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## The FDA Should Revise Their 1992 Policy Statement to Require Labeling on Certain Genetically Altered Fruits and Vegetables

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Food and Drug Law Final  
Prof. Hult  
1/27/93

Question 1- The FDA Should Revise Their 1992 Policy Statement to Require Labeling on Certain Genetically Altered Fruits and Vegetables.

Biotechnology, specifically recombinant DNA (rDNA) or genetic engineering technology, promises to revolutionize the US agricultural industry. rDNA technology allows scientists to isolate any gene encoding a desirable characteristic in one organism and to transfer it to any other organism. Use of genetic engineering can alter both the

ring drastically  
quantity and quality characteristics of food. Crops have been developed which express resistance to herbicides, pesticides, viruses or frost. Other plants have been engineered to produce food with higher nutritional value, such as an increased proportion of unsaturated fatty acids.<sup>1</sup>

Genes may be transferred from one plant to another or may be transferred across kingdoms. i.e. from animals or microbes to plants. Genes from flounders have been inserted into tomatoes to promote frost-resistance and genes from wax-moths have been inserted into potatoes to retard bruising.<sup>2</sup> The first genetically altered fruit, the Calgene Flavr Savr tomato, has already reached the marketplace.<sup>3</sup>

In order to clarify the regulation of genetically altered foods before they were introduced to the marketplace,<sup>4</sup> the FDA announced its policy towards the regulation of genetically altered fruits and vegetables on May 29, 1992. The FDA stated that the products of genetically altered fruits and vegetables would not be treated any differently than food derived from plants developed by traditional agricultural techniques such as hybridization. 6 The FDA believes that all genetic modification techniques,

including traditional hybrid breeding. have similar potentials to create unsafe food, Since the safety hazard of foods produced by other genetic modification techniques has proven to be low, there is no reason to suspect an increased danger from genetic engineering. Therefore, since foods derived from new plant varieties have not traditionally required premarket approval, such approval will not be required for plants developed by genetic engineering, except in limited circumstances.<sup>7</sup> As long as the gene introduced into the plant is derived from a known food source or is substantially the same as an existing food substance, and is not known to be toxic or highly allergenic, the FDA believes that premarket approval under the food additive regulations is unnecessary.<sup>8</sup>

Consistent with this policy, the FDA determined that, in most cases, labeling indicating that biotechnology was used to develop the food is not required. Labeling may be necessary, however, if: 1 a known allergen were transferred from one food substance to another; 2 the nutrient content of the host food were significantly altered; 3 a protein, carbohydrate or fat not already common to the food supply were added or to a host food were sufficiently altered such that it was misleading to refer to it by the host name.<sup>9</sup> The FDA believes that the derivation of the food from a genetically engineered plant is not material and, since plants derived from more traditional forms of breeding need not be labeled hybrids, no special labeling is necessary for the products of genetic engineering.<sup>10</sup>

This FDA policy statement was issued a few months after the Bush administration announced an intention to ease the regulatory burdens on genetically engineered products in order to foster the growth of the biotechnology industry. Vice President Quayle's Council on Competitiveness was instrumental in developing the biotech policy in

order to prevent overreaulation of the industry, due in part to overlapping jurisdiction of the FDA, EPA and USDA.<sup>11</sup>.<sup>12</sup> Thus, it appears that the FDA may have been influenced by deregulation economics when establishing their policy towards genetically altered fruits and vegetables. This perception has contributed to the public outcry over the policy.

Generally, the FDA policy has prompted vehement complaints both from environmental and consumer groups as being too lenient;<sup>13</sup> however, by far the most controversial component of the policy has been the decision not to require labeling of genetically engineered foods. Over 3300 comments on the policy were received by the FDA. Ninety percent of these comments were from consumers concerned about the lack of labeling requirements for genetically engineered foods.<sup>14</sup> Consumer complaints were based on a number of concerns. Although the FDA requires labeling of genetically altered foods if the added gene is a known allergen, such as peanuts, consumers are concerned about the prospect of the transfer of less common allergens.<sup>15</sup> Some Orthodox Jews feel that the insertion of a pig or shellfish gene into apples renders them non-Kosher.<sup>16</sup> Finally, some consumers feel that genetic engineering is akin to playing god and is morally wrong. **17** .<sup>18</sup> These people want information about the genetic manipulation of their foods so that they can avoid altered foods. These concerns prompted the FDA to reopen the issue in April of 1993 by requesting another round of public comment on whether genetically engineered foods should be labeled.<sup>19</sup>

