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Article

*1645 THE INTRODUCTION OF BIOTECH FOODS TO THE TORT SYSTEM:
CREATING A NEW DUTY TO IDENTIFY

(EXCERPT)

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I. Introduction

The United States is one of the world's largest producers of genetically modified organisms [FN1] used as food (biotech food). [FN2] The first biotech food product hit the market in the United States in 1995. [FN3] Now, industry experts estimate that as much as seventy percent of the packaged food on grocery store shelves may contain bioengineered ingredients. [FN4] However, most consumers are unaware of this fact as food processors in the United States are not required to identify biotech ingredients on food labels. [FN5] In addition, the Food and Drug Administration (FDA) [FN6] does not require pre-market testing to ensure the safety of most biotech food. [FN7] This raises health concerns since the new generation*1646 of biotech food will introduce substances into food that have never been part of the food supply and will contain genetic modifications that will be “substantially more complex than the single-gene, single-trait modifications of the first generation of GE crops.” [FN8] Among the most significant of these health concerns is the introduction of potentially deadly new allergens and toxins into the food supply.

This Article examines the question of whether an unsuspecting consumer who dies from an allergic or toxic reaction [FN9] to an undisclosed biotech ingredient in food can recover damages through the tort system. The surprising answer is that

recovery is very unlikely. This Article outlines why this is the case, then evaluates the merits of several potential solutions to this problem including the possible creation of a common law “duty to identify” biotech ingredients in food.

This Article is arranged as follows. First, a brief primer on the nature of biotech foods is provided. For the reader unfamiliar with the regulatory system governing food products, this Article proceeds to survey the regulatory scheme currently applied by the FDA to most food products, including biotech foods. Then, the Article provides a brief *1647 primer on food allergies and toxicities. This Article then summarizes current theories of tort liability that courts apply to the vast majority of products, except traditional foods. A detailed description of the very distinct theories of tort liability that apply to traditional food products follows.

Next, the Article exposes the unintended result of the FDA's decision to regulate biotech food as if it were traditional food, when this regulatory system, as applied to biotech food, is scrutinized in conjunction with current theories of tort liability for harm caused by the ingestion of food products. Juxtaposing one against the other reveals that the entire biotech food industry may be insulated from liability for harm from potential new allergens or toxins contained in its products.

In the final section, this Article suggests several possible solutions to this inadvertent tort immunity problem, evaluating the merits of each and concluding that the most plausible solution may lie in the court system. [FN10] This Article proposes that courts avoid the application of food product liability theories to evaluate harm from the ingestion of biotech food and instead apply the utilitarian risk/utility theory of liability that governs all other ordinary [FN11] products in the majority of jurisdictions. Applying risk/benefit balancing erases the barriers created by the current system and allows an innocent, injured consumer to reach the jury on the merits of her claim. A jury may then balance the benefits of a biotech product against the likely occurrence and severity of injury it may cause, factoring in whether a reasonable alternative design exists, such as identifying the biotech ingredient on the product label. In this fashion, juries can act in a reasoned fashion to weed out those biotech food products which are not beneficial to society pursuant to the same enterprise liability, fairness, and moral principles that govern any ordinary new product. This utilitarian approach could lead to the creation of a new common law “duty to identify” biotech ingredients in food which would inform consumer choice, facilitate risk avoidance, and result in the compensation of innocent consumers. Thus, the tort system could be used to indirectly accomplish a reform that consumers *1648 overwhelmingly desire [FN12] but that legislatures, to date, have refused to adopt.

II. Biotech Foods

For almost ten thousand years, agriculture focused on the domestication of wild species of plants. [FN13] Ancient agricultural, horticultural, and animal husbandry techniques targeted breeding to improve the characteristics of crops and livestock. Approximately one hundred years ago, Gregor Mendel, in his work with peas on the inheritability of genetic traits, laid the groundwork for the fundamental principles of genetics and inheritability. [FN14] Mendel's principles provided geneticists with the ability to selectively breed plants and animals to produce new hybrid varieties [FN15] with enhanced resistance to disease, nutritional value, and production yields. [FN16] Now, after a century of traditional breeding practices, [FN17] the majority of modern agricultural food products have been “genetically modified.” [FN18] However, traditional techniques are limited to transferring genetic material between a wild species and a modern crop plant. [FN19]

