Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead

A report prepared by the USDA Advisory Committee
on Biotechnology and 21st Century Agriculture

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Introduction

This paper was prepared by the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) in partial fulfillment of one of the charges under its Charter: "The Committee is charged with examining the long-term impacts of biotechnology on the U.S. food and agriculture system and USDA, and providing guidance to USDA on pressing individual issues, identified by the Office of the Secretary, related to the application of biotechnology in agriculture." The Committee has defined "long-term" impacts to be those that may occur over the period of the next 5 to 10 years. Two other reports related to this overall charge were provided to the Secretary of Agriculture on May 9, 2005. One was entitled "Preparing for the Future" and another "Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States."

The AC21 consists of 20 members (See Appendix A) representing the biotechnology industry; the seed industry; international plant genetics researchers; farmers; food manufacturers: commodity processors, handlers, and exporters; environmental and consumer organizations; and academics. Prior Committee members have contributed to the deliberations that helped shape this report. However, they did not participate in the finalization of this document and are not signatories to the report. Representatives from the Departments of Commerce, Health and Human Services, and State, and the Environmental Protection Agency, the Council on Environmental Quality, and the Office of the United States Trade Representative serve as ex officio members. The AC21 has met 12 times in public plenary sessions since its establishment in 2003.

In preparing this paper, the Committee worked in both plenary sessions and work groups. AC21 members drew on their own experiences, expertise, perspectives and their constituents' perspectives while discussing potential products of modern biotechnology in the next five to ten years and the agricultural, political, social, and economic context in which these products will be introduced. The Committee also gathered information provided by outside experts, *ex officio* members of the AC21, and employees of USDA with relevant expertise.

AC21 members share a vision of a safe and abundant food supply and a diversified agricultural marketplace that can meet the needs and preferences of customers and consumers in the United States and the world for a variety of products, including those derived from modern biotechnology. AC21 members have diverse views about the appropriate role of plants and animals produced using modern biotechnology in the food and agricultural marketplace, as well as how USDA should assess and address the many factors shaping the context within which these products will be introduced. This paper provides a brief summary of the extensive deliberations by the Committee in exploring the potential products that technically could enter the marketplace in the next five to ten years, the many factors shaping the future context in which these products will be introduced, and a broad range of topics Committee members think relevant for USDA to consider. The series of topics discussed reflects the range of perspectives of the AC21 membership. Each topic was initially identified by one or more members of the Committee as likely to be of significance to the Secretary and USDA over the next

decade. The topics included are not of equal importance to all members of the Committee and they are not prioritized. The paper as a whole is a consensus product of the full committee; however, for topics 8, 14, 15, 16, and 24 in this report, a range of views of different members is presented.

Biotechnology is the application of technology to living organisms. This paper focuses primarily on organisms produced through genetic engineering and their products. The terms "genetically engineered," "derived through modern biotechnology," and "transgenic" are used interchangeably to refer to these organisms.

The Past Decade and the Next Decade

The first ten years

Over the past decade, traits developed using modern biotechnology have been introduced into U.S. agricultural commodities including corn, soybeans, cotton, and canola. They have been adopted rapidly by American farmers, and also are being grown by farmers in other countries. The new varieties were intended to provide increased productivity, profitability, and improved environmental management (e.g., reduced pesticide use and expanded conservation tillage). Most of the new varieties were developed to be incorporated into existing undifferentiated commodities. Genetically engineered traits have been part of a multifaceted biotechnology research milieu in which enhanced breeding, a greater focus on germplasm improvement, and advances in understanding the molecular basis of growth, productivity and disease resistance jointly have led to substantial increases in agricultural productivity.

In the United States, these transgenic varieties are largely undifferentiated and fully integrated into commodity markets. In 2005, 52% of corn, 87% of soybeans, and 79% of cotton planted in the United States was genetically engineered, according to the National Agricultural Statistics Service. In addition, in 2005 transgenic crops were planted globally on about 222 million acres,[1] roughly 5.8% of the estimated 3.8 billion acres devoted to crops.[2] Transgenic varieties thus far in the marketplace have been beneficial to farmers and the environment, but have not provided marketing advantages to food retailers or improved nutrition or taste to attract consumers. In some countries, there have been increased risk management requirements as well as opposition to introduction of the transgenic seed varieties and the foods produced from those crops. Food processors and retailers have been reluctant to introduce food products developed from transgenic crops in markets where there is a requirement for mandatory labeling of food products and/or perceived consumer resistance to genetic engineering technology. The resistance stems in part from some governments' and consumers' perception that there are unknown risks associated with genetically engineered foods and an absence of obvious consumer benefits. The development of new transgenic products, controversies related to such products, varying national requirements, and different consumer preferences have driven numerous market responses, including the development of segregated markets and

