digit dialing approach with the full U.S. population covered each year. Future plans include integrating the CSFII with the DHHS' National Health and Nutrition Examination Survey, allowing for a significant increase in sample size and coverage of population subgroups and use of a common dietary methodology and nutrient data base.

For the past two years extensive methodologic research has been conducted to develop an improved USDA multiple-pass 24-hour recall method to collect the dietary information by telephone. Both cognitive research and field tests have been conducted as components of this research. Activities also have been ongoing to automate the recall method and other survey questionnaires for administration by telephone. During the next year, development and testing of the computer-assisted recall method and other questionnaires will continue. The computer-assisted telephone interviews will be tested and evaluated in two nationwide pilot studies. Data collection for the main CSFII will begin in January 2001.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 90 minutes per response.

Respondents: Non-institutionalized individuals of all ages residing in private households in the U.S.

Estimated Number of Respondents: 5,000 over 1 year.

Estimated Total Annual Burden on Respondents: 7,500 hours.

Copies of this information collection and related instructions can be obtained without charge from Lori G. Borrud, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, U.S. Department of Agriculture, 4700 River Road, Unit 83, Riverdale, MD 20737, (301) 734–8457.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Alanna J. Moshfegh, Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, U.S. Department of Agriculture, 4700 River Road, Unit 83, Riverdale, MD 20737, (301) 734–8457.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

6 MOS

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

TELEPHONE (202) 720-3631 FAX (202) 690-2119

FAX COVER SHEET

DATE: _____

NUMBER OF PAGES, INCLUDING COVER SHEET: _____

PLEASE DELIVER TO: Tara Bradner

FAX NUMBER: ( ) _____ PHONE NUMBER: ( ) _____

FROM:☐ DAN GLICKMAN, SECRETARY
- ☐ JOHN GIBSON, SPECIAL ASSISTANT

☐ GREG FRAZIER, CHIEF OF STAFF
- ☐ JOSE VENZOR, EXECUTIVE ASSISTANT & BRIEFINGS DIRECTOR

☐ BART CHILTON, DEPUTY CHIEF OF STAFF

☐ CLYDE WILLIAMS, DEPUTY CHIEF OF STAFF
- ☐ JUSTIN PASCHAL, STAFF ASSISTANT

☒ ERIC OLSEN, COUNSEL TO THE SECRETARY FOR DOMESTIC POLICY

☐ JANET POTTS, COUNSEL TO THE SECRETARY

☐ ISI SIDDIQUI, SPECIAL ASSISTANT TO THE SECRETARY FOR TRADE

☐ BOB EPSTEIN, SCIENCE ADVISOR TO THE SECRETARY

- ☐ LAURETTA MILES, ADMINISTRATIVE ASSISTANT
- ☐ JANNA PASCHAL, STAFF ASSISTANT

MESSAGE: FYI – this is going to be a big

Bruce, E Thanks

Food Fight

AGRICULTURAL BIOTECHNOLOGY SEEMS TO ATTRACT A LOT OF ATTENTION THESE DAYS. Unfortunately, most of it is the wrong kind.

The genetic engineering of plants will almost certainly be needed to feed a human population that will stabilize at 10 billion or more sometime during the next century. Furthermore, it's the first arena where the techniques of genetic manipulation, developed during the 1970s, are being applied on a large scale. Therefore, the attention is justified, since we need to be mindful of what we as a species are doing to the other species on the planet when we modify the genes of our food crops.

The problem is that the debate on this topic seems to have been hijacked by extremists on both sides: environmentalists crying disaster and corporate spokespersons telling us soothingly that there's nothing to worry about—that there's nothing sinister or even unusual about genetic engineering, which, they argue, simply extends methods farmers have used since the beginning of agriculture to improve crops and livestock.

Both extremes are wrong. Certainly global disaster isn't just around the corner. On the other hand, there *is* something novel and extraordinary about our ability to insert the genes of one species among the genes of another. And, as with the introduction of any remarkable new technology, unforeseen consequences are inevitable.

One possible consequence is addressed in detail by Charles C. Mann in this issue's cover story, "Biotech Goes Wild." Mann, one of the nation's very best science and technology journalists, reveals that crops genetically engineered to produce or resist pesticides could interbreed with wild plants, giving rise to "superweeds" that could be very hard to eradicate and might choke food crops. Many biologists have dismissed the threat of such phyto-promiscuity, but some scattered data are unsettling. And the fact is that science can't yet tell us whether to be alarmed.

Why are we still in ignorance on this important issue? One reason is that the biologists who engineer genes into plants aren't trained to think about the whole organism and its habitat; they're molecular folk, lacking an ecological perspective.

Another reason is the patchwork of U.S. regulatory agencies that govern agricultural biotech: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). Mann writes that none of these agencies is responsible for superweeds, which could grow between the bureaucratic cracks. The FDA doesn't look at plants engineered to express pesticides, because pesticides are exempt from the agency's reach. The EPA is required to treat such foods as pesticides and simply establish human tolerances for each compound. USDA tries to make sure the crop grows as the producer says it will.

There's only one thing omitted from this patchwork: the public interest. To stitch it back in two things are needed. One is additional research, from biotech companies and the federal government on the ecological consequences of genetic engineering. The other is a revision of the regulatory framework to make at least one of the agencies responsible for testing the environmental consequences of agribiotech. These changes would acknowledge the growing impact of this remarkable new technology and help us steer a course between wrongheaded extremes.

—John Benditt

MIT'S MAGAZINE OF INNO
TECHNOL REVIEW

EDITOR IN CHIEF
John Benditt

SENIOR EDITORS
Herb Brody
Jon Paul Potts
David Rotman

ASSOCIATE EDITORS
Antonio Regalado
Abigail Micko Vargus
Rebecca Zacks

ASSISTANT EDITOR
Deborah Kreuze

CONTRIBUTING WRITERS
Robert Buderi
Steve Ditlea
Simson L. Garfinkel

WEBMASTER
Jeff Foust

PRODUCTION MANAGER
Valerie V. Kiviat

EDITORIAL ASSISTANT
Ellen Huntzinger

COPY EDITOR
Troy Martin

ART DIRECTION
kellydesign, inc
Kelly McMurray
Margot Grisar

SUBSCRIPTIONS: 800-877-5230, fax
subscriptions@techreview.com; cos
Canada residents add $6, other fore
countries add $12

QUESTIONS: 617-253-8292,
subscriptions@techreview.com

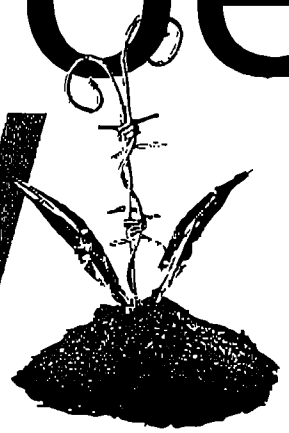
ADDRESS CHANGES: General 815-734-
address@techreview.com;
MIT Records 617-253-8270

PERMISSIONS: 978-750-8400,
http://www.copyright.com

REPRINTS: 717-560-2001, sales@rmsrc
or http://www.rmsreprints.com

TECHNOLOGY REVIEW
201 Vassar St., W59-200
Cambridge, MA 02139
Tel: 617-253-8250
Fax: 617-258-8778
comments@techreview.com
www.techreview.com

Biotech Goes Wild



Genetic engineering will be essential to feed the world's billions. But could it unleash a race of "superweeds"? No one seems to know. And nobody's in charge of finding out.

BY CHARLES C. MANN

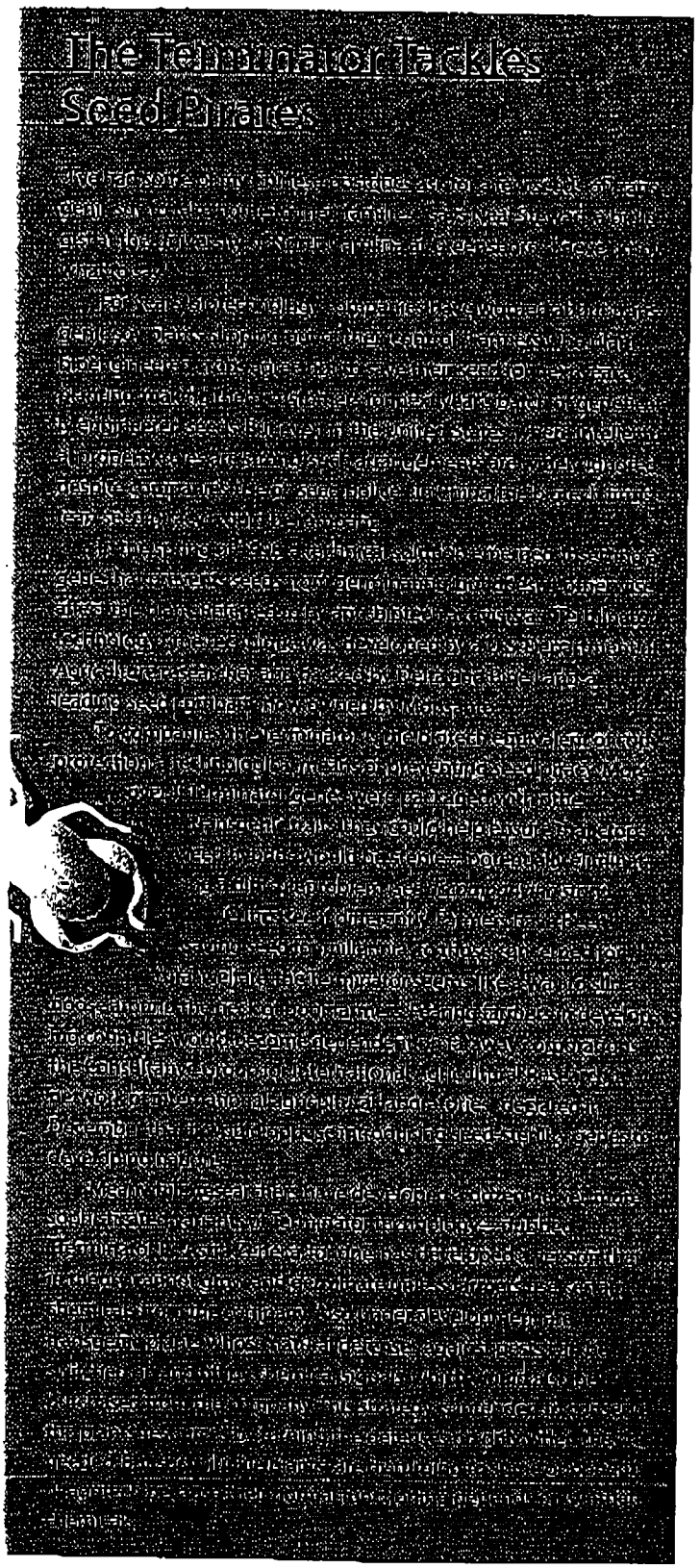
A FEW MILES OUTSIDE SACRAMENTO, several large greenhouses sit behind a fence. In the summer the familiar heads of sunflowers are visible through the glass and in the fields surrounding the greenhouses. The plants are tall, straight and healthy, with thick leaves that reach for the California sunlight. They look exactly like sunflower plants grown throughout the United States—except for the plastic cages around each flower.

The flowers are covered by biologists at Pioneer Hi-Bred's research facility in Woodland, Calif., which owns the greenhouses, the fields around them, and the sunflowers in both. The plants are transgenic—that is, genes from other organisms have been inserted into their chromosomes. Caging the sunflower heads helps prevent the breeze from wafting genetically engineered pollen around the area, which would violate federal laws banning release of unapproved transgenic organisms.

To protect Pioneer's trade secrets, the researchers are chary of discussing their work, but government permits suggest that the sunflowers in Woodland have been subjected to the full armamentarium of contemporary biotechnology. Pumped up by genes from as many as a half a dozen other species, the plants repel moths and viruses, fight off fungus diseases, and produce seed with a shelf life beyond that of their nonengineered cousins. To Pioneer, these super-sunflowers, as they are sometimes called, will be a small but significant step forward in the struggle to feed the world's exploding population, which is projected to level off at 10 billion or so. But to critics, they—and the agricultural biotechnology that created them—are an ecological menace that will wreck the natural systems on which human life depends.

PHOTOGRAPHS BY VITO ALUIA

The battle between these entrenched views is fierce. In the last year, farmers and activists ruined five metric tons of transgenic seed in France, trashed fields of genetically altered crops in Germany, and convinced seven European supermarket chains to stop selling store-brand goods containing bioengineered products. This February, a coalition of 70 groups and individuals sued the U.S. Food and Drug Administration to block the use of a dozen transgenic crops as an "imminent" threat to the environment.



Even as the U.S. government promotes agricultural biotechnology, European countries are backing away from what activists call "Frankenfoods." Austria and Luxembourg have banned genetically modified corn; Norway has also outlawed the corn as well as five other biotech crops; France has prohibited all transgenic plants. To push the British government to enact a moratorium, Greenpeace dumped four tons of genetically modified soybeans outside 10 Downing Street in February.

Biotech's supporters, on the other hand, argue that it will create nothing less than a second Green Revolution. In the first, agricultural scientists used conventional breeding techniques to create the high-yielding strains of wheat and rice that have doubled world grain harvests since the 1950s. During that time the number of hungry people fell by three-quarters, according to the U.N. Food and Agricultural Organization, despite a huge population increase. But global population numbers continue to rise, and researchers now must do it all over again. According to a projection released last August by the International Food Policy Research Institute, a think tank in Washington, D.C., world demand for rice, wheat and maize will increase 40 percent by 2020—and the only way to feed those mouths is through biotechnology. If activists succeed in banning transgenic crops, argues Robert L. Evenson, an agricultural economist at Yale University, they will end up "hurting the poor of three continents."

Caught between these extremes is a group of agricultural ecologists and plant geneticists who are trying to understand the implications of the new technology. Although some activists claim genetically altered crops are a direct threat to human health, researchers generally dismiss such fears: There is little evidence that transgenic genes, in and of themselves, are likely to be toxic or promote disease. However, biologists do believe that in some cases foreign genes in crops can pass into other, nonagricultural species, with potentially dangerous effects. "It's inevitable that they will get out," says ecologist Joy Bergelson of the University of Chicago. "That doesn't necessarily mean that there will be negative repercussions. But there could be some. And right now we don't know enough about what they could be and when they could occur."

"The technology is brilliant," says Paul Arriola, a plant geneticist at Elmhurst College, in Elmhurst, Ill. "In many respects, it's a godsend." Nonetheless, Arriola believes biotech is outpacing both the scientific understanding of its risks and the development of a regulatory apparatus to supervise its use. Because, in Arriola's view, "we don't really know what to regulate, or how to do it," the world is in the middle of "a huge, ongoing experiment. We could create a real environmental mess. And that could stop this technology from doing some real good."

Superweeds

THE FIGHT OVER TRANSGENIC FARMING IS ANYTHING BUT ACADEMIC. In 1996, the first year transgenic seed was widely available, farmers planted 1.74 million hectares (4.3 million acres) of the new varieties. This year, according to Clive James, head of the nonprofit International Service for the Acquisition of Agribiotech Applications, as many as 50 million hectares worldwide—an area bigger than Germany—are planted with genetically modified crops. "It's one of the fastest adoptions of technology I've ever seen," James says.

About three-quarters of that land is in the United States, most

of it planted in bioengineered corn and soybeans. But the technology is growing even faster in Argentina—the area the country devoted to transgenic soybeans tripled between 1997 and 1998. Although exact figures are not available, China, the world's biggest producer of cotton and tobacco, is, according to James, "aggressively increasing" the land planted with genetically altered versions of both crops.

The worry is that biotech crops will spontaneously breed with wild relatives creating "superweeds."

