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US Food Manufacturer Assessment of and Responses to Bioengineered Foods

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Food manufacturers routinely face decisions regarding the choice of ingredients and processes for producing foods. In the case of bioengineered foods, they must choose whether to produce foods not containing bioengineered ingredients and, in the near future, whether to produce foods containing ingredients enhanced through bioengineering. Food manufacturers' decisions regarding the use of bioengineered ingredients are influenced by the nature of the regulatory environment and both demand-side and supply-side considerations. This paper summarizes the current state of the domestic and foreign regulatory environments and results of interviews with food manufacturers about the demand-side and supply-side considerations affecting their decisions.

Key words: bioengineered foods, consumer-level traits, food manufacturers, identity preservation, processing-level traits, regulation.

Introduction

In recent years, food manufacturers have begun to face choices regarding the use of agricultural commodities and food ingredients produced through bioengineering.[1] Most bioengineered food technologies have been developed for farm-level (referred to as "input trait") characteristics of agricultural crops—particularly soybeans, corn, cotton, and canola. These traits include fungal resistance, herbicide tolerance, and insect resistance. Thus far, most food manufacturers in the United States have been indifferent about whether agricultural commodities are produced through bioengineering, unless they are producing organic foods[2] or foods that are labeled as nonbioengineered. Without analytical testing, which has a number of limitations, input-trait bioengineered foods are indistinguishable by consumers from their traditional counterparts.

As bioengineered crops with output traits become increasingly available, food manufacturers face a different set of choices regarding the use of bioengineered ingredients. Output traits affect the food production processes (processing-level traits) or consumer demand for the finished product (consumer-level traits). Processing-level traits include those that reduce food processing requirements (e.g., less energy or labor) or eliminate the need for particular ingredients. Consumer-level traits include improved nutritional value, extended shelf life, and improved or novel sensory attributes. In both cases, manufacturers must predict the size of the market for the introduced bioengineering innovation. In the case of processing-level traits, food manufacturers will need to weigh the reduced production costs against the increased costs of the raw commodity or ingredient. For consumer-level traits, food manufacturers will need to evaluate potential increased consumer willingness to pay (WTP) for improved attributes against the increased costs of the raw commodity or ingredient and potentially higher production costs. In addition, food manufacturers continuing to use both conventional and bioengineered ingredients in the same facility will incur the costs of developing and implementing identity preservation systems to preserve the attributes of the products they produce.

We separate the discussion of the emerging bioengineered foods market into three components: (1) the nature of the regulatory environment, both domestic and foreign; (2) the expected effect of a manufacturer's decisions on product revenues (i.e., demand-side effects); and (3) the expected effect of a manufacturer's decisions on production costs (i.e., supply-side effects). We explored each component by reviewing available studies and conducting industry interviews. Because it is impos-

1. *Throughout this paper, we use the term "bioengineering" to refer to the use of recombinant DNA techniques to change the characteristics of agricultural commodities. We refer to foods produced through bioengineering as "bioengineered foods" rather than the more frequently used terms "genetically modified foods" and "genetically modified organisms" because almost all foods have undergone some form of genetic modification (see the US Food and Drug Administration's response in US General Accounting Office, 2002).*
2. *The National Organic Program Final Rule (USDA Agricultural Marketing Service, 2000) states that organic foods may not contain bioengineered ingredients.*

sible to construct a statistically valid sample for surveying activity that has not yet taken place, we conducted a series of interviews to generate hypotheses of how production practices may change. We also identified current practices and markets that resemble those that may emerge for the output trait products produced through bioengineering. We conclude with a discussion of food manufacturers' likely choices about the use of bioengineered ingredients and whether and where to produce bioengineered foods.

The Regulatory Environment for Bioengineered Foods

Biotechnology firms and food manufacturers choosing whether to use bioengineered ingredients face a diverse and evolving international regulatory burden. Below, we focus on two aspects of international regulation having the greatest effect on bioengineered foods: approval and labeling. Although the United States and the European Union represent only two of many major agricultural markets, biotechnology regulatory policy in the rest of the world generally follows their approaches. Therefore, it is useful to discuss policies using these two models as a starting point.

Approval Process

The United States (US) government regulates agricultural plant-based biotechnology through three agencies: the US Department of Agriculture (USDA), the US Environmental Protection Agency (EPA), and the US Food and Drug Administration (FDA). Jurisdiction is defined primarily by the product's intended use, and products or crops often fall under the jurisdiction of more than one agency.

