Regulation of Genetically Engineered Food Products: A Market-Oriented Perspective

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Only twenty years after the landmark Asilomar meeting where scientists discussed the opportunities and possible risks presented by the ability to transfer DNA from one organism to another,' bioengineered products have moved outside the confines of the laboratory into commercial uses in the pharmaceutical and food-processing industries. Recent advances in molecular biology and the application of new technologies to the production of food have opened the door to a new world of bioengineered food. Agricultural biotechnology[2] has the potential to meet the needs of a rapidly growing population and minimize the toxic influences of traditional farming practices on the environment.[3] Furthermore, it promises to improve human nutritional intake and can even aim to satisfy our desire for novel or exotic foods with aesthetically appealing textures, appearances and tastes. At the same time, however, the public remains

[1]Paul Berg et al., ***Asilomar Conference on Recombinant DNA Molecules,*** **188** SCENCE **991 (1975)** . **The Asilomar meeting has been recognized as the beginning of public oversight, rather than mere scientific debate, over recombinant DNA experimentation.** ***See generally*** **Judith P. Swazey et al.,** ***Risks and Benefits, Rights and***

Responsibilities: ***A History of the Recombinant DNA Research Controversy,*** **51 5. CAL. L. REv. 1019 (1978).**

[2]For purposes of this paper, the terms biotechnology and a **genetic engineering refer to the ability to effect specific genetic changes via techniques such as recombinant DNA (rDNA) (i.e., joining together pieces of DNA from different organisms together in vitro), cell fusion (used to create homogeneous antibodies that recognize only one kind of antigen), and recombinant RNA (rRNA) (the newest techniques in which RNA is modified by inserting segments of foreign RNA).** ***Cf.*** **Diane**

E. Hoffmann, ***The Biotechnology Revolution and its Regulatory Evolution,*** **38 DRAKE** ***L.*** REV. **471, 471 n.l (1988) (employing this definition); OFFICE** OF TECHNOLOGY ASSESSMENT, cO˜¶ERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS, **3— 4, 503 (1984) (adopting similar definition)**

[3]council on scientific Affairs, Am. Medical Ass'n, ***Biotechnology and the American Agricultural Industry,*** **265 J. AM. MED. Ass'N 1429, 1429-34 (1991)**

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suspicious of the uses to which genetic engineering may be put, as well as somewhat wary of the foods derived from genetically engineered organisms.[4] Critics of the new technology have long argued that recombinant DNA techniques and products derived from them pose significant and ill-understood risks to human health and safety) Against this backdrop, the federal Food and Drug Administration (FDA) has sought to fulfill its statutory mission to protect the safety and wholesomeness of the food supply) Because the FDA has chosen to address the novel issues raised by the application of biotechnology to food through existing statutory authority, manufacturers and producers of bioengineered food, as well as others concerned with the availability of safe, nutritious and inexpensive food, have sought clarification from the FDA about how these decades-old standards will be applied. In the near-term future at least, the **FDA'S** response, published in l992,˜ appears likely to direct commercial efforts at bioengineered foods into channels that may not realize the full benefits of

e.g.,* Michael Schrage, *Innovation's Growth Industry Lies

Where High Tech and Low Brow Meet, WASH. POST, Dec. **30, 1994, at D2**

(observing that Calgene must constantly assure consumers that its

genetically engineered Flavr-Savr tomatoes are not Frankenfoods) [5] *See, e.g.,* **Ruckelshaus, *Risk, Science, and Democracy,* 1** ISSUES

SCI. TECH. **19, 21 (1985) (arguing that the risks inherent in biotechnology are the greatest people have ever confronted from advances in the natural sciences); Wald, *The Case Against Genetic Engineering,* 16** SCIENCES **7 (1976).**

[6]This paper will concentrate primarily on the FDA's regulation of foods and food additives produced by biotechnology. It will not discuss the FDA's oversight of genetically engineered drugs, nor will it specifically address the role of other federal and state agencies in regulating biotechnology.

257 **Fed. Reg. 22,984 (1992) [hereinafter FDA Statement).**

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biotechnology, both from consumerist and marketing perspectives, as quickly and efficiently as possible.

