

**CASE STUDY:
TO LABEL OR NOT TO LABEL-THAT IS THE QUESTION**

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BACKGROUND: A petition has been filed that requires a public vote in Oregon. The issue to be decided is whether or not to attach labels stating “Genetically Engineered” on surfaces or outside packaging of genetically-engineered foods sold or distributed in or from Oregon. A list of the products that would be affected is extensive. A copy of Measure No. 27 in its original form is attached for your perusal.

ACTIVITY: Your assignment is to produce and perform a public service radio announcement either opposing or supporting Measure 27. You will be assigned into one of the four interested groups listed below. Your goal is to sway voters to vote in support of your position. After the performance of your announcement, you should also be ready, willing, and able to argue your position using information from your groups attached literature. First, individually read the attached information produced by your group and then rejoin your partners to put together your radio announcement and arguments supporting your groups position.

Interested Groups:

Biotechnology Industry Organization—BIO is the world’s largest biotechnology organization. Its stated mission is to provide advocacy, business development, and communication services for more than 1,200 members worldwide

Mothers for Natural law—MNL was founded in 1996 to address practical steps that every mother can take to safeguard the health, well-being, and innocence of our children. While their stated goals include many issues, they have suspended all other initiatives to concentrate on helping to pass Measure 27 for the first four years of their existence.

Consumers Union-CUO is an offshoot of ‘Consumer Reports’ publications and whose mission is to work for a fair and just marketplace for all consumers.

Food an Drug Administration-FDA, specifically the Center for Food and Applied Nutrition division-CFSAN, is the federal governmental agency assigned with the task of keeping safe our nation’s supplies of foods, cosmetics, drugs, biologics, etc.

All attached documents were accessed from the worldwide web on June 18, 2009.

Measure No. 27

Proposed by initiative petition to be voted on at the General Election, November 5, 2002.

BALLOT TITLE

REQUIRES LABELING OF GENETICALLY-ENGINEERED FOODS (AS DEFINED) SOLD OR DISTRIBUTED IN OR FROM OREGON

RESULT OF "YES" VOTE: "Yes" vote requires labeling of foods derived from or processed using genetically-engineered (as defined) materials with label prepared by the Oregon Department of Agriculture.

RESULT OF "NO" VOTE: "No" vote rejects requiring labeling of foods derived from or processed using genetically-engineered (as defined) materials with label prepared by Oregon Department of Agriculture.

SUMMARY: Requires label stating "Genetically Engineered" on surface or outside packaging of genetically-engineered foods (as defined) sold or distributed in or from Oregon. Defines "genetically engineered" to mean produced by biological changes to the molecular or cell biology of an organism by means not possible under natural conditions; definition excludes breeding, hybridization, tissue culture, certain other processes. Applies to all foods derived from, or prepared with, genetically-engineered material, regardless of whether that material is present in the final product. Creates additional labeling requirements for genetically-engineered foods whose composition or nutritional value is significantly altered and those resulting from gene transfers from other species to allow those with dietary restrictions to observe those dietary guidelines. Legislature to implement and enforce requirements. Other provisions.

ESTIMATE OF FINANCIAL IMPACT: The financial impact of this measure on state and local government expenditures cannot be determined because the Legislative Assembly must act to carry out this measure. There is no impact on state or local revenues.

(The State Treasurer dissents from this estimate.)

TEXT OF MEASURE

Be it Enacted by the People of the State of Oregon:

The Oregon Revised Statutes, is amended BY THE ADDITION OF THE FOLLOWING NEW PART ____, TO READ:

Part ____ . Labeling of genetically engineered food. (1) Declaration of the People.

Labeling of genetically engineered food and food additives shall be required in order to create and enforce the fundamental right of people in Oregon to know if they are buying or eating genetically engineered food and to have the choice in buying or eating foods that have been altered through genetic engineering.

(2) **Definitions.** As used in this part ____ unless the context otherwise requires:

(a) "Agricultural products" means any agricultural, horticultural, viticultural, or vegetable product grown or produced;

(b) "Food" means any articles used for food or drink for man or other animals, chewing gum, and articles used for components, including food additives, of any such article;

(c) "Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and including any source of radiation intended for any such use);

(d) "Genetically Engineered" means grown, manufactured, processed or otherwise produced or altered with techniques that change the molecular or cell biology of an organism by means or in a manner not possible under natural conditions or processes, including but not limited to recombinant DNA techniques, cell fusion, micro- and macro-encapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes. "Genetically Engineered" shall not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization and tissue culture processes;

(e) "Label" means a display of written, printed, or graphic matter upon or connected to the immediate container or surface of any article; and by or under the authority of this section a requirement that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if any, of the bulk, wholesale or retail package of such article or is easily legible through the outside container or wrapper;

(f) "Labeling" means all labels and other written, printed, or graphic matter upon an article or any of its containers or wrappers, or accompanying such article; and

(g) "Principle display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for bulk, wholesale or retail sale.

(3) **Labeling.** All foods in the following categories sold or distributed in or from Oregon, shall bear a label, created by the Oregon State Department of Agriculture, that is plainly visible on the principal display panel and contains the words "Genetically Engineered":

(a) All foods derived in whole or in part from any genetically engineered microorganisms, plants or livestock, if that genetically engineered material accounts for more than one tenth of one percent of the weight of the product;

(b) All food products prepared or processed using genetically engineered enzymes or other genetically engineered processing agents, whether those enzymes or agents are present in the final product or not;

(c) All foods derived from agricultural products cultivated using genetically engineered agricultural inputs, whether those agents are present in the final product or not;

(d) All dairy and meat products derived from livestock that have been fed genetically engineered feed or feed additives or ingredients, or derived from livestock that have been treated with genetically engineered hormones or drugs;

(e) All genetically engineered foods that are significantly altered in composition or nutritional value, or that require preparation steps different from their natural counterparts which shall, in addition to being labeled "genetically engineered," be labeled to specify those changes in properties;

(f) All genetically engineered foods resulting from trans-species gene transfers which shall specify, in the label, the source of the transgene used and the purpose of the transfer. For instance, "This squash contains viral genetic information designed to make it resistant to viral infection."; and

(g) All genetically engineered foods resulting from transfer of animal genes into plants which shall be labeled to indicate this fact in a manner that will allow vegetarians and those with dietary religious restrictions to observe their dietary guidelines. For instance, "this tomato contains genetic material derived from the flounder, a fish of the family Bothidae."

(4) **Enforcement.** By the effective date, the legislature shall prescribe, enact and enforce measures implementing this new part ____.

(5) **Effective date.** This new part ____ shall become effective ninety days after the proclamation of the vote by the governor and shall supercede any federal law, act or regulation which contains less stringent or less complete labeling information for any product subject to the provisions of this part.

(6) **Revisions of this law.** The voters of Oregon authorize the legislature to make changes consistent with the intent of this law so long as the changes further the purpose of this amendment. Substantive changes, such as changes to the categories of foods or food additives,

the full or partial omission of any category of food or food additive, tolerance levels expressed as a percentage, definitions pertaining to terms used in this part or labeling requirements are to be referred to a vote of the people.