[1] James, C., 2005. Global Status of Commercialized Biotech/GM Crops: 2005. ISAAA Brief 34.
[2] FAOSTAT data, 2006, last accessed April 12, 2006.

differentiated product streams (genetically engineered and non-engineered). Other market responses have included regionalized production and ingredient sourcing, new testing methods, new systems for identity preservation and certification, and the development of marketing and risk management tools. AC21's earlier report, entitled, "Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States," describes in greater detail strategies developed to meet various traceability and labeling requirements. The report, presented to the Secretary of Agriculture on May 9, 2005, may be accessed under the topic "Biotechnology" from the Agriculture subject page on the USDA website (www.usda.gov).

The next ten years

It is impossible to predict exactly which new modern biotechnology-derived plants or animals will be ready for the marketplace over the next decade. Some possibilities include:

- Genetically engineered plant varieties that provide improved human nutrition (e.g., soybeans enriched in omega-3 fatty acids);
- Products designed for use in improved animal feeds (providing better nutritional balance by increasing the concentration of essential amino acids often deficient in some feed components, increased nutrient density, or more efficient utilization of nutrients such as phosphate that could provide environmental benefits);
- Crops resistant to drought and other environmental stresses such as salinity;
- Crops resistant to pests and diseases (e.g., fusarium-resistant wheat; chestnut-blight resistant chestnut; plum pox resistance in stone fruit; various insect resistant crops);
- Additional crops containing a number of transgenic traits incorporated in the same plant (stacked traits);
- Crops engineered to produce pharmaceuticals, such as vaccines and antibodies;
- Crops engineered for particular industrial uses (e.g., crops having improved processing attributes such as increased starch content, producing useful enzymes that can be extracted for downstream industrial processes, or modified to have higher content of an energy-rich starting material such as oil for improved utilization as biofuel); and
- Transgenic animals for food, or for production of pharmaceuticals or industrial products (e.g., transgenic salmon engineered for increased growth rate to maturity, transgenic goats producing human serum factors in their milk, and pigs producing the enzyme phytase in their saliva for improved nutrient utilization and manure with reduced phosphorus content).

There are several factors beyond whether a genetically engineered crop or animal can be developed and found efficacious which will help determine whether it is successful as a marketable product. For each such possibility, before any product reaches the marketplace, the federal government must ensure it is safe for human consumption, safe

for the environment, and will not adversely affect the food supply. To appropriately manage risk, the government might impose additional measures on developers, farmers, or others throughout the food and feed chain that may affect the economic or technical viability of the product and the realization of potential benefits.

AC21 members have diverse views about the appropriate role of plant and animal products derived from modern biotechnology in the food and agricultural marketplace. Members recognize that new products will be entering a world that is very different from the one that existed a decade ago when the first agricultural products of modern biotechnology were introduced:

- Many of the "first-generation" transgenic organisms developed in the United States have now been adopted by farmers in other nations, including developing nations;
- Some of the transgenic plant varieties intended for food use developed over the next few years will likely emerge from the developing world. For example, if transgenic rice varieties (probably insect-resistant varieties) that have been developed in the developing world (e.g., in China or India) are commercialized, this could have a significant impact on the global genetic engineering debate because large populations of humans will be consuming a staple transgenic whole food;
- Some of the "next generation" of transgenic varieties and products may need to be produced under identity preservation conditions or require strict segregation from food or feed product streams;
- Media coverage and public debate have made consumers more aware of genetically engineered products than when the first crops were adopted. Increased awareness along the food and feed chain will continue to influence the acceptance of new products derived from modern biotechnology;
- Genomic information is being used to enable the development of improved crops and animals through both transgenic and non-transgenic approaches;
- National regulatory systems for evaluating the safety of new transgenic products are being developed and implemented in many countries around the world, eliminating some uncertainties but, in some cases, complicating the path to market;
- Many countries now require mandatory labeling for food products derived from modern biotechnology, and some require traceability of those products throughout the food and feed chain. Food manufacturers who do not want to label their products as containing transgenics are sourcing non-transgenic crops, further segmenting the marketplace;
- U.S. regulations are evolving slowly and many governing statutes were written before modern agricultural biotechnology was developed. That system may not be optimal to meet the needs of producers and consumers.
- The commercialization of a transgenic plant or animal product is affected by considerations beyond the safety of the product. Technical challenges may arise when turning a beneficial trait into a marketable food. New products must gain acceptance by consumers and trading partners;