The USDA's Animal and Plant Health Inspection Service (APHIS) regulates organisms or products that may be plant pests (USDA APHIS, 2002). Any introduction into the United States of an organism or product derived from biotechnology must be identified to the USDA, which then decides if it is a "regulated article" or a potential plant pest or disease. If the USDA determines that the article should be regulated, a written approval usually is issued that designates conditions for introduction of the article to limit risk (such as requiring a buffer zone). However, most articles and products produced through biotechnology have not been considered regulated articles.

Through the USDA's approval process, ten food crops have been approved with input modifications, and three have been approved with output modifications (soybeans, rapeseed, and tomatoes). Table 1 lists food crops that are currently undergoing field trials, have a pending petition for deregulation (which allows commercialization), or have been approved for commercialization with modifications affecting input-, processing-, or consumer-level traits. A significant number of modifications are under field testing in each category.

The EPA regulates the distribution, sale, use, and testing of pesticides, even if produced within a plant through the addition of a gene, such as corn that creates Bt toxin (e.g., StarLink). The EPA also sets pesticide tolerances for crops destined for both human and animal consumption, although it has stated that it will no longer give "split approvals" for bioengineered plants.[3]

The FDA's policy regarding bioengineered foods is based on the concept of "substantial equivalence." Bioengineered foods that are not substantially equivalent are considered a food additive if they are significantly different in structure, function, or amount than substances currently found in food and thus are subject to premarket approval.[4] Thus far, the FDA has determined that most bioengineered food crops are substantially equivalent. The FDA also proposed a rule in January 2001 (not yet finalized) requiring companies to notify the FDA of any product being produced through bioengineering (FDA, 2001b). This notification requires evidence of substantial equivalence and will replace a voluntary notification system that has had 100% industry compliance.

Besides the United States, Argentina, Canada, and China have been the most permissive with agricultural biotechnology approvals. These three countries, along with the United States, account for 99% of the total acreage of bioengineered crops. The United States and Argentina alone grow 90% of the transgenic crop acreage, although Argentina placed an effective freeze on new approvals in 1999 (James, 2002). However, only the United States and Canada assert that in many cases bioengineered crops do not need formal government approval. Canada requires (Health Canada, 2002), and the United States probably will soon require, a notification system that includes safety information.

European Union (EU) directives establish that all varieties of bioengineered food products must be approved by member country authorities before pro-

3. *Split approvals are those for which a crop is approved for animal but not human consumption.*
4. *Premarket approval is a process whereby the FDA approves a product's safety before it is introduced on the market.*

Table 1. Input-, processing-, and consumer-level traits of bioengineered food crops in field testing or commercialization.

Crop	Input	Processing	Consumer
Apple	F	F	F
Barley	F	F	F
Beet	F, A		
Brassica oleracea	F		F
Carrot	F	F	F
Cassava			F
Coffee		F	
Corn	F, P, A		
Cotton	F,A	F	F
Cranberry	F		
Cucumber	F		
Eggplant	F		
Grape	F	F	F
Grapefruit	F		
Lettuce	F	F	F
Melon	F		F
Oat	F		
Onion	F		
Papaya	F, A		F
Pea	F	F	F
Peanut	F		
Pear	F		F
Pepper	F		F
Peppermint			
Persimmon	F		
Pineapple	F	F	F
Plum	F		F
Potato	F, P, A	F	F
Rapeseed	F, P, A	A	A
Rice	F, P, A	F	F
Russian wildrye	F		
Sorghum	F		
Soybean	F, A	A	A
Squash	F, A		
Strawberry	F		F
Sugarcane	F		
Sunflower	F	F	
Sweet potato	F	F	F
Tomato	F, A		A
Walnut	F		
Watercress	F		
Watermelon	F		
Wheat	F	F	F

Note: F = field testing, P = pending petition for deregulation, A = approved for commercialization. From "Food Manufacturer Responses to Bioengineered Foods," by M.K. Muth, R.H. Beach, M.S. Fanjoy, E.C. Gledhill, D.L. Kendall, C.L. Viator, and Thomas J. Hoban, April 2002. Report prepared for the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition. Research Triangle Park, NC: RTI.

ceeding to test plantings and marketing. This approval process includes a determination of safety to humans and a full environmental risk assessment. Although 18 varieties were approved under this process between 1997 and 1998, none have been approved since then, and 12 applications are pending. The European Commission (EC) characterized the approval stoppage as a "de facto moratorium" put in place because of public concerns about agricultural biotechnology, and five EU member states subsequently banned already approved varieties (European Commission Health and Consumer Protection Directorate-General [EC], 2000). A new EU directive came into force on October 17, 2002, recasting the approval process. In particular, the new directive (a) calls for the use of the precautionary principle, (b) states that the consideration of the ethical position of member states with regard to biotechnology should be considered, (c) specifies the need for a traceability system for approved products, and (d) clarifies that these requirements also apply to imported products.

