The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify

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

Katharine Van Tassel

I. INTRODUCTION

The United States is one of the world's largest producers of genetically modified organisms used as food (biotech food). The first biotech food product hit the market in the United States in 1995. Now, industry experts estimate that as much as seventy percent of the packaged food on grocery store shelves may contain bioengineered ingredients. 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. In addition, the Food and Drug Administration (FDA) does not require pre-market testing to ensure the safety of most biotech food. This raises health concerns since the new genera-
tion 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." 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 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


Genetic engineering, like other forms of breeding, can change the composition of food in a number of ways that could affect safety.

Unanticipated effects. The insertion of genetic material can sometimes result in unanticipated changes. For example, the genetic material could inactivate a host gene or alter control of its expression. Or, the gene product could interact with other metabolic processes in an adverse way.

Naturally occurring toxicants. Many food plants contain natural toxicants that are used to ward off pests, but these toxicants often exist at such low levels that they can cause no harm in food or can be removed in processing. Genetic modifications can inadvertently increase the level of naturally occurring toxicants or cause the expression of a new toxicant.

Nutrients. Genetic modifications can change the level of nutrients or alter their form to make a food crop less or more nutritious.

New Substances and Allergens. Genetic engineering permits breeders to insert novel genes (and their expressed proteins) into food crops that could significantly differ from the proteins that ordinarily are found in food. Such substances could affect nutrients or have toxic or allergenic properties.

Antibiotic Resistance Markers. Genetic engineering involves the use of genetic markers, including antibiotic resistance markers, to help breeders determine which plants have taken up the intended genetic change. To the extent these markers are included in the genetic material in the food, it is possible they could make enzymes that would inactivate antibiotics taken orally.

Adventitious Presence of Nonfood Substances. Genetic engineering is being used to modify crops so that they can make industrial and pharmaceutical chemicals. While such plants are not intended for the food supply, the accidental mixing of these crops with food crops (i.e., their adventitious presence in the food supply) might occur...

id. at 69 (italics added).

9. Scientists have identified allergic or toxic reactions as the most likely of the possible human harms that may result from the ingestion of biotech foods. See infra notes 87-97 and accompanying text.
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. 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 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

10. This Article does not dispute the fact that the most comprehensive and direct solution may be legislative in nature. As such, this Article adds the specter of potential tort immunity from harm caused by biotech food products to the arguments in support of a legislative solution. However, even in the unlikely event that mandatory labeling legislation is passed, the tort system may still bar recoveries for a substantial group of consumers if they are injured by biotech food products. See infra notes 97-104, 157-79 and accompanying text. Consequently, a concurrent modification of tort principles as applied to food is needed.

11. The definition of ordinary products excludes such inherently dangerous products as pharmaceuticals that have special standards for determining liability for harm. See, e.g., RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) [hereinafter RESTATEMENT (THIRD)].
overwhelmingly desire\textsuperscript{12} but that legislatures, to date, have refused to adopt.

\section*{II. BIOTECH FOODS}

For almost ten thousand years, agriculture focused on the domestication of wild species of plants.\textsuperscript{13} 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.\textsuperscript{14} Mendel’s principles provided geneticists with the ability to selectively breed plants and animals to produce new hybrid varieties\textsuperscript{15} with enhanced resistance to disease, nutritional value, and production yields.\textsuperscript{16} Now, after a century of traditional breeding practices,\textsuperscript{17} the majority of modern agricultural food products have been “genetically modified.”\textsuperscript{18} However, traditional techniques are limited to transferring genetic material between a wild species and a modern crop plant.\textsuperscript{19}

The limits of traditional methodologies, which blocked the transmission of genetic information between different genuses such as a fish and

\begin{itemize}
  \item \textsuperscript{12} See infra notes 102-103 and accompanying text.
  \item \textsuperscript{13} See Kenneth J. Frey, An Overview of Crop Improvement: Chairman’s Introduction, in GENETIC ENGINEERING OF PLANTS: AN AGRICULTURAL PERSPECTIVE 3 (Tsuné Kosuge et al. eds., 1983); Michael A. Whitaker, Comments, Reevaluating the Food and Drug Administration’s Stand on Labeling Genetically Engineered Foods, 35 SAN DIEGO L. REV. 1215, 1216 (1998).
  \item \textsuperscript{15} Hybridization occurs when two varieties of a plant are crossed combining the most desirable characteristics of each in the resultant plant. For example, if a flavorful variety of tomato is susceptible to fungus infections, an attempt could be made to hybridize it with a different variety of tomato that is fungus-resistant. By cross-pollination, a tomato with the most useful traits of both original plants can be created. The breeder will repeatedly “back-cross” the next generations of plants with the original flavorful fruit plant and retain those plants with the tasteless fruit but that also retain the fungus-resistant trait. Kunich, supra note 14, at 810; see also David J. Earp, Comment, The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor’s Transgenic Vegetable Patch?, 24 ENVTL. L. 1653, 1644 (1994).
  \item \textsuperscript{16} Foods Derived from New Plant Varieties, supra note 6, at 22986.
  \item \textsuperscript{17} Id. at 22984-22986. Wide crosses, mutagenesis by physical or chemical means, tissue culture techniques, and hybridization within a species are included in traditional techniques. Genetic engineering refers to any technique capable of producing a transgenic plant or animal. See generally ANIMALS WITH NOVEL GENES (Norman MacLean ed., 1994); GENETIC IMPROVEMENTS OF AGRICULTURALLY IMPORTANT CROPS (Robert T. Fraley et al. eds., 1980).
  \item \textsuperscript{18} Foods Derived from New Plant Varieties, supra note 6, at 22984-86.
  \item \textsuperscript{19} Id.
a tomato, a cow and a pig, or a soy bean and a brazil nut, have been overcome with the use of recombinant DNA technologies. 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. Some of the traits that have been genetically introduced into host organisms are the ability to resist ice damage, to grow in highly salty soil and desalinate that soil while growing, to grow

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20. One of the first biotech products used in food production was recombinant bovine somatotropin (r-BST) introduced as a new animal drug to increase the production of milk in dairy cows. See Robert A. Bohrer, Food Products Affected by Biotechnology, 55 U. PITT. L. REV. 653, 653 (1994). The first biotech product intended for direct human consumption was Calgene's slow-rotting Flavr Savr tomato. The Pew Initiative on Food and Biotechnology, supra note 4. Sales in the first year were 14 million out of a total market for tomatoes of $4 billion. See Greg Beaubien, Genetic Growth Lab: Work is Deluded, CHATTANOOGA TIMES, Sept. 19, 1996, at F1; see also Whitaker, supra note 13, at 1242.


22. Although there are various techniques, the method by which genetic engineering places new or 'foreign' DNA into an organism is usually as follows. First, the target genetic material is identified. An enzyme, i.e., a biological catalyst, is then employed to excise the desired DNA segment from one organism. Next, through the use of a second enzyme, the new segment is spliced into some of the recipient organism's preexisting DNA. To facilitate this process, foreign DNA is often joined to a small circular piece of bacterial DNA called a plasmid, which contains the necessary biochemical signals to exist and to replicate within a cell. A plasmid with newly inserted foreign DNA is considered genetically engineered or rDNA. To get the recombinant plasmid into the recipient organism, the plasmid is sometimes chemically treated under temperature-controlled conditions. Alternatively, DNA encoding the desired trait is painted on microscopic metal particles that are loaded into a so-called 'gene gun' and fired as projectiles at plant cells growing in the laboratory. These miniature, gene-carrying 'bullets' penetrate the cells where the fluids inside wash the DNA off the metal particles. In either method, the mixture is then returned to normal culture conditions so the cells can recover and grow. Kunich, supra note 14, at 809 (citing DAVID FREIFELD, ESSENTIALS OF MOLECULAR BIOLOGY 215-22 (1983); JUNE GOODFIELD, PLAYING GOD 12-21 (1977); BERNARD PERLMAN, A PRACTICAL GUIDE TO MOLECULAR CLONING 411-16 (2d ed. 1988); JAMES D. WATSON ET AL., RECOMBINANT DNA: A SHORT COURSE, 20-90 (1988); Larry Thompson, Are Homogenized Foods Safe?, FDA CONSUMER, Jan.-Feb. 2000, at 18, 22).


25. See infra note 220.
larger and more quickly, to stay fresh longer, to metabolize pollutants into nontoxic products, to produce large amounts of insulin and interferon inexpensively, to eradicate allergens, to resist pests and herbicides, and to have enhanced nutritional value. In 2002, approximately 81% of the United States' soybean crop, 40% of the corn crop, and 54% of the canola crop was genetically modified with recombinant DNA technology. 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.

26. See infra note 224.
27. National Briefing Health and Science: Tinkering With Tomatoes, N.Y. TIMES, Apr. 12, 2002, at A22 (tinkering with a gene that controls ripening allows farmers to leave tomatoes on the vine longer resulting in tomatoes that taste fresher and that stay firm enough for shipping).
29. See Arnold L. Demain & Nadine A. Solomon, Industrial Microbiology, Sci. AM., Sept. 1981, at 66, 74 (stating that interferon and insulin can be produced by rDNA technology and that, as a result, the cost of interferon may decrease from about $2 million for fifty impure milligrams to as little as pennies per pure milligram).
30. Andrew Pollack, Geni-Jugglers Take to Fields For Food Allergy Vanishing Act, N.Y. TIMES, Oct. 15, 2002, at F2. Scientists are working on removing allergens by actually deleting genes from foods like wheat, rice, and peanuts and a major cause of hay fever, ryegrass. Id. Another target of bioengineering is the removal of ricin from castor plants. Ricin is one of the deadliest substances known and is a potential bioterrorism weapon. Id. In 1978, a Bulgarian defector strolling on the streets of London was killed when he was injured by an umbrella tip coated with ricin. Id.
31. See infra note 226.
32. See infra note 229.
34. The Pew Initiative on Food and Biotechnology, supra note 8.
35. Id.
36. Pew Initiative on Food and Biotechnology, supra note 4. Examples of genetically engineered food now on the market include abalone, canola oil, catfish, chymosin, corn, cottonseed oil, potatoes, prawns, salmon, soybeans, and tomatoes. Examples of those under development are alfalfa, apples, asparagus, barley, beet, broccoli, carrots, cauliflower, chicory, cucumbers, flaxseed, grapes, kiwi, lettuce, melons, papayas, peanuts, pepper, raspberries, rice, squash, strawberries, sugar cane, sunflowers, sweet potatoes, walnuts, watermelons and wheat. See Marian Burros, Eating Well, N.Y. TIMES, May 21, 1997, at B2.
III. Regulatory Structure Governing Biotech Foods

The Food, Drug & Cosmetic Act (FD&CA) assigns general regulatory authority for food to the FDA. 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).” These common, longstanding whole foods are “traditional food” in the generic sense and are presumed safe for human consumption. The FD&CA does not require pre-market testing of the safety of these traditional foods and the FDA cannot preclude these traditional foods from entering the market. 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. In these court actions, the FDA has the burden of proving that the product is adulterated. For a naturally occurring substance found in the food product, the food product is rendered adulterated if the substance is ordinarily injurious to health. 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. Regardless, as the FDA carries the burden of proof, it must first conduct scientific studies of the food product in order

41. Foods Derived from New Plant Varieties, supra note 6, at 22988; Richard A. Merrill, Regulating Carcinogens in Food: A Legislator’s Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act, 77 Mich. L. Rev. 171, 186-90 (1978); Noah & Merrill, supra note 40, at 340-43. “If a food is of ‘natural biological origin,’ was commonly consumed in the United States prior to 1958, and has not been modified by any process which was introduced after 1938, then it is essentially only regulated for manufacturing practices and labeling.” Bohrer, supra note 20, at 655, (citing 21 C.F.R. § 170.30 (1998)). Examples include raw agricultural products such as apples, carrots, wheat, corn and soy. This Article refers to this category of food product as “traditional food.”
42. 21 U.S.C. § 342(a)(1) (1994); Merrill, supra note 41, at 186-90.
43. Merrill, supra note 41, at 186-90.
44. Id.
45. Id.
47. Id.
to gather the data necessary to proving its case. This may take years. 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.

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. The Food Additives Amendment established a pre-market approval requirement for "food additives." 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. 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).

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.

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. This is because both traditional and biotech foods have been altered from their original state by genetic manipulation. The FDA asserts that, under
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.\footnote{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.\footnote{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.}
This GRAS 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. 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. 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. 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.

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.

60. Id.
61. 21 C.F.R. § 101.5.
63. Food Derived from New Plant Varieties, supra note 6, at 22991.
64. Id.

FDA stated that developers should initially assume that a protein derived from a food that commonly causes allergic reactions is an allergen and that labeling would be required to alert sensitive individuals, unless scientific evidence demonstrated that the introduced protein was not an allergen (57 FR 22984 at 22987 and 22991). FDA cited several examples of foods that commonly cause allergic reactions: milk, eggs, fish, crustaceans, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans) (57 FR 22984 at 22987). Although not expressly addressed in the 1992 policy, FDA did not anticipate that labeling would be necessary in cases where the protein was not present in the finished food (e.g., refined vegetable oil).


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” 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. 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. A district court from New Plant Varieties, supra note 62, at 25839 (“A food is misbranded if its labeling is false or misleading. Under section 201 (n) of the FD&C, labeling is misleading if it fails to reveal all facts that are ‘material in light of . . . representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or such conditions of use as are customary or usual.”). 66

67. Id.
68. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000). The Center for Food Safety (CFS) provides a very succinct and accurate summary of the causes of action brought by the complaint: the CFS

and numerous other plaintiffs, including leading scientists, religious leaders, and consumers filed a lawsuit on May 27, 1998, challenging the FDA’s failure to require labeling and premarket safety testing of genetically engineered foods. The lawsuit, filed in the U.S. District Court for the District of Columbia, alleges that the FDA’s policy on bioengineered foods violates U.S. food safety laws and ignores the significant health and environmental risks associated with genetically modified foods.