- Sometimes social and ethical concerns may influence decisions about commercialization. For example, the development of transgenic animals may generate, for some people, higher levels of concern than those for plant breeding;
- Some international agreements specific to modern biotechnology, e.g., the Cartagena Protocol on Biosafety, and standards related to modern biotechnology under Codex Alimentarius, now exist. Additional efforts under these bodies are continuing, but their future outcomes are uncertain;
- There is an ongoing trade dispute over modern biotechnology-derived products between the EU and a number of complainants, including the United States, nearing a final report from the World Trade Organization;
- Technology producers, food producers and processors increasingly recognize the global interdependence of markets and the importance of resolving genetic engineering- related issues;
- With the increased use of genetically engineered organisms, other issues such as testing, liability, coexistence, and intellectual property rights, have emerged.

Achieving AC21's shared vision of a safe and abundant food supply and a diversified agricultural marketplace that can meet the needs and preferences of customers and consumers will require national and international regulatory systems with several characteristics. These characteristics include assurance that the food and feed supply is safe for humans and animals, that the environment is protected, and that the regulatory processes maintain commercial viability of products and engender public trust. An effective international marketplace also requires agreement to and enforcement of fair, clearly defined trading rules. All recognize that achieving the vision will be a worthwhile but not an easy endeavor.

AC21 has discussed a number of topics that some or all members believe are relevant to USDA's efforts to adapt to this changing world and ensure that American agricultural products, including current and future transgenic products, remain competitive in the global marketplace. The following are brief descriptions of those topics, some of which were discussed at considerable length by the AC21. While none of these descriptions completely captures the extent and richness of committee discussions on the topics, the Committee is willing to provide further information to the Secretary on any that are of particular interest.

TOPICS OF DISCUSSION

1. The extent of domestic and global adoption of transgenic crops has influenced, and may increasingly influence, U.S. producers and agricultural production patterns.

The adoption of genetically engineered corn, soybeans, cotton and canola has influenced cropping patterns in the United States. The availability of genetically engineered crops is one of the major factors affecting production of other crops for which transgenic varieties are not currently commercially available. For example, a recent North Dakota State University study[3] suggests that availability of genetically engineered corn and soybeans, along with other variables, has corresponded with an increase in acres planted to those crops in the Dakotas and Minnesota, replacing acres planted to wheat. Adoption of transgenic crops in other countries, including Argentina and Brazil, also has contributed to changes in cropping patterns in the United States. Such changes could have important implications on market access, food security, research programs, biodiversity and competitiveness.

2. Farmer demand has become a driver for the continued development of new agricultural traits derived from modern biotechnology because benefits have been delivered to the production segment of the food and feed chain.

Since the first commercial transgenic crop traits were introduced in the United States, herbicide tolerant crops and insect protected (Bt) crops have generated substantial production benefits including: improved soil conservation through enhanced use of no-till or minimal tillage systems; lowered pesticide use; improved flexibility and ease in pest management, which has been documented in at least one instance to result in greater net returns for farmers; and improved crop quality of Bt corn in those cases where decreased insect damage leads to decreased fungal damage and reduced levels of natural mycotoxins. Most farmers who have grown transgenic crops anticipate growing varieties containing new traits. This demand will help drive the development of new traits. However, some farmers believe that there are downsides to modern biotechnology and that similar benefits can be attained through other methods.

3. Crops with energy specific traits may be developed to help meet the growing demand for renewable alternative fuels.

Currently, commodity crops (e.g., corn and soybeans), a substantial portion of which are genetically engineered for agronomic purposes, are being increasingly used for energy. In

[3] Wilson, W. W., Janzen, E. L., Dahl, B. L., and Wachenheim, C. J. 2003. Issues in Development and Adoption of Genetically Modified (GM) Wheats. Agribusiness and Applied Economics Report No. 509. North Dakota State University.

the future, genetic engineering could be employed to engineer traits in both food and non-food crops (e.g., grasses and trees) that specifically relate to energy production. The large scale production of such energy crops could have tremendous implications for U.S. agricultural systems. As with other genetically engineered crops, all regulatory and safety issues must be addressed before commercialization. Bioenergy uses will be visible to consumers and their scale alone could raise concerns for them, although meeting bioenergy needs using genetically engineered crops could be seen by consumers as a benefit as well.

4. The private sector provides most of the funding for research and development of new genetically engineered crops, and this funding is largely directed toward major crops that offer a substantial return on the research investment.