By far the most important bioengineered trait today is herbicide tolerance, which accounts for two-thirds of all transgenic crops. A technology dominated by Monsanto, it lets plants withstand the use of selected weed-killing chemicals, so that farmers can apply them without fear of destroying their crops. Monsanto's "Roundup Ready" soybeans, which resist the company's Roundup herbicide, were introduced in 1996; last year, they covered an estimated 10 million hectares—a third of the U.S. farmland devoted to that crop. Next in importance is insect-resistant corn, including DekalBt corn, modified by Monsanto's recently acquired Dekalb subsidiary to produce a bacterial insecticide, and StarLink corn, produced by AgrEvo, a joint venture of German chemical giants Hoechst and Schering. Principally aimed at fighting off the European corn borer, transgenic corn last year occupied 6.5 million hectares in the United States—a fifth of the nation's total corn crop.

More—much more—is on the way. As sales of bioengineered seeds rose from $75 million in 1995 to more than $1.5 billion last year, half a dozen huge companies in Europe and the United States positioned themselves to exploit a market that is widely believed to be on the verge of exploding. According to U.S. Department of Agriculture records, some 4,500 genetically altered plant varieties have been tested in this country, more than 1,000 in the last year alone. About 50 have already been approved for unlimited release, including 13 varieties of corn, 11 tomatoes, four soybeans, two squashes, and even a type of radicchio. Hundreds more are in the pipeline, among them plants that will produce industrial and pharmaceutical chemicals *(see "The Next Biotech Harvest," TR September/October 1998).*

This rush to market alarms some biologists, who believe transgenic crops are being released before the environmental implications are understood. The most immediate worry is whether genetically engineered crops will spontaneously breed with their wild relatives, creating hybrid "superweeds." Just as a single Brazilian bee researcher created a continent-wide nuisance by accidentally letting aggressive African bees hybridize with gentle domestic bees, the release of alien genes could, in theory, produce noxious "killer-bee" plants.

Surprisingly little is known about such natural hybridization, explains plant geneticist Norman C. Ellstrand of the University of California at Riverside. Until recently, agricultural scientists focused on protecting farmers; the small amount of hybridization research done in the past primarily concerned the introgression of genes from the wild into cultivated species, rather than the other way around. "People had the idea that [crop-weed hybridization] wasn't a very common or interesting phenomenon," Ellstrand says. "But when they finally got around to looking at it, they basically spent a lot of time being surprised at what could happen."

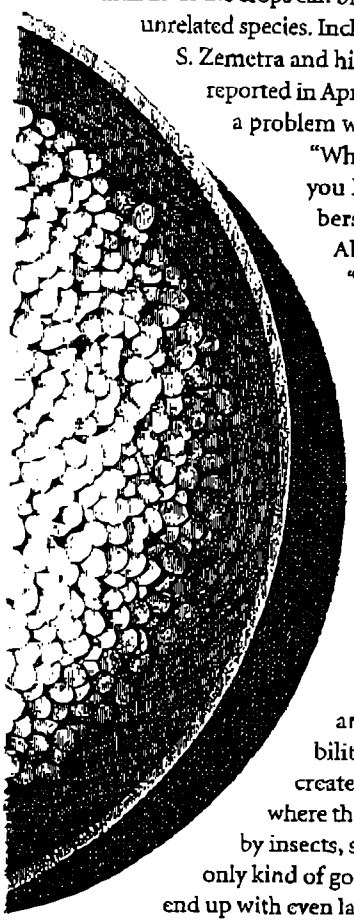
Initially, scientists thought genes were unlikely to flow from transgenic crops to weeds, because known crop-weed hybrids are often sterile. But last September, Bergelson and two Chicago colleagues startled researchers with a study of *Arabidopsis thaliana*, a mustard species often used as a test organism by plant geneticists. Usually, the plant pollinates itself, implying to scientists that foreign genes in transgenic *A. thaliana* would not escape by hybridization. But after the researchers planted ordinary *A. thaliana*, transgenic herbicide-resistant *A. thaliana*, and a naturally occurring, herbicide-resistant mutant variety, they learned that the transgenic plants were 20 times more likely to outcross than the mutants—they were "promiscuous," as a headline in the journal *Nature* put it. "Nobody knows why," Bergelson says. "We're still trying to find the mechanism that drives the pattern we saw. There's a lot we don't understand, including how common it is."

The implications are ominous. A decade ago, for instance, European sugar beets spontaneously mixed with a wild relative, creating a hybrid species that is now a continent-wide problem. Whereas the sugar beet is biannual—the root is harvested at the end of the second year—the new weed is an annual. At the end of the year, Ellstrand says, "the root turns into a chunk of wood that damages farm equipment or gets into the sugar-beet processing plant and screws up the machinery. You can't kill it with an herbicide because any herbicide that gets the weed hits its relative. It's not until the thing blooms and flowers that you see it, and by that time it has set seed that gets into the beet field forever."

Transgenic crops have already shown the potential to create similar problems. The prospect of herbicide- or insect-resistant superweeds is particularly dismaying. In 1995, Monsanto and AgrEvo introduced herbicide-tolerant oilseed rape *(Brassica napus)*, the

plant that is the source of canola oil. One year later, an 11-member team from the Scottish Crop Research Institute reported, to scientists' surprise, that pollen from oilseed rape fields can travel as much as two kilometers. At almost the same time, three Danish geneticists discovered that transgenic *Brassica napus* readily breeds with a weedy relative, *Brassica campestris*. The resulting plants look much like *B. campestris*—but are unaffected by herbicides. Taken together, says Dean Chamberlain of the University of North Carolina at Greensboro, the two reports "showed that hybridization is a real concern and that you need a very large buffer area around your plot to control it."

When Ellstrand reviewed the literature on the 30 most agriculturally important plant species, most scientists he consulted believed few hybridize easily. In fact, he found evidence that more than 25 of the crops can break the species barrier, sometimes with unrelated species. Included in that list is wheat, which Robert S. Zemetra and his colleagues at the University of Idaho reported in April can outcross with bearded goatgrass, a problem weed in the western United States.



"What really shocks me as a biologist is that you have two species with different numbers of chromosomes hybridizing," says Allison Snow, a botanist at Ohio State. "Goatgrass has 28 chromosomes and wheat has 42, but they can cross." Biologists have regarded viable offspring from such mismatches as almost impossible. As a result, they thought the range of species that could hybridize was limited. The goatgrass-wheat hybridization suggests that the range is bigger than had been thought.

"You get very low rates of reproduction," Snow says. "But when you're talking about acres and acres of wheat with goatgrass all around them, even a very low probability event can occur." If hybridization created insect-resistant goatgrass in areas where the weed's spread is naturally controlled by insects, she says, "that could end up being the only kind of goatgrass you have, and then you might end up with even larger infestations of it than we already have." Such fears are one reason that insect-resistant Bt crops—which contain genes from the bacterium *Bacillus thuringiensis*—have been targeted by activists.

In the United States, transgenic corn is unlikely to pose much risk of hybridization because it has no close relatives. But Mexico has *teocinte*, the wild plant that may be the ancestor of modern corn. What would happen if Mexican farmers planted bioengineered corn? Could the new genes affect the fitness of *teocinte*, which some agricultural ecologists view as a potential storehouse of valuable genes for future corn breeders? "With the information we have now," Snow says, "it's hard to tell when the long-term risks are serious enough to ban certain crops."

Looming behind the ecologists' fears is the belief that molecular biologists who work with DNA on the laboratory bench don't understand fully how it behaves in the field. According to Rosemary S. Hails of the British National Environmental Research Council's Institute of Virology and Environmental Microbiology, "The risk assessment of transgenic organisms is a multidisciplinary subject, which should include ecologists, molecular biologists, agronomists and sociologists." Instead, companies tend to delegate decisions about the release of transgenic crops to molecular biologists—who are not trained to appreciate the full complexity of how the genetic code interacts with environmental factors.

"How fast would a new weed get around?" Snow asks. "Nobody really knows. I'm sort of assuming that most of these crops will be approved eventually and people like me will study what the consequences are. Then, after the cat is out of the bag, we may figure out how to regulate this technology."

A Hungry World

GIVEN THESE RISKS, WHY DO SO MANY OF THESE SCIENTISTS SUPport the continued development of agricultural biotechnology? One answer is witchweed. Witchweed, the common name for three species in the genus *Striga*, is a parasitic plant that feeds on the roots of cereals and legumes in much of Africa. Attacking maize, sorghum and millet—the continent's three most important cereal crops—*Striga*, in the view of Gebisa Ejeta, an agronomist at Purdue University, is a "scourge" of African agriculture. It has been estimated that the weed destroys 40 percent of the continent's total cereals harvest—a staggering loss in the world's hungriest places.

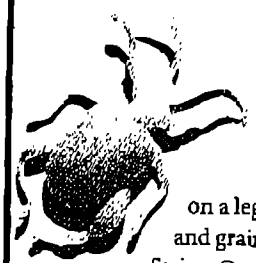
From a biological perspective, *Striga* is fascinating. Its seeds, smaller than grains of sand, lie dormant for as long as 20 years, waking only when aroused by a chemical emitted by the roots of the host plant. While still underground, the parasite plants develop root-like organs called haustoriums, which penetrate the host roots and siphon nutrients. Scores or hundreds of *Striga* plants can attack the same host. Witchweed eventually grows into fields of five-foot-tall plants with pretty pink flowers, but by that time it has long destroyed the crops it feeds on. Because each plant produces as much as 100,000 seeds, witchweed is almost impossible to eradicate—the United States spent four decades wiping out a single small outbreak in the Carolinas.

Because witchweed rapidly adapts to new hosts, losses in Africa keep growing. When the parasite made it impossible to grow sorghum in eastern Sudan, desperate farmers tried to grow pearl millet. At first millet was immune. But within a few years witchweed was wreaking havoc on the new crop, too. "People are literally starving because of

Striga," says Ejeta.

Ejeta and several other Purdue scientists have spent years trying to breed varieties of sorghum that produce low levels of the chemicals needed to germinate *Striga*. But parasite-infested cropland has such dense concentrations of fallow seeds that even the improved varieties can be "overwhelmed," according to Fred Kanampiu, an agricultural researcher in Kenya for the International Maize and Wheat Improvement Center, a Mexico-based laboratory that is usually known by its Spanish acronym of CIMMYT. "The solution is obvious," Kanampiu says. "Herbicides kill witchweed. But unless we can engineer herbicide-resistant sorghum, the herbicides also kill the crop."

Another "obvious" example of the need for biotech in poor countries is broomrape, according to Jonathan Gressel of the Weizmann Institute's Department of Plant Genetics in Israel. The common name for several parasitic species in the genus *Orobanche*, broomrape—the name, Gressel says, comes from its effects



Economic models show global malnutrition will increase if biotech is stopped.

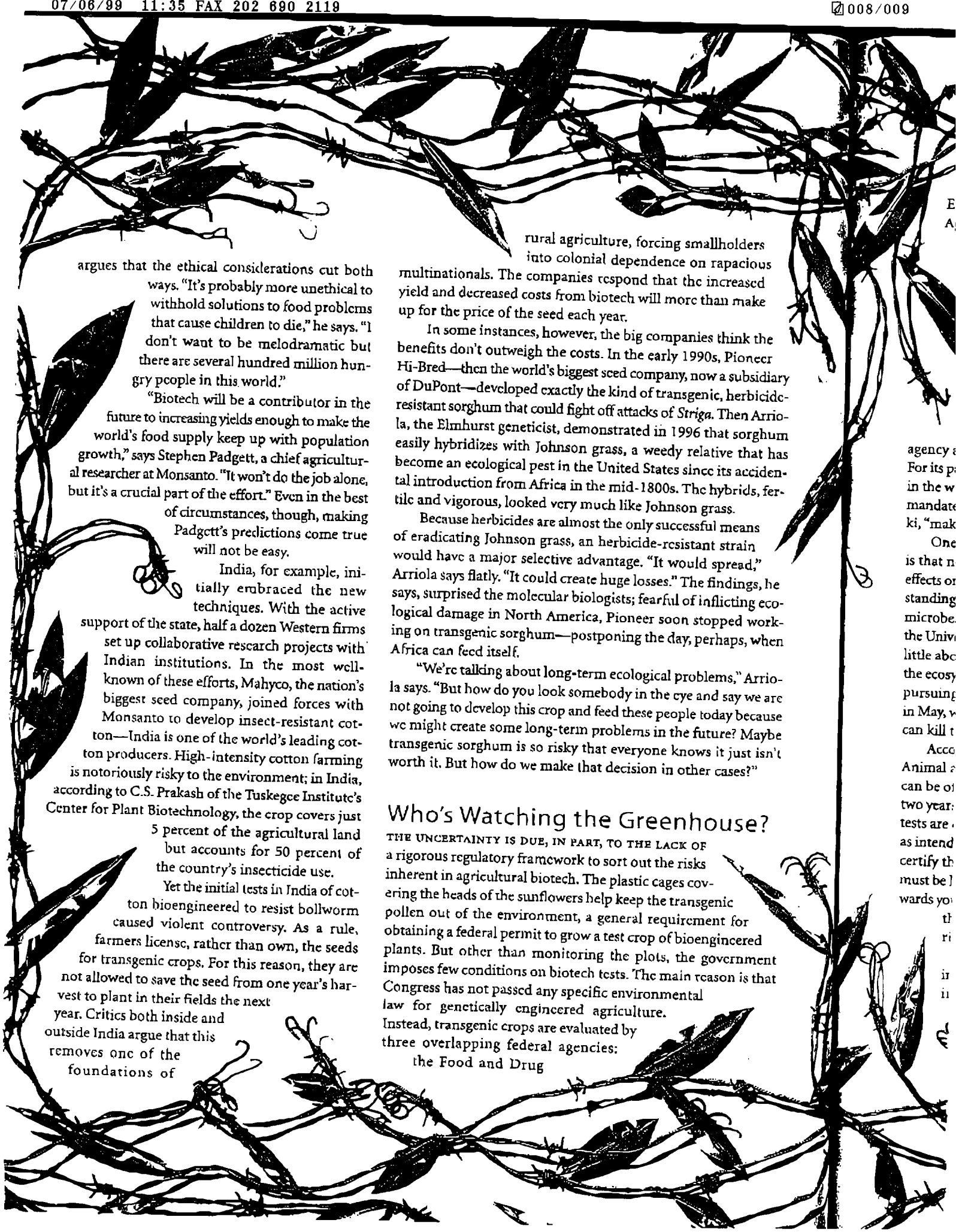
on a legume called broom—plagues vegetables, sunflowers and grain legumes throughout the Middle East. Like its cousin *Striga, Orobanche* produces tens of thousands of tiny seeds that lie dormant, ruining all attempts at planting the land. "The seeds are the size of talcum powder, maybe 50 cells per seed," Gressel says. "How they can live for 20 years is beyond me." Methyl bromide, the only available treatment, is expensive, not terribly effective and toxic. "The activists want to ban biotech and herbicides and have farmers pull out the weeds by hand," he says.

According to economists, witchweed and broomrape epitomize the most important potential targets of agricultural biotechnology: the problems of farmers in developing nations. "At first blush you look at this technology and you say this is the last thing that's appropriate for poor farmers," says James of the International Service for the Acquisition of Agribiotech Applications. "It's proprietary, so farmers have to buy seed they now get for free, it's developed by industrial countries, so money flows from the poor to the rich—it must all be ill-suited for developing countries. But when you look at it carefully, the specs of the technology allow you to fit almost exactly what the small farmer needs."