Part I of this paper briefly explains relevant provisions of the federal Food, Drug and Cosmetic Act[8] (FD&C Act) leading up to the analytic framework set forth by FDA in its 1992 statement of policy. Part II discusses the scientific and regulatory climate in which Calgene, a manufacturer of a genetically altered tomato, brought its product to market in consultation with the FDA. Part III attempts to place the substantial discretion vested in the **FDA** in a broader context as part of the ongoing debate about the safety of genetic engineering. Finally, Part IV explores how the FDA'S positions could inhibit or enhance the development of an active and efficient market for genetically engineered products.

I. Basic Statutory Framework of the FD&C Act

Under current federal law, foods and food additives are regulated by the FDA under the FD&C Act. The Act prohibits the introduction or delivery into interstate commerce of misbranded or adulterated food. Under § 402(a) (1) of the Act,

food shall be deemed to be adulterated [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the

821 U.S.C. §5 301-92 (1988 & **Supp. 1993).**

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quantity of such substance in such food does not ordinarily render it injurious to health.[9] According to § 402(a) (2) (C), a food is deemed

adulterated if it is, or it bears or contains, any food additive which is unsafe within the meaning of § 409. In turn, § 409 effectively creates a pre-market approval requirement for food additives by providing that a food additive is presumed unsafe unless the additive and its use conform with a regulation prescribing the conditions under which such additive may safely be used.'[0] Finally, § 201(s) defines food additive as

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, ... if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures [or, for substances used in food prior to 1958, through experience based on common use] ... to be safe under the conditions of its intended use.'[1]

Thus, the FDA may declare a food adulterated and subject to seizure'[2] if it includes a poisonous or deleterious substance that either may render or ordinarily render[s] the food injurious to health, depending on the agency's determination of the substance as added or not added. It is clear that the FDA understands the ordinarily render clause of § 402(a) (1) to allow greater tolerance of potentially

˜21 **U.S.C. x 342(a)(1).**

'[1] *1d.* § **348 (also permitting food additives pursuant to certain investigational exemptions)**

"***Id.*** x 321(s).

'[2]Other sanction include injunctive proceedings against the producer or criminal prosecutions.

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dangerous substances that occur naturally in foods. However, the FDA regards any substance that is not an inherent constituent of food or whose level in food has been increased by human intervention to be added within the meaning of §402(a) (1) •13 Moreover, the mere presence of an unauthorized food additive or a permitted additive under unauthorized conditions will cause the food to be adulterated within the meaning of the FD&C Act. The practical effect of finding a substance to be a food additive is to place the burden of showing safety upon the proponent manufacturer, whereas the FDA has the burden of proving by a preponderance of the evidence that the substance is injurious to health.'[4]

As far back as 1984, the FDA indicated that it would not seek additional congressional authority to develop guidelines for the regulatory oversight of bioengineered food products.'[5] The agency confirmed this view in 1986 when it announced that it need not establish new administrative procedures to deal with generic concerns about biotechnology.'[6] The refinement of recombinant DNA techniques and other forms of genetic engineering, however, contributed to a climate of uncertainty

[13] *See* **United States v. Anderson Seafoods, Inc., 622 F.2d 157 (5th Cir. 1980), *afff'g* 447 F. Supp. 1151, 1155 (D. Fla. 1978) (holding that mercury in fish that had been picked up from the environment could be considered added for purposes of x 402)**

'[4] *See* **United States v. An Article of Food, 678 F.2d 735, 739 (7th Cir. 1982)**

[15] *5ee* **Statement by Frank E. Young, Comm'r of Food and Drugs, before the Subcomm. on Oversight and Investigations of the House Comm.**

on Energy and Commerce 1 (Dec. 11, 1984) (FDA does not believe that the use of biotechnological techniques requires any additional laws or regulations.).

1651 **Fed. Reg. 23,309 (1986).**

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regarding exactly how the FD&C Act's provisions were to be applied to food produced through these techniques.'[7] Conceptually, was genetic engineering to be treated as a more efficient and targeted form of classical hybrid breeding procedures, which had not be subject to any greater regulatory scrutiny, or as the creation and manipulation of organisms in which human intervention had, by definition, inserted new additives into the ultimate food products?