<http://www.sos.state.or.us/elections/nov52002/guide/asures/m27>

science for Life



BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. Our mission is to be the champion of biotechnology and the advocate for our member organizations—both large and small.

BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies. Corporate members range from entrepreneurial companies developing a first product to Fortune 100 multinationals. We also represent state and regional biotech associations, service providers to the industry and academic centers. Visit the [BIO Member Directory](#) to browse BIO members and Web site links as well as BIO state and international affiliates.

Member services include:

- Federal and state advocacy on issues affecting the industry
- A dozen or more investor and partnering meetings throughout the year, with discounts for members
- Communications services that disseminate information about the benefits of biotechnology
- BIO Business Solutions discounts for a variety of goods and services

Brief History

BIO was created in 1993 through the merger of the Association of Biotechnology Companies and the Industrial Biotechnology Association. The goal was for the entire industry—from young startups to established companies—to speak with one voice for the industry on such issues as FDA reform, reimbursement policy, national healthcare policy, regulation of biotech crops, and small business and economic development issues.

Over the last 12 years, we have made progress on many fronts:

- Enactment of FDA reform in the 1997 Food and Drug Administration Modernization Act
- The Medicare Modernization Act of 2003 largely incorporated BIO's principles for establishing coverage of outpatient drugs
- From the first significant commercial plantings in 1996, double digit growth in each subsequent year has led to more than 252 million acres of biotech crops planted in 2006 in 22 countries
- At least 40 states have programs in place to promote bioscience-related economic development
- The U.S. government has established aggressive, but realistic, targets for biofuels production, including key incentives for continued development of biotech-based fuels
- Agricultural biotechnology has helped enable large shifts in agronomic practices that have led to significant and widespread environmental benefits, such as improved soil makeup and water, reduced runoff, and reduced greenhouse gas emissions from agriculture.
- Since their introduction in 1996, biotech crops have increased global farm income by \$27 billion
- Cloning can be used to protect endangered species. In Southeast Asia, both the banteng and the guar, which are meat-type bovines, have been cloned in conservation efforts to increase populations of

species threatened by extinction

- BIO supports strong regulatory oversight for agricultural biotechnology from three federal agencies

Specific issues may have changed over the years, but our core mission of fostering biotechnology innovation through advocacy, business development and communications remains the same.

BIO International Convention

BIO produces the annual [BIO International Convention](#), the world's largest gathering of the biotechnology industry. The BIO International Convention attracts more than 20,000 attendees from around the world including more than 500 members of the international press. Convention attendees hear from global biotechnology leaders, learn about the latest biotech innovations and network with their peers from established and emerging biotech companies, research institutions, service providers and biotech hubs.

BIO also produces a series of industry-leading investor and partnering meetings held around the world.

BIO Senior Staff

Names, titles and biographies for BIO's senior staff. [View the list.](#)

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Labeling Of Biotechnology Food Products

Issue in Brief:

Mandatory Labeling of Food Products Based on the Method of Production Is Not Justified

[T]here is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education.

**American Medical Association Council on Scientific Affairs,
Genetically Modified Crops and Foods (I-00) Full Text (2000)**

The biotechnology industry supports accurate and informative product labeling that communicates to consumers material information relevant to health, safety and nutrition. Misleading label information makes informed consumer choices harder. BIO believes that a system of mandatory labeling of biotech products would confuse consumers by inaccurately suggesting that these products are inherently different or pose safety concerns when compared with traditional foods.

The food products of biotechnology are subject to the same [Food and Drug Administration](#) labeling requirements applied to other foods. The FDA's 1992 policy states that there is no reason to conclude that bioengineered foods differ from other foods in any meaningful or uniform way or that they present a greater safety concern than foods developed using traditional methods. Its position is that foods should be labeled according to their characteristics, not their method of production. Therefore, FDA does not require special labeling of biotechnology foods or the products of animals fed these foods.

FDA policy does require a label on food products, including those produced using biotechnology, when they pose a potential health or safety risk or when there has been a material change in the food and it no longer substantially equivalent to its traditional counterpart. These can include changes in composition, nutritional value or safety. (For more on the concept of substantial equivalence, click [here](#).)

This policy has been supported by a number of scientific groups, including the [American Medical Association](#), [American Council on Science and Health](#), [Council for Agricultural Science and Technology](#) and [Institute of Food Technologists](#). A report by AMA, for example, found that "[T]here is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education."

Mandatory labeling would cost consumers more because bioengineered and traditionally bred foods would have to be segregated, or "identity preserved," throughout the entire distribution system. While economical for high-value products like fresh fruits, fresh vegetables and some grains, the cost to segregate commodity products such as corn and soybeans, which are ingredients in 70 percent of processed foods, would exceed the added value of the enhanced trait. Consumers would therefore be forced to pay higher prices simply to cover the cost of getting foods labeled "biotechnology."

FDA allows manufacturers to make voluntary claims about whether their products contain biotech ingredients. Like all product claims, these must be truthful, clear and not misleading. The

FDA has developed labeling [guidance](#) for food manufacturers who want to place voluntary claims on labels for food with or without biotech ingredients. This guidance is to ensure that labels provide accurate information.

A voluntary system will allow niche markets to develop that will cater to consumers interested in purchasing products produced in a particular way, as in the case of organic foods. Ultimately, consumers will dictate the degree to which food producers segregate and label biotech products.

The current science-based labeling policy informs and protects consumers by giving them material information about the food product. The idea that food crops improved through biotechnology are not necessarily different from their traditional counterparts, the basis of FDA's regulatory policy, has been supported by the National Academies and other prestigious scientific bodies.

The FDA's policy does not just make sense to scientists; it makes sense to consumers, too. A 2002 survey conducted by the [International Food Information Council](#) finds that, once it is explained, nearly six in 10-59 percent-agree with the current FDA labeling policy.

This IFIC survey was consistent with the results of a 2002 Oregon ballot initiative that would have mandated special labeling of biotech foods. Despite a huge effort by biotech opponents, the labeling initiative was rejected by voters 72 to 28 percent. The outcome of the Oregon vote confirms that when consumers are presented with the facts about biotechnology and food labeling issues, they agree with the FDA's existing labeling criteria. Consumers also are aware that the new "organic" certification provides choices for consumers who wish to avoid biotech products.