Privately funded research and private sector development of genetically engineered crops are driven by potential profitability. Publicly funded research aimed at development of new varieties has remained static over the past several years. As a result, crops that do not appear to offer substantial market returns are deprived of adequate research funding and are not able to attract research personnel. Advances through biotechnology could provide improvements in some specialty crops, including forest trees, vegetables and fruits, yielding public benefits, if adequate research funding were available.

5. The application of modern biotechnology to specialty crops continues to be limited by the cost of product development and the unique characteristics of specialty crops.

Nearly all of the genetically engineered crops currently on the market are major commodity crops such as corn, soybean, and cotton as opposed to "specialty crops" (a term defined by Congress[4] to mean "fruits, vegetables, tree nuts, dried fruits, and nursery crops [including floriculture]"). The public could potentially benefit from modern biotechnology-derived innovation of specialty crops, but the extent of commercialization of transgenic specialty crop is currently limited by multiple characteristics. Those characteristics include, but are not limited to, the small market size of specialty crops, access to intellectual property, acceptable return on investment, unique or individual biological characteristics of specialty crops, the dynamics of the marketplace, and other commercial challenges.

6. There is a need for more publicly sponsored data collection and peer-reviewed analyses on the use and broad impacts of transgenic organisms. Such data and analyses should be publicly available.

USDA has a unique role in collecting primary data and providing information to the public in a fair, understandable, and factual way. Relevant topics include not only environmental impacts (e.g., on pesticide use patterns, pest resistance management, soil loss, etc.), but also social and economic impacts (e.g., on net farm income, distribution of

[4] DB: In the Specialty Crops Competitiveness Act of 2004

benefits, economic opportunities, etc.). USDA also has an important role in encouraging external, independent peer-reviewed analyses of the data it gathers.

7. Some of the gene manipulation technologies that are being employed or are under development may produce organisms that are not regulated by the U.S. government under the current biotechnology regulatory framework or may require development of new assessment methodologies.

Some technologies to remove, mutate or silence the expression of particular genes arguably do not produce "transgenic" organisms. In addition, new transgenic organisms may result in substantially different types of products than have thus far been reviewed by U.S. regulatory agencies. In either case, some of these organisms may not be regulated under the current regulatory system, while others may require new or modified regulatory assessment methodologies or may pose challenges for the traditional boundaries of agency responsibility. As a result, this new generation of biotechnologies may influence the debate on genetic engineering.

8. There are concerns that food crops genetically engineered to produce medical or industrial products never intended for food or feed use could inadvertently end up in a food or feed product.

New genetically engineered organisms designed for medical and industrial markets could offer substantial health and economic benefits. There are a number of new products under active development in these categories, and some of those being produced in plants have been engineered for production using important food crops. Consumers generally do not want such substances in their food.

One group of committee members believes that the federal government should not approve the use of food crops for the production of medical and industrial substances, even if the substances are deemed safe, because no regulatory process or containment system can assure that these products will never enter the food supply.

Other committee members believe that adequate regulatory oversight of crops producing medical or industrial products utilizing a tiered risk-based approach can ensure the safety and integrity of the food and feed supply. These members believe that at small scale, complete segregation from food products can be ensured by a combination of physical and biological containment strategies. As scale or potential risk increases, food safety assessment may be required in addition to stringent containment procedures.

Still another group prefers the use of non-food crops for such products. They believe that, if food crops are to be used, it is impossible to guarantee the absolute absence of such substances in the food supply. Therefore, in their view, no food crop should be used without thorough regulatory review of food safety and the establishment of stringent safeguards to prevent intermingling with the food supply.

For the last two groups, the Federal government's ability to successfully address the issues of containment and public confidence in that containment system remains critical for the development of these products.

9. There is no clear, comprehensive federal regulatory system to assess the environmental and food safety of transgenic animals before they are commercialized.

The next generation of genetically engineered products will include transgenic animals developed for food and non-food purposes. The federal government has not clearly indicated how and under which laws and regulations transgenic animals will be regulated. The Office of Science and Technology Policy (OSTP) published a package of regulatory case studies in 2001, one of which described a prospective pathway for the regulation of transgenic salmon using FDA's "new animal drug" authorities under the Federal Food Drug and Cosmetic Act. FDA indicated in that case study that it "…intends to publish draft guidance on how the new animal drug provisions of the FFDCA pertain to transgenic animals, and on procedures by which companies developing transgenic animals can comply with those provisions." However, the government has issued no further guidance on the scope or implementation of such a policy. If FDA's new animal drug regulatory process is used to regulate transgenic animals, there are concerns about the lack of transparency and public participation in the process. There are also concerns about whether FDA has adequate legal authority to assess and address the full range of environmental risks that could arise. In 2003, USDA indicated that it was reviewing whether it might have the legal authority to regulate certain transgenic animals. As research involving transgenic animals moves toward commercialization, a credible, appropriate and transparent federal regulatory framework applicable to genetically engineered food and non-food animals is increasingly important.

