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Food Manufacturer Responses to Bioengineered Foods

Final Report

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Executive Summary

U.S. food manufacturers routinely face decisions regarding the choice of food ingredients and production processes used for producing foods. In recent years, they have begun to face choices regarding the use of agricultural commodities and food ingredients that have been produced through bioengineering. Food manufacturers may choose to

- ➤ produce foods without regard to bioengineered content,
- ➤ produce foods not containing bioengineered ingredients, or
- ➤ produce foods with ingredients that have been enhanced through bioengineering (for improved nutritional value, sensory attributes, or shelf life).

Bioengineering refers to the use of recombinant DNA techniques to alter the characteristics of agricultural commodities.

Their choices depend on a variety of economic factors including the effects on costs of production and on consumer demand for their products.

U.S. food manufacturers already have experience producing foods with particular attributes based on consumer demand for those attributes. They may therefore apply this experience in producing foods without bioengineered ingredients or foods enhanced through bioengineering. For the most part, U.S. food manufacturers have produced foods without regard to their bioengineered content because U.S. consumers have had few concerns or limited awareness of bioengineered foods. However, many U.S. food manufacturers have begun to produce foods that do not contain bioengineered ingredients based on their ongoing assessments of U.S. and foreign consumer demand. Because foods enhanced through bioengineering are still early in the development process,

U.S. food manufacturers have yet made few decisions regarding their use.

This report focuses on how food manufacturers are currently assessing, considering, and responding to bioengineered foods. It provides a foundation for future analyses that the Food and Drug Administration (FDA) may conduct in fulfilling its regulatory mission.

E.1 SUPPLY-SIDE ISSUES FOR BIOENGINEERED FOODS

Identity preservation refers to a system for retaining the attributes of particular crops or foods through segregation, record keeping, and verification activities.

The supply-side issues related to bioengineered foods arise most directly from their effects on the production process for foods and on the cost of inputs used in producing food products. The production process may be affected either because food manufacturers must conduct identity preservation activities for commodities with different characteristics or because the commodities themselves have been modified in such a way that they must be processed differently. The cost of inputs may be lower for commodities that are produced using input trait technologies because they are less costly to produce on the farm, but they may be higher for commodities that must be segregated (to either retain their nonbioengineered status or their enhanced bioengineered properties).

Bioengineered food crops that have been approved with **input trait** modifications include canola (rapeseed), chicory (radicchio), corn, cotton, flax, papaya, potatoes, rice, soybeans, and squash.

Bioengineered food crops that have been approved with **output trait** modification include canola (rapeseed), soybeans, and tomatoes.

Thus far, most bioengineering technologies currently in use were developed for farm-level (input trait) characteristics of agricultural crops. Because these technologies have not, for the most part, affected processing-level or consumer-level (output trait) characteristics, food manufacturers have not made substantial production-related changes to address issues related to their use. However, food manufacturers that produce organic foods or foods for export to countries with restrictions on bioengineered content have made or are making production-related changes to exclude bioengineered content.

The costs associated with maintaining the identity of particular foods include the costs incurred as the food manufacturer segregates the commodity or ingredient, maintains records on the commodity or ingredient, and conducts verification activities such as testing and supplier audits. The complexity of the food production system

within the United States adds to the costs of identity preservation because it must be conducted at multiple stages of production. These multiple stages of production include seed growers, crop farms, grain elevators and other raw commodity handlers, intermediate or ingredient processors, food manufacturers, and retail establishments (restaurants, institutions, and grocery stores). Cross-pollination may occur at the seed grower or crop farm, and commingling may inadvertently occur further along the production process. Thus, if particular tolerances must be met for foods with particular attributes, all of these stages of production must be controlled.

The availability, cost, and timeliness of test methods for bioengineered foods are significant issues with regards to verifying the content of identity preserved foods. ELISA-based tests are less costly and quicker, but they can only test for a single bioengineered event and can only be used if the protein in the food has not been denatured through processing. PCR-based tests are relatively expensive and take longer, but they can test for multiple events. However, the DNA must be intact for PCR-based tests. For many processed foods, there is no currently available and reliable method of testing for bioengineered content.