The CFS litigation sought to change FDA’s regulation of genetically engineered foods through several legal causes of action:

The first main cause of action challenges the FDA’s failure to abide by the public notice and legal procedures required by the Administrative Procedure Act because the agency has established a de facto policy of allowing genetically engineered foods into the marketplace.

The second main cause of action challenges the FDA’s policies on genetically engineered foods as violative of the Federal Food Drug and Cosmetic Act (FFDCA). Plaintiffs believe that the FFDCA requires the mandatory labeling of genetically engineered foods because of the “material” changes in such foods.

The third main cause of action asserts that the FDA must treat all genetic changes to foods caused by genetic engineering techniques as food additives, thus triggering the FDA’s need for specific safety testing and approval of each genetically engineered food before it could be considered generally recognized as safe.

The fourth main cause of action asserts that many plaintiffs object to consuming either all or some genetically engineered foods on the basis of religious principle and that FDA’s failure to label such foods burdens their free exercise of religion in violation of the First Amendment of the U.S. Constitution and the Religious Freedom Restoration Act . . . In addition, the lawsuit challenges the FDA’s failure to regulate and label each of the thirty-six genetically engineered foods known to be on the market.

court found that the FDA’s position was not arbitrary or capricious and granted the FDA’s motion for summary judgment.

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. 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. Thus, a genetically engineered soybean with a brazil nut protein will be judged safe or unsafe based on experience with consumption of brazil nuts. If the foreign protein has no history of allergenicity or toxicity, it is presumptively GRAS and safe for human consumption. Food producers are permitted to make their own independent determination whether a new biotech food is GRAS and, therefore, safe for human consumption.

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70. See *Whittaker*, supra note 13, at 1226.
71. FDA emphasized its concern regarding commonly allergenic foods with a hypothetical example of a tomato that contains a newly introduced peanut protein. The agency explained that, unless scientific evidence established that the introduced protein was not allergenic, labeling would be required for a new variety of tomato that contained peanut protein so that peanut-sensitive consumers could avoid the new food. In such circumstances, the presence of a protein derived from a food that commonly produces allergic reactions would be a fact whose omission would misbrand the new food under sections 201(n) and 403(a) of the act (21 U.S.C. 321(n) and 343(a)) (57 FR 22984 at 22991).
72. See *Food Derived from New Plant Varieties*, 57 Fed. Reg. at 22984 (provides comprehensive scientific guidance to industry to aid in assessing the safety of foods derived from new plant varieties, including varieties developed using recombinant DNA technology).
73. Id. at 22991; *Food Labeling: Food Derived from New Plant Varieties*, supra note 62, at 25840.
74. In October 1997, the FDA provided guidance to industry on procedures for consultations between industry and the agency to address proactively issues that are relevant to bioengineered foods (the 1996 procedures). See *Guidance on Consultation Procedures: Foods Derived from New Plant Varieties,* (October 1997) available at http://www.fda.gov/~ohr/consulpr.htm. Under that process, FDA recommends that a developer who intends to commercialize a bioengineered food meet with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food prior to commercial distribution. When the developer believes that it has accumulated adequate data or information to address any issues raised during the consultation, the developer begins the 'final consultation' by submitting to FDA information that explains its scientific and regulatory assessment of the food. This information should be sufficient to permit agency scientists to understand the approach the firm has followed in identifying and addressing relevant issues. This assessment should include a discussion of any information regarding any known or potential allergenicity of the expression products and the basis for concluding that foods containing the expression products can be safely consumed. In addition, the assessment should also include a discussion of the available information that addresses whether the potential for the bioengineered food to induce an allergic response has been altered by the genetic modification. See *Bohrer*, supra note 20, at 682.
without any mandated FDA review of the data supporting the producer's conclusion. 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.

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. 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 to a food that the body mistakenly believes is harmful. Once the immune system decides that a particular food is harmful, it creates specific antibodies to it. The

75. Id.
76. Id.
78. See David Kitts et al., Allergic Reactions to Food Constituents: Allergy, Intolerance, and Auto Immunity, 75 CAN. J. PHYSIOLOGY & PHARMACOL 241 (1997). Food hypersensitivity is an abnormal reaction resulting from a heightened immuneologic response to glycoprotein components in foods. Food allergies involve an IgE response. The classic “immediate” hypersensitivity reactions are hives, asthma, gastrointestinal problems, and anaphylaxis within a few minutes of exposure. Oral allergy syndrome is an immediate reaction largely confined to the mouth. Acute dermatitis is an eczema-like reaction. Other types of reactions include allergic eosinophilic esophagitis, gastritis, and gastroenterocolitis. There are non-IgE reactions seen exclusively in infants and children, such as dietary protein enterocolitis, proctitis, enteropathy, and celiac disease. These are seen in 1%-2% of children. See Medication Protocols Patients with Peanut Allergies, National Jewish Medical Research Center, Mar. 10, 2003, available at http://www.njmc.org/news/peanut.html; Anaphalaxis, National Jewish Medical Research Center, available at http://www.njmc.org/medfacts/anaphalaxis.html.
79. "An allergic reaction occurs when a foreign substance, known as an antigen or allergen, enters a person’s body and causes antibodies in the immune system to attack the invading substance.” James A. Henderson, Jr., Process Norms in Products Litigation: Liability for Allergic Reactions, 51 U. PITT. L. REV. 761, 777 n.64 (1990)(citing LEO H. CRIP, CLINICAL IMMUNOLOGY AND ALLERGY (2d ed. 1989)).
80. After a first exposure to an allergen, the body develops antibodies to that allergen. When re-exposed, these antibodies explode into attack mode, triggering the allergic reaction. Therefore, as a general rule, an allergic reaction cannot occur without at least one prior exposure, although repeated exposures may be necessary before sufficient sensitivity develops. Occasionally, a spontaneous allergic reaction will occur
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, and 2% of adults, or roughly four and one-quarter million, suffer from food allergies. 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. 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. There are no shared properties of allergens, but an allergic reaction is most often a reaction of the body's immune system to a protein.
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." 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. Even trace amounts of such an allergen can cause a fatal reaction. At least one food, a Pioneer Hi-Bred International soybean, was abandoned by developers because of this problem. 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

89. An example of just how small an amount can cause a life-threatening reaction is the report by Dr. Hugh H. Sampson of the Mount Sinai School of Medicine of a patient who broke out in hives and started gasping for air after he ate a Christmas cookie that had been removed from a cookie sheet using a spatula to remove peanut cookies. Gina Kolata, Drug is Found to Limit Allergies to Peanuts, Exonerating Fear of Many, N.Y. TIMES, Mar. 11, 2003, at A1. Many people live in constant fear of peanuts, worrying that just the smell of a peanut could cause a reaction that can vary from abdominal pain, vomiting, hives, breathing problems, decreased blood pressure to death within minutes. Id. Many people with peanut allergies must live altered lifestyles as a result of a legitimate fear of eating in restaurants, other people's homes, and at other social occasions such as office parties. Id. See also information available on Dr. Sampson's web site located at National Jewish Medical Research Center, http://www.njc.org/news/peanut.html. One of the benefits of bioengineering may be the ability to remove a highly deadly allergen from food products such as the one that causes the peanut allergy. See Pollack, supra note 30.
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. 91

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. 92 As was explained in a recent report commissioned by the Pew Initiative on Food and Biotechnology, 93 [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. 94

91. Agency records, provided to the Center For Food Safety as a result of its lawsuit, see supra note 66, disclose that several FDA scientists stated that foods produced through genetic engineering differ from those produced through traditional crossbreeding and thus cannot be presumed to be safe merely because their conventional counterparts are. The 44,000 page record reveals that FDA scientists expressed several concerns about bioengineered foods, including allergenicity, toxicity and antibiotic resistance.

For example, the Divisions of Food Chemistry and Technology and Contaminants Chemistry warned that premarket testing of genetically engineered foods should be conducted because ‘some undesirable effects such as increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals), and undesirable alterations in the levels of nutrients may escape breeders’ attention unless genetically engineered plants are evaluated specifically for these changes.’

Center for Food Safety, supra note 68.


93. Bucchin & Goldman, supra note 87, at 5.

94. Id.

Aventis CropScience applied for EPA’s approval of StarLink corn that carried Cry9C, a protein that confers resistance to the European corn borer, a significant corn pest. Cry9C had not been present previously in the food supply and its allergenic potential was unknown. Cry9C does have some characteristics of an allergen, such as resistance to digestion, that
As described previously, the possible health risks of foods containing unknown or unexpected proteins are multifold. With these dangers in mind, the authors of this report conclude that today, 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.

raised concerns about its allergenicity. However, no definitive tests proved either that it is an allergen or that it is not. In the absence of reliable scientific information, regulators were unable to demonstrate its safety, as is required by law, and were forced to deny its use for human consumption. It was, however, approved for use as animal feed. Unfortunately, somewhere in the supply chain, StarLink corn was mixed in with food products that then made their way onto grocery store shelves.

Id. at 8.

There is no cure for food allergies. The only way to prevent allergic reactions is to avoid exposure to the allergen. However, avoidance can be problematic. If there is hereditary predisposition to immediate allergic reactions to some products, the consumer may have some degree of notice. But if that person has never had a reaction, she may not think she is at risk. For delayed allergic reactions, it is not possible for a consumer to know with any certainty that she has an allergic predisposition until an adverse reaction occurs. Complicating matters, building up a sensitivity sufficient to trigger an allergic reaction may take repeated exposures over a long period of time without any notice of a building susceptibility until the reaction finally explodes into existence. See CREP, supra note 79, at 670-673; LOUIS R. FRUMER & MELVIN L. FRIEDMAN, PRODUCTS LIABILITY § 49.07(1)(a) (1987).

Bucchini & Goldman, supra note 87, at 6, 10.

To properly regulate novel food products and protect public health, scientists, health professionals, and regulators must be able to predict whether new proteins introduced to food have the potential to cause allergic reactions in susceptible individuals. To make such predictions we need to understand what characteristics make a protein allergenic, how people become sensitized to food allergies, how allergic reactions are triggered, and whether safe levels of a potential allergen can be established. Furthermore, we need a comprehensive picture of the prevalence and incidence of food allergy in the U.S. population and how it is changing over time... Although scientists and health professionals have been working on answers to these questions for some time, our understanding of food allergy is still far from complete.

Id. at 9; see also Report of the Expert Panel on Food Allergy Research, National Institute of Allergy Research and Infectious Disease, National Institutes of Health, 6 (June 30 and July 1, 2003), available at http://www.niaid.nih.gov/dait/pdf/11-20-03FAreport1.pdf [hereinafter Expert Panel] ("The Expert Panel on Food Allergy concluded that food allergy research is poised to make significant advances in the prevention and treatment of food allergies and anaphylaxis. New initiatives will eliminate critical gaps in understanding GI physiology and immunology and the mechanism of oral tolerance; the pathophysiology of food allergy and anaphylaxis and the molecular characteristics of food allergens.") (emphasis added).
The incidence of food allergies reported to researchers has risen significantly over the past ten years. This increase parallels the proliferation of biotech foods on U.S. grocery shelves. 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.

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. Very few were aware that more than 70% of the packaged foods sold in U.S. supermarkets may contain bioengineered ingredients. The most likely outcome for the consumer with a mild reaction to a biotech food is that the

97. Report of the Expert Panel, supra note 96, at 1 ("Published reports document the increasing prevalence of food allergy and food induced anaphylaxis, reasons for these increases are poorly understood."); Hugh A. Sampson et al., Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents, 327 NEW ENG. J. MED. 380, 384 (1992) ("It is our belief and that of other investigators studying food allergy that the frequency of fatal and near fatal food-induced [allergic] reactions has risen over the past several years"); Susan Dominus, The Allergy Prison, N.Y. TIMES MAGAZINE, June 10, 2001, at 62-63; see also Burks & Stanley, supra note 81, at 588-93 (reporting that the incidence of all allergic diseases appear to be on the increase in industrialized societies).

98. See supra notes 34-37 and accompanying text. Of course, this parallel could be purely coincidental and this increase could be due to any number of other environmental factors. The point is that the means to create a scientific study to eliminate this possibility does not exist by virtue of the current regulatory scheme.

99. Bucchini & Goldman, supra note 87 (pointing out that researchers and policy makers lack data on the prevalence, incidence, or trends of food allergy. Tracking data on allergies as a whole indicates an increased incidence of these diseases. However, without appropriate epidemiological data, no conclusions regarding causation can be drawn). The data that supports the conclusion that the total number of food allergies, and their severity, is believed to be increasing is an extrapolation from small, isolated studies. Sampson, supra note 97, at 384.


101. Id. A new Gallup poll reports that 10% of Americans have heard "a great deal" about food biotechnology, 40% had some knowledge, and 50% had heard nothing or not much. Robert Sievers, Americas Back, Would Pay for Biotech Food Labels, Poll Says, ST. LOUIS POST-DISPATCH, Oct. 7, 1999 at A16. These findings are consistent with surveys by other polling firms. Id.
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. 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.

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.

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 and international pressure, the FDA

102. It is estimated that over 30,000 visits to the emergency room are made every year for the most severe of the reactions to food allergens, anaphylactic shock, which is life-threatening. See *The Food Allergy and Anaphylaxis Network*, supra note 83.

103. This is in contrast, for example, to the legally-mandated post market surveillance systems that are in place for the reporting of adverse events for both drugs and medical devices.