The FDA's power to regulate labeling derives from §403 of the Food, Drug and Cosmetics Act (FDCA). Subsection 403(a)(1) provides that a food is misbranded if its labeling is false or misleading in any particular.<sup>20</sup> Whether or not a label is misleading depends on

not only representations made or suggested ... but also the extent to which the labeling ... fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates...<sup>21</sup>

This materiality provision has been used by the FDA to prescribe labeling requirements which are not mandated in §403.22 Thus, in determining whether to require labeling of genetically engineered foods, the FDA must examine the materiality of such information.

The FDA could also look to §403.1 of the FDCA for guidance in labeling genetically altered fruits and vegetables. §403(1)(1) requires that a nonstandardized food bear on its label its common or usual name. 23 According to 21 CFR 102.5, promulgated under §403.1(b).

the common or usual name of a food ... shall accurately identify or describe the basic nature of the food .... The name shall be uniform among all identical **01.** similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name...

Thus, according to the regulation, if a fruit or vegetable has been altered to such an extent that it is no longer the same food product, the label would have to indicate the difference between the two products. The FDA's policy seems to reflect this fact,<sup>24</sup> but labeling difficulties are likely to surface when trying to determine whether a host organism has been altered to such an extent that it may no longer be considered the same food. 25 Since §401 of the FDCA prohibits establishing standards of identity

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for fresh or dried fruits and vegetables,<sup>26</sup> these problems may not be eliminated by the issuance of a standard of identity. The FDA should rely

on §403(a) and §201(n) to establish rules for all genetically altered fruits and vegetables rather than proceeding under §403Uu 1) and determining on a case by case basis whether each altered crop is or is not the same as the host plant.

Under §403(a), for the FDA to mandate disclosure of the genetic alteration of fruits and vegetables, it must deem the information material. Such a determination would be a valid exercise of FDA power and not arbitrary or capricious. The FDA has utilized the materiality provision to require additional affirmative disclosures. Courts have traditionally interpreted the misbranding provisions as being protective of the consumer and grant broad deference to the FDA in its field of expertise.<sup>27</sup> Thus, the determination that the genetic engineering of foodstuffs is material would doubtlessly be upheld by a court, if ever challenged. Moreover, the FDA could find precedent for requiring labeling of genetically engineered foodstuffs in its regulation of irradiated foods. The FDA mandates that irradiated food must be labeled as such. The FDA determined that a labeling requirement was necessary even though, as in the case of genetic engineering, it was satisfied that the procedure did not create a health hazard.<sup>28</sup>

Given the fact that the FDA could legally mandate labeling of genetically engineered fruits and vegetables whether they should do so requires examining the relevant policy issues. A number of issues influence whether it is good policy for the FDA to require labeling of genetically altered foods. These issues include respect for consumer concerns and autonomy, public perception, effect on the growth of the industry, the cost of the labeling requirement, and the uncertainty as to the health effects of the technology.

As pointed out previously, consumers are interested in whether or not their food has been genetically altered. Some consumers fear health effects, others have dietary restrictions due to religious beliefs and still others do not believe that human beings should be tampering with life, or at least certain higher life forms. Since it is impossible for a consumer to determine whether food has been genetically altered unless this is disclosed to her, the consumer relies on the food label for her information. The FDA should respect consumer autonomy by mandating that the information which they deem relevant be provided by manufacturers. The FDA indicated that public concerns are relevant in establishing mandatory labeling requirements when it promulgated the labeling rules for irradiated foods. In a release accompanying the final rule on irradiated food, the FDA noted that

whether information is material under section 201(n) of the act depends not on the abstract worth of the information but on whether consumers view such information as important. (3C)

The FDA found that the fact that a large number of consumers requested labeling was evidence of the significance consumers placed on irradiation and, therefore indicative of materiality.<sup>31</sup>

Although the FDA has traditionally interpreted the term material to include only information which effects the attributes of the food itself,<sup>32</sup> the FDA should expand the definition to include all information which is relevant to the consumer's decision whether or not to purchase a food product. If consumers deem the use of technology to be relevant in their food consumption decision, the FDA should respect this and mandate that food producers include this information. Since the FDA has taken non-safety, subjective views into account in setting some of its own policies,<sup>3</sup> it

would be hypocritical of the agency to then determine that certain consumer ethical and religious concerns are irrational and, therefore not material, no matter how widespread the concerns are in the population.