10. There is no comprehensive domestic policy regarding adventitious presence of transgenic events in seed, grain, or food.

In the context of modern plant biotechnology, adventitious presence (AP) refers to unintentional, low levels of transgenic material (or a specific transgenic event) in seed, grain, or food and feed products. AP can arise from transgenic organisms that have satisfactorily completed all regulatory procedures or those that have not. Such adventitious presence can result in regulatory, contractual, and/or consumer issues. Although federal policies address some aspects of AP, the federal government has not set forth comprehensive policies, guidelines, or standards regarding the adventitious presence of transgenic events.

This topic is discussed at greater length in the above-cited report previously submitted to the Secretary of Agriculture by the AC21.

11. The concerns of some people about genetically engineered products are not addressed by a regulatory system designed to assess and manage health and safety risks.

In addition to safety, some people consider other factors in their food purchasing decisions. They also may be concerned with a product's origins and whether the foods are "wholesome," "pure" or "natural." Some consumers may raise moral or ethical issues

about certain products. As one example, some find the genetic engineering of animals to be ethically problematic and may object to the presence of meat and milk from these animals if they enter the food supply. These concerns may continue to impact the marketplace and, if so, may influence the development and acceptance of aspects of modern agricultural biotechnology.

12. Transparency in the regulatory system is important for stakeholders including the consuming public, in the United States and around the world, to have confidence in the safety of genetically engineered organisms.

Transparency enables the public to learn about, and gain access to key information on the regulatory requirements established to ensure food, feed, and environmental safety of new products. In a transparent system, organizations and individuals would have the ability to gain timely access to information about the regulatory process and to the safety information submitted in support of new products. In addition, the public would have information about the basis for federal regulatory actions and the regulatory systems and structures from which they derive, and would be able to comment on proposed actions. Although aspects of the federal regulatory system have been very transparent, other portions could improve in this area.

13. The success of some future food products derived from transgenic plants or animals will be influenced by whether food processors and retailers embrace these products. Their purchasing decisions will, in turn, be influenced by whether customers and consumers perceive that the resulting genetically engineered food products provide value to them.

Most transgenic crops currently on the market were developed primarily for advantages they confer on productivity and agricultural management. They have produced some environmental benefits. However, there are no foods now on the market that use genetically engineered traits to provide retail consumers with improved quality, nutrition or particular safety benefits, such as reduced pathogens or allergenicity. There are some such products under development, although the appeal of these products for consumers is difficult to assess and anticipate. Polling data indicate a wide variety of responses to questions regarding genetically engineered food, complicating assessment of consumer response to future transgenic products. Typically, consumers' choices on product purchases involve a diverse array of considerations including not only price, convenience, safety, and nutrition, but taste, familiarity, appearance, wholesomeness and in some cases, considerations of morality and ethics. Many future transgenic products may be major components of foods or may in themselves constitute a whole food. Products designed to offer consumer-specific improvements, such as improved nutrition or health benefits, may also be more visible and therefore potentially more controversial. Food processors and retailers are responsive to consumer preferences and are likely to play an increasing role in determining whether, when and how such new products reach the marketplace.

14. While all AC21 members agree that ensuring the food and feed safety of transgenic crops is important, members differ in their views about whether the current FDA regulatory system for transgenic crops is adequate to ensure safety and public acceptance.

For foods and feeds derived from transgenic crops, FDA employs a voluntary consultative process to review safety data. While FDA does not require pre-market approval of these products, FDA does require pre-market approval of food additives regardless of method of production.

In considering this system, some AC21 members have noted that all foods from biotechnology-derived plants that are on the market today have successfully completed the FDA's pre-market consultation process and that the same safety standards apply to all foods regardless of their source, so that the consultation process mirrors the voluntary process widely used by the food industry to notify FDA prior to marketing new conventionally-produced substances that are "generally recognized as safe." The submissions reviewed by FDA scientists under the consultation process provide the basis for the developer's conclusion that the food is as safe as conventionally-produced counterpart foods and may lawfully proceed to market. The biotechnology and food industries understand that, although the FDA consultation process is technically voluntary, marketing a food from a biotechnology-derived plant without completing a consultation with FDA is simply not a viable commercial option, making the FDA process effectively mandatory. These members support making this consultation process mandatory.