Resources:

Food and Drug Administration:

- [Guidance for Industry, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, Draft Guidance \(January 2001\).](#)
- [Report on Consumer Focus Groups on Biotechnology \(October 20, 2000\).](#)
- ["Statement on Policy: Foods Derived from New Plant Varieties; Notice," Federal Register May 29, 1992, 57\(104\): 22984-23001.](#)

Other Resources:

- [AgBioForum, Public Acceptance of Agrobiotechnology, 1\(1\), 1998.](#)
This issue of the online journal is devoted to consumer perceptions and labeling.
- [Ag BioTech InfoNet.](#)
Provides alternative views on the labeling issue.
- [American Council on Science and Health, Biotechnology and Food \(2000\).](#)
"When there is no discernable difference between two foods, labeling one of them only causes confusion and jeopardizes the value of meaningful labels."
- [American Medical Association Council on Scientific Affairs, Genetically Modified Crops and Foods \(1-00\) Full Text \(2000\).](#)
- [American Public Health Association, Policy Statement, Support of the Labeling of Genetically Modified Foods \(2001\).](#)
Read the response:

[Council for Agricultural Science and Technology, Comments to the American Public Health Association in Response to Its Draft Resolution Regarding Genetically Modified Foods \(2001\).](#)

"We have looked for and, to date, have found no health-based or environmental safety reasons to label all foods containing approved products of modern biotechnology"

- [Campaign to Label Genetically Engineered Foods.](#)
- [Colorado State University, Department of Soil and Crop Science, Transgenic Crops: An Introduction and Resource Guide-Labeling Transgenic Foods.](#)
- [Conko G. 2002. Eat, Drink and Be Merry: Why Mandatory Biotech Food Labeling is Unnecessary, Cascade Policy Institute.](#)
- [Conko G. 2000. "Labelling and Risk: The Case of Bioengineered Foods," Ecology, Liberty, and Property, Competitive Enterprise Institute.](#)

"Leaving labeling to private markets encourages firms to differentiate themselves by providing information about their products that actually matters to consumers."
- [Elise Golan, Fred Kuchler, Lorraine Mitchell, Cathy Greene and Amber Jessup. Economics of Food Labeling, USDA Economics Research Service, Agricultural Economic Report No. 793 \(January 2001\). Read the report \[here\]\(#\).](#)
- [Greenpeace International.](#)
- [Grocery Manufacturers of America.](#)

Good source for information on labeling and traceability.
- [Institute of Food Technologists, "Labeling of rDNA Biotechnology-Derived Foods," Expert Report on Biotechnology and Foods \(2000\).](#)

"Labeling initiatives for rDNA biotechnology-derived foods are likely to have substantial effects on the production, distribution, and cost of food to consumers." Labeling chapter, a one-page chapter summary and an IFT background on labeling available.
- [International Food Information Council, U.S. Consumer Attitudes Toward Food Biotechnology \(conducted August 2002\).](#)
- [Pew Initiative on Food and Biotechnology, Labeling Genetically Modified Foods: Communicating or Creating Confusion? National policy forum held June 27 in Chicago with consumer activists, food manufacturers and academics on whether to label genetically modified foods.](#)
- [Pew Initiative on Food and Biotechnology, Knowing Where It's Going: Bringing Food to Market in the Age of Genetically Modified Crops \(September 11, 2001\). Proceedings from a workshop sponsored by the Pew Initiative on Food and Biotechnology and the USDA Economic Research Service.](#)

A look at identity preservation and other distribution issues.
- [The Royal Society, Genetically Modified Plants for Food Use \(September 1998\).](#)

"We strongly support mechanisms by which consumers can be informed about developments in biotechnology, including the labelling of foods containing GM material where the equivalence of a food is substantially changed, according to established criteria and provided such labelling is appropriately monitored."
- [Evan Schulz. 2000. The Opportunities and Hazards of Agricultural Biotechnology, Economic Strategy Institute Provides a good discussion of voluntary labeling; available \[here\]\(#\).](#)
- [Robbin Shoemaker \(Ed.\), Economic Issues in Agricultural Biotechnology, USDA Economic Research Service Agriculture Information Bulletin No. 762 \(March 2001\).](#)

For more links, [click here](#).

About Mothers for Natural Law

P.O. Box 1177 • Fairfield, Iowa 52556

Work is being continued by The Organic Consumers Association.

[click here for information about the OCA](#)

Mothers for Natural Law was founded in June 1996 to transform the overwhelming problems facing families into simple, practical action steps every mother can take to safeguard the health, well-being and innocence of her children. Our agenda originally embraced everything from the environment to crime, education, health and the economy. However, because of its extreme urgency, we made genetic engineering our only focus for our first four years, and put all of our other plans on hold.

In July 1996, Mothers for Natural Law launched a national public awareness campaign on the dangers of genetically engineered foods, and an initiative to secure rigorous pre-market safety testing, mandatory labeling and a moratorium on these foods. In just one year the organization became a nationally recognized clearinghouse on the issue, working closely with industry and consumers alike to create financially viable, environmentally responsible solutions to the challenges the issue raised for all of us. The following are highlights of some of our achievements:

- **Public Education**—Knowledge has organizing power. As one of the primary consumer spokespersons for the GE issue in the US, our executive director, Laura Ticciati is regularly invited to speak at conferences and conventions all over the country, give print and radio interviews, work with TV reporters to develop stories, create informational materials, newsletters and action alerts to increase public understanding, enliven awareness and empower consumers to take action. Our initial vehicle for raising public awareness, our Information Packet (developed in July 1996), was designed to translate the scientific details of genetic engineering into lay language for consumers. The packet has been used not only by other American organizations, but by groups in countries as far away as Japan and Pakistan. Safe Food News, an unprecedented 32-page full color expose on GE, sold out (500,000 copies) to health food stores nationwide, within weeks of its summer 2000 printing. Our materials have generated support from consumers and businesses in every state, and have led to the creation of Mothers for Natural Law in other countries.
- **Natural Products Industry Support**—The first step we took in this area was to find out what the industry knew and felt about genetic engineering. In response to our initial inquiries, we developed a version of our Information Packet, specifically designed to

provide support materials for manufacturers, distributors and retailers on the safety, environmental, ethical and consumer concerns about genetic engineering. Our orientation was to provide solutions which will bring strength to the industry, and position it as a haven for non-genetically engineered foods for the American consumer. We were the primary non-commercial and cost-free resource for locating non-genetically engineered ingredients for manufacturers so that their products can be kept genetically natural. Our sourcing research was responsible for a large number of non-genetically engineered alternatives both in the U.S. and Europe. During our 1998 campaign, we created a GE Retail Kit to help natural products retailers educate their customers. Our work has been covered by almost every industry-related publication including Natural Foods Merchandiser, Delicious!, Vegetarian Times, Coop Grocer, Conscious Choice, Natural Health, Provender Alliance, Natural Business, Business and the Environment, and Nutrition Science News, as well as every major news outlet, including the New York Times, the LA Times, the Boston Globe, the Associated Press, the Financial Times, National Public Radio and PBS.