The **FDA'S** articulated position regarding the regulation of biotechnology products as of 1936 did not clarify matters much. After asserting that existing statutory authority would guide the FDA into the realm of genetically engineered food, the statement held that the administrative review of products using biotechnology [would be] based on the intended use of each product on a case-by-case ˜ Experts advised that it was important to evaluate whether new procedures resulted in changes in the chemical identity of the ingredient, the introduction into the food supply of new or altered levels of impurities, or an increase in dietary exposure of consumers to the ingredient that was not justified by available safety data.'[9] If the FDA found that the food ingredient manufactured by a new method had been altered significantly, the agency would either conclude that

[17] *.see, e.g.,* **Steven W. Frank,** ***Food Additive Models for the Regulation of Recombinant DNA Technology Under the Federal Food, Drug, and Cosn˜etic Act,*** **45 FOoD DRUG COSM. L.J. 169, 171 (1990)**

'˜51 Fed. Reg. 23,309,

'[9]See James H. Maryanski, ***Prospects for the Safety Evaluation of Foods in the United States of America in Connection with Biotechnology*** **(paper presented June 9-10, 1988)**

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the new ingredient was also generally regarded as safe (GRAS) or that it was not GRAS and was subject to the food additive provisions of § 409 of the FD&C Act.[20] The law did not preclude an ingredient produced by recombinant DNA techniques, or other novel methods, from being affirmed as GRAS. However, to be affirmed as GRAS, the food ingredient must be shown to meet the criteria of a GRAS food ingredient, including a wide recognition of safety based largely on published information concerning the intended use of the ingredient. Furthermore, these experts cautioned that the microbiological review has a pivotal role in assessing the potential for toxic substances to be present in food as a result of genetic modifications.[2]' As per the FDA's policy, the food manufacturer should adequately identify all of the organisms and vectors used to construct the commercial production strain and characterize fully the introduced genetic alterations through techniques such as restriction mapping and nucleotide sequencing to establish the absence of sequences that may code for harmful or unexpected substances.[22] Information was also needed to assess whether the production culture produces antibiotics or toxins, and whether the production culture was pathogenic.

These general guidelines, however, failed to resolve numerous inquiries received by FDA on issues such as whether the agency would conduct pre-market review of new genetically

[20] *5ee* *id.*

[21] *5ee* *id.*

[22] *5ee* **51 Fed. Reg. 23309 (1986)**

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engineered foods, whether and under what conditions such foods would be challenged by FDA when introduced into interstate commerce, whether special labeling would be required for these new foods, and what scientific information would be necessary to satisfy FDA that such foods were safe and in compliance with the FD&C Act and other applicable statutes *23*

II. Building upon the Framework: The Flavr Savr Tomato Case and the 1992 Policy Statement

Calgene, one of the larger companies dedicated to the agricultural uses of biotechnology,[24] became the first producer to request consultation with the FDA concerning a new plant variety developed by recombinant DNA techniques.[25] Basically, there were two parts to Calgene's regulatory concerns with respect to its Flavr Savr tomato, which contained an antisense gene sequence that allowed the tomatoes to be picked ripe and then shipped to the consumer without rotting. In April of 1991, Calgene submitted to the FDA a request for an advisory opinion on the safety of using a common research tool, the kan(r) gene, as a marker to facilitate the selection of plants which have been successfully transformed with the desired trait (i.e.,

[23] *5ee* **57 Fed. Reg. 22,984, 22,984 (1992).**

[24] Robert A. Bohrer, ***Food Products Affected by Biotechnology,*** **55 U.** PITT. L. REv. 653, **670 (1994).**

[25] *5ee* **57 Fed. Reg. 22,294, 22,985 (1992).**

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inhibited production of polyglacturonase, the enzyme that causes rotting) ˜26 Second, Calgene sought the FDA's advice regarding the safety of adding a non-coding, anti-sense genetic sequence for the gene that ordinarily produces the enzyme responsible for degrading the cell walls of ripened tomatoes.[27] This sequence slows the rate of expression of polyglacturonase, the plant enzyme that causes pectin to degrade, an essential step in the softening of ripe fruit.

The FDA's response to Calgene's requests and the prevailing uncertainty was embodied in a Statement of Policy issued May 29, l992.˜ Basically, the statement creates an analytic framework for new varieties of genetically engineered food plants that yields one of three possible outcomes: a position of no concern; an admonition to consult FDA, which could include both informal regulatory approval as well as the requirement for formal GRAS affirmation or food additive review; or a determination that the new variety is not acceptable.[29] The statement then considers four major classes of genetically-induced effects and the appropriate regulatory treatment for each, which are discussed in greater detail below.