The approval process for bioengineered crops in Japan falls somewhere between the US and EU policies. Although Japan requires comprehensive safety and environmental assessments similar to that of Europe before approving the introduction of transgenic crops, as of October 2002, Japan completed safety assessments on 44 biotech crops (Ministry of Health, Labor and Welfare, 2003). The Minister of Agriculture, Forestry and Fisheries assesses and grants approvals (Agriculture, Forestry and Fisheries Research Council, 2002). Japan recently announced a council, headed by the prime minister, that will discuss biotechnology strategies and seek to deregulate the introduction of new crops (Japan Bioindustry Association, 2002).

Most of the rest of the world either bans bioengineered foods and crops outright or mandates approval. Although most wealthy industrial countries in theory permit the planting and importation of biotech products, most of the developing world does not. In those countries, it is illegal to plant bioengineered crops or to import bioengineered commodities (Paarlberg, 2002). Among international organizations, the Codex Alimentarius Commission expressed the need for safety and environmental assessments of new bioengineered varieties and has published preliminary guidelines. These guidelines are very general, have not yet been adopted by the full commission, and remain agnostic on what policy mechanisms are needed to administer them (Codex Alimentarius Commission, 2002).

Obtaining approvals for domestic planting of imports of bioengineered products or plants can be con-

sidered a fixed cost of production for the biotechnology companies that develop them. In practice, the intent of the governing body seems just as important as the letter of the regulations for promoting or restricting these products. The letter of the EU approval directives is not substantially different from the North American notification guidelines or the Japanese approval process. However, in actual practice, European application approvals have been completely stalled for four years. In addition, the introduction of strict new EU procedures could have a large secondary effect on world markets, because the EU is the largest importer of agricultural goods. By prohibiting the use of agricultural biotechnology, some developing countries may obtain a nonbioengineered premium for their exports to the EU and Japan, the two largest agricultural import markets.

Labeling Requirements

Many countries require (or intend to require in the future) labeling of foods containing bioengineered ingredients. The major exceptions are the United States and Canada, which only require labeling based on a substantial change in the characteristics of the food. For example, a company producing a food higher in a specific vitamin would be required to disclose that fact through a label statement or a change in the common name. However, even in this instance, the food would not need to be identified as bioengineered. The United States has proposed voluntary labeling guidance that companies can use if they choose to label their foods as not bioengineered (FDA, 2001a).

With few exceptions, the European Union requires labels on all final products containing bioengineered ingredients, including food additives and flavorings. The latest directive, in place after October 17, 2002, calls for the following label statement: "This product contains genetically modified (GM) organisms" (European Parliament, 2001). However, the EU has not definitively set the necessary *de minimus* threshold for bioengineered content. A 2000 EC regulation specifies 1% bioengineered ingredient content as a labeling trigger (European Parliament, 2000), and the European Parliament recently voted for a 0.5% threshold ("European Parliament committee," 2002).

Many other countries require mandatory labeling of bioengineered foods.[5] Of the major countries, Australia and New Zealand recently adopted a 1% threshold for required labeling, but they exempt highly refined food (such as corn oil) in which both the modified DNA and protein are no longer present (Food Standards Australia New Zealand, 2002). Japan has also adopted a mandatory labeling system, but with a 5% threshold.

Because many consumers interpret any special label advisories as warnings, required labeling likely implies lower prices for foods labeled as bioengineered and higher prices for those labeled as nonbioengineered. A voluntary policy allowing for the labeling of nonbioengineered foods but not requiring mandatory positive labels, which is the likely US policy, will likely have much less effect on the potential market for bioengineered foods. However, a mandatory labeling requirement in major agricultural importing countries brings great pressure on exporting nations, including the United States, to conform to importer requirements for maintaining access to these substantial markets.