- **Protecting the Organic Market**—In February '97, we helped create a national coalition of over forty scientists, consumer groups, business leaders and organizations to keep genetically engineered organisms out of the organic market. (Members included, Citizens For Health, Pure Food Campaign, Farm Verified Organic, Seventh Generation, Eden Foods, Council for Responsible Genetics, Whole Foods Markets.) This coalition generated national press coverage, including reports by the LA Times, NPR, UPI and Christian Science Monitor Radio. Members of this coalition also launched a nationwide response to the proposed USDA regulations on organic standards resulting in the largest public response in USDA history. In March 1998, Mothers was invited to represent the organic consumer at the largest annual natural products industry press conference, with 50 reporters present, leading to several interviews with prestigious mainstream media publications.
- **Certification Procedure**—With a small group of industry members, we initiated a pilot study—to uncover and resolve all the challenges from seed to consumer—in order to create a non-GE label. This study led to the creation of a 'genetically natural' certification 'sticker' available to manufacturers now through Genetic ID, the primary GE certification and testing company in the world.
- **Consumer Right to Know Campaign**—In 1998 we put all of our attention on mandatory labeling. We used this aspect of the genetic engineering issue both as an educational tool and a simple action step everyone can take to get involved—signing a petition. The CRTK petition had two forms—VIP, with nearly 200 signatories including Susan Sarandon, Whole Foods, Seventh Generation, Wild Oats, New Hope Natural Media, Senator Diane Watson, Paul Hawken, Physicians Committee for Responsible Medicine, NOW Foods, Eden Foods, the Humane Society, Stephen Collins, Rabbi Michael Lerner, Mothers and Others, the Environmental Media Association and more—and a grass roots petition, which generated nearly 500,000 signatures. This petition was distributed through health food stores, regional coordinators and on university campuses,

as well as tens of thousands of signature gatherers all over the country, and continues to generate thousands of signatures even now. In 1999 we expanded the petition to include safety testing, accountability and a moratorium, though we have not launched a new initiative.

- **First US Consumer Book on GE**—Laura Ticciati and Robin Ticciati, Ph.D., M4NL Executive Director and scientist husband, wrote the first book for consumers on GE in the US. This introductory book on genetic engineering is in its second printing and was featured on the national PBS series, Healthy Living, hosted by Jane Seymour. Genetically Engineered Foods: Are they Safe? You Decide. (Keats/NTC Publishing Co., 1998)
- **National Summit on the Hazards of GE Foods**, June 1999, Washington, DC—On June 17, 1999, M4NL presented the first 500,000 signatures on our petition for mandatory labeling at a three hour press conference. Our speakers included eminent scientists, physicians, international and national food industry leaders, clergy, farmers, consumers and trade, finance and public policy experts. This summit was hooked up via teleconference to government officials and dignitaries from fifteen European Union nations visiting the United States to discuss the GE issue. The Summit was covered by almost every major national and international media service and heralded as the turning point for this issue in the U.S. Immediately following this summit, Laura Ticciati and Dr. John Hagelin met with House Democratic Whip David Bonior to initiate the first wave of legislative action on the GE issue on Capitol Hill.

Mothers for Natural Law is recognized and respected throughout the country, as professional, competent, stable, reliable and honest. Our approach to every situation is to uphold and support—to take problems and turn them into solutions. People hear us because we speak from the perspective that we are all on the same side. We translate the science and technical details into down-to-earth, common sense language. We work to transform the economic challenges into practical opportunities. We simply tell the truth. And people are listening.

Right now our food is at risk. The biotech industry is buying up the world's seed supply. If we don't engage the support of our government for serious caution, for rigorous safety testing, for a moratorium, genetically engineered foods will become the norm, labeling will be redundant and our children will live in a world where real food, natural food, is no longer available. We urge you to work with us. Help us raise public awareness, and create a wave of understanding for the far-reaching implications of genetic engineering in the United States, so that our nation can join the rest of the world in its desire for safety first.

About Our Name

Natural law is the organizing power that governs the universe. From the tiniest seed, to the

beating of our hearts, to the stars in the galaxies, natural law is the seamless web that nourishes and connects us all.

When we started our organization, we had a long list of problems to be solved. But we didn't want our name to be about problems, we wanted our name to be about solutions. We chose the name "Mothers for Natural Law" to reflect our belief that when we align ourselves with the laws of nature, we gain the support of nature's unlimited strength, intelligence, and creativity—the solution to all problems.

We recognize that the phrase "natural law" may have little impact on the ordinary person in the street. To let it go, however, would be to sacrifice our fundamental mission—to reawaken the experience and understanding of natural law in the individual as the only practical means to solving the serious problems facing our world.

Mothers for Natural Law
PO Box 1177 • Fairfield, IA 52556
Safe Food—Campaign 2001 hotline: (800) REAL-FOOD

What are the Dangers?

Fundamental Weaknesses of the Concept

- **Imprecise Technology**—A genetic engineer moves genes from one organism to another. A gene can be cut precisely from the DNA of an organism, but the insertion into the DNA of the target organism is basically random. As a consequence, there is a risk that it may disrupt the functioning of other genes essential to the life of that organism. ([Bergelson 1998](#))
- **Side Effects**—Genetic engineering is like performing heart surgery with a shovel. Scientists do not yet understand living systems completely enough to perform DNA surgery without creating mutations which could be harmful to the environment and our health. They are experimenting with very delicate, yet powerful forces of nature, without full knowledge of the repercussions. ([Washington Times 1997](#), [The Village Voice 1998](#))
- **Widespread Crop Failure**—Genetic engineers intend to profit by patenting genetically engineered seeds. This means that, when a farmer plants genetically engineered seeds, all the seeds have identical genetic structure. As a result, if a fungus, a virus, or a pest develops which can attack this particular crop, there could be widespread crop failure. ([Robinson 1996](#))
- **Threatens Our Entire Food Supply**—Insects, birds, and wind can carry genetically altered seeds into neighboring fields and beyond. Pollen from transgenic plants can cross-pollinate with genetically natural crops and wild relatives. All crops, organic and non-organic, are vulnerable to contamination from cross-pollination. ([Emberlin et al 1999](#))

Health Hazards

- **No Long-Term Safety Testing**—Genetic engineering uses material from organisms that have never been part of the human food supply to change the fundamental nature of the food we eat. Without long-term testing no one knows if these foods are safe.
- **Toxins**—Genetic engineering can cause unexpected mutations in an organism, which can create new and higher levels of toxins in foods. ([Inose 1995](#), Mayeno 1994)
- **Allergic Reactions**—Genetic engineering can also produce unforeseen and unknown allergens in foods. ([Nordlee 1996](#))
- **Decreased Nutritional Value**—Transgenic foods may mislead consumers with counterfeit freshness. A luscious-looking, bright red genetically engineered tomato could be several weeks old and of little nutritional worth.
- **Antibiotic Resistant Bacteria**—Genetic engineers use antibiotic-resistance genes to mark genetically engineered cells. This means that genetically engineered crops contain

genes which confer resistance to antibiotics. These genes may be picked up by bacteria which may infect us. ([New Scientist 1999](#))

- **Problems Cannot Be Traced**—Without labels, our public health agencies are powerless to trace problems of any kind back to their source. The potential for tragedy is staggering.
- **Side Effects can Kill**—37 people died, 1500 were partially paralyzed, and 5000 more were temporarily disabled by a syndrome that was finally linked to tryptophan made by genetically-engineered bacteria. ([Mayeno 1994](#))

Environmental Hazards

- **Increased use of Herbicides**—Scientists estimate that plants genetically engineered to be herbicide-resistant will greatly increase the amount of herbicide use. ([Benbrook 1999](#)) Farmers, knowing that their crops can tolerate the herbicides, will use them more liberally.
- **More Pesticides**—GE crops often manufacture their own pesticides and may be classified as pesticides by the EPA. This strategy will put more pesticides into our food and fields than ever before.
- **Ecology may be damaged**—The influence of a genetically engineered organism on the food chain may damage the local ecology. The new organism may compete successfully with wild relatives, causing unforeseen changes in the environment. ([Metz 1997](#))
- **Gene Pollution Cannot Be Cleaned Up**—Once genetically engineered organisms, bacteria and viruses are released into the environment it is impossible to contain or recall them. Unlike chemical or nuclear contamination, negative effects are irreversible.

