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Genetically modified foods raise new legal issues

Bioengineered comestibles face a long chain of regulations, and potential tort claims, as well.

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THE ACCIDENTAL RELEASE into the human food chain of genetically modified corn—approved for animal consumption and industrial uses, but not for human consumption—has contributed to a nationwide debate over genetically modified foods.¹ The debate has focused on whether the United States should permit, much less promote, the dissemination of genetically modified foods for human consumption, and whether and how those foods should be grown, processed and distributed. This article discusses these issues; surveys the types of tort claims that could arise for manufacturers, distributors and growers of these food products; and suggests several ways that industry participants can take precautions to potentially reduce the risk of exposure.

Genetically modified foods, often referred to as genetically engineered or bioengineered foods, are commercially produced products that have been modified with the genetic material of another organism, such as a plant, animal or bacterium. The modification is accomplished through techniques by which the genetic material, known as DNA, from one organism is introduced into the DNA of another organism. The effect is that the recipient organism develops certain “agronomic traits,” such as resistance to insects, herbicides or disease.

The means of combining the DNA from one organism with that of another is often referred to as recombinant DNA or genetic engineering technology, and the introduced DNA usually comes in the form of a gene. Genes are segments of DNA that provide instructions as to how to manufacture certain proteins. Proteins are molecules that exhibit certain properties and perform specific biological functions. An organism

essentially uses the instructions contained in a gene as directions for building the proteins that allow the organism to function.

Bioengineered crops such as corn might be genetically modified to contain one or more genes that confer certain beneficial properties. For example, genes from bacteria that encode insect-resistant or herbicide-resistant proteins might be inserted. The inserted gene then allows the genetically modified plant to produce the insect- or herbicide-resistant proteins and confer those agronomic traits on the plant. Other examples of bioengineering include gene modifications that extend the shelf-life of fresh foods, such as tomatoes.

The public and legal debate

The public policy debate over human consumption of bioengineered foods has been active, particularly in Europe. The many commentators who support bioengineering focus on its potential to increase the world food supply and curb world hunger, poverty and disease. Proponents argue that the powerful tool of genetic engineering is no different from any other technological advance and that responsible use of this technology, based on validated scientific principles, holds the potential for significant advances in human and animal health, land productivity, food availability and environmental protection because it will reduce the need for chemical pesticides, herbicides, fungicides and the like. Yet those who object to genetically modified crops believe that the plants could contaminate the environment, damage ecosystems or otherwise adversely affect the ecological balance.

In fact, the legal controversy over bioengineered plants and foods is not new. There have been numerous lawsuits over the right to commercialize the products of recombinant DNA technology, as well as the intellectual property rights to the technology

itself. The early legal battles centered largely on whether genetically modified microorganisms and genetically engineered drugs were patentable.

More recently, legal disputes have arisen over the ownership rights to the various technological components, as well as the privacy issues related to the use of genetic technologies to ascertain information about the genetic makeup of individuals. The U.S. Patent and Trademark Office, the federal agency responsible for issuing patents, has itself struggled with whether genes and the products of recombinant DNA technology are patentable, and it recently issued guidelines for biotechnology inventions.²

In 2000, farmers throughout the world grew genetically modified strains of a wide variety of crops—including soybeans, cotton, corn, canola, potatoes, squash, papayas, melons and tomatoes. Bioengineered agricultural products grow on many millions of hectares worldwide. As the numbers increase, human consumption of genetically modified foods will also increase, as will the number of people living near the fields that grow bioengineered crops. These facts alone will inevitably produce a reciprocal harvest of new liability theories brought by fearful or dissatisfied claimants.

Regulatory web

As an initial matter, it is important to note that genetically modified foods can be subject to myriad overlapping, and potentially inconsistent, regulatory regimes by various federal agencies. The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA), to name a few, each has some jurisdiction over genetically modified foods. Depending on the commodity in question, the products can be subject to multiple sets of regulations and guidance documents promulgated by separate divisions within each agency. For

the commercial market for these products to grow, the industry must quickly develop strategies for moving products from the laboratory to greenhouses and to the field, while simultaneously reporting the data demanded by each applicable regulatory body.