The original Green Revolution crops depended heavily on irrigation, artificial fertilizer and chemical pesticides. By contrast, James says, the fruits of bioengineering are encapsulated in "the simplest technology of all—the seed." Pest-resistant seed corn, for example, needs no costly spraying equipment, is not very complicated to grow, and releases little toxin into the environment. Because poor countries often owe their poverty to bad soils or lack of agricultural water, James believes they will disproportionately benefit from bioengineered crops that can grow in barren land or stand up to drought.

"People in developed countries spend a relatively small part of their budgets on food," says Evenson, the Yale economist. As a result, he argues, productivity increases from transgenic crops will not mean much to Europe or the United States. "We can afford to throw away the technology—it's a luxury for people who already have enough to eat." The situation is different for the destitute. "In some places," Evenson says, "you can get food being more than 75 percent of people's budgets. In rice-based areas, you'd have half of that being on rice. So if rice prices are 20 percent higher than they would otherwise be, it's not a small thing." Last October, he presented a model that, among other things, projected an increase in global malnutrition from stopping biotechnology for 10 years. The exact tally of the starving, he says, "depends on the assumptions, but they are never something to ignore."

"What really bothers me is the increasing opposition, especially in Europe, to using biotechnology for agriculture," says Per Pinstrup-Anderson, director-general of the International Food Policy Research Institute. Although some activists believe that the potential side effects make transgenic research unethical, Pinstrup-Anderson



argues that the ethical considerations cut both ways. "It's probably more unethical to withhold solutions to food problems that cause children to die," he says. "I don't want to be melodramatic but there are several hundred million hungry people in this world."

"Biotech will be a contributor in the future to increasing yields enough to make the world's food supply keep up with population growth," says Stephen Padgett, a chief agricultural researcher at Monsanto. "It won't do the job alone, but it's a crucial part of the effort." Even in the best of circumstances, though, making Padgett's predictions come true will not be easy.

India, for example, initially embraced the new techniques. With the active support of the state, half a dozen Western firms set up collaborative research projects with Indian institutions. In the most well-known of these efforts, Mahyco, the nation's biggest seed company, joined forces with Monsanto to develop insect-resistant cotton—India is one of the world's leading cotton producers. High-intensity cotton farming is notoriously risky to the environment; in India, according to C.S. Prakash of the Tuskegee Institute's Center for Plant Biotechnology, the crop covers just 5 percent of the agricultural land but accounts for 50 percent of the country's insecticide use.

Yet the initial tests in India of cotton bioengineered to resist bollworm caused violent controversy. As a rule, farmers license, rather than own, the seeds for transgenic crops. For this reason, they are not allowed to save the seed from one year's harvest to plant in their fields the next year. Critics both inside and outside India argue that this removes one of the foundations of rural agriculture, forcing smallholders into colonial dependence on rapacious multinationals. The companies respond that the increased yield and decreased costs from biotech will more than make up for the price of the seed each year.

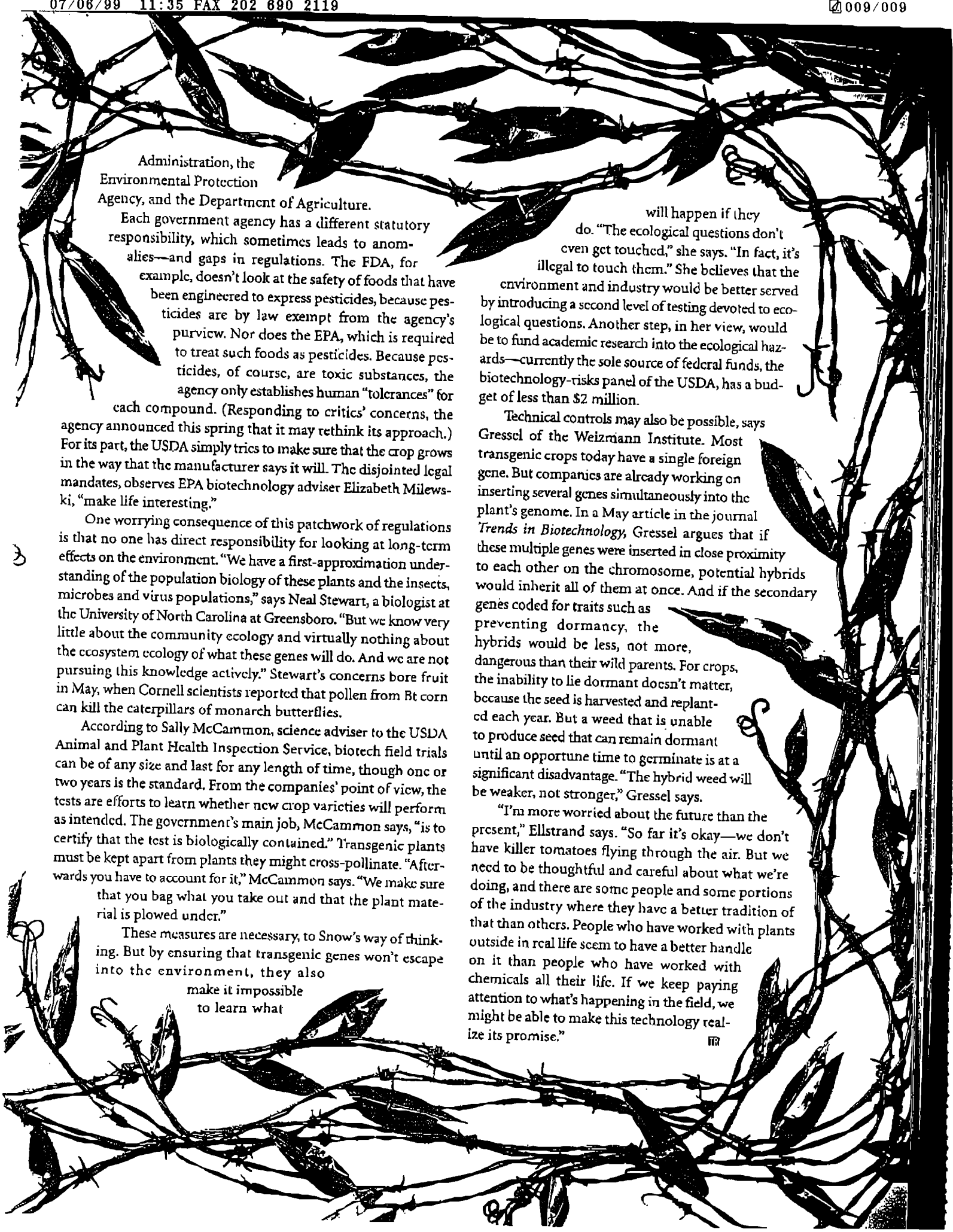
In some instances, however, the big companies think the benefits don't outweigh the costs. In the early 1990s, Pioneer Hi-Bred—then the world's biggest seed company, now a subsidiary of DuPont—developed exactly the kind of transgenic, herbicide-resistant sorghum that could fight off attacks of *Striga*. Then Arriola, the Elmhurst geneticist, demonstrated in 1996 that sorghum easily hybridizes with Johnson grass, a weedy relative that has become an ecological pest in the United States since its accidental introduction from Africa in the mid-1800s. The hybrids, fertile and vigorous, looked very much like Johnson grass.

Because herbicides are almost the only successful means of eradicating Johnson grass, an herbicide-resistant strain would have a major selective advantage. "It would spread," Arriola says flatly. "It could create huge losses." The findings, he says, surprised the molecular biologists; fearful of inflicting ecological damage in North America, Pioneer soon stopped working on transgenic sorghum—postponing the day, perhaps, when Africa can feed itself.

"We're talking about long-term ecological problems," Arriola says. "But how do you look somebody in the eye and say we are not going to develop this crop and feed these people today because we might create some long-term problems in the future? Maybe transgenic sorghum is so risky that everyone knows it just isn't worth it. But how do we make that decision in other cases?"

Who's Watching the Greenhouse?

THE UNCERTAINTY IS DUE, IN PART, TO THE LACK OF a rigorous regulatory framework to sort out the risks inherent in agricultural biotech. The plastic cages covering the heads of the sunflowers help keep the transgenic pollen out of the environment, a general requirement for obtaining a federal permit to grow a test crop of bioengineered plants. But other than monitoring the plots, the government imposes few conditions on biotech tests. The main reason is that Congress has not passed any specific environmental law for genetically engineered agriculture. Instead, transgenic crops are evaluated by three overlapping federal agencies: the Food and Drug



Administration, the Environmental Protection Agency, and the Department of Agriculture. Each government agency has a different statutory responsibility, which sometimes leads to anomalies—and gaps in regulations. The FDA, for example, doesn't look at the safety of foods that have been engineered to express pesticides, because pesticides are by law exempt from the agency's purview. Nor does the EPA, which is required to treat such foods as pesticides. Because pesticides, of course, are toxic substances, the agency only establishes human "tolerances" for each compound. (Responding to critics' concerns, the agency announced this spring that it may rethink its approach.) For its part, the USDA simply tries to make sure that the crop grows in the way that the manufacturer says it will. The disjointed legal mandates, observes EPA biotechnology adviser Elizabeth Milewski, "make life interesting."

One worrying consequence of this patchwork of regulations is that no one has direct responsibility for looking at long-term effects on the environment. "We have a first-approximation understanding of the population biology of these plants and the insects, microbes and virus populations," says Neal Stewart, a biologist at the University of North Carolina at Greensboro. "But we know very little about the community ecology and virtually nothing about the ecosystem ecology of what these genes will do. And we are not pursuing this knowledge actively." Stewart's concerns bore fruit in May, when Cornell scientists reported that pollen from Bt corn can kill the caterpillars of monarch butterflies.

According to Sally McCammon, science adviser to the USDA Animal and Plant Health Inspection Service, biotech field trials can be of any size and last for any length of time, though one or two years is the standard. From the companies' point of view, the tests are efforts to learn whether new crop varieties will perform as intended. The government's main job, McCammon says, "is to certify that the test is biologically contained." Transgenic plants must be kept apart from plants they might cross-pollinate. "Afterwards you have to account for it," McCammon says. "We make sure that you bag what you take out and that the plant material is plowed under."

These measures are necessary, to Snow's way of thinking. But by ensuring that transgenic genes won't escape into the environment, they also make it impossible to learn what will happen if they do. "The ecological questions don't even get touched," she says. "In fact, it's illegal to touch them." She believes that the environment and industry would be better served by introducing a second level of testing devoted to ecological questions. Another step, in her view, would be to fund academic research into the ecological hazards—currently the sole source of federal funds, the biotechnology-risks panel of the USDA, has a budget of less than $2 million.

Technical controls may also be possible, says Gressel of the Weizmann Institute. Most transgenic crops today have a single foreign gene. But companies are already working on inserting several genes simultaneously into the plant's genome. In a May article in the journal *Trends in Biotechnology*, Gressel argues that if these multiple genes were inserted in close proximity to each other on the chromosome, potential hybrids would inherit all of them at once. And if the secondary genes coded for traits such as preventing dormancy, the hybrids would be less, not more, dangerous than their wild parents. For crops, the inability to lie dormant doesn't matter, because the seed is harvested and replanted each year. But a weed that is unable to produce seed that can remain dormant until an opportune time to germinate is at a significant disadvantage. "The hybrid weed will be weaker, not stronger," Gressel says.

"I'm more worried about the future than the present," Ellstrand says. "So far it's okay—we don't have killer tomatoes flying through the air. But we need to be thoughtful and careful about what we're doing, and there are some people and some portions of the industry where they have a better tradition of that than others. People who have worked with plants outside in real life seem to have a better handle on it than people who have worked with chemicals all their life. If we keep paying attention to what's happening in the field, we might be able to make this technology realize its promise." TR

bio-tech.

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

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

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

b.5 xcel

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.

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.

End September – proposal

→ Mandatory labeling
→ protec[illegible]

→ [illegible] [illegible]
→ b.b [illegible]

→ List of options

⇒

2nd week September

Food safety options
[illegible]
comment

CEA – study – [illegible] labeling

Voluntary labeling scheme
Sharon [illegible]

Voluntary labeling ⇒

DRAFT

NEC Deputies Paper on the Safety of Biotechnology Derived Crops/Foods

~5 pages

- Traditional breeding practices and underpinning science (one page)
- Led to the coordinated framework/authorities under existing statutes (one paragraph)
- Major safety issues and how they are addressed (one to two paragraphs each)

  Environmental
  Gene transfer to other plants/recombination events (e.g., with viruses)
  Weediness
  Non-target effects (biodiversity, endangered species)
  Resistance (managing genetic resources)
  Long-term impacts

  Food Safety
  New Allergens
  Antibiotic resistance markers
  Nutritional considerations
  Toxicants
  Long-term impacts

- Case study (2 pages)

ISABELLE ROUVILLOIS—AFP

A Greenpeace protest in France against genetically modified corn—and against America's desire to sell it around the world

Frankenstein Foods?

That's what Europeans are calling genetically modified crops that abound in America. Exporters have been forced to listen. BY KENNETH KLEE

DON'T LOOK FOR THE SOUTHern French town of Montredon on your globe. It isn't even on local road maps, perhaps because it has only 20 inhabitants. But one of them, a Parisian intellectual turned activist-farmer named José Bové, may change that. He's the leader of the mobs of farmers who've trashed several McDonald's in France lately. Last week, with 200 supporters chanting outside the jail, Bové declined a Montpellier court's offer of bail and remained behind bars, the better to spotlight his cause. And that would be? "To fight against globalization and advance the right of people to eat as they see fit," he explained. Grievance No. 1: the U.S. desire to export genetically modified crops and foods.

So far, so French, right? But spin that same globe to Peoria, Ill., home of U.S. agribusiness giant Archer Daniels Midland. There, even as Bové's judges readied their decision, the self-styled "supermarket to the world" was demonstrating that the customer is, indeed, always right. In a fax to grain elevators throughout the Midwest, ADM told its suppliers that they should start segregating their genetically modified crops from conventional ones, because that's what foreign buyers want. It didn't matter that GM crops are widely grown by U.S. farmers, and that there's no evidence that the taco chips and soda you're enjoying right now are anything worse than fattening. ADM had noticed something new sprouting under the bright, warm sun of economic interdependence: a strange hybrid of cultural and economic fears. So it decided to act before the problem got any bigger.

Public opposition to GM foods in Europe has been mounting for more than two years, especially in Britain and France. Both Prince Charles and Paul McCartney have come out against the stuff. Now the protests and the tabloid headlines about "Frankenstein Foods" have reached such a pitch that they're reverberating across the Atlantic. Secretary of Agriculture Dan Glickman, a longtime backer of biotech-

nology, admitted as much in a key speech in July. So did Heinz and Gerber when they announced the same month that they'll go to the considerable trouble of making their baby foods free of genetically modified organisms. Groups such as Greenpeace, which have long fought biotech on both continents, are crowing. U.S. trade officials, who face a tough fight keeping markets open for American agricultural products, are worrying. And U.S. consumers, who have never really thought much about genetically modified foods, are just plain confused.

As well they might be, given the vastly different experiences the United States and Europe have had. In the United States, the FDA issued a key ruling in 1992 that brought foods containing GM ingredients to market quickly, and without labels. Companies such as Monsanto introduced herbicide-resistant soybeans and corn that makes its own insecticide. U.S. farmers loved the products; by 1998, 40 percent of America's corn crop and 45 percent of its soybeans were genetically modified. In Europe, meanwhile, there was no real central regulator to green-light the technology and allay public concerns, and many more small farmers for whom biotech represented not an opportunity but a threat. Leaders have tried to steer a course between encouraging a new industry and giving the voters what they want, including labeling rules.