Because bioengineered food labeling requirements have such a large potential effect on world trade, many observers consider these issues a subject of a possible World Trade Organization (WTO) complaint and the next significant trade conflict between the United States and the EU. The WTO approach to labeling appears to be similar to the US position. The WTO considers most approved varieties of bioengineered foods "substantially equivalent"; therefore, positive mandatory labeling may be a technical barrier to trade under Article 2.1. However, the EU is challenging this position. In the Codex Alimentarius, the debate on labeling is unresolved, with the United States and the EU arguing their own labeling policies and traceability requirements. In particular, the traceability provisions implied by a strict mandatory labeling policy by the EU are a major point of contention ("Traceability issue," 2002).

Methodology

To evaluate how food manufacturers are assessing and responding to issues arising from the availability of bioengineered foods, we reviewed the literature on demand-side and supply-side factors affecting food manufacturers' responses to bioengineered foods and developed a process for interviewing trade associations,

5. *For example, in addition to labeling policies already in place, Indonesia is considering a mandatory label regulation with a 5% threshold ("Biotech labeling moves closer in Indonesia," 2002), Colombia requires the "identification of imported bioengineered foods" ("Colombia establishes rules for biotech imports," 2001), Chile intends to require labels with a 2% threshold ("Chile moves toward mandatory biotech labeling," 2001), and Thailand is beginning to require labels on some products with either a 3% (corn) or 5% threshold ("Thailand sets biotech labeling rules," 2001).*

certification and supervision agencies, food companies, and industry experts. Many of the same factors that affect organic and kosher food manufacturers affect (or will affect) nonbioengineered or enhanced bioengineered food manufacturers; therefore, we interviewed not only conventional food manufacturers but also individuals involved with organic and kosher food production.

The interview protocol included development of interview guides for each type of manufacturer, reviews of the interview guides by a biotechnology expert and trade associations, and development of a list of potential candidates for interviews.[6] For conventional food manufacturers, the interview guide contained multiple questions on identity preservation (IP) activities, testing or other validation activities, advantages or benefits of identity preservation, disadvantages or costs of identity preservation, implementation issues, and methods of assessing consumer response to product characteristics. For food manufacturers affected by the StarLink corn event, we also asked questions about how they were affected and what changes they had made in response.[7] For organic and kosher food manufacturers, the interview guide contained multiple questions on the use of dedicated equipment or facilities, procedures for ensuring that inputs are organic (or kosher), the types of activities conducted to ensure organic (or kosher) status, and the use of analytical testing.

During summer and fall 2001, we used the interview guides in conducting interviews by telephone. First, we interviewed six large (greater than 1,000 employees) and three small (fewer than 1,000 employees) US conventional food manufacturers.[8] As we conducted the interviews, we found that many of the conventional food manufacturers also produced kosher or organic foods in the same or separate production facilities. In those cases, we asked for additional information about IP systems for kosher and organic production. We also conducted interviews with a large ingredient supplier and a large European food manufacturer to obtain alternative viewpoints.

Next, we interviewed three organic food manufacturers (all also produced conventional foods), two independent organic inspectors, and rabbis at five kosher supervision agencies. Because the rabbis are present in the plants when kosher food production and "kosherization" are occurring, they were able to provide responses to questions on IP activities.

Demand-Side Findings

In deciding whether to produce differentiated products (i.e., either nonbioengineered or enhanced through bioengineering), food manufacturers evaluate the potential demand-side effects of their decisions. This evaluation includes both potential effects on consumer willingness-to-pay (WTP) and product volume sold.

A few studies have documented increased consumer WTP by US consumers for nonbioengineered foods. For example, Chen and Chern (2002) estimated increased WTP for non-genetically modified (GM) vegetable oil (5% to 8%), salmon (15% to 28%), and corn flake cereal (12% to 17%) using contingent valuation survey data. Another study using survey data estimated increased WTP values of 20% for nonGM foods, without reference to specific foods (Mendehall & Evenson, 2002). Similarly, using experimental auction data, Rousu et al. (2002b) and Huffman et al. (2002) estimated average decreased WTP values of 14% for foods labeled as GM compared with nonlabeled foods. Also, consumers appear to value nonbioengineered foods with lower tolerances. Rousu et al. (2002a) estimated average decreased WTP values of 10% for nonbioengineered foods with 1% or 5% bioengineered content relative to nonbioengineered foods "certified to have no GM content," using experimental auction data. Using actual market data, Good, Bender, and Hill (2000) reported premiums of 6% to 8% for bulk nonbioengineered soybeans and corn, which indicates an increased derived demand for these commodities relative to undifferentiated soybeans and corn. In comparison to nonbioengineered foods, foods enhanced through bioengineering have attributes for which consumers may be willing to pay more.