104. See infra notes 108-109 and accompanying text.

105. “States have emerged as the key battlegrounds on issues raised by agricultural biotechnology...” In 2001-2002, 138 pieces of legislation (139 bills and 19 resolutions) were introduced in 39 states...” dealing with agricultural biotechnology. Twenty-eight percent dealt with the protection of agricultural facilities or products from being damaged or destroyed. Pew Institute on Food and Biotechnology, *2001-2002 Legislative Activity Related to Agricultural Biotechnology* (2003), available at http://pewagbiotech.org/resources/factsheets/legislation/factsheet2002.php. Since 1999, acts of eco-terrorism have included the sabotage of the University of Idaho’s biotechnology building in protest of the bioengineering studies of potatoes, News Release, *Earth Liberation Front Claims Responsibility For Action Against Genetic Engineering at University of Idaho*, at http://earthliberationfront.com/news/2001/010618.html; the burning of the Michigan State University Agriculture building to destroy research on the bioengineering of crop vegetables, the destruction of research cornfields at University of California at Davis by groups such as Future Farmers and Reclaim the Seeds, John J. Miller, *Against the Grain: Eco-Terrorists Attack Farms*, NAT’L REV., Mar. 6, 2000, at 22, and the bombing of the construction site of the new Microbial and Plant Genomics Research Center at the University of Minnesota’s St. Paul campus, News Release, *ELF Takes Action Against Biotechnology Research at the University of Minnesota* [Jan. 29, 2002], available at http://earthliberationfront.com/news/2002/020129.html. Since 1998, there have been over 40 direct actions against biotech engineering, including the
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. 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. In January 2001, the FDA published a proposed rule


In May of 2003, the United States initiated a case in front of the World Trade Organization (WTO) against the 15-nation European Union to force the EU countries to accept unlabeled biotech foods. U.S. Requests WTO Panel in EU Biotech Food Case, ASSOCIATED PRESS, Aug. 8, 2003. Up until 1999, only nine biotech agricultural products were approved by the European Union (EU) for planting or import. Office of the U.S. Trade Representative and the U.S. Department of Agriculture, U.S. Requests Dispute Panel in WTO Challenge to EU Biotech Monoratorium, (Aug. 7, 2003), available at http://www.state.gov/c/eb/rls/othr/23109.htm. Six EU member states (Austria, France, Germany, Italy, Greece, and Luxembourg) banned even these crops. Id. From 1999 until recently, the EU suspended consideration of all new applications for approval until traceability and labeling concerns could be addressed. Id. On July 22, 2003, the EU adopted The Traceability and Labeling Regulation which “will require that biotech products be traced throughout the commercial chain, and that food containing biotech products comply with certain labeling [sic] requirements.” Id. “The WTO Agreement on [S]anitary and [P]hytosanitary [M]easures (SPS) recognizes that countries are entitled to regulate crops and food products to protect health and the environment.” Id. “The WTO SPS agreement requires, however, that members have ‘sufficient scientific evidence’ for such measures.” Id. The United States claims that there is no scientific evidence for any hazard from biotech food and that therefore the labeling requirements are merely an unfair trade tactic. Id.


107. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (codified at 21 C.F.R. pt. 192, 592); available at http://www.cfsan.fda.gov/~ldf/ft010118.htm. The premarket biotechnology notice (PBN) would require that biotech food manufacturers notify the FDA 120 days before a new biotech food was marketed. In addition, the PBN requires the submission to the FDA of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. The FDA states that it is “taking this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made
entitled "Premarket Notice Concerning Bioengineered Food" 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. 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." 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. 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

consistently and in full compliance with the law." Id. The question remaining is what is the "appropriate" information.  

108 Id.  

109. "Require" is a relative term. There are no sanctions for violating the rule. Moreover, many are questioning whether the FDA even has the authority to require notification. S. Clapp, Industry Presses FDA For Premarket Biotech Notification, 44 FOOD CHEMICAL NEWS 42 (Dec. 2, 2002). Traditional food requires no premarket notice and both the FDA and the industries' position is that biotech food is no different than traditional food. Even if the FDA were to entertain a complete policy shift, the agency would have a heavy burden to justify changing its position. The FDA made a scientific determination that biotech food is presumptively GRAS because of its similarity to substances already in the food supply. When the agency's prior determination is a scientific one, and not just a policy preference, the agency must provide new scientific information to justify the change in order to survive a legal challenge. Motor Vehicle Manufacturers Association of the United States, Inc. v. State Farm Mutual Automobile Insurance Company, 463 U.S. 29 (1983). These flaws would be corrected under the legislation proposed by Senator Dick Durbin (D-Il.), infra note 185 and accompanying text, which would require FDA safety review of all bioengineered foods and a special environmental review for biotech animals. Id.  

110. "Discussion Paper, Conference on Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops, (Apr. 18-19, 1994) (copy of transcript at Docket No.94N-0053; document TR-1 or summary available at http://www.cfsan.fda.gov/~lrd/biodlrg.html) (the conference scientists acknowledged that there are no direct methods to assess allergenicity of proteins from sources that are not known to produce a food allergy).  

111. Id. The approach currently used by developers was recommended by scientists at the 1994 Allergenicity Conference sponsored by EPA, USDA, and FDA and endorsed by the FDA's Food Advisory Committee.

The approach recommended by scientists at the 1994 Allergenicity Conference relies upon a comparison of the characteristic properties of the new proteins to those of food allergens. The characteristics that are considered relevant to this assessment include source of the protein (i.e. is the source known to cause allergic reactions and if so is patient sera available), sequence similarity to known food allergens, heat stability, stability under simulated conditions of gastric and intestinal digestion, glycosylation and expression levels in food.
characteristic properties of known food allergens, then the FDA has taken the position that the newly constituted biotech food is safe.\textsuperscript{112} 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."\textsuperscript{113} 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.\textsuperscript{114}

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."\textsuperscript{115} This principle recommends taking health-protective actions while the dangers of not taking such actions remains uncertain.\textsuperscript{116} However, the FDA has repeatedly rejected this position as scientifically unportable.

The FDA has created the new Food Biotechnology Subcommittee of the Agency's Food Advisory Committee (Food Advisory Committee) to

\textsuperscript{112} Id.


\textsuperscript{114} Discussion Paper, supra note 64, at 6.

\textsuperscript{115} See Appelgué, supra note 1, at 247-49.

\textsuperscript{116} See, e.g., Principle 15, United Nations Conference on Environment and Development: Rio Declaration on Environment and Development, 31 I.L.M. 874, 879 (1992) ("Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.").
evaluate whether the aforementioned additional tests will reveal previously unknown allergenic properties of biotech foods, a step that could identify biotech foods that are currently on the market which have undetected allergy inducing properties. 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. 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 . . .”

117. The first public hearing was held August 13-14, 2002. “The purpose of this meeting is to discuss science-based approaches to assessing whether new proteins and bioengineered foods are likely to cause allergic reactions in some individuals in order to assist FDA in developing draft guidance for industry.” Alan Rulis, Director of the Office of Food Additive Safety, Hearing, Food Biotechnology Subcommittee of the Food Advisory Committee, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (College Park, MD Aug. 13, 2002) (copy of transcript on file with author).

118. Considering new guidelines for more rigorous testing appears to be an acknowledgment of both citizens’ and the international communities’ concerns with regard to the risks of allergenicity. On the other hand, these may be steps taken in an attempt to ameliorate the continued tensions between the European Union and the United States with regard to trade. The European Union’s regulations are extremely stringent and require labeling. In an effort to improve trade relations, the United States and the European Union formed the European Union-United States Biotechnology Consultative Forum after tense trade discussions at the May 2000 United States-European summit meeting. Andrew Pollack, Panel Backs Stronger Rules for Some Food, N.Y. TIMES, Dec. 18, 2000, at A9. The Forum was a committee of twenty members, half from both sides which included scientists, environmentalists, consumer activists, representatives of the biotech industry, lawyers, and ethicists. The Forum prepared an international report that recommended mandatory labeling and testing of biotech foods. Marion Burros, Eating Well: Labeling Foods With Designer Genes, N.Y. TIMES, Jan. 3, 2001, at F2.

119. Although the FDA is confident of its existing approach, to the assessment of potential allergenicity, we believe it is important to reexamine this issue in light of current scientific data and information and the possibility that proteins introduced into foods via bioengineering in the future may present new scientific challenges. FDA is presently evaluating these recommendations regarding sequence homology, serum testing, digestibility/stability and the use of animal models. The FDA goes on to raise numerous questions regarding the usefulness of these additional tests. FDS Discussion Paper, supra note 110.

120. The Pew Institute on Food and Biotechnology, supra note 4 (quoting Craig Winters, Executive Director of the Campaign to Label Genetically Engineered Foods). This “experiment” violates one of the most deeply entrenched principles in American culture and law, the principle of autonomy. Pursuant to this principle, society has long protected a mature individual’s right to control the decisions that affect their own bodily integrity and life prospects. Peter H. Schuck, Revisiting Informed Consent, 103 YALE L.J. 899 (1994). This principle of autonomy provides the underpinning for the tort system’s refusal to permit an individual’s bodily integrity to be threatened by another unless the individual has knowingly and voluntarily consented to the intrusion as reflected in the doctrine of informed consent. The major exceptions to this principle in American law include military conscription and compulsory immunization.
VI. CURRENT STANDARDS FOR THE EVALUATION OF FOOD PRODUCT LIABILITY

In analyzing whether a general, non-food product is defective, the law first categorizes the claimed defect into one of three different types: a manufacturing defect, a design defect, or an information defect. Each category has its own distinct criteria. While courts pay lip service to the conclusion that this tripartite categorization of defects still plays a role in the context of evaluating harm from food products, this trichotomy is ignored when courts actually perform the analysis. Thus, food products are treated very differently from other products. It is this disparity in treatment, along with the regulatory framework governing food products, that creates an unworkable system for measuring the greatest potential harm from the ingestion of biotech foods, i.e., harm from allergic/toxic reactions.

In the following sections, both the minority and majority views on the appropriate theories of liability for evaluating defects in ordinary, non-food products are explained, including the treatment recommended by the Restatement Third, Torts, Product Liability (Restatement Third). The fact that the FDA insists that biotech foods are no different than traditional food, coupled with a long jurisprudential history of treating food products as a special variety of product, creates a strong likelihood that courts are likely to reject the theories germane to general, non-food products and apply traditional food product liability theories to biotech foods. In order to demonstrate that this choice produces untenable results, a summary of traditional food product liability is provided. Then, the undesirable consequences of applying traditional food

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121. The general rule is that "[a] product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings." Restatement Third, supra note 11, at § 2. The Restatement Third goes on to explain that a product:

(a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
(b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Id. Liability is strictly for a manufacturing defect but is arguably based in negligence for design defect and explicitly grounded in negligence for warning defects. Of course, a plaintiff can plead in the alternative, arguing that the claimed defect has qualities that can be evaluated in multiple categories.
product liability theories to biotech food is explained in light of the current regulatory scheme for biotech foods. The final section argues that the appropriate mechanism for evaluating harm from biotech foods is the same risk/utility balancing approach adopted by the Restatement Third to evaluate harm from ordinary, non-food products.

A. Theories of Tort Liability for Ordinary Products

1. Manufacturing Defects

The first of the three types of defects is the manufacturing defect. To determine whether such a defect exists, courts have uniformly adopted a very simple test referred to as the “manufacturing defect test.” A product has a manufacturing defect if there is a difference between its actual condition when it leaves the manufacturer’s possession and its intended condition according to the manufacturer’s specifications. This is true despite the level of care exercised by the manufacturer. In other words, there is strict liability when the product fails to conform to its design. In an uncontroversial position, the Restatement Third acknowledges that this is the uniformly accepted standard by stating “[a] product: (a) contains a manufacturing defect when the product departs from its intended design even though all possible care [is] exercised in the preparation and marketing of the product . . .” Examples of manufacturing defects include products that are “physically flawed, damaged, or incorrectly assembled.”

2. Design Defects

The second of the three types of defects is a design defect. The correct standard for determining whether there is a design defect is not as straightforward as with manufacturing defects. A hotly contested debate is being waged over whether the reasonable consumer expectation test or the risk/utility balancing analysis constitutes the most

122. Id.
124. RESTATEMENT THIRD, supra note 11, § 2.
125. Id., at § 2, com. c.


suitable theory for evaluating whether the design of a product is defective.

a. Reasonable Consumer Expectations

A minority of courts continue to apply the traditional "reasonable consumer expectation" test to evaluate whether a product's design is defective.127 According to this test, the design of the product is defective if it is dangerous "to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." This standard was set forth in the Restatement Second: Torts, § 402A (1965) (hereinafter "§ 402A").128

In the nearly four decades that have passed since the adoption of § 402A by the American Law Institute, a majority of courts have replaced the reasonable consumer expectation test with a risk/utility analysis.131 These courts appear to adopt the view that the reasonable consumer expectation test grounds jury verdicts solely on an individual's idiosyncratic beliefs.132 This lack of objective standards or guidance leads to jury lawlessness and arbitrariness, under this view, with a resultant high degree of unpredictability.133

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129. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. l (1965). In 1964, the American Law Institute adopted the Restatement (Second) of Torts § 402A, Special Liability of Seller of Product for Physical Harm to User or Consumer (1965). This provision was the first acknowledgment by the Institute of privity-free strict liability for sellers of defective products.

130. Id.


132. Id.

133. Id.
b. Risk/Utility Balancing and The Restatement Third: Products Liability

The adoption of the risk/utility analysis by the Restatement Third,\(^{134}\) as a reflection of the current legal trend, continues to be highly controversial.\(^{135}\) Consumer advocates bemoan this position as a rejection of hard-fought-for strict liability for product defects and an untenable return to the more lenient negligence standard. According to the Restatement Third, risk/utility balancing renders a product "defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . and the omission of the alternative design renders the product not reasonably safe . . ."\(^{136}\) Factors that are relevant to the risk/utility balancing for determining whether the omission of a reasonable alternative design renders a product not reasonably safe include, among others:

- the magnitude and probability of the foreseeable risks of harm,
- the instructions and warnings accompanying the product, and
- the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing,
- the likely effects of the alternative design on production costs,
- product longevity, maintenance, repair and esthetics; and
- the range of consumer choice among products are factors that may be taken into account.\(^{137}\)

While a reasonable consumer’s expectations are one factor that a jury may consider in its risk/utility analysis, it is no longer the *sine qua non* for determining whether a design is defective. One of the rationales for this switch is based on the principle that a jury in a product liability case should not determine what a reasonable consumer *actually* expects, but what a reasonable consumer has a *right* to expect. A reasonable consumer has a right to expect a reasonably designed product. To decide whether the design is reasonable, the jury must weigh the benefits of the product against its risks, factoring in whether there is a reasonable alternative design.