Briefly, one type of bioengineering transformation is to alter the production levels of a protein endogenous to the plant. Such intra-generic efforts would include, for

[26] *5ee* **56 Fed. Reg. 20,004 (1991) (FDA requesting comment on Calgene's request)**

[27] *5ee* **57 Fed. Reg. 22,772 (1992).**

2857 **Fed. Reg. 22,984 (1992).**

[29] *5ee* **57 Fed. Reg. at 22,992.**

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example, the Calgene tomato's inhibition of the production of the rotting enzyme. These cases present the clearest analogy to traditional hybridization efforts, albeit in a much more specifically targeted fashion. Thus, the FDA indicated that its degree of concern would depend on whether such changes have an effect on toxicants present in that species and whether the result is a significant change in the nutritional value of that food)[0] Where there are no increases in toxicant levels or the changes in the overall nutritional value of the food, the FDA will not require consultation or pre-market approval — a no concern position.[3],

Genetic engineering may also seek to introduce a non-native protein to the plant in order to confer desirable characteristics from the transferor plant or animal on the host plant. If the protein does not have a history of safe use in food and will be found in foods produced from the plant, the FDA will consider the effect of the new protein on levels of any native toxicants that may exist as well as the allergenicity and toxicity of the introduced protein.[32] Significantly, unless the new protein appears on limited lists of known allergenic proteins or known toxic proteins, the producer of the genetically engineered new variety may make its own determination that the food is not one that may be harmful to human health and therefore is generally

[30] *5ee* **57 Fed. Reg. at 22,993 (Figure 1).**

[31] *See id.*

[32] *5ee id.* **at 22,999—23,000 (Figure 4).**

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recognized as safe.[33] However, if the new protein without a safe history of safe food usage is likely to be a macroconstituent in the human or animal diet, the FDA will require pre-market consultation and possibly approval as a food additive.[34]

The twin questions of GRAS status and macroconstituent treatment are not trivial to the manufacturer and will likely influence the types of innovation pursued by food manufacturers. Manufacturers favor GRAS status over the food additive petition process for several reasons. First, GRAS status allows the sponsor of an ingredient to decide whether the studies and tests conducted on the substance justify the conclusion that the substance is GRAS. Second, GRAS determinations are generally broader than the very narrow uses permitted for food additives, and subsequent expanded uses of GRAS substances are obtained more easily. In addition, where the sponsor of an ingredient seeks FDA affirmation of its GRAS status, the FDA review process itself is likely to be quicker and less cumbersome.[35] FDA approval of direct food additives, on the other hand, generally takes between five and seven years.[36]

[33] *See id.; see also* **Bohrer, *supra* note 24, at 662.**

[34] *See* **57 Fed. Reg. 23,000 n.17e.**

[35] Bohrer, ***supra* note 24, at 658.**

[36] coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology science Coordinating Committee, 50 Fed. Reg. 47,174, 47,177 (1985), ***cited in* Karen Goldman Herman, Comment, *Issues in the Regulation of Bioengineered Food,* 7** HIGH TECH. L.J. **107, 124 (1992).**

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The Statement also propounds two questions regarding changes in or additions to the carbohydrates found in a plant variety. First, does the resulting carbohydrate contain any structural features not ordinarily found on food carbohydrates, and, if the carbohydrate is likely to be a macroconstituent of the diet, are there any changes that are likely to affect digestibility or nutritional qualities?[37] Although some commentators have noted that the FDA's position will likely mean that new carbohydrates are treated more stringently than new proteins,[3] it does appear that a genetically engineered carbohydrate similar in structure, digestibility, and nutritional value will avoid FDA premarket review.

Finally, new or modified fats or oils must be considered under a slightly different framework. For such lipids, the first question is whether the resulting fat or oil will be a macroconstituent of the diet.[39] If so, then the manufacturer must consult with the FDA, without regard to whether there are changes in digestibility or nutritional value. Second, the **FDA'S** flowcharts articulate a policy decision that if the new or modified lipid is not unusual or toxic, then the producer can make its own determination of safety and avoid pre-market review. *40*