For example, genetically modified corn is regulated by the EPA under the Federal Insecticide, Fungicide and Rodenticide Act³; by the FDA under the federal Food, Drug and Cosmetic Act⁴; and by the USDA under the Animal and Plant Health Inspection Act (which is part of the Federal Plant Pest Act)⁵ and the Plant Protection Act.⁶

In May 2000, the Clinton administration's Council on Environmental Quality and the Office of Science and Technology Policy established an Interagency Working Group to conduct a six-month "interagency assessment of Federal environmental regulations pertaining to agricultural biotechnology and, if appropriate, make recommendations to improve them."⁷ The group produced an impressive collection of research and case studies but ran out of time to propose improvements to the complicated regulatory scheme.⁸

Products liability claims

Despite the benefits of the technology and the absence of proof as to harm from bioengineered foods, a number of products liability claims could potentially emerge as the manufacture and distribution of these products increase. Because tort law is flexible and designed to evolve, it is often difficult to predict the type and scope of future tort claims. Creative plaintiffs' attorneys are likely to craft claims based on a host of legal theories, including negligence and strict products liability, economic injury or even claims for emotional distress. Manufacturers and distributors of these food products must be proactive in anticipating and avoiding such claims.

A negligence or strict products liability claim could arise in a variety of situations, such as the unintentional introduction of a product containing secondary toxins as byproducts, or a product containing antibiotics that allegedly cause a consumer to develop resistance to that antibiotic. Perhaps the most widely discussed area of potential concern is the possible introduction of new allergens. Because

producers need not label products that contain genetically altered material unless they carry a known allergen, consumers might not realize that a substance to which they may be allergic is contained in a bioengineered product. This could place the agricultural biotechnology industry in the unenviable position of trying to disprove the alleged relation of its product to allergic reactions.

Similar claims could involve allegations that a product has somehow compromised a consumer's immune system, much like claims advanced in the recent breast implant litigation. Or there could be claims that a bioengineered food has caused other difficult-to-measure ailments, such as impaired learning ability, similar to contentions plaintiffs have made in the ongoing lead paint litigation. This type of claim would pose enormously complex causation issues, given the many potentially relevant influences on mental ability. Again, industry participants in the promising field of agricultural biotechnology may face similar legal challenges.

A further, but remote, possibility might be a claim for infliction of emotional distress filed by a consumer of a bioengineered food product containing genetic material from an organism whose mere presence arguably violates the consumer's religious or moral beliefs. For example, a vegetarian or vegan might object to consuming vegetables bioengineered with growth hormones of animal origin. Similar issues might arise in the context of dietary restrictions observed in orthodox religious traditions. Such claims, although exceedingly unlikely to succeed, or even to be brought, are nevertheless within the realm of possibility.

Taking precautions

Manufacturers and distributors should be proactive to lessen chances of legal exposure. They can aim to protect themselves contractually to some extent by including indemnity provisions and consequential damages limitations in their agreements with one another and with others in the distribution chain. They might also consider

negotiating limitations on liability for later-discovered detrimental health and environmental effects, to the extent practicable. As with any contractual arrangement, precise language is more likely to be enforced by a court than vague disclaimers. Manufacturers and distributors should also investigate whether they can secure special insurance coverage to protect against later-discovered health and environmental effects or against unintended releases.

There is no substitute, however, for communication and education. Manufacturers and distributors can educate others in the distribution chain about what the genetically altered product in question contains and why it was so modified; for example, some

corn is modified with insect-resistance genes to promote decreased pesticide use. They can also take an active role in helping to educate the public about the health and environmental benefits of this technology, as well as industry efforts to guard against adverse effects.

Similarly, the press does not widely cover the extensive testing required before a product can gain regulatory approval—testing that costs millions of dollars, takes years and addresses a host of health and environmental concerns. The more open and balanced the debate, the better the true risks and benefits of genetically modified foods will be understood.

A remote possibility is a claim for infliction of emotional distress by a consumer on moral grounds.

(1) See, e.g., "Kellogg Shuts Memphis Plant Over Genetically Altered Corn," N.Y. Times, Oct. 22, 2000, at 22; Marc Kaufman, "Firm Seeks Temporary Approval for Biotech Corn," Wash. Post, Oct. 26, 2000, at A3.

(2) See Elizabeth S. Weiswasser, "New PTO Guidelines to Affect Biotech Inventions," NLJ, Feb. 5, 2001, at C3.

(3) 7 U.S.C. 136 et seq.

(4) 21 U.S.C. 301 et seq.

(5) 7 U.S.C. 150aa et seq. as amended by Pub. Law No. 106-387, Oct. 28, 2000, 114 Stat. 1549.

(6) 7 U.S.C. 7711 et seq.

(7) See Center for Environmental Equality & Office of Science and Technology Policy, CEQ and OSTP Assessment: Case Studies of Environmental Regulations for Biotechnology, Jan. 12, 2001, at 1, available at www.ostp.gov/html/012201.html.

(8) Id.