E.2 DEMAND-SIDE ISSUES FOR BIOENGINEERED FOODS

Demand-side issues related to bioengineered foods arise from consumer responses to these foods. U.S. food manufacturers may choose to use or avoid bioengineered foods based on perceived or actual consumer responses. In the United States, some consumers have positive perceptions of input trait bioengineered foods because they may potentially reduce agricultural chemical usage or increase agricultural productivity. However, other consumers have negative perceptions of input trait bioengineered foods because of uncertain health effects, moral or ethical concerns, and potential adverse environmental effects. Whether output trait bioengineered food technologies are successful in the future will depend on consumer responses to improved nutritional value, sensory attributes, and shelf-life of these foods. As noted above, few output trait bioengineered foods have thus far been commercialized but many are in the development process.

Bioengineered foods can be described in terms of their attributes:

- **credence**—foods labeled as nonbioengineered or enhanced for nutritional value;
- **experience**—foods enhanced for taste or extended shelf life; and
- **search**—foods enhanced for appearance.

Numerous surveys and focus groups have been conducted in the United States and internationally to assess consumer perceptions of bioengineered foods. However, none of these studies have provided definitive measures of consumer willingness to pay for nonbioengineered or enhanced bioengineered foods. These studies instead provide indications of attitudes that influence willingness to pay.

Compared to consumers in other countries, U.S. consumers are generally more accepting of or less concerned about bioengineered foods. Several surveys have found that U.S. consumers are optimistic or supportive of the use of biotechnology in general in food and agriculture. However, they often have little information on which to base their beliefs. Although some recurring surveys have found modestly decreasing support for bioengineered foods in the United States over time, others have found increasing support for bioengineered foods with specific characteristics such as improved nutritional value or environmental effects.

European consumers are the most opposed to bioengineered foods, and their attitudes have affected awareness and opposition to bioengineered foods throughout the world.

In contrast to American consumers, European consumers are the most opposed to bioengineered foods, and their attitudes have affected awareness and opposition to bioengineered foods throughout the world. Many Europeans oppose bioengineering because they believe it is not natural. However, some researchers attribute the attitudes in Europe to a lack of trust in government and the regulatory process, particularly because of the events related to bovine spongiform encephalopathy in cattle. Consumers in Japan appear to have attitudes towards bioengineered foods that are similar to Europe, consumers in Canada have attitudes that are similar to U.S. consumers, and consumers in Australia and New Zealand are between the two extremes.

Labeling of bioengineered foods affects awareness and acceptance because in the absence of labeling, consumers do not know which foods are (input trait) bioengineered. In the United States, food manufacturers are not required to label bioengineered foods unless the nutritional content or composition of the food has changed from its traditional counterpart. However, in the future, food manufacturers will likely be allowed voluntarily to label foods that are nonbioengineered. They will not be able to label foods as *free* of bioengineering because it is nearly impossible to substantiate.

The specific tolerances that will be required to label a food as nonbioengineered in the United States have not been established. Many other countries, such as those in the European Union, limit the quantity of bioengineered content that may be present in foods without including a statement on the label. In reaction to this requirement, some U.S. food manufacturers produce foods without bioengineered content for export to those countries.

Food manufacturers must assess not only direct consumer reactions to bioengineered foods but also the reactions of retailers (which are based on the retailers' perceptions of consumer reactions). In the United States, some retail grocery chains have pledged to keep bioengineered foods out of their stores to appeal to consumers that are concerned about bioengineered foods. Also, some fast food chains have rejected particular bioengineered food technologies because of potential consumer reactions.

E.3 CURRENT FOOD MANUFACTURER PERCEPTIONS OF BIOENGINEERED FOOD ISSUES

Food manufacturers already have experience with identity preservations either because they are producing foods for export to countries with limits on bioengineered content or they are producing some type of differentiated food product for sale in the United States.