Food manufacturers might also increase the volume of products sold if they can differentiate them as nonbioengineered, either because they appeal to consumers concerned about the uncertain effects of bioengineered foods, or they give food manufacturers access to additional export markets (Golan, 2000). Based on a survey conducted in the United States, Moon and Balasubramanian (2001) found that 44% of respondents would buy "nonbiotech" breakfast cereal compared with 8% that would not do so and 48% that did not know if they would buy it or had no preference. In general, however,

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6. *Copies of the interview guides are available from the authors.*
7. *StarLink corn, which was approved for use in animal feed but not human food, was found in the US food supply in fall 2000.*
8. *We limited the number of interviews with food manufacturers to nine to avoid the lengthy Office of Management and Budget survey clearance process.*

many surveys have found that the number of US consumers who are aware of or concerned about bioengineered foods is limited (see Muth et al., 2002, for a review of surveys). Thus, the size of the total market for nonbioengineered foods in the United States may be small, and, depending on the expected strategies of their competitors, food manufacturers may decide not to serve this market. This finding is in contrast to the market for nonbioengineered foods in Europe, where first private label and then branded food manufacturers removed bioengineered ingredients from their food products (Kalaitzandonakes & Bijman, 2003).

Because of the rapidly changing nature of consumer attitudes toward bioengineered foods, food manufacturers said in the interviews that they are constantly reassessing consumer perceptions using a variety of primary and secondary data collection methods. Nearly all food manufacturers rely on secondary data sources, such as trade association magazines and reports, newspaper articles, and surveys conducted by universities and other third-party groups. These are all low-cost means of assessing consumer demand. Some food manufacturers said they rely most heavily on reports that influence consumers, such as newspaper articles, whereas other food manufacturers did not consider them relevant. As reported by Hoban (2001), few food manufacturers rely on claims by environmental and consumer groups opposed to biotechnology.

Several food manufacturers conduct their own proprietary research, including monitoring direct consumer feedback through web sites and toll-free numbers. In the past, bioengineering-related calls to toll-free numbers have been infrequent but typically increase in response to specific events (e.g., StarLink corn). A few large food manufacturers have marketing research departments with extensive capabilities, including conducting their own consumer surveys to assess demand for bioengineered foods. These companies believe surveys conducted by third-party groups tend to be biased and that their internal surveys are the best source of information.

Many of the food manufacturers interviewed believed that only a small segment of the US population is truly concerned about bioengineered food. They agreed that the market for nonbioengineered foods is essentially the same as for organic foods and that the market is not large enough (or distinguishable enough) to warrant a separate class of nonbioengineered, nonorganic foods. They believe that consumers who wish to avoid bioengineered food products can and will purchase organic foods, which cannot contain bioengineered ingredients.

Supply-Side Findings

In addition to assessing demand for nonbioengineered or enhanced bioengineered foods, food manufacturers evaluate the potential supply-side effects of their decisions. The overall interview responses for conventional, organic, and kosher food production indicate that many food manufacturers already have experience with the types of IP systems needed to produce nonbioengineered or enhanced bioengineered foods. In addition to food manufacturers' production of organic or kosher foods, this experience comes from producing other types of differentiated food products[9] and controlling allergens in food products. Furthermore, because of the StarLink corn event, many food manufacturers who had not previously had any experience with IP systems implemented what might be considered the first steps of such a system. Because ingredients derived from corn are used in many processed food products, the event affected a large proportion of food manufacturers in the United States and other countries. To ensure that StarLink corn was not inadvertently introduced into the production system, food manufacturers began to require supplier certifications and to test incoming ingredients.[10]

As we learned through the interviews, a more extensive IP system might include one or more of the following general steps:

- ingredient control and supplier certifications;
- ingredient testing;
- separation of facilities and equipment;
- scheduling of production and conducting changeovers;
- use of written guidelines;
- use of recordkeeping systems;
- final product testing; and
- use of third-party certification.