So, to each his own, right? Not in 1999. If Europe is selling America Chanel perfume and Land Rovers, America will want to sell Europe its soybeans and corn—and maybe even its fervent faith in progress. While European biotech companies such as Novartis avoided the limelight, St. Louis-based Monsanto decided to press its case. The timing was terrible. GM fears were already running high last summer when Monsanto ran an informational campaign; Britain's 1996 bout with mad-cow disease, though unrelated, had weakened European confidence in regulators and industrial-strength agriculture. Monsanto's PR effort only made the mood worse, as have a string of bad-news food headlines since then: dioxin-contaminated chicken in Belgium last spring; tainted Coke in Belgium and France this summer, and a punitive U.S. tariff on imports of foie gras and other products, imposed in July because Europe won't accept American hormone-fed beef.

That last, also nongenetic, dispute actually triggered the vandalism at McDonald's last month. But to many of France's famously irascible small farmers, it's all of a piece. Even among the broader public in France and Britain, the GM-foods issue seems to be intersecting with second thoughts about globalization. French farmers protest American imperialism. But just last week their biggest customers, grocery giants Carrefour and Promodès, announced a $16.5 billion merger that will position them well in a global battle with America's Wal-Mart—and put further cost pressures on farmers. Britain is a hotbed for Internet start-ups. But Brits still tune in to the BBC radio soap "The Archers" to see if young Tommy will go to jail for helping a group of eco-warriors wreck a GM-crop trial site on his uncle's land.

Would an American jury let Tommy go? Probably not. Consumers Union, whose Consumer Reports magazine features a big piece on GM foods this month, has put together an array of poll data suggesting Americans would like to see GM food labeled, but

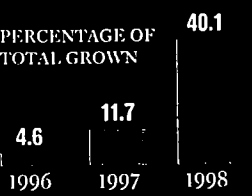
They're in Every Cupboard ...

The FDA says foods with genetically modified ingredients are perfectly safe, and they have become nearly ubiquitous in just a few years. Most Americans never noticed—until recently.

Tex-Mex and down-home: *All these products use GM corn*

Corn of Plenty

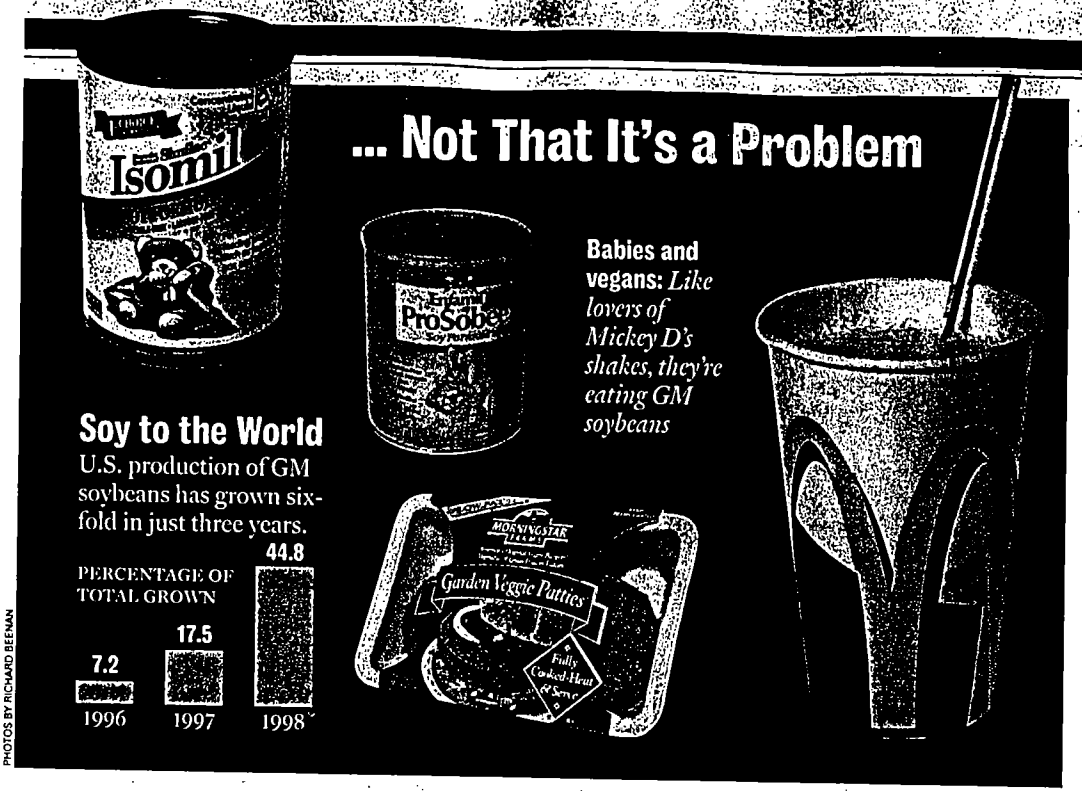
Farmers in the United States eagerly reaped the benefits of GM corn.



PHOTOS BY RICHARD BEENAN

MAXPPP—CORBIS-SYGMA

Big Mac attacked: *French farmers dumped tons of apples at a McDonald's in Cavaillon*



remain interested in its benefits. Of course, if Tommy's trial were held in Berkeley, Calif., where the school board has announced a ban on GM foods, he might walk.

U.S. activists, encouraged by the successes of their European brethren, hope to build on such sentiments. Some of the rhetoric is extreme, and one group—or perhaps it's just one person—has resorted to vandalism, trashing a test-bed of GM corn at the University of Maine last month and crediting the act to "Seeds of Resistance." But there's science going on, too. A Cornell University study published in the journal Nature in May found that half of a group of monarch-butterfly caterpillars that ate the pollen of insecticide-producing Bt corn died after four days. What if the pollen spreads to the milkweed the monarchs lay their eggs in? "The arguments aren't enough to say we shouldn't have any biotechnology," says Rebecca Goldburg of the Environmental Defense Fund. "But they are enough to say we should be looking before we leap."

Of course we should, says Gordon Conway, president of the Rockefeller Foundation and an agricultural ecologist. Invited to speak to the Monsanto board in June, he used the forum to talk about the need to go a little slower. But, he adds, don't worry about the monarch. Bioengineers can stop the pesticide (which is *supposed* to kill caterpillars; they eat the corn) from being expressed in pollen. "There are always problems in the first generation of a new technology," he says. And, he adds, successes. The foundation just unveiled a genetically modified rice grain it funded to improve nutrition in the developing world. If a shouting match over GM foods should derail such not-for-profit efforts, he says, "that would be a tragedy."

Agriculture Secretary Glickman doesn't see Americans growing as fearful as Europeans, mainly because he thinks Americans have more faith in their regulators. He also thinks that labeling of GM foods is a big part of the answer—not mandatory labeling, which industry opposes and activists demand, but voluntary labeling. "I'm not going to mandate this from national government level," he told NEWSWEEK, "but I believe that more and more companies are going to find that some sort of labeling is in their own best interest." Especially companies that want to export.

Because, as ADM showed with its heartland-stopping announcement on Thursday, it isn't only up to Americans anymore. Brian Kemp, a Sibley, Iowa, farmer, made an urgent call to his elevator on Thursday to see if it would still buy his GM corn. It will—this year. "Europe is so important to the industry that it could mean we'll really have to pull back on growing GM crops in this country," says Walt Fehr, head of Iowa State University's biotech department. "Given the choice, who wants to grow GM?"

Glickman says the trade issue—which is sure to generate plenty of heat at the November World Trade Organization meeting in Seattle—will be a tough one to resolve. "But I think over the next five years or so we can get it done." That's a mighty slow pace, considering how quickly the industry came along in the previous half decade. But then, you generally do travel faster when you travel alone.

With JOHN BARRY *in Washington*, SCOTT JOHNSON *in Montpellier*, JAY WAGNER *in Des Moines*, WILLIAM UNDERHILL *in London and* ELIZABETH ANGELL *in New York*

GERARD JULIEN—AFP

José Jailed: *Activist Bové leaves a Montpellier court in handcuffs last week*

FOOD FIGHT

The battle heats up between the U.S. and Europe over genetically engineered crops

By JEFFREY KLUGER

THE FOLKS AT MCDONALD'S COULD not have expected an especially warm reception in France, but the manure in the parking lots still must have taken them by surprise. For the past three weeks it's been hard to visit a McDonald's anywhere in France without running the risk of encountering mountains of fresh manure—as well as not-so-fresh fruit and vegetables—dumped in front of the restaurants by protesting farmers.

There's a lot about McDonald's that angers the farmers—its sameness, its blandness, the culinary hegemony it represents—yet at the outset the demonstrations were remarkably genteel, with protesters occupying restaurants and offering customers an alternative meal of baguettes stuffed with cheese or foie gras. But lately things have turned nasty. Protesters are finding ever more to dislike about the uniquely American food—especially the very genes that make the McDonald's beef or bun or potato what it is.

Around the world people are taking a closer look at the genetic makeup of what they're eating—and growing uneasy with what they see. Over the past decade, genetically modified (GM) food has become an increasingly common phenomenon as scientists in the U.S. and elsewhere have rewoven the genes of countless fruits and vegetables, turning everyday crops into *über*-crops able to resist frost, withstand herbicides and even produce their own pesticides. In all, more than 4,500 GM plants have been tested, and at least 40—including 13 varieties of corn, 11 varieties of tomatoes and four varieties of soybeans—have cleared government reviews.

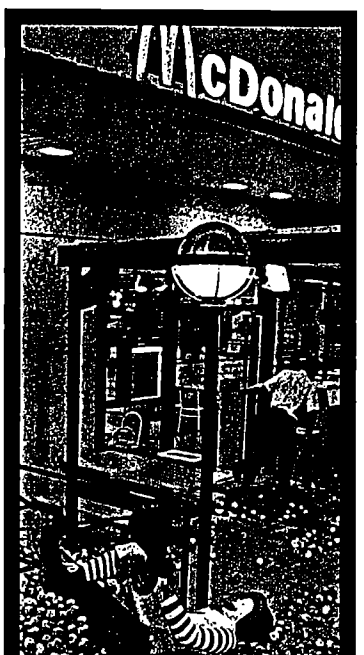
For biotech companies such as Monsanto, based in the U.S., and Novartis AG, based in Switzerland, the rise of GM technology has meant boom times. Sales of GM seeds rose in value from $75 million in 1995 to $1.5 billion last year, and the crops they produce are turning up not only on produce shelves but also in processed foods from cookies to potato chips to baby food.

But many people question whether it's a good idea for fallible human beings to go mucking about with the genes of other species. It's one thing if a scientific experiment goes wrong in a lab, they say, but something else entirely if it winds up on your dinner plate. To date, there's nothing to suggest that re-engineered plants have ever done anyone any harm. Nonetheless, the European Union has blocked the importation of some GM crops, and since 1997 has required that foods that contain engineered DNA be labeled as such. Plenty of trade watchers in Washington see the European actions as one more tweak from an increasingly powerful E.U. no longer intimidated by U.S. economic might. While that may be, the fact remains that the U.S. Congress may address a labeling bill of its own this fall, and some private groups are threatening lawsuits to force the issue. Even without legal action, public opinion is turning a more skeptical eye on GM technology. "The farmers in France are right," observes Dennis Kucinich, a House Democrat from Cleveland, Ohio, who stumbled across the GM-food issue in the spring, and is turning it into something of a cause. "There's nothing more personal than food."

If the outcry in France indeed portends global trouble, it's by no means clear whether it ought to. For all the controversy that GM technology is causing, the fact is that biotech companies have succeeded in dreaming up some extraordinary plants. Monsanto, which produces the hugely popular herbicide Roundup, has made just as big a hit with its line of genetically modified crops that are immune to the Roundup poison—thanks to a gene that company scientists tweezed out of the common petunia and knitted into their food plants. Other GM crops have been designed to include a few scraps of DNA from a common bacterium, rendering the plants toxic to leaf-chewing insects but not to humans.

Such souped-up plants are understandably popular with farmers, for whom even a slight increase in yield can mean a big increase in profits. Last year in the U.S., 35% of the soy crop and 42% of the cotton crop were grown with GM seeds. Says Karen Marshall, a Monsanto spokeswoman: "These really do work and have tremendous benefits to growers."

But what happens when they don't work? Several years ago, a company developed a soybean with some genetic threads borrowed from the Brazil nut in an attempt to boost the bean's amino-acid content. The soy began acting like the nut—so much so that it churned out not just amino acids but also chemicals that can trigger allergies in nut-sensitive consumers. The company quickly scrapped the product. Last spring a study published by Cornell University showed that pollen from some strains of corn with built-in pesticides can kill the larva of the Monarch butterfly,



The clown falls as farmers trash a French McDonald's

PHOTOGRAPHS FOR TIME BY MARK WEISS

a pest by nobody's standards. "When butterflies start dying," says Kucinich, "I think it's fair to start asking questions."

Overseas, they have been asking them for some time. In recent years Europeans have become increasingly jumpy about bad food—and with good reason. Since the outbreak of mad-cow disease in 1996, the appearance of dioxin-contaminated Belgian chickens last spring and the later recall of contaminated cans of Coca-Cola in France and the Benelux nations, health officials have grown fussier about what their citizens consume—raising the doubts about GM food even higher.

Since 1990 the E.U. has approved the sale of 18 GM products. (The U.S. Government views GM components in foods as mere additives and thus does not require the FDA to approve them. Instead, it subjects them to a less formal review, a relatively low high-bar that's easy to clear.) This year the E.U. banned the importation of non-approved GM corn. In the U.S., GM strains are mixed with ordinary strains, so the country's entire corn export to Europe was effectively outlawed. "Until we have new rules, we don't want new substances released," says Jürgen Trittin, Germany's Environment Minister. "It's a de facto moratorium."

But one country's moratorium is another country's protectionism, and the U.S. is suspicious of Europe's actions. Tension between the U.S. and the E.U. was already running high this summer after Europe decided to continue a ban on hormone-raised U.S. beef and the U.S. hit back with a 100% tariff on some E.U. food exports. Coming in the midst of such a catfight, the GM ban looks like vengeance as much as prudence. What's more, if Europe is so worried about GM foods, why is it growing them? France produces its own small crop of GM corn and uses more of the stuff than any other country in Europe.

The transatlantic food fight will probably be high on the agenda of the World Trade Organization when it meets in November—good news for companies like Monsanto. Two years ago, CEO Robert Shapiro gambled big on biotech, spinning off the company's chemical division to focus on the new science. While the move made Monsanto a Wall Street darling for a while, investors aren't as sweet on it anymore. A year ago, Monsanto stock perched at a lofty 63; today it's mired in the upper 30s.

Events in Washington could make things worse. Since lawmakers have not yet addressed the labeling question, private groups are hoping to take the lead. Organizations like the Sierra Club and Greenpeace, along with Jewish and Muslim groups, have waded in, lobbying the FDA for labeling and in some cases filing suits to compel it. Their legal claim is bolstered by internal FDA memos in which the agency's own scientists expressed doubts about GM products. A scientist noted the "profound difference" between genetically engineered and traditional crops—though he stressed that different needn't mean dangerous.

