BREEDING DISTRUST:
AN ASSESSMENT AND RECOMMENDATIONS FOR IMPROVING THE REGULATION OF PLANT DERIVED GENETICALLY MODIFIED FOODS

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EXECUTIVE SUMMARY

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Public acceptance of these foods ultimately depends on the credibility of the testing and regulatory process.[1]

Modern genetic engineering techniques are capable of modifying plants and animals in ways that go far beyond the capabilities of conventional breeding techniques. Genetically modified foods have the potential to increase crop yields, reduce pesticide use and generally improve the efficiency of agriculture throughout the world. Past experience with useful food production and food processing technologies, however, suggests that such benefits frequently come with associated risks to human health and the environment. Because genetically modified (GM) foods have the potential to cause serious and widespread harm to humans and the environment, government has an important role to play in assessing and managing the risks posed by the new genetic engineering technologies. Moreover, because public trust is essential to the marketability of genetically modified foods, an adequate regulatory regime is critical to the future of the budding agricultural biotechnology industry itself.

After a brief description of how modern agricultural biotechnologies work, this Report examines the ongoing debates over the risks and benefits of those technologies from both a technical perspective and from a broader policy perspective. It identifies seven generic attributes of an adequate regulatory regime and evaluates how those elements advance the sometimes conflicting goals of scientific accuracy, consumer and environmental protection, economic and administrative efficiency, technological progress, and public trust. The bulk of the Report consists of a detailed examination of the regulatory regime that has evolved in the United States to address public concerns about the health and environmental risks that widespread marketing of GM foods may present. To provide a comparative perspective, the Report briefly describes and analyzes the regulatory regimes that have evolved in the European Union and Brazil to regulate GM foods. Finally, the Report measures the existing U.S. regulatory regime against the seven suggested elements of an adequate regulatory regime, finds the existing regulatory seriously deficient in several important regards, and suggests significant changes aimed at improving the quality of regulatory decisionmaking and enhancing public acceptance of governmental decisions regarding GM foods.

How Genetic Engineering Works.

In the early 1970s, scientists discovered enzymes that allowed them to clip a piece of DNA from one organism and insert it into another. Since then, scientists have developed many more techniques for causing one organism to take up and express segments of another organism's DNA. Currently, scientists may introduce genes from a living organism (called the "donor") into a plant (called a "host") through one or more of several methods, including: (1) direct DNA uptake by the plant cells mediated by chemical or electrical treatments; (2) microinjection of DNA directly into plant cells; (3) biolistics, or firing tiny metal particles coated with the DNA of interest into plant cells; and (4) employing a bacterium, such as the soil bacterium *Agrobacterium tumefaciens*, as a vehicle to carry the DNA into plant cells.

Once laboratory tests have verified that an engineered plant is adequately expressing the desired protein, fat or oil, the manufacturers test the new plants in the field to ensure that they can survive under normal environmental conditions and that they do not possess any unanticipated characteristics that might cause adverse health or

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1 Bettelheim, Reluctant Congress, at 939 (quoting Perry Adkisson, chancellor emeritus of Texas A&M University).

environmental impacts or otherwise render them unmarketable. At present, most GM plants are tested extensively in the field for economically important agronomic characteristics before the biotech companies that created them move to the next stage of scaling up for commercial production. GM foods presently receive limited health, safety and environmental testing to determine possible adverse effects on human health.

Potential Benefits of GM Foods.

Applying modern genetic engineering techniques, scientists have successfully incorporated into plants both "input traits" designed for the convenience of growers, processors and marketers and "output traits" aimed at providing direct nutritional and food quality benefits to consumers. *Input traits* successfully designed into (GM) foods include pest and disease resistance, herbicide resistance, and other techniques designed to increase crop yields; changes in tolerance to temperatures and soils aimed at increasing crop adaptability to a wider variety of growing conditions; and various changes in food plant characteristics to improve food handling, distribution and processing capabilities. *Output traits* include improvements in nutritional content; improvements in food quality, including texture, uniformity and appearance; enhanced food safety; and even medicinal qualities. Finally, modifications in both input traits and output traits can bring about positive environmental improvements as farmers use fewer herbicides and pesticides and farm animal wastes contain fewer pollutants.

BENEFITS OF GM PLANTS

Input Traits	*Output Traits*
Pest resistance	Improved nutritional content
Disease resistance	Improved texture
Herbicide resistance	Improved uniformity
Tolerance to temperatures	Improved appearance
Tolerance to soils	Enhanced safety
Changes to:	Medicinal qualities
Improve handling	
Improve distribution	
Improve processing	

The widespread adoption and acceptance of GM foods will probably have significant *distributional consequences*. Improved input traits and better yields may benefit farmers if falling prices do not wipe out efficiency gains. Enhanced output and falling prices attributable to higher yields may benefit consumers. In addition, many proponents of agricultural biotechnologies emphasize their potential to benefit impoverished citizens of developing countries by making more food available at less cost and by making vitamin-enhanced GM foods available to combat disease throughout the world. The fact that the vast bulk of GM corn is presently being used to feed cattle and the fact that most private agricultural biotechnology research is devoted to crops grown in moderate climates, however, suggest that social engineering as well as genetic engineering will be required to fulfill the promise of GM foods to alleviate world hunger.

The Risks Posed by Genetically Modified Foods

Although there have been no confirmed cases of disease or illness associated with human consumption of GM foods in the published literature, agricultural biotechnologies do have the potential to cause significant harm to

human health and the environment. Fortunately, the companies that develop and market GM foods usually detect undesirable traits during initial trials and eliminate the plants that bear them before commercialization. Unfortunately, the tools for assessing health and ecological risks of GM plants are still quite primitive. Thus, the best way to ensure that developers continue to conduct careful screening programs and that any dangerous products that do slip through privately maintained safety nets are removed from the market is to establish an adequate regulatory regime.

Direct risks to human health posed by GM foods are a function of the likelihood that the item will produce a protein that is toxic or allergenic to some or all human beings, the nature and potency of that protein's toxicity or allergenicity, and the magnitude of dietary exposure to that protein. Since pest- and disease- resistant GM plants produce proteins that are intended to be toxic to insects and viruses, it is possible that those proteins may be toxic to some human beings. Genetic modifications designed to enhance input or output traits might incorporate proteins that induce allergenic responses in some sensitive people. Genetic engineering can yield intentional or inadvertent changes in host plant metabolism that can in turn result in the production of greater quantities of a toxic protein that the plant already produces in small quantities or in the production of new toxic proteins in foods in which they are not expected.

GM foods can pose *indirect risks to human health* by inadvertently reducing the expected level of important nutrients in foods in order achieve other desirable changes in the plant's characteristics. The "marker genes" that scientists have traditionally inserted into GM plants to make them resistant to particular antibiotics for the purpose of easy identification in the laboratory remain in the GM foods and may decrease the efficacy of those antibiotics or increase the speed with which pathogenic bacteria become resistant to those antibiotics. Herbicide resistant GM crops could cause indirect human health effects if farmers, relying upon the heightened resistance of their crops, overuse the herbicides and thereby expose humans to greater quantities of those chemicals.

Direct risks to the environment and public welfare posed by GM foods include the risk that the traits (such as pest-, disease- and herbicide-resistance) that are designed into desirable food crops to give them an advantage will turn them into weeds that proliferate in places where they are not wanted. GM crops may also pose direct risks to nontarget species, like monarch butterflies, that are susceptible to the protein that causes the plant to be resistant to the target pests.

Unanticipated consequences of GM foods may include *indirect risks to the environment and public welfare* through several possible routes. If pest species are continuously exposed to the proteins that cause GM crops to be pest resistant and if the crops are not very carefully managed, the pests themselves will become resistant to the toxic protein, and its value will be lost not only to the farmers who purchase the GM seeds but also to conventional and organic farmers who rely upon the bacteria from which the genes coding for the toxic proteins are derived. As the genes that developers deliberately insert into food plants "flow" through cross-pollination or other transfer mechanisms from the plants into which they were incorporated to related species, the result could be a generation of "superweeds" or (at the other extreme) a genetically weakened endangered species. Herbicide overuse resulting from widespread adoption of herbicide resistant crops may cause ecological and economic damage in the same way that it may cause adverse human health effects. Finally, widespread adoption of GM crops will no doubt accelerate the worldwide trend toward monocultures, thus threatening biodiversity and increasing the risk of catastrophic loss of one or more important food crops.