Other AC21 members believe the Federal government needs to establish a mandatory pre-market approval process for transgenic crops eaten by humans and animals. They note that those crops receive such treatment in virtually every developed country where such crops are marketed. With the next generation of transgenic crops poised to include more scientifically complex products as well as crops developed in other countries and imported into the United States, a regulatory system that provides mandatory pre-market assessment for environmental and agricultural concerns related to those crops but not a similar food safety assessment is not protective of the public that will consume those crops. These members further note that, when informed that there is no mandatory pre-market safety approval for foods regulated by FDA, most Americans respond that they are unaware and that they would be more inclined to accept the foods if there were such a process.

15. AC21 members have different points of view regarding how strongly consumers feel about having information about whether their food is genetically engineered and whether the food should be labeled as such.

AC21 members agree that consumers are interested in having access to more information about their food and that, food issues are more visible and discussed more frequently.

The first group thinks that American consumers have a fundamental right to know about the origin and makeup of ingredients in their food. Having information about whether foods are, or are derived from, genetically engineered organisms included on the label

would allow consumers to choose to purchase or avoid those products without being restricted to limited or higher priced options. The EU and other governments require such information on labels and members of this group do not understand why US consumers should not also get that information.

In addition, these members believe that consumers are more likely to be uncomfortable with or opposed to some future genetically engineered products, especially milk and meat derived from transgenic animals. Unlike the first generation of products that have been largely invisible because virtually all are used as animal feed or ingredients in processed foods, future modifications may be more controversial. For example, even if consumers accept that genetically engineered animals are safe, they may want to avoid them because they have moral or religious objections to altering sentient animals. These members believe mandatory labeling of products of modern biotechnology is the middle ground: allowing such products to come to market but making it possible for consumers to avoid products they oppose.

Other AC21 members believe consumer interest is not focused on whether food products are derived through agricultural biotechnology or contain genetically engineered ingredients. They assert that those consumers who do have an interest in whether products are developed from genetic engineering, have multiple means of finding this information, including the Internet, calling the company and other avenues. Some specialty or niche markets have been developed for those consumers who want to avoid these products. Consumer preference can be addressed by market driven voluntary labeling that provides truthful, non-misleading and verifiable information to consumers and allow market forces to operate. These members also believe that the majority of American consumers are primarily interested in food quality, safety and cost. To mandate labeling of products generally has led to avoidance of such ingredients, reformulation of food products and limited choice in the marketplace. They also believe that mandatory labeling would send the wrong message regarding safety of these products – potentially and erroneously confusing consumers.

16. Public ballot or legislative initiatives at the state and/or local level in the United States to establish moratoria on certain uses of transgenic organisms or to regulate them will lead to regulatory differences across the country and will impact the use of these products.

Regulation of genetically engineered agricultural products is a role that has been filled primarily by the federal government. Recent initiatives have been launched in certain states and counties seeking to regulate locally the commercial use of transgenic plants or animals.

Some members believe that local regulation is not necessary in light of federal regulation and think that a potential patchwork of additional regulations will significantly increase costs throughout the system, impede commerce, deny choice, and slow the development of new products. Other members think that state and local involvement with the regulation of transgenic organisms is a reaction to inadequate federal regulation and may lead to greater safety, increased information to the public, a more transparent and

participatory regulatory process and a regulatory system that is more responsive to the public's concern.

17. As transgenic organisms developed in other countries and products made from them are imported into the United States, it is important to have adequate U.S. regulatory systems in place to address their safety.

U.S. regulations and procedures for evaluation of an increasing number of imported transgenic crops and their products into the United States must ensure their food, feed, and environmental safety and be implemented and enforced in a manner that maintains confidence in the U.S. food and feed system. In addition, when imports of agricultural products are allowed from countries developing and approving new transgenic events, a new potential consideration is raised: the adequacy of the U.S. regulatory system to address adventitious presence (AP) of events that have not completed all applicable regulatory procedures in the United States.

18. Managing the coexistence of different agricultural products and production methods intended to meet different market specifications has become more complex with the emergence of genetically engineered crops.

Commingling of different classes of conventional crops (e.g., yellow corn in a white corn shipment) has been addressed for many years in the marketplace through tolerances, title transfers, and testing. Currently, rules and procedures appropriate to address commingling of genetically engineered crops with other crops are evolving in the marketplace. The use of Identity Preservation (IdP) systems, including those for organic production methods and genetically engineered plant varieties, is expanding. These systems enable producers to participate in new value-added markets, some of which depend on the ability of producers to achieve high standards of purity. This has resulted in questions as to which party should bear responsibility for managing production practices, defining the specifications for different products, and assuring the level of crop purity in different systems.