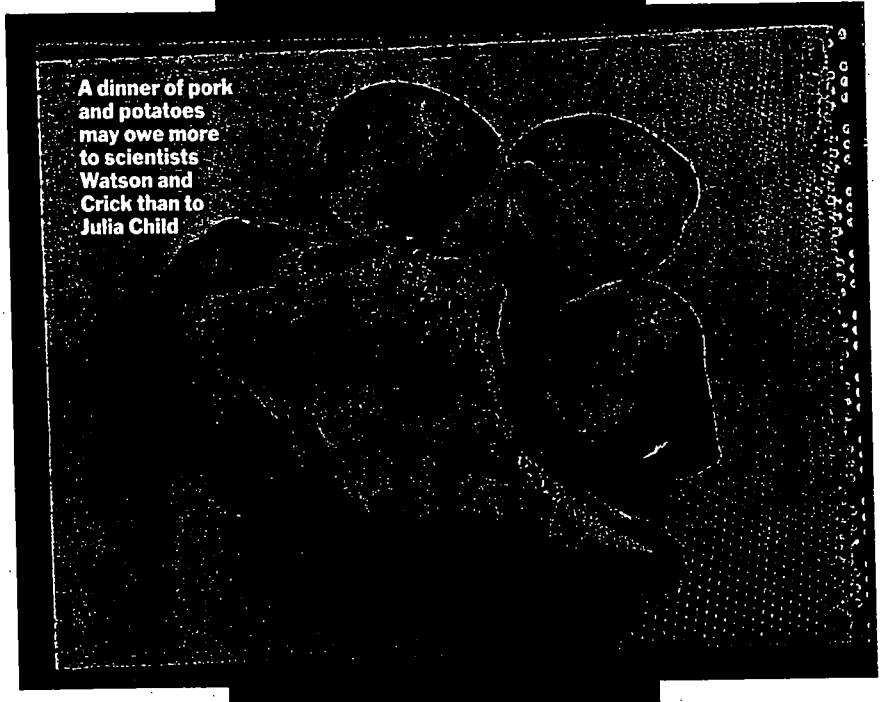
Still, it's becoming clear in Washington that the labeling problem is not going away. U.S. Agriculture Secretary Dan Glickman admits that ultimately the activists will probably prevail. Glickman hopes that labels will not be written to alarm consumers but instead to inform them, letting them know that while a product was manufactured with the aid of genetic techniques, it can also, say, lower cholesterol.

For now, the most GM foes can hope to push through an agri-friendly Congress is a proposal for voluntary labeling that biotech companies would be free to honor or ignore. In a demand-driven market, however, they would ignore it at their peril. In Europe the Gerber baby-food company, a division of Novartis, gave in to anti-GM sentiments and announced that its products would no longer contain genetically modified ingredients. "This decision was not a safety issue," insists Novartis spokesman Mark Hill, "but rather a response to preferences expressed by our consumers." Not for the last time, to be sure, it's consumers who will have the final word. —*Reported by James Carney and Dick Thompson/Washington, Bruce Crumley/Paris and Maggie Sieger/Chicago*

WHAT'S FOR DINNER?

There's a lot more than seasoning in your food. Everything from meat to fruit to baby food is developed with the aid of genetic manipulation. Since the Federal Government sees GM components as mere additives, they require little government oversight. Even the simplest meal is loaded with small DNA tricks

APPETIZER
Some tomato juice is made from tomatoes containing enzymes from Arctic flounder—an attempt to help crops withstand low temperatures



A dinner of pork and potatoes may owe more to scientists Watson and Crick than to Julia Child

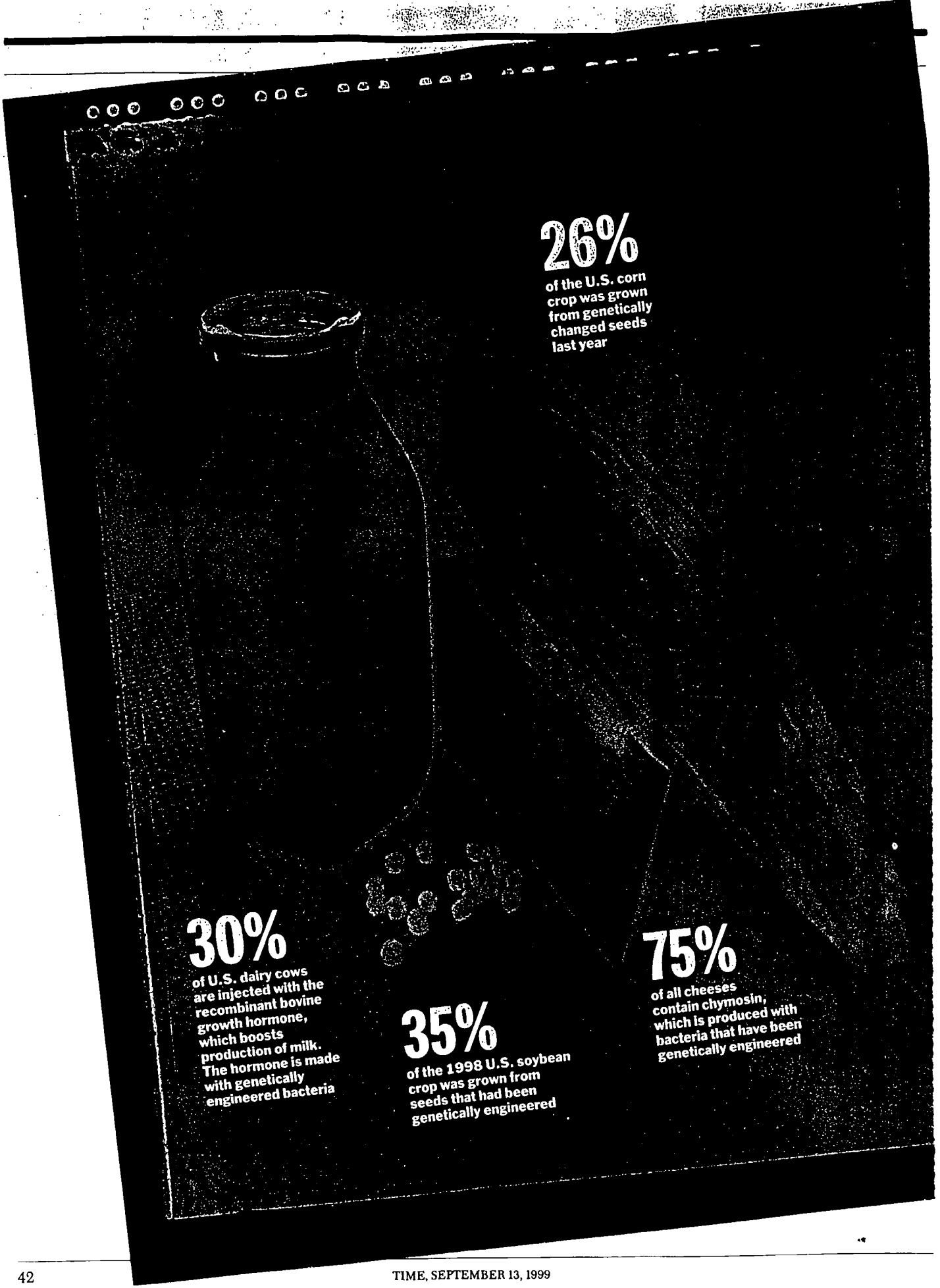
ENTREE
Pork loins could come from hogs treated with human-growth hormones to help them get bigger faster

Potatoes could include genes from the *Bacillus thuringiensis*, a naturally occurring bacterium toxic to insects

Squash may be inoculated with watermelon- and zucchini-virus genes to make the squash virus resistant

The corn in corn bread and other foods could contain a firefly gene, providing a phosphorescent marker to tag other implanted genes

DESSERT
The milk in that innocent-looking rice pudding may have been drawn from cows treated with genetically engineered bovine growth hormone to help boost milk production


26%
of the U.S. corn crop was grown from genetically changed seeds last year
30%
of U.S. dairy cows are injected with the recombinant bovine growth hormone, which boosts production of milk. The hormone is made with genetically engineered bacteria
35%
of the 1998 U.S. soybean crop was grown from seeds that had been genetically engineered
75%
of all cheeses contain chymosin, which is produced with bacteria that have been genetically engineered

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GMA GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FMI FOOD MARKETING INSTITUTE

September 7, 1999

Mr. Bruce Reed
Assistant to the President and Director
Domestic Policy Council
Executive Office of the President
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. Reed:

Technological breakthroughs in the science of biotechnology now provide us with the opportunity to deliver food that is more nutritious, tastes better, stays fresher longer and requires fewer chemicals to grow and process. It is important that these new technologies be well understood by our nation's producers, consumers and policy makers.

The U.S. Government has played – and will continue to play – a vital role as agricultural biotechnology is increasingly used worldwide. We have prepared the enclosed information to help you better understand the latest technological developments and the promises biotechnology brings to the global marketplace, the environment and the fight against world hunger.

Recent public opinion polls reveal that Americans support the use of agricultural biotechnology when they understand that its safety is backed by sound science and reviewed by a credible regulatory system. Many American farmers have embraced this new technology to improve food-producing crops. Some current and future benefits of this technology include:

- Grains, fruits and vegetables that contain more nutrients, such as proteins, vitamins and minerals.
- Fruits and vegetables that stay fresher longer, reducing spoilage and damage.
- Higher-yielding crops that require less land and less tillage.
- Grains, fruits and vegetables with pesticide-resistant and herbicide-tolerant characteristics.
- Plants that are able to grow in less than ideal climates, helping increase food productivity in the developing world.

It is only natural that questions and concerns about these products may be raised by your constituents. The enclosed information should help you address any issues about the use of biotechnology in food production.

In addition, we are in the process of forming a national alliance to encourage a fact-based discussion of the role biotechnology can play in our food supply. Our members will represent diverse agriculture and food related groups, farmers, scientists and professionals in other fields.

We look forward to continuing an open dialogue with you. Please feel free to call Rosemarie Watkins at AFBF at (202) 484-3608, Mary Sophos at GMA at (202) 337-9400 or John Motley at FMI at (202) 429-8262 if you have any thoughts or questions about the materials.

Sincerely,

Dean Kleckner
President
American Farm Bureau
Federation

C. Manly Molpus
President and CEO
Grocery Manufacturers
of America

Tim Hammonds
President and CEO
Food Marketing
Institute

GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

BIOTECHNOLOGY INFORMATION KIT

PHOTOCOPY PRESERVATION

AMERICAN FARM BUREAU FEDERATION

600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

FOOD MARKETING INSTITUTE

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Food Biotechnology Overview

Modern biotechnology provides farmers and food producers with the latest tools in the search for better, more healthful foods, as well as foods that are resistant to certain pests and tolerant to environmental stresses such as drought. With biotechnology, producers can provide a more abundant, better quality and more nutritious food supply to consumers.

Food biotechnology is based on age-old principles of selective breeding. Farmers have used these processes for centuries to provide variety, improve taste and produce new or more healthful foods. Modern biotechnology allows food producers to do the same thing today, but with greater understanding and selectivity.

Traditionally, when breeding plants to achieve hardier or healthier produce, farmers had to breed thousands of plants to obtain a desired trait. Modern biotechnology now allows us to focus on particular genes in plants, rather than the entire plant, and to identify and transfer the specific gene that governs a desired trait. This offers farmers a more precise way to produce plants and foods that possess certain beneficial characteristics.

After a decade of research and development, the first whole food produced through modern biotechnology was introduced in 1994, when the Food and Drug Administration (FDA) determined that a tomato developed through biotechnology was as safe as those bred by conventional means. Unlike conventional tomatoes, which are harvested when they are still green and ripen during the trip to market, the tomato – Flav Savr™ – stays on the vine longer to ripen to full flavor before it is harvested. Other food biotechnology products available, or soon to be available, in the U.S. include:

- Grains, fruits and vegetables with pesticide-resistant and environmentally friendly herbicide-tolerant characteristics;
- Rice and fruit that resist viruses that cause loss of yield and crop quality;
- Tomatoes that ripen more slowly, giving them more flavor, color and texture;
- Grains, fruits and vegetables that contain more nutrients, such as proteins, vitamins and minerals, and have reduced fatty acid profiles;
- Modified potatoes that contain less starch and water, making for a healthier french fry or potato chip; and
- Allergen-free rice and peanuts.

Several federal agencies have been involved in determining the safety of biotechnology in food production, including the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA) and the U.S. Environmental Protection Agency (EPA).

The safety of biotechnology has been supported by numerous national and international health organizations, including the United Nations Food and Agriculture Organization, the World Health Organization, the National Research Council, the American Medical Association and the American Dietetic Association.

Biotechnology is an important element of today's food supply

Biotechnology is already a part of everyday life in the United States. Since 1996, growers have increasingly used biotech seed stock. According to USDA Secretary Dan Glickman, approximately 44 percent of soybeans and 36 percent of all corn grown in the United States in the last year was grown from biotechnology-enhanced seeds.

According to Thomas Hoban, a professor at North Carolina State University, "Regardless of how we measure consumer perceptions, between two-thirds and three-quarters of American respondents are positive about plant biotechnology." A 1999 survey commissioned by the International Food Information Council (IFIC) found that three out of four Americans believe biotechnology will provide benefits for their family in the next five years.

Through the use of biotechnology, foods already have been developed that are better tasting, stay fresh longer and are more disease and insect resistant. Food biotechnology can improve the quality, taste and nutritional benefits of food – providing a healthier diet to consumers and a greater availability of foods in all seasons.

Food biotechnology also helps protect the global environment. Biotechnology-enhanced crops have been developed that are herbicide tolerant, or are more resistant to insect or virus damage, thus requiring fewer chemical applications and reducing strain on the environment. Biotechnology-enhanced crops also require less land and other natural resources, and can be grown in less than ideal climate conditions. This is particularly important in developing countries where valuable temperate and tropical forests are routinely cut down for farmland.

Food biotechnology can help increase the world's food supply. The United Nations estimates that the world's population will reach up to 12.5 billion by the year 2050, compared to 6 billion today. Much of that population growth will be in some of the world's poorest regions. Through food biotechnology, researchers are developing crops that require less farmland, and that can be grown in places where agriculture has been difficult because of adverse climate conditions. In fact, the 1997 World Bank and Consultative Group on International Agricultural Research (CGIAR) determined that biotechnology could be expected to help increase world food productivity by up to 25 percent in the developing world.

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Modern Food Biotechnology: Facts and Figures

- After more than a decade of research and development, the first whole food product derived from modern biotechnology arrived on the market in 1994. Since then, according to figures from the International Service for the Acquisition of Agri-biotech Applications (ISAAA), the number of acres of commercialized biotech crops under cultivation worldwide has grown from 7 million acres in 1996 to an estimated 75 million acres last year.

- United States Department of Agriculture Secretary Dan Glickman has stated that approximately 44 percent of soybeans and 36 percent of all corn grown in the United States in 1998 were grown from seeds enhanced with biotechnology.

- ISAAA estimates the economic benefits of certain biotechnology-enhanced crops to growers in the US and Canada at roughly $465 million for 1996-97.

- Farmers and other experts have conducted years of outdoor testing for each crop variety enhanced through biotechnology. Fifty varieties of biotechnology-enhanced crops have been approved to date in the United States.

- According to a 1999 survey commissioned by the International Food Information Council (IFIC), three out of four Americans believe biotechnology will provide benefits for their families in the next five years.

- Researchers are close to developing fruits and vegetables that contain more beta carotene and Vitamins C and E, which may help to reduce incidences of cancer and heart disease, as well as a banana that can be used to deliver vital oral vaccines for diseases such as hepatitis B.

- The United Nations estimates that the world's population will reach up to 12.5 billion by the year 2050, compared to 6 billion today. Much of that population growth will be in some of the world's poorest regions. ISAAA estimates that some 800 million people are already victims of malnutrition daily.

- Few other technologies will be able to approach biotechnology's potential to help counter world hunger in the next century. According to the 1997 World Bank and Consultative Group on International Agricultural Research (CGIAR), biotechnology is expected to help increase food productivity by up to 25 percent in the developing world.

09/02/99

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Health and Nutritional Benefits of Food Biotechnology

Modern biotechnology provides farmers and researchers with the latest tools in the search for better, more healthful foods. The ability to identify and encourage beneficial traits in food crops is not new: farmers have crossbred and hybridized plants for generations. What modern biotechnology brings to that process, however, is the ability to target very specific characteristics for enhancement, making the process of providing higher quality foods more precise.