The limits of traditional methodologies, which blocked the transmission of genetic information between different genres such as a fish and *1649 a tomato, [FN20] a cow and a pig, or a soy bean and a brazil nut, have been overcome with the use of recombinant DNA technologies. [FN21] This new method allows the insertion of specific DNA sequences that reflect a desired trait from any source, without regard to species barriers, into an agricultural product. [FN22] Some of the traits [FN23] that have been genetically introduced into host organisms are the ability to resist ice damage, [FN24] to grow in highly salty soil and desalinate that soil while growing, [FN25] to grow *1650 larger and more quickly, [FN26] to stay fresh longer, [FN27] to metabolize pollutants into nontoxic products, [FN28] to produce large amounts of insulin and interferon inexpensively, [FN29] to eradicate allergens, [FN30] to resist pests [FN31] and herbicides, [FN32] and to have enhanced nutritional value. [FN33] In 2002, approximately 81% of the United States' soybean crop, [FN34] 40% of the corn crop, [FN35] and 54% of the canola crop was genetically modified with recombinant DNA technology. [FN36] At least one observer has predicted that, by 2010, almost all crops in the United States will either be genetically modified or be mixed with genetically modified products. [FN37]

*1651 III. Regulatory Structure Governing Biotech Foods

The Food, Drug & Cosmetic Act (FD&CA) [FN38] assigns general regulatory authority for food to the FDA. [FN39] As the FDA explains, “[m]ost foods derived from plants predate the establishment of national food laws, and the safety of these

foods has been accepted based on extensive use and experience over many years (or even centuries).” [FN40] These common, longstanding whole foods are “traditional food” in the generic sense and are presumed safe for human consumption. [FN41] The FD&CA does not require pre-market testing of the safety of these traditional foods [FN42] and the FDA cannot preclude these traditional foods from entering the market. [FN43] If the FDA does have concerns about the safety of a traditional food product, it must use its seizure or injunctive powers to remove the product from the market. [FN44] In these court actions, the FDA has the burden of proving that the product is adulterated. [FN45] For a naturally occurring substance found in the food product, the food product is rendered adulterated if the substance is ordinarily injurious to health. [FN46] However, if the substance in the food product is “added,” the food product is adulterated if the substance “may render” the food injurious to health. [FN47] Regardless, as the FDA carries the burden of proof, it must first conduct scientific studies of the food product in order *1652 to gather the data necessary to proving its case. [FN48] This may take years. [FN49] The practical result is that an unsafe food may remain on the market for a long period of time before the FDA can take action. [FN50]

The picture is much different if the food at issue is deemed a “food additive.” In response to the public's concern over the steadily increasing amounts of chemicals added to food as food processing technology developed, Congress enacted the Food Additives Amendment of 1958. [FN51] The Food Additives Amendment established a pre-market approval requirement for “food additives.” [FN52] This placed the burden on the food processor to establish, through scientific methodology, that the additive was safe for its intended use before placing the food additive on the market. [FN53] This is referred to as the pre-market approval process. A “food additive” is defined as any substance whose intended use results in it becoming a component of food or affecting the characteristics of food, unless the substance is generally regarded as safe (GRAS). [FN54] Importantly, a substance added to food is not a food additive and, therefore, does not require pre-market approval if it is GRAS. A substance is considered to be GRAS if there is a general consensus among informed experts that a substance is safe. [FN55]

Since 1992, the FDA has stated that, for safety purposes, biotech foods will be treated as though they are not fundamentally different from foods created through traditional breeding techniques. [FN56] This is because both traditional and biotech foods have been altered from their original state by genetic manipulation. [FN57] The FDA asserts that, under *1653 the current regime, it has enjoyed great success in regulating foods created through traditional breeding techniques.

Therefore, according to the FDA, the same regime that governs traditional food is adequate to the task of ensuring the safety of biotech foods and no separate regulatory scheme for biotech food need be created. [FN58] Consider, as an example of this approach to safety, the following: if a genetic modification altered the allergenicity or toxicity of a food creating a health risk, the allergen or the toxin could be considered an “added” substance that “may render” the food injurious to health making the food adulterated. However, the limit of this approach is that, just as with traditional foods, the FDA could only act after the product was already on the market.