The stringency of the system affects the degree to which each of these steps is or would be included in a particular food manufacturer's IP system. As indicated in Figure 1, systems for excluding particular ingredients

9. *In general, the types of identity preservation systems currently in use are those for foods enhanced through traditional plant breeding methods, foods enhanced through processing (e.g., additional vitamins and minerals), and foods that are linked to their regional origins.*

10. *In addition to prompting food manufacturers to implement identity preservation systems, many food manufacturers believe the StarLink events demonstrated the impossibility of maintaining zero tolerances for commingling with the bulk commodity handling system in the United States.*

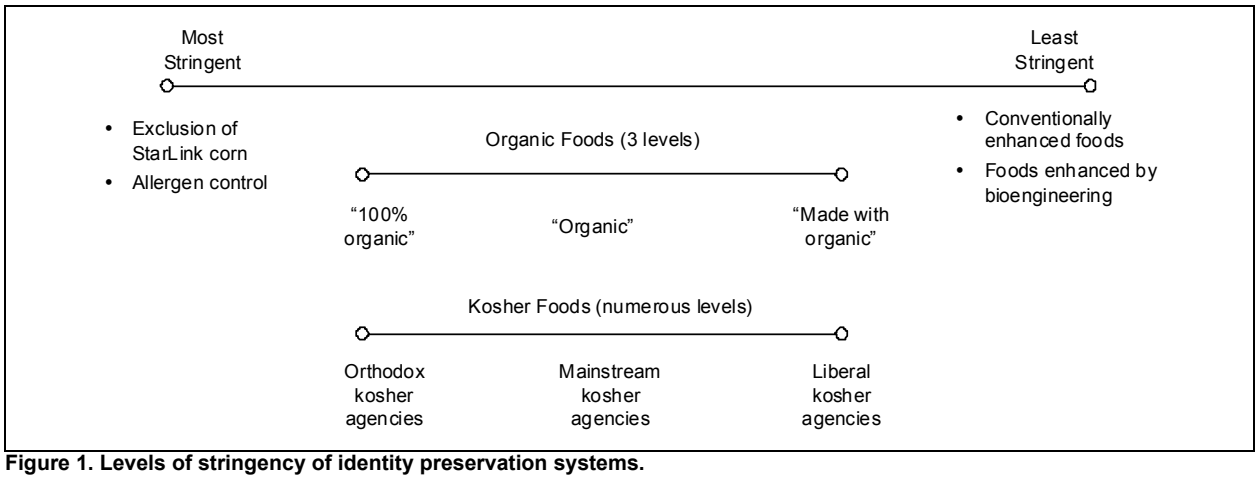

Figure 1. Levels of stringency of identity preservation systems.

(or ingredients with particular attributes) are generally more stringent than those for retaining particular product attributes.[11] Specifically, the most stringent systems for avoiding contamination or commingling are those for allergen control and exclusion of StarLink corn. The least stringent systems are those for producing foods enhanced through conventional methods or bioengineering because their functional properties are preserved with a small amount of contamination. Organic and kosher production systems have levels of stringency that fall between the two extremes. Food manufacturers may choose to produce organic foods at three levels of stringency as specified by the National Organic Program. For kosher foods, food manufacturers follow the standards of one or more of several hundred kosher supervision agencies with different levels of stringencies.

In implementing IP systems, issues facing food manufacturers include feasibility of implementation, cost of implementation, and availability of testing as verification or validation of the system. We address each of these issues below.

Feasibility of Identity Preservation

Feasibility issues are those that affect food manufacturer choices in the short run. They include availability of information for implementation, availability of financial resources for developing the system, cultural constraints within the food manufacturing company, and availability of commodities or ingredients with desired attributes.[12] For many types of food manufacturers, feasibility is not a concern because they have already implemented IP systems. For both organic and kosher food manufacturers, the existence of external standards (through the National Organic Program and kosher supervision agencies) has facilitated the development of such systems.

In their responses to our interviews, conventional food manufacturers that recently implemented IP systems for some type of differentiated food product said that development of the system required expertise not previously available within the company. They either had to hire consultants or experienced employees or develop it internally. These food manufacturers also said they believed their IP systems could be adapted to production of nonbioengineered or enhanced bioengineered foods. However, the complexity of identity preservation is much greater if one or more of a product's ingredients are from a commodity that has bioengineered and conventional varieties. Many food manufacturers also said that the internal culture of the company had to be changed to accommodate the requirements of the IP system. In particular, they developed new management practices and educated employees on the need for particular production practices.