[37] *See* **57 Fed. Reg. at 23,001.**

[39] *See* **Bohrer, *supra* note 24.**

[39] *See* **57 Fed. Reg. at 23,003 (Figure 6).**

[40] *5ee id.*

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In many cases, therefore, the choice presented to a manufacturer hinges on whether the FDA will require consultation (and potentially a time-consuming food additive petition) or whether the manufacturer will be able to make its own determination of safety based on its own testing, often guided by FDA protocols. One striking features of the **FDA'S** analysis is its use of a macroconstituent threshold (e.g., for proteins, carbohydrates, and lipids) . The FDA will require pre-market consultation and possibly pre-market approval for a new protein that is likely to be a macroconstituent in the human diet, even where the protein is not from a donor species commonly allergenic, is not reported to be toxic, and is of the type of protein ordinarily well-digested in humans.[4]' Such concern may be unwarranted; in this case, the manufacturer would appear to be well-equipped to make the determination of safety for itself. On the other hand, as the statement itself indicates, one possible class of proteins that could be consumed at a substantial level comprises the enzymes used as selectable marker genes, introduced into many plants.[42] Because the introduction of these proteins may be susceptible to coordination problems among market participants, none of whom individually may introduce the marker protein in sufficient quantities to warrant concern, it may be appropriate for the FDA to protect consumer welfare by acting

[41] *See id.* **at 23,000 n.16; Bohrer, *supra* note 24, at 663.**

[42] *5ee* **57 Fed. Reg. at 23,000 n.16.**

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in this sphere. Ultimately, the better way for the FDA to resolve this question may be to evaluate and add appropriate gene markers to the list of substances considered to be GRAS[43] so as to eliminate uncertainty in this area.

In May of 1994, the FDA notified Calgene and other interested parties that it had concluded that Flavr Savr tomatoes have not been significantly altered when compared to varieties of tomatoes with a history of safe use.[44] At the same time, the FDA took action on the food additive petition[45] that Calgene had filed in July of 1993. The FDA amended the food additive regulations to provide for the safe use of **APH(3** minutes)II as a processing aid in the development of new varieties of tomato, oilseed rape, and cotton.[46]

Consistent with the thrust of the FDA's 1992 policy statement, the agency did not establish any broad precedent in its approval of the Calgene tomato. Indeed, formal rulemaking procedures and guidelines are virtually impossible to frame or implement in the context of genetic engineering, which offers the prospect of limitless ability to combine or manipulate an organism's DNA. Because the case-by-case consideration and adjudication of applications of bioengineering to food raises costs and increases delay to manufacturers and to the agency, there is a concern, however, that innovation could be slowed or inhibited. Ultimately,

[43] *5ee* **21 C.F.R.** x **170.30(d).**

˜*See* 59 Fed. Reg. 26,647 (1994). ˜˜5B Fed. Reg. 38,429 (1993). [46] *5ee* **59 Fed. Reg. 26,700 (1994).**

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the success or failure of the FDA's regulatory scheme and, in turn, the success or failure of the bioengineered food industries will rest on how the FDA applies the discretion with which it is vested in allocating resources to the regulation of genetically engineered food and how it addresses and is affected by the broader social policies that underlie public concern about genetic engineering.

III. Arguments for and against Genetically Engineered Foods

Beyond the specific statutory provisions of the FD&C Act and the interpretations announced by the FDA, it is important to emphasize FDA's substantial discretion and the informal nature of the consultation approach adopted by the FDA. The visibility of the FDA'S actions, which are widely reported on in the media, make the agency a lightning-rod for the interest groups' and the general public's criticisms. Thus, genetic engineering's future in food products must be viewed against the ongoing societal debate over the uses and feared abuses of bioengineering.

On the one hand, as recently as 1987, nearly a quarter of the American people harbor moral or religious objections to gene splicing or recombinant DNA to produce hybrid animals and plants.[47] Some people criticize it as playing God with

[47] *See* **Food and Drug Admin., Office of Tech. Assessment, New Developments in Biotechnology: Background Paper — Public Perceptions of Biotechnology 57 (1987) (24% of Americans who have heard of the techniques say creating hybrids through direct manipulation of DNA is morally wrong; 68% say it is not morally wrong).**

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living organisms. Although the objections may have become more muted as the technology has grown more established, the popular suspicion of recombinant DNA techniques obviously exerts a powerful hold on Americans' imagination even today, as demonstrated by the spectacular success of the 1993 movie *Jurassic Park.* Even food experts and scientists are not immune. In response to the FDA's statement of policy, one thousand of the nation s top chefs vowed to boycott genetically engineered foods. As one chef explained, I am not willing to offer my patrons, my family or myself as a testing ground for a new generation of bioengineered foods.[48] The existence of such sentiments, despite the FDA's conclusions, suggests that genetic engineering may prove to be an issue that opens up a schism between the FDA and the public, which has long reposed great confidence in the agency.

