



IFT Expert Report on Biotechnology and Foods

Background—Biotechnology and Foods: Executive Summary

The Institute of Food Technologists (IFT) in 1999-2000 convened three panels of experts, consisting of IFT members and other prominent biotechnology authorities, to prepare a comprehensive scientific report on biotechnology. The report consists of four sections: Introduction, Safety, Labeling, and Benefits and Concerns. The sections were published in the August, September and October 2000 issues of *Food Technology*. This document summarizes the findings of the panels.

Introduction

Modern biotechnology refers to a group of techniques that have wide application in research and commerce. One of these applications, recombinant deoxyribonucleic acid (rDNA) biotechnology, has become the focus of intense public scrutiny and debate. Commonly known as genetic modification or gene splicing, rDNA biotechnology allows for the effective and efficient transfer of genetic material from one organism to another. Instead of cross-breeding plants for many generations or introducing mutations to introduce a desired trait—processes that are imprecise and that sometimes introduce unwanted changes—scientists can identify and insert one or more genes responsible for a particular trait into a plant or microorganism with greater precision and speed. These transferred genes, or transgenes, do not have to come from a related species in order to be functional, and can be moved virtually at will among different living organisms.

The first rDNA biotechnology-derived food plant marketed in the United States was the *FlavrSavr*TM tomato, introduced in 1994. This tomato carried an “antisense” gene for the enzyme that is responsible, in large part, for fruit softening. The antisense gene reduced the production of the ripening enzyme. Other rDNA biotechnology-derived crops that soon followed included squash resistant to some strains of zucchini yellows and watermelon mosaic viruses in 1994, insect-resistant potato and corn in 1995 and 1996, and herbicide-tolerant soybean and canola in 1996. Others under development are expected to appeal more directly

to consumers. These include fruits, root and leaf vegetables, and grains with enhanced nutritional and health-promoting properties.

Although biotechnology is widely viewed as new, the plants and animals that modern agriculture produces today to feed the world’s people are the result of over 10,000 years of continuous genetic modification and refinement. Corn, for example, is a classic example of traditional selective breeding. Other crops resulting from such conventional breeding techniques include tomato, potato, corn, oat, sugar beet, bread and durum wheat, rice, and pumpkin. Conventional techniques for crop improvement share the disadvantage that they are by nature imprecise and unpredictable, and only occasionally useful.

Recombinant DNA techniques involve the introduction of one or a few defined genes into a plant much more precisely than the techniques breeders have employed for millennia. Recombinant DNA techniques have provided both an important new set of tools for scientists and access to a broader range of markets. They enable researchers to identify, characterize, enhance, and transfer the appropriate individual genes rather than work with undefined and randomly assorted groups of genes, hoping the desirable ones were included using conventional selected breeding. With precision, researchers can now readily move selected and well-characterized genetic material from virtually any source in nature, greatly increasing the diversity of useful genes available for crop and microbe improvement.

Two methods of plant transformation involving rDNA biotechnology are in use at the present time: free-DNA and T-DNA. In the free-DNA method, DNA carrying the gene of interest is literally shot into cultured plant cells. This method allows the introduction of precise sequences of DNA, but it is difficult to predict exactly where the sequence will be integrated. In the T-DNA method, nonpathogenic DNA from a bacterial plant pathogen, *Agrobacterium tumefaciens*, carries the genes of interest into the host-cell chromosome. The T-DNA method greatly increases the precision of DNA insertion. In both cases, the precision of rDNA biotechnology permits

In an effort to contribute to a meaningful dialogue on scientific issues and consumer concerns about rDNA biotechnology, the Institute of Food Technologists, a 29,000 member non-profit society for food science and technology, conducted a comprehensive review of biotechnology. IFT convened three panels of experts, consisting of IFT members and other prominent biotechnology authorities, to evaluate the scientific evidence and write a report divided into four sections: Introduction, Safety, Labeling, and Benefits and Concerns. Copies of the complete report are available from IFT. E-mail: sciencecom@ift.org; phone: (312) 782-8424; www.ift.org.

accurate determination of the location and number of copies of the inserted DNA, even if the location of DNA insertion cannot be controlled.

Government Regulation. The Coordinated Framework for Regulation of Biotechnology, prepared by the Office of Science and Technology Policy (OSTP) and published in the June 26, 1986, *Federal Register*, is the comprehensive U.S. policy for ensuring the safety of biotechnology research and products. It explains the coordination among federal agencies.