DNA is actually not well understood. 97% of human DNA is called ³junk² because scientists do not know its function. The workings of a single cell are so complex, no one knows the whole of it. ([San Diego Union-Tribune 2000](#)) Yet the biotech companies have already planted millions of acres with genetically engineered crops, and they intend to engineer every crop in the world.

The concerns above arise from an appreciation of the fundamental role DNA plays in life, the gaps in our understanding of it, and the vast scale of application of the little we do know. Even the scientists in the Food and Drug administration have expressed concerns. ([Alliance for Biointegrity](#))

Concerns Expressed by Government Scientists

The quotes below were extracted from documents obtained by the Alliance for Bio-Integrity during the preparation for their law suit against the FDA. Please visit the website of the [Alliance](#) for the complete documents and details of the case against the FDA.

"The process of genetic engineering and traditional breeding are different, and according to the technical experts in the agency [FDA], they lead to different risks."

"I wonder if part of the problems associated with this approach - using scientific issues to set the stage for the policy statement - are due to the fact that the scope of technical experts assigned to the project did not include any whose usual job is risk analysis."

Dr. Linda Kahl, FDA compliance officer, to Dr. James Maryanski, FDA's Biotechnology Coordinator, about the Federal Register document "Statement of Policy: Foods from Genetically Modified Plants". Dated January 8, 1992

"A genetically engineered plant may contain an identical profile of expected plant toxicant levels (i.e. expected toxicants) as is normally found in a closely related, natural plant. However, genetically modified plants could also contain unexpected high concentrations of plant toxicants. The presence of high levels of toxicants in the bioengineered food plant could occur by two or more mechanisms. For example, normal levels of toxicants could be amplified through enhancement of toxicant gene transcription and translation. This might occur as a result of up-stream or down-stream promotion of gene activities in the modified plant DNA. In addition, plant toxicant genes which were normally inactive could be expressed in the modified plant gene as a result of insertion of the new genetic material (i.e. positional mutagenesis). Thus, the task of analysis of all major toxins in genetically engineered plant food includes the assessment of both expected toxicants and unexpected toxicants that could occur in the modified plant food."

Edwin J. Mathews, Ph.D., in a memorandum to the Toxicology Section of the Biotechnology Working Group. Subject: Analysis of the Major Plant Toxicants. Dated October 28, 1991.

"At this time it is unlikely that molecular and compositional analysis can reasonably detect or predict all possible changes in toxicant levels or the development of new toxic metabolites as a result of genetic modifications introduced by the new methods of biotechnology."

"We cannot assume that all gene products, particularly those encoded by genes from non-food sources, will be digestible. For example, there is evidence that certain types of proteins (e.g., plant lectins and protein allergens) are resistant to digestion and can be absorbed in biologically active form."

Samuel I. Shibko, in a memorandum to Dr. James Maryanski, FDA Biotechnology Coordinator. Subject: Revision of Toxicology Section of the Statement of Policy: Foods Derived from Genetically Modified Plants. Dated January 31, 1992.

"Unexpected Effects - This is the industry's pet idea, namely that there are no unintended effects that will raise the FDA's level of concern. But time and time again, there is no data to backup [sic] their contention, while the scientific literature does contain many examples of naturally occurring pleiotropic effects. When the introduction of genes into plant's genome randomly occurs, as is the case with the current technology (but not traditional breeding), it seems apparent that many pleiotropic effects will occur. Many of these effects might not be seen by the breeder because of the more or less similar growing conditions in the limited trials that are performed. Until more of these experimental plants have a wider environmental distribution, it would be premature for the FDA to summarily dismiss pleiotropy as is done here."

"Chart IV, box that reads - "Newly introduced protein present in food from the plant?" This does not take into account, nor does the document as a whole, those introduced proteins (enzymes) that while acting on one specific, intended substrate to produce a desired effect, will also affect other cellular molecules, either as substrates, or by swamping the plant's regulatory/metabolic system and depriving the plant of resources needed for other things. It is not prudent to rely on plant breeders always finding these types of changes (especially when they are under pressure to get a product out). Nowhere is such an issue discussed or examined in this document."

Dr. Louis J. Pribyl, in comments on the "Biotechnology Draft Document, 2/27/92". Dated March 6, 1992.

"Lines 9-17 appear to provide justification for the use of tox[icology] studies in safety assessment, citing as an example the inability of analytical or molecular methods to detect the presence of a [sic] unknown toxin produced by activation of a previously cryptic gene. However, lines 8-end of paragraph say that the tox[icology] studies will not be needed if DNA insertion is limited to only a single site of known genomic location. This discussion implies that pleiotropy (i.e., production of a [sic] unknown toxin due to activation of a previously cryptic gene) will disappear or be negligible if gene insertions are limited to a single copy at a known genomic location. Evidence should be provided to support this position."

"It is my understanding that pleiotropic effects are unpredictable, and may be triggered by gene insertion at a single site, as well as at multiple sites, the plant genome."

Carl B. Johnson, in comments on the "draft statement of policy 12/12/91". Dated January 8, 1992.

"As I know you are aware, there are a number of specific issues addressed in the document for which a scientific consensus does not exist currently, especially the need for specific toxicology

tests. Also, the quantity and quality of data that would be required is not addressed and is difficult to specify at this time. I think the question of the potential for some substances to cause allergenic reactions is particularly difficult to predict."

Dr. Jams Maryanski, FDA Biotechnology Coordinator, in a letter to Dr. Bill Murray, Chairman of the Food Directorate, Canada. Subject: the safety assessment of foods and food ingredients developed through new biotechnology. Dated October 23, 1991.

"In response to your question on how the agency should regulate genetically modified food plants, I and other scientists at CVM have concluded that there is ample scientific justification to support a pre-market review of these products. As you state in the Notice, the new methods of genetic modification permit the introduction of genes from a wider range of sources than possible by traditional breeding. The FDA will be confronted with new plant constituents that could be of a toxicological or environmental concern. The Notice further describes unintended or pleiotropic effects that pose unknown safety concern. It has always been our position that the sponsor needs to generate the appropriate scientific information to demonstrate product safety to humans, animals and the environment.

"A marked-up copy of the Notice with our comments will be provided to you directly by the Center's scientists. Generally, I would urge you to eliminate statements that suggest that the lack of information can be used as evidence for no regulatory concern."

"Residues of plant constituents or toxicants in meat and milk products may pose human food safety problems. For example, increased levels of glucosinolates or erusic acid in rapeseed may produce a residue problem in edible products."

Gerald B. Guest, DVM, Director of the Center for Veterinary Medicine, in a memorandum to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Regulation of Transgenic Plants - FDA Draft Federal Register Notice on Food Biotechnology". Dated February 5, 1992.