Many Americans fear that the risks are not well understood or that genetically engineered organisms, either as food or in the environment, may present unforeseen long-term risks. The 1987 survey mentioned above found that 52% of the public believes that genetically engineered products are at least somewhat likely to represent a serious danger to people or the environment.[49]

[48] *5ee* **Sue Kirchhoff, *Chefs to Boycott Genetically Engineered Food,* Reuter Bus. Rep., July 28, 1992.**

[49] *See* **Food and Drug Admin., Office of Tech. Assessment, *supra* note 47.**

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The introduction of new proteins into foods or novel combinations of proteins in foods creates the possibility of allergic responses in susceptible individuals. In the absence of labeling requirements, a person would not be able to know that possibly allergenic substances had been introduced into the food. Although the 1992 policy statement did not impose a per se requirement of special labeling on genetically altered foods,[50] the FDA has recently requested comments on whether these foods should be labeled as such.[5'] Although consumers who demand sufficient information upon which to make an informed choice might favor a label, a useful label that actually identifies the types of genetic engineering (intra-generic versus inter-generic, for example) or the sources of the DNA used would likely create an extremely complex label that few consumers are likely to be able to interpret. Moreover, while public fears linger, any label that alludes to a bioengineered origin may devastate the marketability of the product.[52]

Finally, religious or ethical dietary proscriptions may prevent some people from accepting the new technologies. **A** moral vegetarian would perhaps be disturbed to learn that an apparent grain product had been genetically altered with

[50] *Cf.* **57 Fed. Reg. at 22,992 (noting that consultation with FDA may result in special labeling required)**

5I˜g **Fed. Reg. 25,837 (1993).**

[52] *Cf. Citing Survey, Monsanto Says Any BST Label Will be*

Misleading, Fooo LABELING NEWS, **Apr. 4, 1994 (survey comparing public response to variety of labels found that regardless of the apparent innocuousness of the label, 87-97% thought milk from cows not treated with a genetically engineered drug was safer, tastier, or more nutritious than milk from treated cows)**

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animal DNA, for instance. Although the number of DNA nucleotides affected by genetic engineering is infinitesimal compared to the total **DNA** in an organism, the dietary dictates of Orthodox Judaism or the moral imperatives of veganism may be difficult to reconcile with these new procedures.

On the other hand, there is no scientific evidence that rDNA alters the toxicity, safety, or allergenicity of foods. Proponents of the new technology identify the many individuals' concerns as stemming from their qualitative assessment of the risks involved as new, complex, uncontrollable, and involuntary (to the extent that bioengineered products are not specially labeled) .˜ The development of plant varieties capable of resisting disease and inhibiting rotting leads to less wasted food, easier transportation, and a commensurate savings of resources. Biotechnology may be employed to enhance crop yields and nutritional contents of foods, which may offer the only way to feed a rapidly expanding world population and to cope with periodic droughts that afflict certain regions of the world.

Although the controversy over genetic engineering may be simplistically characterized as a debate over the magnitude of the risks and uncertainties involved, the public acceptance and commercial success of bioengineering food products depends on how the FDA and the food industries are able to address the public's concerns. The next section

[53] *See* **Bohrer,** *supra* **note 24.**

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examines whether and how the FDA should use its institutional prestige and goodwill with the public to facilitate the marketability of bioengineered foods.

IV. Implications for the Development of a Market

Many commentators have explored the application of traditional FDA regulatory structures in the biotechnology arena as well as critiqued the adequacy of this regime to control the emerging new technology. Another approach, however, is to consider the implications of the existing regulatory framework for the introduction to market of new food products obtained through genetic engineering techniques. This section examines the signals and incentives that the FDA's regulatory positions may be establishing for actual and potential market participants, as they consider to what kinds of innovative food products they should dedicate their scarce financial and scientific resources. I argue that the current regulatory regime may be inhibiting the introduction of certain types of products that would be likely to find a receptive public market. Moreover, the FDA's unwillingness to aggressively counter many of the public's irrational fears of genetic engineering may reduce the incentives of biotechnology food manufacturers to invest

[54] *See, e.g.,* **Bohrer,** ***supra*** **note 24; Daniel D. Jones,** ***Food Safety Aspects of Gene Transfer in Plants and Animals: Pigs, Potatoes, and Pharmaceuticals,*** **43 FooD** DRUG COSM. **L.J. 351 (1988); Herman,** ***supra*** **note 36.**

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in bioengineer foods because of the limited economic return achievable.