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134. In 1964, when § 402A was adopted, litigation over design and warning defects was in its infancy. As such, § 402A was basically silent with regard to design and warning defects. In the almost one-quarter century following the adoption of § 402A, literally thousands of cases explored these areas. Consequently, the *Restatement Third* totally supplants § 402A in these areas. See Introduction, *Restatement Third*, supra note 11.


137. id. at § 2, cmt. f.
design. This allows a jury to consider objective factors to help inform its decisions, eliminating arbitrariness and enhancing verdict predictability. This calculus also reflects the reality that products are not generically defective merely because they are dangerous. Many product-related accident costs can be eliminated only by removing product features that are essential to the inherent value and usefulness of the product. This means a rational examination of tradeoffs must be employed to determine whether accident costs are more equitably borne by injured victims or by consumers through higher costs imposed by enterprise liability.

3. Warning Defects

The last of the three types of defects is described by the common law as an information defect, most commonly labeled as a failure to warn. A manufacturer is subject to liability for failure to warn about a risk inherent in the way a product is designed that renders the product unreasonably dangerous, if a reasonable consumer would not be aware of the risk. These are risks that cannot be designed out of the product because to do so would undermine the utility of the product.

138. An example provided by the Restatement Third is the automobile, which is an extremely dangerous instrumentality. The design of a compact car is not defective merely because it is less safe than larger vehicles. The value is its lower cost and fuel economy. The cost of making the car larger is unacceptably great as it would remove consumer choice. As the risks and benefits of the relative size of cars is generally known, decisions of what to purchase along with the attendant risks that are being assumed should be left to consumers. Id. § 2, illus. 9.

139. See supra notes 192-98 and accompanying text.

140. RESTATEMENT THIRD, supra note 11, at § 2.

141. Id. In addition to the tort theories of liability, a plaintiff bringing a product liability case may also assert a breach of warranty claim. Current product liability law is actually an amalgamation of tort and contract theories. Scan M. Flower, Note, 11 Strict Product Liability in Torts Identical to Implied Warranty in Contract in the Context of Personal Injuries, 62 Mo. L. Rev. 381 (1997). Analyzing a product under contract theories renders a manufacturer liable if the product is "unmerchantable," U.C.C. § 2-314. In order to determine whether a product is unmerchantable, an inquiry is made into whether the product "is fit for the ordinary purposes for which such goods are used," W. PAGE KEeton ET AL., PROSSER & KEeton ON TORTS, 679-81 (1984) (hereinafter PROssER). Historically, this question was answered by applying the reasonable consumer expectation test. Flower, supra, at 394. If the same product is analyzed using tort theories, the manufacturer is liable if the product is "defective." As discussed earlier, to determine whether there is a defect, the majority of jurisdictions use either the manufacturing defect test or, in design defect cases, apply risk/utility balancing. See supra notes 120-37. As breach of warranty is considered a separate theory of liability, consumers generally have had the ability to plead it in the alternative in a personal injury action.

Many scholars have argued that these claims are, in fact, one and the same and should be treated that way. William L. ProSSer, The Fall of the Gئتel (Strict Liability to the Consumer), 50 MINN. L. Rev. 791, 801-05 (1966); FRUMER & FRIEDtAN, supra note 95, § 9.04(1)(a), at 9-47-9-48 ("A product that is defective is inevitably unmerchantable and vice versa, at least in personal injury and property damage lawsuits."). It is argued that both claims were developed to respond to the same problem and are driven
B. Food Product Liability Theories

Food product liability theories are distinct from those liability theories of general, non-food products. This distinction is grounded in an essential difference between the roles of a general product manufacturer and manufacturers of food products. “Manufacture” means literally, make by hand. Food is not made by hand, but rather is made by nature and found “by hand,” i.e., human intervention. Food processors, for the most part, do not “make” food, but rather gather it, remove any deleterious substances (foreign or natural), add chemicals for both flavoring and preserving the food, prepare it for storage, and package it for delivery to consumers. In other words, the functional equivalent for “manufacturing” in the context of food is the process the food goes through prior to distribution for human consumption. The end product of the food manufacturing process is the food product as it exists after the deleterious substances have been removed and chemicals have been added.

As a result of the unique nature of food, food product liability theories have evolved differently than theories of liability for ordinary products. As the next section describes, the foreign/natural test, which grew out of the FDA’s “adulteration” criteria, has now been supplanted by the reasonable consumer expectation test.

by the same policies. It appears that courts have responded favorably to these arguments and are now fairly uniform in holding that merchantability, in the context of personal injury actions, will be determined by the tort liability test that is followed in that particular jurisdiction. See Flower, supra, at 387. In the main this means that merchantability of ordinary products will be decided by either the manufacturing defect test or, in design defect cases, risk/utility balancing.


143. This signal distinction has long been recognized and incorporated into the federal and state pure food and drug acts and the administrative regulations which govern the actual daily processing of food and is reflected in the FDA’s statement that “it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects.” Food and Drug Administration, Food Defect Action Levels (1998), available at http://vm.cfsan.fda.gov/~dms/dhbook.html. The processing of food is fundamentally different from the manufacture of other consumer goods. A machine can detect amazingly small variations in a product like a ball bearing because the machines that made the bearing carefully controlled their size to begin with. That fine tolerance is impossible with a non-uniform field crop. The wide variation in product caused by weather and other environmental factors makes food processing which perfectly eliminates all natural variations and imperfections economically impossible. Because it must handle this inevitable range of size or texture, the machinery used by packers and canners cannot produce products as unvarying as those from a machine shop.

1. Foreign/Natural Dichotomies

Almost seventy years ago, the California Supreme Court in *Mix v. Ingersoll Candy Co.* was presented with a claim of an injury by a chicken bone fragment in a chicken pie. The Mix court stated that: (1) a deviation from the perfection of food, particularly if it is such a nature as in common knowledge could be reasonably anticipated and guarded against by the consumer, may not be such a defect as to result in the food being not reasonably fit for human consumption; (2) if the customer has no right to expect such a perfect product, and we think he is not entitled, then it cannot be said that it was negligence on the part of the restaurant keeper to fail to furnish an entirely perfect product.

The Mix court went on to find that, because a chicken bone is natural to chicken, a reasonable consumer must expect it as a matter of law. In so holding, the Mix court created what has been known for over one-half of a century as the foreign/natural test: if the alleged defect is natural to the product, liability does not attach, no matter how careless the manufacturer. On the other hand, if the alleged defect is foreign to the food product, then strict liability is imposed on the seller. If a food product is defective under this test, it is irrelevant whether the food processor failed to exercise reasonable care in the preparation of the food product. This standard is still followed by a handful of state courts. The majority of state courts, however, have rejected this...
pointing out that it follows an either/or approach that incorporates an artificial and wooden distinction.

a. Natural Substances and Absolute Immunity

The criticisms courts offer for rejecting the foreign/natural test are straightforward. If the injury-causing substance is natural to the product, liability does not attach, even if the food processor was extremely careless in its failure to remove the allegedly harmful substance. This bestows absolute immunity on the processor. However, this test fails to impose any duty on the food processor to employ reasonable care in preparing the food so as to minimize or eliminate natural artifacts. Practically speaking, if the manufacturer is not held liable for a failure to remove natural substances, regardless of their potential for harm, there is no incentive for the processor to follow reasonable manufacturing practices designed to minimize the occurrence of harmful substances in the food product. Thus, one of the most important goals of the tort system, deterrence of faulty conduct, is undermined.

On the positive side, this standard acknowledges that food is not made by hand, but by nature, and takes into account that foods can incorporate an almost infinite number of naturally occurring variations and imperfections. This standard also imposes a duty of care upon the consumer to act in a reasonable fashion. The presumption is that, if the substance is natural to the product, the consumer is the least-cost

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accident avoider as she has notice of the risk and is in the best position to avoid injury from it. This may have been true decades ago when this judicial prescription was created. At that point, consumers had greater control over the food preparation process. With the advent of the food processing industry as we know it today, a large portion of the American public's dietary intake consists of highly processed, pre-packaged, and pre-prepared food. In these situations, the consumer is forced to rely upon the processor to use reasonable care in the process of removing natural, but potentially deleterious components from the end product.

b. Foreign Substances and Absolute Liability

On the other hand, this standard recognizes the difference between substances that are natural to food and those that may be inadvertently added by human carelessness. These objects include screws, bolts, container glass, hairnets, and other manufactured goods that have inadvertently been included with the food crop, presumably while the crop was in the human chain of transportation or processing. With relation to its premises, employees, and equipment, the foreign/natural test does recognize that a food processor does stand in the same shoes as any other sophisticated manufacturer. Moreover, a careful consumer cannot reasonably anticipate the presence of glass or metal in a food product.

152. In *Pelman v. McDonald's Corp.*, No. 02 CIV. 7821 (S.D.N.Y. Jan. 22, 2003), available at 2003 WL 1455804, the plaintiffs alleged that McDonald's food was unreasonably dangerous in that it caused them to become obese. While the court granted a motion to dismiss, it encouraged the Plaintiffs to file an amended complaint based on the following theory:

For the first time in their opposition papers, the plaintiffs attempted to show that over consumption of McDonald's is different in kind from, for instance, over-consumption of alcoholic beverages or butter because the processing of McDonald's food has created an entirely different and more dangerous food than one would expect from a hamburger, chicken finger or french fry cooked at home or at any other restaurant other than McDonald's. They thus argue that McDonald's food is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics'... If true, consumers who eat at McDonald's have not been given a free choice, and thus liability may attach. The argument is akin to one that might be used in a products liability case regarding genetically engineered food... The genetically modified soybean, potato and ear of corn look exactly like the organically grown soybean, spud and corn. Yet these plants have been substantively, if subtly, modified into something else. Any dangers from eating a genetically modified plant are latent and thus not commonly well known in the absence of a label revealing that the object that looks like a soybean is actually a soybean carrying a bean nut protein. 16. at 43 (citations omitted) (listing, for example, the unexpected approximately 30 ingredients found in Chicken McNuggets compared to traditional "one-ingredient" chicken a consumer might reasonably expect that they were eating).
product, and cannot exercise care against harm. Thus, just as in any product case, a food processor can reasonably be held strictly liable for any injury caused by an artifact of human activity found in the food product.

2. Reasonable Consumer Expectations

As the courts have slowly cast aside the foreign/natural test, the vast majority have replaced it with the reasonable consumer expectation test.138 According to most courts, "a harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient."134 Interestingly, with regard to general non-food products, many of these courts ultimately became critical of and discarded the reasonable consumer expectation test, choosing to move to the comparative assay for manufacturing defects and a risk/utility analysis for design defects as described in the Restatement Third.155 However, while scorning the reasonable consumer expectation test as unworkable in other contexts, these courts consciously retained it as the standard for both manufacturing and design defects when it came to food products.156 The Restatement Third partially followed suit, offering the following conclusions to defend its position that, while unacceptable for evaluating ordinary products, the reasonable consumer expectation test should be followed when analyzing for manufacturing defects in food products: (1) Food processors do not follow design specifications so there is nothing to test the end product against to determine if there is a manufacturing defect; and, (2) A consumer expectations test in this context relies on culturally defined, widely shared standards that food products ought to meet. Although consumer expectations are not adequate to supply a standard for defect in other contexts, assessments of what consumers have a right to expect in various commercial food preparations are sufficiently well informed that judges and triers of fact can sensibly resolve whether liability should be imposed using this standard.157

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133. See supra notes 148-49.
134. Restatement Third, supra note 11, § 7; see also Ross Labs. v. Thies, 725 P.2d 1076 (Alaska 1986) (grocery store owner and manufacturer are liable for selling dangerous chemicals packaged to look like baby formula. Reasonable expectation test was applied for mothers who believed that the package did contain baby formula).
135. Restatement Third, supra note 11, §7.
136. Id.
137. Id. § 7, cmt. b. This Article asserts that consumers do not have “culturally defined, widely shared standards” of what to expect with biotech food. In fact, a good argument can be made that consumers are equally at a loss with regard to what to expect with a large amount of the highly processed
VII. THE UNWORKABLE APPLICATION OF TRADITIONAL FOOD PRODUCT LIABILITY THEORIES TO BIOTECH FOODS

The FDA's position is that biotech food is no different than traditional food products and that both are to be regulated in the same fashion. The natural implication is that the tort system should treat biotech food the same way as traditional food products. As such, it is likely that many courts will attempt to apply either the reasonable consumer expectation test or the foreign/natural test to evaluate harm from biotech food. The next sections argue that the courts should avoid this route for several reasons. First, the rationales for the unique treatment of traditional food products are eradicated when it comes to biotech food. Second, applying the reasonable consumer expectation or the foreign/natural tests to evaluate harm from biotech food will lead to unconscionable results that fly in the face of the goals of the tort system. Instead, this Article recommends that courts evaluate biotech food using the same risk/utility analysis that the majority of courts and the Restatement Third apply to evaluate harm from ordinary, non-food products.

A. The Rationales for Traditional Food Products Liability Do Not Apply to Biotech Food

The rationales advanced by the common law, as summarized by the Restatement Third, for refusing to evaluate traditional food like ordinary products break down in the context of biotech food. The first of these rationales is that food has no design, so the end food product cannot be tested against the design to reveal a manufacturing defect like ordinary products. However, biotech foods clearly have a design. The design is the blueprint that adds a foreign gene to the host product. Therefore, measuring for a manufacturing defect can be done just as easily as with ordinary products. For example, imagine that a biotech tomato has an intended design to be fresher longer than a traditional tomato, but its intended design is to be in every other way identical to a traditional tomato. In order to accomplish this, a fish gene is added to create the biotech tomato. If, in fact, the biotech tomato has unintended additional properties that create a toxic or allergic reaction,

foods that are currently part of their daily diet. An example is McDonald's Chicken McNuggets which contain approximately 30 ingredients compared to the traditional one-ingredient chicken that a consumer may actually believe they are consuming. See supra note 152. Another example is that consumers are generally unaware that a large amount of whole foods and processed foods which are part of their daily diet contain pesticide residues in amounts deemed safe by the FDA.
it can be argued that the biotech tomato differs from its intended design and contains a manufacturing defect.