Food biotechnology will allow for a number of health and nutritional benefits:

- Grains, fruits and vegetables that contain more nutrients, such as proteins, vitamins and-minerals, and have reduced fatty acid profiles.

- Modified potatoes with more solid content, permitting less oil to be absorbed during cooking and making for a healthier, reduced-fat french fry or potato chip.

- Improved nutrients in strawberries.

- Vitamin-enhanced sweet potatoes, rice and canola oil.

- Allergen-free rice and peanuts.

- In addition, researchers have begun developing fruits and vegetables that contain more beta carotene and vitamins C and E. They also are working on developing a banana that can be used to deliver vital oral vaccines for diseases such as hepatitis B. Biotechnology could make possible crops with extra high vitamin content or tomatoes with even more naturally occurring antioxidants.

Biotech foods can be better tasting, ripen less quickly after they are picked, are more disease and insect resistant and have an increased tolerance to herbicides.

- Slower-ripening fruits and vegetables, for example, have improved flavor and can remain fresh longer.

- Grains, fruits and vegetables containing pesticide-resistant and herbicide-tolerant characteristics can require fewer chemical applications. These more resilient plants can tolerate farmers' application of very specific herbicides for weed control, thus reducing the overall need for chemical applications.

09/02/99

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Environmental Benefits of Food Biotechnology

Agricultural biotechnology has many environmental benefits. The same technology that helps make farmlands more productive also reduces the amount of land needed for agriculture. This is particularly important in developing countries where valuable temperate and tropical forestlands are being converted into farmland at a rapid pace.

The use of agricultural biotechnology benefits the environment in other ways, including:

- **Plants protected from disease and insects.** Strains of corn, cotton and potatoes have been developed through biotechnology that are protected from insect damage, thus requiring fewer pesticides and reducing the strain on the environment. Researchers also have developed disease-resistant strains of corn, rice, sweet potato, squash and papaya. These new varieties essentially have been "vaccinated" against crop-destroying viruses, making them more naturally resistant to diseases and thereby reducing the amount of fungicides being introduced into the environment.

- **Greater tolerance of herbicides.** The development of more resilient plants that can tolerate the application of chemical sprays allows farmers to use a specific herbicide or a more effective rotation of herbicides for weed control, thus reducing the overall need for chemical application and promoting reduced tillage. According to *Science* magazine, reduced tillage has meant less soil erosion for fields planted with biotech soybean crops [*Science*, vol. 285 16 July 1999].

- **Greater disease and insect protection means fewer acres that need to be cultivated.** Hardier strains of fruits, vegetables and grains mean that growers are able to plant fewer acres to ensure a good harvest, allowing greater conservation of resources through the use of less fuel, labor, water and fertilizer.

- **Less damage from fertilizer run-off.** According to the International Food Information Council, American farmers spend approximately $12 billion on fertilizer a year. Nearly half of the fertilizer used evaporates or is washed away into waterways and estuaries, thus endangering the environment. Biotechnology enables researchers to improve some plants, such as corn, to draw more nitrogen directly from the soil, reducing the need for fertilizers.

- **Biotechnology enhanced corn has proven highly successful in controlling agricultural pests.** According to a report issued July 13, 1999 by the National Center for Food and Agricultural Policy, biotechnology-enhanced crops are effective for controlling insect infestations. The use of biotech seed stock replaced the use of chemical sprays that were becoming more ineffective against the pest population in certain regions. The result was a gain in total corn yields of 47 million bushels in 1997 on 4 million Bt corn acres, and an additional 60 million bushels on 14 million acres in 1998.

09/02/99

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Benefits of Food Biotechnology for World Hunger

Despite increasingly limited resources, the world's population continues to grow at a staggering pace. According to the International Food Information Council, the United Nations estimates that within the next 50 years, the global population will reach up to 12.5 billion, compared to 6 billion today. Much of that growth will be in some of the world's poorest regions. At the same time, most of the world's arable farmland is already being utilized. Environmentally sensitive areas, such as tropical forests, are disappearing at an alarming rate, while the need for new farmlands increases. Many developing countries are struggling with how to continue to feed an exploding population with existing resources.

The use of food biotechnology allows farmers to reap bigger harvests from currently cultivated lands, while sustaining the land's ability to support continued farming. In addition, by increasing a crop's ability to withstand environmental factors such as heat and drought, growers will be able to farm in parts of the world currently unsuitable for crop production. Increased food production may also provide developing economies with greater employment opportunities and greater productivity.

The benefits of food biotechnology have not been lost on the larger global audience:

- Rice is by far the most important crop in Asia, in some countries accounting for nearly 80 percent of calories consumed. Researchers at the Rockefeller Foundation's International Rice Biotechnology Program hope to increase rice production in Asia 20 percent by 2005, while minimizing environmental degradation.

- In Sub-Saharan Africa, where soil-nutrient depletion and yield losses to pests and disease pose major obstacles for food production, biotechnology holds the promise of increased food production.

- In Nepal, biotechnology is used to grow disease-resistant potatoes that increase production yields and decrease production costs.

- Food biotechnology is also being used in the Philippines, Sri Lanka and India to increase legume production.

- According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), the world's available cultivable land per person has declined steadily since 1960, and will be reduced by half again over the next 50 years. At the same time, in rural, food- producing regions of the developing world, approximately 800 million people are already malnourished, and another 100 million go hungry every day.

- The need to provide more plentiful, healthful and environmentally friendly crops will only increase over time. Nobel laureate Norman Borlaug, cited recently in *Science* magazine [*Science*, vol. 285, 16 July 1999], estimates that global cereal yield will have to increase by 80% over 1990 yields in order to feed the burgeoning world population. Biotechnology may pose one solution to the problems of increasingly resource-poor, hungry nations and a viable alternative to subsistence farming.

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington, D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

In Support of Food Biotechnology

Biotechnology is a safe way to produce healthier food in greater quantities, as well as to ensure a cleaner environment. Experience shows it. Regulation requires it. And science proves it.

Biotechnology is beneficial to both consumers and the environment. Through the use of biotechnology, foods already have been developed that are better tasting, stay fresher longer and are more disease and insect resistant. Food biotechnology also can help protect the global environment, and is a key to the urgent problem of feeding a growing world population.

Numerous experts have already weighed in on the benefits of biotechnology:

Food Biotechnology is Safe

"We have spent a considerable amount of time and resources examining the science of gene technology and how it would impact on the food supply and have concluded that, provided that companies take the proper steps to examine the important safety issues, these foods should be as safe as other foods on the market...In addition to those steps that breeders normally take, for products of [biotechnology], companies are doing far more extensive testing than has ever been done on commercial varieties. They are doing chemical analyses for important nutrients, for toxicants. They are examining the new substances, such as proteins that have been introduced into these foods, in terms of possible toxicity and allergenicity and taking other steps under the guidance of our scientists in the government to ensure proper adequate testing before they go to consumers."

U.S. Food and Drug Administration Biotechnology Coordinator James Maryanski, Ph.D., May 26, 1999 Worldnet interview

"One of the great consumer questions of our time is: Will the world accept biotechnology? From a purely scientific perspective, it's an odd question. We already have. Biotechnology's been around almost since the beginning of time. It's cavemen saving seeds of a high-yielding plant. It's Gregor Mendel, the father of genetics, cross-pollinating his garden peas...Our best scientists have searched for risks. Without exception, the biotech products on our shelves have proven safe."

Dan Glickman, Secretary, U.S. Department of Agriculture, March 13, 1999

"It is the policy of the AMA to (1) endorse or implement programs that will convince the public and government officials that genetic manipulation is not inherently hazardous and that the health and economic benefits of recombinant DNA technology greatly exceed any risk posed to society; (2) where necessary, urge Congress and federal regulatory agencies to develop appropriate guidelines which will not impede the progress of agricultural biotechnology, yet will ensure that adequate safety precautions are enforced; (3) encourage and assist the state medical societies to coordinate programs which will educate physicians in recombinant DNA technology as it applies to public health, such that the physician may respond to patient query and concern; (4) encourage physicians, through the state medical societies, to be public spokespersons for those agricultural biotechnologies that will benefit public health; and (5) actively participate in the development of national programs to educate the public about the benefits of agricultural biotechnology."

American Medical Association Policy Position H-480.985
Biotechnology and the American Agricultural Industry

"We do not believe that obligatory [biotech] labeling is necessary, because it would suggest a health risk where there is none...Mandatory labelling could mislead consumers about the safety of these products and require segregation of [biotech] and [non-biotech] foods."

Isi Siddiqui, Special Assistant for Trade to the U.S. Secretary of Agriculture
Quoted by Reuters, July 27, 1999

"I have absolutely no anxiety...I am worried about a lot of things, but not about modified food."

James Watson, Ph.D., co-discoverer of DNA structure and Nobel Laureate
From the Daily Telegraph of U.K. February 25, 1999

"All the food we eat, with the exception of wild game, has been genetically engineered. It's interesting as a political issue, but I haven't seen much that points to any safety concerns."

Hank Greely, Co-Director of Stanford University's
Program in Genomics, Ethics & Society, June 18, 1999

"From the standpoint of the Food and Drug Administration, the important thing for consumers to know about these new foods is that they will be every bit as safe as the foods now on store shelves. All foods, whether traditionally bred or genetically engineered, must meet the provisions of the Federal Food, Drug, and Cosmetic Act."

FDA Consumer magazine article: "Genetic Engineering Fast Forwarding to the Future Foods"
published April 1995 and revised February 1998

"The overwhelming scientific evidence argues against the supposition that DNA from transgenic plants will somehow contaminate bacteria in humans and animals and in some way cause mutations in people that eat foods from genetically modified plants. The concern approaches the ridiculous when critics propose that remnants of DNA that are found in soy meal or soy oil will cause harm in humans."

Roger N. Beachy, Ph.D., President of the Donald Danforth Plant Science Center on behalf of the Council for Agricultural Science and Technology, March 3, 1999

"Crops modified by molecular and cellular methods should pose risks no different from those modified by classic genetic methods for similar traits."

National Research Council Report, 1989

"A broad scientific consensus holds that modern techniques of genetic engineering are essentially a refinement of the kinds of genetic modification that have long been used to enhance plants, micro-organisms and animals for food. The products of the newer techniques are even more predictable and safer than the genetically engineered foods that have long enriched our diet."

Henry Miller, Fellow at Stanford University's Hoover Institution, in an op-ed in the Financial Times, June 17, 1999

"In addition to safer foods, biotechnology also has the potential to bring about the creation of more nutritious foods...it would be a significant loss to humanity if the many benefits of biotechnology were not realized because of concerns that have little basis in scientific fact."

Brian Larkins, Ph.D., President, American Society of Plant Physiologists and Professor, Department of Plant Science at the University of Arizona, in a Letter to the Editor, The Wall Street Journal, July 29, 1999

"The newer biotechnology techniques open up very great possibilities of rapidly improving the quantity and quality of food available. The use of these techniques does not result in food which is inherently less safe than that produced by conventional ones."

Report of a Joint Food and Agriculture Organization/World Health Organization Consultation, World Health Organization, 1991

Food Biotechnology Benefits Consumers

"It is the position of The American Dietetic Association that biotechnology techniques have the potential to be useful in enhancing the quality, nutritional value, and variety of food available for human consumption and in increasing the efficiency of food production, food processing food distribution, and waste management."

Position statement adopted by the American Dietetic Association on October 18, 1992 and reaffirmed on September 9, 1994

"Agricultural biotechnology holds promise for a hungry and ecologically fragile world. The development of new crop varieties that offer increased yields, reduced inputs, and offer specialized traits that meet end-user needs is merely the starting point."

Stephen S. Censky, Chief Executive Officer, American Soybean Association, May 26, 1999

"Regardless of how we measure consumer perceptions, surveys document that between two-thirds and three-quarters of American respondents are positive about plant biotechnology."

Thomas Hoban, professor at North Carolina State University; The Financial Times Limited, February 19, 1999

Food Biotechnology Benefits the Environment

"Biotechnology provides new and powerful tools for research and for accelerating the development of new and better foods...The benefits of biotechnology are many and include providing resistance to crop pests to improve production and reduce chemical pesticide usage, thereby making major improvements in both food quality and nutrition."

Report of a joint consultation between the United Nations Food and Agriculture Organization and the World Health Organization, September 30-October 4, 1996

"Scientists are gaining the ability to insert genes that give biological defense against diseases and insects, thus reducing the need for chemical pesticides, and convey genetic traits that enable crops to better withstand drought conditions. With this powerful new genetic knowledge, scientists have the capability to pack large amounts of technology into a single seed."

Norman Borlaug, Ph.D., Nobel Peace Prize Laureate, testimony before the U.S. Senate Agriculture Committee, July 31, 1997

Food Biotechnology Benefits Farmers

"...what everyone must understand is to maintain the productivity of agriculture, we must continue to improve the agricultural seeds that are used. We have been doing this for generations. We are now blessed through research and technology with new methods of actually speeding up the process of improving the seeds and the products we get from them... The most important thing we have to do is get the message out about the benefits of these [biotech] products."

Melinda Kimble, Acting Assistant Secretary of State for Oceans and International and Environmental Scientific Affairs; Worldnet interview, May 26, 1999

"Simply put, [agricultural biotechnology] is the most promising, precise and advanced strategy available today for meeting the challenges of reduced use of synthetic chemical pesticides, the need for nutritionally and functionally improved plants, and the need for improved resistance to pests and diseases."

Institute of Food Technologists, October 1996

"Biotechnology is an important tool which must be made available to emerging markets. This investment helps U.S. farmers by creating a greater demand for our agricultural products and much of the technology comes back to U.S. farmers to make them even more competitive."

Per Pinstrup-Andersen, Ph.D., Director, International Food Policy Research Institute February 5, 1999

"If we turn our back on [agricultural biotechnology] we are turning our back on the next generation of plants for farmers."

Dr. Tony Conner, Crown Research Institute in New Zealand, June 15, 1999

Food Biotechnology Can Help Counter World Hunger

"If imports like these [biotechnology crops] are regulated unnecessarily, the real losers will be the developing nations. Instead of reaping the benefits of decades of discovery and research, people from Africa and Southeast Asia will remain prisoners of outdated technology. Their countries could suffer greatly for years to come. It is crucial that they reject the propaganda of extremist groups before it is too late."

Former President Jimmy Carter, in The New York Times, August 26, 1998

"Bioengineered crops...could improve food yields by up to 25 percent in the developing world and help feed the 3 billion people to be born over the next 30 years."

1997 World Bank and Consultative Group on International Agricultural Research (CGIAR)

AMERICAN FARM BUREAU FEDERATION
600 Maryland Avenue S.W. • Suite 800 • Washington D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Food Biotechnology: U.S. Government Requirements

The food industry stands behind foods and food products that have been improved through biotechnology, and ensures that they meet all federal requirements for food quality and safety. Food companies have a critical stake in ensuring and safeguarding the integrity of their brands.

The U.S. Government as well plays an important role in ensuring food safety. In particular:

- All foods must be safe to be marketed. Several federal agencies are involved in determining the safety of biotechnology in food and food production, and a coordinated framework to ensure human and environmental safety was put into place more than a decade ago. These agencies and their responsibilities are: the U.S. Food and Drug Administration (FDA), which has responsibility for the safety and labeling of whole foods and food ingredients, including food additives; the U.S. Department of Agriculture (USDA), which has authority over biotech plants and meat and poultry ingredient labeling, and production processes; and the U.S. Environmental Protection Agency (EPA), which registers the use of pesticides and herbicides.

- Prior to commercialization, food and food products enhanced through biotechnology must conform with state and federal marketing requirements, including seed certification laws, the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Plant Pest Act.