The FDA's policy statements regarding how the agency intends to regulate bioengineered food products implicitly favor certain types of relatively conservative tinkering at the expense of arguably more radical, but not necessarily more dangerous, engineering of food products. In addition to the possibility that the FDA will find itself in a continual struggle to keep pace with the accelerating rate of scientific and technological breakthroughs, the FDA has outlined its position with respect to four major categories of possible effects of genetic engineering that appear to make it more difficult, expensive and time-consuming for a biotechnology firm to bring a certain types of innovative food product to market, despite several arguments that would support allowing such products to be sold.

For example, the obligation to consult the FDA with respect to possible allergenics introduced into a product creates the possibility that many firms will decide that the extra developmental costs and risks are not worth the risk. Essentially, the pre-market notification and review process may have an *in terrorarn,* chilling effect on the introduction of certain products. For example, although producers may unquestionably sell properly-labeled peanuts and peanut-based products on the market, the 1992 Statement does not explicitly adopt a comparative risk analysis that would look to making the product available, perhaps with a simple

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warning directed to individuals allergic to peanuts, despite its allergenicity to certain consumers in the market.

Consumers are likely to respond to genetically engineered foods in a manner different from, say, bioengineered drugs. Although the demand for food generally is probably rather inelastic (after all, one must consume calories and nutrients, and the purchase of food has a high priority in an individual's budget), the demand for any particular variety of food product is relatively elastic. The elasticity of genetically engineered foods is particularly high, given the fact that, at least for the near future, bioengineered foods will have very close substitutes in the eyes of most consumers. For example, the Flavr Savr tomato competes in the market with several ordinary varieties of tomatoes. Contrast the situation with bioengineered drugs, in which a new product's greater efficacy and reduced side effects in treating a particular disease or condition may make the drug unequaled and consumers' demand for it far less elastic. Thus, the FDA should be wary of imposing great costs, in the form of regulatory compliance expenses and delay, on manufacturers who seek to introduce genetically engineered food.

On the other hand, because the scientific research and technical know-how involved in genetically altering a food source entail substantial costs, the manufacturer needs to be able to recoup his expenses by being able to charge a higher price for the benefits of the new product. Calgene's

products, for example, provided improved taste because the tomatoes were vine-ripened, rather than artificially ripened by exposure to ethylene gas; they also reduced wholesalers' and retailers' losses due to soft tomatoes damaged during shipment.

Given the FDA's unrivaled visibility among government agencies and its unique role in safeguarding the food supply, the FDA can facilitate the development of the bioengineered food industries by continuing to assure the public of the safety of these foods. When the Calgene tomato received regulatory approval, approximately five years after it was first created, FDA Commissioner pronounced the vegetable as safe as any tomato on the market.[56] Even as the Flavr Savr tomato finally begins to enjoy modest regional sales today, however, Calgene still finds that [m]anaging consumer ignorance becomes more important than providing a quality innovation.[57] In the short term, industry may welcome the FDA's case-by-case analysis of the first bioengineered foods and the attendant public generated by the process, because FDA approval will help to assuage the public's concerns about safety and boost public confidence in these products. On the other hand, in the longer term, industry representatives

[55] *5ee* **Bohrer, *supra* note 24, at 671 (noting difference in taste).**

Of **course,** the reduction in **loss damage would tend to reduce the prices; however, for many other types of genetic engineering that do not affect transportation or disease characteristics, such as true flavor or nutritional hybrids, this effect is negligible.**

[56] *Long March of the Tomato,* WASH. PosT, **May 21, 1994, at A22.**

[57] schrage, *supra* **note 4, at D2.**

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argue that bioengineered foods should require no more screening than traditionally produced foods.[58]

The issue of labeling genetically engineered foods as such puts market participants in a difficult dilemma. On the one hand, voluntary labeling of genetically engineered products may justify price differentials over traditional foods. Furthermore, over the long term, it can help to eliminate public concern about these products by highlighting the genetically altered products' nutritional, aesthetic and gustatory equality or superiority to their traditionally produced forerunners. However, the possibility of an unreasoned consumer rejection of genetically engineered foods might prevent any one firm from making the first move. Thus, the question becomes whether the FDA should cut through this coordination problem by imposing a labeling requirement on all producers. If the FDA simultaneously uses its public goodwill to disseminate its scientific basis for the safety of bioengineered foods, it may be able to achieve public acceptance of such foods and competitive equality (in fact, competition on nutritional and other merits of the products, rather than on scare tactics) in the marketplace.