OSTP's 1992 document, *Exercise of Federal Oversight within Scope of Statutory Authority: Planned Introductions of Biotechnology Product into the Environment*, describes a risk-based, scientifically sound approach to the oversight of planned introductions of rDNA biotechnology-derived products into the environment. It focuses on the characteristics of the product and the environment into which it is introduced, not the process by which the product is created. The ultimate goal of the regulatory agencies is to ensure the overall safety of foods, food ingredients, and feeds produced using rDNA biotechnology.

Food Safety. FDA is responsible for ensuring the safety and proper labeling of human food and animal feed. The agency's policy on foods and animal feed derived from new plant varieties developed by conventional and new breeding techniques is that existing requirements mandate the same safety standards for foods, food ingredients, and feeds, regardless of the techniques used in their production and manufacture. FDA maintains a "voluntary consultation procedure," in which producers of rDNA biotechnology-derived foods are asked to consult with the agency before marketing their products.

Meat and Poultry Safety. The Food Safety and Inspection Service (FSIS) of the U.S. Dept. of Agriculture (USDA) is responsible for regulating the safety and labeling of meat and poultry products for human consumption. FSIS consults with FDA regarding the safety of food ingredients.

Field Testing and Permits. Under the Plant Quarantine Act and the Federal Plant Pest Act, the Animal and Plant Health Inspection Service (APHIS) regulates the importation and interstate movement of plants and plant products that may result in the entry into the United States of injurious plant diseases or insect pests. The field-testing and the commercial sale of rDNA biotechnology-derived crops are regulated by APHIS through a permit and notification system.

Animal Vaccines. APHIS regulates animal vaccines under the Virus-Serum-Toxin Act. In general, animal vaccines are subject to pre-market approval, based on testing to show their safety and effectiveness.

Pesticides. Pesticides produced by plants developed using rDNA biotechnology are regulated by the Environmental Protection Agency. EPA's 1994 proposed rule states that plants are subject to regulation only if they produce plant

pesticidal proteins as a result of modification with rDNA techniques. The National Research Council accepts this approach, but 11 major scientific societies representing more than 80,000 biologists and food professionals oppose it.

Safety

Products derived through rDNA biotechnology are assessed for safety before their introduction into the food marketplace. Food manufacturers also must ensure the safety and quality of products that contain ingredients derived from rDNA biotechnology. In 1992, FDA provided a general outline for the safety assessment of rDNA biotechnology-derived food products based on risk analysis related to the characteristics of the products.

Substantial Equivalence. In the safety assessment of rDNA biotechnology-derived foods, it is helpful to compare the new plant variety to its traditional counterpart because the counterpart has a history of safe use as a food. Substantial equivalence is not an absolute determinant of safety per se, since compositional changes in an rDNA biotechnology-derived food may have no impact on the safety of the food. However, substantial equivalence provides a process to establish that the composition of the plant has not been changed in such a way as to introduce any new hazards into the food, to increase the concentration of inherent toxic constituents, or to decrease the customary content of nutrients. Recombinant DNA biotechnology-derived foods without conventional counterparts need to be evaluated on a case-by-case basis and would be subject to some types of toxicity assessments, depending on the nature of the modification.

Allergenicity. Virtually all food allergens are proteins, although only a small fraction of the proteins found in nature (and in foods) are allergenic. Since genetic modifications involve the introduction of new genes into the recipient plant and since these genes would produce new proteins in the improved variety, the potential allergenicity of the newly introduced protein should be a key component of the safety assessment process.

International Scientific Consensus on Safety. The safety of rDNA biotechnology-derived foods has been extensively reviewed by a number of scientific organizations, at the national and international level. These organizations recognize that the use of rDNA biotechnology in itself has no impact on the safety of such foods.

The National Research Council published a report in 2000 reaffirming principles set forth in a 1987 National Academy of Sciences white paper, stating that with "careful planning and appropriate regulatory oversight, commercial cultivation of transgenic pest-protected plants is not generally expected to pose higher risks and may pose less risk than other commonly used chemical and biological pest-management techniques."

In 1991, a joint report of the Food and Agriculture Organization (FAO) and the World Health Organization

(WHO) of the United Nations concluded: “Biotechnology has a long history of use in food production and processing. It represents a continuum embracing both traditional breeding techniques and the latest techniques based on molecular biology. The newer biotechnological techniques, in particular, open up very great possibilities of rapidly improving the quantity and quality of food available. The use of these techniques does not result in food which is inherently less safe than that produced by conventional ones.”