Additionally, some consumer concerns do relate to the attributes of the food products and, therefore, do not require a reanalysis of the term material. Many consumers are concerned about allergenicity of these foods. Although the FDA will require labeling of foods containing highly allergenic substances, many individuals have allergies to other proteins which may be transferred from one food substance to another via genetic engineering. These consumers have a right to know that a gene from a substance to which they are allergic has been transferred to another food. This concern has to do with the safety of the food and would not require the FDA to alter its definition of materiality.

In determining whether genetic engineering of foods is sufficiently material to require disclosure on food labels, the FDA must be wary of mandating that too much information be disclosed on food labels. If the FDA takes the position that any information which might be relevant to a consumer's decision to purchase food must be on all food labels, then the

labels will contain too much information to be useful. Being faced with so

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many words, the consumer not read the label and, therefore, not receive the most important information. Thus, the FDA must be certain to mandate the inclusion of only highly relevant information on food labels. Genetic engineering, however, meets this strict requirement. Many consumers have indicated that such information is relevant to them. Consumer polls show that a majority of the public has difficulties with certain forms of genetic engineering. Moreover, such information may be necessary to protect people from allergic reactions.



The FDA should respect consumer concerns for a reason other than deference to personal autonomy. The FDA must ensure that it maintains public confidence. If the FDA continues to ignore consumer concerns, then the public will lose faith in the agency. The public may begin to scrutinize FDA determinations and refuse to buy an approved product for fear that it had not been adequately regulated.<sup>34</sup> Additionally, if the FDA ignores public concerns, the public may lobby Congress for action. Congress may exert increased influence in the FDA's field by introducing legislation or conducting Congressional hearings. Such a reaction to the FDA's refusal to label genetically altered foods and drugs is already occurring. Congress has commissioned the Office of Technology Assessment to run a study on consumer perception of genetically altered crops and has held hearings on the subject. The hearings and the OTA report disclosed public dissatisfaction with FDA regulation of the biotech food industry. A bill requiring labeling of genetically altered foods has been introduced in Congress.<sup>36</sup> To avoid additional political pressure, the FDA should pay increased attention to public concern in this area.

A second factor in the determination of whether to mandate labeling of genetically altered crops is the cost to industry. Although the FDA's mandate is to protect public health, the agency should and does take the economic costs into account when regulating. Ignoring economic consideration would result in food market which is extremely safe and yet too expensive for most consumers.

The agricultural biotechnology industry has objected to labeling of genetically altered foods for a number of reasons. Primarily, the industry is concerned with the irrational fears of the public. The industry believes that consumers will not purchase bio-engineered products for fear that the

products will harm their health, even though there is little or no scientific evidence for this premise. Thus, the argument goes, the fledgling biotechnology industry will be destroyed if consumers are informed that what they are consuming is a product of genetic engineering. This argument is not sufficient to justify denying consumers information which they deem material to their consumption decisions. If the biotech industry is concerned that consumers have irrational fears and do not adequately understand the safety and benefits provided by biotechnology, it is up to the industry to educate the public.<sup>37</sup> The provision of adequate information should be sufficient to allay any consumer fears. 3S When the food industry complained about consumer fears of irradiation, the FDA determined that this was inadequate to prevent labeling of irradiated foods and stated that the way to address this was for the industry to

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educate the public.<sup>39</sup>

A related industry concern is that consumers will perceive any labeling of genetic alteration as a safety warning and, therefore, will be deterred from purchasing the food for unreasonable fears of health dangers.<sup>40</sup> This concern again underestimates consumers. Since the FDA mandates that many things be included on labels including ingredients, weight, food name and nutritional content, consumers know that many label disclosures do not indicate safety problems. Moreover, the fact that the FDA has mandated Warnings in situations of health concerns such as saccharin and alcohol, should indicate to consumers that not all labeling constitutes a health warning. As with the concern over irrational consumer fears, any misunderstanding caused by the labeling can be addressed by increased consumer education. When the food industry raised this concern to avoid labeling irradiated food products, the FDA

found the argument unpersuasive and stated that any problem could be solved by increasing public information.<sup>41</sup>