- Since 1992 the FDA has determined that foods from plants produced through biotechnology are, as a class, as safe as those from plants developed through conventional breeding, and should therefore be regulated the same as any other foods entering the market. Accordingly, the FDA evaluates the application of biotechnology to food products on a case-by-case basis, as it does with any other food.

- Under the Food, Drug and Cosmetic Act, the FDA usually focuses on the product, the food, or food ingredients rather than on the plant development processes used in their production, as the basis for regulation. The same holds true for food and ingredients derived from biotechnology. The FDA offers a decision-tree approach for companies developing plant-based biotech foods. These decision-trees represent a series of testing procedures that enable food processors to anticipate safety concerns and to consult with the FDA as necessary for regulatory review of new plant varieties and product testing under development.

The FDA assessment process focuses on the following areas:

- The safety and nutritional value of newly introduced proteins.
- The identity, composition and nutritional value of modified carbohydrates, fats or oils.
- The concentration and bioavailability of important nutrients for which a food crop is consumed.
- The potential for food allergens to be transferred from one food source to another.
- Toxins characteristic of host and donor plants.

To ensure safety, a variety of toxicological and other product safety data may need to be supplied to the FDA for food products or ingredients produced through the use of new plant varieties.

USDA and EPA currently have primary responsibility for assessing the ecological effects of new plants developed through biotechnology. The Animal and Plant Health Inspection Service (APHIS) within the USDA is the primary agency regulating the safety testing of biotechnology-enhanced plants that are not insect or disease resistant. APHIS approval generally must be obtained before proceeding to field-test or commercialize a biotechnology-derived plant.

In order to test a biotechnology-derived plant in the field, applicants seek from APHIS an environmental release permit. The applicant must include information on the plant, the origin of any new genes or gene products it contains and the purpose and method of conducting the test. APHIS evaluates the application and any potential environmental impact of the proposed test field. A streamlined notification process is also available, in which APHIS has 30 days to review the notification prior to any testing. The safety requirements for both procedures are the same.

Once testing is allowed, APHIS and state agriculture officials can inspect the test field throughout the process to ensure that tests are conducted safely.

Before biotechnology-enhanced crops can be grown commercially, a petition must be submitted to APHIS containing scientific details about the plant, results of field tests and any indirect effects on other plants. This petition is published in the *Federal Register*, allowing the public time to comment.

In addition to APHIS, the EPA, which also regulates herbicides, also has jurisdiction over crops that are insect and disease resistant under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Environmental exposure to pesticide substances produced in crops is regulated by the EPA to ensure that there are no unreasonable adverse effects on the environment, including non-targeted insects, birds, fish, deer and other species.

The EPA's regulations focus on the pesticide produced by the plant, rather than on the plant as a whole. Such pesticides are subject to registration requirements similar to other pesticides. The agency requires developers of new plant-pesticides to obtain experimental use permits, and EPA officials prior to any field testing must review and approve permit applications for genetically enhanced pesticides in crop plants containing pesticidal properties.

Biotechnology's strong track record of safety has been affirmed by the world's leading international health organizations, including the United Nations Food and Agriculture Organization, the World Health Organization, the National Research Council, the American Medical Association and The American Dietetic Association.

AMERICAN FARM BUREAU FEDERATION
500 Maryland Avenue S.W. • Suite 800 • Washington D.C. • 20024 • (202) 484-3600

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

FOOD MARKETING INSTITUTE

Accurate and Informative Food Product Labeling

Labels on all packaged food must provide consumers with truthful, clear and non-misleading information. For this reason, we support the current Food and Drug Administration (FDA) policy, which requires, among other things, that food be labeled if it poses a safety concern, as is the case for all foods. Safety issues can arise where food produced through biotechnology or other means is significantly different from its traditional counterpart.

The FDA currently requires biotechnology-enhanced foods to be labeled if, for example, the food is significantly changed from its traditional form, such as when its nutritional content has been significantly altered or when it could cause an allergic reaction in some people, or other safety problems. Where none of these or other significant differences exist, generally speaking biotechnology-enhanced food is not materially different from other foods and does not need to be labeled differently from other foods.

Every food product on a grocery store shelf must meet the law's requirements for safety and labeling. Federal regulation has never required that food labels describe the plant development process by which food is produced. Such processes are not material information that must be labeled. Because the law is aimed at ensuring safe food and informative labels, biotechnology products should not be singled out for special regulatory treatment unless there is a significant difference in composition or, otherwise, a safety problem exists, or where material information is missing.

Current law and policy

The FDA established a policy in 1992 that all foods derived through biotechnology be regulated in the same fashion as those developed through traditional methods. This means:

- Products of food biotechnology are subject to the same FDA labeling and safety policies applied to all foods in the U.S. marketplace.

- Different labeling is required when, for example, biotechnology results in a significant change in the composition of a food product. *Putting new proteins into a tomato for enhanced processing capabilities is an example of a substantial compositional change.*

- FDA requires a label on biotechnology products, as needed, to inform consumers of any potential health or safety risk, such as if a protein poses an allergy risk, unless scientific data show that the allergen is not present. Common allergens include milk, eggs, wheat, fish, crustacea, tree nuts, and legumes (such as peanuts and soybeans). *Peanuts are a common allergen. If a peanut gene is inserted into potatoes or corn – products where consumers would not expect to find peanut allergens – the resulting product would need a label to inform sensitive consumers.*

- A label also is required if a food is changed so that its nutritional content no longer conforms to the normal expectations. *Altering the Vitamin C content of an orange to levels significantly above or below the normal range is a good example.*

- The FDA is able to evaluate the safety of biotech ingredients added to foods in the same way it evaluates any new ingredient, such as a new preservative or a new food-coloring agent.

- The FDA can stop a food product from being sold at any time if it determines that a product or ingredient is unsafe for public consumption or if it is mislabeled.

Key issues:

- Labels provide a consumer's first impression of most packaged food products. Labels list ingredients, describe features, give instructions, explain benefits and deliver advisories and warnings. Information considered essential to health and safety is mandated by law to appear on the label.

- Labels on food identifying the presence of ingredients derived through biotechnology could unduly alarm consumers about potential safety risks. In fact, the FDA and the manufacturer must address any potential safety risks of a food product before the product enters the marketplace and, if a safety problem exists, the food will not be marketed or will be labeled to identify the safety risk.

- Labeling of biotech foods differently from their traditional counterparts would have the unintended and unfortunate consequence of misleading consumers into thinking that biotech products have different health effects. This would lead to the kind of consumer confusion that labels are designed to avoid.

November 12, 1999
DRAFT

ACTION

MEMORANDUM FOR THE PRESIDENT

FROM:

REF: **Decision on Biotechnology Issues**

Purpose: There is considerable discussion in the U.S. and around the world (particularly in Europe) 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

Man has been genetically engineering crops through cross-breeding in ways that nature could not for 10,000 years. Modern biotechnology or bioengineering, which is now nearly two decades old, 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 food crops with beneficial characteristics such as pest and drought resistance, higher yield, enhanced nutrition, better taste and vaccine delivery. With global land *per capita* available for cultivation expected to shrink by over 40% and population projected to possibly double, boosting agricultural productivity is perhaps the only way to prevent serious humanitarian crises and environmental degradation in the next century. Biotechnology has the potential to help mankind meet this challenge and, in so doing, advance our national security interests. 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 in some countries. Indeed, some consumer activists have alleged that these foods are unnatural, calling them "Frankenfoods."

In 1986, an interagency group led by OSTP determined that the statutes underpinning the framework for regulating existing technologies provided appropriate authority for regulating the products of biotechnology. In publishing the "Coordinated Framework for Regulation of Biotechnology," the interagency group determined that existing health and safety laws were sufficient to provide immediate regulatory protection and certainty for industry. In light of a general scientific consensus that the *process* of genetic engineering posed no inherent risk, the policy determined that regulation should continue to be based on product uses, applying the existing standards with respect to health and environmental risks of new products. Should the existing standards be found insufficient for a given class of new products, agencies would promulgate regulations under their existing authorities. For example:

- USDA promulgated regulations requiring developers of bioengineered crops to obtain a permit before planting such crops in the field. After USDA obtained significant experience with certain bioengineered crops, a more streamlined notification system was established for them. USDA regulations focus on 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 unacceptable 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 that were 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. This policy has been challenged in litigation that is pending in the District Court for the District of Columbia.

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

Current US Government Perspective. Federal regulatory agencies remain confident that bioengineered crops and foods sold in the U.S. are safe. 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 the demands of some NGOs and consumers for labels and other information about the bioengineered content of food . Some other NGOs privately admit that they are not concerned about biotechnology but will not say so publicly because of the politics of the environmental community. The strength of the U.S. regulatory system is its independence from political interference in decisions affecting health, safety or environment. Indeed, the EU is seeking to replicate such a system. Steps here that appear to be undermining our regulators' independence would adversely affect public trust and provide arguments for those in Europe who want to block such a system.

International Considerations. Even though the large majority of bioengineered corn and soybeans are used for domestic purposes, the international considerations are substantial. The EU is proving increasingly problematic, in part due to recent food safety scares unrelated to biotechnology. 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. No products would be approved until the completion of this process, which the EU admits could take at least three more years. US producers are being

adversely affected by this effective moratorium on regulatory approvals of bioengineered products. Corn growers are losing up to $200 million per year in exports because the EU has refused to approve seven US-approved corn varieties that are co-mingled with the sole EU-approved variety.

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 without much regard to the validity of their claims and despite recognition that genetically engineered food is safe. 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 and sound approaches by foreign governments to biotech issues 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 Academy of Sciences and it's British counterpart, the Royal Society;

- 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.

- Active participation in the 156-member CODEX Alimentarius Committee on Food Labeling Biotech Working Group, which is scheduled to report in May 2000 on guidelines and recommendations on labeling of biotech food and additives, and may reconfirm that biotech foods are equivalent to conventional foods and need not be labeled.

- In the January 20 – 28 high-level negotiations in Montreal on the Biosafety Protocol, cooperation with our Miami Group allies to ensure that the talks do produce an unworkable agreement that unduly restricts trade or imposes high costs without commensurate environmental benefits.

Domestic Considerations

- 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, while advocating that such products are safe. 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. However, these efforts have not, so far, influenced the vast majority of U.S. consumers to demand labeling.

- Industry. 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 companies fear that international resistance to the products, especially in Europe, could eventually spill over into the US market. If this were to occur, an extremely valuable technology would be jeopardized. Industry has not reached a consensus on what direction the U.S. should take to address the problems of commodity segregation and consumer product labeling. Food processors and their trade organizations (e.g. Grocery Manufacturers Association, National Food Processors Association) are opposed to the labeling of GMOs mainly because of the increased cost. They are also concerned that efforts to facilitate or promote voluntary labeling domestically would ultimately lead to mandatory labeling and foster the perception that engineered foods are less safe than their conventionally-derived counterparts. However, some 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, which, so far, no country has been able to do.

- Medical and Scientific Community. The medical and scientific community, both academic and industry, is concerned that steps the Administration takes regarding bioengineered foods may have spill-over to public perceptions about the safety of pharmaceuticals and therapeutics developed through biotechnology.

- 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. Currently, farmers are receiving a modest premium for non-GMO corn and soybeans. However, growers must also self-certify that their crops are GMO-free and must retain full liability for the commodity throughout the marketing chain, even in the absence of uniform and reliable standards, segregation methods and testing capabilities.

- Environment. Finally, agricultural genetic engineering could have significant environmental impacts, both good and bad. Examples of projected 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. Examples of potential 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). It is important to note that most, if not all, of these risks are not new to food production systems. 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. It should be noted that HHS believes that any decisions affecting FDA policy should not be made until FDA has completed three public meeting scheduled between November 18, 30, and December 13, reviewed the comments received, and reported to HHS and the White House on what it learned. In addition, none of the options in this paper would be likely to facilitate access for U.S. products in other countries. Countries that are requiring approval and labels, such as the EU, have their own regulations (which they have not been able to implement), and U.S. products must meet their regulations.

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

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.

b) Direct CEQ/OSTP to Organize an Interagency Process to Examaine 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 qualify 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 examaine 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.

_____ _____

Approve Recommendation Disapprove Recommendation

Attachments

Tab A Memorandum to NEC High-Level Group Principals

Biotechnology

DOMESTIC POLICY COUNCIL

Date: 9/14/99

To: Tom Freedman

From: Anna Richter

~~Telephone~~: Fax: 67431

Subject: Deputies Mtg on Biotechnology

Pages: 22 (Including this cover sheet)

Comments:

Biotechnology Mtg Agenda and Discussion Paper

SECOND FLOOR WEST WING ❖ WASHINGTON, DC 20502
TELEPHONE (202) 456-6515 ❖ FACSIMILE 456-2878

NEC High-Level Group on Biotechnology

Meeting Agenda

September 14, 1999

5:00 – 6:30 p.m.

Roosevelt Room

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

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

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.

---

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.

---

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

The Washington Times
FRIDAY, OCTOBER 8, 1999

EPA official allays fears of hazards from biotech food

ASSOCIATED PRESS

The federal regulators responsible for ensuring the safety of genetically engineered crops sought yesterday to dispel concerns that hazardous biotech products could reach the market.

"Our regulatory system is based on the most rigorous scientific information available, is credible, is defensible and will serve to protect the environment and public health," Jane Anderson, an Environmental Protection Agency official, told the Senate Agriculture Committee.

The EPA is one of three agencies responsible for regulating genetically modified crops and foods, with the Food and Drug Administration and the Agriculture Department.

"We're very confident about the assurances that are put forward," said James Maryanski, biotechnology coordinator for the FDA's food safety office.

Critics of the technology say the agencies depend too heavily on companies to conduct research and report problems, and that the science is not advanced enough to guarantee the safety of the food. Environmental and consumer groups are pushing the Clinton administration to require the labeling of foods that contain biotech ingredients.

"We don't know what the products will prove to be in the long run. To say we know is an expression of faith, not of knowledge," said Mark Silbergeld, a representative of Consumers Union.

Backers of genetic engineering insist it is not fundamentally different from traditional breeding, in which one plant might be cross-pollinated with a wild cousin to produce a hardier variety. Genetic engineering involves splicing a single gene from one organism to another.

A major concern of scientists is making sure transplanted genes do not cause allergic reactions. Biotech ingredients, primarily from soybeans and corn, already are in wide use in supermarkets and fast-food restaurants, in everything from tortilla chips to soda and baby formula.

A major concern of scientists is making sure transplanted genes in products do not cause allergic reactions.

When consumers realize that, they will demand such foods be labeled, Mr. Silbergeld said. "They want to make the choice for themselves."

The food industry fears such labeling would stigmatize genetically modified ingredients. The FDA does not consider biotech ingredients fundamentally different from conventional ones and says there is no need for the labels.

Half the soybeans that U.S. farmers are growing this year were engineered to withstand a popular weedkiller, and a third of the corn crop is biotech, having been altered to produce its own pesticide. There also are genetically modified tomatoes, melons and potatoes. Crops are in development that would be nutritionally enhanced or engineered to deliver vaccines or medicine.

American scientists and farmers have been surprised by the growing public resistance to genetic engineering in Europe. In Britain, where biotech products are derided as "Frankenfoods," supermarkets have started advertising their goods as free of genetically modified ingredients.

Concern about the technology has grown since a laboratory study at Cornell University found evidence that pollen from a genetically modified corn can kill larvae of the monarch butterfly.

EPA scientists knew that the pollen could kill insects but do not believe the butterflies, which feed on milkweed, not corn, would be exposed to the toxin outside the laboratory, said Miss Anderson, director of EPA's biopesticides and pollution prevention division.

The EPA is monitoring field tests of the corn and could impose restrictions on its use if necessary, she said.

Spending package cuts needle exchange

3 departments get $324 billion

By John Godfrey
THE WASHINGTON TIMES

The Senate yesterday approved a $324 billion spending bill for the departments of Education, Labor, and Health and Human Services (HHS).