"The insertion of any DNA into the plant genome may result in various phenotypic changes (desirable or undesirable) referred to as pleiotropic effects. Undesirable phenotypes may include, for example, poor growth, reduced levels of nutrients, increased levels of natural toxicants, etc. Pleiotropic effects occur in genetically engineered plants obtained with *Agrobacterium*-mediated transformation at frequencies up to 30% (Ref.)^[sic]. Most of these effects can be managed by the subsequent breeding and selection procedures. Nevertheless, some undesirable effects such as increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals), and undesirable alterations in the levels of nutrients may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes. Such evaluations should be performed on a case-by-case basis, i.e., every transformant should be evaluated before it enters the marketplace. (A similar approach was recommended by the International Food Biotechnology Council (Ref.)^[sic]).

"To address unrecognized toxic substances that may unexpectedly appear in transgenic plants

or to evaluate plants that normally contain many toxic substances at very low levels, toxicological evaluation of the edible plant tissue may be more appropriate than using chemical identification and quantification procedures."

Division of Food Chemistry and Technology and **Division of Contaminants Chemistry**. Subject: "Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information." Dated November 1, 1991.

"Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible."

Phil Angell, Director of Corporate Communications, Monsanto. (The New York Times of 10/25/98)

"Except for a handful of new "food additives" such as artificial sweeteners, which must receive premarket approval from FDA before entering the marketplace, most new foods are introduced under the "postmarket" authority of the Food, Drug, and Cosmetic Act. Under this authority, foods made up of proteins, fats and carbohydrates with a history of safe use in food can be sold once companies are satisfied the new product is safe without first getting FDA permission.

John Henkell, "[Genetic Engineering - Fast Forwarding To Future Foods](#)," in the FDA Consumer, April 1995.

These concerns were expressed in light of a policy proposal by the Food and Drug Administration. In fact, the FDA implemented policies which conflict directly with the recommendations of these government scientists. Naturally enough, other scientists, being free to take a broader look at genetic engineering, have also [raised concerns](#).

About Consumers Union

Consumers Union (CU) is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. The organization was founded in 1936 when advertising first flooded the mass media. Consumers lacked a reliable source of information they could depend on to help them distinguish hype from fact and good products from bad ones. Since then CU has filled that vacuum with a broad range of consumer information. To maintain its independence and impartiality, CU accepts no outside advertising and no free samples and employs several hundred mystery shoppers and technical experts to buy and test the products it evaluates.

CU publishes *Consumer Reports*, one of the top-ten-circulation magazines in the country, and **ConsumerReports.org**, which has the most subscribers of any Web site of its kind, in addition to two newsletters, Consumer Reports on Health and Consumer Reports Money Adviser. They have combined subscriptions of more than 8 million. All of CU's work is informed by the more than 1 million readers who respond to our Annual Ballot & Questionnaire, among the largest and most comprehensive consumer studies in the world. In 2008, CU also launched several initiatives, including **ConsumerReportsHealth.org** and the Consumer Reports Health Ratings Center, which serve to educate and empower consumers to make more informed health-care decisions and to help change the market.

To further advance its mission, Consumers Union employs a dedicated staff of lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 600,000 online activists to change legislation and the marketplace in favor of the consumer interest.

The organization generates more than \$200 million in revenue, and a staff totaling more than 600 work at CU's 50 state-of-the-art labs and offices in Yonkers, N.Y.; its 327-acre Auto Test Center in East Haddam, Conn.; and our three advocacy offices, in Washington, D.C., Austin, Texas, and San Francisco. Consumers Union is governed by a board of 18 directors who are elected by CU members and meet three times a year.

[Read the history of Consumers Union and Consumer Reports.](#)

<http://www.consumersunion.org/about/>

October 23, 2002

Governor John A. Kitzhaber, M.D.
State Capitol Building
900 Court Street, NE
Salem, Or 97301

Dear Governor Kitzhaber:

This letter explains why Consumers Union (publisher of Consumer Reports) supports Measure 27, the ballot initiative that would require mandatory labeling of foods and food additives produced using genetic engineering sold in Oregon, or produced in Oregon.

First and foremost, consumers have a fundamental right to know what they are eating. Many laws, at the federal, state and even local level, are designed to inform consumers of facts they want to know about food. These include laws that require labeling of juice made from concentrate, milk that is homogenized, imported food as to its country of origin, food that is frozen or irradiated, as well as ingredients and additives. All these foods are regarded as safe by the US Food and Drug Administration. However, this information is required to be given to consumers at the point of purchase because consumers care and want to know about these aspects of food. With this information, they are able to make informed choices for themselves and their families.

Second, we believe, based on our research, that there are clear differences between foods that are genetically engineered and foods that are not, and these differences are significant to many consumers.* Genetically engineered foods are foods developed and produced using recombinant DNA technology, rather than traditional breeding techniques. Recombinant DNA technology adds to or alters genetic material in a laboratory that could not be added through normal plant or animal breeding. As examples, this material includes bacterial genes that code for antibiotic resistance, which serve as "marker" genes, and viral genes that "turn on" introduced genetic material. Other commonly introduced genes include a bacterial gene that causes a plant to produce a substance toxic to insect larvae and a bacterial gene that makes the plant invulnerable to herbicides. It may be FDA's opinion that these differences are not "significant," but many consumers regard them as very significant and have told the agency so via tens of thousands of comments to FDA Federal Register notices.

The differences between a genetically engineered potato and a traditionally bred potato are arguably greater than the differences between a frozen potato and a fresh one, or between an Oregon potato and the same variety grown in Canada. Under current law, the last two facts have to appear on the label. Consumers have a right to know about all these differences.

With regard to safety, while none of the genetically engineered foods currently on the US market have been shown to be unsafe for human consumption, we are deeply concerned that the federal government does not adequately insure or test for safety to consumers and the environment. The US regulatory system for such foods is a patchwork with serious gaps and weaknesses. For example, FDA, the nation's primary food safety agency, relies solely on a voluntary consultation process with the developer to assure human and environmental safety--which puts the basic responsibility for public safety on the companies developing the products. We think this is far too lax a process for such a new technology. Many critical data have not been gathered under this system.

Moreover, it is not even mandatory for a company to inform the FDA when a newly engineered variety of food is going on the market. Given the rapid globalization of the food supply, we are concerned that genetically engineered foods could be grown in foreign countries with no safety assessment systems at all and be legally sold in the US. The Oregon initiative would at least require such foods to be labeled.

A critical question in a safety assessment is whether a genetically engineered food poses a risk of an allergic reaction. A gene that produces an allergen could be transferred from one food to another. For example, when scientists introduced a Brazil nut gene into soybeans to improve its protein content, the engineered soy turned out to cause an allergic reaction in Brazil-nut-sensitive individuals. While this product was never commercialized, it illustrated that this problem can easily occur. There is also a question about whether newly introduced proteins that have never been in the diet before could turn out to be allergenic. Labels could help health professionals identify such a problem.

We thus disagree with the thrust of the letter sent to you on October 4, 2002, by FDA Deputy Commissioner Lester M. Crawford. Unlike FDA, we think the differences between genetically engineered food and non-engineered traditional foods are significant. We believe that FDA should have required labeling of genetically engineered food as a material fact under the Food Drug and Cosmetic Act. Indeed, several years ago more than 50 members of Congress sent a letter to the FDA Commissioner agreeing that genetic engineering is a material fact under the FDCA.