19. Commercial differentiation between conventional and transgenic agricultural products is creating opportunities and challenges for the U.S. marketing system.

The current U.S. commodity handling system is extremely efficient at managing commodity streams segregated by distinct functional characteristics as long as there are commercially-viable tolerances for off-types and AP. Segregation of transgenic products that do not have distinct functional characteristics may be difficult. The cost, complexity, and time involved in differentiating between transgenic and non-transgenic products increase when contractual specifications detail stringent segregation requirements.

This topic is discussed at greater length in the above-cited report previously submitted to the Secretary of Agriculture by the AC21.

20. To reduce the commercial risks associated with supplying grain and grain products based on transgenic testing results, improved standards for testing and common sampling methods are required to address issues associated with such tests.

Many of the currently available testing methods to detect transgenic traits in numerous crops, plants and foods, are not accepted internationally and have not been validated based on international standards. The commercial risk associated with providing grain and grain products based on transgenic testing results could be reduced if international organizations would foster the development of mutually recognized reference materials, validated method performance criteria, and common sampling protocols that reflect the test method being applied, the material being tested, and any specified detection levels.

This topic is discussed in greater detail in the above-cited report, "Global Traceability and Labeling Requirements for Agricultural Biotechnology-Derived Products: Impacts and Implications for the United States."

21. Adventitious presence remains a significant trading issue internationally for the food and feed supply chain.

Adventitious presence of transgenic varieties in commodities for food or feed use can occur with transgenic events not yet approved in export markets, events unapproved in all markets, or events present in conventionally sourced specialty programs. The development of country-specific AP policies that do not encompass considerations of international trade is unlikely to satisfactorily resolve trade issues. Development of global, commercially viable AP policies that also ensure food, feed and environmental safety might minimize trade disruptions in the food and feed supply chain. The adoption of different approaches to AP by different countries hinders the flow of food and feed products and exposes trade to shipment rejections and substantial costs. Situations in which no AP of a particular transgenic event is allowed carry the risk that even after multiple tests at origin have tested negative, a subsequent positive test at destination may place a shipment out of compliance. This is an important and complicated issue requiring input from a broad range of interested stakeholders.

This topic is discussed at greater length in the above-cited report previously submitted to the Secretary of Agriculture by the AC21.

22. The emergence of markets that seek only non-transgenic products has introduced a new level of commercial risk, creating additional liability and insurance implications for some participants in the food/feed chain.

Certain insurance companies have exclusions in their policies for claims arising from the presence of transgenic material. This creates uncertainty as to which agents in the food and feed chain will bear the liability for a transgenic-related claim. Additionally, the rules for apportioning liability along the food/feed chain are still evolving in certain situations: (1) when shipments tested at origin meet transgenic specifications but then test outside transgenic specifications at destination; and (2) when transgenic trait testing is imposed under commercial contracts for products produced under an identity-preserved process providing a verification "paper trail."

23. As more transgenic events become commercially available and enter the global marketplace, the issue of asynchronous approvals will become increasingly important.

Trade of modern biotechnology derived crops commercialized in the U.S. and other countries has encountered obstacles stemming from asynchronous regulatory approvals. Asynchrony of regulatory approvals will continue in some cases to affect market access and the acceptance and adoption of crops and products derived from modern biotechnology. Resolving how the marketplace addresses events that have satisfactorily completed regulatory procedures in some countries but not others and are present in commodity food and feed or present in conventionally-sourced specialty products is important. The market impact of asynchronous approvals may be reduced through the development of commercially viable thresholds for AP in food and feed markets.

24. Other governments' moratoria on allowing the entry of new transgenic crops or *de facto* moratoria on reaching decisions on such crops are limiting the ability of the United States to sell those transgenic crops and other commingled varieties.

Market access for transgenic varieties and derived products that have completed U.S. regulatory review is required for those goods to reach a broad cross-section of users, including consumers. However, some governments, such as those in the European Union, have effectively prevented trade in some products through *de facto* moratoria on approvals of particular transgenic varieties. Such moratoria can affect not only the import or growing of transgenic varieties, but also the import and use of the wider range of derived food and feed ingredients. The existence of such moratoria is a disincentive for the commercialization of new transgenic varieties and even for trade with some other nations without moratoria.

Some members believe that the incorporation of political or socioeconomic criteria into some nations' regulatory evaluation processes, as has been done in Argentina and South Africa, are factors that could also inhibit the development and deployment of potentially useful new crops. Other members believe that conditioning regulatory decisions based on social and economic considerations is a legitimate exercise of sovereign authority. These members see no evidence that socioeconomic considerations within the regulatory process have prevented a transgenic crop from being commercialized and believe there are ways that those issues can be addressed by those governments without impacting trade from the United States.

