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# The Role of Identity-Preservation Systems in Food-Manufacturer Responses to Bioengineered Foods

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With the availability of bioengineered food ingredients, food manufacturers must choose whether to produce foods that do not contain bioengineered ingredients and, in the near future, whether to produce foods that contain ingredients enhanced through bioengineering. In either of these cases, food manufacturers must develop an identity-preservation system to preserve the attributes of food products throughout production and distribution. Using information obtained through interviews with food manufacturers, trade associations, and industry consultants, this paper focuses on the characteristics of identity-preservation systems that may be needed for producing nonbioengineered or enhanced bioengineered foods.

Food manufacturers routinely make decisions regarding the choice of ingredients 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.<sup>1</sup> 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. However, bioengineered foods with output traits are becoming increasingly available. Output traits affect the food-production processes (processing-level traits) or consumer demand for the finished product (consumer-level traits). Pro-

cessing-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.

Food manufacturer decisions regarding the use of bioengineered foods are influenced by the nature of the regulatory environment in which they operate, including both domestic and foreign regulations and policies; the expected effects of their decisions on product revenues, particularly because of changes in consumer willingness to pay; and the feasibility of and expected changes in costs associated with identity-preservation systems.

This paper focuses in particular on the third factor—the role of identity-preservation systems on food manufacturer decisions. The ability of food manufacturers to produce foods that either do not contain bioengineered ingredients or do contain enhanced bioengineered ingredients depends on their ability to develop and implement identity-preservation systems. If food manufacturers use *only* nonbioengineered ingredients or *only* enhanced bioengineered ingredients, then identity preservation refers primarily to the set of activities associated with verifying that incoming ingredients meet their specifications. If manufacturers produce foods with both bioengineered and nonbioengineered ingredients in the same establishment, then identity preservation refers to the multiple steps needed to prevent commingling in the production process and to maintain records on product characteristics and handling.

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<sup>1</sup> 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 U.S. Food and Drug Administration’s [FDA’s] response in U.S. General Accounting Office [GAO] 2002).

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### Definitions Of Identity-Preservation Systems

To describe the systems that food manufacturers might adopt to produce foods meeting particular requirements, three terms are commonly used: segregation, identity preservation, and traceability. Segregation *without* identity preservation refers to systems in which recordkeeping and testing requirements are minimal, particularly if differences in commodity characteristics are visually observable. Segregation may be all that is required for many future enhanced bioengineered foods if differences from conventional foods are visually observable. In comparison, segregation *with* identity preservation includes both recordkeeping and testing activities. Foods that are to be marketed as nonbioengineered, particularly if their ingredients include crops with varieties that have been bioengineered for input traits, would require both segregation and identity preservation. The strictest type of system, traceability, refers to a system with segregation and identity preservation and the ability to trace a food product to its original source. For foods produced from a commodity with bioengineered varieties, a traceability system may be the only method of achieving required tolerances for countries with extremely low labeling-threshold tolerances for bioengineered content. Also, traceability would be required in cases where a test method cannot detect if a food is bioengineered and the manufacturer would like to label the food as nonbioengineered (e.g., wet-milled corn products such as corn syrup, oil, and starch).

### The Regulatory Environment For Bioengineered Foods

Most government regulations regarding bioengineered foods focus on either approval of crops or required labeling. Although the United States and the European Union (EU) represent only two of many major agricultural markets, biotechnology regulatory policy in the rest of the world generally follows either the United States or the European approach. The types of identity-preservation systems adopted by firms depend on these requirements.

### Approval Process

In the United States, ten food crops have been approved with bioengineered input-trait modifications. Only three food crops have been approved with output modifications. The U.S. government regulates agricultural plant-based biotechnology through three agencies. The U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) regulates organisms or products that may be plant pests (2002), but most products produced through bioengineering are not considered regulated articles under this permit system. The U.S. Environmental Protection Agency (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 the Bt toxin (e.g., StarLink). The U.S. Food and Drug Administration's (FDA) policy regarding bioengineered foods is based on the concept of "substantial equivalence." 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, that requires companies to notify the FDA of any product being produced through bioengineering (2001b).

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.