The second of these common law rationales is that the reasonable consumer expectation test should apply to food as consumers have "culturally defined, widely-shared standards" of what to expect with food. This rationale is also rendered impotent as applied to biotech food. Unlike traditional food, consumers do not have "culturally defined, widely-shared standards" of what to expect with biotech food. Not only are biotech foods too novel, most consumers are not even aware that they are consuming biotech food. Consequently, both rationales advanced for the disparate treatment of traditional food are insupportable when it comes to biotech food.

The most commonly cited potential harm from the consumption of biotech food is potential allergic or toxic reactions. An example of how the tort system breaks down when attempting to evaluate liability for this type of harm from biotech food arises in the context of a plaintiff attempting to recover for an allergic reaction to a biotech food.

1. The Consumer Expectation Test as Applied to Biotech Foods

To a consumer, a biotech food will look exactly like an original host traditional food product. A biotech tomato with a fish gene added to prolong freshness will look and basically taste like a traditional tomato. Therefore, based on her prior uneventful relationship with traditional tomatoes, the consumer will not expect that eating the biotech tomato will cause an allergic reaction. In the tort system, if, in fact, the consumer suffers from an allergic or toxic reaction, it would appear that this particular consumer's expectation with regard to that tomato will not have been met and she should recover for her injury. However, this conclusion fails to take into consideration the idiosyncratic reaction defense which, when coupled with the FDA's failure to require labeling, functionally creates a constructive immunity for allergic and toxic reactions to biotech food.

B. The Special Case of Liability for Allergic and Toxic Reactions to Food: Trumping the Reasonable Consumer Expectations Test with the Idiosyncratic Response Defense

The law has developed an additional wrinkle when it comes to allergic and toxic responses to products. According to the majority of courts, food products do not ordinarily involve a risk of serious injury or death. However, they are products that can bring about toxic, allergic,
or idiosyncratic reactions in some persons at least on some occasions. The reason most often quoted to support the general rule denying compensation to unusually allergic users of products was articulated by the Supreme Court of Utah:

Every substance, including food which is daily consumed by the public, occasionally becomes anathema to him peculiarly allergic to it. To require insurability against such an unforeseeable happenstance would weaken the structure of common sense, as well as present an unreasonable burden on the channels of trade.159

The reasonable consumer expectation test enforces this edict. This test does not ask whether a particular consumer’s expectations have been met, but rather, whether the ordinary consumer’s expectation has been met. The jury will be asked to use its common knowledge and determine whether there was a risk that was unusually dangerous to the ordinary consumer that the ordinary consumer would not have expected.160 The defendant is entitled to have the jury consider the idiosyncratic allergic response defense in reaching a conclusion to this question.161 To establish this defense, the defendant may produce evidence that the reaction was the result of an idiosyncratic or allergic response of the plaintiff.162 The general rule under the common law is that an allergic reaction is a reaction that a normal or ordinary consumer would not have.163 Therefore, as there is no risk to the ordinary consumer, the product is not defective. The argument is that there is no defect in the food product; the defect is in the plaintiff. In other words, the consumer’s expectations of the product were not dissatisfied, but her expectations of herself were.164

Once the defendant asserts the idiosyncratic allergic response defense, the burden of production shifts to the plaintiff to rebut the inference that the defect was in the plaintiff by showing that the defect was in the product. The plaintiff must produce evidence that, rather than it being

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159. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. 1.
160. PROSSER, supra note 141, § 687.
162. Id.
163. The idiosyncratic plaintiff defense plays in the analysis for both design defects and failures to warn. The idiosyncratic plaintiff defense addresses the issue of whether there is a defect in the product in the first instance. If a plaintiff is found to be idiosyncratic, the defect is considered to be in the plaintiff and not in the product. Therefore, there is no design defect and no duty to cure with a warning.
merely idiosyncratic, she shares this response with an appreciable number of people. This requirement is based on the notion that a defect is shown to exist in a product upon a “showing that there was a risk or hazard of sufficient magnitude to involve adverse effects to an appreciable number of persons.” There is no consideration of the severity of the injury to that particular plaintiff—not even the plaintiff’s death is considered. As an example of the numbers that have been recognized as “substantial,” consider the case of an asthmatic response to sulfites. Approximately one percent of the population has this life-threatening allergy. Of the current U.S. population of 290 million, 2.9 million have this reaction. Consequently, a plaintiff claiming an allergic reaction to a biotech food who attempts to overcome the idiosyncratic allergic response defense bears the burden of establishing that she falls within a class as comparably numerous as this asthmatic class. As the next section establishes, this obstacle currently is insurmountable.

C. The Idiosyncratic Allergic/Toxic Response Barrier, the Regulatory System, and the Creation of Unintended Immunity for the Biotech Food Industry

The consumer seeking compensation for an injury caused by an allergic reaction to a biotech food faces insurmountable obstacles in light of the FDA’s refusal to require labeling coupled with the idiosyncratic response twist to the reasonable consumer expectation test. Take, for example, an allergic reaction to a biotech tomato. First, the injured consumer is very unlikely to be aware that she was injured by a biotech food. There is no information on the label to indicate that the food contains biotech ingredients. The consumer will proceed with the assumption that she was harmed by a traditional tomato. Contacting a plaintiff’s attorney could cause the attorney to quickly search the Internet. This search would reveal that there are not an appreciable number of consumers who have allergic reactions to traditional toma-

164. Id.; see also Habeeb, supra note 158, at 963.
166. PROSSER, supra note 141, § 96, at 688.
toes. The plaintiff's attorney will, in all probability, inform the injured consumer that he will be unlikely to prevail because, under the idiosyncratic allergic response defense, the defect was in the consumer, not the tomato.

But consider the consumer who is sufficiently injured to prompt a visit to a health professional, and that health professional was diligent enough (and lucky enough) to trace the injury to the tomato. Assume further that the health professional thinks to send the tomato to a specialty lab that identifies it as a biotech food. The problem then, of course, is that the plaintiff will be unable to produce any data on the numbers of individuals who have suffered an allergic reaction to the biotech tomato as this data is not being collected by researchers or the CDC. The absence of such data will allow the defendant biotech food manufacturer to assert that the plaintiff's allergic response is idiosyncratic, thus gaining the protection of the idiosyncratic allergic response defense. Consequently, the fact that the regulatory system for biotech foods does not require labeling, coupled with the tort system's unique treatment of food, virtually insulates the biotech food industry from ever being held liable for injury from the ingestion of its products.

Even if the FDA suddenly reversed its position and required labeling of biotech foods, the unique approach of the tort system for examining liability for food products would entail that injured consumers would still be unable to recover until a critical mass of consumers who have suffered from allergic reactions has been achieved. The solution to this problem is the abandonment of the reasonable consumer expectation test and its attendant idiosyncratic allergic defense doctrine. The question then becomes, what is the appropriate standard that should be applied in its place?

168. In fact, the defendant biotech food manufacturer can use the data on the traditional tomato, and the data on the fish that the foreign gene came from, to show that there are not an appreciable number of people who suffer from allergic reactions to either traditional product.

169. This data is being reported to, and collected by, researchers conducting small, isolated studies as reactions to the host food product, not the biotech ingredient, as there is no indication on the label that the product contains a biotech ingredient. The CDC does not collect any data on food allergies. The data that supports the conclusion that the total number of food allergies, and their severity, is believed to be increasing is an extrapolation from small, isolated studies. See Sampson et al., supra note 97, at 380 ("there is no code for the diagnosis of food induced [allergic reactions] in the International Classifications of Diseases so it has been difficult to ascertain the incidence of these [such reactions]"); Jonathan Bridges, Note, Suing For Peanuts, 75 NOTRE DAME L. REV. 1269, 1270 (2000); John W. Yunginger, Lethal Food Allergy in Children, 327 NEW ENGL. J. MED. 380, 421 (1992) ("there are no reliable data on the incidence, prevalence, or mortality rates for food-induced [allergic reactions] in either children or adults.")
1. Foreign/Natural Distortions

The foreign/natural test does not resolve this problem either, as its application to biotech food creates equally untenable results. Once again, the consumer must go to great lengths to even identify the fact that the food is a biotech product. Once the food is identified as a biotech food, the issue becomes whether the introduced proteins that triggered the allergic response are natural or foreign to the biotech food. According to the FDA, the DNA inserted into the host traditional food is natural to the resulting food. DNA is a normal constituent of any living thing. If a court follows the FDA’s lead and finds that the biotech food contains nothing that is “foreign,” then the biotech food manufacturer will not be liable as a matter of law.

On the other hand, if the introduced proteins are considered “foreign,” there would be absolute liability for all of the harm that the biotech food inflicts. The biotech food industry would consequently become the absolute insurers of the safety of biotech food, a situation that exists with no other product. The result would hamper fledgling American biotech companies in international markets and curtail investment and innovation in food biotechnology. This is of great concern to third world countries worried about feeding their populations. Many developing countries anxiously await and embrace new products that offer increased nutritional value, pest and weed resistance, and enhanced crop yields.

2. Duty to Warn

The injured consumer faces the same insurmountable hurdle in seeking to establish liability for the failure to warn as she faced with attempting to establish liability based on either a manufacturing or defective design. The majority of courts follow the general rule that there is no duty to warn of the risk of an allergic or toxic reaction unless the percentage of such foreseeably endangered consumers is “substan-

170. It is the product of the DNA (the physical expression of the DNA) that comes under FDA scrutiny. Only if the biotech food differs from the original food to such an extent that the common name no longer applies will there be a finding by the FDA that the biotech food contains a foreign ingredient. See supra notes 39-77.

171. See Applegate, supra note 1, at 208. On the other hand, several drought-stricken South African countries have refused genetically modified food aid, including Angola, Zimbabwe, Zambia, Malawi, and Mozambique. This is despite growing malnutrition and starvation. Michael Wines, Angola’s Plan to Turn Away Altered Food Imports Aids, N.Y. TIMES Mar. 30, 2004, at A3. These countries cite both safety concerns and concerns that the biotech seeds will contaminate local crops grown for sale to other countries that are a key part of the countries’ economy. This contamination could create importation issues to countries with stringent limitations on biotech food.
This appears to reflect a judgment that the benefits of such warnings justify their costs only if the number of endangered persons reaches a critical mass. Once again, the circular reasoning that is born from the marriage of the FDA's stance on labeling with the tort system neutralizes this theory of liability. The absence of labeling providing notice that the food contains a biotech ingredient means that there never will be knowledge of the existence of a critical mass. There will be no requirement for labeling until there is knowledge of the existence of a critical mass.

Unfortunately, this same result is reached even by the small group of courts that reject the appreciable number criteria and approach the issue of the duty to warn by using a risk/benefit analysis. These courts reject simple quantitative standards and weigh the amount of danger to be avoided by a warning against the burden of guarding against the harm without unduly discouraging beneficial use.

172. One of the earliest cases adopting this position is Hamilton v. Harris, 204 S.W. 430, 451 (Tex. Civ. App. 1918) (injuries that were the result of plaintiff's hypersensitivity means verdict for defendant). Courts have readily adopted the language of the Restatement (Second) of Torts § 402A, cmt. j (1965), in justifying the denial of recovery. Comment j states in part:

Where . . . the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it . . . Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

(emphasis added). See also Henderson, supra note 79, at 781-82; Habeeb, supra note 158; Restatement Third, supra note 11, § 2, cmt. k.

173. Henderson, supra note 79, at 782. Most law review commentary has been supportive of finding liability for breach of duty to warn when consumers suffer allergic reactions. See, e.g., Fischer, supra note 165, at 556 n.134; Holzman, supra note 163; Keeton, supra note 163; Schouten, supra note 165; Richard F. Yarborough, Jr., Comment, Strict Liability and Allergic Drug Reactions, 47 Miss. L.J. 526 (1976); Rogers, supra note 165. For the position that the consumer should bear the cost of the injury as the least cost avoider when the consumer is aware of their allergy and has notice of the ingredient in the product that causes the reaction, see, e.g., Guido Calabresi & Kenneth C. Bess III, Right Approach, Wrong Implications: A Critique of McIntosh on Products Liability, 38 U. Chi. L. Rev. 74, 86 (1970).

174. See generally M. STUART MADDOCK, PRODUCTS LIABILITY ¶ 10.10, 2d ed. 1988. ("particularly when only a very small proportion of the population is at risk, the severity of the illness or injury to which the warning would be directed is properly a factor in determining whether the manufacturer has a duty to warn.")

175. This reasoning has been carried forward into the Restatement Third:

The general rule in cases involving allergic reactions is that a warning is required when the harm-causing ingredient is one to which a substantial number of persons are allergic. The degree of substantiality is not precisely quantifiable. Clearly the plaintiff in most cases must show that the allergic predisposition is not unique to the plaintiff. In determining whether the plaintiff has carried the burden in this regard, however, the court may properly consider the severity of the plaintiff's harm. The more severe the harm, the more justified is a conclusion that the number of persons at risk need not be large to be considered "substantial" so as to require a warning. Essentially, this reflects the same risk-utility balancing undertaken in warning cases generally. But courts explicitly impose the requirement of substantiality in
balancing test, however, foreseeability principles create a roadblock to recovery. There can be no negligence in the failure to warn about a risk in the absence of evidence that would justify a finding that the manufacturer or other seller knew or in the exercise of ordinary care should have known about the risk. The required level of knowledge of the risk is defined by the information obtainable from a reasonable inquiry of experts and a reasonable search of scientific literature on the state of the art. There is no duty to warn of risks that are undisclosed by current levels of scientific knowledge. While scientists have stridently voiced their concern over the possibility of new allergens and toxins, there has yet to be any scientific proof of that possibility becoming a reality. Once again, the frustrating circularity of the current system manifests itself. No labeling means that the biotech industry can remain blissfully unaware of any risks associated with its products. And as long as there is no knowledge of risks, biotech products will not be labeled.