IFT’s Conclusions. Based on its evaluation of the available scientific evidence, IFT’s Human Food Safety Panel reached the following conclusions:

- Biotechnology, broadly defined, has a long history of use in food production and processing. It represents a continuum that encompasses both centuries-old traditional breeding techniques and the latest techniques based on molecular modification of genetic material. The newer rDNA biotechnology techniques, in particular, offer the potential to rapidly and precisely improve the quantity and quality of food available.
- Crops modified by modern molecular and cellular methods do not pose risks any different from those modified by earlier genetic methods for similar traits. Because the molecular methods are more specific, users of these methods will be more certain about the traits they introduce into the plants.
- The evaluation of food, food ingredients, and animal feed obtained from organisms developed with the newer rDNA biotechnology techniques of genetic manipulation does not require a fundamental change in established principles of food safety; nor does it require a different standard of safety, even though, in fact, more information and a higher standard of safety are being required.
- The science that underlies rDNA biotechnology-derived foods does not support more stringent safety standards than those that apply to conventional foods.
- The use of rDNA biotechnology and molecular techniques of genetic manipulation significantly broadens the scope of the genetic changes that can be made in food organisms and broadens the scope of possible sources of foods, but this does not inherently lead to foods that are less safe than those developed by conventional techniques. By virtue of their greater precision, such products can be expected to be better characterized, leading to more predictability and an easier safety assessment process.

Labeling

Labeling requirements that apply to foods in general also apply to foods produced using rDNA biotechnology. Generally speaking, the FDA has authority over food labeling, and the Federal Trade Commission (FTC) has authority

over food advertising. Under the Federal Food Drug and Cosmetic Act (FFDCA), FDA regulates food labeling through a series of requirements that are intended to assure that the information of significance about a food product is provided and that the food labeling is truthful and non-misleading. FDA’s authority to require specific labeling on foods is limited to the existence of material fact by the FFDCA and considerations of the First Amendment of the Constitution.

FDA requires labeling of rDNA biotechnology-derived foods that differ significantly in composition, nutritional value, or safety from their conventional counterparts. If a safety or usage issue exists for the new food, a statement must be made on the label to describe the issue. For example, if a food produced using rDNA biotechnology has significantly different nutritional properties, its name must reflect the difference (e.g., “high oil corn”). Likewise, if a new food includes an allergen that consumers would not expect based on the name of the food, such as the hypothetical use of a peanut protein in a tomato, the presence of that allergen must be stated on the label.

Foods that are not rDNA biotechnology-derived may be labeled as such in a truthful and non-misleading manner. A processor asserting that a product includes no rDNA biotechnology-derived ingredients must be able to substantiate that claim to provide reasonable assurance of its accuracy.

International Perspectives. The regulation of rDNA biotechnology-derived foods differs widely in other countries. Some countries do not allow them to be imported at all, on the basis that not enough is known about the long-term effects of consuming rDNA biotechnology-derived foods. Other countries permit such foods, with requirements that each food disclose on the label that it was produced using rDNA biotechnology. Still other countries, like the United States, compare the new plant variety to varieties produced using conventional breeding to identify differences for safety evaluation and to determine whether the differences need to be described on the food label. These countries do not require statements that the food was derived using rDNA biotechnology.

The primary international forum for discussion of labeling of biotechnology-derived foods is the Codex Alimentarius Commission (Codex). The Codex Committee on Food Labelling (CCFL) has been discussing how rDNA biotechnology-derived foods should be labeled for several years. The goal is to have a single approach to labeling requirements.

Consumer Opinion. In a 2000 survey by the Wirthlin Group, the majority of consumers supported FDA’s labeling policy, and 28 percent opposed the policy. When presented with an alternative view, that all rDNA biotechnology-derived products should be labeled, 52 percent continued to support FDA’s policy, 43 percent supported labeling all products, and 5 percent did not know.

General consumer research has shown that label statements should be clear and not misleading and should provide salient facts to the consumer. Consumers indicated that labeling should be in laymen's terms, use consistent terminology, and follow a standard format.