Overall, the greatest feasibility issue cited by food manufacturers was the availability of identity-preserved ingredients. When ingredients with particular attributes are not available, food manufacturers must contract with farmers or ingredient manufacturers to ensure adequate supplies for their production processes. However, securing commodity or ingredient supplies may take a few

11. See Muth, Mancini, and Viator (in press) for a more complete characterization of the identity preservation systems noted in Figure 1.

12. In the long run, feasibility issues are really a subset of cost issues, because all issues of feasibility can be overcome at some cost to the food manufacturer.

years because of the time required to develop seedstock and the seasonality of commodity production. Some food manufacturers noted that they would not invest in IP systems for producing enhanced bioengineered foods unless the availability of ingredients could be assured. Food manufacturers noted that ingredient suppliers sometimes have different standards for identity preservation that do not conform to their own. Also, a few food manufacturers said many suppliers would not certify ingredients as nonbioengineered. Furthermore, on occasion, ingredient suppliers have certified ingredients as nonbioengineered, but random testing indicates that the ingredients are actually from bioengineered sources.

Costs Associated with Identity Preservation

The costs of IP systems arise from five general activities: (a) certifying and obtaining ingredients, (b) testing incoming ingredients or final products, (c) separating equipment and facilities, (d) scheduling production and conducting changeover procedures, and (e) conducting recordkeeping activities. Each of these activities may have associated capital equipment, labor, and materials costs.

Nearly all of the IP systems require some type of ingredient control or supplier certification, although most food manufacturers do not conduct ingredient testing once ingredients arrive at their plant. Some food manufacturers said costs would not increase for this aspect of identity preservation, because they would be conducting the same activities they already perform to ensure adequate supplies of ingredients with desired levels of quality. However, other food manufacturers said the costs of obtaining and certifying ingredients would be or already are substantially higher for nonbioengineered ingredients. Both organic and kosher ingredients must be certified by an outside agency; thus, the costs are borne in part by the supplier.[13] Over time, private companies are beginning to offer certification services for nonbioengineered ingredients, which will reduce the burden on food manufacturers of ensuring incoming supplies have their desired attributes.

Several conventional food manufacturers that test incoming commodities and ingredients said that this testing was the greatest portion of the costs of identity preservation. However, food manufacturers producing nonbioengineered foods generally do not conduct final product testing. They often rely on the use of controls earlier in the process, and, as noted below, test methods are not available in many cases.

Food manufacturers choosing to use separate facilities or equipment for production of foods with different characteristics have higher costs of capital equipment and ongoing maintenance than do those choosing to use a single facility or shared equipment. Many food manufacturers said they do not (or would not) maintain separate facilities or equipment because they did not (or would not) have sufficient volume to keep equipment running at capacity. Some food manufacturers, particularly smaller ones, said they would exclude bioengineered foods from their plants or not distinguish between nonbioengineered or bioengineered foods; thus, they would have no need for separate facilities or equipment.

If food manufacturers produce multiple product types within the same facility and on the same equipment, they follow procedures to ensure that commingling of different product types does not occur. If they produce single product types on each production line in shared facilities, the costs of maintaining separate lines are those associated with not sharing labor across production lines (to avoid inadvertent commingling) and potentially lost profits from not maximizing line capacity. If they produce multiple product types on a single line, the costs of preventing commingling include additional labor and lost revenue because of more frequent line shutdowns for cleaning.

Food manufacturers producing organic or kosher foods on the same line already follow the types of procedures required to exclude bioengineered content or ensure enhanced bioengineered content of foods. In both cases, they begin production after a complete plant clean-up by producing the differentiated product (i.e., organic or kosher) first, followed by the nondifferentiated product. Some manufacturers of organic foods reported that they treat the first part of the organic production run as nonorganic. For kosher foods, manufacturers begin with kosher pareve (nondairy), followed by kosher dairy and then conventional foods. The plant must remain idle for 24 hours after the plant clean-out procedures; then a rabbi oversees the kosherization (or sterilization) process for any heated kosher foods. Food manufacturers with experience producing nonbioengineered foods report similar practices for producing nonbioengineered foods first after a plant clean-out and then discarding (or treating as bioengineered) the first part of the production run. The level of effort, and thus the costs of these activities, is higher when a food product is pro-

13. One exception to the certification requirement is that fresh fruits and vegetables (with the exception of grapes) are inherently kosher and do not need to be kosher certified.

Table 2. Methods of testing for bioengineered content.