RISKS OF GM FOODS

Direct risks to human health

Production of allergenic proteins
Production of new toxic proteins
Enhanced production of existing toxic proteins

Indirect risks to human health

Reductions in expected levels of nutrients
Decreased efficacy of antibiotics
Speedier development of antibiotic resistant bacteria
Greater human exposure to herbicides

Direct risks to environment and public welfare

Turning crops into "superweeds"
Reduced populations of beneficial nontarget species

Indirect risks to the environment and public welfare

Speedier development of pesticide resistant pests
Loss of valuable biological pesticides
Turning related species into "superweeds"
Greater environmental exposure to herbicides
Threat to biodiversity

At present, there are *substantial uncertainties* in the existing state of knowledge regarding the risks and benefits of GM foods that call for *informed societal judgments* about whether and how to grow GM plants and animals. Modern societies typically rely upon regulatory agencies to make these informed judgments through a two-step process of *risk assessment*, which requires the agency to analyze and interpret the scientific data and make informed predictions about the risks posed by an activity, and *risk management*, which requires the agency to make legal and policy judgments about how to employ the regulatory options that are available to the agency under its governing statute. While the latter exercise is obviously policy-dominated, the former exercise also involves policy judgments in contexts in which scientific uncertainties proliferate. In both cases, the policies that the agency employs should derive primarily from the agency's statute.

The Policy Debates Over Genetically Modified Foods.

Since its origins in the late 1970s, modern biotechnology has been in the center of a contentious public debate that goes beyond disagreements over the proper assessment of risks and benefits of particular technologies. Some of the most significant debates revolve around the novelty of modern genetic engineering techniques, the proper applicability of the "substantial equivalence" doctrine to the scope of the regulatory programs for GM foods,

the proper realm of the "precautionary principle" in those regulatory programs, the extent to which GM foods and their precursors should undergo testing prior to their release for commercial use, the extent to which GM foods should be labeled, the "transparency" of the regulatory decisionmaking process, and the degree to which the participants in the debates are motivated by irrational biases and/or self-interest.

The debate over the *novelty of modern genetic engineering techniques* focuses on whether modern agricultural biotechnologies are really so novel that special regulatory attention to the products of those technologies is warranted. Proponents of the technologies maintain that they represent "nothing new under the sun." The regulatory focus should, as with any food, be on the food product itself, and not the process that produced it. Critics are convinced that modern agricultural biotechnologies represent a radical and potentially dangerous departure from traditional plant breeding techniques, and therefore warrant regulatory programs designed with those unique processes in mind. Indeed some critics raise moral objections to GM foods that depend entirely upon the fact that the food products resulted from the genetic modification process.

Under the doctrine of "*substantial equivalence,"* a GM food that the relevant regulatory agency determines as a "scientific matter" to be substantially equivalent to a food that is already in the food supply should not be subject to additional regulatory requirements, such as toxicological testing or product labeling, designed to protect public health and the environment. Agricultural biotechnology proponents maintain that since GM foods are not likely to be any more hazardous that non-GM foods, the substantial equivalence doctrine can eliminate the need for expensive premarket testing and analysis of innocuous GM foods. The critics maintain, however, that the substantial equivalence approach is likely to ignore subtle changes in delicately balanced biochemical pathways within genetically engineered plants that may affect the safety or environmental impact of those plants. More importantly, they do not trust what they perceive to be industry-dominated regulatory agencies to make highly subjective substantial equivalence determinations.

The *precautionary principle* is another highly subjective approach to regulatory decisionmaking that requires regulatory agencies to proceed with caution, paying particular attention to the views of scientists from various disciplines and from the affected public, when dealing with activities that pose potentially irreversible health and environmental risks. Critics of the precautionary principle fear that it will cause agencies to limit agricultural biotechnologies unnecessarily based upon hypothetical risks. Lacking the industry's faith in the powers of risk assessment, given the current state of information on the risks posed by agricultural biotechnologies, proponents of the precautionary principle argue that it simply implements a cautious public policy of looking before we leap when adequate scientific studies that would allow for accurate assessment of the particular risks posed by particular products have not yet been undertaken.

The debate over the degree to which GM products should undergo rigorous *premarket testing* is closely related to the debates over substantial equivalence and the precautionary principle. Public interest groups argue that for regulatory agencies to presume that GM foods are safe without full-scale toxicity and allergenicity testing and environmental assessment is to make guinea pigs out of the consumers of those foods and to subject the environment to unwarranted risk. The agricultural biotechnology industry argues that testing whole foods in laboratory animals is highly impractical, and allergenicity testing of all GM foods in humans would be wasteful and exceedingly expensive.

THE SUBSTANTIAL EQUIVALENCE DOCTRINE

Principle

A GM food that is substantially equivalent to an existing food should not be subject to additional regulatory requirements

Advantages

- Uses historical consumption of existing food as baseline for safety determination
- Avoids potentially unnecessary and expensive testing
- Recognizes that objective tests may not exist for determining safety of GM foods

Disadvantages

- Not capable of dealing with subtle and/or unexpected changes induced by genetic engineering
- Depends upon subjective determinations made by manufacturers and low level bureaucrats
- Based upon a policy of encouraging GM foods, rather than scientific principles

Perhaps the most contentious of the public policy debates over GM foods to date has been the debate over whether GM foods should be *labeled* so that consumers can easily ascertain whether the foods that they are consuming have been genetically modified or contain genetically modified components. Although agricultural biotechnology proponents do not reject labeling outright, they argue that it is only appropriate when genetic modifications of traditional foods result in significant changes in their nutritional or safety status. Labeling proponents argue that accurate labeling is essential to informed consumer choices about the quality, safety and other important aspects of the food that they eat. They believe that whether food has been genetically modified is a "material fact" that consumer have a right to consider in making food choices. Consumers should be allowed to decide for themselves whether GM foods pose heath risks, whether they care to assume any additional risks attributable to GM foods, whether they should avoid certain GM foods on moral or religious grounds, and whether they want to encourage greater use of GM crops. There is also a lively constitutional debate over whether mandatory labeling requirements for GM foods would violate the companies' constitutional free speech rights.

The debates over *transparency* center on the degree to which regulatory decisionmakers must allow public participation in the decisionmaking process. After recent events in Europe, there seems to be an emerging consensus that the decisionmaking process should to the maximum degree possible be open to the public and should be receptive to public input. Disagreements still exist over whether health and safety related information that companies claim to be trade secret should be shielded from public view and whether members of the public should be put on notice of and allowed to attend premarket "consultations" between regulatees and regulatory agency officials. There is also an emerging controversy over the appropriateness of sophisticated industry-sponsored "public education" campaigns conducted through public relations firms.

In the end, the future of modern agricultural biotechnologies depends upon whether the public becomes convinced that the industry and the regulatory agencies that legislatures have created to protect consumers and the environment are worthy of *public trust*. No matter how strong the scientific evidence appears to the proponents of the technology, the ultimate test for the success of the industry is whether the public trusts the decisionmakers who interpret that scientific information and use it to assess and manage risks. At this point, there is a good deal of distrust on both sides of the debates. Each side questions the other's motives, and there is very little face-to-face dialogue. In the end the public will not trust modern agricultural biotechnologies and consumers will not purchase its end products if they are not fully convinced that the existing regulatory regime is fully capable of ensuring that GM

foods are safe and that the relevant regulatory agencies are doing an adequate job of implementing and enforcing the relevant regulatory requirements.

The Regulatory Regime in the United States.

While modern agricultural biotechnologies are producing GM foods in the U.S. at a vigorous pace, the adequacy of the existing federal regulatory regime to protect human health and the environment has not been seriously tested. The current regulatory structure was erected with chemical contaminants and weeds, not biotechnology in mind, and the relevant statutes do not always address critical regulatory issues in an unambiguous fashion. The primary regulatory programs for GM foods in the U.S. are administered by the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

The United States Department of Agriculture.