We interviewed food manufacturers and two trade associations that represent food manufacturers to learn what food manufacturers are already doing or expect to be doing with regard to bioengineered foods and identity preservation systems. Many food manufacturers already have experience with identity preservation either because they are producing foods for export to countries with limits on bioengineered content or they are producing some type of differentiated food product for sale in the United States. In many aspects, these identity preservation systems are like Hazard Analysis and Critical Control Point (HACCP) systems in which food manufacturers identify several control points and establish a system to prevent commingling of different types of ingredients.

Whether food manufacturers are able to implement identity preservation systems depends on the feasibility (from both internal and external factors) and the costs of the systems. Some of the **internal factors** affecting the feasibility of identity preservation systems include the following:

- ➤ availability of information on implementing an identity preservation system—many food manufacturers already have experience with identity preservation systems so the availability of information is not a significant issue, but they have had to learn how to implement the systems on their own;
- ➤ availability of financial resources for implementing an identity preservation system—food manufacturers have had to obtain financial resources if identity preservation is necessary to meet buyer requirements;
- ➤ ability to overcome internal cultural constraints affecting implementation of an identity preservation system—food manufacturers have had to train employees to do things differently than they may have in the past; and
- ➤ availability of ingredient suppliers as part of an identity preservation system—food manufacturers that use substantial volumes of identity-preserved ingredients have had problems with sufficient availability of suppliers that meet their standards.

Some of the **external factors** affecting the feasibility of identity preservation systems include the following:

- ➤ the limited availability (or unavailability for some food products) of standardized and validated testing methods,
- ➤ the limited availability of laboratories to conduct testing,
- ➤ the inability of the bulk commodity handling system in the United States to segregate many types of commodities, and
- ➤ the large range of tolerances and labeling guidelines throughout the world.

To establish and implement an identity preservation system, food manufacturers incur **costs** for capital equipment, labor, materials, and laboratory tests for the following types of activities:

- ➤ certifying and obtaining ingredient supplies—most food manufacturers require documentation that ingredients meet their specifications and on occasion audit their suppliers;
- ➤ testing incoming ingredients and final products—most food manufacturers test incoming ingredients either for bioengineered content or some other attribute, and some also test finished products;
- ➤ scheduling production and conducting changeovers—if food manufacturers do not maintain separate production facilities, then they must follow specific procedures to change over production from one type of food to another and avoid commingling; and
- ➤ conducting record-keeping activities—almost all companies maintain records for their identity preservation systems.

Some food manufacturers are optimistic about future enhanced bioengineered foods for which consumers may be willing to pay more. However, other food manufacturers report that they will avoid use of bioengineered ingredients in the future.

Food manufacturers conduct or are considering conducting identity preservation activities to produce foods with attributes desired by consumers. However, they face considerable uncertainty about consumers' willingness to pay for the product attributes maintained through identity preservation. Food manufacturers generally believe that U.S. consumers will not be willing to pay more for nonbioengineered foods, but they may be willing to pay more for other product attributes. U.S. consumers that are willing to pay more for nonbioengineered foods will likely purchase organic foods rather than a separate class of conventional, nonbioengineered foods. Some food manufacturers are optimistic about future enhanced bioengineered foods for which consumers may be willing to pay more. However, other food manufacturers report that they will avoid use of bioengineered ingredients in the future.

Food manufacturers use a variety of mechanisms for assessing consumer acceptance of bioengineered foods. They rely on available publications such as trade magazines, newspaper articles, trade association reports, and surveys conducted by universities and other third party groups. Larger food manufacturers may also conduct their own surveys to avoid what they perceive to be positive or negative spins on surveys conducted by others. Some manufacturers also monitor direct consumer feedback, such as through their 800 number calls, to determine whether consumer sentiment toward bioengineered foods is changing.