The sweeping 73-25 vote came after the Senate struck a provision that would have allowed the HHS secretary to create a clean-needle exchange program for addicted drug users.

"Giving an addict a clean needle is like giving an alcoholic a clean glass," said the amendment's sponsor, Sen. Spencer Abraham, Michigan Republican.

"We have proved beyond a reasonable doubt that needle-exchange programs increase the rate of HIV infection and the use of drugs," Mr. Abraham said.

He said that in Vancouver, British Columbia, the number of drug-related overdoses has increased fivefold since 1988, the year the city began its own free needle-exchange program.

Allowing the needle-exchange provision to stand would "send the wrong message to our children and hurt our communities," Mr. Abraham said.

Sen. Paul Wellstone, Minnesota Democrat said, "We are passing a prohibition . . . which will translate into many of our citizens — many of them from the inner city, many of them poor, and too many of them children — becoming HIV infected and dying of AIDS."

Sen. Arlen Specter, Pennsylvania Republican, said there "is no doubt that the reuse of needles by drug addicts does result in infecting more people with AIDS."

Mr. Specter noted that the provision in yesterday's bill would have required the HHS secretary to certify that a needle-exchange program would not increase the use of drugs and would decrease the spread of HIV. He also said that the secretary has never tried to use the provision.

Nonetheless, the Senate accepted the Abraham amendment without a vote.

Passage of the underlying bill sets up a conflict with the House, which has yet to take up its own version of the legislation. A House committee version is substantially less than the Senate-approved measure, and Republican leaders are struggling with a way to find $9 billion in program cuts to attach to the bill to avoid dipping into the Social Security trust fund in 2000.

The Senate measure passed with 20 Republicans and five Democrats voting no.

It includes $2.8 billion more for education than was appropriated last year and $500 million more than the president requested. It adds $2 billion to the budget for the National Institutes of Health, and adds $600 million to the Head Start program.

Top religious conservatives reassured privately by Bush

He spoke with them at D.C. hotel 2 weeks ago

By Joan Lowy
SCRIPPS HOWARD NEWS SERVICE

While Texas Gov. George W. Bush has publicly distanced himself from his party's right wing, he has been privately reassuring religious conservatives that he is agreeable to their concerns on abortion and other social issues.

Mr. Bush, the front-runner for the Republican presidential nomination, met with nearly a dozen conservative Christian leaders in Washington two weeks ago to assuage concerns that he might be soft on abortion, homosexual rights, school choice, church-state separation and other issues.

Overlooking the White House from a conference room at the Hay Adams Hotel, Mr. Bush fielded questions for about 90 minutes from some of the top religious conservative leaders, according to participants.

On abortion, Mr. Bush continued to assert that if elected president he will not have a litmus test for Supreme Court nominees. But he also urged conservatives to look at his record in Texas, where he has consistently appointed judges who oppose abortion to the bench, participants said.

The issue is of paramount importance to conservative Christian activists because it is widely anticipated that the next president will have as many as three Supreme Court vacancies to fill. That could tip the balance on the court and lead to overturning the 1973 Roe vs. Wade decision legalizing abortion.

"He spoke of the need to protect human life in terms that were consistent with our values," said Michael Farris of the Home School Legal Defense Association, who organized the meeting. "He talked not only about abortion, but euthanasia and issues like Dr. [Jack] Kevorkian and expressed the preciousness of human life at all stages, which was warmly received."

On homosexual rights, Mr. Bush told conservatives he wouldn't appoint an openly homosexual person to his administration, nor would he fire an appointee if he later learned that the person was homosexual, participants said.

On the United Nations, Mr. Bush assured conservatives that he firmly believes in "U.S. sovereignty," which participants said they interpreted as an assurance that he would not place U.S. soldiers participating in multinational operations under the direction of U.N. authorities or permit them to wear U.N. insignia.

> *"He spoke of the need to protect human life in terms that were consistent with our values."*
>
> *—Michael Farris*

Other issues Mr. Bush addressed included separation of church and state, home schooling and scaling back the U.S. Department of Education, among other federal departments.

Scott McCellan, a spokesman for Mr. Bush, said the candidate frequently meets privately with interest groups and there was nothing unusual about the meeting.

Republican candidates Alan Keyes, Pat Buchanan, Gary Bauer and Steve Forbes also have had private meetings with the group.

Mr. Bush, who attends a Methodist church, shared his "personal relationship with Christ," participants said.

"He was not a bit ashamed or reticent to do that," Marshall said. "That was very encouraging to all of us."

Mr. Farris said he came away from the meeting feeling he could support Mr. Bush if he wins the GOP nomination but is not ready to endorse him.

"He's not rising out of the social conservative ranks so he's not going to be 100 percent harmonious with us, but the question is whether he is reasonably harmonious. The answer is, yeah, we thought he was," Mr. Farris said.

Barry Lynn, executive director of the Americans United for Separation of Church and State, criticized the meeting.

"It's appalling to me that Bush feels the need to have this kind of secretive meeting in front of a board of inquisition made up of religious right leaders," he said. "He's clearly winking at them" to let them know "they're going to get the right answer" if he's elected president, Mr. Lynn said.

The Washington Times

FRIDAY, OCTOBER 8, 1999

Food Fright

Biotech Scare Sweeps Europe, and Companies Wonder if U.S. Is Next

Hain Labels Its Snacks as Free Of Genetic Engineering; Other Firms May Follow

Veggie Burgers Feel the Heat

By Scott Kilman
Staff Reporter of The Wall Street Journal

Will U.S. shoppers demand that the foods they eat be "biotech-free," the same way they want "fat-free" or "organic" items?

"The more press it gets, the more it will become an issue for consumers," says Andrew Jacobson, a senior executive of Hain Food Group Inc., which recently decided to slap labels on its Little Bear line of natural snacks, assuring consumers that no ingredients come from genetically modified plants.

In the executive corridors of America's premier food and drink companies, no issue is more urgent than whether Mr. Jacobson is right. Although most U.S. consumers aren't aware of it, ingredients made from genetically modified crops are present in various products made by Coca-Cola Co., Kellogg Co., General Mills Inc., H.J. Heinz Co., Hershey Foods Corp., Quaker Oats Co., McDonald's Corp. – and on and on.

European Uproar

Nothing would please these companies more than for Americans to remain oblivious or indifferent to this fact. But that's hardly likely. Consumer uproar already has prompted the European Union to begin imposing mandatory labeling for some foods that contain genetically modified ingredients, and now British supermarket chains are making biotechnology a competitive issue, advertising their house brands as "GMO-free" (no genetically modified organisms). Regulators in Australia, New Zealand, Japan and Canada are devising strategies for labeling such foods, and many other countries are considering similar actions.

Increasing the likelihood that such concerns will spread to the U.S., the same organizations that incited the GMO consternation in Europe – among them Greenpeace and Friends of the Earth – are considering ways to awaken Americans to the issue. Already, the groups's efforts helped push two of the biggest baby-food makers in America, Gerber and Heinz, to try to keep their products free of genetically modified ingredients.

Half of the soybean crop and a third of the corn crop in the U.S. these days 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, just to name a few.

What Consumer Benefit?

If pressure builds in the U.S. to label all genetically modified foods, the impact on sales could be chilling. That is because genetically modified products don't offer an obvious benefit to consumers the way "organic" or "diet" products do. At this point, "genetically modified" simply means that the crops processed into ingredients were easier for farmers to grow, because of resistance to bugs, disease and weeds.

On the other hand, if food companies decide to eliminate genetically altered ingredients from their products, farmers harvesting their bumper crops in Iowa this week could one day be left with a bounty nobody wants. Moreover, the grain industry has no system in place for separating conventional crops from their genetically engineered cousins.

Such a backlash also would be a devastating blow to U.S. biotechnology pioneers Monsanto Co. and DuPont Co. The premium prices they are charging farmers for genetically modified seed is only now beginning to help them recoup the billions of dollars they invested in biotechnology research and acquisitions.

Hardly Hysterical

At the moment, Americans are hardly hysterical about the issue. McDonald's, Quaker Oats and Tyson Foods Inc. say only a tiny fraction of the calls they get from U.S. customers are about the genetically modified crops they use to make their products. Hershey says it has received fewer than 25 inquiries about the issue so far this year, a period in which the candy maker handled hundreds of thousands of calls.

But that could change in a flash – the European backlash developed almost overnight – and for that reason it is a subject industry executives have little willingness to discuss, for fear that doing so will only generate more press. The list of companies unwilling to make executives available to discuss the matter for this story is long: Coca-Cola, Procter & Gamble Co., Sara Lee Corp., Kellogg, BestFoods, General Mills, and Pillsbury, the Minneapolis food division of Diageo PLC, among others.

The food industry is commissioning surveys to track public sentiment toward biotechnology. Hershey is among several companies checking to see how quickly they could switch their factories from genetically modified ingredients if attitudes soured.

Some companies aren't waiting. "We're very concerned about consumer sentiment," says a spokeswoman at Heinz, which says it "will seek to avoid" genetically modified crops in all its U.S. products. That is easy for the ketchup ma... do with tomatoes, because the com... breeders were skeptical of biotechn... from the beginning and stayed away. ... complete ban at Heinz would hurt mil... that supply it with the sweetener used in ... ketchup. A lot of that sweetener is made from genetically modified corn.

After a Consumer Reports magazine article last month identified several soyburger brands as containing genetically modified soybeans, Worthington Foods Inc., which makes Morningstar Farms veggie burgers, swore off genetically modified soybeans. Company executives, who believe altered soybeans are perfectly safe to eat, have begun to remove them from some products anyway, figuring many vegetarians don't trust modern food. "This is a technology they don't understand yet," says Ronald L. McDermott, vice president of research and technology at the Worthington, Ohio, company.

Ben & Jerry's Homemade Inc. says it is making sure that the brownies going into its products are made from nongenetically modified soybean flour. It has taken to buying soybean flour from Natural Products Inc., a small Grinnell, Iowa, company that processes unmodified soybeans and that expects its sales to triple next year to about $10 million.

Two of the food companies doing the most to dodge genetically modified ingredients are closely tied to big-name brands. Worthington is being acquired by Kellogg, and Heinz is acquiring a 19.5% stake in Hain Food Group, the Uniondale, N.Y., firm that is putting nonbiotech labels on its organic snacks. To make sure its new labels are correct, Hain is switching the oil it uses in its fryers from corn to safflower, a plant yet to be genetically modified.

Most food executives are keeping their plans under wraps, but a look at Europe offers some insight into how they would respond to a choice between the use of labeling or ditching genetically modified ingredients. American firms that export to Europe are going to great lengths to avoid the mandatory labels there. British McDonald's fast-food restaurants, for example, have sworn off genetically modified ingredients. Likewise, Pillsbury changed the corn it uses to make the chips it sells in Britain.

Just this week, the fear of a public backlash in the U.S., and what it might push food companies to do, prompted Monsanto to swear off a promising area of research. Robert Shapiro, chief executive officer of the St. Louis company, announced Monday that Monsanto won't commercialize the so-called terminator gene, an experimental

THE WALL STREET JOURNAL
THURSDAY, OCTOBER 7, 1999

Business Bulletin

A Special Background Report On Trends in Industry And Finance

A1

ROAD RAGE stirs up lawmakers and inspires some products and services.

Several states have considered laws that would define and better control aggressive driving, but only a handful have them so far, says the National Conference of State Legislatures, Denver. Lawmakers say such statutes can be tough to define and enforce. Others develop ways to help handle the problem. Zurich U.S., a Schaumburg, Ill., unit of Zurich Financial Services Group, markets a defensive-driving program that includes screening drivers for road rage.

The publishing division of Unity School of Christianity, Unity Village, Mo., markets "The Peaceful Driver: Steering Clear of Road Rage," a self-help guide on audiotape or CD. And Leon James, a psychology professor at the University of Hawaii who calls himself DrDriving, says his educational materials can help achieve "a driving-personality makeover."

Eagle One Industries, a Carlsbad, Calif., maker of car-care products, sells scented vent clips called "Stress Relief."

THE PUMPKIN PATCH is looking a little bedraggled in parts of the U.S.

The Department of Agriculture says pumpkin sizes may be smaller and prices higher in areas that were parched all summer and then soaked with rain. In New York, the second-biggest producing state, wholesale prices are up about 20% from last year, when pumpkins were larger, says Gary Lucier, a USDA economist. Crops in Connecticut and Pennsylvania have also suffered. Dry, hot weather inhibits growth, and lots of moisture later encourages rot.

But Illinois, the largest pumpkin-producing state, is expected to have a good crop, says Mr. Lucier. Ditto for third-ranked California. The USDA doesn't officially track pumpkins, but notes they have become attractive cash crops as fall festivals and farm outings have grown in popularity with families, says Mr. Lucier. In 1997, farmers harvested 74,354 acres of pumpkins – nearly triple the 1982 amount. Still, with an estimated value of $150 million in 1997, pumpkins were far below, say, apples, which totaled $1.5 billion.

BABY, THIS IS BUSINESS. Parents, hospitals and retailers ogle newborns.

The Greater New York Hospital Association says GNYHA Ventures Inc., its for-profit unit, has a Web-based way to show a new baby to friends and family who can't visit in person. The enterprise, called babypressconference.com, is offered to hospitals across the country and will use camera-and-computer kiosks to Netcast baby and parents to an invited group. Aunt Bertha can log on at home for a live-action look at baby, a chat – and a format to send a gift. Free to patients, the perk is expected to start at six hospitals in December.

For hospital administrators, "this is a positive experience that focuses on life," says Lee Perlman, CEO of the new venture. Backers hope it will be a positive experience for retailers, too. Toys "R" Us is a 10% investor and an e-commerce partner, says Chairman Michael Goldstein, who calls it a "natural link." And Sony Classical plans to promote its "Build Your Baby's Brain Through the Power of Music" series.

The gamble for the start-up is whether folks actually buy gifts during the show. Vendors get exposure either way.

DEEP FRYERS are in and food steamers are out, says NPD Group Inc., a market research firm in Port Washington, N.Y. It says 692,044 deep fryers were sold in the first half, up 32% from a year ago, while sales of steamers were flat.

'CEO EXCHANGE' is a public-television series being underwritten by consultant A.T. Kearney, a unit of Electronic Data Systems Corp. Programs are expected to begin in January and each will feature two chief executives discussing a big topic such as globalization.

TROUBLED ALLIANCES: An 18-month study by Andersen Consulting, New York, found that executives of big firms believe 61% of their business alliances formed since 1997 have failed or underperformed their expectations. More than 300 executives were surveyed.

BIG RIGS may be in store for an easier haul through Europe.

Some trucks and their cargoes have been stranded at border crossings when rolling into countries that don't allow trucks on weekends. So, the European Commission proposes a "harmonization" of weekend trucking bans. It suggests banning heavy trucks from circulating between 7 a.m. and 10 p.m. on Sundays, rather than the divergent bans now in place. Seven EU governments ban freight trucks on Sundays and five others ban trucks from Saturday to early Monday at various times of year.

But several governments bristle at the idea of allowing more heavy-truck traffic on interstate highways on weekend nights. A blocking minority, including France, Germany and Italy, planned to fire a salvo against the proposal at this week's meeting of transport ministers. The opponents say the proposal would water down their stricter rules, which apply to all roads, not just interstate highways.

The commission says it is willing to consider even more sweeping proposals – if EU governments produce them.

BRIEFS: Debt Counselors of America, a nonprofit group in Rockville, Md., publishes "Living Together: A Financial Contract for Unmarried Couples." . . . Garage.com, a Web-based, venture-capital firm, informs prospective "angels" about start-ups on a page called "Heaven."

—PAMELA SEBASTIAN