The Federal Plant Pest Act (FPPA) empowers the USDA to regulate imports and movement within the United States of plant pests, which may be microorganisms, plants, or insects. USDA may seize, quarantine, destroy or apply other remedial measures to articles that it believes to be infested or infected by or contain a plant pest. USDA has exercised this authority to establish a permit regime for all organisms that "can directly or indirectly injure or cause disease or damage in any plants or parts thereof." The Department may refuse to issue a permit when "such movement would involve a danger of dissemination" of plant pests. USDA promulgated special regulations in 1987 requiring manufacturers and importers of certain GM plants that may be plant pests to conduct field testing as a condition to obtaining a permit, and in 1993 it modified the regulations to establish a petition process for exempting GM plants so that they may be sold and planted commercially without individual permits.

The USDA permitting regime for GM plants is limited to "regulated articles," a term that is defined to include any genetically modified organism, if the donor organism, recipient organism, or vector is on a long list of designated organisms and the modified organism otherwise meets the statutory definition of plant pest. The term does not strictly include unlisted plants that have been modified (through micropipetting and biolistics) without the aid of listed vectors, a gap in coverage that will no doubt grow as genetic engineers rely more frequently upon these techniques. Even if the host, donor or vector for a modified plant is on the list, the modified plant must independently meet the definition of plant pest before it becomes a regulated article, and the manufacturer is the entity that makes this determination in the first instance. Once a regulated item has been sufficiently tested in field tests, the manufacturer may file a petition for "nonregulated status" to obtain an exemption from the USDA regulatory program.

The Environmental Protection Agency.

The Environmental Protection Agency has the primary authority for federal pesticide regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Food Drug and Cosmetic Act (FDCA). Under FIFRA, no person may sell, distribute, or receive a pesticide unless it has been "registered" with the EPA. GM pest resistant crops are pesticides, because they are "intended for preventing, destroying, repelling, or mitigating pests." As such, the manufacturers must obtain a license, called a registration, from EPA. To obtain such a registration, the registrant must demonstrate that when used in accordance with widespread and commonly recognized practice, the pesticide will not generally cause "unreasonable adverse effects on the environment." This ordinarily requires the registrant to submit to EPA extensive information on the pesticide's identity, its environmental fate, its potential toxicity to humans and other animals, and its potential for ecological disruption. EPA does, however, have the authority to exempt whole classes of pesticides.

Under the FDCA as amended by the 1996 Food Quality Protection Act, a food is adulterated if it contains a pesticide residue, unless EPA has established a "tolerance" for the pesticide residue on that food. The tolerance must be set at a "safe" level, and safety is defined to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA may exempt a pesticide residue from the tolerance requirement if the agency finds that the exemption is "safe" according to the same "reasonable certainty of no harm" standard.

EPA has invoked the substantial equivalence doctrine to grant broad categorical exemptions to some GM pest resistant crops from both the FIFRA registration and the FDCA tolerance requirements. Under FIFRA, EPA has exempted GM plants that are derived from closely related plants. The agency reasoned that transfers between closely related (i.e. sexually compatible) species would not result in levels of toxic proteins that greatly exceeded the normal range of levels exhibited in individual plants. EPA has exempted two categories of GM plants from the tolerance requirements: (1) GM pest resistant plants resulting from closely related (i.e., sexually compatible) plants (relying upon the same rationale as the FIFRA exemption); and (2) GM pest resistant plants derived from unrelated food plants that do not involve significantly different dietary exposures (relying heavily upon the substantial equivalence doctrine). EPA guidelines detail the conditions that constitute significantly different dietary exposures.

The Food and Drug Administration.

The FDA regulatory program is perhaps the most complex and least scrutible of the existing U.S. regulatory programs. Although FDA's statutory authority extends to all foods that might become adulterated and therefore be unhealthy, FDA has ceded to EPA all regulatory authority over plants that have been genetically modified to express pesticidal substances so long as they have not also been modified to express nonpesticidal substances. Plants genetically engineered to enhance plant resistance to chemical herbicides are not pesticides and are therefore subject to FDA's exclusive jurisdiction.

The 1958 Food Additives Amendment to the FDCA established a pre-market approval process for food additives. The agency may not grant a food additive petition if the information available to the agency (provided for the most part by the petitioner) fails to establish that the proposed use of the food additive will be safe." The "safety" finding requires the proponent of a food additive "to demonstrate to a reasonable certainty that no harm will result from the intended use of the additive."

The term "food additive" is defined in the statute to mean any substance that may become a component of or otherwise affect the characteristics of any food, but only if the substance is not generally recognized as safe (GRAS). A substance added to food is GRAS if the manufacturer or importer determines that qualified experts have concluded based upon "scientific procedures" or in the case of a substance used in food prior to January 1, 1958 through experience based upon common use in food that the substance is generally recognized as safe.

Ultimately, the agency leaves it up to the manufacturer or importer to determine whether an added substance is GRAS or a "food additive." Nothing in the statute or regulations prevents a manufacturer or importer from relying upon its own scientists or academic consultants hired by the manufacturer to draw conclusions about what is commonly known in the scientific community. Manufacturers frequently contract with private standard-setting agencies or panels assembled by trade associations to make GRAS determinations for particular substances. A manufacturer or importer may even establish the GRAS status of a substance based upon "scientific procedures" when the substance has never been used in food at all. Thus, it is conceivable that a manufacturer or importer could design a brand new food additive through genetic modification techniques, conduct its own scientific studies, publish the results of those studies in the scientific literature or circulate them widely (e.g., on the internet), monitor comments from interested scientists, and allow its own scientists and/or consultants or a favorably disposed panel assembled by a trade association to conclude on the basis of the resulting "common knowledge" that the substance is GRAS. Although a manufacturer or importer is not required to notify FDA that it has made a GRAS determination with respect to a GM food, FDA has established an "affirmation" process under which the agency may on its own initiative announce or a manufacture may petition for and receive an agency affirmation that a particular substance is GRAS.

In a 1992 policy statement, FDA took the position that "the transferred genetic material and the intended expression product or products" in GM foods would ordinarily be "food additives" if those materials were not GRAS. Relying upon the substantial equivalence doctrine, the policy statement concluded that "[i]n most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food" and will therefore pass the GRAS test. The primary exceptions to the agency's willingness to presume that transferred genes and their expression products are GRAS involve transfers of genes coding for proteins, carbohydrates, fats or oils that: (1) might cause allergenic responses in some consumers, (2) are known to be toxic, or (3) are likely to become a "macroconstituent in the human or animal diet" and thereby affect the nutritional value of the genetically modified food.

U.S. REGULATORY AUTHORITIES

Unites States Department of Agriculture (USDA)

Statute:	Federal Plant Pest Act (FPPA)
Scope:	Most, but not all, GM plants that are "plant pests"
Regulation:	Permit to enter interstate commerce

Environmental Protection Agency (EPA)

Statutes:	Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Federal Food Drug and Cosmetic Act (FDCA) -- §§ 408, 409
Scope:	Pest Resistant GM plants
Regulations:	Pesticide Registration Pesticide Tolerance

Food and Drug Administration (FDA)

Statute:	Federal Food Drug and Cosmetic Act (FDCA) -- §§ 402, 409
Scope:	Substances deliberately added to foods that are not generally recognized as safe (GRAS)
Regulations:	Food additive petition GRAS consultation

Other Regulatory Regimes.

The Regulatory Regime for Genetically Modified Foods in the European Union.

Unlike the United States, which has attempted to regulate genetically modified food through pre-existing regulatory frameworks aimed primarily at chemical risks, the European Community (EC) has adopted two major regulatory initiatives dealing specifically with the production and sale of genetically modified food. The EC Council in 1990 adopted a directive requiring all member states to adopt legislation concerning deliberate release into the environment of genetically modified organisms ("GMOs"), including food-related plants. Since directives are not directly applicable in the EC member states, each state is free to choose the specific form and method by which it will comply with the directive's mandate. Subsequently, in January 1997, the EC Council and European Parliament adopted a regulation concerning "novel foods and novel

food ingredients," including foods and food ingredients that contain consist of or are produced from GMOs. Unlike a directive, the regulation is directly applicable in the national legal systems of each member state.