Further, we think labels could promote public health since they would result in government agencies becoming aware of genetically engineered foods grown in other countries that may not have gone through any safety assessment process. In addition, such labels could help health professionals identify any unexpected effects that might have been missed in the company's voluntary consultation with FDA, in the same way that health professionals identify unexpected difficulties with FDA-approved pharmaceutical products.

Based on the experience of the twelve countries of the European Union that have instituted mandatory labeling of genetically engineered food, we anticipate that the impact on consumer food prices will be negligible.

A mandatory labeling law in Oregon could have benefits in terms of agricultural exports. Not only European countries, but also, Japan, South Korea, China, Australia and New Zealand all have mandatory labeling requirements, and a labeling law would put Oregon in a good position to sell products in those markets.

There is ample legal precedent for Measure 27, such as Proposition 65 in California, which mandated labeling of any consumer products that contained a substance found to cause cancer in animal tests.

At the bottom line, however, the consumer is entitled to make an informed choice about buying genetically engineered food, and without such labels, they are in the dark.

We hope you will find these views useful and will support Measure 27.

Sincerely,

R. David Pittle, Ph.D., Senior Vice President, Technical Policy

Jean Halloran, Director, Consumer Policy Institute

Michael K. Hansen Ph.D., CPI Research Associate, Consumers Union

* See further discussion in our paper, "[Genetic Engineering is Not an Extension of Conventional Breeding](http://www.consumersunion.org)," posted on www.consumersunion.org.

About the Center for Food Safety and Applied Nutrition

The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products.

The Center has over 800 employees, who range from secretaries and other support staff to highly specialized professionals--such as chemists, microbiologists, toxicologists, food technologists, pathologists, molecular biologists, pharmacologists, nutritionists, epidemiologists, mathematicians, and sanitarians.

The Center provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical foods' issues. Most Center staff members work in the Center's headquarters in College Park, Maryland. The Center also operates research facilities in Laurel, Maryland and in Dauphin Island, Alabama. Other locations include the Joint Institute for Food Safety and Applied Nutrition in College Park, Maryland and the National Center for Food Safety and Technology near Chicago, Illinois.

CFSAN Organization

- [Center for Food Safety and Applied Nutrition Organization.](#)

CFSAN - What We Do

Mission

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

Scope of Responsibility

Consumers spend twenty-five cents of every consumer dollar on products regulated by the FDA. Of this amount, approximately 75 percent is spent on foods.

The Center regulates \$417 billion worth of domestic food, \$49 billion worth of imported foods, and over \$60 billion worth of cosmetics sold across state lines. This regulation takes place from the products' point of U.S. entry or processing to their point of sale. There are over 377,000 registered food facilities (including approximately 154,000 domestic facilities and 223,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States and several thousand cosmetic firms. These figures do not include restaurants, institutional food service establishments, or supermarkets, grocery stores, and other food outlets regulated by state, local, and tribal authorities that receive guidance, model codes, and other technical assistance from FDA. FDA enhances its programs by supporting these authorities with training and guidance to direct uniform coverage of food establishments and retailers.

The economic importance of the American food industry is enormous. It contributes about 20 percent of the U.S. Gross National Product, employs about 14 million individuals, and provides an additional 4 million jobs in related industries.

FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and frozen, dried and liquid eggs, which are under the authority of the U.S.

Department of Agriculture (USDA's Food Safety and Inspection Service (FSIS), the labeling of alcoholic beverages (above 7% alcohol) and tobacco, which are regulated by the U.S.

Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), and the U.S. Environmental Protection Agency (EPA), which establishes tolerances for pesticide residues in foods and requirements for drinking water.

FDA's responsibility in the area of cosmetics covers all domestic and imported products.

The Center's primary responsibilities include:

Food

- the safety of substances added to food, e.g., food additives (including ionizing radiation) and color additives

- the safety of foods and ingredients developed through biotechnology
- seafood and juice Hazard Analysis and Critical Control Point (HACCP) regulations
- regulatory and research programs to address health risks associated with foodborne, chemical, and biological contaminants
- regulations and activities dealing with the proper labeling of foods (e.g., ingredients, nutrition health claims)
- regulations and policy governing the safety of dietary supplements, infant formulas, and medical foods
- food industry postmarket surveillance and compliance
- industry outreach and consumer education
- cooperative programs with state, local, and tribal governments
- international food standard and safety harmonization efforts

Cosmetics

- regulations and policy governing the safety of cosmetic ingredients and finished products
- regulations, policy, and other activities dealing with proper labeling of cosmetics
- regulatory and research programs to address possible health risks associated with chemical or biological contaminants
- post-market surveillance and related compliance activities
- industry outreach and consumer education
- international standard-setting and harmonization efforts

Although the U.S. food supply is among the world's safest, the increase in variety of foods and convenience items available has brought with it public health concerns. The complexity of the food industry, and the technologies used in food production and packaging, is increasing. Sources of food contamination are almost as numerous and varied as the contaminants themselves. These include everything from preharvest conditions to contamination introduced during processing, packaging, transportation, and preparation. Some of CFSAN's current areas of food safety concern are:

- biological pathogens (e.g., bacteria, viruses, parasites)
- naturally occurring toxins (e.g., mycotoxins, ciguatera toxin, paralytic shellfish poison)
- dietary supplements
- pesticide residues
- toxic metals (e.g., lead, mercury)
- decomposition (e.g. histamine formation) and filth (e.g., insect fragments)
- food allergens (e.g., milk, eggs, peanuts, tree nuts, soybeans, wheat, fish, shellfish)
- nutrient concerns (e.g., vitamin D overdose, pediatric iron toxicity)
- dietary components (e.g., fat, cholesterol)
- radionuclides
- Transmissible Spongiform Encephalopathy-type diseases (e.g., chronic wasting disease in elk)
- product tampering

As with foods, the complexity of the cosmetic industry and the technologies and ingredients used in production of cosmetics is increasing. The increase in global trade of cosmetics has also increased the challenges in a number of areas, as products and ingredients are entering the U.S. from a wide variety of countries with different regulatory frameworks and safety standards. Some of the current areas of focus for cosmetics include:

- microbiological contaminants
- chemical contaminants
- drug vs. cosmetic products
- use of nanoscale materials as ingredients
- botanical ingredients
- alternatives to animal testing

Statutory Authority

FDA's regulatory authority for food and cosmetics comes from:

- The Federal Food and Drugs Act of 1906
- The Federal Import Milk Act (1927)
- The Federal Food, Drug, and Cosmetic Act of 1938, as amended
- The Public Health Service Act (1944)
- The Fair Packaging and Labeling Act (1966)
- The Infant Formula Act of 1980, as amended
- The Nutrition Labeling and Education Act of 1990
- The Dietary Supplement Health and Education Act of 1994
- Food Allergen Labeling and Consumer Protection Act of 2004
- Food and Drug Administration Amendments Act of 2007
- Other Related Statutes