The agricultural biotechnology industry has also complained that required labeling would be administratively difficult and inefficient. The industry argues that, although it would not be difficult to label genetically altered fruits and vegetables which are sold fresh or as whole frozen or canned foods, it would be extremely burdensome to require labeling of processed foods made from genetically altered crops.<sup>42</sup> Labeling would be particularly difficult for the bread, grain and cereal industry because grain distributors generally combine grains from various sources and sell this stock to producers. Mandatory labeling would require isolating genetically engineered grains from un-altered grains. The administrative requirements imposed by labeling might be so high that they would outweigh any efficiency gains from biotechnology and, thus, effectively preclude the genetic engineering of the grain supply. Here industry raises a valid complaint. However, in requiring labeling, the FDA need not require that all processed products be labeled. The FDA could mandate that only whole foods which are genetically altered need be labeled and allow processed foods made from genetically altered ingredients to escape the labeling provisions. This route was taken by the FDA for irradiated foods ~ Alternatively, the FDA could mandate that processed foods which are made from both genetically altered and non-altered crops indicate this on their label. This action would be similar to the treatment of oils or dough conditioners, where the FDA allows an ingredient list to state that the food includes one of more of the following.<sup>44</sup>

A final concern is the uncertainty of the safety of genetically altered fruits and vegetables. As discussed earlier, the transfer of genes from one

organism to another brings the prospect of transferred allergenicity as well. Although the FDA is mandating disclosure of known allergens, the people who suffer from less common allergies will not be protected. Additionally, although genetic engineering has not been proven dangerous, neither has it been proven safe. Some scientists have questioned whether the antibiotic resistant markers necessary to determine gene uptake in the genetic engineering process might confer resistance to human pathogens.<sup>45</sup> Moreover, although the FDA has been claiming that genetic engineering is little different from traditional genetics, it is qualitatively different in the sense that it allows the transfer of genes from very distantly related species and even between kingdoms. The effect of this on toxicity and allergenicity is unknown and the fact that one gene often controls more than one phenotypic characteristic, a characteristic known as pleiotropy, bolsters the fear that unknown dangers may result.<sup>46</sup> In the face of this uncertainty, consumers should be provided with information so that they may make their own cost/benefit analyses as to whether the increased quality or decreased price of the genetically altered food is worth a slight, but unknown, health risk.<sup>47</sup>

In addition to weighing all the policy issues, the FDA must consider what alternatives to mandatory labeling exist and what is likely to occur if the FDA decides not to require labeling. One suggested alternative is that the industry develop a niche market for foods which have not been genetically altered. This would be similar to the organic foods market.<sup>48</sup> The producers participating in the niche market would reverse label their foods as not containing bio-engineered products.<sup>49</sup> Niche marketing has the advantage of providing information to consumers and allowing them to determine whether to purchase these non-manipulated foods.

However, this alternative poses certain problems. One difficulty is how is the FDA to police these assertions? Should the FDA assert jurisdiction or should the industry be left on its own? Moreover, foods sold in a niche market are likely to be significantly higher in price than the general food supply.<sup>50</sup> Finally, the niche market alternative does not address the needs or desires of people who are not adverse to biotechnology in general but, either for religious, moral or allergy reasons, cannot purchase certain genetically manipulated foods. Thus, it does not appear that the niche market is an adequate replacement for mandatory labeling of genetically engineered foods.

If the FDA does not mandate labeling of genetically altered fruits and vegetables, state and local governments may do so. States like North Carolina, Hawaii and Minnesota have already enacted laws which regulate biotech food products more stringently than the Federal government.<sup>51</sup> Moreover, a bill was introduced in New York City which would mandate labeling of bio-engineered food products.<sup>52</sup> State and local regulation in this area creates tremendous problems in a national food distribution system. If food producers must comply with differing labeling requirements in different localities, it may be all but impossible for bioengineered foods to be marketed on a nationwide level. This would have a significantly more harmful effect on the industry than reasonable regulation by the FDA.

Weighing all of these factors, it appears that the FDA should mandate disclosure of genetic alteration on food labels. The public concern over the issue, along with possible health concerns, like allergenicity, render the information material, making mandatory labeling a prudent policy for the FDA. It is not necessary, however, for the FDA to require labeling of all

genetically altered food substances. The best course would be to require labeling only for those foods which have been engineered with gene products from a species outside of the host's genus. This would be the least restrictive way of adequately protecting the public. Since many genetically engineered crops contain genes from close relatives or, like the Calgene tomato, are made by the elimination or downregulation of one of the host's gene products, a significant fraction of genetically altered foods need not be labeled.