In summary, the tort system has created a body of food product liability law that is clearly distinguishable from that applied to ordinary, non-food products. While courts and commentators disagree over cases involving adverse allergic reactions.

RESTATEMENT THIRD, supra note 11, § 2, cmt. k.

176. Unlike the dispute between the courts on the rule of foreseeability, if any, in the context of design defect cases, courts agree that the principles of negligence with regard to foreseeability continue to operate in the realm of the duty to warn. Thomas Parker Redick, Atomic Tests Seminar: Genomic Toxic: Twenty-first Century Toxicogenomics Meets Twentieth Century Mass Tort Procedure: Is There a Duty to Warn of a Hypothetical Harm to an "Eggshell" Gene?, 42 WASHBURN L.J. 547, 563 (2003).

177. Id.

178. Id. See also RESTATEMENT THIRD, supra note 11, § 2, cmt. m.

179. See supra notes 87-96 and accompanying text.

180. Once again, the injured plaintiff can attempt to assert a breach of warranty claim. As the biotech food manufacturer does not expressly warrant that its product is "harmless to all users," a consumer will be unable to make out a claim for breach of any express warranty. Therefore, the consumer is limited to pursuing a breach of the implied warranty of merchantability. The issue is whether the product was fit for its ordinary purpose, i.e., fit for human consumption. Once again, courts that apply risk/utility balancing to determine merchantability of ordinary products revert back to the old consumer expectation test when it comes to the issue of the merchantability of food. See generally 17 AMERICAN LAW OF PRODUCTS LIABILITY §§ 80:1 - 80:14 (T. Travers, 3d ed. 1987); 35 AM. JUR. 2d Food §§ 93-97 (1967); 39 A C.J.S. Food §§ 57-62 (1961); Annotation, Liability for Injury or Death Allegedly Caused by Food Product Containing Object Related to, but not Intended to be Present in, Product, 2 A.L.R.5th 189 (1992). Consequently, a consumer pursuing a breach of warranty claim encounters the same conceptual difficulties that arise in connection with the reasonable consumer expectation test in the context of a tort claim— i.e., the product is merchantable in the sense that it is fit for the ordinary, non-allergic consumer. 77 U.C.C. § 2-314 (1988) indicates that no express promise of safety is required to create an implied warranty of merchantability. To be merchantable a product need only be reasonably fit for its intended use by a consumer. Id. Some courts in addressing this issue have regarded the implied warranty as giving the producer the “right” to expect that the product will be used only by normal individuals and that no liability attaches to someone who does not fall within this normal category. Prosser also advances this idea. See Prosser, supra note 141, at 814 (“[T]he rule which has emerged is that, if the product is safe for the normal user, there is no liability when it injures the rare abnormal one.”).
whether to apply either the reasonable consumer expectation test or the risk/balancing test to evaluate harm from ordinary, non-food products, there is a general consensus that the reasonable consumer expectation test should apply to food products. Unfortunately, the reasonable consumer expectation test carries with it the idiosyncratic allergic response doctrine. This doctrine, coupled with the FDA's failure to require labeling for biotech food, creates an unintentional immunity from liability for harm from biotech food.

This Article next addresses potential solutions to this problem. The Article concludes that the most viable solution lies within the judiciary. First, the reasonable consumer expectation test in the context of biotech food should be abandoned by the courts. The question becomes what standard should replace it. The Article points out that the long discredited foreign/natural test is not a viable solution, as it is even more unworkable in the context of biotech food than it was when applied to traditional food. The Article concludes that the most practical solution is for the courts to adopt risk/utility balancing set forth in the Restatement Third. As explained in the next section, this choice is in both in keeping with the goals of the tort system and overcomes the barriers raised by the idiosyncratic allergic defense doctrine.

VIII. POTENTIAL SOLUTIONS

A. Pre-Market Approval Under Current FDA Regulating Authority

One way to eliminate tort immunity for biotech foods is for the FDA to require pre-market testing of the newly constituted biotech food as opposed to relying on pre-existing data collected on traditional food. However, such action is unlikely, as it would entail the FDA abandon its position that biotech foods are no different than traditional foods. Even if the FDA were to entertain a complete policy shift, the agency would have a heavy burden justifying its new position. The FDA made a scientific determination that biotech food is presumptively GRAS because of its similarity to substances already in the food supply.\(^{181}\) When the agency's prior determination is a scientific one, and not just a policy preference, the agency must provide new scientific information to justify the change in order to survive a legal challenge.\(^{182}\)

Moreover, while pre-market testing may identify some allergens or toxins that otherwise would pass undetected, such testing is a long way

\(^{181}\) 57 Fed. Reg., supra note 5, at 22984-22986.

from perfect. The pathophysiology of food allergy is far from being completely understood. No lab test currently exists which will reveal all of the potential allergens and toxins that may be lurking within a new biotech food. The only way to conclusively identify allergens and toxins is through human experimentation. As industry experts estimate that seventy percent of the food now on grocery shelves may contain unlabeled bioengineered ingredients, it is claimed that “consumers are currently [and unknowingly] being used as human guinea pigs in a massive feeding experiment...”

B. Legislative Reform

Another approach is to enact the very simple legislation recently proposed by Senator Dick Durbin, D-Ill. This proposal calls for the revision of FDA regulations to require that biotech ingredients be listed on a food product’s label along with all of the other ingredients. The listing of biotech ingredients on food product labels has received a continuous stream of support in both the legal literature and by consumer advocates. This support has multiple rationales, including consumer choice based upon religious and moral beliefs including vegetarianism. The

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187. See infra notes 103-104 and accompanying text.

188. Hearing, Biotechnology in the Year 2000 and Beyond, Public Meeting, Department of Health and Human Services, Food and Drug Administration (Washington D.C., Nov. 18, 1999) (transcripts on file with author).

189. See Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D. D.C. 2000). Many plaintiffs in this class action objected to consuming either all or some genetically engineered foods on the basis of religious principles and asserted that FDA’s failure to label such foods burdens their free exercise of religion in violation of the First Amendment of the U.S. Constitution and the Religious Freedom Restoration Act. Id.

190. Twenty-six percent of consumers in America felt that it was actually morally wrong to genetically engineer plants. Fifty-three percent felt it was morally wrong to genetically engineer animals. Survey
problem of tort immunity from damage awards that this Article identifies adds yet another rationale to the growing list of compelling arguments for including biotech ingredients on food product labels. However, not only is the adoption of this simple solution unlikely in the current economic and political environment, mandatory labeling of biotech ingredients will only solve part of the problem. Even in the unlikely event that food labeling legislation is passed, large numbers of consumers may have been, and may continue to be, the victims of serious injuries from the ingestion of biotech food. The tort system as currently constituted will not compensate any of these victims for their injuries until a critical mass of injured individuals is achieved. Only then will subsequent victims be compensated.

As the following section sets forth, the most plausible solution may lie in the hands of the court system.

IX. A PROPOSAL FOR ADOPTING THE UTILITARIAN RISK/UTILITY ANALYSIS FOR EVALUATING HARM FROM BIOTECH FOOD

A. General Goals of the Tort System

The prime objective of the tort system is to compensate innocent victims harmed by faulty conduct. However, shifting the cost of these injuries onto the wrongdoers is arguably instrumental in achieving many other equally laudatory objectives. Forcing a manufacturer to bear the costs of injuries incurred from its products that are faulty in...
their manufacture or design may deter future misconduct and may tacitly encourage more careful behavior, such as increasingly diligent testing and product design.197 The cost of injuries from the use of a product may also then be built into the price of the product and passed on to the consumer. If these effects are realized, several goals that commonly fall under the rubric of "enterprise liability" may be accomplished. First, the cost of the risk will be borne by society generally, instead of the innocent victim alone. Second, the price of the product will reflect its true social cost.198 This price will then mediate consumer choice, resulting in optimum levels of production and purchase. As the price of the product increases as a result of internalizing the cost of injuries, the consumption of the product will decline as consumers switch to less costly alternatives, resulting, ultimately, in a decrease in injuries due to the use of the product.199 Thus, through enterprise liability, the tort system arguably insulates against the overuse and over-consumption of relatively risky products. Moreover, enterprise liability may place the cost of injury avoidance on the least-cost accident avoider. The manufacturer is often in the best position to accurately access the various ways of avoiding costs of injuries through redesign, quality control, and other safety measures.200 As a result of its level of access, the manufacturer is also often in the best position to insure against future injuries. Internalizing all of these costs, as well as the costs associated with injuries, into the price of the product may ultimately force a manufacturer to consider the true cost of certain products when making its choices of which products to produce. It is hoped that the end result of enterprise liability is a socially efficient output.

Finally, placing the cost of the injury from the product onto the manufacturer that reaps the profits from the sales of the product is morally the right and fair outcome.201

200. Henderson, supra note 79, at 783-86.
201. Thomas A. Cavan, Some Policy Issues for Products Liability, 17 Stan. L. Rev. 1077, 1087-92 (1965); Paul A. LeBel, Inert and Recklessness as Bases of Products Liability: One Step Back, Two Steps Forward, 32 Ala. L. Rev. 31, 67 (1980) (describing the "sense of outrage, frustration, and demonization that accompanies the realization that the lives or physical well-being of a certain number of people have been written off by a manufacturer in pursuit of an economically efficient allocation of resources"); see also Santita v. White Motor Co., 210 N.E.2d 182, 186 (Ill. 1965) (liability of manufacturer stems in part from the fact that it profits from an activity that involves defect that causes harm).
B. Failure of the Tort System to Further Its Goals in the Context of Biotech Foods

Currently, the tort system will both fail a consumer seeking compensation for an allergic or toxic reaction to biotech food and will, in this failure, betray its own instrumental and moral goals. This is the case even if the adverse reaction causes death. Not only does the tort system fail in its primary role of compensating negligently injured victims, it also fails in its role to deter faulty conduct and encourage carefully tested and designed products. As the biotech industry is insulated from liability, there is no incentive for it to voluntarily take on the burden of vigorously testing or labeling its products. In fact, the tort system gives it every incentive not to do so. By avoiding the expense of testing, and both the knowledge of and impact of injuries that may flow from labeling, the industry avoids the true social costs of its products and bypasses a test by the market of their viability. The price of biotech products may remain artificially low, actually incentivizing consumer consumption and aggravating the, as yet, undiscovered injury rate.

As a legislative or regulatory solution appears unlikely, the key to cutting this gordian knot lies with the judiciary. In order to fashion a remedy, courts could choose one of two courses of action. The first choice involves allowing a cause of action for breach of the duty to warn using a hindsight test for foreseeability. The second choice involves creating what this Article will refer to as a “duty to identify.” This duty would be placed on manufacturers when, unbeknownst to consumers, products that already exist in the marketplace (with established consumer expectations with regard to safety) are being created for the first time using new biotechnologies. The following two sections examine these two choices for fashioning a remedy for consumers injured by biotech foods.

C. Breach of the Duty to Warn Using the Hindsight Test

As previously discussed, the general rule is that there is no duty to warn of the risk of an allergic or toxic reaction unless the percentage of foreseeably endangered consumers is substantial or appreciable. This precondition is impossible to meet under the FDA’s current no-label policy. Neither can the injured consumer look to the small group of courts which reject the appreciable number criteria and approach the

\[\text{202. See infra notes 256-58 and accompanying text.}\]

\[\text{203. See supra notes 169-70 and accompanying text.}\]

\[\text{204. Id.}\]
duty to warn by using a risk/utility analysis. An essential pre-
condition for liability for a failure to warn for these courts is that the
manufacturer knew, or in the exercise of reasonable care should have
known, about the risk. Once again, while scientists have stridently
voiced their concerns that manufacturers may be introducing new
allergens and toxins into the food supply, there is no scientific proof of
this risk.

In order to fashion a remedy under a duty to warn theory, a hindsight
test must be applied. Under a hindsight test, a manufacturer will be
strictly liable for failure to warn of a risk “if, had he known of the
danger, he would have been negligent in failing to warn of such risk.”
One of the major drawbacks of this approach is the same as that found
with the foreign-natural test: unlike the general product manufactur-
ing industry, the fledgling biotech manufacturing industry would be
singled out and unfairly forced to bear the costs of scientifically unknow-
able risks creating a disadvantage in international markets and curtailing
innovation in food biotechnology.

D. Design Defect Approach

An arguably more reasoned and balanced approach is to allow an
injured plaintiff to proceed under a design defect theory using risk/
utility balancing. By applying the same risk/utility analysis to evaluate
alleged defects in biotech food products as is applied to all other
products, the functional immunity from tort liability that the biotech
food industry currently enjoys can be eliminated and the true social and
economic cost of biotech foods will be placed on the biotech food
industry. As described in the next section, this entails viewing the listing
of an ingredient on a label as a reasonable alternative design. Attacking
the problem from this angle sets the stage for finding a new “duty to
identify” novel biotech ingredients on food product labels. As will be
discussed, this duty to identify is separate, distinct, and much less
burdensome for biotech manufacturers than imposing liability for
breach of the duty to warn by use of a hindsight test. The creation of a
“duty to identify” may represent a fair compromise in the distribution
of the burdens and risks between consumers and manufacturers in our
new biotech world which brings the likelihood of a marked increase of

205. *See supra* notes 171-75 and accompanying text.
206. *Id.*
207. *See supra* notes 85-94 and accompanying text.
208. *PROSSER, supra* note 141, § 99 at 697.
209. *See supra* notes 167-68 and accompanying text.
the later discovery of currently scientifically unknowable risks associated with biotech products.