The EC's 1990 directive establishes a permit regime for all "deliberate releases" of GMOs into the environment and for marketing products "containing, or consisting of" a GMO intended for subsequent release into the environment. The directive defines "GMO" as any organism "in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." The directive defines "deliberate release" as any intentional introduction into the environment of a GMO without provisions for containment, and treats any product that is "supplied or made available to third parties" as having been "placed on the market." The 1997 Novel Food regulation applies to placement on the EC market of "novel foods and food ingredients" that had not previously been used for human consumption "to a significant degree within the Community." This category includes both foods and food ingredients consisting of or produced from GMOs.

The Regulatory Regime for Genetically Modified Foods in Brazil.

Like the EU, Brazil has enacted a separate permitting regime for genetically modified organisms. Under Brazilian law, products containing or consisting of GMOs may not be released into the environment or placed on the market without prior approval by an eighteen-member biotechnology commission (the CTNBio). In addition, the Ministries of Health, Agriculture and the Environment are responsible for registering products containing or derived from GMOs that are marketed for human, animal or plant use or for release into the environment, and for maintaining a register of all institutions and professionals carrying out activities and projects related to GMOs. In addition, any organization that uses genetic engineering techniques must create an Internal Biosafety Commission. This internal commission is legally responsible for: establishing prevention and inspection programs to assure that facilities comply with biosafety rules; maintaining "individual progress reports" for each activity or project involving GMOs; notifying the CTNBio and public health authorities of the results of any risk assessment; and investigating any accident or disease "possibly related to" GMOs and reporting the results of the investigation to the CTNBio.

Elements of an Adequate Regulatory Regime.

The starting point for an analysis of any governmental program for regulating GM foods is an assessment of the elements of an adequate regulatory regime. Acknowledging the absence of any generally agreed upon generic list of requirements that any regulatory program should include, this Report suggests the following elements:

- *Notice* -- Entities proposing to engage in new risk creating activities like the production of GM foods should provide notice of that fact to a governmental agency.

- *Transparency and Public Participation* -- Because public trust is absolutely critical to the success of any regulatory regime and to the success of the budding new agricultural biotechnology industry, the regulatory process should be as transparent as possible and should provide representatives of public interest groups a direct role in any decisions to regulate or not to regulate particular GM commodities.

- *Data Collection* -- Testing novel products in laboratory animals and/or other surrogate systems before allowing them onto the marketplace or into the environment is generally necessary to protect human health and the environment.

- *Data Evaluation* -- Having collected testing data, a regulatory agency must have the capacity to assess the quality of those data, analyze and interpret them, and draw scientifically valid conclusions.

- *Risk Assessment* -- Most modern regulatory regimes require the relevant regulatory agency to combine the data assessments, analyses and interpretation into a qualitative or quantitative risk assessment.

- *Consumer Choice* -- In a mass market economy, accurate information about consumer products is critical to ensuring public trust in the marketplace, and government has a legitimate role to play in ensuring that food manufacturers accurately inform consumers of material facts relevant to the composition and the safety of their products.

- *Risk Management* -- When risk assessments suggest that particular agricultural biotechnologies pose unacceptable risks if left unregulated, an adequate regulatory regime must be capable of employing one or more regulatory requirements to reduce or eliminate those risks.

- *Avoiding Unnecessary Delays* -- Because unnecessary delays in the regulatory process can keep valuable crops off the market and thereby deprive consumers of low cost, high quality food, regulatory agencies must avoid unnecessary delays in regulatory decisionmaking.

- *Monitoring and Enforcement* -- An adequate regulatory regime should also be capable of monitoring regulated activities and detecting violations of existing regulatory requirements. Agencies concerned with effective enforcement must think about enforceability when they promulgate regulations.

- *Retrospective Evaluation* -- An adequate regulatory regime should be capable of evaluating whether past decisions to regulate particular activities (or to exclude particular activities from regulation) have achieved the relevant regulatory goals.

- *Institutional Posture* -- Although an agency's willingness to regulate fairly and effectively is not amenable to precise quantitative measurement, any assessment of the adequacy of a regulatory regime should attempt to characterize the institutional culture of the relevant agencies as an indication of their willingness to exercise their regulatory powers aggressively to protect human health and the environment.

ELEMENTS OF AN ADEQUATE REGULATORY REGIME

Notice

Transparency and public participation

Data collection, data evaluation and risk assessment

Consumer choice

Risk management

Avoiding unnecessary delays

Monitoring and enforcement

Retrospective evaluation

Institutional willingness to regulate fairly and effectively

Adequacy of the Existing U.S. Regulatory Regime.

Like most other public policy aspects of modern agricultural biotechnology, the adequacy of the current regulatory regime, when measured against the preceding criteria, is the subject of much debate. The manufacturers and processors of GM foods are generally of the opinion that the existing regulatory regime is more than adequate to protect consumers and the environment from any potential threats, most of which are highly speculative in their view. By contrast, many consumers and public interest groups are not convinced that the current regulatory regime in the U.S. is providing adequate protections for human health and the environment, because the legal underpinnings for that regime are located in statutes that Congress enacted to address health and environmental effects of toxic chemicals and weeds. More importantly, the current regulatory framework was built on the foundational assumption that "the techniques of biotechnology are not inherently risky and that biotechnology should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of other technologies."

Scope.

By far the most profound difference between the U.S. regulatory regime and those in place in the European Union and Brazil is the scope of those regimes. Both the EU and Brazil have adopted process-oriented regulatory programs aimed at all GM organisms. The laws in the EU and Brazil broadly encompass all GM foods, because they include all GM organisms within their scope. By contrast, the legal underpinnings for the U.S. regulatory regime are scattered through several unrelated statutes that Congress enacted to address health and environmental effects of toxic chemicals. Consequently, the implementing agencies have had to stretch and manipulate existing statutory authorities to fit the unique risks and benefits of GM foods. The system has become "balkanized" as three different agencies have carved out their regulatory "turf." The patchwork approach that the U.S. has taken to date may well contain regulatory gaps, and at least some of the legal interpretations that form the foundation of the current regulatory edifice might not survive a serious attack in court by a determined regulatee.

The patchwork quilt of the U.S. regulatory regime has also prevented any comprehensive environmental assessment of the adverse environmental effects of GM plants. FDA has deferred environmental assessment responsibilities to USDA, and USDA consistently finds that its decisions to allow full-scale commercialization of GM plants will have no significant impact on the environment, and, as a consequence, has never prepared an environmental impact statement for such a decision. EPA lacks any opportunity to play the review role that the National Environmental Policy Act assigns to it, and EPA exempts its own actions under FIFRA from the environmental impact statement requirement on the ground that its background documents are substantially equivalent to an EIS. The bottom line is that although much attention has been given to a few particular impacts of many GM plants, especially with respect to threatened or endangered species, very little comprehensive environmental impact assessment has been accomplished by any agency.

Notice.

In contrast to the European Union and Brazil, where manufacturers and importers must provide competent regulatory authorities prior notice prior to deliberately releasing *any* GMO into the environment and/or the marketplace, pre-release and pre-manufacture notice requirements are applicable to only a limited number of GM plants under the complex and porous system of interrelated notice requirements in place in the United States. Companies must provide USDA with pre-release notice for any "regulated article" that is a plant pest, but the term "regulated article" does not include unlisted plants that have been modified (through micropipetting and biolistics) without the aid of listed vectors, and the manufacturer is allowed to make the "plant pest" determination in the first instance. Thus, the USDA plant pest program will ensure that USDA will receive pre-release notice of most, but not all GM plants.

EPA should receive notice of plans to introduce most GM pest resistant plants into the environment sufficiently far in advance to take any necessary regulatory action. The agency has, however, elected to exempt from the registration requirement "plant-pesticides derived from closely related plants." It has also exempted from the

tolerance requirements plant-pesticides from closely related plants and plant-pesticides derived from food plants that are not closely related.

FDA does not receive notice of any GM-plant pesticides, and its 1992 Policy Statement suggests that it requires very little notice for foods derived from the vast majority of GM plants. If a manufacturer or importer decides that a genetic modification results in the addition of a "food additive" to food, it must provide notice to FDA by way of a petition for approval of that food additive prior to marketing the food. FDA's current policy, however, allows manufacturers and importers to market GM foods that they determine to be GRAS without informing FDA, and FDA's 1992 Policy Statement employs the substantial equivalence doctrine to allow manufacturers to declare most GM foods to be GRAS.