FDA's Tools for Protecting the Food and Cosmetic Supplies

- inspection of establishments
- collection and analysis of samples
- monitoring of imports
- monitoring of adverse event reports and consumer complaints
- premarket review (e.g., food and color additives)
- notification programs (e.g., food contact substances, infant formula)
- regulations/agreements (e.g., memoranda of understanding)
- consumer studies, focus groups
- laboratory research
 - develop/improve methods for detecting pathogens and chemical contaminants in food and cosmetics

- determine health effects of food and cosmetic contaminants
- determine effects of processing on food composition and allergenicity
- determine health effects of dietary factors
- investigate factors that contribute to virulence of biological contaminants
- determine skin penetration of cosmetic ingredients and contaminants
- pilot plant for food processing and packaging and biotechnology studies
- cooperative activities/technical assistance
- issuance of model codes and guidance documents
- stakeholder awareness through education and public meetings
- information and outreach on Center activities

International Arena

Because a growing proportion of the American food and cosmetic supplies is imported, CFSAN also works with international organizations (World Health Organization, Food and Agriculture Organization of the United Nations, Codex Alimentarius Commission, International Cooperation on Cosmetic Regulation) and occasionally directly with foreign governments to educate them on U.S. requirements and to harmonize international standards. The Center is increasingly called on to work with international organizations, such as the Codex Alimentarius Commission--an international food standard-setting organization of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO)--and foreign governments, to help establish internationally recognized safety standards, rules and regulations for imported products. In the past, most of the Center's standard-setting efforts dealt with U.S. products, but that is changing as a result of recent international treaties and the increasing amount of food and cosmetics that is moving in international commerce.

Collaboration with Other Federal and Local Authorities

FDA maintains close communications with these and other federal agencies such as the U.S. Department of Commerce's National Marine Fisheries Service; the Centers for Disease Control and Prevention (CDC), the U.S. Department of Treasury's U.S. Customs and Border Protection; the Federal Trade Commission (FTC), the U.S. Department of Transportation (DoT), the Consumer Product Safety Commission (CPSC) and the U.S. Department of Justice (DoJ). In many instances, FDA has interagency agreements with them to delineate respective responsibilities.

FDA regulates food and cosmetic products sold in interstate commerce, whereas products made and sold entirely within a state are regulated by that state. Center personnel work with state agriculture and health departments, to resolve food or cosmetic safety concerns and economic fraud cases, for example.

Collaboration with Academia and Industry

The Center is actively involved in high-visibility endeavors with several academic institutions through its Centers of Excellence (COE) program. These collaborations yield critical information that enhances our on-going efforts to protect the food supply. CFSAN has four COEs, the National Center for Food Safety and Technology (NCFST) with the Illinois Institute of Technology; the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) with the University of Maryland; the FDA COE for Botanical Dietary Supplement Research at the National Center for Natural Products Research (NCNPR), University of Mississippi; and the Western Center for Food Safety (WCFS) with the University of California at UC, Davis. In addition, formal agreements with the states for conducting inspections enhance the Center's ability to meet its public health mission.

<http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/WhatWeDo/default.htm>

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 4, 2002

Governor John A. Kitzhaber, MD
State Capitol Building
900 Court Street NE
Salem, Oregon 97301-4047

Dear Governor Kitzhaber:

This letter explains why FDA objects to the pending ballot initiative to require the mandatory labeling of foods and food additives produced using genetic engineering sold in Oregon, or produced in Oregon and shipped to other states. In brief, FDA's scientific judgement is that there is no significant difference between foods produced using bioengineering, as a class, and their conventional counterparts. (By "genetic engineering," we refer to foods produced using recombinant deoxyribonucleic acid (rDNA) technology and not traditional breeding techniques; this technology is also referred to as "bioengineering" or "biotechnology.") Further, FDA's scientific evaluation of bioengineered foods continues to show that these foods, as currently marketed in the United States, are as safe as their conventional counterparts. Moreover, mandatory labeling to disclose that a product was produced through genetic engineering does not promote the public health in that it fails to provide material facts concerning the safety or nutritional aspects of food and may be misleading to consumers.

Under the Federal Food, Drug and Cosmetic Act ("the FD&C Act"), FDA is responsible for ensuring the safety of the nation's food supply, ensuring that food labeling is truthful and not misleading, and for regulating food additives. 21 U.S.C. § 321, et. seq. Foods and food ingredients produced using bioengineering must adhere to the same safety and labeling standards under the FD&C Act as their conventionally bred counterparts. FDA is not aware of any information or data that would suggest that any genetically engineered foods that have been allowed for human use are not as safe as conventional foods.

After numerous meetings and public comments on this issue,¹ FDA concluded that a safety assessment of any new food should focus on the traits and characteristics of that food, no matter which techniques (traditional breeding or genetic engineering) were used to develop the food. Food produced via bioengineering should be treated just like its conventional counterparts because, from a scientific standpoint, there is no evidence that these foods differ as a class from traditionally bred foods in any meaningful or uniform way. Nor is there evidence that, as a class, foods developed by rDNA breeding techniques present any different or greater safety concerns

¹ FDA has carefully considered the issues surrounding foods produced using bioengineering. As part of this consideration, FDA has reviewed public comments on its bioengineered food policies and has held public hearings on FDA's approach and experiences with foods produced via bioengineering. In May 1992, FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy), which is available for your information at 57 Federal Register 22984 (May 29, 1992) or the FDA's web site at www.fda.gov.

than foods developed via traditional breeding. FDA's scientific evaluation to date has shown that the substances added to food via bioengineering have been well-characterized proteins that are functionally very similar to other proteins that are commonly and safely consumed in the diet every day.

FDA has previously concluded that requiring mandatory labeling for bioengineered foods is not scientifically or legally warranted. Rather, the labeling for foods produced using bioengineering must comply with the law applying to the labeling for all foods. Among other things, food labeling must reveal all facts that are material in light of representation made in the labeling or in light of consequences that may result from the use of foods. 21 U.S.C. § 321(n).

For example, FDA would consider mandatory labeling where:

- the food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food – FDA has required labeling for two foods (a soy oil and a canola oil) where the fatty acid composition was changed to mimic that of food oils not associated with the modified plant;
- an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use;
- the food has significantly different nutritional properties; or
- a new food includes an allergen that consumers would not expect to be present in the food based on the food's name.

Accordingly, the proposed legislation for mandatory labeling of foods produced using bioengineering would be contrary to FDA's position that the use of bioengineering, standing alone, is not a material fact that requires disclosure in food labeling. Moreover, as is summarized above, and described in more detail in FDA's public notices cited above, mandatory labeling of bioengineered foods is contrary to the science that currently shows no significant difference between foods produced using bioengineering and their conventional counterparts.

Moreover, the proposed legislation would impermissibly interfere with manufacturers' ability to market their products on a nationwide basis. If passed, manufacturers producing products in Oregon or manufacturers selling products in Oregon produced in another state would be required to create special labeling to comply with Oregon law – labeling not required by FDA or other states. Thus, as a practical matter, the Oregon law would require different labels for different states impeding the free flow of commerce between the states.

We hope you find these views useful.

Sincerely,
Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner

<http://www.bio.org/local/foodag/Kitzhaber.pdf>