As the FDA has indicated, traditional crop manipulation has not had adverse effects on the safety of fruits and vegetables. Since traditional

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crop manipulation is performed on plants one genus. this proposed regulation takes into account the proven safety of these techniques by not requiring labeling of intra-genus genetic manipulation. However, since Inter-genus genetic manipulation differs significantly from traditional agricultural techniques. this policy would recognize the uncertain safety of the new technique and mandate disclosure so that consumers could make their cost/benefit analysis.

Moreover, the proposed policy would adequately protect consumers who suffer from allergies. People with allergies to one food are normally on notice not to eat closely related foods and, therefore, do not require information on whether a gene from a wild species of plant has been inserted into an inbred species. However, consumers will be informed when inter-genera gene manipulation has occurred and, therefore, may steer away from foods containing genes derived from a substance to which they are allergic.. Similarly, this regulation addresses concerns of vegetarians and people who have dietary restrictions due to religious reasons by disclosing the transfer of animal genes into plants.

Finally, this policy takes into account the predominant view of the public towards genetic engineering.<sup>53</sup> Most people do not object to genetic manipulation within the plant kingdom, but a majority of the public does object to the insertion of animal genes into plants. Therefore, this policy provides information that the public deems relevant. Although a certain sector of the population believes that all genetic manipulation is immoral, the FDA cannot protect all consumers, but must try to protect only the vast majority. ~ Moreover, those consumers who are morally opposed to all

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genetic manipulation should be adequately served by a niche market. Labeling of processed foods containing genetically altered fruits and

vegetables should be required because the major concerns of allergenicity, dietary restriction and moral concerns are no less relevant in processed foods than in unprocessed foods. However, processed food producers should be able to indicate that the product may contain genetically manipulated foods so that inefficient practices, such as the segregation of biotech and non-biotech foods is unnecessary.

The FDA should consider including a sunset provision, so that this policy may be reviewed in, say, 10 years. If after a number of such inter-genus genetically engineered crops have been marketed, no safety problems have arisen and the public has accepted the technology, then the genetic manipulation of the product may no longer be material and mandatory labeling could, perhaps, be eliminated.<sup>55</sup>

One final consideration is what to require on the label. Since listing the added gene or protein in the ingredients would be inconsistent with FDA's decision not to treat newly introduced genes and gene products as food additives, such a policy is not prudent. The FDA should require that the food indicate that it is genetically engineered somewhere on the label,

allowing the producer to add the purpose of the engineering, such as genetically engineered to preserve freshness. This policy was followed by the FDA in the irradiation regulation<sup>56</sup> and is prudent because it allows the producer to promote genetic engineering by indicating its benefits.

organism from which the introduced gene was derived should be indicated on the label to protect allergic consumers.

*I See* Karen Goldman Herman, Comment, *Issues in the Regulation of Bioengineered Food*, 7 HTLJ 107, 107-08 (1992) and *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1430-31 (1991).

<sup>2</sup> Linda Marsa, Food *Fi. ~ht: Protest Against Genetically Engineered Foods*, OMM, June 1993, 18.

<sup>~</sup> Shari Caudron. *Supercows and Flounder Berries. ~ Innovations in Agricultural Biotechnology*. Industry Week. Dec. 6, 1993, 50, 51. Calgene has inserted an anti-sense copy of the polygalacturonase (PG) gene into the tomato. The antisense gene results in a lower level of PG in the tomato. Since PG is an enzyme which is responsible for softening of the tomato, the Calgene tomato softens more slowly than unaltered tomatoes. Thus, the Calgene tomato has an increased shelf life and may be vine-ripened before it is shipped, rather than picked ~eeri and reddeniied at the sale sight by ethylene gas. Calgene, Inc.; Request for Advisory Opinion. 57 Fed. Reg. 22.772 (1992').

<sup>~</sup> Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (1992)

<sup>~</sup> Id. at 22,984.

<sup>6</sup> Id. at 22,984-85.

<sup>~</sup> Id. at 22,988.

<sup>8</sup> See David Kessler et.al., *The Saferty of Foods Developed by Biotechnology*, 256 SCIENCE 1747, 1751 (1992).

<sup>9</sup> 57 Fed. Reg.. *supra*, note 4, at 22,991; *See also*, Mary Sudduth, *Genetically Engineered Foods: Fears & Facts*, FDA CONSUN~, Jan.-Feb. 1993, 10.