E.4 FOOD MANUFACTURER EXPERIENCES WITH IDENTITY PRESERVATION SYSTEMS

We examined the effects of the StarLink corn event, because it had far-reaching effects on food manufacturers and the food industry, and four types of identity preservation systems currently in use by food manufacturers. One of these types of systems, which is to maintain the identity of foods enhanced through traditional methods, is similar to the types of system that will likely evolve for enhanced bioengineered foods. The other three types of systems have aspects that are similar to the types of systems that will likely evolve for either nonbioengineered or enhanced bioengineered foods.

The StarLink corn event caused many food manufacturers to implement what might be considered the first steps in an identity preservation system.

The **StarLink corn event** had far-reaching effects in the food industry because ingredients derived from corn are used in many processed food products and because it raised consumers' awareness of bioengineered foods in the United States. StarLink corn, which was approved for use in animal feed but not human food, was found in the U.S. food supply in fall of 2000. Since that time, many food manufacturers that did not previously have an identity preservation system implemented what might be considered the first steps in such a system. In particular, many food manufacturers began to require supplier certifications and to test incoming ingredients. Many food manufacturers believe that the StarLink events demonstrated the impossibility of maintaining zero tolerances for commingling with the bulk commodity handling system in the United States.

Many food manufacturers have experience with aspects of identity preservation systems from

- implementing allergen control systems,
- producing conventionally enhanced foods,
- producing certified organic foods, and
- producing certified kosher foods.

Many food manufacturers maintain **allergen control systems** to ensure the absence of allergenic ingredients in food products that should not contain them. The most common food allergens are peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat, but other less common foods cause allergic reactions in some individuals. Allergenic ingredients may be inadvertently introduced into food products because proper procedures are not followed in the production process (e.g., because the production lines are not properly cleaned after production of a food containing an allergenic ingredient). Also, allergenic ingredients may be inadvertently left off the product label so that consumers are unaware of their presence. Because allergen control systems must achieve a high degree of stringency, they are similar to those that some food manufacturers use to produce nonbioengineered foods with strict tolerance levels for bioengineered content.

Many food manufacturers also maintain identity preservation systems to retain the value of specific product attributes derived through **traditional methods**, such as plant breeding or different food processing procedures. The level of stringency of these systems is less than for other identity preservation systems because a limited amount of commingling will not have observable effects on the final food products. These systems are thus more like the systems that will likely evolve for enhanced bioengineered foods. As with food crops enhanced through traditional methods, many

food manufacturers will likely contract with farmers to ensure a sufficient supply of food crops enhanced through bioengineering.

U.S. food manufacturers that produce **organic foods** and conventional foods in the same plant already conduct identity preservation activities to prevent commingling of conventional foods in organic foods. An estimated 80 percent of organic food manufacturers also produce conventional foods in the same plant. Organic foods must be produced following the standards specified in the National Organic Program final rule, and all organic food manufacturers must be certified by an accredited third party. Many of the activities they conduct are similar to those that food manufacturers conduct or will be conducting in the future to market foods as not containing bioengineered ingredients (because organic foods may not contain bioengineered ingredients) or for foods that are enhanced through bioengineering. However, organic food manufacturers generally do not routinely test organic inputs as a verification activity because there are no tests available to ensure that an input is truly organic.

As with organic foods, U.S. food manufacturers that produce **kosher foods** and nonkosher foods in the same plant must conduct identity preservation activities to prevent commingling of nonkosher foods and kosher foods. Many kosher food manufacturers produce both kosher and nonkosher foods in the same plant, and many mass marketed foods are kosher certified. Kosher foods are produced following the standards of particular kosher supervision agencies, which have different levels of stringency depending on their interpretations of the kosher dietary laws. The specific kosherization (sterilization) process required when switching from nonkosher to kosher food production is likely more rigorous than would be required when switching from conventional to enhanced bioengineered foods, but as rigorous as would be required when switching from bioengineered to nonbioengineered foods. Kosher food manufacturers generally do not test kosher ingredients as a verification activity because all ingredients received into the plant, with the exception of most fresh fruits and vegetables, must be kosher certified and display the symbol of a kosher certifying agency.