One need not be a fierce skeptic of GM foods to conclude that the existing regulatory regime allows manufacturers and importers a great deal of discretion in deciding whether to notify regulatory agencies of their plans to introduce GM plants into the environment and into commerce. Although a company that desires to "play it safe" will voluntarily provide notification to USDA, EPA and FDA in close cases, no serious consequences are likely to befall companies that decline to provide notice to those agencies if they can plausibly argue that their plants are not regulated articles or plant pests (in the case of USDA), are GRAS (in the case of FDA) or come within the agency-created exemptions (in the case of EPA). In the case of imports, the likelihood that FDA will even detect the presence of a GM food that an importer has quietly, but incorrectly determined to be GRAS is quite low. Given the aggressive development of GM foods in some countries (e.g., China), consumers may not trust importers and exporting countries to make decisions with the best interests of U.S. consumers in mind.

Transparency and Public Participation

There appears to be a growing consensus in the U.S. that the regulatory process has not been sufficiently transparent. None of the agencies provides for any sort of public hearing prior to release or marketing of GM crops and foods. Under its existing regulations USDA need not provide for any public awareness of, or participation in, field testing permit decisions beyond posting of some limited information about notifications and applications on the Department's website and providing an opportunity to read and comment upon the typically quite brief environmental assessments. The public does, however, have an opportunity to participate in USDA decisions on petitions for "nonregulated" status for GM plants that are about to be commercialized. FDA does not automatically invite the general public to the informal consultations between FDA and the manufacturers of GM foods that take place when the GRAS status of GM foods is in question. Only when the manufacturer elects to petition for approval of a food additive is the public afforded a formal opportunity to request a full-scale hearing, and this has only happened on one occasion. The opportunities for public participation in the EPA's pesticide registration decisions are much more extensive for GM plants that are not covered by one or more of the exemptions, but those opportunities are still limited by the general inaccessibility of health and safety data. Thus, while the public has not been excluded from regulatory policymaking, the agencies have not actively encouraged public participation. Past agency practice suggests that the agencies have viewed their liberal use of advisory committees as an appropriate substitute for direct public participation in regulatory decisionmaking.

In this regard, the EU experience differs from the U.S. regulatory regime only modestly and generally in the direction of less public participation. Transparency is achieved primarily through the publication of official reports and the minutes of official exchanges of information. The EU Directive and Regulations make no specific provisions for public participation in individual decisions to allow GM plants into the environment and to allow GM foods into the marketplace, and they are quite vague on the right of outsiders to review health and safety data that are deemed trade secrets by the companies submitting them. The Brazilian regime is, if anything, even less receptive to public participation. Although it requires organizations employing genetic engineering techniques to provide employees health and safety related information, the general public has little access to the data underlying the regulatory decisions of the relevant regulatory agencies. Moreover, the CTNBio must preserve the confidentiality of any issue submitted to the plenary commission, and it is not required to allow the public to attend any of its meetings, though it may do so if it deems public participation "necessary."

Data Collection, Data Evaluation, and Risk Assessment

The existing U.S. regulatory regime provides for surprisingly little data collection, data evaluation and risk assessment for GM foods. For those GM plants that do not even require pre-release and pre-market notification, any

testing and risk assessment is, of course, entirely voluntary. Even when notification and permits are required, manufacturers face very few pre-release and pre-market testing and risk assessment requirements. The agencies require very little long-term testing of whole GM foods or of the novel proteins produced by inserted genes prior to release and commercialization. For the vast majority of GM foods, agencies apply the "substantial equivalence" concept to allow manufacturers to forego all testing except that necessary to meet the threshold substantial equivalence showing. In the remaining cases, the agencies and the manufacturers negotiate out the relevant testing requirements on a "case-by-case" basis. Environmental groups claim with some justificatoin that manufacturers are frequently able to substitute "hand waving, qualitative rationalizations, and incomplete field studies" for hard data in these one-on-one sessions. The contrast between the EPA and FDA approaches to GM foods with respect to testing and risk assessment requirements and the much more prescriptive approaches of the same agencies to chemical pesticides and additives is striking.

The Brazilian, EU and U.S. regulatory regimes appear to differ only slightly with respect to requirements for data collection, data evaluation and risk assessment. The Brazilian regime requires applicants for permission to distribute GMOs commercially to provide "appropriate" data and bibliographic references to support their answers to detailed questions, but they do not specify in detail how the studies necessary to supply "appropriate" data are to be conducted. The EU Directive and Regulations provide for extensive assessments of the risks to human health and the environment posed by GMOs and products containing GMOs prior to release and marketing, but they provide very little guidance as to the details of the tests that manufacturers must undertake or the models that they should employ in the risk assessments. Moreover, the "simplified procedures" available for GM foods that are "substantially equivalent" to existing foods or food ingredients may provide a loophole through which the otherwise extensive data gathering and risk assessment requirements may be avoided.

Consumer Choice.

The contrast between the EU regulatory regime and those in the U.S. and Brazil is starkest in the area of consumer choice. The relevant federal authorities in the U.S. have applied the substantial equivalence doctrine to avoid requiring GM foods to be labeled. Although a Brazilian court has recently ordered CTNBio to promulgate labeling regulations, it remains unclear whether the agency will comply with that order. In the European Union, by contrast, all food produced from genetically modified maize or soya must indicate this on the label, unless "neither protein nor DNA resulting from genetic modification" is present in the food or any of its ingredients, or unless "material derived from" GMOs is detected at a level of less than one percent of the food or any or its ingredients.

Risk Management

All three of the relevant U.S. agencies administer laws that putatively require manufacturers of GM foods to obtain permits prior to releasing or marketing them. Yet all three provide for such broad waivers and exemptions that the permit requirement does not stand as a significant obstacle to new GM foods. The USDA requires GM plants that may be plant pests to have a permit prior to field testing, but it allows the manufacturer to make the critical "plant pest" determination. EPA requires a permit for the sale, distribution and use of a pesticide and a tolerance for any pesticide that is used upon food or feed crops, but it freely grants exemptions from the permit and tolerance requirements. A food additive for which FDA has not granted a food additive petition is subject to seizure, unless the manufacturer first determines that it is GRAS.

The criteria for obtaining a permit in the U.S. vary from statute to statute. As USDA interprets the Plant Pest Act, a permit may not be issued unless the released plants can be adequately managed and the permute must take all "feasible" steps to prevent the release of the permitted plants. Under FIFRA, EPA may not grant a registration to a new pesticide unless the registrant demonstrates that it will not cause "unreasonable adverse effects" on humans or the environment, a test that clearly calls for a risk-benefit balancing approach. The FDCA allows EPA to grant a pesticide tolerance for pesticides in food upon a showing to a reasonable certainty that no harm will result. The same test applies to FDA regulation of food additives that do not otherwise come within the GRAS exemption.

The regulatory regime in the EU provides for a complex multi-step permit process, the substantive criteria for which vary depending upon whether the proponent wants to release a GMO into the environment or introduce it into the European product market. For releases generally, the authorizing state must ensure that "all appropriate measures" are taken "to avoid adverse effects on human health and the environment." The same test applies when member states issue a permit to market a product containing a GMO, and in addition the authorizing state must

ensure that the product will not "present a danger for the consumer," "mislead the consumer," or "differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer." The European Commission has suggested that a "precautionary principle" should apply whenever preliminary scientific evaluation indicates that there are "reasonable grounds for concern" about adverse environmental or health effects. However, precautionary measures should be: proportional to the chosen level of protection; non-discriminatory in their application; consistent with similar measures taken in other areas; based on an examination of potential benefits and costs; and subject to review in light of new scientific findings.

Risk management of GM foods in Brazil is greatly complicated by the apparent willingness of the judiciary to overturn agency action under a regime that provides very little in the way of statutory criteria for granting or denying permits. The federal agencies appear favorably disposed toward the commercial sale and human consumption of GM food. Limited evidence on the cultivation of smuggled GM seeds and the dearth of inspectors for vast geographical regions suggests that the risk management on the ground in Brazil may not match the risk management regime on paper. Finally, the authority of state regulators effectively to overturn prior federal approvals is a further source of uncertainty that prevents drawing strong conclusions about the adequacy of the Brazilian regulatory regime.