According to the EU directives, all varieties of bioengineered food products must be approved by member-country authorities before proceeding 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, with 12 applications pending. The European Commission (EC) characterized the approval stoppage as a "de facto moratorium" put in place because of public concerns over agricultural biotechnology, and five EU member states subsequently banned already approved varieties (EC 2002).

The approval process for bioengineered crops in Japan falls between the U.S. and EU policies. Although Japan requires comprehensive safety and environmental assessments similar to those of Eu-

rope before approving the introduction of transgenic crops, as of March 2000 Japan had approved 29 biotech crops for field testing.

Most of the rest of the world either bans bioengineered foods and crops outright or mandates their approval. Although most wealthy industrial countries in theory permit the planting and importing 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).

### *Labeling Requirements*

Many countries require, or intend to require in the future, mandatory 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. 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 EU requires labels on all final products containing bioengineered ingredients, including food additives and flavorings. A 2000 EC regulation specifies 1% bioengineered-ingredient content as a labeling trigger (EC 2002), and the European Parliament recently voted for a 0.5% threshold (*Food Traceability Report 2002*). Both of these thresholds would be difficult to meet in an area containing both nonbioengineered and bioengineered foods.

Many other countries require mandatory labeling of bioengineered foods. 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 [FSANZ] 2002). Japan has also adopted a mandatory labeling system, but with a 5% threshold. Food manufacturers can likely meet this with a much lower investment in identity-preservation systems than would be required for a 1% threshold.

A voluntary policy allowing for the labeling of nonbioengineered foods but not requiring mandatory positive labels, which is the likely U.S. policy, would have minimal effect on the potential market for bioengineered foods. Food companies making

a nonbioengineered labeling claim would have to put in place some sort of identity-preservation system to support their claim, but would only do so if the expected premium for their product was sufficient to cover the costs of the identity-preservation system. However, a mandatory labeling requirement in major agricultural importing countries such as the EU and Japan may bring great pressure on exporting nations, including the United States, to conform to importer requirements in order to maintain access to these substantial markets. In this case, if food companies wanted to avoid a positive bioengineered label, they would bear the burden of putting in place an identity-preservation system but would likely not obtain a price premium for the product.

### **Manufacturer Interviews**

As part of a larger study to evaluate how food manufacturers are assessing and responding to issues arising from the availability of bioengineered foods, we investigated the types of identity preservation systems currently in use by food-manufacturing establishments.<sup>2</sup> We developed a protocol for conducting interviews with food manufacturers producing conventional, organic, and kosher foods. As part of the interviews with conventional food manufacturers, we also asked questions about their perceptions and reactions to the StarLink corn incident.<sup>3</sup>

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.<sup>4</sup> We conducted the interviews during the summer and fall of 2001.

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<sup>2</sup> See Muth, Mancini, and Viator (2002) or Muth et al. (2002) for descriptions and results of the larger study.

<sup>3</sup> The StarLink corn incident occurred when corn approved for use in animal feed was inadvertently introduced into the U.S. food supply in fall 2000.

<sup>4</sup> Copies of the interview guides are available from the authors.

## Results Of Interviews

The overall responses of the interviews for conventional, organic, and kosher food production indicate that many food manufacturers already have experience with the types of identity-preservation systems needed to produce nonbioengineered or enhanced bioengineered foods. This experience comes not only from producing organic or kosher foods but also from producing other types of differentiated food products and controlling allergens in food products. Furthermore, because of the StarLink corn event, many food manufacturers who previously did not have any experience with identity-preservation systems implemented what might be considered the first steps of such a system. To ensure that StarLink corn was not inadvertently introduced into the production system, food manufacturers using corn ingredients began to require supplier certifications and to test incoming ingredients.

As we learned through the interviews, a more extensive identity-preservation system might include one or more of the following general steps: (1) ingredient control and supplier certifications, (2) ingredient testing, (3) separation of facilities and equipment, (4) scheduling of production and conducting changeovers, (5) use of written guidelines, (6) use of recordkeeping systems, (7) final product testing, and (8) 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 identity-preservation system. The least stringent systems are those for producing foods enhanced through conventional methods or bioengineering, because their functional properties are preserved even with a small amount of contamination. The most stringent systems are those for avoiding the introduction of allergens into the food products or for maintaining extremely low tolerances for bioengineered content. Organic and kosher production systems have different levels of stringency that fall between the two extremes. Food manufacturers may choose to produce organic foods at three different levels of stringency as specified by the National Organic Program (USDA AMS 2000). For kosher foods, food manufacturers follow the standards of one or more of several hundred different kosher supervision agencies with different levels

of stringencies.