10 Sudduth, *supra* note 9 at 2-3.

11 See Keith Parr, *Developments in Agricultural Biotechnology*, 19 WM.

MITCHELL L. REV. 457, 479 (1993); *Bush Loosens Control on Biotech Industry*,

L.A. TIMES, Feb. 25, 1992, D1; Lawrence Fisher, *Biotechnology Industry Rejoices*

*with Caution*, N.Y. TIMES, Feb. 26, 1992, D2 and Malcolm Gladwell, *Food Products*

*Won't Require Special Rules, FDA Decides*, WASH. POST, May 26, 1992, A4.

12 FDA Commissioner Kessler later stated to a Congressional Subcommittee that **the involvement of the Council on Competitiveness undermined the public's confidence in the FDA's policy, making it difficult for industry and the FDA to convince consumers that the policy adequately protects public health and is not an example of de-regulation.** *Kessler Sees Slant on Biotech Policy as Setback*, FOOD CHEMICAL NEWS, Apr. 26, 1993, 13.

13 The two most prominent groups in the fight for increased regulation of genetically engineered foods are the Pure Food Campaign, led by Jeremy Rifkin, the National Wildlife Federation and the Environmental Defense Fund. Rifkin is leading a boycott against Campbell Soup which has a financial tie to Calgene and has enlisted 2000 chefs nationwide who promise not to use genetically altered foods. His PEC has even set up a hotline, 1-900-PURFOOD, for interested consumers. See Lawrence Fisher, *Tomato Gene Submitted for Approval*, N.Y. TIMES, Jan. 6, 1993, D4; *Rifkin, Campbell Spar over Flavor Savr Biotech Tomato Use*, FOOD CHEMICAL NEWS, Jan. 18, 1993, 48; Caudron, *supra*, note 3 at 52; Gladwell, *supra*, note 11 at 4 and Tom Dunkel, *Souped-up Biofood is Ripe for a Fight*, INSIGHT, March 1993, 14, 16.

14 Jane Brody, *Genetically Engineered Food: Scientific Miracle or Nightmare*, HOUSTON CHRONICLE, May 23, 1993, Lifestyle 4.

15 See Judith Blake, *Corn that Glows in the Dark? Gene Transfer Raises Concern*, SEATTLE TIMES, Aug. 5, 1992, C1.

16 Brody, *supra*, note 14 at 4.

17 Diane Hoffman, *The Biotechnology Revolution and its Regulatory Revolution*, 38 DRAKE L. REV. 471, 482-83 (1989); See also, Drew DeSilver, *...And a*

*Side Order of DNA, Please: Genetically Altered Foods*, VEGETARIAN TIMES, Dec.

1992, 29, 32.

18 A recent study conducted by Thomas Hoban, a professor at North Carolina

State University, and Patricia Kendall, a professor at Colorado State University, found that most people support plant-to-plant genetic transfers, but that most do not support transferring animal genes into plants. Only 24% of

those sun'eyed felt that it was morally wrong to use biotechnology to change plants, but 53% felt that it was morally wrong to genetically alter animals. DeSilver, *supra*, note 17 at 32. *See also, Consumers Prefer Idea of Altered Tomatos to Some Other Fuods*, WORLD FOOD REG. REV. (BNA). A study of Dutch consumers found that they were even less accepting of genetically altered foods. Andy Coghlan, *Dutch Lack Appetite for Genticly Altered Foods*, NEW SCIENTIST, Aug. 17, 1991, 9.

**19 Food Labelling; Foods Derived from New Plant Varieties, 58 Fed. Reg. 25837**

(1993); *See also*, Alex Barnum, *FDA Max' Change Policy ~ Bio-Engineered*

*Foods: Agency to Decide Whether Labels are Required*, S.F. CHRONICLE, May 24,

1993, Cl.

20 21 L.S.C 343(a)(1) (1993).

21 Food, Drug and Cosmetics Act, §201(n), 21 U.S.C. 321(n) (1993).

22 PETER BARTON HUTT & RICHARD MERRILL, **FOOD AND DRUG LAW 61(1991).**

23 21 U.S.C. 3431i(1) (1993).

24 Sudduth. *supra*, note 9, at 11.

25 Jeffrey Gibbs and Jonathan Kahan, *Federal Regulation of Food and Food Additive Biotechnology*, 38 ADMIN. L. REV. 1, 20 (1986).