Addressing these barriers for transgenic crops and derived products will directly impact trade, technology advancement, and diffusion.

25. As new transgenic organisms are developed in the United States and enter the international marketplace, US embassy staff will be approached with questions about the safety of those organisms and how they are regulated in the United States.

Increasingly, the questions that arise regarding new transgenic organisms require detailed knowledge, but U.S. officials with the appropriate expertise are not always available at embassies to answer questions about the safety of those organisms and the U.S. regulatory system. Science officers and agricultural attaches who serve as primary conduits for information between foreign interests and domestic experts are typically generalists who may have neither the time nor the specialized training to adequately answer questions about transgenic organisms. Continued prominence of modern biotechnology in agricultural developments in the United States will lead to further questions to embassy staff regarding biotechnology and products of biotechnology, placing increasing claims on embassy priorities, knowledge and expertise.

26. The least developed countries often lack capacity to address scientific and regulatory issues related to modern biotechnology.

The least developed countries are formulating national biosafety regulatory systems to address organisms developed through modern biotechnology, but they often lack sufficient capacity to address many of the relevant scientific and regulatory issues. There is an ongoing need to provide them with assistance to develop their regulatory systems. If countries have their own trained scientists, technical experts, and policymakers, they will be able to make informed decisions, about both policy options and the safety of individual organisms and products. The United States participates in capacity-building efforts in these areas, but there are also vital roles for international organizations. USDA has a role to play in encouraging effective and appropriate efforts.

27. Protection of intellectual property (IP), in key international markets and elsewhere, is essential for the capture of sufficient product value to justify and recoup costs of developing and marketing transgenic organisms.

The cost of developing and marketing new transgenic varieties is substantial. Other costs are likely to mount as new varieties increasingly require the assembly of IP from multiple sources and as gaining access to such IP becomes increasingly complex. Recouping costs for new product development depends on effective IP protection, nationally and internationally. The ability and/or willingness of foreign governments to protect IP associated with transgenic varieties have been highly variable. For some markets and uses, IP protection is likely to be ineffective or non-existent in the foreseeable future. Nonetheless, the overall level of IP protection internationally and the effectiveness of U.S. efforts to promote adherence to IP standards by other nations will influence technology transfer and investments in developing and in some cases marketing new transgenic crop and animal varieties.

28. Humanitarian use licenses are important for the transfer of transgenic technologies and transgenic plant and animal varieties to the poorest, most food-insecure nations. It is sometimes difficult to secure all the necessary licenses for these transfers.

Future transgenic crop and animal varieties, especially those intended for humanitarian uses, are likely to involve an increasingly complex mixture of intellectual property from many sources, both public and private. The priorities and attitudes of IP holders towards contributing to humanitarian use licenses vary.

Appendix A

The following is the list of individuals involved in the preparation of this paper who were committee members at the time of its completion and therefore joined in consensus:

Patricia Layton (Chair) Clemson University

Daryl Buss, University of Wisconsin at Madison

Leon Corzine, Farmer

Carole Cramer, Arkansas State University

Michael Dykes, Monsanto Company

Carol Tucker Foreman, Consumer Federation of America

Randal Giroux, Cargill

Duane Grant, Farmer

Robert Herdt, Cornell University

Josephine Hunt, Kraft Foods

Gregory Jaffe, Center for Science in the Public Interest

Russell Kremer, Missouri Farmers Union

Margaret Mellon, Union of Concerned Scientists

Ronald Olson, General Mills

Bradley Shurdut, Dow Agrisciences

Jerome Slocum, Farmer

Alison Van Eenennaam, University of California at Davis

Lisa Zannoni, Syngenta Corporation.

The following individuals participated in some preparatory discussions for this paper but were no longer members of the AC21 at the time of the paper's completion and therefore were not asked to join in consensus:

Juan Enriquez-Cabot, Biotechonomy

Richard Crowder, American Seed Trade Association (now at the Office of the United States Trade Representative)

David Hoisington, CIMMYT (now at ICRISAT)

David Magnus, Stanford University

Terry Medley, DuPont Company

Keith Triebwasser, Procter and Gamble.

The following individuals were members of the AC21 at the time of completion of this report but joined the committee too late to participate in the preparation of this paper and therefore were not asked to join in consensus:

Nicholas Kalaitzandonakes, University of Missouri at Columbia

Steven Pueppke, Michigan State University.