As the FDA develops regulatory expertise in the particular applications and techniques of biotechnology, the costs of bringing a genetically engineered product to market

[5]*See* **International Food Biotechnology Council, *Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification,* 12** REG. TOXICOLOGY & PHARMACOLOGY **xvi, *cited in* Herman, *supra* note 36, at 126.**

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will likely be reduced. Currently, food manufacturers are likely to hire and train the top researchers and scientists in genetic engineering. As the technology becomes more established and knowledge filters into the agency as **it** obtains personnel and experience in these specialized fields, the FDA will perhaps be able to develop more specific protocols and regulations to announce acceptable substances and procedures, for example, a better idea of the dietary effects, if any, of various genetic markers that may be used throughout the industry. Already, food manufacturers are able to proceed through the FDA notification and consultation phase more quickly because the FDA has previously dealt with analogous substances or vectors)[9] In turn, manufacturers could likely reduce the time and resources spent in consultation with the FDA. One could argue, however, that risk and safety assessment is actually an expertise distinct from and better understood than that required for recombinant DNA. The FDA might well be equipped to analyze toxicity and allergenicity data from a substance without necessarily understanding the bioengineering origins of the product. Essentially, this issue strikes at the heart of FDA's determination to regulate genetic engineering via its *products* rather than its *procedures.* However, just as the FDA has adopted what is effectively a process-oriented approach to traditional hybrids (i.e., foods derived from

[59] *See FDA Complete Consultations on Seven New Biotech Products,* FOOD cHEMICAL NEWS, **Nov. 21, 1994.**

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cross-breeding require no special oversight), a partial shift to this type of approach in the rDNA field would likely reduce the barriers to entry and expand the market for genetically engineered foods. Also, an improved understanding of the specific techniques at work can also allow the FDA to conclude more quickly that certain procedures achieve results (in terms of protein expression) substantially equivalent to approved products and therefore new products can be approved more quickly with no additional safety risk)[0] Thus, accumulated regulatory expertise in this area would also stimulate greater competition for the benefit of consumers.

Fortunately, to date FDA regulation of genetic engineering has not been driven by the exigencies of addressing a human tragedy due to unsafe or contaminated food. While the agency's 1992 policy statement thoroughly examines a wide variety of scientific knowledge regarding food safety, it has failed to satisfy many consumer advocates, environmentalists, and others in the public whose concerns often stem from a lay qualitative perception of the risks of genetic engineering.bI Thus, some have predicted

[30] *5ee id.* **(three manufacturers are effectively duplicating the Flavr5avr tomato through other genetic mechanisms with the same phenotypic expression).**

[61] *5ee, e.g., FDA Scientific Advisers Ponder Regulation of Bioengineered Food,* FOOD CHEMICAL NEWS, **Nov. 14, 1994 (giving examples of consumer advocate and other interest groups criticizing the current FDA position) . Of course, some scientists also have been outspoken skeptics of the safety of genetic engineering. *See* note 59 (molecular biologist calling for 50-year moratorium on release of genetically engineered**

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that mounting public pressure on Congress and the FDA may result in additional regulatory oversight.[62] Given the inevitable consumer demands for additional sources of novel, nutritious and improved foods, it also seems wise for the FDA to contemplate the implications of its decisions and regulations on the development of the food markets,[63] even as it continues its traditional role of safeguarding our food supply.

organisms and returning grant money, because such research is

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irresponsible without knowledge of long-term consequences)

~[2] *See* **Bohrer, *supra* note 24, at 666.**

b[3]The food industry may be greatly affected by apparently small changes in food composition. One commentator has predicted that tomato processors can anticipate savings of $100 million for every one percent increase in the solids content of tomatoes. ***See*** **Kunimoto, *Commercial*** *Opportunities in Plant Biotechnology for the Food Industry,* **Food Tech., Oct. 1986, at 60, *cited in* Frank, *supra* note 17, at 179.**

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