Arguably, biotech food could be regulated under the food additive provisions of the FD&CA, thereby triggering the pre-market approval process under Section 409 of the FD&CA. The foreign genetic materials and their expression products (such as nucleic acids, oils, carbohydrates, and fats) that are transferred into the host species could be considered the food additive. However, the FDA has rejected this position:

With respect to transferred genetic material (nucleic acids), generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation. Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food. In regulatory terms, such material is presumed to be GRAS. [FN59]

*1654 This GRAS [FN60] designation not only allows food processors to avoid the pre-market safety approval process, it also directly impacts the FDA's position on the labeling of biotech foods. Section 403 of the Act and the accompanying regulations require that a food product be described by its common or usual name or, in the absence thereof, an appropriately descriptive term. [FN61] Section 403(i) of the Act also requires that, in the case of foods fabricated from two or more ingredients, a food product bear on the label the common or usual name of each ingredient. [FN62] As biotech foods have been deemed by the FDA as no different than the traditional host food products, the biotech food must be described to consumers by the common name of its traditional host food. [FN63] The FDA explains: Of course, the utility of DNA in genetic engineering does not lie in the DNA itself, but instead in the expression of that DNA once it is inserted into the recipient plant or animal. Rather than the addition of the DNA then, it is the products of the DNA expression that come under FDA scrutiny. Labeling is required to alert the consumer only if the genetically engineered food differs from

the original food to such an extent that either the common name no longer applies, or a safety issue is apparent. [FN64]

The FDA further explained:

The law says labeling for foods must disclose information that's material, as well as avoid false or misleading statements. It's our view that the method by which a plant is developed by a plant breeder is not material information in the sense of the law . . . If genetic engineering or any other technique changes the composition of a tomato in a way that it's really not the same tomato anymore, then it would have to be called something different. [FN65] *1655 As a result of the FDA's stance that biotech food is no different from traditional food, the FDA does not require that a food product's label disclose the fact that the food contains biotech ingredients. For example, the FDA states that "a tomato does not become 'fish-like' following the addition of a copy of a fish gene" [FN66] which was added to prolong freshness. As long as the tomato looks and tastes like a tomato, the only information that will be provided to the consumer is that which is traditionally provided with tomatoes. [FN67] In 2000, a coalition of groups and individuals, including scientists and religious leaders, brought a lawsuit challenging the FDA's position that biotech food requires no labeling. The coalition argued that foreign DNA added to a host product is a food additive which requires labeling. [FN68] A district *1656 court found that the FDA's position was not arbitrary or capricious and granted the FDA's motion for summary judgment. [FN69]

A. FDA's Policy on Allergens and Toxins in Biotech Foods

The FDA policy, that biotech food is no different than traditional food, is carried through in its approach to warning of the potential of allergenicity or toxicity by product labeling. [FN70] Only if the added foreign DNA has a history of a known allergic or toxic effect in its original form (i.e., prior to being used to create the biotech food) to a specifically identifiable population will the manufacturer be required to notify consumers of its introduction into the host product. [FN71] Thus, a genetically engineered soybean with a brazil nut protein will be judged safe or unsafe based on experience with consumption of brazil nuts. [FN72] If the foreign protein has no history of allergenicity or toxicity, it is presumptively GRAS and safe for human consumption. [FN73] Food producers are permitted to make their own independent determination whether a new biotech food is GRAS and, therefore, safe for human consumption [FN74] *1657 without any mandated FDA review of the data supporting the producer's conclusion. [FN75] On the other hand,

the FDA does encourage the biotech food producer to consult with the FDA regarding its safety data prior to marketing the biotech food. [FN76]

However, predictions of which combinations of foreign DNA and host food products will cause allergic or toxic responses are only as good as the data upon which they are based. The data that food processors are currently being allowed to rely upon is incomplete in that it is gathered before the foreign DNA and the host product were merged. This ignores the very real possibility that, in combination, the foreign DNA and host product could produce new and unpredictable consequences. [FN77] As will be described in Part IV, the impact of inaccurate predictions that expose the potentially susceptible population to these latent dangers can be very severe.

IV. Food Allergens

A. Allergic and Toxic Reactions to Traditional Food

A food allergy is an immune system response [FN78] to a food that the body mistakenly believes is harmful. [FN79] Once the immune system decides that a particular food is harmful, it creates specific antibodies to it. [FN80] The *1658 next time the individual eats that specific food, the immune system releases massive amounts of chemicals, including histamine, in order to protect the body. These chemicals trigger a cascade of allergic symptoms that can affect the respiratory system, gastrointestinal tract, skin, or cardiovascular system. In the United States, approximately 5% to 8% of children, or about four to six million kids, [FN81] and 2% of adults, or roughly four and one-quarter million, [FN82] suffer from food allergies. [FN83] These reactions can range from hives, rashes, difficulty in breathing or intestinal upset to serious, long-term illnesses such as eosinophilic esophagitis, gastritis, and gastroenterocolitis. [FN84] As many as two hundred people in the United States die each year from allergic reactions to food, often to just trace amounts of allergens. [FN85] There are no shared properties of allergens, [FN86] but an allergic reaction is most often a reaction of the body's immune system to a protein.