Table 1 provides a qualitative comparison of the types of controls that might be part of an identity-preservation system for allergen control, exclusion of StarLink corn, organic foods, kosher foods, and segregation of nonbioengineered or enhanced bioengineered foods. The identity-preservation system for excluding StarLink corn is perhaps the least difficult of these; once ingredients are tested, no other activities are usually needed. The other control mechanisms may or may not be required for the remaining identity-preservation systems.

In implementing identity-preservation systems, issues facing food manufacturers include feasibility of implementation, cost of implementation, availability of testing as verification or validation of the system, and assessment of consumer demand for products with attributes preserved through 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 perceptions within the food-manufacturing company, and availability of commodities or ingredients with desired attributes.

The costs of identity-preservation systems arise from five general activities: certifying and obtaining ingredients, testing incoming ingredients or final products, separating equipment and facilities, scheduling production and conducting changeover procedures, and conducting recordkeeping activities. Each of these activities may have associated capital-equipment, labor, and materials costs. In addition, food manufacturers incur costs for testing to verify that incoming commodities and ingredients have their desired attributes and that the identity-preservation system has prevented comingling during the production process. However, no test method exists for detecting bioengineered content in processed foods without intact DNA or protein.

## Conclusion

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

**Table 1. Comparisons of Controls for Different Types of Identity-Preservation Systems.**

Types of Controls	Allergen Control	StarLink Corn	Organic	Kosher	Segregation of Nonbioengineered/Bioengineered
Ingredient Control and Supplier Certifications	<ul style="list-style-type: none"> <li>• Conduct ingredient supplier audits.</li> <li>• Request allergen content information on a specified frequency.</li> </ul>	<ul style="list-style-type: none"> <li>• Require suppliers to certify that incoming corn ingredients are not produced from StarLink corn.</li> </ul>	<ul style="list-style-type: none"> <li>• Require ingredients to be certified organic.</li> <li>• Some contract with farmers.</li> <li>• Conduct supplier field audits.</li> </ul>	<ul style="list-style-type: none"> <li>• Require ingredients to bear a kosher seal (except fresh fruits and vegetables).</li> <li>• Ingredients must be on approved list on file with the rabbi.</li> </ul>	<ul style="list-style-type: none"> <li>• Require certificate of analysis or other documentation for ingredients.</li> <li>• Some contract with farmers.</li> </ul>
Ingredient Testing	<ul style="list-style-type: none"> <li>• Not usually conducted.</li> </ul>	<ul style="list-style-type: none"> <li>• Require suppliers to test for StarLink corn or use an ELISA dipstick test.</li> </ul>	<ul style="list-style-type: none"> <li>• Not usually conducted because ingredient suppliers are certified organic.</li> </ul>	<ul style="list-style-type: none"> <li>• Rarely conducted except in unusual circumstances.</li> </ul>	<ul style="list-style-type: none"> <li>• If a test method is available, test ingredients using PCR or ELISA-based test.</li> </ul>
Separation of Equipment and Facilities	<ul style="list-style-type: none"> <li>• Some manufacturers dedicate equipment or facilities to all allergenic or allergen-free foods.</li> </ul>	<ul style="list-style-type: none"> <li>• Not applicable (excluded from plant).</li> </ul>	<ul style="list-style-type: none"> <li>• Most manufacturers use shared equipment with conventional production.</li> </ul>	<ul style="list-style-type: none"> <li>• Most manufacturers use shared equipment with nonkosher production.</li> </ul>	<ul style="list-style-type: none"> <li>• Some manufacturers will dedicate equipment and facilities, and others will share these.</li> </ul>
Scheduling of Production and Conducting Changeovers	<ul style="list-style-type: none"> <li>• Produce nonallergenic foods first and then allergenic foods.</li> <li>• Clean the system prior to starting nonallergenic food production.</li> <li>• Test first part of nonallergenic food production run or discard.</li> </ul>	<ul style="list-style-type: none"> <li>• Not applicable.</li> </ul>	<ul style="list-style-type: none"> <li>• Produce organic foods first, then conventional foods.</li> <li>• Clean the system prior to starting organic production again.</li> <li>• Treat first part of organic production as conventional.</li> </ul>	<ul style="list-style-type: none"> <li>• Produce kosher pareve (non-dairy) first, then kosher with dairy, followed by nonkosher.</li> <li>• Kosherize the system in the presence of a rabbi prior to starting kosher pareve production.</li> </ul>	<ul style="list-style-type: none"> <li>• Produce nonbioengineered or enhanced bioengineered first, then switch, with clean-out procedures between production runs.</li> </ul>