Avoiding Unnecessary Delays and Restrictions.

All three of the relevant U.S. agencies have gone to extraordinary lengths to ensure that agricultural biotechnologies become available to farmers and consumers as rapidly as possible. USDA created a "notification" process in 1993 that allows many GM plants to escape its permit process. EPA has provided generous exemptions for categories of low-risk plant-pesticides, and it has so far not imposed burdensome data-generating requirements on manufacturers. The FDA's formal food additive approval process is hardly a paradigm of a smoothly functioning regulatory system, but the agency has issued a policy statement that suggests that most GM foods are GRAS. Although the GRAS affirmation process does not move very rapidly, delays do not slow down the introduction of new foods into the marketplace, because manufacturers are free to market products that they determine to be GRAS while FDA's affirmation is pending.

The complex regulatory regime in place in the European Union, by contrast, provides many opportunities for countries that opposed the introduction of GM foods to delay the required approvals. Although the regulatory regime in Brazil as administered by the relevant federal agencies does not appear to result in large delays in the approval process, judicially imposed environmental impact assessment procedures and the threat of regulatory intervention at the state level could result in significant delays.

Monitoring and Enforcement.

It appears that monitoring for enforcement may be the Achilles heel in all three of the regulatory regimes examined here. None of the relevant agencies in the U.S. has created an enforcement program to match the regulatory programs that they have created for the new agricultural biotechnology industry. USDA requires that persons conducting field tests of GM plants pursuant to Federal Plant Pest Act permits monitor for adverse environmental impacts, but it is not clear that USDA devotes any significant resources to investigations of possible violations of the permit requirements. FDA has no systematic monitoring program in place to determine whether or not manufacturers have been abusing the GRAS process and marketing GM foods that are legally subject to the food additive requirements. Although both FDA and EPA conduct fairly extensive monitoring for and enforcement of violations of EPA tolerance requirements for chemical pesticides, it does not appear that either agency has established a program for testing crops for pesticidal proteins produced through genetic modifications. Finally, EPA does not have an effective monitoring and inspection program in place for detecting violations of FIFRA's registration requirements for GM foods.

Perhaps because of the de facto moratorium on new GM product approvals and the de facto ban on GM foods in some countries, information on enforcement in the EU is sketchy. There is little evidence, however, indicating that the bans are being ignored within the five countries or that GM crops other than those authorized are being grown in the remaining countries. Nor is there any evidence that states favorably inclined toward GM foods are less enthusiastically enforcing conditions imposed by authorizing states. By contrast, there is some evidence from Brazil of significant deficiencies in the government's inspection and enforcement capability, and recent reports

of unauthorized plantings of smuggled GM seeds suggest that enforcement efforts have not been especially effective.

Retrospective Evaluation.

Except for USDA's sensible requirement that companies report the results of all field tests that the Department authorizes, little in the way of monitoring and retrospective evaluation of GM foods is required or undertaken in the U.S. EPA's decision to register GM plant-pesticides only "conditionally" until 2001 may yield retrospective data as the registrants attempt to support their applications for full registrations and EPA conducts its promised "comprehensive reassessment" of those registrations. Given the current absence of any FDA labeling requirements for GM foods, it is difficult to see how any monitoring and retrospective health and safety evaluations could be undertaken by the manufacturers, the agency, or anyone else.

In the EU, by contrast, companies seeking permits to release or market GMOs must submit plans for monitoring releases and reporting any adverse health or environmental effects that monitoring efforts reveal. In addition, the labeling regime in effect in the EU should give epidemiologists a tool for identifying persons whose diets contained GM foods in subsequent investigations. In Brazil, the CTNBio is supposed to monitor "the development and technical and scientific progress of biosafety and related areas," to ensure "the safety of consumers and the general population" with "constant surveillance to protect the environment." Moreover, the manufacturers' Internal Biosafety Commissions must prepare "individual progress reports" for all project involving GMOs and establish procedures for investigating and reporting all accidents or diseases "possibly related to" to GMOs. Thus, it appears that the regulatory regimes in place in the EU and Brazil have a much larger potential to yield relevant retrospective evaluations than the U.S. regulatory regime.

COMPARISON OF U.S., EU, AND BRAZIL

	U.S.	**EU**	**Brazil**
Separate Regulatory Regime for GM plants	No	Yes	Yes
Pre-Release Notification	Field Tests, Yes Pesticides - Yes Foods - No, if GRAS	Yes	Yes
Specific Testing Protocols	No	No	No
Permit Required	Field Tests, Yes Pesticides - Yes Foods - No, if GRAS	Yes	Yes
Mandatory Labeling	No	Yes	?
Concerns about Transparency	Yes	Yes	Yes
Concerns about Delay	No	Yes	Yes

Institutional Posture.

Thus far, the institutional posture of all of the relevant U.S. agencies has been exceedingly receptive to new agricultural biotechnologies. Despite recent indications that the Secretary of Agriculture would like to adopt a somewhat more aggressive regulatory approach, the USDA staff is apparently convinced that GM plants are nearly always benign. EPA regulators have made liberal use of the substantial equivalence doctrine to make it much easier for a company to obtain an initial registration for a GM plant than for a new chemical pesticide. FDA's institutional posture is at least as protective of the new agricultural biotechnology industry as that of USDA.

In its current mercurial political setting, the EU regulatory regime appears indisposed toward (or incapable of) allowing new GM foods to be approved under any conditions. That posture could change with changing political circumstances, and the underlying regulatory structure (with its heavy reliance upon scientific advisory committees) seems much more favorably disposed toward GM foods than the politically accountable institutions. The institutional posture of Brazil is especially difficult to assess, because there seems to be very little agreement among the relevant institutional actors. The Minister of Agriculture has joined five other ministers in lauding the virtues of GM foods and concluding that they will probably bring about "no losses" of either biological safety or environmental protection. At the same time, concerns about the potential environmental and economic impact (primarily upon export markets) of GM crops have prompted several efforts to restrict these crops at the state level, including the adoption of a two-year moratorium on commercial plantings of GM crops in one state.

Suggestions for Improving the U.S. Regulatory Regime in Light of the Experience in Other Countries and the Considerations Analyzed Above.

As protests in Europe and (to a lesser extent) in the United States have focused public attention on the ease with which genetically modified foods have found their way into the U.S. food supply, it has become increasingly clear that the U.S. "hands off" approach to regulating GM foods may have backfired for the industry that it was designed to promote. Many important economic actors have concluded that public trust in the existing regulatory regime is not sufficiently high in the U.S. that a general public acceptance of GM foods is a foregone conclusion. Although it is by no means clear that the critics have won the public policy debates, it seems reasonably certain that the agricultural biotechnology industry has a bumpy road ahead of it if some changes are not implemented fairly quickly.

Beyond Substantial Equivalence.

The foundation upon which the U.S. agencies have erected the current *laissez faire* approach to GM foods is the "substantial equivalence" doctrine. Substantial equivalence is not a "scientific" theory; it is a debatable public policy that is currently driving risk management decisions in the U.S. As a risk management policy, substantial equivalence is extremely vague and, as such, presents a very weak foundation for a regulatory regime that, as a practical matter, does not regulate. Quite apart from its vagueness, expert-assessed similarities between a GM food and its natural counterpart provide little assurance that the GM food is safe for human consumption. The new Administration should throw out the poorly aging 1986 Coordinated Framework and reassess the heavy role that the substantial equivalence doctrine has played in the U.S. regulatory regime. The recommendations below presume that Congress and the U.S. regulatory agencies will be willing to examine seriously regulatory options that do not rely upon substantial equivalence, despite the predictable opposition of the regulated industries.

Scope.