*1659 B. Allergic and Toxic Reactions to Biotech Food

When a piece of foreign DNA is added to a host food product, the foreign DNA adds a foreign protein to the host food product. The sources of the foreign DNA fall into three different categories: (1) food that has a history of allergenicity; (2)

food that has no history of allergenicity; and (3) sources that have never been used for food.

If the source of foreign protein “is a food known to have allergenic potential, product developers can readily test the genetically modified food to see if the allergenic properties have indeed been carried over into the new variety.” [FN87] Genetic engineering can transfer allergens from foods people know they are allergic to over to foods that they think are safe. This risk is not merely hypothetical. A study by the New England Journal of Medicine showed that when a gene from a brazil nut was engineered into soybeans, people allergic to nuts had serious reactions to the engineered product. To an individual allergic to brazil nuts, consuming this food product could be life threatening. [FN88] Even trace amounts of such an allergen can cause a fatal reaction. [FN89] At least one food, a Pioneer Hi-Bred International soybean, was abandoned by developers because of this problem. [FN90] As will be discussed, the FDA requires labels for these types of biotech foods.

When the source is a food that has no history of allergenicity, the unanswered question is whether the newly added foreign protein will have the same safe level of allergenicity in the host product as it did in the original product. The concern of many scientists is that, even *1660 though a protein added by genetic engineering might exist at safe levels in a single food, that same protein might become a danger as either: (1) more and more foods in a typical diet become genetically engineered and exposure levels to the protein become additive; or (2) the protein increases the level of concentration of an allergen or a toxicant to a level that becomes significant to a susceptible population. [FN91]

Finally, some foreign DNA used to create biotech food comes from novel sources that have never been part of the human diet. The biotech foods developed from these sources could be creating entirely new allergic responses. Each genetic “cassette” being engineered into a host food may contain a number of novel proteins (in the form of altered genes, genes from bacteria and viruses, marker systems, and vectors) which may never have been part of the human diet. Each of these numerous novel proteins could create an allergic response in some consumers. [FN92] As was explained in a recent report commissioned by the Pew Initiative on Food and Biotechnology, [FN93]

[t]he more difficult issue is posed by the introduction of novel proteins that have not been previously in the food supply. Without prior exposure data, the ability to predict the potential of the protein to cause an allergic reaction is very limited. This

problem became readily apparent in the recent recall of food products that had been inadvertently contaminated with StarLink, a genetically modified corn variety that had not been approved for human food by the Environmental Protection Agency (EPA) because it could not be shown that the novel protein in StarLink was not an allergen. [FN94]

*1661 As described previously, the possible health risks of foods containing unknown or unexpected proteins are multifold. [FN95] With these dangers in mind, the authors of this report conclude that

[t]oday, our scientific understanding of food allergy is incomplete, making it difficult for food regulatory agencies to evaluate the potential allergenicity of novel foods . . . [and] current federal efforts are insufficient to provide the timely and comprehensive information needed by food safety regulators . . . This deficit has left food safety regulators without some of the critical tools they need to fully assess the potential allergenicity of novel food products, particularly those developed through biotechnology. [FN96]

*1662 C. Practical Impact of FDA's Failure to Require Labeling of Biotech Foods

The incidence of food allergies reported to researchers has risen significantly over the past ten years. [FN97] This increase parallels the proliferation of biotech foods on U.S. grocery shelves. [FN98] However, as a result of the FDA's position that biotech foods are to be regulated as traditional foods, and that foreign material will not be considered food additives, there is no requirement that most biotech food be labeled as such. Practically, this means that there is no way to know or learn if the general increase in the incidence of food allergies is related to biotech foods. [FN99]

Allergic or toxic reactions to food products range from mild to severe. If an individual consumes an unlabeled biotech food and has a reaction to that variety of host food product for the first time, the only likely consequence will be a misinformed avoidance of that variety. Most probably, the individual will be unaware that she has consumed a biotech food. This presumption finds support in a recent survey conducted by the University of Richmond in which 62% of those surveyed said that they had never consumed a biotech food. [FN100] Very few were aware that more than 70% of the packaged foods sold in U.S. supermarkets may contain bioengineered ingredients. [FN101] The most likely outcome for the consumer with a mild reaction to a biotech food is that the *1663 consumer will simply avoid the host food product in the future. A mild allergic reaction will not

usually warrant a trip to the doctor. Consequently, this incident will never be reported to a physician.