Note: FDA/CFSAN = U.S. Food and Drug Administration, Center for Food Safety and Nutrition; GMP = good manufacturing practices; NOP = national organic program; PCR = polymerase chain reaction; SOP = standard operating procedures; UPCs = universal product codes.

**Table 1. Comparisons of Controls for Different Types of Identity-Preservation Systems.**

Types of Controls	Allergen Control	StarLink Corn	Organic	Kosher	Segregation of Nonbioengineered/Bioengineered
Use of Written Guidelines	<ul style="list-style-type: none"> <li>Internally developed by the manufacturer as part of GMPs or SOPs.</li> </ul>	<ul style="list-style-type: none"> <li>Guidance provided by FDA/CFSAN.</li> </ul>	<ul style="list-style-type: none"> <li>Developed jointly with an organic inspection agency.</li> </ul>	<ul style="list-style-type: none"> <li>Developed jointly with the kosher supervision agency.</li> </ul>	<ul style="list-style-type: none"> <li>Internally developed by the manufacturer as part of GMPs or SOPs.</li> </ul>
Use of Specialized Record Keeping Systems	<ul style="list-style-type: none"> <li>Use a coding system for traceability of product.</li> </ul>	<ul style="list-style-type: none"> <li>Not applicable.</li> </ul>	<ul style="list-style-type: none"> <li>Maintain records on sources of ingredients (using UPCs) for all batches, cleaning, and inspection.</li> </ul>	<ul style="list-style-type: none"> <li>Limited additional records because a rabbi is present when commingling might occur.</li> </ul>	<ul style="list-style-type: none"> <li>Depends on type of ingredient (more required if the crop from which it is derived has ever been bioengineered).</li> </ul>
Final Product Testing	<ul style="list-style-type: none"> <li>Frequently conducted to verify no residues.</li> </ul>	<ul style="list-style-type: none"> <li>Not applicable.</li> </ul>	<ul style="list-style-type: none"> <li>None because controls are in place earlier in system.</li> </ul>	<ul style="list-style-type: none"> <li>Rarely conducted.</li> </ul>	<ul style="list-style-type: none"> <li>Test methods are not effective on many processed food products.</li> <li>Tests are costly and only conducted if a problem is suspected.</li> </ul>
Third-Party Certification	<ul style="list-style-type: none"> <li>None.</li> </ul>	<ul style="list-style-type: none"> <li>None.</li> </ul>	<ul style="list-style-type: none"> <li>Through public and private organic inspection agencies.</li> <li>Three levels of standards specified in the NOP.</li> </ul>	<ul style="list-style-type: none"> <li>Through kosher supervision agencies.</li> <li>Hundreds of different levels of standards.</li> </ul>	<ul style="list-style-type: none"> <li>Developing through private certification companies.</li> </ul>

Note: FDA/CFSAN = U.S. Food and Drug Administration, Center for Food Safety and Nutrition; GMP = good manufacturing practices; NOP = national organic program; PCR = polymerase chain reaction; SOP = standard operating procedures; UPCs = universal product codes.

consumer preferences. Thus, depending on the regulatory environments in the markets in which they produce and market food products, food manufacturers appear to have the capability to produce nonbioengineered or enhanced bioengineered foods. However, some food manufacturers, particularly smaller ones, will choose to avoid the use of bioengineered foods. In addition, the availability of testing methods for verification of the identity-preservation systems may be a limitation for many types of food products.

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