The patchwork U.S. approach under which three regulatory agencies attempt to cover all aspects of all genetically engineered food plants may not ensure that all GM food plants receive proper regulatory attention. The European Union and Brazil have ensured that their respective regulatory regimes cover all GM food plants by enacting new statutes that specifically address all GM organisms. The U.S. regulatory regime may well contain regulatory gaps, and it may not withstand judicial challenge by a determined litigant. Congress should seriously consider addressing the problem of the potentially limited scope of the U.S. regulatory regime by enacting an omnibus statute similar to those in place in the EU and Brazil that establishes regulatory requirements for all GM

organisms including GM food plants. One approach would be to lodge all authority for safety regulation of foods in a single agency that Congress specifically empowered to regulate all GM foods. Similarly, Congress could lodge all regulatory authority for protecting the environment from GM plants in a single agency with expertise in environmental assessment and regulation.

Should Congress decide to leave the existing regulatory regime in place, USDA should take its environmental impact assessment responsibilities more seriously. The agency has never prepared a full-fledged environmental impact statement for a decision to grant nonregulated status to a GM plant, and the brief environmental assessments that it does prepare for those decisions suggest that it focuses primarily upon the risks that the regulated articles pose to economically valuable crops and to threatened or endangered species. They do not take a comprehensive view of the potential impacts on complex ecosystems or other important environmental entities; nor could they, because USDA does not require manufacturers to elicit that sort of information during the field tests that the Department approves under the FPPA. USDA should lower the threshold for preparing full-fledged environmental impact statements for decisions to grant nonregulated status, so that more EISs will be available for EPA and public review. At the very least, USDA should prepare a comprehensive programmatic EIS for its program of granting nonregulated status petitions on an ad hoc basis with no particular data or information requirements.

Notice.

It is hard to instill public trust in a regulatory regime that articulates a vague and highly manipulable test for entry into that regime and then leaves it to the discretion of the regulatees to decide whether their products meet that test. A good first step in gaining public trust in the existing regulatory regime would be to require pre-release and pre-market notice to the appropriate regulatory agency, whether or not the GM food that is the subject of the notice is deemed to be substantially equivalent to an unregulated food. USDA could accomplish this by requiring that all plants modified through modern genetic engineering techniques undergo at least the modest notification process that it created in 1993. Similarly, EPA should amend its regulations to require manufacturers to notify it of every determination that a pest-resistant GM plant falls within one of the exemptions and the reasons underlying that determination. Both agencies should make such determinations available on their websites to ensure public awareness.

FDA could ensure that it receives notice of all introductions of GM foods into commerce by adopting the position that no GM foods can be considered GRAS and must therefore attain formal food additive status. Failing that, the agency should write regulations (not unenforceable guidelines) that narrowly confine the GRAS concept to GM foods that clearly meet the statutory criteria. At the very least, FDA should carefully monitor petitions to USDA for determinations of nonregulated status. If the agency fails to take any action at all, Congress should amend the Food Drug and Cosmetic Act to ensure that manufacturers and (perhaps more importantly) importers provide notice of and adequate testing data for all GM foods.

Transparency and Public Participation

In the age of the Internet, there is simply no excuse for the opacity of the existing regulatory process. The USDA should promulgate procedural regulations that provide for publication of permit applications for genetically engineered plants and that allow for informed public to comment by letter or by e-mail. EISs should be fully downloadable from the Department's website, and all studies that the agency relies upon in issuing permits should be available on the website. Likewise, FDA should publish notice of informal GRAS consultations on its website, make the relevant information available to the public via the website, and elicit public comments. EPA's pesticide registration procedures seem reasonably well tailored for eliciting public participation in registration decisions to the extent that plant-pesticides are not exempt. The agencies should continue to make liberal use of advisory committees, but recognize that advisory committees are not an adequate substitute for full public participation. All three agencies should attempt to make more information about the risks and benefits of GM foods available to the public via the internet.

Data Collection, Data Evaluation, and Risk Assessment

The present testing regime, in which a manufacturer or importer can avoid virtually all testing by simply finding that its product is substantially equivalent to existing food, is probably not adequate to protect human health and the environment, and it is certainly not sufficient to secure public trust in the regulatory process.

Human Health Assessment.

At the very least, the federal government should explicitly require manufacturers and importers to test GM foods for allergenicity if they derive from GM plants containing genes transferred from plants that are known to be allergenic. The federal government could considerably enhance public trust in the regulatory process if it required some form of allergenicity testing for *all* GM foods. The federal agencies should promulgate allergenicity testing guidelines that establish protocols for the kinds of tests that manufacturers and importers must conduct prior to marketing GM foods in the United States. These guidelines should be flexible enough to allow for changes as scientists learn more about allergenicity.

Beyond allergenicity, the agencies should establish protocols for testing GM foods generally for adverse effects on human health. These protocols should be designed to detect unintended and unanticipated risks of adverse health effects posed by GM foods. The protocols should start with thoroughgoing chemical analyses of the molecular characteristics of the altered food, including testing for the stability of the transferred genes and testing for the presence or absence of key nutrients, toxicants, vitamins, etc. To the extent that the inserted gene codes for a particular protein, fat or oil, the protocols should specify testing for that substance. Although it is difficult to design animal studies to test for toxicity of whole foods, animal studies must play a role in the safety assessment of GM foods.

Environmental Assessment.

Both USDA and EPA should require more extensive testing of GM plants for adverse ecological effects including especially the adverse effects of pest resistant plants on beneficial nontarget species. A tiered approach to testing offers a cost-effective way of determining data needs for GM plant generally with nontarget species and gene flow studies that extend for at least two growing seasons being part of the first tier of required testing. The agencies should articulate in advance clear criteria for moving from first tier testing to second and third tier tests based upon information gleaned from mandatory first tier testing. The President and/or Congress should give EPA the responsibility for environmental assessment of all GM plants, whether or not they are plant pesticides, and require EPA to conduct an environmental assessment and, if necessary under NEPA, prepare an environmental impact statement for all FDA, USDA and EPA decisions that may significantly affect the human environment.

Government Funding.

Independent academic research sponsored by the federal government is an essential component of a protective regulatory system. Of the three agencies with primary responsibilities for regulating GM foods, only USDA has a significant program for supporting academic research, and it is devoted primarily to developing new applications of biotechnology, not to discovering the adverse health and environmental effects of the products of the new technologies. Congress should create a separate program in EPA or the National Institutes of Health to fund research on the potential adverse health and environmental effects of GM crops and animals. If additional resources are not available to expand the budget of the Department of Health and Human Services to create such a program, then Congress should redirect some of the ample resources that USDA currently devotes to promoting biotechnology.

Consumer Choice.

FDA should promulgate regulations ensuring that all foods containing GM constituents in greater than predetermined de minimis amounts are clearly labeled to inform consumers of that fact. FDA could easily accomplish this result through a modest expansion of its interpretation of the "materiality" concept in section 201(n) of the Food, Drug and Cosmetic Act to include changes that are in fact material to most consumers. Failing that, FDA should explore its authority under section 403(i) to require labeling for GM foods that are fabricated from two or more ingredients. Although the constitutional legitimacy of GM food labeling requirements is not entirely free from doubt, FDA should be able to articulate a rationale, based upon a "substantial" governmental interest, capable of surviving

the relatively modest judicial scrutiny afforded to such limited intrusions on commercial speech under the relevant Supreme Court First Amendment precedent. If FDA fails to take action, Congress should enact a separate labeling requirement.

Risk Management

Although the existing regulatory regime is not so seriously deficient that the only alternative is to ban GM foods altogether, selective bans could play a very useful role in protecting consumers and the environment from some especially dangerous aspects of some GM plants and in stimulating alternative ways to produce and grow GM crops. EPA, USDA and FDA should, for example, ban all uses of antibiotic resistance marker genes in GM plants when alternative marker technologies are available. All remaining GM foods should undergo a full-scale pre-market approval. In particular, FDA should abandon the substantial equivalence justification for its liberal interpretation of the GRAS concept in the context of GM foods and treat all GM foods as food additives. Finally, the relevant federal agencies should ensure that any product bans or other requirements and restrictions that they place on the release and marketing of GM crops are fully enforceable. One way to enhance enforceability is to employ the innovative techniques of modern biotechnology to ensure that GM crops are designed in ways that simplify monitoring for their presence in food and the environment.

Avoiding Unnecessary Delays and Restrictions.