26 21 U.S.C. 341 (1993).

27 *See US v. An Article of Food ... Schmidt's Blue Ribbon*, 1969-1974 FDLI Jud.

Rec. 139 (D. Md. 1973); *U.S. v. 62 Packages ... Marmola Prescription Tablets*, 48

F.Supp. 878 (W.D.Wis. 1943).

28 57 Fed. Reg. 13376 (1986).

29 *See* Barnum. *supra*. note 19. at Cl.

~ 51 Fed. Reg.. *supra*. note 28 at 13380.

31 Id.

32 58 Fed. Reg., *supra*. note 19 at 25838.

~ For example, the FDA has taken personal tastes into account in determining to ban sassafras tea and Commissioner Kessler's decision to ban breast implants for cosmetic purposes was influenced by his personal bias against cosmetic surgery. Peter Barton Hutt, Lecture to Harvard Law School Food and Drug Law Class (Jan.20, Jan. 24, 1993).

~ *See* William Rice and Steven Pratt, *Biotech Talk: Genetically Engineered Tomato Feeds the Continuing Controversy over Commercial Gene Splicing*, CHICAGO TRIBUNE, May 20, 1993, Food Guide 7. In this article, Henry Miller of the FDA's Office of Biotechnology indicates that maintaining public confidence in new biotech foods is one of the major challenges facing the FDA.

~ *See* Michael Unger, *Bio-Tech Food Fight; Report to Congress Raises Safety*

*Concerns*, NEWSDAY, Aug. 18, 1992, 29.

36 Michael Unger, *In the Age of Gene-Altered Foods*, NEWSDAY, July 26, 1992, 5.

~ See Coghlan, *supra*, note 18 at 9.

38 See Hoffman, *supra*, note 17 at 547; *Position of the American Dietetic Association: Biotechnology and the Future of Food*, 93 J. Amer. Dietetic Assoc. 189, 191

(1993).

3~ 51 Fed. Reg., *supra* note 28 at 13383.

40 See Steven Frank, *Food Additive Models for the Regulation of Recombinant DNA Technology Under the Federal Food, Drug and Cosmetic Act*, 45 FOOD, DRUG

AND COSMETIC L.J. 169, 201 (1990); Thomas Stenzel, *Letter to the Editor*, USA

TODAY, May 29, 1992, 12A.

41 5i Fed. Reg., *supra*, note 28 at 13382.

42 See Sudduth, *supra*, note 9 at 11; Henry Miller, *Foods of the Future: The New Biotechnology and FDA Regulation*, 268 JAMA 910 (1993).

~ 51 Fed. Reg., *supra*, note 28 at 13380. 4~ See Hutt, *supra*, note 22 at 80-81.

~ Dunkel, *supra*, note 14 at 16; *See Calgene Seeks FDA Approval of Marker*

*Gene Used in Tomatos*. FOOD CHEMICAL NEWS, Jan. 11, 1993, 33; *Anti-Biotech Forces Prepare for Battle*. FOOD PROTECTION REPORT, Mar. 1993, 6.

46 See Fisher, *supra*, note 13 at D4; Sharon Schmickle, *Genetically Altered Tomatos. Vanguard of Uncertain New Era*. STAR TRIBUNE, Mar. 15, 1993, 1A.

47 See Elaine Povich, *Sale of Gene-Spliced Food Without Labels Okd*, CHICAGO TRIBUNE. May 27, 1992, C2.

48 See, 58 Fed. Reg., *supra*, note 19 at 25841.

~ See Barnum, *supra*, note 19 at C2; Ann Cony, *Altered Tomato Raises Fears of Unknown Dangers*, SACRAMENTO BEE, Sept. 27, 1993, A13.

50 See *Added Gene Should Trigger Ingredient Label, Rifting Says*, FOOD

LABELING NEWS, Aug. 26, 1993, 42.

~1 See Sharon Schmickle, *Debate on Engineered Foods Heats up in Minnesota*,

STAR TRIBUNE, May 27, 1992, 1A.

52 Unger, *supra*, note 36 at 5.

~ See note8, *supra*.

The FDA's ban on swordfish in the 1970s to protect 500 people in Northern  
Maine and the subsequent public reaction are strong evidence of this premise.  
*See* Hutt. *supra*. note 22 at 300-02.  
~ *See* Herman. *supra*, note 1 at 134.  
56 51 Fed. Reg., *supra*, note 28 at 13380.