If the reaction is moderate to severe, the consumer likely will seek medical treatment. [FN102] However, as the patient generally is unaware that the offending food product was a biotech food, when the adverse reaction is reported to a physician, it will be incorrectly reported as a reaction to the host product, not as a reaction to a biotech food. This problem is compounded by the fact that data on food allergies is only being collected in small, isolated studies conducted by interested researchers. The Centers for Disease Control and Prevention (CDC) does not collect this data and there is no national reporting system in place. [FN103] Under the current system, there will never be an accumulation of data by researchers with regard to the allergenicity of a biotech food. This absence of a reporting system can be traced to the FDA's position that foreign materials added to food via biotechnology are not food additives required to be listed on a food product's label. As discussed herein, this regulatory position ultimately acts to short-circuit the tort system. [FN104]

V. Two Alternative Proposals for a Pre-market Approval Process for Biotech Food Based on Current FDA Regulatory Power

As a result of both national [FN105] and international¹⁰⁶ pressure, the FDA ^{*1664} is reviewing its approach to the assessment of the allergenicity of foreign materials that are introduced into food derived from new bioengineered animals and plants. [FN106] Currently, the FDA recommends, but does not require, that a developer who intends to bring a biotech food to market “consult” with the FDA regarding relevant safety concerns, including allergenicity. [FN107] In January 2001, the FDA published a proposed rule ^{*1665} entitled “Premarket Notice Concerning Bioengineered Food” [FN108] which would make this “consultation” mandatory. This rule would require submission of data and information regarding the known or potential allergenicity of the proposed biotech food to the FDA 120 days prior to placing the biotech food on the market. [FN109] The FDA is now examining its position on which of two different types of data must be submitted.

One type of data submission will not require any pre-market testing of the actual new biotech food. This choice is consistent with the FDA's position that “scientific procedures are not currently available to test directly whether a protein will cause an allergic reaction and it is not possible to conduct a definitive evaluation of food allergenicity if the source of the introduced protein has no history of use in food.” [FN110] Based on this position, to date the FDA has relied on the premise that the

only mechanism available to evaluate new proteins for allergenicity is by determining if they have characteristic properties that are similar to known food allergens. [FN111] In other words, if the biotech food only contains proteins that are similar in structure or function to proteins currently found in traditional food, and those proteins do not exhibit the *1666 characteristic properties of known food allergens, then the FDA has taken the position that the newly constituted biotech food is safe. [FN112] No pre-market testing of the actual biotech food would be required.

The second type of data that the FDA is considering involves both the submission of the preexisting data outlined above and the actual testing of the newly constituted biotech product for allergenicity. The FDA is considering this choice based on its recent acknowledgment “that the scientific methods to assess allergenic potential are evolving. Recent reports on the assessment of potential food allergenicity . . . have reevaluated earlier approaches [including the FDA's] and recommended some new strategies based on recent scientific opinions on this issue.” [FN113] For example, in 2001, the Joint Expert Consultation on Foods Derived from Biotechnology convened by the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) published an approach to evaluating allergenicity that builds upon previous approaches to examining allergenicity but also includes several additional strategies. These strategies are targeted serum screening of proteins from sources with no known history of allergenicity in addition to no sequence homology to known allergens; the use of animal models; and the elimination of human testing. [FN114]

In other words, this approach evaluates allergenicity by testing the newly constituted biotech product itself, to determine if, by its unique structure, it has created new allergens. The underlying philosophy for finding that these additional tests are warranted derives from what legal commentators have labeled the “precautionary principle.” [FN115] This principle recommends taking health-protective actions while the dangers of not taking such actions remains uncertain. [FN116] However, the FDA has repeatedly rejected this position as scientifically unsupportable.

The FDA has created the new Food Biotechnology Subcommittee of the Agency's Food Advisory Committee (Food Advisory Committee) to *1667 evaluate whether the aforementioned additional tests will reveal previously unknown allergenic properties of biotech foods, [FN117] a step that could identify biotech foods that are currently on the market which have undetected allergy inducing properties. [FN118] Not surprisingly, the language used by the FDA in the summary of the

Food Advisory Committee's task seems to indicate a predisposition to ignore new methods of testing and continues to rely on the basic presumption that preexisting data, based solely on characteristics of traditional food, is sufficient to the task.

[FN119] This perpetuates the circularity of the problem. Without testing, potential new allergens will go undiscovered and unreported, permitting the biotech industry to continue to operate in blissful ignorance and permitting consumers to be “used as human guinea pigs in this massive feeding experiment . . . “ [FN120]