1. Risk Utility Analysis: The Standard

When a consumer files suit to recover for her injuries under a design defect theory, a court should be persuaded to evaluate the biotech product just like it would any other product, under a risk/utility analysis. Under a risk/utility analysis, the focus is on what a reasonable consumer has a right to expect. A reasonable consumer has a right to expect a reasonable design, not a perfect design. As Professor David Owen explains:

[S]ince the degree of risk or safety in every product design is counter-balanced by considerations such as cost, utility, and aesthetics, the basis of responsibility for design choices logically should be based on the principle of optimality inherent in the philosophical notion of utility and in the economic concept of efficiency. That is, the goal of both design engineers and the law should be to promote in products an ideal balance of product usefulness, cost, and safety.  

To decide whether a design is reasonable under the risk/utility balancing approach, the majority of courts require that a jury weigh the benefits of the biotech food product’s design against its risks, factoring in whether there is a reasonable alternative design. Other factors that the jury should consider include: the manufacturer’s ability to eliminate...
the danger without eliminating the product's usefulness or making it too expensive, the user's ability to avoid the danger, the anticipated awareness of the danger, and the feasibility of the manufacturer's spreading the risk through insurance and pricing.\footnote{212}

The first and most satisfying result of applying risk/utility balancing to evaluate harm from the ingestion of biotech food is that the preclusive effect of the idiosyncratic reaction defense is bypassed. Under risk/utility balancing, the focus turns from an evaluation of the plaintiff's reasonable expectations to an evaluation of the conduct of the manufacturer. The focus is on whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product.\footnote{213} If so, the omission of the alternative design renders the product not reasonably safe.\footnote{214} In determining whether the cost of the alternative design is reasonable, the magnitude of the risk to be avoided is considered. In risk/utility balancing, the degree of injury to the individual plaintiff is factored into the equation, as well as the amount of risk the product poses to all consumers. Unlike the case with the reasonable consumer expectation test, the fact that a consumer's reaction is idiosyncratic will not, in and of itself, bar the consumer from presenting her case to a jury.

For example, in the case of a consumer who dies from anaphylactic shock induced by the ingestion of a biotech food, the risk of harm to that particular plaintiff, as well as any other risks engendered by the biotech food, will be aggregated and then balanced against the utility of the biotech food. The existence of an alternative design will be taken into account in deciding whether the original design is unreasonably unsafe. The simple alternative design that the jury will be asked to consider in the context of a consumer injury from an allergic reaction is the listing of the biotech ingredient on the product's label.\footnote{215} By identifying the biotech ingredient on the label, the manufacturer has arguably obviated the danger to the consumer without eliminating the product's usefulness or making it too expensive.

\footnote{212. Id.}
\footnote{213. \textit{Restatement Third}, supra note 11, at \S 2, cmt. d.}
\footnote{214. Id.}
\footnote{215. It is important to note that this involves accepting the premise that the information, graphics, and other artwork on a label can be considered part of a product's overall design. The consumer is not pursuing a failure to warn claim by arguing that the manufacturer should have warned the consumer of the risks associated with the biotech ingredient. Instead, the consumer is asserting that the biotech ingredient should have been part of the label's design (which is part of the product's overall design), along with the graphics such as the company's logo.}
2. Applying Risk/Utility Balancing to Biotech Products

a. Benefits Associated with Biotech Foods

The benefits of each new biotech food are varied in their type and ultimate advantages. The benefits of the design that will be part of the risk/utility calculus will depend on the variety of food product that injures the consumer. While still relevant to the analysis, the benefits of some biotech products are quite modest—such as adding to convenience in shipping, storage, and handling, as is the case with the frost-resistant tomato. There, a gene from a cold-tolerant fish, a flounder, was added to a tomato to allow it to thaw without turning to mush. On the other hand, many biotech foods have extraordinary benefits that could have far-reaching and positive effects on the world’s struggle to create a global food supply.

The planet currently has a population of six billion. In fifty years, this number is expected to increase by fifty percent to nine billion. The amount of food required to meet the nutritional needs of the world population over just the next forty years is quantitatively equal to the amount of food produced throughout the entire history of mankind. Dozens of bioengineered plants and animals are being geared toward meeting these concerns head on. For example, every year, twenty-five million acres of farmland in the world become too salty to support crops. Scientists have genetically engineered a tomato plant by adding a gene from a mustard plant. The novel plant not only can grow in salty soil, it desalinates the soil, returning it to normal productive use. The resulting fruit is free from salt. Scientists claim that, with proper funding, all plants can be altered in the same way. Another example is Golden rice. Golden rice has been called the “poster child” for the potential of biotech food. Golden rice is engineered to contain beta-carotene, which the human body turns into vitamin A. Vitamin A deficiencies cause blindness and death in hundreds of thousands of children every year in Asia and Africa.

217. Dr. Barbara Glenn, Executive V.P., Public Meeting, Biotechnology in the Year 2000 and Beyond, (Department of Health and Human Services Nov. 18, 1999) (copy of transcript on file with author).
219. Id.
220. Id.
221. Id.
Other examples include the sweet potato, the regular potato, salmon, and corn. The sweet potato contains very little protein. But it is a staple food in Asia and Africa. Researchers inserted a gene that boosts protein production; the result was a sweet potato with five times the amount of protein of the original potato. Also under development is a potato that resists viruses and fungi of the type that caused the Great Potato Famine in Ireland. Salmon and other fish have been genetically modified to grow faster, while consuming less food. The closest to market is the Atlantic salmon with an added gene from another fish, the ocean pout. The ocean pout gene helps the salmon produce more growth hormone that speeds the salmon's growth to consumable size. BT corn is one example of a plant that has been bioengineered to contain natural insecticides that reduce the need for pesticides. This benefits the environment, the farmers themselves, and consumers who ingest food.

children died from nutrition-related illnesses. Talk of the Nation, supra note 216.

223. Biotech Crop Rundup, supra note 222.

224. All Things Considered, Profile: California Assembly Considers Tough New Restrictions on Genetically-Altered Salmon and Other Most, National Public Radio, Mar. 11, 2002. A proposed bill in California would bar farming fish in the state and require labeling of all imported transgenic fish products. Id.

225. "Bacillus thuringiensis (Bt) is a bacterium found in soil and on plants... Bt produces a... protein, which is highly toxic to particular types of insects... By isolating the gene that encodes this toxin and introducing it into plants, researchers (genetically altered the plants so that they contain) the insecticidal toxin in their tissues, thus making those plants resistant to insect damage." Se Earp, supra note 15, at 1630-31. First approved for sale in 1996, Bt corn has swiftly gained a large market share, reaching about one-third of the U.S. crop in 1999. See Rick Weiss, EPA Restricts Gene-Altered Corn in Response to Concerns, WASH. POST, Jan. 16, 2000, at A2; Kunich, supra note 14.

226. Professor Kunich explains that mixtures of Bt, a bacterium that is toxic to insects, have been used to spray crops for over fifty years. When used conventionally, however, the Bt toxin generally loses its effectiveness in the environment within a few days, sometimes necessitating frequent spraying. In transgenic crops, Bt toxin is continuously produced and is protected from the elements, thereby retaining its ability to kill insect pests during the entire growing season. Also, the toxin is present in essentially every part of the plant, including internal tissues that are difficult to protect with topically applied pesticides. This internal toxin production supplies protection against pests that are internal feeders such as the pink bollworm in cotton and the European corn borer in corn. The result is crops that contain their own chemical-free protection from insect pests. (Bt corn, cotton, and potatoes) have reduced the incidence of pest damage and in reduced use of chemical pesticides in many cases. [citing PEST PROTECTED PLANTS 2000, supra note 36]. For example, as a result of the planting of genetically engineered cotton, a reduction of 2 million pounds of chemical insecticide was achieved from 1995 to 1996, a decrease of over 5 million acre-treatments.


227. "Roundup-Ready" crops are genetically modified to be resistant to the common herbicide glyphosate, so that when fields are treated with this potent herbicide the crops are unharmed and only the "seeds" are destroyed. Roundup-Ready crops now constitute more than half of the U.S. soybean crop in 1999. Kunich, supra note 14, (citing Kristin Davidsen, Unsafe in Any Seed: U.S. Obstructionism Defeats Adoption of International Biotechnology Safety Agreement, MULTINATIONAL MONITOR, Mar. 1999, at 10, 11).
contaminated with pesticide residues. Plants that have been engineered with an increased resistance to herbicides increase crop yields. These examples are just the tip of the iceberg. The possibilities are only limited by the imagination and ingenuity of the biotech scientists.

b. Risks Associated with Biotech Foods

But there is a dark side to these exciting developments. While this Article deals specifically with an increased risk of harm from novel allergens and toxins, other types of risks are equally daunting and, in some cases, more scientifically documented. An awareness of some of the other types of risks associated with biotech food is important, as all of the risks associated with a particular food product are first aggregated and then weighed together in a risk/utility balancing process.

With regard to physical injuries to humans that could result from the ingestion of biotech food, another commonly raised concern involves the antibiotic resistance that renders commonly used antibiotics less effective for treating infections.
While only a short list of possible physical harms to humans from biotech foods exists, there are numerous potential risks to the ecosystem. These risks include the likely adaptation of the insect population to the plants engineered to create their own insecticides, which could increase pest tolerance to the natural insecticides used by organic farms. Plants with herbicide resistance may allow farmers to use more than normal amounts of herbicides to control weeds, as there would be no damage to the biotech plant. Concerns about the industry's ability to contain bioengineered plants and animals have become a reality. There are already examples of biotech plants and animals not approved for human consumption slipping inadvertently into the human food supply. Studies have identified the fact that bioengineered crops have spread to unintended areas, in some cases as far away as Mexico.

The ancillary health risks and risks to the environment associated with each particular product can be aggregated with the risk of the particular harm suffered by the consumer to complete the package of risks that the jury may consider in its risk/utility evaluation.

231. The constant presence of B.t. toxin in genetically engineered crops throughout the growing season has led to concerns about its persistence in the environment and the increased probability of pests evolving to overcome the protection mechanism. Id.; see also Kunich, supra note 14.


233. Whittaker, supra note 13, at 1218.

234. The Union of Concerned Scientists reported that it had detected "tiny quantities of genetically modified seeds in most of the bags of unmodified corn, soybean and canola seeds it tested." Andrew Pollack, Modified Seeds Found Amid Unmodified Crops, N.Y. TIMES, Feb. 24, 2004, at C6. "Low levels of biotech traits present in conventional seed is not new and is something that has been around for eight years or so now." Id. (quoting the President of the American Seed Trade Association, Richard Crowder). The biggest concern cited by the Union was "the health risk [that] would occur if genes now being tested to produce pharmaceuticals from crops were to get into seeds for food crops" and end up on our breakfast tables. Id.

235. Pigs that were engineered to either grow faster without hormone injections or have increased milk production were sold to a livestock dealer who may have sold them for use as food. Andrew Pollack, F.D.A. Says Food Supply May Contain Altered Pig, N.Y. TIMES, Feb. 6, 2003, at A26. Massive quantities of B.t. corn approved only for livestock feed, were accidentally mixed with other types of corn destined for human food. Andrew Pollack, Group Reports Genetically Engineered Corn in European Food, Nov. 7, 2000, at C2 (environmental group Friends of the Earth reported that tests revealed bioengineered corn variety called Round-Up Ready in four brands of tortilla chips sold in Britain and Denmark). Technology Briefing: Biotechnology, Corn Dogs Seized to Contain Genetically Engineered Corn, N.Y. TIMES, Mar. 9, 2001, at C2 (Greenpeace reported "that vegetarian corn dogs made by the Kellogg Company contained StarLink corn, a bio-engineered corn that is banned for human consumption.

236. The damage to the ecosystem could be devastating. For example, bioengineered plants with herbicide resistant qualities could transfer this trait to weeds making them immune to herbicides. Hansen & Halloran, supra note 92.
c. Reasonable Alternative Design

The next factor that the jury must weigh when balancing risk against utility is the existence of a reasonable alternative design. A consumer injured as a result of an allergic reaction who claims a design defect is asserting that a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product and that the omission of this alternative design rendered the product “not reasonably safe.” The consumer can argue that the biotech industry can eliminate much of the danger of allergic reactions by a simple cost-effective mechanism—adding the fact that the food product contains a biotech ingredient to the list of other ingredients on the label. This involves accepting the premise that the information, graphics, and other artwork on a label can be considered part of a product’s overall design. In other words, the consumer is asserting that the biotech ingredient should be part of the label’s design, along with the graphics such as the company’s logo.

The biotech industry has repeatedly asserted that the monetary cost of this alternative design far exceeds the safety benefits. And, in all fairness, the biotech industry could refer to the general rule that the existence of a safer design does not, ipso facto, mean the original design is defective. It is true that a manufacturer has no obligation to provide the safest design or provide for the ultimate in safety. The industry claims that the requirement of adding this information to a label will impact the utility of the product by unreasonably driving up costs. In order to ensure that all food containing biotech ingredients is so labeled, the food supply from farms using biotech ingredients must be segregated from those that do not. At this time, none of the collection and storage facilities segregate biotech food. Furthermore, a continuous inspection process must be instituted to ensure that there is no cross-contamination. The biotech food industry contends that

237. Ross Lab v. Thies, 725 P.2d 1076, 1079 (Alaska 1986) (viewing additional labeling information is essentially costless); Cook v. Carter-Wallace Inc., 478 N.Y.S.2d 375, 376-77 (N.Y. App. Div. 1984) (in the context of a warnings claim rather than a design defect, the court stated that “[s]ince the cost of providing warnings is often minimal, the balance usually weighs in favor of an obligation to warn.”).

238. It bears repeating that this design claim can be distinguished from a failure to warn claim that the manufacturer should have warned the consumer of the risks associated with the biotech ingredient. It is also different from the duty to identify that arises under the rubric of duty warn as there is no “appreciable number” precondition to recovery. See supra notes 158-179 and accompanying text.