If some or all of the foregoing recommendations are implemented and the U.S. moves away from the current hands-off approach toward a more protective regime, a somewhat tighter regulatory grasp will no doubt replace the gossamer touch of the current approach. Inevitably, the speed with which new GM products are introduced and absorbed will decline as manufacturers struggle to implement more rigorous testing requirements and assume the burden of demonstrating the health and environmental safety of their products with real world data rather than generic assumptions based upon substantial equivalence. Competitive pressures from companies operating in countries with less stringent regulatory regimes will grow, and some U.S. companies will probably threaten to relocate operations into such regimes.

The regulatory regime must therefore be willing to consider the need for expedition and flexibility while pursuing the primary goal of protecting health and the environment. The agencies must satisfy regulated entities that any delays are necessary and that burdensome regulatory requirements are not being imposed for no good reason. In the final analysis, the regulated industry is generally happy with the current regulatory regime and will not be as happy with the one that replaces it. The agencies can attempt to relieve industry pain by attempting to apply regulatory restrictions in a fair and flexible way. To the extent that the system is working to protect the public, however, industry pain will never go away entirely.

Monitoring and Enforcement.

From the enforcement perspective, most aspects of the current U.S. regulatory regime are entirely inadequate because they are voluntary and therefore unenforceable. FDA has no systematic monitoring program in place to determine whether or not manufacturers and importers have been abusing the GRAS process and marketing GM foods that are legally subject to the food additive requirements. FDA should establish a monitoring regime, similar to the regime currently in place for monitoring for pesticide residues, for testing domestic and imported foods for the presence of GM food. Congress should provide FDA with adequate resources to accomplish the task. FDA should begin by initiating (perhaps in a cooperative agreement with EPA) a monitoring program for GM pest resistant plants using available tests for the presence of Bt endotoxins in food. The program should be expanded as tests for other proteins that are characteristic of GM foods become available.

EPA's experience with StarLink® corn demonstrates that even when tests are available and even when the conduct resulting in the presence of GM food in the food supply is clearly illegal, the monitoring and enforcement regime that is currently in place can fail. This failure was almost certainly attributable to the fact that neither FDA nor EPA have adequate resources to conduct random testing of foods for the presence of illegal residues. If the public is to trust even a substantially improved regulatory regime, Congress must allocate substantial additional resources to EPA and FDA for the purpose of monitoring and enforcement.

Although EPA has begun to insist that pesticide labels provide for "refuges" to reduce selective pressures toward resistance, it is not clear that farmers are abiding by these requirements in the real world. According to some observers, many in the industry frankly acknowledge that with the advent and widespread use of Bt GM crops, it is only a matter of 7-10 years until the Bt toxins are no longer effective against important plant pests. In this instance, effective risk management requires effective enforcement, even it that means having to endure complaints by farmers that the government is trying to tell them how to farm. Strong enforcement of refuge and other requirements aimed at delaying pest resistance may appear to be burdensome and unnecessary to some farmers, but it is critical for the survival of other farmers.

EPA must come up with innovative ways for simplifying enforcement at the time that it issues the registrations for GM pest resistant plants. For example, the agency could require that the seeds for any GM pest resistant plant that is not registered for general food use must be colored differently from normal seeds. It could even explore requirements that the GM plant itself be genetically engineered to ensure that the plant and all edible constituents are colored differently. Implementation of such innovative approaches could prevent future StarLink® fiascoes.

Retrospective Evaluation.

Nearly all critics of the current regulatory regime believe that the government needs to do more to ensure that someone is attempting long-term assessments of the health and environmental consequences of large-scale introduction of GM plants into the environment and food supply. The U.S. regulatory agencies should establish formal tracking mechanisms designed to follow a statistically meaningful subset of transgenic crops from the point at which the seeds enter the marketplace to the point at which the resulting GM crops are consumed. The agencies should also establish and implement enforcement-related monitoring requirements designed to ensure that any regulatory restriction on the growth, processing, sale and consumption of GM foods are observed in the real world. At this point, attempts to monitor for the presence of GM material in foods is facilitated by the presence of antibiotic resistance marker genes in most GM foods. As companies move to marker technologies that do not rely upon antibiotic resistance, the relevant agencies should promulgate requirements aimed at ensuring that GM foods are still identifiable through relatively inexpensive analytical tests.

Institutional Posture.

The ultimate impact of changes to the regulatory regime will not be noticeable if the institutional posture of the implementing agencies does not change from that of "cheerleader" for the new technologies to that of cautious regulator of new and potentially risky products. There are few indications, however, that the institutional posture of the relevant agencies, which had its origins in the 1986 Coordinated Framework, has changed during the eight years of the Clinton Administration. The impetus for change in institutional approach may come from the increasingly visible protests of GM foods that are taking place in Europe and, more recently, the U.S. Or it may come from the regulated industry as it realizes that many important markets for GM foods are being cut off by consumer resistance and the reluctance of food processors and distributors to take the risk that GM foods will fare poorly in the marketplace. In the final analysis, the internal culture of decisionmaking in the U.S. regulatory agencies will have to change substantially before the public will be willing to trust the regulatory regime to protect human health and the environment.

Conclusions.

Public trust is essential to the future of the agricultural biotechnology industry in the United States. While the benefits of agricultural biotechnology may never match the high expectations of its proponents, it can produce changes in the world food supply that will make all of our lives healthier and easier. But agricultural biotechnology poses potential risks to human health and the environment, some of which are well-known and largely avoidable, but many of which are poorly understood and unanticipated. The fact that agricultural biotechnology, like any ubiquitous modern technology, poses risks is, of course, no reason to deny society its benefits. Its potential risks are grounds, however, for proceeding ahead with humility and caution. As the recent StarLink® experience has amply demonstrated, one or two well-publicized incidents of disease or destruction attributable to GM foods may be sufficient to inspire society to shelve modern agricultural biotechnology for the foreseeable future.

While the public has been largely content to allow laboratory scientists to regulate themselves so long as their activities were confined to laboratories and small test plots, it will not trust the agricultural biotechnology industry to establish and enforce its own health and environmental standards. Government must play a strong and highly transparent role in health and environmental regulation of the growth, processing and sale of GM foods. If it does not play that role at the federal level in the United States, it will play it at the state and/or local levels because consumers will demand it. The early efforts of one biotechnology company literally to force one of the products of modern agricultural biotechnology (BST-laden milk) down their throats without their knowledge roused considerable consumer resistance, and consumers are not likely to tolerate similar efforts in the future.

Unfortunately, the statutes that form the underlying foundation for the current federal regulatory regime were not enacted with biotechnology in mind and therefore leave several serious institutional and interpretational questions unresolved. More importantly, the agencies that have been administering the existing regulatory programs have relied far too heavily upon the "substantial equivalence" principle to allow the agricultural biotechnology industry to proceed full-speed-ahead with new products. The increased reluctance of consumers and major food processors and distributors to accept GM foods and the recent StarLink® fiasco suggest that significant changes in the current regulatory regime are in order.

At the very least, manufacturers and importers of GM foods must be required to provide notice to a federal regulatory agency of the fact that they are introducing such foods into the marketplace. The relevant regulatory agencies should not allow such products onto the market until the manufacturers and importers have demonstrated with real scientific data, not broad and largely untestable assumptions, that there is a reasonable assurance that no harm will result to humans or the environment. The regulatory process should be transparent so that watchdogs in the public interest groups can participate in and evaluate the decisions that the regulatory agencies reach. The agencies should have sufficient resources available, preferably from permit fees, to undertake serious evaluations of the data, to enforce the requirements that they impose, and to undertake retrospective evaluations of past decisions. Finally, consumers should through fair and accurate labeling of GM foods be given the right to choose whether or not to consume particular GM products. This may require significant changes in the agricultural distribution system to facilitate segregation of GM crops, and this may for a time increase the costs of both GM and nonGM foods. The alternative, however, is a food distribution system that the public no longer trusts and that breeds a continuous stream of multi-million dollar lawsuits.

Most of the changes suggested in this Report can be implemented without legislation if the agencies, the industry, and ultimately the reviewing courts are favorably disposed. It may be time, however, for Congress to take a fresh look at GM foods through committees that are not mere cheerleaders for the regulated industries and write a new statute that addresses directly the risks and benefits of GM foods and provides an adequate regulatory regime (and the resources to support that regime) for the future.