Test Method	Advantages	Disadvantages
PCR[a]	• Can test for multiple bioengineering events • Can test processed foods if DNA can be isolated • Very sensitive	• Lack of standard method for isolating DNA • Can only test if modification uses a particular primer or terminator gene • Requires expertise to conduct test • Must be conducted in a laboratory • Costly (about $250 to $350 per test)
ELISA Laboratory Test	• Can quantify a specific protein in a specific commodity • Less costly (about $50 per test)	• Cannot test processed foods if protein is not intact • Used for a specific bioengineering event • Must be conducted in a laboratory
ELISA Strip Test	• Requires little equipment or training • Conducted on-site • Least costly (about $5 to $10 per test)	• Cannot be used to test processed foods if protein is not intact • Used for a specific bioengineering event

[a] *PCR = polymerase chain reaction.*

duced from a commodity that has bioengineered varieties and when the manufacturer is trying to achieve a 1% (versus a 5%) level of tolerance.

All IP systems require some type of specialized record keeping, both for outside scrutiny and for internal control. Greater requirements for record keeping increase the costs of food production. Record-keeping costs include the costs of computer systems, specialized software, and data-recording devices; installation of data recording stations on the production line; worker time for recording data; and data storage.

Availability of Testing for Verification

Food manufacturers rely on testing to verify that incoming commodities and ingredients have their desired attributes and that the identity preservation system has prevented commingling during the production process. As noted in Table 2, the three available test methods for bioengineered foods are the polymerase chain reaction (PCR) test, the ELISA (enzyme-linked immunosorbent assay) laboratory test, and the ELISA strip test. The PCR test can test for multiple modifications in a single food and, if DNA can be isolated, can be used for processed foods. However, it is costly and must be conducted in a laboratory. The ELISA tests can test only for a single modification and thus cannot be used to screen foods for bioengineered content. Because ELISA tests are based on detection of proteins, which denature with heat, they cannot be used for many processed food products. No test method exists for detecting bioengineered content in foods without intact DNA or protein. For this reason, many ingredients used in food processing, such as vegetable oils, cornstarch, and high fructose corn syrup, cannot be tested for bioengineered content using any of the three test methods.

Conclusions

US food manufacturers respond to domestic and foreign regulatory environments and to supply and demand factors in their choices about what to produce, where to produce, and for whom to produce. The processes they use to produce nonbioengineered foods or foods enhanced through bioengineering are similar to those that they already use to produce other types of differentiated food products. Through interviews with conventional, organic, and kosher food manufacturers, we found that many food manufacturers already have experience producing foods with particular attributes based on consumer preferences. Although many food manufacturers (particularly smaller ones) will choose to avoid or ignore the use of bioengineered foods, others will produce and market both nonbioengineered and enhanced bioengineered foods.

Based on the results of our study, we expect most US food manufacturers to continue to use ingredients without regard to whether they are bioengineered, at least for the vast majority of their food products (see Table 3). However, we expect a few manufacturers to produce foods labeled as not containing bioengineered ingredients for the domestic or foreign markets. Some larger manufacturers already produce foods in foreign countries for foreign consumption because it is easier to meet tolerance levels for bioengineered content by producing in those countries. We expect a few manufacturers to produce foods enhanced through bioengineering for domestic consumption but none to produce such foods for foreign markets, given the current foreign regulatory environments. Although a few enhanced bioengineered commodities are being developed to help alleviate nutritional deficiencies in developing countries, these markets do not appear to be ones in which US manufacturers expect to have a substantial presence.

Table 3. Overview of US food manufacturer choices regarding bioengineered foods.

Food Manufacturer Choices	Production/Consumption Location Choices	Expected Frequency of Choice for US Food Manufacturers
Market foods without regard to bioengineered content	Produce domestically for US consumption	Majority of US manufacturers
	Produce domestically for export to foreign countries	Few manufacturers, all sizes
	Produce in foreign countries for foreign consumption	Few manufacturers, all sizes
Market foods not containing bioengineered ingredients	Produce domestically for US consumption	A few mostly small manufacturers
	Produce domestically for export to foreign countries	A few manufacturers, all sizes
	Produce in foreign countries for foreign consumption	A few larger manufacturers
Market foods enhanced through bioengineering	Produce domestically for US consumption	A few manufacturers, all sizes
	Produce domestically for export to foreign countries	Likely no manufacturers
	Produce in foreign countries for foreign consumption	Likely no manufacturers

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