239. RESTATEMENT THIRD, supra note 11, at § 2, comm. a.

240. Id.

241. See Transcript, supra note 84.

242. Id.

243. Id.
these measures are extremely expensive and will drive up the cost of biotech food unjustifiably in light of the minimal nature of the risk of allergenicity and toxicity. In other words, the industry position is that the risk of harm, if any, should be borne by the consumer; the consumer will be responsible for guarding against any risks from the ingestion of biotech food.

d. User’s Ability to Avoid the Risk

The food industry’s argument, while legitimate at first blush, distracts from the appropriate analysis of who, between the manufacturer and the consumer, should bear the burden of safety precautions. In fact, risk/utility balancing appropriately makes consumers instead of manufacturers responsible for exercising safety precautions only in very narrow circumstances. This switch should only occur when two preconditions have been met. First, the benefits of the product must outweigh its risks and the risk at issue cannot be designed out of the product at a reasonable cost. Second, the risk must be one that a reasonable consumer should be aware of by virtue of its open and obvious nature, common knowledge, or adequate warning. When these preconditions have been met, asking the consumer to shoulder the responsibility for exercising safety precautions is both a fair and socially efficient outcome. Requiring consumers to use products responsibly prevents careless users from being subsidized by prudent consumers who would then be forced to pay higher prices. However, when the consumer has no knowledge of the risk because it is latent, and there is no warning, it is both unfair and socially inefficient to place an impossible burden on the consumer to guard against the risk.

With the risk of allergenicity, the law switches the burden onto the consumer to guard against the risk only in the following circumstances: (1) when the allergenicity of the product is open and obvious, such as with strawberries, eggs, and nuts in their raw, unprocessed form; (2) when all of the ingredients are listed on the product label so that the idiosyncratic consumer has notice and can guard against the risk; or, (3) when the product label both lists an ingredient and provides a warning when the ingredient is a common allergen. None of these

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244. *Id.* The Pew Initiative on Food and Biotechnology, supra note 4 ("a Canadian study estimated that mandatory labeling would cost that country’s consumers $700 million to $950 million annually").
245. *Restatement Third,* supra note 11, at §2, cmt. d-g.
246. *Id.* at §2, cmt. k.
247. See Rogerson & Trebilcock, supra note 165, at 83-100.
248. *Id.*
essential preconditions to switching the burden onto the consumer to guard against the risk exists with biotech food. The majority of consumers are unaware of the extent to which America's food supply consists of biotech food. Consequently, when a consumer purchases and consumes a biotech tomato, the consumer expects it to be a traditional tomato and nothing more. Because the biotech ingredient is latent, the consumer is unable to guard against the risk associated with it. As the law will not require an impossibility, the law must provide the consumer the means to meet the burden it places upon her. In this case, the law must impose a duty on the biotech industry to identify the biotech ingredient so that the consumer is placed on notice of the risk and can fulfill her legal obligation to guard against it. This duty is referred to as the "duty to identify."

Recognizing this "duty to identify" biotech ingredients on a food product's label also would reanimate the biotech industry's completely separate duty to warn which, under the current legal regime, is meaningless. In the context of allergens, the duty to warn is only triggered if a precondition is met: the consumer must show that she is one of an appreciable number of consumers who have an allergic condition to a particular ingredient and, therefore, that she is not idiosyncratic or unique. Once again, it is reasonable to infer the existence of a "duty to identify" biotech ingredients based on this precondition, since the law would not place a condition on recovery that was impossible to meet. Requiring the biotech industry to identify the biotech ingredient supplies the mechanism allowing the consumer to establish the existence of such an appreciable number triggering the industry's duty to warn.

Acknowledging a duty to identify biotech ingredients would also optimize levels of safety. Much of the danger of allergic reactions is in the nature of repeated exposures. While it is arguable whether the identification of the presence of a biotech ingredient will avoid the impact of an immediate severe reaction, most allergic reactions start off as fairly mild and are exacerbated as a result of repeated exposures.

249. See supra note 100.

250. In the case of biotech foods, the consumer is precluded from guarding against the risk by the very conduct that the consumer claims is wrongful, the failure to list the ingredient on the package. See e.g., Bexig-GHR Corp., 290 A.2d 281 (N.J. 1972); DAN B. DORIS, THE LAW OF TOXINS § 200, at 500-502 (2000).

251. See supra notes 136-77 and accompanying text.

252. A consumer who has a history of extreme allergic reactions or has multiple allergy syndrome is the type of consumer who is the most likely to suffer from an immediate allergic reaction. This type of consumer is likely to scrutinize labels closely to avoid exposure to new ingredients except under closely supervised conditions. Therefore, identifying the biotech ingredient could avoid the immediate reactions as well.

253. See supra notes 78-86 and accompanying text.
initial symptoms are likely to be a rash with mild itching. As exposure is repeated, the mild itching may progress in its severity as the rash develops into hives. Ultimately, this may blossom into a full anaphylactic reaction with difficulty breathing, shock, and death. As each individual's immune system is unique, the point at which a threshold sensitization will be reached so that net exposure will spark an allergic reaction may vary significantly. Therefore, the risk of a severe injury decreases the more quickly the allergen can be identified and eliminated.

The process of elimination used to identify the cause of an allergic/toxic reaction can take weeks to months. Health professionals will counsel that, initially, the most likely suspects are any new foods/products with which the consumer has interacted. In the case of allergic reactions to biotech food, since the host product will probably be a food the consumer has ingested all of her life, it will be very low on the suspect list. The risk of harm escalates the longer the hidden allergen goes undiscovered. If the biotech product is clearly labeled as containing a genetically modified ingredient, the consumer could immediately eliminate it from her diet as a test for causation. If it is the cause, the rapid elimination of the biotech food would avoid much of the damage, because it would allow the consumer to avoid re-exposure to the allergen.

Biotech food companies may counter that labeling is not a reasonable alternative design, relying upon the general rule that the omission of an alternative design does not render the product not reasonably safe simply because "the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product other dangers of equal or greater magnitude."

The biotech food industry and the FDA continually assert that identifying the fact that the food product contains a biotech ingredient on a label is likely to cause more harm than good. They base this position on the cautions of cognition experts, who note that room for conveying information on labels is limited and that there is a risk that too much data packed into a small space can result in information

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254. Id.
255. Id.
256. Id.
257. Id.
258. Id.
259. Restatement Third, supra note 11, at §2, comm. f.
260. See Transcript, supra note 84.
overload. As such, imposing a duty to warn of farfetched or trivial risks would tend to distract the consumer’s attention from warnings about risks of greater significance. The biotech industry argues that the risk of allergic reactions is minimal at best and does not, therefore, merit a position on a product’s label.

In so arguing, the biotech industry misconstrues the nature of the duty to identify. The duty to identify merely insists that the fact that a product contains a biotech ingredient be listed on the label just like any other ingredient. It does not require that a warning of the risks of harm arising from the ingestion of the biotech ingredient be listed as well. The information costs associated with information overload are the dilution of the effectiveness of a warning. Here, this information cost is irrelevant. The consumer who has had a newly identified allergic response reviews the label for new ingredients, in order to identify the offending allergen and to avoid potentially deadly repeat exposures. The consumer who knows she is generally at risk for allergic reactions reviews labels for ingredients she has yet to be exposed to, in order to make an informed decision on whether to ingest the product. Consequently, the label is searched to elicit specific information and is not being relied upon to provide a warning that will be noticed and responded to.

e. Anticipated Awareness of the Danger: Foreseeability of the Risk

For the first consumers attempting to recover for an injury from an allergic or toxic reaction to biotech food under risk/utility balancing, the


262. Many courts caution that a great deal of discretion should be used to avoid imposing requirements that too much information be listed on a label in light of the risk of information overload. See Doc v. Miles Labs, Inc., 927 F.2d 187, 194 (4th Cir. 1991) (“If pharmaceutical companies were required to warn of every suspected risk that could possibly attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings.”). See also Gatton v. Buckeye Gas Prods. Co., 840 F.2d 933, 937-39 (D.C. Cir. 1988); Kerr v. Koehn, 557 F. Supp. 283, 288 n.2 (S.D.N.Y. 1983); Finn v. G. D. Searle & Co., 677 P.2d 1147, 1153 (Cal. 1984); Broussard v. Coni’ Oil Co., 433 So. 2d 354 (La. App. 3 Cir. 1983); Dunn v. Lederle Labs., 328 N.W.2d 576, 580-81 (Mich. App. 1982). See Thomas Scarlett, The Relationship Among Adverse Drug Reaction Reporting, Drug Labelling, Product Liability, and Federal Premption, 46 FOOD DRUG COSM. L.J. 31, 40 (1991) (“Although the FDA is not rigidly opposed to adding more precautionary information to labeling, it is conscious of the problem of information overload [and it] would not acquiesce in defensive labeling that lacked medical support.”).

263. See Transcript, supra note 64.

264. See supra note 230.

265. The individual with strong moral or religious beliefs is scanning the ingredients to be sure that consuming the product will not violate those beliefs.
last remaining hurdle is establishing that the biotech industry could foresee the risk. Once the first consumers establish the reality of the risk, proving this factor for subsequently injured consumers will not be as difficult. The Restatement Third explains that

> [m]ost courts agree . . . for the liability system to be fair and efficient, the balancing of risks and benefits in judging product design and marketing must be done in light of the knowledge of risks and risk-avoidance techniques reasonably attainable at the time of distribution.

Holding a manufacturer liable for unforeseeable risks is inefficient as it fosters increased manufacturer investment in safety based on mere guesswork and unfair in that it judges their conduct by a normative standard that is impossible to meet. Unlike a breach of the duty to warn claim, where foreseeability of the risk is an essential and central ingredient to finding fault, the degree of foreseeability is just one element of the calculus in risk/utility balancing. If the degree of harm is high, e.g., death, and the impact of the alternative design on the utility of the product is low, which was arguably established earlier, then the degree of foreseeability of the risk on the part of the biotech industry may be commensurately low.

In light of the national and international debate over the risk that biotech food will create new allergens and toxins, the biotech industry will be in a unique position with regard to how a jury will fix the degree to which the biotech industry could foresee these risks. The scientific community is in agreement that there is no hard scientific proof of new allergens being created by biotech foods. However, while many refuse to be persuaded absent this proof, large numbers of scientists are stridently arguing that the strong likelihood, based on logical inferences, that new allergens are being created is not negated merely because scientific tests are not currently sensitive enough to detect new allergens.

If, in fact, the risk turns out to be real, the question becomes what impact this debate should have on the issue of whether the biotech industry could foresee the risk. A finding of at least a small degree of foreseeability in this unique circumstance appears to be consistent with both efficiency and fairness principles. Finding liability will not foster enhanced investment in safety measures based on mere guesswork. As

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266. Restatement Third, supra note 11, at § 2, cmt. a.
267. Id.
268. While this lack of scientific proof is likely to insulate the industry from any claim of breach of the duty to warn based on the state of the art defense, in this unique situation it is questionable whether this lack of hard data should create a complete defense in the context of a design defect case when scientists are divided on the issue and the only way to make a determination is to experiment on the American public.
a result of the debate, the possible risk has been clearly identified, the biotech industry was aware of the possibility of the risk,269 and the safety measure proposed is an alternative design closely tailored to avoid the identified risk. Any claim of unfairness based on impossibility lacks merit as this risk avoidance technique was attainable at the time biotech foods were first introduced into the marketplace. In addition, the biotech food industry has been aware of this alternative design through constant consumer and international demands that the alternative design be adopted to avoid this very risk.

\textit{f. The Feasibility of the Manufacturer’s Spreading the Risk Through Insurance and Pricing}

Finally, biotech food companies are in the best position to spread the risk thorough pricing of their products and insurance. However, as a result of the failures in the current legal system, any potential harm will be borne by the unsuspecting and innocent consumer. Moreover, as with organic food labeling, the cost of labeling products\textsuperscript{270} as “non-biotech” will fall on the non-biotech food producers.\textsuperscript{271} This cost will be passed onto the consumers of non-biotech food. The additional expense will mean that low-income consumers will be driven to purchase the lower cost, yet arguably riskier food product. This creates two tiers of food products: one for higher income food purchasers and one for low-income food purchasers. Moreover, it still leaves consumers unaware that they are consuming biotech food products.

\textbf{X. CONCLUSION}

With a risk/utility balancing approach, the barriers created by the FDA regulatory scheme coupled with the tort system’s unique treatment of food products can be eliminated to allow an injured consumer to reach a jury on the merits of her claim. A jury then could balance the

\begin{footnotesize}
269. While scientists cannot prove with hard scientific data that the risk does exist, the biotech industry must acknowledge that the risk is possible; as it is equally true that scientists cannot establish that the risk does not exist.

270. A Gallop poll reported that 68\% of Americans would be willing to pay more for labeling of biotech foods. See Steyer, supra note 101.

271. One estimate is that labeling will add 17\% to the cost of the food product Editorial, \textit{Be More Clear: On What’s in Soup Cone}, N.Y. TIMES, Sept. 17, 2000, at 14N15. Study cited by Christine Bruhn, Director of the Center for Consumer Research at the University of California at Davis, estimating that the European Union’s mandatory labeling policy will increase food costs by 17\%. Ironically, the cost of this labeling is currently being placed on the organic food industry. Marian Burros, \textit{U.S. Imposes Standards for Organic-Food Labeling}, N.Y. TIMES, Dec. 21, 2000, at A22.
\end{footnotesize}
benefits of a biotech product against the likely occurrence and severity of injury it may cause, including an increase in food allergies, antibiotic resistance, or negative ecosystem impact. The jury could also factor in whether a reasonable alternative design exists, including the identification of the biotech ingredient on the food label. In this fashion, juries could weigh the benefits of a biotech food against its risks in a reasoned fashion to weed out those which are not beneficial to society pursuant to the same instrumental, enterprise liability, fairness, and moral principles that apply to any ordinary 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 overwhelmingly desire, but that legislatures, to date, have refused to adopt.