IFT's Conclusions. IFT's Labeling Panel concludes that the following facts are fundamental to resolving issues regarding the labeling of rDNA biotechnology-derived foods in the United States:

- Within the constitutional framework, the FFDCFA provides for a food labeling regulatory regime that is intended to ensure that information about food products is presented to consumers in a truthful, non-misleading manner. This regulatory system requires disclosure of any significant difference in the characteristics of an rDNA biotechnology-derived food when compared with its conventional counterpart. In addition, voluntary label statements must be substantiated and not misleading, either overtly, by implication, or by omission.
- Mandatory label disclosure requirements may not reach beyond addressing material facts about a food. If rDNA biotechnology were used in the development of a plant variety but the rDNA biotechnology-derived food was not significantly different from the conventional counterpart, there would be no material fact regarding the food to disclose. Thus, absent significant differences, the fact that a food is rDNA biotechnology-derived is not by itself a material fact.
- Voluntary labeling has been used to establish markets for niche categories of foods desired by consumers.
- Any labeling requirements or policies to distinguish rDNA biotechnology-derived foods from other foods would require definitions and monitoring tools sufficiently precise to meet the objectives of the requirement or policy.
- Labeling initiatives for rDNA biotechnology-derived foods are likely to have substantial effects on the production, distribution, and cost of food to consumers.
- If a voluntary labeling initiative to distinguish rDNA biotechnology-derived foods is pursued, broad stakeholder agreement should be achieved regarding appropriate substantiation of claims.
- Terminology used in labeling should convey information to the public in an understandable, accurate, and non-misleading manner.

Benefits and Concerns

New technologies rarely receive a broad and enthusiastic welcome. Canned food, for its first hundred years, was viewed apprehensively, and not without reason. In those pre-bacteriology days, it was far more an uncertain art

than a solid science. Pasteurized milk, a life-saving technology in its elimination of the microorganisms causing tuberculosis and undulant fever, was originally viewed with deep suspicion. Artificial insemination of farm animals—critical in selective breeding of improved livestock—was regarded as tampering with nature. Recombinant DNA biotechnology is no exception.

Recombinant DNA biotechnology offers numerous benefits and raises a number of concerns, some more legitimate than others. Examination of the science diffuses many of these concerns. Other concerns are less or no more severe than those associated with conventional breeding techniques that have been practiced for centuries.

Based on its evaluation of currently available scientific information, IFT's Benefits and Concerns Panel concludes that further development and use of food rDNA biotechnology provides a number of benefits:

- A more abundant and economical food supply for the world.
- Continued improvements in nutritional quality, including foods of unique composition for populations whose diets lack essential nutrients. For example, "golden rice" has been genetically modified through rDNA biotechnology to have increased beta-carotene content, which may help to overcome the severe vitamin A deficiencies which cause millions of poor children to go blind or die every year in low-income, rice-consuming cultures.
- Fresh fruits and vegetables with improved shelf life.
- Foods with reduced allergenicity. For example, rDNA biotechnology has already been used to dramatically reduce the levels of the major rice allergen. Similar approaches could be attempted with more commonly allergenic foods such as peanuts.
- The development of functional foods, vaccines, and similar products that may provide health and medical benefits. Researchers, for example, have developed a system to produce in tobacco plants a therapeutic vaccine against non-Hodgkin's B-cell lymphoma in mice.
- Further improvements in production agriculture through more efficient production practices and increased yields. Plant breeders, for example, have used rDNA biotechnology to develop a corn that is easier for farm animals to digest. A further improvement came with the development of nutritionally dense corn, which has increased amounts of oil, protein, and essential amino acids necessary for optimal animal growth.
- The conversion of nonproductive toxic soils in developing countries to productive arable land.
- More environmentally friendly agricultural practices through improved pesticides and pesticide usage

practices, less hazardous animal wastes, improved utilization of land, and reduced need for ecologically sensitive land such as rain forests.

With regard to several environmental and economic concerns about rDNA biotechnology-derived food production, IFT's Benefits and Concerns Panel concludes that:

- New rDNA biotechnology-derived foods and food products do not inherently present any more serious environmental concerns or unintended toxic properties than those already presented by conventional breeding

practices, which have an impressive safety record.

- Appropriate testing by technology developers, producers and processors, regulatory agencies, and others should be continued for new foods and food products derived from all technologies, including rDNA biotechnology.
- Programs should be developed to provide the benefits of safe and economical rDNA biotechnology-derived food products worldwide, including less-developed countries. ●